Texas Senate
Health Committee

Report to the 77th Legislature

August 2000

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THE SENATE OF TEXAS

COMMITTEE ON HEALTH SERVICES

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August 20, 2000

The Honorable Rick Perry
Lieutenant Governor of Texas
P.O. Box 12068
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Dear Governor Perry:

The Senate Health Services Committee submits this report in response to the interim studies you have assigned to this committee.

The committee has solicited and considered public testimony on the effectiveness and efficiency of Medicaid Managed Care; analyzed biotechnology, pharmaceutical research and genetics related issues, including issues surrounding the establishment of a statewide bioterrorism response plan; and conducted a comprehensive study of our current regulatory controls to prohibit the inappropriate dissemination of personally identifiable healthcare information. The committee has also reviewed the option of provider choice in our Vaccines for Children program; assessed the current state of our health care workforce, including opportunities to improve patient access through telemedicine to complement existing provider patient relationships; and has followed the implementation of the Children's Health Insurance Program.

The committee has contacted affected consumers, providers, businesses, and agency personnel to provide you with an objective and accurate depiction of each facet of the interim charges. We appreciate the leadership and foresight you have displayed by providing this committee with the opportunity to seek remedies and solutions to these key issues, which will improve the health of our fellow Texans.

Respectfully submitted,

Senator Jane Nelson
Chair

Senator Mike Moncrief

Senator Frank Madla

Senator Jon Lindsay

Senator Drew Nixon

INTERIM CHARGES OF THE SENATE HEALTH COMMITTEE

The Senate Health Committee shall:

1. Evaluate the changes in the Medicaid system since the beginning of Medicaid reform. The Committee shall assess reform efforts in light of the original goals for implementation of Medicaid managed care, as well as the impact of Medicaid managed care on patient outcomes, cost implications to the state, and the impact on traditional providers of indigent care. The Committee shall also specifically evaluate the ability of Medicaid managed care organizations and the state to manage chronic illnesses and develop specific strategies for disease management for certain populations.

2. Inventory and analyze the amount and type of research related to pharmaceuticals, biotechnology and genetics currently occurring in Texas to maximize the benefits to Texans in these fields. The Committee shall also examine the ethical implications associated with pharmaceuticals, genetic and biotechnology research.

3. Review the type, amount, availability, and use of patient-specific medical information, including prescription data, and current statutory and regulatory provisions governing its availability. The report shall explore if statutory and regulatory provisions are consistent and adequately enforced.

4. Study impacts of the degree of choice granted physicians to administer immunizations to children under the Vaccinations For Children (VFC) Program. The Committee shall focus on the health and fiscal implications to the public and private sectors of granting choices to physicians where more than one manufacturer produces the same vaccine at an equivalent price.

5. Assess the preparedness of the Texas health care workforce to meet the health care needs of Texans beyond the year 2000, including methods to retain Texas-trained medical personnel. The Committee shall evaluate the availability of health care providers in rural and urban areas. The Committee shall also review the oversight of medical procedures performed by medical residents and disclosure provided to patients prior to treatment.

6. Monitor the implementation of SB 445, 76th Legislature, Regular Session relating to the Children's Health Insurance Program.

ACKNOWLEDGMENTS

The Senate Health Committee would like to thank the following for their contribution to this interim report:

Office of the Governor
Office of the Lt. Governor
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The Texas State Medicaid Office
The Texas Department of Health
The Texas Department of Mental Health and Mental Retardation
The Texas Department of Insurance
The Texas Area Health Education Centers (East Texas)
The Texas State Board of Pharmacy
The Texas Statewide Health Coordinating Council
The Texas Center for Rural Health Initiatives
The University Health Science Centers in the State of Texas
The Centers for Disease Control and Prevention
The Texas Legislative Council
Texas Senate Media Services
Texas Senate Publications and Printing

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INTERIM CHARGE 1

Medicaid Managed Care

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Medicaid Managed Care

Interim Charge #1

Evaluate the changes in the Medicaid system since the beginning of Medicaid reform. The Committee shall assess reform efforts in light of the original goals for implementation of Medicaid managed care, as well as the impact of Medicaid managed care on patient outcomes, cost implications to the state, and the impact on traditional providers of indigent care. The Committee shall also specifically evaluate the ability of Medicaid managed care organizations and the state to manage chronic illnesses and develop specific strategies for disease management for certain populations.

Background

In the era of managed health care, Medicaid programs are increasingly turning to managed care organizations and systems to deliver health care services. According to the U.S. Department of Health and Human Services, 15.3 million Americans enrolled in Medicaid managed care in 1997, up from 2.7 million in 1991. All states except Alaska and Wyoming are pursuing some type of managed care initiative. As of June 1997, nearly 48 percent of the national Medicaid population was enrolled in managed care. [1]

The STAR Program

The Texas Medicaid program is continuing major reforms that have brought most of the State's Medicaid population under managed care arrangements. The Medicaid acute managed care program in Texas is known as "State of Texas Access Reform" or STAR. In 1993, Texas' Medicaid program began two pilot programs under a 1915(b) waiver, which allows states to waive the freedom of choice clause, in Travis County and in the Galveston area. In December of 1995, the Galveston area pilot was expanded to include three additional contiguous counties. In September 1996, the Travis County pilot was expanded to include all contiguous counties. Lubbock, Bexar and Tarrant Counties service areas were brought online in 1996. In December 1997, Texas continued expansion by implementing Medicaid managed care in Harris County. The

[1] TEXAS HEALTH AND HUMAN SERVICES COMMISSION, STATE MEDICAID DIVISION., TEXAS MEDICAID IN PERSPECTIVE. (1999).

STAR program primarily serves Medicaid clients receiving Temporary Assistance to Needy Families (TANF) benefits. However, in the Harris County expansion, Senate Concurrent Resolution (S.C.R.) 55 of the 74th Legislature authorized the implementation the STAR+PLUS pilot program. This pilot integrates Medicaid long-term and acute care services for aged and disabled clients in Harris County. The expansion into Harris County nearly doubled the number of Medicaid managed care recipients in Texas. The latest expansion occurred in 1999, with the inclusion of the Dallas and El Paso service areas. The Dallas expansion integrated the NorthSTAR behavioral health pilot to address mental health needs of Medicaid enrollees. The El Paso rollout also included the Prepaid Health Plan (PHP) model. In 1999, the Texas Legislature passed House Bill (H.B.) 2896 placing a moratorium on the further expansion of Medicaid managed care in Texas. This law also directed the Health and Human Services Commission (HHSC) to undertake a comprehensive evaluation to determine the effectiveness of Medicaid managed care's four critical areas and original goals: cost efficiency, improved quality, increased access, and utilization.

Managed Care History in Texas

In the past decade Texas has undertaken a number of initiatives to address rising health care costs and implement innovative cost-effective methods to provide quality health care. H.B. 7 in 1991 was the impetus behind the establishment of the Medicaid managed care pilot in Travis County and the Galveston area. In 1995, lawmakers passed a series of bills including Senate Bill (S.B.)10, enacting a comprehensive statewide restructuring of Medicaid. In 1997, the Legislature passed H.B. 2913 and S.B.'s 1163, 1164, and 1165 to strengthen Medicaid managed care client and provider protections. In 1999, lawmakers passed H.B. 2896 to evaluate Medicaid managed care and to determine if it has met its original goals.

The primary Medicaid reform legislation passed in 1995, S.B. 10, authorized HHSC to seek a 1115 waiver from the Health Care Financing Administration (HCFA) to fundamentally restructure Medicaid service delivery and funding in Texas. The 1115 waiver refers to section 1115 of the Social Security Act and allows HCFA to grant exception to a broad range of federal requirements allowing states latitude in structuring innovative, cost efficient delivery systems. S.B. 10 also authorized HHSC to continue pursuing 1915(b) waivers, which had been used for

the initial pilot sites and to implement Medicaid managed care in other areas of the State while awaiting approval of the 1115 waiver.[2]

Texas continues to operate its Medicaid managed care program through 1915(b) waivers. HHSC submitted a 1115 waiver to HCFA for review in 1995. In November 1996, HHSC submitted an amendment to that waiver and, in April 1997, responded to HCFA's concerns regarding the amended sole-source arrangement provisions. During this same period, HHSC devised a schedule for implementing Medicaid managed care statewide through 1915(b) waivers. The implementation chart can be found on page 10 of this report.

How Medicaid Works in Texas

Federal Oversight

The Social Security Act and federal regulations establish minimum levels of coverage that states must provide in order to operate a Medicaid program. Federal law and regulations also establish optional coverage categories, all or part of which states may choose to offer. Each state covers the required services and eligibility groups, but develops unique programs by determining which optional services and eligibility groups to include in coverage.

While states are responsible for the hands-on operation of Medicaid, the federal government plays a very active oversight role. HCFA, a division of the U.S. Department of Health and Human Services, oversees the Medicaid program. HCFA approves each state's Medicaid State Plan, as well as any waivers for which states apply.[3]

Single State Agency

Federal Medicaid regulations require states to designate a single state agency to be responsible for the Medicaid program. The Texas Health and Human Services Commission (HHSC) was selected to manage the Medicaid program in January 1993. Within HHSC, the State Medicaid

[2] TEXAS HEALTH AND HUMAN SERVICES COMMISSION, STATE MEDICAID DIVISION, TEXAS MEDICAID IN PERSPECTIVE. (1999).
[3] *Id.*

Director administers the Medicaid program and is responsible for building an operational team to implement Medicaid managed care. That team also includes staff of the Texas Department of Health (TDH), Texas Department of Human Services (DHS), Texas Department of Mental Health and Mental Retardation (MHMR), and Texas Commission on Alcohol and Drug Abuse (TCADA).

As the designated single state agency, HHSC has final authority for Medicaid policies and operations. HHSC's State Medicaid Office responsibilities include:

- Serving as the primary point of contact with the federal government;
- Establishing policy directions for the state's Medicaid program;
- Administering the Medicaid State Plan;
- Contracting with state agencies to carry out the technical operations of the Medicaid programs;
- Approving Medicaid policies, rules, reimbursement rates, and operations of the state agencies contracted to operate Medicaid programs;
- Organizing and coordinating initiatives to maximize federal funding; and
- Administering the Medical Care Advisory Committee (mandated by federal Medicaid law)[4].

Texas Medicaid Managed Care Administrative System (TMAS)

TDH contracts with several private entities to operate portions of the Medicaid managed care program. An explanation of their functions follows.

Claims Administrator

National Heritage Insurance Company (NHIC) processes and adjudicates all claims for Medicaid Services outside the scope of capitated arrangements between the health plans and the State. As part of these responsibilities, NHIC:

- assists TDH in the implementation of Medicaid policy;
- is responsible for provider recruitment, contracting, education, and communications in traditional fee-for-service Medicaid;

[4] TEXAS HEALTH AND HUMAN SERVICES COMMISSION, STATE MEDICAID DIVISION., TEXAS MEDICAID IN PERSPECTIVE. (1999).

- collects and processes encounter data from the Medicaid managed care health plans; and
- conducts federally required Surveillance and Utilization Review System activities for TMAS, including recovery of third party reimbursements.

Enrollment Broker

MAXIMUS assists in educating Medicaid clients concerning their health plan and primary care provider choices and enrolls them into Medicaid managed care. As part of these responsibilities, MAXIMUS:

- receives lists of Medicaid clients who are eligible to enroll in managed care programs;
- provides enrollment materials through the mail;
- educates clients in their selection between available plans and in selection of Primary Care Providers (PCP) within the health plans; and
- makes default assignments for clients who do not select their own plan or PCP.

The Texas Health Network (THN) Administrator

Birch and Davis Health Management Corporation is the plan administrator for the state-administered plan. Birch and Davis:

- develops and manages the Primary Care Case Management (PCCM) model and provides oversight of new program models, such as a Prepaid Health Plan (PHP) model;
- provides management functions, such as care coordination of services, member and provider services, health education, and credentialing for these models; and
- develops a network of PCP's and hospitals for this model.

External Quality Monitor

Texas Health Quality Alliance (THQA) reviews access to care and quality of care provided to Medicaid enrollees in managed care plans. As part of its responsibilities, THQA:

- reviews clinical care;
- determines effectiveness of plans' quality improvement activities;
- surveys members about their satisfaction with their health plans;
- surveys providers about their satisfaction with Medicaid managed care; and

- reviews and assesses program utilization data collected and submitted by the health plans.[5]

Populations Served

Eligibility

In 2000, a monthly average of more than 500,000 Texans were on the Medicaid program rolls. Medicaid serves primarily the poor, most Temporary Assistance to Needy Families (TANF) recipients, the elderly, and people with disabilities. A relatively small percentage of Medicaid's most vulnerable clients, the elderly and disabled, account for the largest portion of Medicaid costs. Children make up the majority of Medicaid recipients, but account for a relatively small portion of expenditures. By contrast, the elderly and disabled comprise 23 percent of recipients but account for 64 percent of Texas' Medicaid spending on direct health care costs.

The following Medicaid populations must choose among the available Health Maintenance Organizations (HMOs) and PCCMs in their Service Delivery Areas (SDAs):

- TANF Adults – Individuals age 21 and over who are eligible for the TANF program;
- TANF Children – Individuals under age 21 who are eligible for the TANF program;
- Pregnant Women – Pregnant women who receive paid medical assistance since their family income is below 185 percent of the Federal Poverty Level (FPL);
- Newborn Medical Assistance Only or Medical Assistance Only (MAO)– Children under age one born to Medicaid-eligible mothers receiving MAO;
- Expansion Children – Children under age 18, ineligible for TANF because of the applied income of their stepparents or grandparents; children under age one whose family income is below 185 percent FPL; and children age 1-6 whose family income is at or below 133 percent of FPL;
- Federal Mandate Children – Children under age 19 born after October 10, 1983 whose family income is below 100 percent FPL; and
- Children's Health Insurance Program Phase I (CHIP I) - for children under age 19 born after October 1, 1983, with a family income below 100 percent of FPL.

[5] TEXAS DEPARTMENT OF HEALTH, TEXAS STAR MEDICAID MANAGED CARE REPORT (May 2000).

In addition to those populations that are required to enroll with an HMO or PCCM, the blind and disabled population may choose between receiving care through available managed care programs or the Fee-For-Service (FFS) system. Therefore, the blind and disabled may elect to enroll in the STAR program on a voluntary basis. For enrolled blind and disabled, the HMO will perform case management functions for a fee, but is not financially responsible for the provision of the medical services. As of February 1998, blind and disabled individuals residing in Harris County are not eligible for the STAR program, as a result of implementation of the STAR+PLUS pilot program.

March 2000 Statewide STAR Enrollment

Confirmed Eligibles				**Monthly Enrollment**			
Program	TANF	Blind/Disabled	Total	Defaulted	Elective	Total	Default %
Total STAR enrollees	484,479	19,100	503,579	20,037	66,084	86,121	N/A
STAR+			55,727	369	1,058	1,454	N/A
NorthSTAR			115,533	4,460	10,426	14,886	N/A
Totals			**594,041**			**90,124**	

Source: Maximus

Poverty Income Level

Federal Fiscal Year 1998[6]

Family Size:	Annual Income must be equal to or below:
1 Person	$ 8,050
2 Person	$ 10,850
3 Person	$ 13,650
4 Person	$ 16,450

Providers

[6] TEXAS HEALTH AND HUMAN SERVICES COMMISSION, STATE MEDICAID DIVISION, TEXAS MEDICAID IN PERSPECTIVE. (1999).

Medicaid is both a basic health insurance program and a funding source for services to people with chronic or long-term care needs. Medicaid makes no cash payments to recipients, but instead makes all payments directly to health care and service providers. Health care provider is a general term that includes:

- Health professionals: doctors, nurses, physician assistants, chiropractors, physical therapists, clinical social workers, dentists, psychologists and nutritionists;
- Health facilities: hospitals, nursing homes, homes for persons with mental retardation, clinics, community health centers; and
- Providers of other critical services such as: pharmacy, medical supplies and equipment, and medical transportation.

In 1999, prior to the Dallas and El Paso Medicaid managed care implementation, more than 5,200 primary care physicians were enrolled as providers for the statewide STAR program.

Delivery Models

Traditional Medicaid

Fee-for-Service: In the traditional model, clients may choose any Medicaid provider for their health care. Members are not provided a medical home with a primary care provider. Providers have no obligation to coordinate care. The State contracts directly with providers, who receive reimbursement for provided services. In the traditional Medicaid model, financial risk is shared between the State and the claims administrator.

Managed Care Models

Health Maintenance Organization (HMO): Members in an HMO model are provided a medical home with their chosen and in some cases, defaulted primary care provider. The HMO receives a monthly capitation payment from the State for each enrolled member. The payment is based on a projection of the costs for all medically necessary care for a typical patient. The HMO is at risk for any costs incurred above the capitated amount. Profits are shared between the HMO and the State. All HMOs offer a variety of additional benefits in this model. (See chart on page 12)

Primary Care Case Management (PCCM): The State operates the PCCM model, in which members are provided a medical home with a primary care provider of their choosing. The

physician network contracts with the State. PCP's receive fee-for-service reimbursement and are paid a monthly fee per member to manage all health services for members assigned to them. The State assumes the risk for all Medicaid costs.

Prepaid Health Plan (PHP): A PHP is an entity that accepts partial capitation for physician, laboratory, and radiology services. This model was implemented in the El Paso service area on a voluntary basis in December 1999.[7]

Finance

In 1998, TDH reported that Texas spent $645 million on Medicaid managed care services for its 545,000 enrollees (although some enrollees are considered dual eligibles), an average cost of $145 per member per month. In 2000, HCFA is paying an average cost of $167 per member per month. The implementation of Medicaid managed care was predicated on the reigning in of spiraling health care costs. In FY 1998, cost savings in Medicaid managed care were $50.7 million. The $50.7 million represented a 7.3 percent decrease in the projected expenditure under traditional Medicaid, compared to 4.5 percent in FY 1997. In addition, the State received approximately $14.5 million from experience rebate arrangements with Medicaid managed organizations, for a total of $65.2 million in cost savings.[8] As provided for by H.B. 2896, HHSC is required to perform a program audit to determine the effectiveness of the Medicaid managed care implementation. The report, due in the Fall of 2000, will assess Medicaid managed care program performance and discuss the program's actual expenditures and cost savings.

Direct Payments Made to Managed Care Entities

Covered services are provided to Medicaid recipients by the contracted HMOs. These HMOs receive a monthly capitation payment to cover the estimated costs of coordinating and delivering Medicaid covered services to enrolled Medicaid recipients. The capitation payments are provided to HMOs to compensate them for costs incurred in providing their management activities and the covered benefits (presented in the STAR background section of this report).

[7] TEXAS DEPARTMENT OF HEALTH, TEXAS STAR MEDICAID MANAGED CARE REPORT (May 2000).
[8] *Id.*

If an HMO achieves a profit (capitation payments that exceed HMO expenses), it is required to provide an experience rebate to the State. This experience rebate allows the State to share in the profits achieved by the HMOs. In fiscal years 1996, 1997, and 1998, the State received 50 percent of the profits attained by the HMOs. Beginning in state FY 1999, a tiered approach was implemented with the following allocation of the HMO profits:

Graduated Rebate Method		
Profit (pre-tax)	HMO Share	State Share
0% - 3%	100%	0%
Over 3% - 7%	75%	25%
Over 7% - 10%	50%	50%
Over 10% - 15%	25%	75%
Over 15%	0%	100%

Medicaid Managed Care Penetration

Implementation Schedule for Statewide Medicaid Managed Care (Revised January 1999)[9]

Date	**Service Delivery Area (SDA)**	**Cities/Counties**
12/1/93	Southeast Region SDA	*(Tri-County 12/93)* Chambers, Jefferson, (*Galveston--moved to Harris SDA as of 3/1/98)*
12/1/95		*(Expansion 12/95)* Liberty, Hardin, Orange
8/1/93	Travis SDA	(AUSTIN) Travis
9/1/96		Burnet, Blanco, Hays, Caldwell, Bastrop, Lee, Williamson
9/1/96	Bexar SDA	(SAN ANTONIO) Bexar, Kendall, Comal, Medina, Atascosa, Wilson, Guadalupe
10/1/96	Tarrant SDA	(FT. WORTH) Tarrant, Wise, Denton, Parker, Hood, Johnson
10/1/96	Lubbock SDA	(LUBBOCK) Lubbock, Lamb, Hale, Floyd, Crosby, Garza, Lynn, Terry, Hockley
12/1/97	Harris SDA	(HOUSTON) Harris
3/1/98		Fort Bend, Montgomery, Waller, Brazoria, Galveston *(from Southeast Region*)

[9] TEXAS HEALTH AND HUMAN SERVICES COMMISSION, STATE MEDICAID DIVISION, TEXAS MEDICAID IN PERSPECTIVE. (1999).

7/1/99	Dallas SDA	(DALLAS) Dallas, Ellis, Kaufman, Rockwall, Hunt, Collin, Navarro
12/1/99	El Paso SDA	(EL PASO) El Paso, Hudspeth, Culberson
Implementation of the following SDAs has been postponed indefinitely		
N/A	Travis SDA Expansion	Fayette County
N/A	Hill Country SDA	(FREDERICKSBERG) Gillespie, Kerr, Bandera, Real, Edwards, Kimble, Mason, Llano, San Saba
N/A	Bell/McLennan SDA	Lampasas, Mills, (TEMPLE) Bell, Milam, Hill, Bosque, Hamilton, Coryell, (WACO) McLennan, Falls, Limestone, Freestone
N/A	Northwest Texas SDA	(HHSC Reg 3) Palo Pinto, Erath, Somervelle; (HHSC Reg 2) Jack, Montague, Clay, Wichita, Archer, Young, Stephens, Eastland, Comanche, Brown, Coleman, Callahan, Taylor, Nolan, Fisher, Jones, Shackelford, Throckmorton, Haskell, Stonewall, Knox, Baylor, Willbarger, Hardeman, Foard
N/A	South Texas SDA	(BROWNSVILLE, HARLINGEN) Cameron, Willacy, Kenedy, (McAllen) Hidalgo, Starr, Brooks, (LAREDO) Webb, Zapata, Jim Hogg, Duval, McMullen, Live Oak, Bee, Refugio, Aransas, San Patricio, Jim Wells, (CORPUS CHRISTI) Nueces, Kleberg
N/A	East Texas SDA	(HHSC Reg. 3) Cooke, Grayson, Fannin; (HHSC Reg. 4) Lamar, Red River, Bowie, Delta, Hopkins, Franklin, Titus, Camp, Morris, Cass, Rains, Wood, Upshur, Marion, Harrison, Gregg, Panola, Rusk, Cherokee, Anderson, Henderson, Van Zandt, Smith; (HHSC Reg. 5) Shelby, Nacogdoches, San Augustine, Sabine, Newton, Jasper, Tyler, Polk, San Jacinto, Walker, Trinity, Houston, Angelina, Austin, Colorado, Wharton, Matagorda, Burlseson, Washington, Grimes, Brazos, Robertson, Leon, Madison
N/A	Bexar SDA Expansion	Frio, La Salle, Dimmit, Zavala, Uvalde, Maverick, Kinney, Val Verde
N/A	Midland SDA	(MIDLAND/ODESSA) Midland, Upton, Crane, Reagan, Andrews, Martin, Howard, Glasscock, Ector
N/A	Panhandle SDA	(AMARILLO) Potter, Dallam, Sherman, Hansford, Ochiltree, Lipscomb, Hartley, Moore, Hutchinson, Roberts, Hemphill, Oldham, Carson, Gray, Wheeler, Deaf Smith, Randall, Armstrong, Donley, Collingsworth, Parmer, Castro, Swisher, Briscoe, Hall, Childress, Bailey, Cochran, Yoakum, Dickens, King, Motley, Gaines, Dawson, Borden, Cottle, Mitchell, Scurry, Kent
N/A	West Texas SDA	(HHSC Reg 2) Runnels; (HHSC Reg 10) Jeff Davis, Presidio, Brewster; (HHSC Reg. 9) Reeves, Loving, Winkler, Ward, Pecos, Terrell, Crockett, Sterling, Irion Coke, Tom Green, Schleicher, Sutton, Menard, Concho, McCulloch

Current Texas Medicaid Waiver Programs

*Services paid in FY 98 for unduplicated clients

Program	Operating Agency	Population Served	Approximate Number Served

PCCM-STAR (Primary Care Case Management) Southwest Region 1915 (c)	TDH	Requires TANF and TANF-related Medicaid clients to enroll into a managed care health care delivery system.	25,000
HMO-STAR (Health Maintenance Organization) Travis Service Area 1915 (c)	TDH	Requires TANF and TANF-related Medicaid clients to enroll into a managed care health care delivery system. SSI and SSI-related clients may voluntarily enroll in managed care.	30,000
HMO/PCCM-STAR (Health Maintenance Organization - Primary Care Case Management) Bexar Service Area 1915 (c)	TDH	Requires TANF and TANF-related Medicaid clients to enroll into a managed care health care delivery system. SSI and SSI-related clients may voluntarily enroll in managed care.	100,000
HMO/PCCM STAR (Health Maintenance Organization - Primary Care Case Management) Lubbock Service Area 1915 (c)	TDH	Requires TANF and TANF-related Medicaid clients to enroll into a managed care health care delivery system. SSI and SSI-related clients may voluntarily enroll in managed care.	21,000
HMO-STAR (Health Maintenance Organization) Tarrant Service Area 1915 (b)	TDH	Requires TANF and TANF-related Medicaid clients to enroll into a managed care health care delivery system. SSI and SSI-related clients may voluntarily enroll in managed care.	47,000
HMO/PCCM STAR+PLUS (Health Maintenance Organization - Primary Care Case Management) Harris Services Area 1915 (b)	TDHS	Requires SSI and SSI-related Medicaid clients to enroll into a managed care, acute and long-term care delivery system in Harris County only.	51,000
LoneSTAR Select I (Inpatient Hospital Selective Contracting) 1915 (b)	TDH	Allows the State to selectively contract with hospitals for non-emergency inpatient services for Medicaid recipients (except dual eligibles and Medicaid managed care clients).	N/A
LoneSTAR Select II (Inpatient Psychiatric Services) 1915 (b)	TDH	Allows the State to selectively contract with freestanding mental health facilities to provide non-emergency inpatient psychiatric services for Medicaid recipients under age 21 (except dual eligibles and Medicaid managed care clients).	N/A
PACE Program 1115	TDHS	Only in El Paso, this program provides all health related services to frail and elderly	275

		clients who qualify for nursing facility placement, but choose PACE instead.	
MDCP (Medically Dependent Children's Program) 1915 (c)	TDH	Children under 21 who qualify for nursing facility care.	674*
CLASS (Community Living Assistance and Support Services) 1915 (c)	TDHS	People with Developmental Disabilities (incurred before age 22) who qualify for ICF-MR care.	835
HCS (Home and Community-based Waiver Services) 1915 (c)	TDMHMR	People with mental retardation who qualify for ICF-MR care.	3,800
HCS-OBRA (Home and community-based Waiver Services) 1915 (c)	TDMHMR	A specifically named group of individuals with mental retardation and other developmental disabilities who were inappropriately place in nursing facilities (these qualify for ICF-MR care).	150
DBMD (Deaf, Blind, Multiply Disabled) 1915 (c)	TRC	Adults age 18 and over with multi-sensory disabling conditions incurred before age 22 who qualify for ICF-MR-DD care.	100
CBA (Community-Based Alternatives) 1915 (c)	TDHS	Adults age 21 and over who qualify for nursing facility care.	13,500
CBA-STAR+PLUS (State of Texas Access Reform PLUS Long Term Care Pilot Project)	TDHS	CBA waiver clients are included in the STAR+PLUS program which provides managed care, acute, and long-term care services.	600 CBA waiver enrollees
MRLA (Mental Retardation-Local Authority Pilot Project) 1915 (c)	TDMHMR	People with MR-DD are served in a pilot project in 7 counties in which the local mental retardation authority develops service plans and provides case management.	600

Pilot Projects

STAR+PLUS

STAR+PLUS is a Texas Medicaid pilot project designed to integrate acute and long-term care services through a managed care system. Approximately 56,000 SSI and SSI-related aged and disabled Medicaid recipients in Harris County (Houston) are required to participate in STAR+PLUS in order to receive Medicaid services. Another 5,000 may participate on a voluntary basis.

Enrollees may choose from participating HMOs, two of these participants also offer service to STAR/TANF clients. An enhanced prescription drug benefit is available for Medicaid-eligible enrollees who choose the same HMO for both Medicaid and Medicare services. Children and some recipients with mental illness or mental retardation have a primary care case management option in addition to the above-mentioned choices.

The STAR+PLUS a project was created for patients with chronic and complex conditions who need more than doctor, lab, x-ray, and hospital services. These enrollees usually also need personal care services. The HMOs provide all Medicaid primary, acute, and long-term care services through one service delivery system that begins with ensuring that each client has a primary care doctor. Other acute care services include specialists, home health, medical equipment, lab, x-ray, and hospital services. STAR+PLUS long-term care services include personal care services, and provisions for attendant care to help with daily living activities, and adult day health services. If clients meet the medical necessity criteria to be in a nursing home, they may choose Community-Based Alternatives (CBA) waiver services or nursing facility services. HMO networks have all of these providers, including Medicaid significant traditional providers.

Recipients with complex medical conditions are assigned a care coordinator, an HMO employee who is responsible for coordinating acute and long-term care services. The care coordinator develops an individual plan of care with the recipient, family members and providers, and can authorize services for the client. The emphasis is on providing home and community-based services to avoid the need for institutionalization.

The project requires two Medicaid waivers [1915(b) and 1915(c)] in order to mandate participation and to provide home and community-based services. The federal government approved those waivers in January 1998. STAR+PLUS then became mandatory as of April 1, 1998.[10]

Criticism of STAR+PLUS

HHSC established the STAR+PLUS advisory committee, comprised of providers, advocates and insurers, to identify solutions to problems existing within the system. The Senate Health Committee heard the following concerns through public testimony:

- Under-staffing and lack of consistent care coordination;
- Administrative burdens due to multiple contracts and required forms;
- A reimbursement process that has been difficult to navigate; and
- An increase in administrative costs reducing the amount of available funds for patient services.

The HHSC evaluation will detail both the positive and negative effects of the STAR+PLUS implementation. It will also recommend solutions to address the programs' shortcomings, as well identify the strengths upon which should be capitalized. Please refer to page 19 for further details of the HHSC evaluation report.

NorthSTAR

NorthSTAR is a pilot created by MHMR, TCADA, and HHSC to integrate the publicly funded systems of mental health and chemical dependency services. Using Medicaid dollars, state general revenue, and federal block grant funds, NorthSTAR is designed to create a coordinated, efficient and flexible system of public behavioral health care.

NorthSTAR was implemented in Dallas and contiguous counties (Collin, Hunt, Rockwall, Kaufman, Ellis, and Navarro) in July 1999. Medicaid eligible recipients and non-Medicaid eligible clients who meet clinical need criteria receive services through NorthSTAR.

[10] TEXAS HEALTH AND HUMAN SERVICES COMMISSION, STATE MEDICAID DIVISION., TEXAS MEDICAID IN PERSPECTIVE. (1999).

Physical and behavioral health care for Medicaid recipients was implemented concurrently in the Dallas service area. TDH operates the STAR physical health care plans, while MHMR and TCADA operate the NorthSTAR behavioral health plan. The agencies emphasize clinical coordination of enrollee care between physical and behavioral health. STAR continues to provide some behavioral health services through primary care providers.[11]

Individuals have a choice of behavioral health organizations (BHOs) plans. The contracts include outcome and performance measures specifically designed for behavioral health. The BHOs are required to subcontract with a Specialty Provider Network (SPN) for the provision of a set of specialty treatment services and service coordination services for enrollees with serious mental illness and serious emotional disturbance. The BHOs cooperate with the newly created Local Behavioral Health Authority (LBHA) known as the Dallas Area NorthSTAR Authority (DANSA). DANSA was formed to ensure that local communities are given a voice in the delivery of publicly funded managed behavioral health care. The local authority also provides funds to the programs operational budget. DANSA represents both mental health and chemical dependency interests and concerns.

Effect of NorthSTAR on Consumers

Although NorthSTAR has only been fully operational since December 1, 1999, roughly 200,000 individuals have been enrolled in the NorthSTAR program. While it is still too early to declare NorthSTAR a success, preliminary data and anecdotal reports from consumers and advocates do point to several conclusions:

- Barriers to access have been reduced;
- Waiting lists for services have been eliminated;
- More low income individuals are receiving services than at any time in the past;
- Consumers have the feeling of empowerment that was lacking under the traditional system;

[11] TEXAS HEALTH AND HUMAN SERVICES COMMISSION, STATE MEDICAID DIVISION., TEXAS MEDICAID IN PERSPECTIVE. (1999).

- The number of consumer complaints is very low (averaging 43 complaints per 100,000 enrollees since full implementation) and the majority of consumer complaints have been resolved to the satisfaction of the consumer; and
- More enrolled providers are now available to meet the needs of consumers than at any point in the past. The expanded provider base results in more choice and greater convenience for consumers, enabling them to find providers with offices located closer to home or work.[12]

Criticism of NorthSTAR

Through public testimony, the Senate Health Committee heard a number of criticisms of NorthSTAR, most of which focused on payment and administrative issues. NorthSTAR's pilot program administrators have addressed the following areas in order to establish appropriate methods to improve both the provider and managed care behavioral health firms' business relationships:

- The need to move to an electronic system for claims reconciliation;
- Use of electronic formats to establish a synchronized automated billing system;
- A need for increased staff to handle the billing and reimbursement load; and
- Establishment of a formalized eligibility determination system.

Another concern that affects consumer service levels will be the reaction of MHMR and the remaining contractor ValueOptions to the BHO Magellan's recent decision to cease operations in the NorthSTAR program and addressing the operational questions of ensuring continuity of service, maintaining service levels and conditions another BHO might enter the market. The HHSC evaluation will detail both the positive and negative effects of the NorthSTAR implementation and will recommend solutions that address the shortcomings of the program.

House Bill 2896 Evaluation and Medicaid Managed Care Report

House Bill 2896 of the 76th Texas Legislature requires HHSC to:

[12] TEXAS DEPARTMENT OF MENTAL HEALTH AND MENTAL RETARDATION, NORTHSTAR QUESTIONS AND ANSWERS (June 2000).

- review outstanding administrative and financial issues with the Medicaid managed care pilot programs; and
- review the impact of the Medicaid managed care delivery system on access to care, quality of care, utilization patterns, statewide Medicaid costs, coordination of care, competition in the marketplace, network retention, public hospitals, medical schools, and other traditional providers of indigent health care.

HHSC is directing a review of the Medicaid managed care program to meet the requirements of H.B. 2896. The agency is working with other state agencies and contractors, including TDH, MHMR, TCADA, DHS, and THQA to conduct the review and report to the Legislature by November 1, 2000. HHSC has worked with an external workgroup to gather input on report topics, methodologies, and priorities. The external workgroup consists of individuals active in the development of the legislation, including representatives from advocacy and consumer groups, provider associations, managed care organizations, and behavioral health providers.

The report and underlying analyses will be based on a quality improvement model as defined by HHSC. It will emphasize descriptions and comparisons of structures and processes related to the Texas Medicaid program (both traditional and managed care); new and existing evaluation research, including limited studies on program performance and outcomes; and recommendations for program improvement.

The overview and report will be organized to reflect activities related to descriptions of program structures and processes in each study area; research related to program performance and outcomes, and recommendations for program improvement based on report findings. The results of the study and evaluation will be used by the committee and the Legislature to determine the effectiveness and accomplishments of the program and assist in the determination of the future direction of the Medicaid managed care program in Texas.

HHSC Evaluation Components

I. Access

A. Program structures and processes

1. Eligibility process and time frame;
2. Enrollment process and time frame;
3. Supportive services (linguistic services, cultural competency, and member education);
4. Physical Access (Americans with Disabilities Act, geographic proximity, transportation);
5. Provider network and capacity; and
6. CSHCN requirements, STAR+PLUS and NorthSTAR special population access.

B. Performance and outcome information

1. Eligibility and enrollment time frames for pregnant women;
2. Prenatal visits (traditional and Medicaid managed care); and
3. Provider trends.

II. Quality

A. Program structures and processes

1. State requirements;
2. Quality improvement processes;
3. Continuity of care requirements; and
4. State's methodology for measuring quality of health services provided.

B. Performance and outcome information

1. Asthma Study: Comparing ER use, hospital recidivism, pharmacy use for Children with asthma diagnoses in 1998 for Bexar (PCCM & HMO), Tarrant (HMO), and Dallas (traditional Medicaid) counties.

III. Utilization

A. Program structures and processes

1. Reporting of standard selected utilization trends: ER use and inpatient days.

B. Performance and outcome information

1. New generation medication studies (Harris County), and utilization of home and community-based services in STAR+PLUS.

IV. Cost (waiver cost-effectiveness) and Actuarial Review

A. Program structures and processes

1. STAR

a. Waiver and waiver renewal savings as reported to HCFA (HMO & PCCM) for all SDAs historical to present: total costs, medical costs, administrative costs, and vendor drug costs.

2. STAR+PLUS

a. Waiver and waiver renewal savings as reported to HCFA: total costs, medical costs, administrative costs, vendor drug costs.

3. NorthSTAR

a. Waiver savings as reported to HCFA: total costs, behavior health costs, and administrative costs.

B. Performance and outcome information

1. Review and recommendations on methodology for STAR and STAR+PLUS by a national independent Medicaid Managed Care actuary; and

2. Update analysis of managed care savings for pilots since 1996; total costs, medical costs, administrative costs, vendor drug costs, and long-term care costs in Harris County. Total savings including medical, administrative and vendor drug.

V. Care Coordination

A. Program structures and processes

1. STAR+PLUS
    a. Requirements; and
    b. Description (processes, credentials of staff, number of staff, number of members receiving care coordination).
2. Behavioral Health
    a. Requirements and coordination of physical and behavioral health.
3. STAR
    a. Requirements and processes

B. Performance and outcome information

VI. Administrative Complexity

A. Program structures and processes
1. Providers
    a. Credentialing, contracting, claim appeals, Medicaid eligibility, prior authorization, referrals for specialty care, electronic claims submission, auditing and monitoring.
2. Recipients
    a. Enrollment and recertification, requirements for changing providers or plans and access to specialists.
3. Managed Care Organizations
    a. Administrative requirements, reports, and deliverables.

B. Performance and outcome information
1. Case study of claims payments processes in Medicaid Managed Care with different provider types: STAR+, STAR, and BHOs.

VII. Traditional Providers

A. Program structures and processes

1. Description of traditional provider protections in legislation and contracts.

B. Performance and outcome information

1. Survey of public hospitals, teaching hospitals, medical schools, FQHCs, LMHAs, and significant traditional provider focus groups with Texas Medical Association and other physician organizations regarding the effect of Medicaid managed care on Medicaid business, the ability to provide indigent care, and the overall operations and services.

VIII. Competition and Network Retention

A. Program structures and processes

1. Number of plans, financial viability, provider recruitment and retention with plans, and LTC provider retention.

IX. Cross-area work

A. Program structures and processes

B. Performance and outcome information

1. Complaint study.

2. Summary of provider and consumer satisfaction surveys.

Disease Management

Health care for chronic disease patients consumes a majority of all health expenditures. In the managed care population, studies have indicated that as few as 10 percent of enrollees with chronic illnesses may consume as much as 70 percent of a group's health care costs. Risk factors such as obesity and lack of exercise are increasing among Texas' children, setting the stage for an epidemic of chronic conditions such as diabetes and heart disease. More children are experiencing problems with asthma than ever before. Between 1982 and 1993, the prevalence of asthma in the United States has increased by 46 percent overall and 80 percent in children. In 1995, the Texas Medicaid program spent more than $31 million on asthma-related hospitalizations. Recent reports suggest that many patients with chronic disease are not receiving the appropriate level of

care to effectively manage their conditions. Contributing factors include medication noncompliance, inadequate patient education and secondary prevention services, unexplained clinical variation in treatment, and inconsistency among physicians in following established treatment recommendations and protocol.

Physicians and other health care providers are examining strategies to effectively manage patients with chronic disease and improve clinical outcomes. Public and private health care payors are searching for methods to reduce chronic disease expenditures. Disease management holds promise as a way to address these issues.

Disease management, as defined by the Disease Management Association of America (DMAA), is a multi-disciplinary, continuum-based approach to health care delivery that pro-actively identifies populations with, or at risk for, established medical conditions; disease management:

- supports the physician/patient relationship and plan of care;
- emphasizes prevention of exacerbations and complications utilizing cost-effective, evidence-based practice guidelines and patient empowerment strategies such as self-management; and
- continuously evaluates clinical, humanistic, and economic outcomes with the goal of improving overall health.

Critical components of a disease management program should contain the following:

- A population identification process;
- Evidence-based practice guidelines;
- A collaborative practice model including physician and support-service providers;
- Risk identification and matching of interventions with need;
- Patient self-management education (may include primary prevention, behavior modification programs, and compliance/surveillance);
- Process and outcomes measurement, evaluation, and management;

- A routine reporting/feedback loop (may include communication with patients, physicians, other health care providers, and health plans, and practice profiling); and
- Appropriate use of information technology (may include specialized software, data registries, automated decision support tools, and call-back systems).

A recent *Journal of American Medical Association* study outlined additional areas such as:

- application of evidence-based medicine;
- an integrated health care delivery system capable of coordinating care across the continuum;
- a comprehensive knowledge base of the prevention, diagnosis, treatment and palliation of disease;
- sophisticated clinical and administrative information systems to provide decision support based on established practice guidelines, analyze practice patterns and provide feedback, and track outcomes; and
- continuous quality improvement methods.[13]

The delivery system for disease management programs varies greatly from one vendor to the next, but can generally be described as a primary care-based model. Under such a model, the primary care physician serves as the "team leader" and manages the coordination of care for the patient. The patient's physician can then determine whether a patient is appropriate for a particular program and individualize the program to suit the needs of each patient.

The program assumes primary responsibility for certain components of the patient's care. This entails separating care for a chronic disease from the care provided by the patient's physician. However, primary care models may run the risk of overlooking people with multiple chronic disease conditions and acute problems that may be unrelated to their chronic illnesses. The advantage of the primary care model is faster implementation. In some cases, a disease

[13] G. Ellrodt et al, *Evidence Based Disease Management*, JAMA, November, 1997, at 1687.

management contract can be constructed so that program costs are offset by savings realized by effectively managing care.

It should be noted that several other states have undertaken disease management programs for their Medicaid population. In 1995, the Virginia Health Outcomes Partnership implemented an asthma pilot program for Virginia Medicaid recipients in seven counties. After one year, emergency room and urgent care visits decreased by 42 percent. The net savings to the State was $285,000. The success of the program led to statewide implementation of an asthma disease management program. Projected statewide savings from this program are expected to be $2 million. Virginia also plans to implement a disease management program for patients with congestive heart failure.[14]

The Pharmaceutical Research Manufacturers of America (PhRMA) has reported that 38 states, including Michigan, Tennessee and Illinois have contracted for hemophilia disease management. Alabama has contracted for a diabetes disease management program. Colorado and Maryland use risk-adjusted capitated rates to pay Managed Care Organizations (MCOs) and disease management vendors that treat Medicaid beneficiaries infected with HIV and AIDS. Florida's Medicaid program is implementing four statewide disease management programs that could cover more than 100,000 patients with asthma, diabetes, HIV/AIDS or hemophilia.

The concept of disease management is promising. However, not all programs represent good patient care. Disease management means different things to different people. Ideally, it would serve as a clinical improvement process aimed at ensuring that the best scientific knowledge and practice are incorporated with minimal variation over the entire continuum of care. However, the concept could be used as a disguise for efforts to market a class or classes of drugs and/or to promote drug switching within a class. The commercialization of disease management programs may interfere with the goal of improving care for patients with chronic disease. For example, a

[14] NATIONAL PHARMACEUTICAL COUNCIL, Q&A FOR PHYSICIANS ABOUT VHOP-AN INNOVATIVE MEDICAID OUTCOMES PROGRAM, (1997).

program offered by a drug company may emphasize drug therapy over lifestyle modification, and that particular company may be unlikely to promote a competitor's product.

Disease management is, by definition, a long-term solution to the management of chronic disease. There is question as to whether this model could effectively be implemented within a Medicaid managed care structure. Eligibility requirements remain a valid concern to success, making long-term solutions difficult for a certain portion of the STAR and TANF population. However, for elderly or SSI population, a disease management program could prove beneficial.

Recommendations

The following recommendations are offered as a solution to address a myriad of the concerns that the Senate Health Committee has heard through public testimony during this interim. However, a number of these solutions do not take into account the anticipated Health and Human Services Commission report which is expected to be made public on November 1, 2000.

1. The Health and Human Services Commission shall make efforts to streamline the reporting requirements required by health care providers to reduce the administrative burden placed on providers' practices. The Commission shall review and make recommendations to implement the following: require HMOs to submit a quarterly management report; reduce the complexity of administrative forms health care providers are contractually obligated to provide and complete; identify and eliminate all duplicative and unnecessary provider and insurer requirements; and develop common credentialing and referral forms for all participating Medicaid plans.

   Rationale: *Replacing the numerous smaller reports and combining into one larger, easy-to-read evaluation report will reduce amount of time needed to provide proper feedback to the State. Providers have indicated that simplifying the reporting process would significantly reduce the administrative burden, allowing resources to be redirected into patient care. Streamlining onsite review procedures can assist in determining*

necessary and effective quality measures and required data. Requiring agencies to share information with one another will minimize the duplicative efforts that increase administrative costs.

2. TDI and HHSC shall coordinate efforts to evaluate the effectiveness of requiring health plans participating in the Medicaid program to eliminate pre-authorization requirements for certain routine services that currently have a high approval rate and make recommendations to implement this proposal. Services requiring prior approval should be clearly specified to health care providers. In addition, HHSC shall develop a standardized preauthorization form.

Rationale: *In several instances, certain routine services always approved. In those cases, elimination of the cumbersome preauthorization process will aid in streamlining the administrative function within the health care provider's practice.*

3. HHSC shall determine the impact, including costs, of establishing newborn down-coding and utilization review (UR) criteria and make policy recommendations to determine appropriate utilization review decisions.

Rationale: *Managed Care plans' utilization review practices are resulting in an increase in the down-coding of services and reduced payments to hospitals, which hospitals are required to appeal. The TDH Medical Appeals Division has overturned up to 40 percent of these denials/reductions. Currently, HHSC and TDH are working with providers to establish an appropriate utilization review decision matrix that will assist in interpreting HCFA's rules and regulations.*

4. HHSC shall determine the impact of creating a statewide outreach and education initiative to improve prenatal care for Medicaid managed care clients.

Rationale: *It is estimated that the cost of nearly half of all births in Texas falls to Medicaid. Direct education on adequate prenatal care will benefit the mothers and infants, as well as be cost effective to the State.*

5. HHSC shall review, evaluate, and make recommendations on the benefits of the establishment of a centralized electronic claims processing clearinghouse to be used by Medicaid managed care plans and the traditional Medicaid program. Once the review is complete, HHSC shall implement the system if it is determined to be beneficial.

Rationale: *Prior to the arrival of Medicaid manage care, physicians and other health care providers submitted all Medicaid claims directly to the State's claims payment contractor. Now, physicians participating in Medicaid managed care must submit claims to multiple locations. The State's contracted claims administrator processes more than 83 percent of its claims electronically, whereas only one Medicaid HMO routinely uses electronic claims payment. Implementation of one centralized electronic claims payment system would simplify and expedite the claims payment process for Medicaid.*

6. HHSC shall work with health plans, hospitals, physicians and other key health care providers to develop standardized, statewide programs for case management and specialty care initiatives. HHSC shall coordinate this effort to ensure consistency of knowledge and shared information across state agencies.

Rationale: *Each health plan has its own program for managing high-risk obstetrical patients. Some of these programs work well, while others do not. Each*

program has its own requirements. The State should identify plans with best practices, then duplicate that model in other appropriate plans.

7. Support the continuation of the PCCM model in all existing service areas or other service delivery areas which could benefit from the establishment of a PCCM model.

Rationale: *If Medicaid managed care is to be continued and/or expanded, the PCCM model should be utilized in all appropriate service delivery areas. The State shall consider efforts to "enhance" the PCCM model with expanded case and disease management to ensure that the model is cost-effective.*

8. HHSC shall initiate outreach programs to inform qualified providers of their ability to utilize a presumptive eligibility designation for pregnant women. HHSC shall also propose methods to streamline the process.

Rationale: *Currently, few providers are utilizing the presumptive eligibility option. In addition, streamlining the enrollment process will allow pregnant women to access services earlier in their pregnancy.*

9. As HHSC reviews and studies the implementation and effectiveness of the Medicaid Managed Care system to determine if the STAR program has met its original goals, special attention should be focused on improving the overall delivery system, particularly the NorthSTAR and Star+PLUS pilot projects. The STAR program should encourage access to appropriate care, increased quality of appropriate utilization patterns, coordination of care, and a delivery system based on quantifiable and measurable results.

Rationale: *The State must determine the future direction of the STAR program based upon its original goals and targets.*

10. HHSC shall work with appropriate state agencies to adopt an appropriate definition of disease management for Medicaid recipients.

Rationale: *HHSC, as the umbrella agency, should develop a disease management definition to ensure consistency throughout all health and human services agencies.*

11. HHSC shall develop and implement a targeted pilot project to determine the effectiveness of a disease management program in the reduction of long-term health care costs, improved care, better utilization patterns, and improved coordination of care.

Rationale: *A targeted and time-specific program could benefit Medicaid managed care enrollees suffering from chronic disease.*

12. Disease management outcomes must be monitored by an experienced quality measurement entity, using appropriate tools. Patient education and skills development should be directed and monitored by the treating physician(s) within the appropriate multi-functional disease management team.

Rationale: *A thoughtful and comprehensive evaluation is necessary to determine if the disease management pilot program is meeting its intended goals.*

13. HHSC shall study, review, and assess the impact of limiting the number of health plans participating in the STAR program within each market, and shall make recommendations on the appropriateness and effectiveness of limiting the number of plans within service delivery areas across Texas.

Rationale: *Health plans have a difficult time successfully operating in a market when plans allow for unlimited provider participation. Generally, the number*

of eligible enrollees in a market is limited and a health plan must attain a certain market share to operate effectively. Limiting each market to a PCCM model, non-profit health plan and a for-profit health plan could address the issue of market share and increase the chances of successful implementation.

14. HHSC shall study the feasibility and make recommendations to the Legislature regarding the requirement that Medicaid managed care clients contribute a nominal co-pay, as outlined by federal rule, at the time of treatment.

Rationale: *This will allow patients to take ownership of their health care decisions. Properly structured, this proposal should increase the use of primary care providers and decrease unnecessary emergency room visits.*

15. HHSC shall assess the current reimbursement rates for subspecialty providers generally considered to be primary care to determine if these providers are reimbursed at an equitable level.

Rationale: *The committee heard testimony from medical subspecialty providers who described problems relating to inequitable funding for certain providers in the State. Specifically, the Committee heard that the reimbursement rates for services provided by pediatric neurosurgeons in Houston are low enough that these providers, unable to sustain their practice, are facing a severe workforce shortage.*

INTERIM CHARGE 2

Biotechnology, Genetics, and Pharmaceutical Research

Biotechnology, Genetics, and Pharmaceutical Research
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Biotechnology, Genetics, and Pharmaceutical Research

Interim Charge #2

Inventory and analyze the amount and type of research related to pharmaceuticals, biotechnology, and genetics currently occurring in Texas to maximize the benefits to Texans in these fields. The Committee shall also examine the ethical implications associated with pharmaceutical, genetic, and biotechnology research.

Introduction

The next decade will bring about incredible strides in our understanding of the human body and our ability to resolve, rather than treat, its imperfections. Because science is making advances at a rapid pace, it is imperative that we anticipate the impact of life-changing opportunities that may soon face us all. This report is part of an ongoing effort to better understand the fields of biotechnology, pharmaceuticals, and genetics so that we may better prepare Texas for the impending changes in science. These changes will ultimately affect how decisions are made about our health and the well-being of our families.

Inventory

Biotechnology / Pharmaceuticals

Biotechnology is the collection of industrial processes that involve the use of biological systems. For some industries, these processes involve the use of genetically engineered organisms[1] or the use of living organisms or their products to modify human health and the human environment.[2] Biotechnology research and innovation are both time-intensive and expensive.

Costs of Biotechnology

The drug patent process takes 12 to15 years to complete on average, yet estimates show that five in 5,000 compounds that reach preclinical testing are ever tested on humans. One in five products tested on humans is

[1] PHARMACEUTICAL RESEARCH MANUFACTURERS OF AMERICA, NEW MEDICINES IN DEVELOPMENT: BIOTECHNOLOGY 2000, 39 (2000).

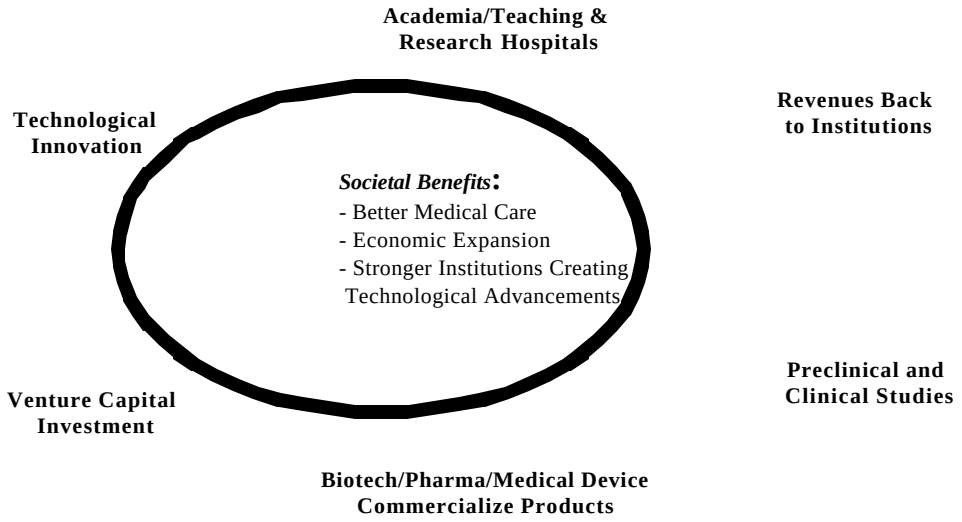
[2] PAMELA PETERS, BIOTECHNOLOGY: A GUIDE TO GENETIC ENGINEERING 3 (1993).

approved by the Food and Drug Administration.[3] According to testimony heard by the Senate Health Committee, the lengthy patent process, combined with the low FDA approval ratio, creates a major challenge for researchers and start-up hopefuls seeking financial support. Venture capitalist firms are more likely to invest in a high-tech product or service because it can turn a profit more quickly than a biotechnology product. In addition, the clinical trial process carries the added risk of public controversy due to social stigmas associated with genetic testing on humans.

Benefits of Biotechnology

Biotechnology innovations provide numerous societal benefits, chief among them lifesaving drugs. It also helps our farmers generate greater crop yields that can contain a higher concentration of vitamins and minerals. The higher nutritional value is a benefit in itself, but additional crop yields allow the U.S. to provide greater assistance to developing countries. Alternative fuels created through biotechnology processes may also be on the horizon.

The Cycle of Innovation



Source: Introgen Therapeutics

[3] PHARMACEUTICAL RESEARCH MANUFACTURERS OF AMERICA, NEW MEDICINES IN DEVELOPMENT: BIOTECHNOLOGY 2000, 43 (2000).

Biotechnology medicines use proteins and other substances produced in the human body to counter disease.[4] The process for approval of new medications is as follows:

Preclinical Testing

Laboratory and animal tests are conducted to determine how the compound reacts against the targeted disease. The compound is also evaluated for safety.

Investigational New Drug Application

After preclinical testing, applicants must file an Investigational New Drug application with the Food and Drug Administration (FDA) for consent to test the drug in humans. The application includes information about previous experiments, the makeup of the compound, its function, any negative results, how it will be manufactured, and how and by whom new studies will be conducted. The FDA has 30 days to disapprove it; if no disapproval is given after 30 days, the company may proceed to the next step. The Institutional Review Board (IRB) in the city or region where the studies will be conducted must also review and approve the application. The applicant must also submit annual progress reports to the FDA.

Clinical Trials, Phase I

Clinical tests begin with the involvement of about 20 to 100 normal and healthy volunteers. The tests study the drug's safety profile and the safe dosage range. These studies also determine how the drug is absorbed, distributed, metabolized, and excreted, as well as the length of time the drug takes to perform its function.

Clinical Trials, Phase II

In the next clinical phase, the applicant recruits 100 to 500 volunteer patients who have a targeted disease to undergo controlled studies and to assess the drug's effectiveness.

Clinical Trials, Phase III

This phase usually involves 1,000 to 5,000 patients based in clinics and hospitals. Physicians will monitor patients closely to confirm efficacy and identify adverse reactions.

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[4] PHARMACEUTICAL RESEARCH MANUFACTURERS OF AMERICA, NEW MEDICINES IN DEVELOPMENT: BIOTECHNOLOGY 2000, 39 (2000).

New Drug Application

If the drug successfully completes these three phases of clinical trials, the applicant then files a New Drug Application with the FDA. This application includes all scientific data about the drug. A typical application can be 100,000 pages or more. Technically, the FDA has six months to review, but the average review time for drug approval is about 18 months.

Approval

Once the drug is approved by the FDA, physicians may prescribe the new medicine. In some cases, the FDA will require an additional phase of testing to assess long-term effects. The applicant is also required to submit periodic reports to the FDA that include quality control records and any reportable adverse reactions.[5]

Biotech Research in Texas

A recent survey by the Pharmaceutical Research Manufacturers of America (PhRMA) found 369 biotechnology medicines currently in the development process. Of these, only eight are being developed by biotechnology companies based in Texas. California, New Jersey, Massachusetts, and Maryland are home to the bulk of the companies developing the remaining 361.

New Medicines in Development in Texas

AUTOIMMUNE DISORDERS				
Product name	**Company**	**Product Category**	**Indication**	**Development Status**
Veldona® natural human interferon-alpha	Amarillo Biosciences (Amarillo)	Interferon	Sjogren's Syndrome --- Fibromyalgia Syndrome	Phase III --- Phase II
CANCER AND RELATED CONDITIONS				
Adenovirus p53	Introgen Therapeutics (Austin)	Gene Therapy	Bladder, Breast, Lung, Ovarian Cancers, Gilioma	Phase I NCI Trial
ING N201	Introgen	Gene Therapy	Head and Neck	Phase III

[5] TEXAS HEALTHCARE & BIOSCIENCE INST., A PROFILE OF PROGRESS: THE TEXAS HEALTH CARE TECHNOLOGY INDUSTRY 10-11 (1998).

Product name	Company	Product Category	Indication	Development Status
(adenoviral-p53)	Therapeutics (Austin)		Cancer ---------- Prostate Cancer	---------- Phase II
Melacine® melanoma theraccine (therapeutic vaccine)	Southwest Oncology Group (San Antonio)	Vaccine	Stage II Malignant Melanoma	Phase III
GROWTH DISORDERS				
Trovert™ pegvisamont	Sensus Drug Development (Austin)	Human Growth Hormone	Acromegaly	Phase III
HEART DISEASE				
Novastan® argatroban	Texas Biotechnology (Houston)		Heparin-Induced Thrombocytopenia (HIT) Syndrome	Approved June 2000
RESPIRATORY DISEASES				
anti-IgE humanized MAb	Tanox Biosystems (Houston)	MAb	Allergic Asthma, Allergic Rhinitis	Phase III Completed
OTHER				
anti-IgE humanized MAb (HU-901)	Tanox Biosystems (Houston)	MAb	Reduction in sensitivity to peanuts.	Phase I / II

Source: "New Medicines in Development: Biotechnology 2000," Pharmaceutical Research Manufacturers of America, February 2000
** Argatroban is the first drug developed in Texas approved by the FDA.*

Research Universities

According to a report by the Texas Department of Economic Development, Texas' 55 medical research institutions spent about $900 million in research and development (R&D) in life sciences in 1998. Federally funded R&D expenditures are increasing at about 9 percent annually.[6] The next section illustrates some of the research work currently being conducted in Texas' largest research universities.

Baylor College of Medicine

Baylor is one of three participants chosen by the National Human Genome Research Institute to complete the map of the human genome. The human genome is the blueprint of human life, which consists of 3 billion base

[6] Data source: TEXAS HEALTHCARE & BIOSCIENCE INST.

pairs and 100,000 genes on the body's 46 chromosomes. The Baylor Human Genome Sequencing Center received an $80 million, five-year federal grant in 1999 for the final phase of this project. Baylor's chief role is to determine the sequence of chromosomes 3, 12, and X.

The International Center for Cell and Gene Therapy at Baylor, Methodist Hospital, and Texas Children's Hospital combine basic science and clinical research with comprehensive pediatric and adult cell-and-gene-therapy transplant units. Their mission is to develop treatments for genetic diseases and other illnesses in children and adults using therapies with specially designed cells or genes.

The National Space Biomedical Research Institute is a consortium of 27 institutions led by Baylor College of Medicine in cooperation with the National Aeronautics and Space Administration (NASA) to research the harmful effects of microgravity and space radiation. Current studies are probing issues such as bone loss, cardiovascular alterations, human performance, immunology, muscle atrophy, neurovestibular adaptation, radiation effects, and technology development.

The Breast Center at Baylor brings together comprehensive clinical facilities, clinical trials to improve diagnosis, treatment, and prevention of breast disease. It contains the world's largest collection of tumors (more than 100,000) that researchers believe will help develop new treatments.

Texas Children's Cancer Center at Baylor, in partnership with Texas Children's Hospital, is world-renowned for its work in pediatric cancer and hematology disorders. They offer innovative therapies for all forms of childhood cancer and blood disorders.

Baylor also has more than 70 other centers dedicated to research and patient care, including: Children's Nutrition Research Center, the DeBakey Heart Center, a child health research center, the Huffington Center on Aging, a center for AIDS Research, and federally funded research units that collectively form an influenza research center.

The private institution also has two national heart, lung, and blood institute special centers of research, one on arteriosclerosis and one on heart failure. The Matsunaga-Conte Prostate Cancer Research Center, a general clinical research center and a clinical center for the national Women's Health Initiative.[7]

Rice University Institute of Biosciences and Bioengineering

Rice University is completing renovations for a new research facility for the Department of Bioengineering. Also located in this facility will be the new national Center for Excellence in Cellular and Tissue Engineering. The focus of this Center includes cell replacement therapies, computational and living engineered model systems, and molecular characterization of tissue structure and formation. Research efforts are concentrated on the production of tissues, organs, and genetically altered cells for human implantation.

The Institute's key areas of research specialization are:

- cellular and tissue engineering;
- signal transduction;
- fermentation, metabolism, and bioprocessing;
- sequence, structure, and function;
- plant biochemistry and genetics; and
- gravitational biology.

Several Institute faculty members are currently collaborating on the following projects with the Texas Medical Center:

- Flow modulation of cell adhesion and metabolism;

[7] Laurie Stoneham, *Expanding the Frontiers: The Economic and Human Dynamics of Medical Research in Texas*, TEXAS MEDICINE, May 2000, 39-40. Information verified by Thomas Kleinworth, Director, Office of Public Affairs, Baylor College of Medicine.

- Tissue-engineered vascular grafts;
- Tissue-engineered bone;
- Non-viral gene delivery;
- Nutritional immunology;
- Injectable orthopaedic biomaterials;
- Arterial thrombosis;
- Bone cell signaling pathways;
- Gene therapy;
- TNT (trinitrotoluene, the explosive) and the process of biodegration;
- Tissue engineered neurocranial prosthetics;
- Fermentation technology and new protein expression systems; and
- Computer-aided drug discovery.[8]

Scott & White Memorial Hospital and the Scott, Sherwood and Brindley Foundation

Scott &White is involved in research exploring new medications for the treatment of a variety of conditions including:

- Osteoporosis;
- Type I and II diabetes;
- Hypertension;
- Parkinsonism;
- Osteo and rheumatoid arthritis;
- Interventions designed to decrease the initial damage in a myocardial infarction; and
- Interventions preventing complications during open heart surgery.

Research is also ongoing in cancer treatment with emphasis on studies preventing breast and prostate cancer. A new research focus is the exploration of immunotherapy in the treatment of childhood malignancies.[9]

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[8] INSTITUTE OF BIOSCIENCES AND BIOENGINEERING OF RICE UNIVERSITY, ANNUAL REPORT (1999).

[9] Information provided by Lee Ogburn-Russell, Assistant Administrator for Research and Education, Scott & White Memorial Hospital and the Scott, Sherwood and Brindley Foundation.

Texas A&M University Health Science Center

The College of Medicine's Cardiovascular Research Institute within the Texas A&M University Health Science Center is studying the behavior of blood vessels at the microscopic level to better understand the causes of cardiovascular disease, what happens after damage has occurred, and what factors stimulate blood vessels to open and stay open, including the use of nitric oxide. The institute is also working on ways to encourage the body to create collateral blood vessels.

The Department of Pharmacology, within the College of Medicine, is evaluating the effectiveness of eye drops as a vehicle for medication delivery. Clinical trials involve the administration of insulin through eye drops.

The Department of Human Anatomy and Medical Neurobiology is studying fetal alcohol syndrome, as well as examining the effect alcohol, tobacco, and other drugs have on fetuses at the anatomical and neurological levels.

The Department of Pathology, Department of Medical Microbiology and Immunology, and Department of Medical Biochemistry and Genetics are collectively researching the causes of diseases resulting from infectious agents and from genetic disorders, including tuberculosis, immune disorders, and cancer.

The School of Rural Public Health is comprehensively studying the causes of breast cancer among various population groups.

Baylor College of Dentistry (part of the A&M System) has a major research emphasis on environmental and genetic factors affecting craniofacial disorders and understanding how to prevent or treat such disorders. This work includes studies of oral cancers due to environmental factors such as use of tobacco products and how to prevent or cure such cancers. Improved dental care also derives from research to develop new biomaterials for use in dentistry for healthier teeth and gums.[10]

[10] Information provided by Kay Kendall, Deputy Director, Office of Communications, Texas A&M University System Health Science Center.

Texas A&M Institute of Biosciences and Technology

The Institute of Biosciences and Technology is engaged in researching if and how edible foods could be a potential vehicle for delivering vaccines.

Also underway are projects studying how to attack bacteria that cause infections, the development of a vaccine for Lyme Disease, and a treatment for mastitis in cattle. The major emphasis is on infectious diseases of bone and connective tissues.

The Center for Genome Research is looking at the structure of DNA to learn how to predict and treat disease states earlier and more effectively.

The Center for Cancer Biology and Nutrition focuses on understanding the causes of prostate cancer and how nutrients may influence the expression of prostate cancer and other cancers affecting humans and animals.

The Center for Biotechnology and Genomics is conducting research to improve the health of women and children by understanding environmental and genetic factors and their interactions that affect reproduction and development.[11]

Texas Tech University Health Sciences Center

Researchers at the School of Pharmacy in Amarillo are identifying ways of improving drug and recombinant DNA uptake into the brain across the "blood-brain barrier" for the treatment of central nervous system diseases.

The School of Pharmacy is also conducting studies which focus on identifying new clinical markers of prostate and testicular cancer and novel treatments using immune therapy, as well as drug screening methods for human cytochrome P450.

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[11] *Id.*

Researchers in Amarillo are also studying ways of improving drug pharmaceutical formulations and drug targeting to specific tissues, such as the liver or brain.

Researchers at the Texas Tech School of Medicine at El Paso, Department of Research Development and Internal Medicine, are investigating several new antimicrobial agents (antibiotics) in the following areas:

- Interactions of moxifloxacin with human phagacytic cells;
- Daptomycin in the treatment of complicated skin and soft tissue infections;
- Safety and efficacy of ziracin *vs*. vancomycin in the treatment of serious gram positive infections;
- Synercid nosocomial pneumonia; and
- Linezolid in the treatment of nosocomial pneumonia.

Investigators in the Department of Internal Medicine are also evaluating new therapeutic agents and outcomes in HIV/AIDS patients, as well as conducting multiple studies evaluating the efficacy of antiretrovial agents and long-term outcomes in HIV-infected patients.

Researchers are examining potential local risk factors for antibiotic resistance (Gram-positive cocci) and viral hepatitis.

The Division of Gastroenterology in the Department of Internal Medicine is studying the natural history and response to treatment (Alosetron) in patients with irritable bowel syndrome.

The Department of Neuropsychiatry in the Department of Internal Medicine is conducting several trials of new therapies for depression and schizophrenia.

Another study examines the role of white blood cell (WBC) abnormalities as a predisposing factor for the frequent infections, inappropriate inflammation, and poor wound healing seen in diabetes mellitus. Identification of a specific cause of WBC damage should lead to therapeutic trials using inhibitors of the injurious process, with the goal of preventing infections and other complications of diabetes.

Research in the Department of Emergency Medicine is evaluating the use of near infrared spectroscopy to investigate mitochondrial dysfunction, and its associated causes, in septic shock.

Researchers from the Health Sciences Center in Lubbock are involved in a larger Texas Consortium with the University of Texas at Austin, as well as the University of South Florida, to conduct research on chemical and biological warfare countermeasures.

Researchers in the Department of Dermatology, in collaboration with Harvard University, have discovered the gene responsible for PXE, pseudoxantherma elasticum, a rare skin and cardiovascular disorder.

Researchers from the Texas Tech University School of Medicine at El Paso are working with University of Texas at El Paso researchers on "The Role of Genetic Polymorphisms on the Excretion of 1-Hydro Pyrene."[12]

University of North Texas Health Science Center at Fort Worth

The University of North Texas (UNT) Health Science Center maintains six Research Institutes for Discovery, including the Geriatrics Education and Research Institute, the Cardiovascular Research Institute, the North Texas Eye Research Institute, the Physical Medicine Institute, the Cancer Research Institute and the Institute for Public Health Research.

The level of annual research funding at UNT is approaching $10 million per year. Grant sources include the National Institutes of Health, National Science Foundation, National Aeronautics and Space Administration, Alzheimer's Association, the Department of Education, and the Department of Health and Human Services.

The health science center houses the premier DNA Identity Testing Laboratory in Texas, led by Dr. Arthur Eisenberg, who also chairs the FBI's DNA Advisory Board.

The UNT health science center cooperated in the creation of the MedTech Center, Fort Worth's medical and

[12] Information provided by the Office of Program Planning and Policy Analysis, Texas Tech University Health Sciences Center.

technology business incubator. This project holds promise of creating new businesses and new jobs in and for the city. Intellectual property holdings of the center's faculty are expected to be among the new ideas to be incubated at the MedTech Center.

The UNT health science center has been awarded a $1 million grant from The Robert A. Welch Foundation to establish a chair in biochemistry. The grant creates the health science center's first endowed chair and will provide for placing a senior research scientist on the institution's faculty.

UNT is also conducting research aimed at validating the effectiveness of osteopathic medical procedures. The main initiative focuses on how spinal manipulation can speed nerve traffic through the spine's nerve roots.[13]

University of Texas Health Science Center at Houston

UT-Houston has created a specialized research unit, the Institute of Molecular Medicine to discover molecular mechanisms that can be used to prevent diseases. Special attention is given to genetic causes of diseases and genetic regulation of immune function. Researchers have had early success with new genetic approaches for arthritis, scleroderma, and other autoimmune diseases, and researchers are making great progress in determining the genetic basis of diabetes in Mexican-Americans in Texas.

Texas Prevention Center, School of Public Health, has been successful in the promotion of health and prevention of disease.

Researchers in the Coordinating Center for Clinical Trials provide expertise to guide major national trials of drug safety and efficacy. The center is currently managing a large, multi-center study to establish a matrix to determine the best drugs to prevent heart attacks. Groundbreaking research indicates that the timing of treatments is often as important as the selection of treatments.

[13] Information provided by Carroll Cole, Marketing & Communications Director, University of North Texas Health Science Center at Fort Worth.

The Center for Infectious Diseases addresses infectious diseases that are present in Texas and which are moving into Texas from Latin America. The center has established international research collaborations to identify and contain threats from infectious diseases.

A new Digestive Diseases Center brings together researchers in physiology, pharmacology, gastroenterology, and other areas to address functional, inflammatory, infectious, and drug-induced diseases of the digestive organs.

The Vision Research Center is one of UT-Houston's foremost research units and has won national acclaim for discoveries in retinal structure and function as well as visual pathways in the brain that convert light signals to sight.[14]

University of Texas Health Science Center at San Antonio

UTHSC is pioneering research to learn more about the process in which thermal ablation is used to eradicate liver tumors.

Projects involving growing teeth in mice are gaining international attention and leading toward a time when human teeth can be grown.

Researchers are using a multimillion-dollar positron emission tomography unit to determine the cause of stuttering, including a study of the areas of the brain that are involved.

Some children are born with one or more ribs missing, a potentially fatal defect. Researchers invented and continue to study a rib made of titanium that can be surgically implanted and expanded as the child grows.

The Research Imaging Center conducts a number of studies involving such things as depression, thirst (study

[14] Information provided by Thomas F. Burks, Ph.D., Executive Vice President for Research and Academic Affairs, UT-Houston Health Science Center.

just released), epilepsy, and music therapy.

The Institute of Biotechnology is studying tumor-suppressor genes, including the retinoblastoma gene and p53 gene.

Diabetes is a major focus of research, which includes clinical trials of new drugs, genetics studies, health promotion, and disease prevention initiatives.

UTHSC researchers also treat Alzheimer's patients and studies stroke-related vascular dementia in their Memory Disorders Clinic.

The Department of Surgery researches minimally invasive surgeries of all kinds. Recently, doctors performed the first laparoscopic kidney operation here. Researchers are also studying new techniques in neurosurgery and other areas.

As a member of the Human Genome Project, the Center serves as the worldwide repository for genetic information on Chromosome 3. Other genetics studies include a major group looking at Chromosome 18 and deletion and other related syndromes.

Cardiac research focuses on new types of interventions such as gene therapy and modified rotablation techniques, while orthopedics researchers are examining biomaterials and prosthetic devices for bone.[15]

University of Texas Health Center at Tyler

Research expenditures this year will exceed seven million dollars. The Center partners with Stephen F. Austin State University in a Masters in Biotechnology degree program which has been very successful. Efforts in

[15] Laurie Stoneham, *Expanding the Frontiers: The Economic and Human Dynamics of Medical Research in Texas,* TEXAS MEDICINE, May 2000, 39-40. Information verified by Charles G. Rodriguez, Ph.D., Executive Director of Development and Public Affairs, University of Texas Health Science Center at San Antonio.

conjunction with the Tyler Economic Development Council are underway to develop a Biotechnology Park adjacent to the UT-Tyler campus.

Ongoing National Institutes of Health (NIH) funded research focuses on a range of diseases associated with the lung including Tuberculosis (TB), fibrotic lung disease, and Acute Respiratory Distress Syndrome (ARDS). Efforts are also directed toward developing vaccines for TB, interventions in the progression of fibrotic lung disease, and the clinical efficacy of a peptide inhibitor of IL-8 (patent held) in blocking the metastasis of malignant melanoma. Most of their research is directed toward understanding the basic biochemistry underlying environmentally induced lung disease, immune system function including innate immunity mediated by complement, blood coagulation, the molecular processes of Mycobacterial replication, oxidant mediated DNA damage, and lung specific gene regulation. The basic tenet of this type of research is that it has the potential to identify new drugs and new drug targets.[16]

NIH-sponsored research includes the SPRINT project on pulmonary rehabilitation; a project to identify better ways of controlling asthma in pediatric patients; and the SELECT project studying prostate screening.

Pharmaceutical firms are sponsoring research projects in emphysema, asthma, pulmonary embolization, identification of new techniques to monitor pulmonary function, diabetes, heart disease, management of pneumonia, and migraine headaches.

UTHCT is conducting a broad range of oncology projects, including breast and prostate cancer, lung cancer, non-Hodgkin's lymphoma, bone cancer, and mechanisms to control nausea and the identification of the best chemotherapy strategies for several of these neoplasms.

Projects on the horizon include research in chronic bronchitis, pneumonia, and congestive heart failure.[17]

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[16] Information provided by Mark A. L. Atkinson, M.A., D.Phil., Director of Research, James Robert Montgomery Professor of Biochemistry, University of Texas Health Center at Tyler.

[17] Information provided by Steven Idell, MD, PhD, FACP, FCCP, Temple Professor of Medicine, Director Clinical Research, Chairman Department of Medical Specialty, Chief, Pulmonary Division, University of Texas Health Center at Tyler.

University of Texas M.D. Anderson Cancer Center

The University of Texas M. D. Anderson Cancer Center (MDACC) was ranked the number one cancer center in *U.S. News & World Report's* latest "America's Best Hospitals" survey published in the magazine's July 17, 2000 issue. MDACC was the only hospital in Texas to receive the number one ranking in any medical specialty.

MDACC researchers discovered the first direct evidence that a major chemical carcinogen, benzopyrene, in cigarette smoke seeks out and damages the p53 gene in lung cells. This research confirms at the molecular level how smoking can cause lung cancer and offers new avenues for therapy and prevention.

MDACC was the largest participant in the National Cancer Institute study of tamoxifen in the prevention of breast cancer in women at higher risk which revealed that tamoxifen lowered breast cancer incidence by 40 to 50 percent.

MDACC is one of the nation's leaders in research to discover and treat genetic causes of cancer.

MDACC has led the expansion of diagnostic capabilities to identify molecular changes in individual patient tumor specimens in order to correlate with disease patterns and response to therapy.

MDACC pioneered therapies in two areas of research this year: one based on differences between cancer cells and their cells of origin and the other based on the biological and immunological responses in the patient.

During the last year, the Office of Protocol Research coordinated and tracked more than 450 clinical trials, which compare new cancer treatments against standard therapies. About 6,500 patient registrations were recorded for these studies at MDACC, which for many years has conducted the largest number of clinical trials in the country. Sizeable progress was made in FY97 to make the entire clinical trial process more efficient. As a part of this effort, new offices were created for Clinical Research Quality Assurance to audit studies and expedite problem solving, and for Clinical Research Finance to better evaluate the cost of clinical

trials and help predict total costs before a trial begins.[18]

University of Texas Medical Branch at Galveston

UTMB currently has 200 research grants from the National Institutes of Health totaling more than $48 million. More than $84 million in government grants were recorded by the university in fiscal year 1999, in addition to nearly $19 million in grants and contracts from other sources.

Research strengths include: Environmental health, infectious diseases, neuroscience, aging, structural biology and membrane protein research, cancer, and gastrointestinal diseases. (Selected details appear below.)

Environmental Health:

UTMB's National Institute for Environmental Health Sciences (NIEHS) Center is one of 16 such federally funded centers in the nation. Interdisciplinary studies by scientists there and in other departments focus on environmental pollutants, asthma, toxic exposure, and genetic damage and repair.

The National Institute for Allergies and Infectious Diseases awarded more than three million dollars to UTMB's Asthma and Allergic Diseases Research Center, one of only 12 in the United States and the only one in Texas. Researchers at the center are trying to figure out how and why asthma attacks occur and what elements, including environmental pollutants such as ozone, affect the severity of those attacks.

The NIEHS Center recently received one of only two $3 million grants in a nationwide competition designed to link "research intensive universities" with "historically black colleges and universities." The grant will be used to create a multifaceted research and educational program in which UTMB serves as a template to help Southern University in Baton Rouge, Louisiana, become nationally competitive in basic biomedical and environmental health research.

[18] Information provided by Mark Moreno, Public Affairs, University of Texas M.D. Anderson Cancer Center.

Infectious Diseases:

Infectious diseases are responsible for some 20 million deaths a year, and UTMB scientists are studying many of the most deadly of these diseases.

According to a recent article in *Science* magazine, UTMB is "quietly building a top-flight center for the study of emerging and tropical infectious diseases" that "may well become *the* center for tropical medicine in the world." Scientists at UTMB's World Health Organization Collaborating Center for Tropical Diseases study St. Louis Encephalitis, dengue fever, hantavirus, Venezualan equine encephalitis, and rocky mountain spotted fever, several of which are appearing with increasing frequency in the United States and the world. The center houses the world's largest collection of viruses transmitted by mosquitoes and other arthropods. Center researchers also are trying to discover ways of disrupting the passage of malaria from mosquitoes to humans, while setting the stage for producing and introducing a genetically engineered, malaria-resistant mosquito.

The University of Texas Board of Regents recently granted UTMB permission to proceed with architectural plans for a biosafety level 4 laboratory. Upon completion in 2002, the facility, designed to let scientists study viruses that have no treatment or cure, will be the first of its kind on a U.S. medical center campus.

The National Institute of Allergy and Infectious Diseases will award UTMB $5 million over the next five years, beginning August 1, to renew its Hepatitis Research Center, one of only six in the nation. Studies there include research into how the Hepatitis C virus infects cells, and scientists are trying to devise a system to grow the virus in the laboratory. Such efforts could eventually shed light on ways to devise a Hepatitis C vaccine.

The National Institute of Allergy and Infectious Diseases recently granted UTMB a five-year, $10 million renewal for the university's AIDS Clinical Trials Unit, one of 32 members of the national Adult AIDS Clinical Trials Group, the largest clinical trials network in the world. Group investigators work as a coalition to develop patient-based studies aimed at finding and evaluating new treatments and preventions for AIDS and its related complications. An additional $1.5 million provides continued support for UTMB's Immunology

Support Lab, one of only six in the nation, which helps researchers understand how HIV infection and treatment affect the body's immune system.

Other AIDS projects include: The Pediatric Spectrum of Disease Project, which looks at how HIV disease and treatments affect children, and a national study focusing on how HIV affects the brain. Also underway are worldwide Phase III clinical trials of an experimental AIDS vaccine.

Neuroscience:

UTMB scientists recently discovered an entirely new nerve pathway in the spinal cord, believed to be the way pain messages from the internal organs (such as the colon, pancreas, and intestine) are transmitted to the brain. A pioneering set of surgeries on a limited number of patients revealed that cutting the newly discovered pathway relieves cancer pain that would not respond to even the strongest narcotic drug treatment. Ongoing research aims to determine what kind of pain-relieving drugs might affect the newly discovered pain pathway, possibly some day offering further relief to thousands of people with intractable pain.

Other projects involve studying the effects of injury to the spinal cord and developing chemical compounds to encourage regeneration of damaged nerves.

Aging:

UTMB received $6.5 million from the National Institute on Aging to create a Claude Pepper Older Americans Independence Center. The UTMB center, one of only 10 in the United States and the only one in the Southwest, will focus exclusively on research to improve and sustain muscle function in older Americans with the goal of prolonging their independence. UTMB is also the center of the Hispanic EPESE, the largest trial to follow minority populations as they age.

Structural Biology and Membrane Protein Research:

A $2 million grant from the prestigious Howard Hughes Medical Institute will help UTMB create a unique cross-disciplinary research program focusing on the study of membrane proteins, an important but difficult to study group of molecules. The UTMB center will be the only one in the United States and one of only a

handful in the world to study these molecules. Research there will help scientists understand what goes wrong in numerous genetic and acquired diseases involving membrane proteins, such as cystic fibrosis (the most frequently lethal genetic disease in Caucasians), retinitis pigmentosum (an eye disease that can lead to blindness), and infectious diarrhea (one of the most common acquired diseases in children).

UTMB, together with Rice University and Louisiana State University, received a $1.75 million grant from the National Science Foundation and the National Institute of General Medical Sciences to build a high-tech link that will speed up three-dimensional studies of important biological molecules, thereby facilitating the quest for new drug treatments for various diseases.

Other:

UTMB recently received $10.3 million from the National Institutes of Health, continuing a 37-year tradition of support for the General Clinical Research Center, one of the oldest among a federally supported network of 75 centers whose mission is to conduct, support, and enhance patient-focused studies. The GCRC also received a $1 million, five-year educational grant to enhance clinical research training.[19]

University of Texas Southwestern Medical Center

In 1997, Robert Haley, M.D., chief of epidemiology at UT Southwestern, published three papers in *The Journal of the American Medical Association* that defined Gulf War Syndrome as a disease characterized by a complex and vague set of symptoms linked to chemical exposure in the Persian Gulf War. Dr. Haley is currently researching the cause of the disease and possible treatments for victims.

The Donald W. Reynolds Foundation awarded a $24 million grant for cardiovascular clinical research to UT Southwestern to establish the Donald W. Reynolds Cardiovascular Clinical Research Center. The nationally-competitive grant will advance research into the prevention and treatment of heart disease caused by atherosclerosis, or plaque buildup of the inner lining of the arteries. A heart disease survey of 15,000 Dallas County households has begun as the first phase of the project.

[19] Information provided by Alana Mikkelsen, Science Editor and Managing Editor, Public Affairs Office, UTMB Quarterly magazine, Office of University Advancement, University of Texas Medical Branch at Galveston.

The National Institute of Mental Health (NIMH) awarded a $26.9 million contract to UT Southwestern to study treatment-resistant depression, the largest contract for that speciality ever awarded by the NIMH. Dr. A. John Rush, Vice Chairman for research in the Department of Psychiatry, will oversee clinical trials involving UT Southwestern and 11 other U.S. medical institutions and 4,000 patients, who will be treated over a five-year period.

UT Southwestern is investigating cancer, neuroscience, heart disease, and stroke, arthritis, diabetes, and a number of other diseases.

Researchers are working to define the PPP2R1B gene in human lung and colon cancer, which may lead to methods to accurately predict who has a high risk of developing these malignancies and aid in developing effective therapies for those already afflicted.

UT Southwestern scientists have developed the first animal model for colorectal cancer that will facilitate ways to study the molecular mechanisms of the disease and provide a model system for testing chemoprevention agents and new drugs.

Researchers discovered the location of a gene that causes age-related macular degeneration (AMD) using genetically altered mice to help explain two types of human blindness, AMD and Stargardt's disease.

Clinical trials of a new drug called Infliximab show promising results for significantly decreasing the signs and symptoms of rheumatoid arthritis.

Discovery of a marker that can track thymus function shows how the adult immune system might repair itself after being damaged by human immunodeficiency virus (HIV).

Studies reveal that human cells grown in the laboratory and immortalized by the introduction of the enzyme telomerase are not transformed into cancer cells, perhaps clearing the way for safe, future medical applications.

UT Southwestern scientists have a better understanding of the protective role that estrogen plays in cardiovascular disease. Recent studies demonstrated how estrogen improves blood vessel function and provides the protection pre-menopausal women have against coronary artery disease.

UT Southwestern researchers have isolated the gene believed responsible for the most common genetic cause of heart and facial birth defects. Children with chromosome 22 deletion syndrome, also known as DiGeorge syndrome, can suffer cardiac defects, abnormal facial features, immune deficiencies, cleft palate, and low blood calcium.

A routine test already in use to diagnose prostate cancer and enlarged prostate, the prostate-specific antigen (PSA) level test, could also predict the likelihood of a patient requiring surgery or developing acute urinary retention.

UT Southwestern has developed a method to isolate purified cancer cells, an advancement that may help unravel the mysteries of tumor biology and cancer development.

Using an infrared, nighttime video camera to study genetically engineered mice lacking a molecule known to affect appetite, researchers unexpectedly discovered they had created a rodent with the sleep disorder narcolepsy.

Researchers recently discovered four genes that can halt lupus and may lead to the development of preventive drugs.[20]

[20] Laurie Stoneham, *Expanding the Frontiers: The Economic and Human Dynamics of Medical Research in Texas,* TEXAS MEDICINE, May 2000, 42. Additional information provided by Roy E. Bode, Vice President for Public Affairs, University of Texas Southwestern Medical Center.

Private Sector Research

According to a report by the Texas Department of Economic Development, the health care technology industry cluster in Texas is made up of more than 500 companies with at least $6.5 billion in annual sales, generating more than 48,000 private sector jobs with an average salary of $40,000. Research and development expenditures in Texas companies average $3.1 million per company per year.[21] For private sector wages and employment statistics by county, see Appendices A and B. The following is a listing of some of the larger biotechnology companies, public and private, that are currently located in Texas, and the focus of each company's research. The companies are listed in order by city.

A Sampling of Texas Biotechnology Companies

Company	Location	Research Focus	Publicly Traded?	Website
Ambion	Austin	A market leader in the development and supply of RNA-based life science research and molecular biology products, Ambion specializes in the development of products for stabilizing, synthesizing, handling, isolating, storing, detecting, and measuring RNA. Ambion's RNA Diagnostics division specializes in supporting diagnostic tests based on the detection of RNA. Reagents and enzymes currently produced by Ambion are produced and formatted to the specifications and specialized needs of the clinical customer. In the near future, the RNA Diagnostics division will have the capability of manufacturing reagents and kits under cGMP conditions as well.	Private	www.ambion.com

[21] TEXAS DEPT. OF ECO. DEV., TEXAS: A DIFFERENT BRAND OF BUSINESS (Jan. 2000).

Company	Location	Research Focus	Publicly Traded?	Website
Diagnostic Systems Laboratories (DSL)	Austin	Formed in 1981 with a vision of developing and marketing high quality niche *in vitro* diagnostics, DSL's dedication to immuno-diagnostics has made this company a worldwide leader in hormone analysis.	Private	www.dslabs.com/dslabs/home.htm
Introgen Thera-peutics, Inc.	Austin	Founded in 1993, it was the first company to receive approval to treat cancer by direct introduction of a therapeutic gene inside the body (in vivo). The company has ongoing clinical trials in non-small cell (NSC) lung cancer and head and neck cancer with a p53 gene replacement product as well as ongoing clinical trials for the treatment of liver, prostate, bladder, ovarian, brain and breast cancers. Introgen has treated almost 500 patients with more than 3,000 doses of INGN 201, in over 17 completed and ongoing Phase I and Phase II clinical trials worldwide. A global Phase III trial to treat head and neck cancer has recently begun. Introgen's current and expected clinical trials evaluate its products both alone and in combination with chemotherapy, radiation, and/or surgery. With the poor efficacy and debilitating side effects of current treatments, Introgen's low-toxicity approach to cancer treatment has drawn global interest from oncologists. Introgen's core technologies were developed at the University of Texas M.D. Anderson Cancer Center in Houston. Currently, Introgen is the largest corporate sponsor of research at M.D. Anderson. Introgen is pursuing commercialization of its p53 products in collaboration with Aventis (formerly	Private	www.introgen.com

Company	Location	Research Focus	Publicly Traded?	Website
		Rhône-Poulenc Rorer). Aventis funds all research and development of these products worldwide. In addition to its clinical programs with p53, Introgen is conducting a number of preclinical and research programs involving a variety of genes for the treatment of cancer, including mda-7, PTEN, CCAM and others.		
Sulzer Ortho-pedics, Inc.	Austin	Sulzer Orthopedics was founded in 1999 to encompass all the research and development activities conducted in the biological field by SulzerMedica Inc. SulzerMedica focuses on the development of implantable medical devices and biomaterials for the orthopedic and cardiovascular markets worldwide and has two other companies established in Austin: Sulzer Orthopedics Inc. and Sulzer Carbomedics Inc. Product offerings include artificial joints, spinal and dental implants, products for traumatology and arthroscopy, heart valves, and vascular grafts. SOI has a proprietary mixture of proteins ("Bone Protein" or "BP"), which is purified from bovine bone and contains multiple osteoinductive growth factors. Several orthopedic applications (e.g. spinal fusion, and periodontal, cartilage, meniscus, and spinal disc regeneration) and cardiovascular applications (e.g. treatment of ischemic heart and peripheral vascular diseases, coronary grafts, and valve repair) are currently in development. Ne-Osteo, which is composed of BP and Type I collagen, is undergoing a Phase III multicenter study for the posterolateral lumbar spine fusion in Europe, and is also under investigation in a US Phase I/II study for periodontal regeneration of class II	NYSE: SM	www.sulzermedia.com

Company	Location	Research Focus	Publicly Traded?	Website
		furcations. While the Company is focusing its efforts to reach Phase I/II status with several other projects, it is also exploring the application of its technologies in the markets of wound healing, kidney regeneration, and nerve regeneration. SOI has a pilot facility and a research center in Denver, Colorado and in Switzerland.		
Bio-Synthesis	Lewisville	In the beginning, the primary emphasis was on synthesizing high quality DNA primers and linkers which were the initial uses of oligos. Today, newer technologies, such as synthesis gene construction, PCR, mutagenesis, combinatorial libraries, dye/adduct labeling, DNA microarrays, peptide-nucleic acid chimeras, etc., have challenged the molecular biology field. In response, Bio-Synthesis has branched into several related areas such as DNA paternity testing, DNA HLA typing, PNA's, genomic sequencing, fluorescence based genotyping, and other molecular biology based applications. Not only has Bio-Synthesis continued to provide quality DNA products and services for the research community, it has also become a world leader in providing custom peptide products and services. Using state of the art solid-phase peptide chemistries, Bio-Synthesis provides high quality peptides, carrier conjugation, antipeptide antibody production, antigenic peptide design, long peptides, modified peptides, MALDI TOF analysis contract research, consultation services, and more.	Private	www.biosyn.com

Company	Location	Research Focus	Publicly Traded?	Website
Carrington Labora-tories	Irving	Carrington Laboratories produces products from the inner-leaf gel of the *Aloe vera* plant. Carrington's scientific, patented process guarantees that specific measured amounts of *Aloe vera* can be found in every Carrington product. Carrington formulates the aloe raw materials into a variety of FDA or USDA regulated devices, biologics, drugs in development, adjuvants, and various cosmetic and food grade products.	NASDAQ: CARN	www.carringtonlabs.com
Cytoclonal Pharma-ceuticals	Dallas	Cytoclonal Pharmaceuticals specializes in the development of therapeutic and diagnostic products for the treatment and prevention of cancer and infectious diseases. The company's lead programs involve paclitaxel (active ingredient in Taxol®) production using fermentation and genetic engineering in agreements with Bristol-Myers Squibb, the treatment of Polycystic Kidney Disease using paclitaxel, Quantum Core Technology™, the Company's proprietary rational drug design targeting the human genome and OASIS™ optimized antisense library for regulating genes. Other programs involve the discovery of human genes through Retroselection™ with a focus on lung cancer, breast cancer treatment by peptide inhibition of estrogen receptors and the "immortality enzyme" telomerase.	NASDAQ: CYPH	www.cytoclonal.com
Chrysalis BioTech-nology	Galveston	A biopharmaceutical company developing products to accelerate the healing of hard and soft tissue. Its core technology, Chrysalin™, is a synthetic peptide that accelerates the repair of many different types of tissue. Its lead product is a topical drug for the treatment of chronic diabetic ulcers and is currently in Phase I/II clinical trials. An injectable form of Chrysalin is being clinically tested to accelerate the repair of bone fractures. Chrysalis BioTechnology is the first spinout company of the University of Texas Medical Branch at Galveston (UTMB). The company's core Chrysalin technology is based on 20 years of basic academic research at UTMB and has been supported in part by the National Institutes of Health (NIH) and the American Diabetes Association. Chrysalis has signed a development, marketing, and distribution agreement with OrthoLogic to develop products to accelerate the repair of bone fresh fractures. OrthoLogic has	Private	www.chrysalisbio.com

Company	Location	Research Focus	Publicly Traded?	Website
		initiated a clinical trial for accelerated healing of fresh fractures. In addition, Chrysalis signed a research agreement with Medici Medical to explore possible vascular repair applications of Chrysalin. In March, Chrysalis signed a worldwide partnership with Abbott Laboratories for wound healing applications of Chrysalin.		
Agennix, Inc.	Houston	Agennix is currently developing technology related to human lactoferrin, one of the body's natural anti-infective and anti-inflammatory proteins. The company is evaluating the potential of recombinant human lactoferrin as a prophylactic and therapeutic agent for human use in topical dermatological, ophthalmic and gastrointestinal applications. Phase I/II clinical trials in gastroenterology and dermatology are currently underway on four continents. The company intends to form strategic alliances with selected partners for development and marketing. Agennix is based on technology developed at Baylor College of Medicine.	Private	www.agennix.com
Aronex Pharma-ceuticals	Houston	Aronex Pharmaceuticals formed in 1986 to develop and commercialize proprietary medicines to treat cancer and infectious diseases. Aronex currently has four products in clinical development, all of which were licensed from the University of Texas, M.D. Anderson Cancer Center. Two products (ATRAGEN® and Nyotran®) are in an advanced stage approaching regulatory submission. The company also has a broad pipeline of clinical products in various stages of development. Aronex is currently recruiting patients in the United States and in Europe to analyze the safety and efficacy of our clinical products over a broad range of indications in various phases of development (ATRAGEN® five ongoing clinical trials; Aroplatin™ two ongoing clinical trials; Annamycin two ongoing clinical trials). Aronex also has an alliance for worldwide commercialization of Nyotran with Abbott Laboratories.	NASDAQ: ARNX	www.aronex-pharm.com

Company	Location	Research Focus	Publicly Traded?	Website
Energy Biosystems/ Enchira Biotech-nology	Houston	Enchira Biotechnology incorporates genetic recombination, high throughput screening and bioprocessing in an integrated, directed evolution technology platform. This proprietary platform technology can be used to generate libraries of novel genes for the creation of improved enzymes for a broad range of applications, such as protein-based pharmaceuticals, agricultural crop enhancement and protection products, and industrial enzymes for the manufacture of specialty chemicals, fine chemicals and pharmaceutical intermediates. The ability to generate novel proteins with enhanced or altered properties has stimulated interest in all areas of biotechnology, medicine, and the chemical sciences.	NASDAQ: ENBC	www.energybiosystems.com
Gamma Biologicals, Inc.	Houston	Gamma Biologicals, Inc. manufactures and sells a wide variety of highly refined and specialized testing products known as *in-vitro* diagnostic reagents. Gamma supplies products and services to immunohematology, commonly called "blood banking." Immunohematology is one of the major disciplines within the $2+ billion clinical (laboratory) medicine market. The company sells its products to the blood donation centers (blood banks), transfusion departments of hospitals, medical laboratories, physicians' offices, and research institutions through a direct sales force and a dealer network. Gamma distributes its products to more than 50 countries.	Private	www.gammabio.com
MicroMed Technology , Inc.	Houston	MicroMed Technology, Inc. was formed in 1995 for the purpose of acquiring and developing the NASA (Johnson Space Center) miniaturized auxiliary heart pump technology for human use. The ventricular assist device referred to as the DeBakey VAD is designed to provide increased blood flow to patients who suffer from heart failure. The device is compact in size, weighing less than 4 ounces and is easier to surgically apply compared to other devices currently in the market. MicroMed is currently conducting clinical trials in both the United States and Europe. More than 36 patients have been implanted thus far; the trials are ongoing. MicroMed looks to receive approval for the CE Mark to begin commercialization in Europe by year end 2000. MicroMed has raised $33 million thus far for use in product development	Private	www.micromedtech.com

Company	Location	Research Focus	Publicly Traded?	Website
		and clinical trials. MicroMed currently has 40 employees in its ISO 9001 certified manufacturing facility in Houston. MicroMed plans to research a combination therapy, utilizing a synthetic compound to help revascularize the heart muscle as the heart assist device gives rest and assistance to the patient.		
Tanox, Inc.	Houston	Tanox, Inc. identifies and develops therapeutic monoclonal antibodies to address significant unmet medical needs in the areas of immunology, infectious diseases and cancer. Monoclonal antibodies are genetically engineered antibodies that target a specific foreign substance, or antigen. E25, their most advanced product in development, is an anti-immunoglobulin E, or anti-IgE, antibody. Tanox is developing E25 in collaboration with Novartis Pharma AG and Genentech, Inc. E25 has successfully completed Phase III clinical trials in both allergic asthma and seasonal allergic rhinitis (hay fever). Based on the results of these trials, their collaboration partners filed for marketing approval in the United States, Europe, Australia, and New Zealand in June 2000. In addition, they are developing a number of monoclonal antibodies to treat other allergic diseases or conditions, such as autoimmune diseases, HIV, severe allergic reactions to peanuts, and to restore the suppressed immune systems of chemotherapy patients. Two of these antibodies are currently in early stage clinical trials in the United States and Europe.	NASDAQ: TNOX	www.tanox.com
Texas Biotech-nology Corporation	Houston	Texas Biotechnology Corporation is developing products designed to preserve the vascular system's functional integrity for the treatment of a variety of conditions and serious diseases, including thrombosis, pulmonary hypertension, chronic heart failure, systemic hypertension, asthma, and rheumatoid arthritis. Specifically, the company's efforts are focused on small molecule drugs that will prevent blood clot formation, inflammation, constriction of blood vessels, and the proliferation of smooth-muscle cells at the site of blood vessel injury. The company also has developed both proprietary and non-proprietary technologies for computer-assisted small molecule drug design. Texas Biotechnology's lead product, Argatroban, an intravenous anticoagulant, recently received	AMEX: TXB	www.tbc.com

Company	Location	Research Focus	Publicly Traded?	Website
		approval from the FDA and is expected to be launched in third quarter 2000. SmithKline Beecham is the marketing partner for Argatroban in the U.S. and Canada. Designed to prevent or treat thrombosis by preventing clot formation and growth, the initial proposed use will be in patients with heparin-induced thrombocytopenia.		
Midland Certified Reagent Co.	Midland	Midland Certified Reagent Co. manufactures synthetic nucleic acids (DNA and RNA) for research in all the biological sciences. Midland makes custom DNA oligonucleotides and custom RNA oligonucleotides; performs complete gene construction including sequence verification; produces high-molecular-weight DNA and RNA polymers; and isolates and purifies several enzymes of interest in biological research.	Private	www.mcrc.com
BioNumerik Pharma-ceuticals, Inc.	San Antonio	BioNumerik Pharmaceuticals, Inc. is using a proprietary technology platform for the discovery and clinical development of new small molecule-based pharmaceuticals to treat cancer. BioNumerik's "mechanism based" drug discovery integrates medicine, quantum physics, synthetic chemistry, pharmaceutical sciences, and supercomputing. It simulates molecular interactions and drug transformations in the body using complex proprietary pharmaceutical software running on the fastest parallel supercomputers. The company views its approach as a fourth generation technology relative to drug screening, automated screening and combinatorial chemistry, and rational drug design. BioNumerik has three compounds in Phase I clinical trials and several additional product classes in preclinical development.	Private	N/A
ILEX Oncology	San Antonio	ILEX Oncology is focused predominantly on the development of drugs for the treatment and prevention of cancer. ILEX was spun out of San Antonio's Cancer Therapy and Research Center and began operations in 1994. ILEX currently employs more than 275 people in three states and two foreign countries. The company is advancing a diversified portfolio of anti-cancer drugs through its ILEX Products subsidiary. The ILEX pipeline comprises cutting edge technologies including angiogenesis inhibitors, chemoprevention agents and cytotoxic	NASDAQ: ILXO	www.ilexoncology.com

Company	Location	Research Focus	Publicly Traded?	Website
		drugs with novel mechanisms of action. The company's lead drug candidate, CAMPATH, a humanized monoclonal antibody, is currently at the FDA for marketing approval. ILEX also has six other product candidates in clinical development, including two in pivotal (Phase III) trials, two in Phase II trials and two in Phase I trials. Additionally, the company is developing an emerging platform of angiogenesis inhibitors and expects to take the first of these drug candidates into clinical testing during 2000. ILEX also operates the industry's only full-service, oncology-focused contract research organization (CRO), offering oncology drug development services to pharmaceutical and biotech companies through its ILEX Oncology Services subsidiary.		
OsteoBio-logics, Inc.	San Antonio	OsteoBiologics, Inc. develops and manufactures bioabsorbable tissue-engineering scaffolds (IMMIX™) for the repair and replacement of musculoskeletal tissues. The company's focus is on the repair and replacement of articular cartilage. A unique line of bone graft scaffolds for use in trauma and spinal applications are also under development. To complement the development of its cartilage repair products, OsteoBiologics has developed a cartilage diagnostic instrumentation system (ACTAEON™) which determines the degree and scope of articular cartilage degeneration.	NASDAQ: CNMD	www.obi.com
Lexicon Genetics, Inc.	The Wood-lands	Lexicon Genetics, Inc. defines the functions of genes for drug discovery using large-scale knockout mouse technology. The Company has invented high-throughput gene trapping technology, which alters the DNA of genes in a special variety of mouse cells, called embryonic stem (ES) cells, which can then be cloned and used to generate mice. In these mice, the altered DNA disrupts, or ‘‘knocks out,’’ the function of the gene, enabling the study of the function of the knocked out gene. This technology also enables scientists to obtain DNA sequences of genes from human and mouse cells. Using this technology, Lexicon is discovering thousands of genes and expanding its proprietary OmniBank® library of tens of thousands of knockout mouse clones. The company’s Internet exchange, Lexgen.com™, enables researchers	NASDAQ: LEXG	www.lexgen.com

Company	Location	Research Focus	Publicly Traded?	Website
		worldwide to access the OmniBank library and to form collaborations with Lexicon to discover pharmaceutical products based on genes and knowledge of their functions.		
Sigma-Genosys *(formerly Genosys Biotech-nologies)*	The Wood-lands	Sigma-Genosys is a leading supplier of custom synthetic DNA (oligos), gene arrays, and synthetic peptides, and a supplier of research reagents to the global life science research community. Formerly Genosys Biotechnologies, the company was acquired by Sigma-Aldrich in December 1998. They are a leading supplier of custom synthetic oligonucleotides, peptides and genes, and routinely synthesize technically challenging custom biomolecules.	NASDAQ: SIAL	www.genosys.com
Valentis, Inc.	The Wood-lands	Valentis, Inc. develops proprietary technologies and applies its preclinical and early clinical development expertise to create novel therapeutics. Valentis was formed through the merger of Megabios Corp., GeneMedicine, Inc. and PolyMASC Pharmaceuticals, PLC, in 1999. The company's core technologies include multiple gene delivery and gene expression systems and PEGylation technologies designed to improve the safety, efficacy and dosing characteristics of genes, proteins, peptides, peptidomimetics, antibodies and replicating and non-replicating viruses. Valentis has several products (gene medicines) approaching or already in clinical trials for the treatment of cancer, cardiovascular disorders and systemic diseases such as hemophilia and anemia. Valentis intends to partner all products for late stage development through corporate collaborations with companies such as Roche, Eli Lilly, Boehringer Ingelheim and Bayer.	NASDAQ: VLTS	www.valentis.com
Zonagen	The Wood-lands	Zonagen was founded in 1987 and is developing therapeutic products for the human reproductive system. These products are the result of both in-house research and in-licensing transactions. The Company’s products cover a wide range of areas, including sexual dysfunction, vaccine adjuvants, products for fertility and female health, as well as urological applications, specifically prostate cancer. After investing more than $50 million in its lead product and treating approximately 4,500 patients in its clinical trial programs, Zonagen has filed a New	NASDAQ: ZONA	www.zonagen.com

Company	Location	Research Focus	Publicly Traded?	Website
		Drug Application with the FDA for approval of VASOMAX®, an oral therapy for the treatment of male erectile dysfunction. The company has commenced an offshore Phase II clinical trial program for Vasofem, a product for the treatment of female sexual arousal disorder. In addition, the company is developing a second-generation oral combination therapy for male erectile dysfunction and a multi-component injectable therapeutic for more severe erectile dysfunction. Zonagen has launched offshore pilot clinical trials for these products, as well as for a therapeutic vaccine for prostate cancer. Zonagen is collaborating with a number of vaccine companies to utilize its adjuvants, ImmuMax and ImmuMax-SR®, with their vaccines. These adjuvants amplify human immune responses better than traditional, alum-based adjuvants. In addition, the company has a number of other preclinical products including a novel class of selective progesterone response modulators targeting endometriosis and uterine fibroids, immunocontraceptive vaccines and a vaginal anti-infective product.		

This chart represents some of the larger companies in Texas. Company information obtained from: Walker, Meredith M. "Biotech Bonanza: Prospects for Texas," Southwest Economy, Federal Reserve Bank of Dallas, Issue 4, July/August 1999, page 5; Texas Healthcare and Bioscience Institute, and the companies' websites.

Technology Transfer

"Technology Licensing Offices" or TLOs serve as the liaison between the universities and the marketplace by filing patent applications and assisting in the development of "spin-out" companies that commercialize new products. However, TLOs must often compete with other worthy needs of a research university to obtain university funding for patents, and most are overwhelmed by the demand for their services in the face of inadequate funding. TLOs differ from university to university in Texas, and have minimal interaction with one another. Statistically, other states spend more money on the technology transfer process, spin out more start-ups from universities, and have stronger entrepreneurial support systems and public-private partnerships than does Texas. These factors have

contributed to the loss of Texas-based biotechnology companies in recent years.[22]

Biotechnology Companies Leave Texas for other States

A number of biotech companies once headquartered in Texas have relocated to other states. Several have found greater incentives and resources available to them elsewhere, or have had difficulty in recruiting company leadership who wish to remain in Texas. Some other factors that biotech companies consider are: availability of industry-experienced workforce, venture capital priorities, proximity to research facilities, and proximity to pharmaceutical companies.[23] Below are some examples of companies that have chosen other states over Texas for various reasons.

Inhibitex, a technology that prevents infectious diseases as an alternative to antibiotics, was developed at the Institute of Biosciences and Technology in the Texas Medical Center at Houston. The Texas A&M Fund provided the first round of support for further research for Inhibitex, but when the time came to fund the second round of research and development, the A&M Fund was not able to provide the necessary venture capital. A researcher at the Georgia Research Alliance recognized the potential of Inhibitex and the Alliance provided $3.8 million in venture capital; however, Inhibitex had to move to Atlanta, Georgia. Inhibitex was set up in an incubator lab at Georgia State University in April 1998, and by the end of the year, the number of employees had tripled. In July 2000, Inhibitex became only the second biotech company in Georgia to receive funding of $15 million from a national syndication of venture capitalists. Inhibitex will soon build its own physical plant.[24]

Electropharmacology, Inc. (dba Gemini HealthTech), a publicly held biotechnology company headquartered in Alachua, Florida, acquired two privately held Texas companies in 1998: HealthTech Development, Inc., of

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[22] *Biotechnology: Hearings Before the Senate Health Committee*, 76th Leg. Interim (2000) (statement of Terry Young, Texas A&M Technology Licensing Office).

[23] *Biotechnology: Hearings Before the Senate Health Committee*, 76th Leg. Interim (2000) (statement of Connie Luthy, founder of The Luthy Group).

[24] Memorandum from Fuller Bazer, Ph.D., Regents Fellow and O.D. Butler Chair in Animal Science, Texas A&M University; Director, Institute of Biosciences and Technology, Vice President for Research and Interim Dean, Graduate School of Biomedical Sciences, Texas A&M University System Health Science Center. (on file with the *Senate Health Committee*).

Dallas, and Gemini Biotech, Ltd., of The Woodlands. These two companies were engaged in the development of molecular technologies that identify and facilitate the design of drugs combating cancer and rheumatoid arthritis. In 1999, Gemini was experiencing a cash flow problem and determined that to conserve cash, the company needed to consolidate its operations. Its headquarters were in Pompano Beach, Florida, and its operating division was located in The Woodlands. According to Gemini's CEO, the principal advantage that persuaded them to move to Florida was the support provided by the State of Florida through its state-funded Sid Martin Biotech Incubator located in Alachua.

Interleukin Genetics, Inc., following appointment of a new CEO from Massachusetts, announced in April 2000 that they will relocate to Boston for "better integration of the Company's key resources and also to position it as part of an active biotechnology cluster." The Company was unable to attract a CEO in the San Antonio area.

LifeCell relocated from The Woodlands to New Jersey in 1999 following recruitment of a new CEO from that state.

Medarex, formerly Houston Biotechnologies, was acquired and relocated to Connecticut in 1994-1995.

Rgene Therapeutics, Inc., a spin-out of Baylor College of Medicine, was acquired after its first round of venture financing by the Seattle startup company, Targeted Genetics. All company operations in The Woodlands ceased after the acquisition.

Following the successful creation of Sensus Drug Development Corporation in Austin, the company's board chair planned to create a bioprocessing center also in the Austin area. A nationwide search was conducted to find the most conducive environment for this company, and because there was no effort on behalf of the state of Texas, Travis County, or the City of Austin, the company moved to North Carolina. The North Carolina company, Covance, now has more than $5 billion in revenue and over 425 employees.[25]

[25] TEXAS HEALTHCARE & BIOSCIENCE INST.

Biotechnology Innovation in Texas: Regional Efforts

Across the state, cities, and regions are working together to find ways to capitalize on the economic, not to mention the health benefits, that the biotechnology industry brings to Texas. Following is a sampling of some of the efforts currently underway to attract, maintain, and grow biotechnology research and start-up companies in and around some of the larger Texas cities.

Amarillo

Harrington Regional Medical Center, Inc. (HRMCI), is a not-for-profit corporation that currently provides health care, education, employment, and a myriad of other related activities to over one million people annually in the Amarillo area. In developing a strategy for serving the diverse needs of its regional community, HRMCI has began a project known as ASSET: Alliance to Strengthen Science Education and Technology. The region's dominant economic force, agriculture, is the primary alliance, and together the community hopes to create new opportunities to uncover new knowledge and new schools of thought. ASSET members include the Texas A&M University System represented by an Agricultural Research and Extension Center and Veterinary Medical Diagnostic Laboratory; West Texas A&M University which has a nursing and graduate nursing division as well as a strong department of agriculture; Texas Tech University Health Sciences Center represented by a School of Medicine, a School of Pharmacy and a School of Allied Health; and Amarillo College, a community college with a school of nursing and a school of allied health which trains a vast variety of medical technicians and therapists who provide the necessary knowledge-based workforce for these member institutions.

HRMCI hopes to develop a research consortium to emphasize the public benefits that flow from the constant learning and high order thinking that occurs by aligning the academic, private, and government sectors by providing a foundation to facilitate the administrative activities of such an alliance. ASSET aspires to include agricultural sciences, environmental health sciences, medical health sciences, biotechnology, and pharmacy in pursuit of the health and safety of the region and beyond. The alliance will focus on integrating the dominant components of the regional economy with centers of excellence in agriculture, food science and safety, environment, nutrition, primary health care, aging, immunology/cancer research and prevention, treatment, and

management of illness and disease often found in rural areas with an economy largely based in agriculture.[26]

Austin

The Greater Austin Chamber Commerce supported the formation of the Biosciences Cluster Group to create an effective, self-sustaining organization for the emerging biomedical and biotech industry in the Capitol area. Austin is home to several biotech companies and academic centers. The University of Texas' Institute for Cellular and Molecular Biology has had great success in recruiting leading scientists from around the world. Austin Community College is one of six community colleges in the country to receive a National Science Foundation grant to create an Advanced Education Center and develop a biotechnology curriculum. Texas Healthcare and Bioscience Institute (THBI), based in Austin, is also taking a role in the industry's development. A relatively new organization, THBI's early efforts have focused on collecting and analyzing industry data, and providing opportunities for entrepreneurs, educators, and government to collaborate in the promotion of the biotechnology industry.

The Biosciences Cluster Group goals are:

- To enhance the image and business environment of the bioscience industry in the Austin area;
- To support the industry cluster economic model detailed in the *Next Century Economy* report;
- To advocate change to solve problems and eliminate barriers to bioscience industry growth;
- To communicate the benefits of the cluster's activity to stakeholders within the Austin region; and
- To make industry initiatives self-sustaining.[27]

Austin also plans to create a Biomedical Business Incubator, an organization that would advise early-stage, high-risk companies and provide them with the necessary assistance to make their biomedical-based ventures

[26] TEXAS HEALTHCARE & BIOSCIENCE INST.

[27] Greater Austin Chamber of Commerce, *The Bioscience Industry*, (visited July 2000) <http://www.austinchamber.org/Do_Business/What_s_Hot_Here/Biosciences/Industry_Overview >.

succeed. This incubator will be modeled on the Austin Technology Incubator of the IC^2 Institute.[28]

Dallas

The Dallas Plan is Dallas' long-range plan for its future. The plan is made up of six strategic initiatives, one of which is economic development. Within this initiative, policies direct Dallas to "focus City economic development efforts to support and retain existing businesses while growing Dallas' core industries."[29] One of these "core industries" is health care. To carry out this initiative, The Dallas Plan organization conducted a research project focused on health care and the related biotechnology industry.

Dallas is already home to many assets that support health care biotechnology development, including premier research institutions, educational and medical resources, venture capital funding and other professional services required to support the industry. The University of Texas Southwestern Medical Center is one of the most prominent research and education facilities in the United States and the world. Dallas also has five other premier medical and educational institutions, as well as seven hospitals, each nationally recognized for a different area of expertise. There are three pharmaceutical companies with research facilities in the Dallas area, and 11 biotechnology companies in the Metroplex.[30]

The Dallas Plan research effort led to the development of the following strategies to move the city forward in the health care technology industry:

- Establish an organizational structure for execution of the Dallas Biotechnology Project recommendations;
- Create a strategy for a biotechnology area near UT Southwestern, particularly targeted to start-up companies;
- Make it attractive for large biotech companies to locate expansion facilities here, particularly in the Southern Sector;

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[28] Austin Technology Incubator, (visited July 2000) < http://www.ic2-ati.org>.

[29] Dallas Plan, *Major Recommendations,* (visited July 2000) < http://www.thedallasplan.com/biomajor_rec.html>.

[30] TEXAS HEALTHCARE & BIOSCIENCE INST.

- Secure local start-up funding;
- Maximize investment in the Dallas biotechnology industry by other governmental entities;
- Meet the biotechnology industry's labor force needs;
- Provide other resources for entrepreneurs and start-up companies;
- Help create networks that support local industry growth;
- Link biotechnology to the Dallas community; and
- Spread the word.[31]

Fort Worth

Fort Worth's economic plan is called "Strategy 2000, Diversifying Fort Worth's Future." The city is working toward a diverse economic base with the creation of a "healthy, diverse, less defense dependent economy supported by business development, emerging technologies, international trade, and a world class workforce." Toward this goal, Strategy 2000 identifies three business clusters: biomedical technology, advanced manufacturing, and transportation and distribution. The use of networks to increase job development and placement will help the city capitalize on its potential to be a leading city in each of the business clusters.

The proposed strategy for the biomedical technology cluster is to establish a Medical Industry Cluster Center (MICC) to provide a broad-based spectrum of services and products central to the development of new and growing business in the cluster including:

- Technology transfer;
- Assistance to emerging businesses;
- Medical informatics and communications;
- Clinical trails assistance;
- Manufacturing assistance;
- Workforce and continuing education;
- Networks and alliances;
- Incubator development; and

[31] Dallas Plan, *Major Recommendations*, (visited July 2000) < http://www.thedallasplan.com/biomajor_rec.html>.

- A medical technology park.

Participants in this effort are Strategy 2000, the City of Fort Worth, University of North Texas Health Science Center, Fort Worth South; Health Industry Council of the Dallas/Fort Worth area, and various private businesses.[32]

Fort Worth also has a medical and technology business incubator, the Fort Worth MedTech Center, Inc., which is privately funded and not for profit. The Center provides specialized and industry-specific business assistance to medical and high-technology start-up companies in the Fort Worth area.[33]

Houston

The Greater Houston Partnership is the primary advocate for business in Houston and the surrounding eight-county region. According to the Partnership's Houston Facts 2000, expansion of biotechnology operations in Houston in recent years has moved Houston into the forefront of the industry, aiding Houston's economic diversification.

As a testament to its success in the biotechnology arena, Houston hosted BIO '97 International, which brought more than 3,000 industry leaders and investors to Houston. Houston's biotechnical industry is keyed to three segments:

- The Texas Medical Center;
- Research and development at area universities, health care institutions, and other public and private firms; and
- Spinoff or fully commercial companies engaged in production operations.

Another promoter of the health care technology industry in Houston is the Houston Technology Center, which finds effective ways to retain local entrepreneurs and their emerging technology companies in Houston. The Houston Technology Center brings together entrepreneurs, investors, existing businesses, and talented

[32] Strategy 2000, *Ft. Worth Economic Plan for the Biotechnology Industry*, (visited July 2000) < http://home.flash.net/~strategy/>.

[33] Fort Worth MedTech Center, (visited July 2000) < http://www.medtech.org/>.

professional workforce. The accelerated interaction of these existing elements is helping Houston expand the critical mass needed to generate a new, vibrant economy in key areas such as energy, information technology, life sciences, and NASA-originated technologies.[34]

San Antonio

Unlike other metropolitan areas in the southwest, San Antonio's economy has not yet witnessed major technology-driven growth. The San Antonio Technology Accelerator Initiative (SATAI) mission is to accelerate the growth of its next generation economy by capitalizing on existing technological capabilities and creating new advantages for the formation of technology-driven industry.

San Antonio's strategy focuses on four technology-driven industry clusters: biotechnology/biomedicine/medical devices, information technology, telecommunications, and aviation. Working groups representing each of these four technology clusters have identified shared challenges and developed collaborative action plans that cluster members have volunteered to enact together. Each cluster has prepared a set of actions that include initiatives in networking, technology development, human resources development, financing, marketing, and improving the business climate. SATAI has prepared collaborative actions to promote in each of the four cluster groups, as well as a business plan for an integrated enterprise accelerator initiative that will serve all the technology clusters, including new clusters that might emerge in the future. To sustain the implementation of the voluntary cluster-specific action plans and implement the cross-cutting regional flagships, a multiple-stakeholder, umbrella organization, the San Antonio Technology Collaborative (SATeC), has been created.[35]

Tyler

The Tyler Economic Development Council, with the help of grants from local corporations, has purchased a 120-acre tract next to the University of Texas Health Science Center at Tyler. This land is part of a master plan that includes the development of a biotechnology park. The Development Council is working to recruit

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[34] TEXAS HEALTHCARE & BIOSCIENCE INST.

[35] SATAI, *San Antonio Technology Accelerator Initiative*, (visited July 2000) <http://www.ci.sat.tx.us/edd/satai>.

private sector participation and investors to build an incubator facility and to attract biotech companies that are looking to relocate. The Tyler area is a budding hotbed for biomedical research, and is in the process of establishing a better infrastructure and improved marketing to further benefit their community. With the help of a strategic planning consultant, the Development Council has outlined the mission for the new BioSciences Research & Development Center and its incubator faculty to function as:

- a first-class research unit;
- an initial and long-term production unit;
- a source of economic development for Tyler; and
- an interface to the University of Texas Health Center at Tyler Biotech Research facility, the scientific community worldwide, other bioscience and emerging technology industries, and federal laboratories.

The secondary mission is to provide a physical base for economic development in Tyler by providing state of the art facilities adjacent to a research university.[36]

The Woodlands

Biotech employment in the South Montgomery County Woodlands area increased by 250 percent in the 1990's and continues to grow. This growth is generated in part through the combined efforts of The Woodlands Operating Company, the Houston Advanced Research Center, Montgomery County, and the South Montgomery County Woodlands Economic Development Partnership. The Houston Advanced Research Center plays a vital role by providing incubator space and coaching for firms that are in their embryonic stages, while the Operating Company cooperates with the companies to provide flexible space and promote affordable growth. The county government has been supportive by providing tax incentives that encourage biotech companies to base their facilities in The Woodlands. The Economic Development Partnership, with the cooperation of Montgomery College, has provided assistance to employers through the use of Smart Jobs and Skills Development grants as well as Tuition Assistance Waivers.[37]

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[36] Telephone Interview with Tom Mullins, President and CEO, Tyler Economic Development Council, (Aug. 15, 2000).

[37] Telephone Interview with Ron Bourbeau, CEO of the South Montgomery County Woodlands Economic Development Partnership, and Bob Stout, Governmental Relations Director, The Woodlands Operating Company, (Aug. 17, 2000).

Biotechnology Industry Innovation in Leading States

Other states have made great strides in attracting and maintaining biotech companies. Some of these initiatives have been accomplished through legislation. Following are a few examples of the measures utilized in some of the states that have a flourishing biotech industry sector. (For more information on efforts in other states, see Appendix C.)

In January 1998, New Jersey passed the "High-Tech Job Retention Act," a four-bill economic development package. The package included an investment tax credit, a transferrable research and development (R&D) tax credit, and extended the time that small companies can carry forward net operating losses (NOL) and R&D tax credits from 7 years to 15 years. The Technology Business Tax Certificate Transfer Program permits biotechnology and emerging technology companies with 225 employees or less to transfer their unused net operating loss and research and development tax credits to a private corporate taxpayer for at least 75 percent of the value of the benefit. The selling company may use the proceeds for fixed assets, working capital and certain other expenses. Texas proposed similar legislation in 1999, but it did not pass. Recently, New Jersey added biotechnology firms to the list of acceptable investments in which trust and pension funds may be used as venture capital. The New Jersey State pension fund has already begun investing in biotechnology firms.[38]

Connecticut has made similar efforts to encourage biotech industry growth. In 1999, the Connecticut Legislature passed a tax incentive bill that included an extension of the NOL carryforward from 5 years to 20 years. They also passed an allowance for businesses with $70 million or less in gross sales to exchange unused R&D tax credits with the State for a cash payment equal to 65 percent of the value of the credit. Connecticut also has a sales tax exemption for R&D equipment and a property tax exemption for new equipment purchased by biotech companies.[39]

Arkansas has a 15-year NOL carry forward provision for biomedical companies, and exempts most biotechnology purchases of machinery and equipment from state sales and use tax. Arkansas also offers a 5

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[38] A Survey of State Initiatives, (visited June 2000) <http://www.bio.org/govt/survey.html>.

[39] *Id.*

percent income tax credit for biotechnology companies on the costs of construction, expansion, renovation or purchase of biotechnology facilities and equipment.[40]

In an effort to address the previously mentioned challenges that technology licensing offices and technology transfer organizations face in bringing university research innovation to the marketplace, some states have dedicated state resources to protect their intellectual property assets. The Kansas Technology Enterprise Corporation and the Georgia Research Alliance are two examples of these mechanisms.

In July of this year, California enacted S.B. 465, allowing for a credit against taxes imposed by those laws for increasing research expenses. In general, the amount of the credit is equal to 11 percent of the excess of the qualified research expenses, for the taxable or income year over the base amount and, in addition, 24 percent of the basic research payments.[41]

Genetics

A gene is a portion of a chromosome (DNA) that contains the hereditary information necessary for the production of a protein.[42] The term genome refers to the entire complement of genetic material present in each cell of an organism, or in a virus or organelle. The genome is a complete set of chromosomes inherited as a (haploid) unit from one parent.[43] Genomics is the process by which genetic researchers can derive meaning out of the human genome map.[44]

The much anticipated completion of the U.S. Human Genome Project came in June 2000, three years ahead of schedule. The initiative to sequence the entire human genome began in the mid-1980s, and included the

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[40] *Id.*

[41] NCSL Health Policy Tracking Service, (visited August 2000) <http://www.hpts.org/>.

[42] Monsanto, *Life Sciences Knowledge Center*, (visited June 2000) <http://www.Biotechknowledge.com>.

[43] Food and Agriculture Organization of the United Nations, *Glossary of Biotechnology and Genetic Engineering*, (visited June 2000) <http://www.fao.org/biotech/gloss.htm>.

[44] THE CQ RESEARCHER, HUMAN GENOME RESEARCH: DOES IT OPEN THE DOOR TO DISCRIMINATION?, 404 (May 12, 2000).

governments of the United States, Japan, and several European countries who established laboratories and funding sources for genome sequencing. Baylor College of Medicine was one of three U.S. sites chosen by the National Human Genome Research Institute to participate in the effort to complete the map of the human genome. Researchers at the National Institutes of Health and a private company called Celera Genomics, Inc., both located in Rockville, Maryland, worked separately over the last several years, and announced jointly on June 26, 2000, that they had completed the map of the genetic makeup of humans. Their drafts will be provided to the science community for review in the coming months.[45] The completed map of the human genome provides scientists with a major tool necessary for future work in gene therapy and treatment for genetic disorders and diseases. Other products of the Human Genome Project include: refined methods for gene identification; completed sequences for a number of animals and organisms for the purpose of comparison and further research; creation of databases to allow other researchers access to the information (usually for a fee, depending on who owns the database); and analysis of the ethical, social and legal implications of the Project.[46]

Issues

Cloning

Cloning is a generic term for the laboratory replication of genes, cells, or organisms from a single original entity. As a result of this process, exact genetic copies of the original gene, cell or organism can be produced. Cloning has been in the public eye in recent years after "Dolly" the sheep was successfully cloned in Scotland. This accomplishment created great concern that scientists would soon clone humans. However, a series of legislative proposals and appropriations bills banning federal funding of any business or organization that has engaged in human cloning continue to circulate in Congress, and the industry has observed a voluntary moratorium on human cloning. However, most acknowledge that cloning has its place in science; in addition to its usefulness in pinpointing components of disease and developing treatments for heart conditions, cystic fibrosis, and someday cancer and Alzheimer's disease, cloning is also used in agriculture to produce higher

[45] Laurie Stoneham, *Expanding the Frontiers: The Economic and Human Dynamics of Medical Research in Texas*, TEXAS MEDICINE, May 2000, 39.

[46] REBECCA A. HAMRIN, CHARTING A NEW TERRITORY: LEGISLATIVE GUIDE TO GENETIC PRIVACY AND DISCRIMINATION, 11 (1999).

yield, better quality fruits and vegetables.[47]

This year, Illinois passed a law (S.R. 292) to require the University of Illinois to conduct a study and issue a report on human cloning by January 9, 2001. The statute directs the University to obtain input from the fields of medicine, religion, biotechnology, genetics, law, bioethics, and the general public. S.R. 292 also called for a review and evaluation of current and past public policy and research related to human genetics. Illinois also has a "Human Cloning Act," S.B. 649, currently awaiting passage in the House, which would "place a moratorium on the cloning of an entire human being in order to evaluate the profound medical, ethical, and social implications that such a possibility raises." The legislation also provides that any hospital, sperm bank or ambulatory surgical treatment center that violates the Human Cloning Act would have their registration revoked. If passed, this law would expire in the year 2005.[48] In 1999, Louisiana was the only state to pass a law prohibiting human cloning. In 1998, California, Michigan, and Rhode Island passed laws to prohibit human cloning, while Michigan and Missouri further prohibited the use of state funds for human cloning or research related to human cloning.[49]

Gene Therapy

Gene therapy occurs at the intracellular level by replacing or inactivating the effects of disease-causing genes or augmenting normal gene functions to overcome illness.[50] In other words, gene therapy is replacing faulty genes with good genes rather than treating the symptoms of disease.[51]

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[47] Biotechnology Industry Organization, *Cloning*, (visited June 2000) <http://www.bio.org/aboutbio/guide2000/guide_ethics.html#cloning>.

[48] NCSL, Table of Genetics Testing Laws, June 2000.

[49] Memorandum from Mary R. Anderlik, Health Law and Policy Institute, University of Houston Law Center, (Feb. 2000) (on file with the *Senate Health Committee).*

[50] PHARMACEUTICAL RESEARCH MANUFACTURERS OF AMERICA, NEW MEDICINES IN DEVELOPMENT: BIOTECHNOLOGY 2000, 40 (2000).

[51] THE CQ RESEARCHER, HUMAN GENOME RESEARCH: DOES IT OPEN THE DOOR TO DISCRIMINATION?, 419 (May 12, 2000).

The first gene therapy clinical trial took place in 1990, and research and human trials have expanded since then. Genetic and metabolic diseases, cardiovascular diseases, cancer, and acquired diseases such as HIV and AIDS are the focus of most treatments since few options are available to patients in the late stages of these conditions. As with other products of biotechnology, gene therapy trials involve a lengthy research process and are subject to strict oversight by the FDA. It is the role of the FDA to protect patients, but also to ensure that gene therapy research continues unabated. The death of a clinical trial subject in Pennsylvania this year dampened the public's anticipation for increased use of genetic therapies. Even so, a set of twins born in London this year was doomed to spend their lives in a protective bubble, but escaped such a fate thanks to successful gene therapy.

Potential uses for gene therapy bring up a number of ethical considerations, specifically when determining eligibility for therapy. At this time, patients who receive gene therapy have few or no options to save them from dying and are less likely to be denied this avenue; however, possibilities for pre-birth genetic alterations could spark intense conflict. For the last ten years, a moratorium on germ line gene therapy (the egg and sperm cells that pass on genetic composition to future generations) has been voluntarily observed by academic and industrial research communities.[52]

Genetically-Modified Food/Organisms (GMOs)

Genetically modified foods are food plants that have been genetically altered by the addition of foreign genes to enhance a desired trait.[53] Selective breeding of plants and domesticated animals was the precursor to this science, which has garnered more than its share of controversy in recent years. Concerns related to possible unintended consequences of genetic engineering, such as the inadvertent creation of "super weeds" that herbicides cannot kill, or allergens in food products that are unknown until someone suffers a reaction, have resulted in numerous and continuous protests around the world against industries and farmers who alter the genetic makeup of our food supply. Despite this, biotech companies today promote their use of genetic

[52] Biotechnology Industry Organization, *Editor's and Reporter's Guide to Biotechnology*, (visited July 2000)<http://www.bio.org/aboutbio/guide2000/guide_ethics.html#cloning>.

[53] Cambridge Scientific Abstracts, *Genetically Modified Foods,* (visited June 2000) <http://www.csa.com/hottopics/gmfood/gloss.html>.

modification to:

- produce new and safer vaccines;
- treat genetic diseases;
- provide new and better medicines;
- enhance biocontrol agents in agriculture;
- increase crop yields and decrease production costs;
- decrease allergy-producing characteristics of some foods;
- improve nutritional value of foods;
- increase livestock productivity;
- assist developing countries;
- develop biodegradable plastics; and
- decrease water and air pollution.[54]

Xenotransplantation

Xenotransplantation takes place when an organ is transplanted from one species into another. Diseases related to the heart, kidney, lung, liver, and others have been effectively treated by organ transplantations in recent years. However, the demand has not been met, and according to the United Network of Organ Sharing (UNOS), from 1988 to 1994, the waiting list for patients in the United States for organ transplants grew from 16,026 to 37,609, increasing at a rate of 22.4 percent per year. By the end of 1998, about 60,000 people were registered on transplant waiting lists.[55] Use of organs from other species began in 1905, when a French surgeon transplanted slices of a rabbit kidney into a human. In recent years, organs from chimpanzees have sustained humans for several months. Pig heart valves are frequently used in the treatment of acute heart disease, and numerous health products have been derived from cows' tissues and fluids. Pigs may prove to be a promising source of xenotransplant organs, due to the supply, organ size and function relative to humans', and the ability for breeders to control disease within the swine population.

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[54] Biotechnology Industry Organization, *Editor's and Reporter's Guide to Biotechnology*, (visited July 2000) <http://www.bio.org/aboutbio/guide2000/guide_ethics.html#cloning>.

[55] Biotechnology Industry Organization, *Editor's and Reporter's Guide to Biotechnology*, (visited July 2000) <http://www.bio.org/aboutbio/guide2000/guide_ethics.html#cloning>.

The primary stumbling block to xenotransplantation is the human immune system. Scientists hope that genetic therapy involving the introduction of human genetic material into the donor animal may prevent the human body from rejecting a new organ. Another fear concerns exposure to infectious disease from pigs; however, a study of persons who have undergone pig cell transplantations shows that they have no signs of related illness.

The U.S. Department of Agriculture's Animal and Plant Health Inspection Service/Veterinary Services closely monitors potential animal organ donors. The service includes 300 veterinarians on staff and more than 40,000 veterinarians in private practice who monitor and report on infectious diseases and the health status of the U.S. animal population. The U.S. Department of Health and Human Services Public Health Service has prepared guidelines for conducting xenotransplantation procedures. Xenotransplant research is overseen by the FDA.[56]

Stem Cell Research

Researchers have found that human pluripotent stem cells can divide for indefinite periods in culture, and can develop into most of the specialized cells and tissues of the body, such as muscle cells, nerve cells, liver cells, and blood cells. Human pluripotent stem cells are obtained in two ways; (1) from extra, early-stage embryos donated by people who were undergoing fertility treatment in an in-vitro fertilization (IVF) clinic; and (2) from fetuses obtained from pregnancies that had been terminated.[57]

Federal law prohibits the use of Department of Health and Human Services (DHHS) funds for human embryo research. However, DHHS has determined that the law does not prohibit funding for research utilizing human pluripotent stem cells because such cells are not embryos. DHHS funds cannot be used for the derivation of

[56] Biotechnology Industry Organization, *Editor's and Reporter's Guide to Biotechnology*, (visited July 2000) <http://www.bio.org/aboutbio/guide2000/guide_ethics.html#cloning>.

[57] National Institutes of Health, *Fact Sheet on Human Pluripotent Stem Cell Research Guidelines*, (visited Mar. 2000) <http://www.nih.gov/news/stemcell/factsheet.htm>.

stem cells from human embryos.[58] In 1999, the National Institutes of Health (NIH) convened a working group composed of scientists, patients and patient advocates, ethicists, clinicians, and lawyers to develop draft guidelines for human pluripotent stem cell research. The draft guidelines were published for public comment in the Federal Register on December 2, 1999, and the comment period ended on February 22, 2000. NIH is analyzing the comments received, and after reviewing and considering all comments, the NIH will make revisions to the guidelines, as appropriate, and publish the final guidelines in the Federal Register. The draft guidelines and other information can be found at the URL: *http://www.nih.gov/news/stemcell/draftguidelines.htm.* Until the final guidelines and an oversight process are in place, the DHHS will not fund research using human pluripotent stem cells derived from either human embryos or fetal tissue. [59]

The State of Michigan recently passed a resolution due to state opposition to the proposed guidelines from the NIH on federally funded research using stem cells destructively harvested from human embryos. S.R. 119 recommends that the National Institutes of Health (NIH) withdraw the research guidelines and redraft them to comply with federal law prohibiting NIH involvement in research involving the destruction of human embryos. The Resolution also urges the NIH to redirect funding for stem cell research to projects that do not use stem cells destructively harvested from human embryos. South Dakota recently passed legislation (S. 195) that classifies and sets penalties for the misuse and/or destruction of a human embryo or tissues derived from human embryos for non-therapeutic research.[60]

Ethical Concerns in Genetics

A number of groups have or will seek access to genetic information: insurers, employers, courts, schools, adoption agencies, the military, and certainly others. Genetic information can reveal carriers of disease or disorders, and this information can affect institutions' as well as the individual. Thus, someone must determine

[58] National Institutes of Health, *Fact Sheet on Human Pluripotent Stem Cell Research Guidelines*, (visited Mar. 2000) <http://www.nih.gov/news/stemcell/factsheet.htm>.

[59] *Id.*

[60] NCSL Table of Genetic Testing Laws, July 2000.

what type of information should be private and confidential. The use of genetic information can have a psychological impact - even if an institution or person has no intent of using the information to discriminate, the mere exposure of such personal information can result in stigmatization because that person is genetically "different."

Access to genetic information will also have implications on reproductive decisions. In the future, parents will have even more information available to them. Do persons other than parents have rights to information that may affect the health of a newborn? Do people or institutions other than parents have the right or responsibility to prevent transmission of genetic defects if the capability exists to prevent or correct the defects? Who will draw the line between infringing on the rights of parents and the rights of future generations? In 1997, Texas passed a law to prohibit pressuring patients to terminate their pregnancy based on results of a genetic test.

Genetic information policy involves several ethical dilemmas. Who will educate doctors, other health service providers, patients, and the general public about genetic capabilities, scientific limitations, and social risks? Who will set and enforce standards and quality control measures in testing procedures? Differences in culture, religion, and beliefs will exacerbate the challenges we face regarding human responsibility, free will versus genetic determinism, and concepts of health and disease. These same factors affect decisions concerning safety and environmental issues. Around the world, communities are making decisions about genetically modified foods and organisms, determining whether they are safe for human consumption and safe for the environment.

Finally, we face many difficult decisions concerning the appropriate commercialization of products that depend on the use of genetic materials and/or information. Determining who has property rights and access to data and materials is proving to be one of the primary challenges in this time of great genetic discovery.[61]

Genetics-Related Legislation in Other States

[61] Denise K. Casey, *Genes, Dreams, & Reality; The promises and risks of the NEW GENETICS*, JUDICATURE, November-December 1999 at 105.

Several other states have either passed or proposed legislation concerning genetic privacy, discrimination, as well as various definitions for genetics terms that are used in genetics-related laws. (Refer to Appendices D and E: Genetics Testing Laws and Genetics Testing Legislation) Some examples follow.

Anti-discrimination in Health Insurance and Employment

Forty-four states have enacted laws with some degree of protection from genetic discrimination in health insurance. California, New York, and New Hampshire are among the states that have passed legislation within the last year specifically prohibiting the use of genetic information to deny insurance coverage, and providing penalties for doing so. Genetic discrimination in employment is specifically prohibited in 16 states.[62]

Privacy Protections

A number of states have recently enacted limits to the disclosure of genetic information; New York amended its civil rights law to require authorization for disclosure of genetic information, and require that all samples be destroyed 60 days after the tests are made. The New York law specifies that all results are privileged and confidential information. Oregon law also requires authorization for disclosure and makes genetic information the property of the individual, with the exception of criminal matters. In 1997, Oregon made provisions in state law for anonymous research. Arizona legislation passed this year places limits on the release of genetic information to certain persons and institutions. In addition, Arizona also considers genetic testing and the information derived from genetic testing as confidential and privileged to the person tested. Delaware law also prevents disclosure, but delineates the circumstances under which genetic information and/or the identity of the individual tested can be released without that individual's consent.

Definitions of Genetic Information, Genetic Tests and Genetic Characteristics

The following table gives examples of definitions in other states' laws that concern genetics policy.

Genetics-Related Definitions in Other States' Laws

Term(s)	State	Definition
Genetic information	TX	Information derived from a genetic test.

[62] THE CQ RESEARCHER, HUMAN GENOME RESEARCH: DOES IT OPEN THE DOOR TO DISCRIMINATION?, 408 (May 12, 2000).

Term(s)	State	Definition
Genetic test	TX	**(applies to health insurance and employment law)** A laboratory test of an individual's DNA, RNA, proteins, or chromosomes to identify by analysis of the DNA, RNA, proteins, or chromosomes the genetic mutations or alterations in the DNA, RNA, proteins, or chromosomes that are associated with a predisposition for a clinically recognized disease or disorder. The term does not include (a) a routine physical examination or a routine test performed as a part of a physical examination; (b) a chemical, blood, or urine analysis; (c) a test to determine drug use; or (d) a test for the presence of the human immunodeficiency virus.
Genetic characteristic	CA	Any scientifically or medically identifiable gene or chromosome, or alteration thereof, that is known to be a cause of a disease or disorder, and that is presently not associated with any symptoms of any disease or disorder.
Test of a person's genetic characteristics	CA	A laboratory test which is generally accepted in the scientific and medical communities for the determination of the presence or absence of genetic characteristics.
Genetic information	CT	The information about genes, gene products, or inherited characteristics that may derive from an individual or a family member.
Genetic information	MI	Information about a gene, gene product, or inherited characteristic which information is derived from a genetic test.
Genetic test	MI	The analysis of human DNA, RNA, chromosomes, and those proteins and metabolites used to detect heritable or somatic disease-related genotypes or karyotypes for clinical purposes. A genetic test must be generally accepted in the scientific and medical communities as being specifically determinative for the presence, absence, or mutation of a gene or chromosome in order to qualify under this definition. Genetic test does not include a routine physical examination or a routine analysis, including, but not limited to, a chemical analysis of body fluids, unless conducted specifically to determine the presence, absence, or mutation of a gene or chromosome.
Pre-symptomatic genetic test	MI	A genetic test performed before the onset of clinical symptoms or indications of disease.
Predictive genetic test	MI	A genetic test performed for the purpose of predicting the future probability that the test subject will develop a genetically related disease or disability.
Genetic test	MN	A pre-symptomatic test of a person's genes, gene products, or chromosomes for the purpose of determining the presence or absence of a gene or genes that exhibit abnormalities, defects, or deficiencies, including carrier status, that are known to be the cause of a disease or disorder, or are determined to be associated with a statistically increased risk of development of a disease or disorder. "Genetic test" does not include a cholesterol test or other test not conducted for the purpose of determining the presence or absence of a person's gene or genes.

Term(s)	State	Definition
Genetic test	NC	A test for determining the presence or absence of genetic characteristics in an individual or a member of the individual's family in order to diagnose a genetic condition or characteristic or ascertain susceptibility to a genetic condition.
Genetic characteristic	NC	Any scientifically or medically identifiable genes or chromosomes, or alterations or products thereof, which are known individually or in combination with other characteristics to be a cause of a disease or disorder, or determined to be associated with a statistically increased risk of development of a disease or disorder, and which are asymptomatic of a disease or disorder.
Genetic information	NC	Information about genes, gene products, or inherited characteristics that may derive from an individual or a family member.
Genetic information	NC	**(applies to health insurance)** Does not include the results of routine physical measurements, blood chemistries, blood counts, urine analysis, tests for abuse of drugs, and tests for the presence of HIV.
Genetic characteristic	NJ	Any inherited gene or chromosome, or alteration thereof, that is scientifically or medically believed to predispose an individual to a disease, disorder or syndrome, or to be associated with a statistically significant increased risk of development of a disease, disorder or syndrome.
Genetic test	NJ	A test for determining the presence or absence of an inherited genetic characteristic in an individual, including tests of nucleic acids such as DNA, RNA and mitochondrial DNA, chromosomes or proteins in order to identify a predisposing genetic characteristic.
Genetic information	NJ	The information about genes, gene products or inherited characteristics that may derive from an individual or family member.
Genetic test	NY	**(applies to health insurance)** A test for determining the presence or absence of an inherited genetic characteristic in an individual, including tests of nucleic acids such as DNA, RNA and mitochondrial DNA, chromosomes or proteins in order to identify a predisposing genetic characteristic.
Predisposing genetic characteristic	NY	**(applies to health insurance)** Any inherited gene or chromosome, or alteration thereof, as determined by a genetic test or inferred from information derived from an individual or family member, that is scientifically or medically believed to predispose an individual or the offspring of that individual to a physical or mental disease or disability, or to be associated with a statistically significant increased risk of development of a physical or mental disease or disability.
Genetic test	WI	**(applies to health insurance)** A test using deoxyribonucleic acid extracted from an individual's cells in order to determine the presence of a genetic disease or disorder or the individual's predisposition for a particular genetic disease or disorder.

Term(s)	State	Definition
Genetic test	WI	**(applies to employment law)** A test of a person's genes, gene products or chromosomes for abnormalities or deficiencies, including carrier status, that are linked to physical or mental disorders or impairments, or that indicates a susceptibility to illness, disease, impairment or other disorders, whether physical or mental, or that demonstrates genetic or chromosomal damage due to environmental factors.

Recommendations

1. Require the Legislative Budget Board (LBB) to determine the fiscal implication of allowing research and development tax credits to be transferred and sold. The LBB should determine whether selling the credits to another corporation or back to the State will provide the greatest benefit to the industry and also fit within the state's budget parameters. The LBB should also coordinate with the Comptroller to determine the potential impact on local communities.

   Rationale: *Legislation was passed during the 76th Legislature (S.B. 441) establishing a tax credit for Research and Development with a 20-year carryforward provision. The companies who earn these credits should have the ability to sell tax credits they do not use so the money can be invested immediately back into these companies to support their research and development activities. S.B. 492, 76th Legislature, would have allowed companies to sell unused tax credits to another corporation, but it did not pass.*

2. Require the Texas Higher Education Coordinating Board to investigate the amount and type of federal research funds available to Texas.

   Rationale: *Congress has committed to doubling the NIH budget over a seven-year period, of which we are currently in the third year. The ability to leverage federal dollars with state dollars is critical with the recent completion of the Human Genome Project, three years ahead of schedule. Our state health institutions need to be competitive and be prepared to fully participate in the discoveries*

and opportunities from the Human Genome Project.

3. Require the Texas Higher Education Coordinating board to investigate the benefit of establishing State Investment Funds for biotechnology. These funds should be made available to biotechnology startup companies as well as university technology transfer offices or the departments within universities responsible for filing patents and introducing biotechnology discoveries to the marketplace.

Rationale: *There are examples of successful models in key competitive states such as California, New Jersey, North Carolina, and Wisconsin. (See "Enabling Practices for the Life Science Industry" State Matrix, Appendix C.)*

4. Clarify definitions of genetic test and genetic information:

Genetic Characteristic: Any scientifically or medically identifiable gene or chromosome, or alteration thereof, that is known to be a cause of a disease or disorder, and that is presently not associated with any symptoms of any disease or disorder.

Genetic Test: A pre-symptomatic test of a person's genes, gene products, or chromosomes for the purpose of determining the presence or absence of a gene or genes that exhibit abnormalities, defects, or deficiencies, including carrier status, that are known to be the cause of a disease or disorder, or are determined to be associated with a statistically increased risk of development of a disease or disorder. "Genetic test" does not include a cholesterol test or other test not conducted for the purpose of determining the presence or absence of a person's gene or genes.

Rationale: *Current law has loopholes which could result in genetic discrimination in insurance and employment.*

5. Improve protections against discrimination based on all medical information, not only genetic

information. Consider federal proposals for definitions of medical information and Minnesota statutes specific to medical information and employment discrimination.

Rationale: *Determining how to distinguish between genetic information and medical information is uncertain, because genetic information is medical information, but medical information is not necessarily genetic information.*

6. Limit the release of genetic information to certain persons and institutions, make genetic information the property of the individual, and require authorization for disclosure of genetic information (with the exception of criminal matters).

Rationale: *Patients should have the right to know their genetic information is protected from disclosure unless they choose to allow its dissemination for well-defined purposes.*

7. Prohibit cloning of an entire human being. This law should include an expiration date. Revoke the registration of any hospital, sperm bank, or ambulatory surgical treatment center that engages in human cloning.

Rationale: *Allow for time to evaluate the medical, ethical, and social implications raised by the possibility of cloning a human being.*

INTERIM CHARGE 2A

Bioterrorism

Bioterrorism

Bioterrorism

Background

Since the 1995 release of the nerve agent Sarin in the Tokyo subway by a terrorist cult, the concerns over the possibility of the intentional release of deadly chemicals or microbes in the United States have grown significantly. All assessments of national preparedness indicate that our cities and states are unprepared to adequately respond to the domestic release of these weapons of mass destruction. These weapons have the very real potential, if implemented properly, to injure and kill tens of thousands of people if it were released in a closed environment, such as a large office building, convention center, or auditorium.

People would immediately feel the effects of the chemical and casualties would occur rapidly. This scenario would play out like a large hazardous materials spill with many injuries and deaths. Most Texas cities of moderate to large size have a hazardous materials response capacity; however, all could use improvements. The release of a harmful bacterium or virus could potentially be more devastating than the Tokyo attack because a biological attack can be dissipated by human carriers. This issue was the focus of the Senate Health Committee's interim hearings.

The first signs of this attack would be two to three days after exposure, when a large number of exposed persons sought medical attention with flu-like symptoms. Within days, those people originally exposed would become seriously ill and more than 80 percent of those could die as a result of inhaling anthrax. The epidemic would not be realized or the cause identified until days later while the number of sick and dying rapidly increased. Hospitals would be overwhelmed, local health resources depleted, response would be uncoordinated and ineffective at best, and still more people would die.

Since there is no obvious "attack," there is no "emergency first response". Only after the epidemic is detected and identified will it be clear that an intentional (versus a natural epidemic) outbreak is underway. Prevention of bioterroristic events is very difficult because criminal activity is largely unpredictable. A post-attack response must be rapid and effective, and doing so

requires prior planning, preparation, and training.

Federal Initiatives

The federal government has taken numerous legal steps to strengthen our ability to prevent or respond to a biochemical terrorist attack. There are new laws that make the unauthorized possession of a restricted microbe or the threatened use of such a microbe a federal offense. The Centers for Disease Control and Prevention (CDC) is charged with the development and implementation of a system for tracking the interstate transportation of these microbes.

A large number of resources target improving the national preparedness and response capacity. The U.S. Department of Defense is charged with assisting local governments in bioterrorism preparedness, and the U.S. Department of Justice is working with state and local governments to assess the current state of readiness and preparedness.

The federal government created a list of "120 cities" based mostly on population size that is receiving or have received direct assistance for the creation of Medical Management Response Systems (MMRS). The Texas cities on this list are identified in the table below.

Medical Management Response Systems in Texas	
Participating Texas Cities	**Amount of Grant**
Amarillo	Expected to receive grant
Arlington	$ 600,000
Austin	$ 600,000
Corpus Christi	$ 600,000
Dallas	$ 600,000
El Paso	$ 600,000
Fort Worth	$ 600,000
Garland	Expected to receive grant
Houston	$ 600,000
Irving	Expected to receive grant
Lubbock	Expected to receive grant

San Antonio	$ 600,000

Source: Texas Department of Health and US Public Health Service

These cities have received funds for equipment and training of first response teams for chemical incidents. Several cities have also received support for the development of response plans in the case of a biological weapon use. In addition, the CDC has provided funds to a majority of states through a competitive grant process to improve state and local capacity to detect, diagnose, and respond to a bioterrorist attack.

Texas Activities

The State of Texas has begun a variety of activities aimed at maximizing responses to a bioterrorist attack. The Texas Emergency Management Plan outlines the conceptual basis for preparing and responding to a variety of disasters, including a bioterrorist attack. While the details are not yet complete, the Texas Department of Health (TDH) will have a significant role in responding to a biological terrorist event.

The TDH has internal working groups and committees that are preparing internal operational procedures in the case of an intentionally caused epidemic. These plans include epidemic response and notification, laboratory support, communications, training, and pharmacy support. Each of these plans is generically designed to adapt to the differing needs of Texas cities. The philosophical basis for these plans is that TDH will work to support local governments.

Since the general circumstances of a bioterrorist attack are essentially the same as a large epidemic (although the scale of an attack could quickly outstrip capacity), TDH will use resident expertise in detection, identification, epidemic investigation and control recommendations. TDH will rely on the reporting of communicable diseases by health care providers to local and regional health department offices to detect the first signs of an unusual disease outbreak. Laboratory confirmation of a causative bacterium or virus will begin concurrently with the epidemic investigation. The TDH laboratory is a reference laboratory and serves as a submission laboratory to the CDC laboratory. All samples in Texas will be sent to the TDH laboratory whether for examination and/or forwarding to the CDC. These activities will be coordinated as an adjunct to local and, if needed, federal health resources which can be activated by request from the

Commissioner of Health or the State Epidemiologist.

Texas successfully competed for an estimated $1.1 million annual grant from the CDC to improve disease detection capacity. The improvements will occur through specific enhancements to our disease surveillance system, laboratory diagnostic capacity, and through the implementation of a "Health Alert Network" or HAN. The Texas HAN received $450,000 in federal support and leveraged $4.5 million from the Texas Telecommunication Infrastructure Board (TIF) to deploy a computer-based information sharing system with all of the local health departments within Texas, linking them to TDH regions and central offices. This link will allow for rapid disease reporting from local areas to TDH epidemiologists monitoring unusual occurrences and trends. The HAN also connects all local health departments to public health information on the Internet established specifically for outbreak investigations. Video conference training on the highly technical areas of disease control, microbiology laboratories, and public health response is also an integral part of the HAN. The combination of federal and state funds for this project are considered a highly successful model by the CDC.

Infrastructure and Model Programs

Monitoring the potential threat of a bioterrorist attack is unique because it brings together two fields - public health and law enforcement - to address difficult issues. Since terrorism is a crime, there are significant law enforcement issues such as agency jurisdiction, crime scene investigations, evidence collection and tracking, and criminal case filing jurisdiction. Recent legislation clarifies this kind of terrorism as a federal offense; therefore, the FBI is the lead law enforcement agency. Discussions with FBI Agents in Texas indicate a clear willingness to work directly with local law enforcement and public health agencies when responding to a terrorist event.

The federal government's health resources reside mostly within the CDC and are positioned to take a supportive role to state and local health departments' needs when responding to an epidemic caused by a terrorist attack. Comprehensive communication pathways for notifying the CDC of a potential epidemic are in the process of being established.

No state is completely ready for an attack of this magnitude. Like Texas, most states are grappling with issues of detection, identification, and response. Several U.S. cities have been preparing for a number of years, and therefore have some programs worth modeling. New York City (NYC) is regarded as having the best response system. Emergency Response teams are well versed in public health/epidemic measures and are in constant and direct communication with NYC communicable disease authorities. The epidemic response capacity of NYC is reasonably well staffed. When there is no emergency, these epidemiologists work to maximize their capability to quickly detect any unusual disease occurrence by working directly with hospitals and clinics on a daily basis. This improves their capacity to respond to "naturally-occurring" outbreaks as well. Finally, the city has an emergency response plan in which all city agencies and hospitals participate, with public health agencies playing a leadership role. The plan has been exercised using a variety of exposure or outbreak scenarios and is under constant refinement.

Key Issues

The development of local epidemic emergency response plans is a critical element in preparing Texas cities for a large potential outbreak. In the tense, chaotic experience of a large epidemic, prior agreed-upon protocols for transportation, medical care, epidemic investigation, disaster mortuary services and clean up will prevent ineffective, uncoordinated actions that will ultimately cost lives. Response to local disasters is a municipal government responsibility, but state capacity could, and should, be brought to bear quickly. All plans must integrate capacities across local, state and federal lines, as well as across topical areas such as law enforcement, public health, and medical care.

The key to an integrated response is communication. First, the need for preparedness planning must be a vision shared by all in order to create a maximum response. Also, each entity does not have to be an expert in all aspects, but a multi-functional team with the proper expertise must be available ahead of time. For example, law enforcement does not need to know the details of bacterial disease transmission, but they must know that it is an issue and that TDH and local health partners are ready to participate.

Texas health care providers must be familiar with the diseases of concern in order to diagnose

them quickly and correctly. Many of the illnesses are rarely seen, so the diagnoses may be delayed while other, more common conditions are ruled out. More effort to familiarize health care providers with the signs and symptoms of the important diseases will increase the chances of a rapid diagnosis. Once a diagnosis is suspected or made, that information must be immediately provided to health authorities, where it may require collation and analysis with other disease reports. Obviously, the sooner this information is received, the sooner the illness can be confirmed and a cause identified. With this information, medicines and treatments can be targeted toward the exposed populations, and law enforcement can focus their criminal investigation on the crime scene.

Currently, the level of readiness of Texas cities is unknown. A systematic catalogue of capacity would be of great assistance in directing resources. Through a U.S. Department of Justice survey all states are collecting information regarding readiness assessment, threat assessment, and public health capacity assessment. Governor Bush's office has appointed the Texas A&M Engineering Extension Service (TEEX) as the coordinator of this effort, which promises to highlight needs and capacities in Texas.

In public health parlance, this "disease surveillance" is an ongoing, systematic collection and analysis of communicable disease information that leads to the detection of unusual occurrences, or outbreaks. Surveillance is statutorily mandated (Health and Safety Code, Chapter 86) and is a fundamental core public health function. Therefore, the resources that are available for routine surveillance can be enhanced to adapt to levels needed during a large epidemic. In the event of a bioterrorist event, Texas resources at the local and state levels will be overwhelmed and quickly exhausted.

It is critical in any investigation to review information from disease surveillance analysis, epidemic investigators, and interviews with surviving patients to collect the clues that will ultimately lead to the identification of the source of exposure (Eg. church supper, a family picnic, attendance at a large event). Knowing the "when, who and where" leads to the "how" and possibly the "why" of an outbreak. Only the largest local health departments maintain trained epidemiologists on staff. About half of the TDH regional offices have a trained epidemiologist on staff, and the central office Infectious Diseases Epidemiology and Surveillance Division has three epidemiologist

positions.

Developing the most appropriate system to respond to these events requires interaction and participation from local, state and federal agencies, private and public entities, academic institutions, practicing physicians, hospitals, the military, and others. The complexity of the issues suggests that each locality must bring together these experts to craft the best local response system and ensure that it is implemented, exercised, and refined. At the state level, similar discussions among state agencies, universities, etc., with local participation should be held. Each group has something important to provide to the statewide plan.

Agency Activities

The TDH is advancing an exceptional funding item that, along with federal support already in place, will make the initial steps in preparing Texas to respond to bioterrorism. The focus of this report's recommendations will be to develop a modest state capacity to:

- Detect the first signs of illnesses related to an intentional release;
- Support local government activities in developing and implementing plans; and
- Better educate health care professionals regarding diagnosis and reporting of the illnesses associated with the use of a weapon of mass destruction.

Three possible levels of appropriations include the following:

1. Develop regional epidemic response teams in each of the 8 TDH regional offices. These teams, consisting of four professionals each, will serve a dual purpose. First, they will work directly with cities within their regional boundaries to develop, implement, and exercise bioterrorism response plans, as part of their emergency preparedness planning efforts already in place. For the areas without local health support, the team will work with other county and state resources to develop response mechanisms for those areas. Second, while not working on bioterrorism-related activities, these teams will be improving disease detection and tracking with local health departments, hospitals and clinics. They will serve as a rapid response team to conduct outbreak investigations that are naturally-occurring in support of their local health partners and lead investigations in

those areas without local health departments. The Information Technology (IT) member of this team will maintain and operate the Health Alert Network and the associated disease reporting software, video conferencing and training.

The TDH Central Office Infectious Disease Epidemiology and Surveillance Division support regional teams with disease information, outbreak investigation procedures, and handling the increase of reported cases of communicable diseases resulting from regional team surveillance activities. Also included in the Central Office support is rapid diagnostic laboratory testing of samples in an epidemic setting. Both regional and central office staff will produce written and lecture products to improve the awareness of physicians, nurses, hospital administrators and others regarding bioterrorism and associated illnesses. Professional organizations such as the Texas Medical Association (TMA), the Texas Hospital Association (THA) and the Texas Nurses Association (TNA) will be partners in this education/awareness effort.

The estimated cost for this activity is $3.86 million/biennium, 36 FTEs.

2. A second option is to scale the teams to three members each. The central office technical support group would remain at four people. The number of investigations and surveillance activities will be approximately 15% less than option 1. Professional education efforts will be approximately 20% less than in option 1.

   The estimated cost for this activity is $2.95 million/biennium, 28 FTEs.

3. A beginning effort that will provide minimum assistance to local government would require three professional/technical staff to be added to the Communicable Disease Control and State Epidemiologist's office to coordinate the public health efforts related to planning and responding to bioterrorism. These three staff members would provide minimal input to local plans development and disease detection and analysis of disease reports. They could also coordinate TDH leadership in the State's response to an event and might also help TDH seek additional federal funds in support of activities planned and already underway.

The estimated cost for this activity is $185,000-$200,000 annually, three FTEs.

Recommendations

1. Texas must dramatically enhance disease detection capacity throughout the State.

   Rational: *Since detection is the first critical step of a systematic response, it requires significant attention. This step will have the "dual use" of improving the capacity to detect the naturally and unnaturally occurring outbreaks that are currently missed or receive delayed attention due to minimal capacity.*

2. Local governments must develop, implement, and exercise integrated bioterrorism response plans which will prepare local systems in the event of an intentional release of a deadly bacterium or virus.

   Rational: *These plans should not stand alone, but should be integrated into the current disaster and emergency planning efforts already in place. Since the public health issues of bioterrorism are new to emergency planners, the TDH should develop expertise to assist local governments with these aspects of their plan's development and implementation.*

3. Texas health care professionals must be educated and made aware of the threat of epidemic disease caused by terrorist intent and be prepared to rapidly identify the diseases of concern and to report suspected concerns to the local and state health department.

   Rational: *Texas nursing, medical, and osteopathic universities, as well as medical, hospital, nursing, and local organizations must take an active role with TDH in improving epidemiological diagnosis and reporting.*

4. Texas should mirror the steps the federal government has taken to strengthen abilities to prevent or respond to a terrorist attack using chemicals or microbes. Texas should pass

laws to establish criminal liability for the unauthorized possession of a restricted microbe or making a threat of using such a microbe.

Rational: *The establishment of such laws will assist local and state efforts to prevent possible threats against Texans.*

INTERIM CHARGE 3

Medical Privacy

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Medical Privacy

Interim Charge #3

Review the type, amount, availability, and use of patient-specific medical information, including prescription data, and currently statutory and regulatory provisions governing its availability. The report shall explore if statutory and regulatory provisions are consistent and adequately enforced.

Background

The current debate surrounding the question of personal privacy, and in particular medical privacy, has existed many generations. The privacy debate will continue as technology inevitably advances, but the central question will always remain: to what extent will we allow the use of technology to manage our lives, and what will those advances mean to our personal privacy? Supreme Court Justice Louis Brandeis opined in *Olmstead v. United States* in 1928 that the framers of the Constitution "conferred...[that] the right to be let alone -- [is] the most comprehensive of rights, and the right most valued by civilized men." Earlier this year, a *Business Week* magazine survey reported that 57 percent of Internet users indicated they would support Federal legislation to protect privacy. It is clear that this ethical dilemma will govern how decision makers define the proper use of personal medical data.

Confidential health and medical data are now collected, analyzed, distributed and accessed in unprecedented quantities. Health care providers can access records to diagnose illnesses, coordinate treatment, obtain payment for services, and monitor treatment from other health care providers. Clinical researchers use medical records to gather valuable data on the course of a disease and track response to a treatment. Insurers refer to medical records to determine coverage, make payments on claims, conduct utilization reviews, and for underwriting purposes in an attempt to manage rising health care costs. An employer may use employee health care data to track worker compensation claims and overall health care costs incurred by employees.[1]

[1] HEALTH POLICY TRACKING SERVICE, ISSUE BRIEF ON MEDICAL RECORDS (July 2000).

The issue of access to medical records has become a top concern in today's health care arena and a key political issue. As the ease of obtaining confidential information by a variety of regulated and unregulated entities grows, so does concern regarding loss of consumer control over the use of personal health data. A recent survey conducted by the University of Texas at Austin's Telecommunications and Information Policy Institute reported that almost half of all Texans are "extremely concerned" about giving non-financial information to the government via the internet. Nearly 70 percent of Texans worry about privacy on the Internet. Furthermore, 72.4% of polled Texans think they should be able to "opt-in" to consent for the use of personal data.

Technology and computerization promise many new benefits in health and medical care. There are numerous legitimate uses of medical data disclosure, such as cross-referencing drug interaction, patient education, processing claims efficiently, and reducing fraud and abuse. Areas such as clinical care, research, public health, access, coverage, and improved health outcomes could benefit from a thoughtful, well defined, and consumer friendly health data policy. Furthermore, any application of policy should maintain and promote consistency of all data transfers.

Confidential health care information can include an individual's medical, psychiatric, or psychological history, diagnosis, condition, treatment, evaluation, or prescription drug use. This information is commonly maintained in written, auditory, visual, electronic, and other physical forms. Health professionals know it is critical to keep patient health care information confidential and free from unauthorized access, regardless of storage medium.

Threats to Medical Privacy

- Computerization: While encryption technology is available to ensure privacy and anonymity, the computerization of medical records may actually serve to decrease privacy by compiling information that can be accessed by both authorized and unauthorized users. Computerization, while offering many benefits, may ultimately increase both the amount of accessible information and the risk of unauthorized modification and dissemination.

- Information: Computers have the potential to store an infinite amount of data. Anyone with access to medical records is likely to be able to obtain important personal information such as social security numbers, addresses, dates of birth, diagnoses and prescription drug usage.

- Access: Unlike printed data, networked information may be accessible from any location, by any computer user, at any time. This allows access to a large number of individuals' data and exponentially increases the possibility of mistakes or misuse.

- Modification: Skilled users can potentially modify computer databases. Security can be breached and records could be misused, changed or deleted.

- Dissemination: Collecting, exchanging and transmitting information can occur much faster by computer, thereby increasing the possibility that medical information may be widely disseminated in a short period of time.

Parties Interested in Medical Records

- Insurance Companies: Insurers use information contained in medical records before approving treatment and/or extending coverage.

- Drug Companies: Pharmaceutical companies may have partnerships with doctors, nurses pharmacists, or hospitals that allow prescription records to be used for marketing purposes.

- Judicial System: Patients sometimes are unaware that their medical record history could be used in court. Furthermore, unnecessary information can be included when the records are not adequately screened.

- Employers: Sensitive health data is currently available to employers that offer their own health plans.

- Researchers: Regulations require that prior to using identifiable health information, a research study must be approved by an Institutional Review Board (IRB). Participants must also give their informed consent; however, the law allows the IRB to grant a waiver of informed consent under some circumstances. Increasingly, research is privately funded and may not involve direct contact with patients. As a result, more research that relies primarily on the patient record or "encounter data" is falling outside the scope of federal regulations.

- Pharmacy Benefit Managers (PBMs): PBMs contract with HMOs or with employers to manage their drug benefits. They gather information about patients by analyzing their conditions and corresponding drug utilization. They process this information and tailor drug or product marketing to specific patient groups.

- Consumers: Individuals are concerned that information compiled by data collection entities (which is typically owned by the employer) could create adverse reactions in the workplace. Consumers are generally concerned that these entities have the ability to access and distribute personal information contained in their medical records without their knowledge or permission. Additionally, consumers are concerned about receiving direct mailings that may contain pertinent personal information, banks having access to their medical records, and the ownership of personal health care information.

- Law Enforcement: Law enforcement officials use data to reduce fraud and abuse in the health care system as well as to solve criminal investigations.

- Public Health: Public health officials review medical data to evaluate and address the trends and spread of disease and public health threats such as rabies, West Nile virus, bioterroristic attacks and threats.

Key Issues

The most pressing issue regarding the discussion of access to medical records is how to protect an individual's privacy while, concurrently, allowing for legitimate access to personal health data.

Technology

The growth of managed care organizations has created the opportunity to construct virtual warehouses of medical records and information. This information is increasingly stored on computers and networked databases. The manipulation of medical data has proven extremely helpful to both medical researchers to track public health trends and for commercial interests to provide patient education. Computerization has allowed for innovative and intricate analyses of immense multi-functional health databases. Although the ease of access to this information is beneficial for research, public and commercial interests, it is potentially intrusive to individual patients whose medical records may be accessed without their consent or knowledge.

Disease Management

The challenge to develop innovative methods of treatment while protecting patients' vital health information has come to the forefront of concern for patients, health care providers and disease management organizations. Recently, the California Health Care Foundation released a poll that is related to the privacy discussion, which found that 70 percent of polled adults do not want drug companies to review their medical record for the purpose of marketing new drugs and products. This overwhelming result points to the challenge in developing a Disease Management program that provides educational benefit to patients while respecting their medical privacy. According to the Disease Management Association of America, Disease Management is a multi-disciplinary, continuum-based approach to health care delivery that pro-actively identifies populations with, or at risk for, established medical conditions that:

- supports the physician/patient relationship and plan of care;
- emphasize prevention of exacerbations and complications utilizing cost-effective evidence-based practice guidelines and patient empowerment strategies such as self-management; and
- continuously evaluates clinical, humanistic, and economic outcomes with the goal of improving overall health.

The paramount concern, given the reality of the use of information technology, is to develop an innovative solution allowing for the legitimate transfer of appropriate amounts of patient specific information and encrypted data, while at the same time, preventing any data from being used for unwarranted marketing purposes. There is a need to develop a coherent federal and state privacy policy that clearly establishes the definition of legitimate disease management and overt commercialization of direct marketing to a sometimes vulnerable patient population.

Research

The Pharmaceutical Research and Manufacturers of America (PhRMA) recently published a policy position delineating the concerns of advancing research and protecting the privacy rights of individual patients. PhRMA observed that: Patients who participate in pharmaceutical research are entitled to have their sensitive medical information held in strict confidence. At the same time, research must have sufficient identifying information about its research subjects to enable accurate and thorough studies. The policy further stated that the development of federal standards should include a provision to ensure that:

- protections established for maintaining the confidentiality of medical information do not impede biomedical research;
- all medical information, including genetic information, has equal protection;
- researchers have unrestricted access to encrypted patient information; and
- uniform national standards should govern biomedical research. (Although individual states should be able to prescribe additional penalties for violations of privacy rules.)

It is imperative that policies are consistent and allows for the advancement of research while protecting individuals' privacy rights.

Employer and Employee Issues

Employers must have access to certain health care data for a number of reasons. It is important that policymakers not erect unnecessary burdensome barriers that result in employers choosing not to provide health care benefits to employees. At the same time, an employee's privacy rights are tantamount in this debate. Employers must have access to aggregated data in order to make benefit design choices, payment decisions, and to ensure that their insurance premiums are spent

appropriately. However, there are very limited reasons why an employer might need to obtain or use patient specific health information about an individual employee, such as employees that are relied upon to provide for the safety and well being of those they serve. Proponents for providing employers with full access to patient data cite the need for employers to encourage their staff to participate in disease management programs. While the committee supports disease management strategies, an integrated network of health care providers should manage these initiatives. The committee has received testimony detailing situations in which employers have not only reviewed an employee's medical data, but have used that medical information in an adverse manner. In many cases, the employer has made a decision to enroll its employee into programs to treat the employee's perceived condition, which has been based on prescription drug use history, rather than a specific diagnosis. These enrollment notices are often issued on the patient's company letterhead, marketing a particular drug. The committee feels that this type of information should be conveyed within the sanctity of the relationship between a qualified health care provider and the patient. The patient should always be consulted prior to release of any medical information.

Unauthorized Release of Data

With the demand for health care data, patients and providers are growing increasingly uneasy about the erosion of medical privacy. Anecdotal information in the media has told of countless stories exposing the vulnerability of the security of computerized health records. Recent media articles have reported incidents such as an anonymous source releasing a congressional candidate's psychiatric records to a newspaper on the eve of the election, a banker sitting on a state health commission obtaining confidential information from the state cancer registry to call in loans of cancer registrants who had borrowed money from his bank, and the names of 4,000 AIDS patients being leaked to the media even though they were stored on a computer housed in a locked room where only three individuals had access.[2] These reports have given patients and providers alike justification to be wary of unwarranted disclosure and, in some cases, outright abuse of personal medical records. While struggling to maintain the security of personal health information, it is important that policymakers recognize the rights of a parent or legal guardian who has legal responsibility for a minor or person in their care. Parents and legal guardians must

[2] Brian Wallstin, *No Secrets*, HOUSTON PRESS, November 25, 1999, at p. 1.

have access to the medical records of the person in their care in order to effectively manage their medical care.

Opt-in vs. Opt-out Dilemma

In an attempt to reach a compromise between the legitimate use of personal medical data and assuaging the concerns of consumers, much of the privacy discussion has centered around allowing individuals to either 'opt-in' or 'opt-out' of a program. "Opting-in" means a consumer or patient has the ability to join a program or programs by expressly stating their permission to have their information and data shared and used by entities and/or third parties. "Opting-out" allows an entity to use confidential information and data unless a patient expressly exercises an option to specifically state they do not wish to have their information used or shared. One such compromise proposal is known as the tiered approach. The tiered approach would split data into three or more categories: general information, diagnosis information, and prescription information. General information could be categorized as name, address, age, etc. Diagnosis information would obviously be information related to an individual's diagnosis. Prescription information is prescriptive intervention that a health care provider administers to a patient. In a tiered approach, a consumer would have the ability to choose the level of information that they consent to keep confidential, by exercising an option to either opt-in or opt-out of certain programs. An individual would also be able to review their opt-in/opt-out choices periodically and to alter their choices. A consumer could choose to opt-out of general information, opt-in or opt-out of diagnosis information and opt-in to the sharing of their prescription information. This would allow patients to proactively educate themselves and make themselves eligible to receive important educational material related to their diagnosis. The tiered approach shows promise as a reasonable compromise to allow a consumer to attain as much or as little information they choose to receive or share with others. Often, the patient is offered the opportunity to consent to the release of information; however, the consent is only one component of the entire contract that they must sign to receive care or participate in a particular insurance plan. In order to truly give consumers control of their medical information, it is necessary to present patients with separate and easily discernable consent forms. Moreover, a particular plan or treatment should not be contingent upon the patient's decision to consent to the release of their medical data.

Current Texas Law

Currently, Texas has not enacted a comprehensive privacy act. The Texas Attorney General was asked by the House State Affairs Committee to prepare a compilation of current Texas laws and regulations that address privacy concerns. Please refer to appendix F for a compendium of health-related privacy statutes. The following information summarizes the health-related portion of the Attorney General's recent survey:

Definition of Health Care Information

The Texas Legislature has generally defined health care information as "information recorded in any form or medium that identifies a patient and relates to the history, diagnosis, treatment or prognosis of a patient." The Legislature intentionally defined this term very broadly to apply to most information obtained by health care providers regarding their patients.

Disclosure of Health Care Information by a Physician

The Texas Medical Practice Act protects the confidentiality of "records of the identity, diagnosis, evaluation, or treatment of a patient by a physician that are created or maintained by the physician," as well as communications between a physician and patient. The privilege of confidentiality may be claimed by the patient or the physician on the patient's behalf.

Such records may be released pursuant to the written consent of the patient or the patient's legally authorized representative. The consent must be in writing and must state the information or records to be released, the reasons or purpose for the release, and the person to whom the information is to be released. The patient and legally authorized representative have the right to withdraw consent at any time. However, revocation of consent does not affect records released prior to notice of revocation. A physician is shielded from legal action if he released the records in good faith and upon proper authorization if the physician did not have a written notice of revocation.

The physician is required to furnish copies of the medical records within 30 days of the request. A physician may delete confidential information relating to another patient or a family member of the patient who has not consented to the release. Further, the physician may refuse to release the records if it is determined that such release could be harmful to the physical, mental or emotional well being of the patient. The physician must provide the patient with a signed and dated written statement identifying the reasons for a denial of request.

Various exemptions to the prohibitions against the disclosure of medical records exist and are applicable even when the patient has not consented to the disclosure. The privilege does not apply in a court or administrative proceeding:

- if the proceeding was brought by the patient against a physician;
- in which the patient or the legally authorized representative submits a written consent to release confidential information;
- If the purpose of the proceeding is to substantiate and collect on a claim for medical services rendered to the patient;
- if any civil or administrative proceeding is brought by the patient in an attempt to recover damages for any physical or mental condition if the records are relevant;
- if the proceeding is a disciplinary investigation or other proceeding by the Board of Medical Examiners regarding a physician, provided that the Board protects the identity of the patient;
- if the proceeding is part of a criminal investigation of a physician in which the Board is participating or assisting if the Board protects the identity of the patient (unless the patient is a complaining witness or consents to the release of the records);
- that is an involuntary civil commitment proceeding, proceeding for court ordered treatment, or probable cause hearing;
- when the patient's physical or mental condition is relevant to the execution of a will;
- that is any criminal prosecution where the patient is a victim, witness or defendant;

- to satisfy a request for medical records of a deceased or incompetent person pursuant to the Medical Liability and Improvement Act; and
- to a court or party for an action pursuant to another court order or court subpoena.

Additional exceptions to the confidentiality of health care information by a physician allow disclosure to:

- governmental agencies if the disclosure is required or authorized by law;
- medical or law enforcement personnel if the physician determines that there is a probability of imminent physical injury to the patient, himself, or others, or if there is a probability of immediate mental or emotional injury to the patient;
- qualified personnel for management audits, financial audits, program evaluations, or research if the identity of the patient is not disclosed;
- those parts of medical records reflecting charges and specific services rendered when necessary in the collection of fees;
- any person who has a written consent of the patient or the patient's legally authorized representative;
- individuals, corporations, or governmental agencies involved in the payment or collection of fees for medical services rendered by the physician;
- other physicians and personnel under the direction of a physician who are participating in the diagnosis, evaluation or treatment of the patient;
- in any official legislative inquiry regarding state hospitals or state schools, provided that the identity of the patient is not released unless proper consent is obtained; and
- health care personnel or a penal or other custodial institution in which the patient is detained if the disclosure is for the sole purpose of providing care to the patient.

Any person who receives information which is confidential under the Medical Practice Act may only disclose such information in the manner outlined above. For example, if a physician releases medical records to an insurance company for payment purposes, the insurance company must

maintain that information as confidential and only release it as allowed in the statute. The physician may charge a reasonable fee for copying records in any appropriate medium. The maximum charges are published annually in the Texas Register.

A patient who is aggrieved by a violation of these requirements regarding the disclosure of medical records may seek injunctive relief in the district court in the county in which they reside. Individuals residing out of state must file in Travis County. A patient may also bring suit for civil damages.

Disclosure of Health Care Information by a Hospital or Other Provider

The statute governing the manner in which hospitals disseminate information may also apply to other health care providers such as home health agencies, nursing homes, and ambulatory surgery centers.

A hospital or an agent or employee of a hospital may not disclose health care information about a patient to anyone other than the patient or legally authorized representative without the written authorization of the patient or the patient's legally authorized representative. An authorization, valid for 180 days, must be in writing, dated and signed, and must identify the information to be disclosed. As in the Medical Practice Act, a patient may revoke an authorization at any time. However, the revocation only applies to records not already released and the hospital is not bound to the request until it has received written notice. Authorization to release records for the purposes of making payments to hospitals may not be revoked.

This statute also allows disclosure without written authorization under specific circumstances, which are similar to those in the Medical Practice Act but are not identical. The following are additional circumstances under which records may be released:

- directory information, unless the patient has instructed the hospital not to disclose such information or the information is otherwise protected;
- to a health care provider who is rendering health care to the patient when the request for disclosure is made;

- to a transporting emergency medical services provider for the sole purpose of determining the patient's diagnosis and the outcome of the patient's hospital admission;
- to a member of the clergy specifically designated by the patient;
- to a qualified organ or tissue procurement organization for the purposes of making inquiries related to donations;
- to a prospective health care provider for the purpose of securing the services of that provider as part of the patient's continuum of care;
- to a person authorized to consent to medical treatment in order to facilitate the adequate provision of such treatment;
- to an employee or agent of the hospital who requires health care information for health care education, quality assurance, or peer review or for assisting the hospital in the delivery of health care, or in order to comply with statutory, licensing, accreditation, or certification requirements. Records may also be released if the hospital takes action to ensure that the employee or agent will not disclose or use the information for any other purpose and take steps to protect the information;
- to a hospital that is a successor in interest to the hospital maintaining the health care information;
- to a federal, state, or local government agency or authority;
- to the American Red Cross for the specific purposes of fulfilling the duties of its charter;
- to a regional poison control center to the extent necessary to enable the center to provide information and education to health professionals involved in the management of poison and overdose victims;
- to a health care utilization review agent who requires the information for utilization review of health care;
- for use in a research project authorized by the institutional review board;
- to facilitate reimbursement to a hospital, other health care provider, or the patient for medical services or supplies;

- to a health maintenance organization for the purposes of maintaining a statistical reporting system as required by state agencies;
- to satisfy a request for medical records of a deceased or incompetent person;
- to comply with a court order; and
- related to a judicial proceeding in which the patient is a party and disclosure is requested under a subpoena.

The hospital requested to furnish data has 15 days from the date of the request, once the entity has received payment to honor the request. An aggrieved patient may bring an appropriate action seeking injunctive relief and damages resulting from the unauthorized release of information.

Special Requirements Regarding Disclosure of Mental Health Information

Texas has established specific state laws to protect the confidentiality of mental health information. Accordingly, communications between a patient and health professional (licensed physician, person licensed or certified in Texas to diagnose, evaluate, or treat any mental or emotional condition or disorder, or a person a patient reasonably believes is authorized to do so), as well as records regarding the identity, diagnosis, evaluation, or treatment of a patient which are created or maintained by a professional are confidential. The confidentiality privilege may be claimed by the patient, the patient's legally authorized representative or the health professional on behalf of the patient.

The provisions allowing for the release of information and for revocation of consent are similar to those delineated in the Medical Practice Act. There are a few modifications, including a requirement of disclosure by a mental health professional to the personal representative of the patient if the patient is deceased or incompetent. Disclosure is permitted to an employee or agent of the health professional who requires mental health care information prior to providing services as necessary to comply with statutory, licensing or accreditation requirements. However, the health professional is required to take precautionary steps to ensure that the agent or employee will not use or disclose the information for any other purpose and will take steps to protect that

information. A person who receives information under this statute may not disclose the information except to the extent that the disclosure is consistent with the authorized purposes for which the information was obtained, unless the person is the legally authorized representative of the patient. The provisions allowing release of records in administrative and judicial proceedings are essentially the same as those included in the Medical Practice Act.

This mental health statute also allows a patient the right to have access to the content of his or her own mental health records. However, the patient's health care professional is permitted to deny access to any portion of the record if the professional determines that the release of such information would be harmful to the patient's physical, mental or emotional health. If access is denied, the health care professional must provide the patient with a written statement of the reasons for denial, specify the portions affected and indicate the duration of the denial. The health care professional must redetermine the necessity of denial each time the patient requests access to the records. This statute also contains provisions regarding the redaction of confidential information about another patient or person who has not granted consent. However, it further requires that information regarding the patient which was provided by another person must be disclosed along with the identity of the person in the patient's records. Records must be provided in a reasonable time frame from the time of the request. An aggrieved patient may bring an action seeking appropriate injunctive relief and damages resulting from the unauthorized release of information under this statute.

Requirements Regarding Release of Drug and Alcohol Abuse Records

Federal law protects the confidentiality of "records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to substance abuse education, prevention, training, treatment, rehabilitation, or research" if such activity is conducted, regulated, or assisted by any federal agency. Almost every hospital or other substance abuse treatment facility is required to comply with these very stringent confidentiality requirements. Violation of these requirements subjects the violator to criminal penalties, including a fine of not more than $500 for a first offense and not more than $5,000 for a subsequent offense.

The federal regulations state that they do not preempt state laws in the same field as long as the state law is equally or more stringent regarding the release of information. If the federal regulations permit disclosure but the state law prohibits their release, the state laws will take precedence. However, if the federal laws are more stringent, the federal laws will supercede the state law.

According to the Drug and Alcohol Abuse statute, those records may not be disclosed if they identify a patient as an alcohol or drug abuser (either directly or indirectly). Further, the information may not be used to substantiate or initiate any criminal charges against a patient. These restrictions also apply to the drug and alcohol treatment centers and their employees and/or agents. Regulations stipulate that all related information must be housed in a secure facility.

The regulations specifically restrict a facility from even acknowledging the presence of a patient in the facility unless the patient's written consent is received or the acknowledgment is authorized by a court. Minors may only consent to disclose their drug and alcohol records if they have voluntarily admitted themselves to a drug or alcohol treatment center. If they are not there voluntarily, only a parent or guardian may consent to release records. The regulations also allow a patient access to his or her own records without the necessity of a written consent form. Every disclosure of records which is made pursuant to a patient's consent must contain a statement referencing the federal regulations related to drug and alcohol abuse and the confidentiality restrictions imposed on those records.

Alcohol and substance abuse records may be released without the patient's consent only under specific circumstances. First, patient identifying information may be released to medical personnel who need the information to treat a condition which poses an immediate threat to the patient's health and which requires immediate medical intervention. Information may be released for scientific research to a qualified recipient who is determined to have proper standard IRB security protocol in place. Confidential records may also be disclosed in the course of an audit or evaluation if no records are copied or removed from the premises.

A court order may authorize disclosure of confidential drug and alcohol abuse records if:

- the disclosure is necessary to protect against an existing threat to life or serious bodily injury;
- the disclosure is necessary in the connection with an investigation or prosecution of serious crime; and
- the disclosure is in connection with litigation or an administrative proceeding in which the patient offers testimony or other evidence pertaining to the content of the confidential records.

In general, an order authorizing the release of records may be applied for by any person having a legally recognized interest in the disclosure (in regard to non-criminal matters), by the person holding the records, by a person conducting investigative or prosecutorial activities, or by any administrative, regulatory, supervisory, investigative, law enforcement or prosecutorial agency having jurisdiction over the program's or person's activities.

Release of HIV Test Results

Texas has promulgated statutory requirements governing the confidentiality of HIV test results. In general, a person who has knowledge of a test result may only release the result to:

- the Texas Department of Health, as permitted by law;
- a local health authority, if reporting is required by law;
- the Centers for Disease Control and Prevention, if reporting is required by federal law;
- the physician or other person authorized by law who ordered the test;
- a physician, nurse, or other health care personnel who has a legitimate need to know the result in order to provide the patient with appropriate health care services;
- the person tested or a person legally authorized to consent to the test on the person's behalf;

- the spouse of the person tested if the person tests positive for AIDS or HIV infection, antibodies of HIV, or infection with any other probable causative agent of AIDS;
- a person authorized to receive test results; and
- a person exposed to HIV infection.

A person who is tested or that person's legally authorized representative may voluntarily release, through written consent, the test results to any other person, or may authorize the testing facility to do so. A violation of this statute, in which an unauthorized person releases a test result or allows a test result or other information to become known through criminal negligence is a Class A misdemeanor.

Confidentiality of EMS Records

The Emergency Medical Services (EMS) Act provides that communications between certified EMS personnel or a physician providing medical supervision and a record that are made in the course of providing emergency medical services to the patient are confidential and privileged. This privilege includes records of the identity, evaluation, or treatment of the patient by EMS or by a physician providing supervision. The privilege does not extend to protect information regarding the presence, nature of injury or illness, age, sex, occupation, and the city of residence of a patient who is receiving emergency medical services.

Confidential EMS records may be disclosed pursuant to a written and signed consent by the patient or the patient's legal guardian. The consent must specify the information requested, reason for the request and the person to whom the information is to be released. The consent may be withdrawn at any time. However, the withdrawal of consent does not affect records already released pursuant to the previous consent.

EMS records and communications may be released without the patient's consent under the following circumstances:

- when proceedings are brought by the patient against EMS personnel, a physician providing supervision, or an EMS provider;
- when the purpose of the proceedings is to substantiate and/or collect on a claim for emergency medical services rendered to the patient;
- in any civil litigation or administrative proceeding, if relevant, brought by a patient if the patient is attempting to recover monetary damages;
- when the proceeding is a disciplinary investigation or proceeding against EMS personnel;
- when the proceeding is a criminal investigation in which the patient is a victim, witness, or defendant;
- to medical or law enforcement personnel if EMS personnel, an EMS provider, or a supervising physician determines a probability of imminent physical, emotional or mental danger;
- to government agencies if the disclosure is required or authorized by law;
- to qualified persons to the extent necessary for management audits, financial audits, program evaluation, system improvement, or research; however, the information may not identify that person;
- to TDH for data collection or complaint investigation;
- to other EMS personnel, other physicians, and other health care personnel under the direction of a physician who are participating in the diagnosis, evaluation or treatment of a patient; and
- to individuals, corporations, or governmental agencies involved in the payment or collection of fees for Emergency Medical Services rendered by EMS personnel.

A person aggrieved by an unauthorized disclosure of EMS records may seek injunctive relief and damages in the district where he resides or in Travis County if the person lives outside of Texas if the incident occurred in Texas.

Duty of an Insurance Company to Maintain the Confidentiality of Records

All insurance companies including health maintenance organizations (HMO) are required to maintain the confidentiality of any data or information pertaining to the diagnosis, treatment or health of any enrollee or applicant obtained by an insurance company or HMO from that person or from any physician or health care provider. These entities may release information if the patient provides written consent, a court order, or if a claim is filed by the patient against the insurer or HMO and if the information is relevant to the claim.

State regulations require utilization review agents to maintain the confidentiality of health care information. An agent may not disclose confidential information without a patient's written consent. However, an agent may release the information to a third party under contract or affiliated with the agent for the purpose of performing or assisting with utilization review. If a patient requests confidential personal health information regarding himself or herself, the agent must permit the individual to see a copy of the record within ten days of the request. Confidential information may be released for reviewing purposes to the Commissioner of Insurance without the patient's consent.

All insurance companies that receive confidential information are obligated to use that information only for appropriate statutorily identified purposes and may only disclose the information to others as permitted by this statute.

Duty of Other Providers to Protect Health Care Information

Health care professionals who are licensed or certified by the state of Texas have a duty under their licensing statute to maintain the confidentiality of patient information.

Community and institutional pharmacies are required to provide adequate security for prescription drug orders and patient medication records to prevent unauthorized access. Confidential health care information is considered privileged and may only be released by the pharmacies to:

- the patient or the patient's agent;
- practitioners and other pharmacists, if in the pharmacist's professional judgement release is necessary to protect the patient's health and well-being;
- other persons, the Board of Pharmacy, or other state or federal agencies authorized by law to receive such information;
- a law enforcement agency engaged in investigating suspected violations of the Controlled Substances Act or the Dangerous Drug Act;
- a person employed by any state agency which licenses a health care provider if the person is engaged in the performance of official duties; and
- an insurance carrier or other third party payer authorized by a patient to receive such information.

Other States

Every other state has medical privacy laws; however, many of their efforts mirror Texas' piecemeal approach. The Health Privacy Project at Georgetown University has compiled a compilation of all the states' approaches to privacy protection. The project report states:

> States have been the first to respond to concerns about health privacy and they have enacted many strong protections.
>
> State health privacy statutes cover a broad range of entities and, not surprisingly, are both weak and strong. In terms of broad consumer protections, one can identify many significant gaps and weaknesses in most state statutes: such as a limited right for a patient to access his or her own medical record; little ability for patients to limit disclosure of their medical records; and little recourse when the laws are violated.
>
> On the other hand, state laws enacted in response to a particular public concern, or a public health threat such as in the areas of mental illness, communicable disease, cancer, and genetic testing are often strong, detailed, and aimed at the states' unique experiences with their citizens. State laws address a level of detail not considered in any of the current federal proposals.[3]

[3] Health Privacy Project, *The State of Health Privacy: An Uneven Terrain/A Comprehensive Survey of State Health Privacy Statutes*, (visited July 1999) <http://www.healthprivacy.org/>.

Federal Issues

Currently, there is no comprehensive federal law that protects the privacy of a person's medical records. The 1996 Health Insurance Portability and Accountability Act (HIPAA) included legislative and regulatory deadlines in order to fill this significant gap in federal rules. HIPAA provided that if Congress failed to pass a comprehensive health privacy law by August 21, 1999, the Secretary of Health and Human Services would be required to issue final health privacy regulations by February 2000.

The U.S. Department of Health and Human Services was required to develop recommendations to protect the privacy and confidentiality of health records. Secretary Donna Shalala presented the following recommendations to Congress in 1997:

- Organizations that are entrusted with health information must protect it against deliberate or inadvertent misuse or disclosure. Security measures should be required to protect the information against improper use by employees or threats from outside entities. Organizations hired by providers and payers to process information and complete other tasks also should be bound by the same protections.
- Those who provide and pay for health care should be required to give patients a clear, written explanation of how they will use, keep and disclose information. Patients should be able to see, obtain and correct copies of their records. A history of disclosures would have to be maintained and be made accessible to patients.
- There should be punishment for the misuse of personal health information and redress for people who are harmed by its misuse.
- The federal health privacy legislation should supercede the less protective state law. If either the federal or state law forbids a disclosure, the disclosure should not be made. Thus, the confidentiality protections should be cumulative, and the federal legislation should provide a "floor preemption" in regard to state law.

- Privacy protections must be balanced with the public responsibility to support national priorities such as public health, research, quality of care and the fight against health care fraud and abuse.

Federal Privacy Proposals

On October 29, 1999, the Administration issued the following as its draft regulations, followed by the required 60-day comment period.

Key Points and Explanation to Federal Privacy Proposal	
Access	People would have the right to see and copy their own medical records. Most states do not currently grant people such a sweeping right of access.
Limits on Disclosure	Health care providers and health plans would be required to obtain the patient's consent for disclosures other than those related to treating an individual and paying for his or her care. Under the proposal, the consent must be voluntary, and cannot be tied to the delivery of any benefits or services. Current practice usually requires people to sign broad waivers of their privacy as a condition of receiving health care or health benefits.
Research	All research would fall under a standard set of rules known as "The Common Rule." At present, only federally funded research is governed by the common rule, which requires a research project to be overseen by an Institutional Review Board (IRB) to determine the need for patient authorization.
Penalties	Health care providers, health plans, and clearinghouses would be subject to civil and criminal penalties (up to $25,000/year and 10 years in jail) for violating the law. Currently, the Secretary is constrained under HIPAA from including a private right of action for individuals to sue for violations of the law.
Law Enforcement	Health care providers and plans would be prohibited from releasing patient data to federal, state, or local law enforcement without some form of legal process, including a warrant, court order or administrative subpoena. The Clinton Administration has reversed itself from its 1997 position that law enforcement should continue to have unfettered access to medical records. However, this proposal continues to fall short. There is no requirement that a judge or other neutral magistrate approve or deny law enforcement access.
Preemption	The federal regulations would not preempt, or override, stronger state law. Instead, they would set a baseline floor of protections, above which the states could go to better protect their citizens. A July 1999 report issued by the Health Privacy Project found that while few states have comprehensive health privacy laws, most states have enacted legislation to protect sensitive information such as mental health, communicable disease, and genetic testing.

The public comment period for submitting comments on the proposed privacy regulation closed February 17, 2000. The final privacy regulations are expected to be published by the end of the

Summer of 2000. Since the public comment period has ended, Congressional committees have held numerous hearings on both medical and financial privacy issues, since they are inter-related. Concurrently, the Texas Senate Health Committee and Senate Economic Development Committee held a joint hearing to comprehensively discuss a myriad of privacy issues. Due to the short time prior to its August recess and the dynamics of an election year, Congress is not expected to pass a comprehensive privacy bill this year. However, there are indications that a bill to establish a 17- member Commission to undertake a 18-month study of privacy issues could be passed. Such a panel would include medical, financial and Internet policy stakeholders. Additionally, the Congressional subcommittee reviewing this proposed legislation has indicated its desire for the Commission to examine employer practices regarding the use of personally identifiable information and examine the issue of allowing individuals recourse when their privacy is violated.

Recommendations

1. The Texas Attorney General's office shall be responsible for identifying and setting forth consistent and appropriate penalties for the unlawful release of information.

   Rationale: *Current penalties for privacy related violations are inconsistent. In addition, enforcement officials should have enough power at their disposal to persuade entities and individuals not to break the law and to respect an individual's medical privacy.*

2. Pharmaceutical manufacturers shall be prohibited from using individually identifiable patient medical data for specific marketing purposes.

   Rationale: *There is a distinct need to separate marketing purposes from legitimate health care purposes to protect individuals' privacy.*

3. Individuals shall have the right to "opt-in" in order to consent to any and all disclosures that are not necessary for treatment or payment of claims.

Rationale: *Prior to release of information, patients should have the right to choose to 'opt-in' to the sharing of their medical data with interested entities other than the attending health care provider(s) and the insurer.*

4. Individuals may access and obtain their protected health information. Individuals must also have the right to amend or correct incomplete or inaccurate medical record entries.

Rationale: *Currently, patients have the right to access their medical records for a nominal fee. This proposal is consistent with federal credit rights.*

5. Corporations and organizations shall provide easily understood notices and disclosures regarding the manner in which they use individual medical data. These notices must include the type of information collected, a description of the use and distribution of that information, options the consumer has to further protect their information, a statement of the organization's commitment to data security, and steps identified or taken by the organization to ensure data quality and access protection.

Rationale: *Consumers have a right to know how a corporation handles their private information and what mechanisms it has established to protect such information from unauthorized release.*

6. Non-identifiable personal medical information should be available for public health and research efforts.

Rationale: *Researchers should have the access to encrypted and anonymized data sets to further scientific and research advancements. Such information should be available to public health officials to enable their surveillance of public health threats and trends.*

7. Medical information privacy protections shall apply regardless of the medium involved.

Rationale: *All legislative protections should be applied consistently to cover all types of personal data communication including but not limited to, the following types: electronic, paper, digital, taped, written or any other method of recording information.*

8. Employers shall only have access to non-individually identifiable, encrypted and aggregated forms of medical information regarding their employees' health care. Employers must be able to access appropriate aggregate data to evaluate health care costs and spending trends.

Rationale: *Individually identifiable medical information should be held within strict confidence between the patient, attending health care provider(s), and paying insurers.*

9. Health consumer marketing material shall be sent to patients only after they have received a specific diagnosis code(s). Entities may not send educational material on specific disease states to a patient unless that patient chooses to 'opt-in' and receive such information.

Rationale: *Currently, disease management companies, Pharmacy Benefit Managers (PBMs), and Managed Care Organizations (MCOs) send education materials to individuals based upon a predetermined prescriptive*

identifier, rather than a specific diagnosis code. This will not only provide protections against unwarranted and unwanted direct and focused marketing, but will provide an opportunity for patient education upon the patient's approval.

10. The State shall adopt a multi-tiered opt-in/opt-out system, carefully defining medical privacy and levels of security. This approach shall include appropriate privacy and confidentiality protections that both protects patients and establishes parameters for legitimate commercial interests that use medical data and information.

Rationale: *The multi-tiered approach provides a balanced approach to the protection of medical information. This approach will allow patients to pro-actively determine the level of confidentiality assigned to their medical information. At the same time, this method will allow for less restricted access to a limited amount of information necessary for certain legitimate business practices.*

11. The Legislature shall establish a blue ribbon privacy council that will conduct a thorough evaluation and ongoing review of key issues related to structuring a statewide comprehensive, flexible, and evolving medical privacy policy. The blue ribbon privacy council shall recruit a broad spectrum of representatives from key industries, consumers, professional organizations, state agencies, and the Legislature to provide input on privacy related matters and ensure that State privacy regulations keep pace with the ever-evolving health care industry.

Rationale: *The establishment of a privacy council will keep lawmakers abreast of the latest trends and issues related to privacy policy so that they may effectively address those issues.*

12. The Office of the Attorney General, in coordination with the appropriate governmental bodies, shall serve as a resource to state agencies and institutes of higher education seeking guidance to comply with state and federal privacy regulations.

Rationale: *The committee heard testimony regarding the potential difficulty in implementing regulations mandated by privacy proposals at the state and federal level. Requiring the Office of the Attorney General to serve as the primary legal resource during implementation of any privacy related proposals will ensure consistent application among state entities.*

INTERIM CHARGE 4

Provider Choice in the Vaccines for Children (VFC) Program

Provider Choice in the Vaccines for Children (VFC) Program
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Provider Choice in the Vaccines for Children (VFC) Program

Interim Charge #4

Study impacts of the degree of choice granted physicians to administer immunizations to children under the Vaccinations For Children (VFC) Program. The Committee shall focus on the health and fiscal implications to the public and private sectors of granting choices to physicians where more than one manufacturer produces the same vaccine at an equivalent price.

Background

The Vaccines for Children (VFC) program was created in 1993 as a part of the Omnibus Budget Reconciliation Act (OBRA) to increase childhood immunization rates.[1] The VFC program is a federally funded entitlement program designed to provide recommended vaccines to infants and children 18 years of age and younger who are either Medicaid-enrolled, uninsured, Native American, or Native Alaskan.[2] In addition, underinsured children may receive VFC vaccines at a Federally Qualified Health Center (FQHC) or a Rural Health Clinic. Since the program's inception on October 1, 1994, Texas' immunization rates have risen from 71 percent to the current rate of nearly 75 percent.[3]

The VFC program provides publicly purchased vaccines to public and private health care providers in 50 states, the Commonwealth of Puerto Rico, the Virgin Islands, American Somoa, Guam, and the Commonwealth of the Northern Marianna Islands.[4] Private health care providers may enroll in the VFC program to administer vaccines to eligible children. This private public partnership reduces vaccine cost as a barrier to immunizations, reduces physician referrals to public clinics, ensures that children will have a medical home, and allows states to build an infrastructure to increase vaccine accessibility.

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[1] Centers for Disease Control and Prevention , *National Immunization Program--Vaccines for Children* (visited June 2000) <http://www.cdc.gov/nip/vfc>.

[2] *Id.*

[3] Texas Department of Health Immunization Division, Vaccines for Children Program.

[4] Centers for Disease Control and Prevention , *National Immunization Program--Vaccines for Children* (visited June 2000) <http://www.cdc.gov/nip/vfc>.

Every state purchases vaccines in bulk volume from pharmaceutical manufacturers in order to reduce cost and ensure adequate distribution levels. There are three distinct avenues for states to obtain bulk vaccinations: states may purchase through a federal account, receive federal grants to make purchases, and/or purchase directly with their own funds from a manufacturer using the CDC contract.[5]

In Texas, the State purchases vaccinations through the CDC's quarterly procurement process in which a vaccine manufacturer is awarded a contract if it presents the lowest qualified bid. The State, in turn, makes those vaccines available to health care providers who then provide vaccines to eligible patients. In 1998, Texas spent $35 million on more than 3.4 million doses of vaccines under the Vaccines for Children Program.[6]

Prior to 1994, the Centers for Disease Control and Prevention (CDC) awarded a single contract to the lowest bidder for each vaccine solicitation. OBRA encouraged the award of vaccine contracts to all bidding vaccine manufacturers to better assure stability and market share for each company and a constant revenue stream to fund vaccine research and development. In 1995, the CDC began awarding vaccine contracts to all competing companies, guaranteeing a market share for all bidders, with low bidders being assured the majority of doses purchased through CDC contracts.[7]

However, the act of sharing the purchases created numerous problems. Since more than one manufacturer supplied product, the CDC created a system to automatically allocate VFC purchases between the various manufacturers. Unfortunately, this method did not allow for choice in vaccine brand selection. Additionally, there was the unforeseen problem of children potentially receiving different vaccine brands before the completion of their vaccination series. Finally, it restricted open competition among manufacturers to only the initial bidding process prior to contract awards.[8]

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[5] Texas Department of Health Immunization Division, Vaccines for Children Program.

[6] *Id.*

[7] Letter from Department of Health and Human Services, *Centers for Disease Control and Prevention,* to the Senate Health Committee (Dec. 16, 1998) (on file with the *Senate Health Committee*).

[8] *Id.*

In an effort to address these problems, the CDC embarked on a pilot contract with all licensed manufacturers for the purchase of DTaP and Hepatitis B (Adolescent) vaccines. The DTaP pilot began in April 1997, and the Hepatitis B (Adolescent) contract began in July 1997.[9] This program allowed product choice by the State and/or individual providers. It also guaranteed access to the public sector market for all manufacturers with vaccines utilized in the pilot contracts. This new contracting method was chosen after extensive evaluation which incorporated consultation with vaccine manufacturers, organizations representing the private medical community, public health officials, and the immunization projects. This approach, supported by the majority of the stakeholders, promotes open competition between manufacturers beyond the initial contract award process, assures brand choice, and guarantees all manufacturers access to compete in the public sector market.[10]

Provider Participation

Approximately 340,000 children are born annually in Texas.[11] The Texas Department of Health (TDH) is responsible for providing vaccinations to approximately 70 percent of the newborn cohort. In order to accomplish that goal, TDH has enrolled more than 7,000 public and private health care providers in the VFC program.[12] Each state is responsible for recruiting providers and assuring that they adhere to participation requirements. According to the CDC, providers agreeing to participate in the VFC program must agree to comply with the following:

- Screen the parents of a child to determine eligibility;
- Maintain records on all children immunized;
- Comply with the recommended immunization schedule;
- Provide services free of charge (providers are eligible to recoup an administration fee); and

[9] Letter from Department of Health and Human Services, *Centers for Disease Control and Prevention,* to the Senate Health Committee (Dec. 16, 1998) (on file with the *Senate Health Committee*).

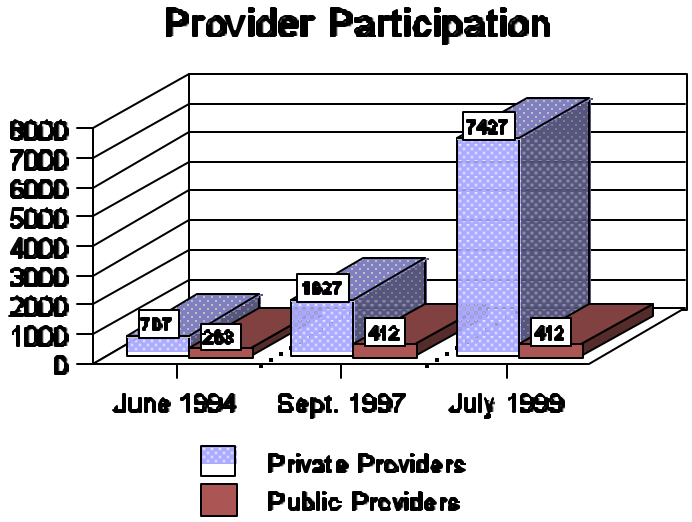
[10] *Id.*

[11] Letter from Sharilyn K. Stanley, MD, *Texas Department of Health*, to the Senate Health Committee (May 5, 2000) (on file with the *Senate Health Committee*).

[12] *Id.*

C Provide educational materials and information relating to immunizations.[13]

Although the CDC has recently recommended that Texas increase its efforts to promote increased provider participation, Texas has been successful in doing so over the past five years. In 1994, there were 707 private providers and 263 public providers participating in the Texas VFC.[14] In 1999, the number of private providers rose to 7,427 and the number of public providers increased to 412.[15] Public providers include community health centers, federally qualified health clinics (FQHCs), local health department clinics, public hospitals, and participating Women, Infant and Children (WIC) program sites. The following chart depicts private and public participation in the VFC program.



Source: Texas Department of Health

Texas is one of many states that requires all Medicaid providers to enroll in the VFC program. Although this requirement is in force, the CDC, in a letter to TDH, recommended that the "Medicaid program should be involved to ensure complete enrollment into the VFC program of all eligible providers," and "Medicaid providers who are not enrolled in the VFC program should be contacted

[13] Centers for Disease Control and Prevention , *National Immunization Program--Vaccines for Children* (visited June 2000) <http://www.cdc.gov/nip/vfc>.

[14] Texas Department of Health Immunization Division, Vaccines for Children Program.

[15] *Id.*

directly to promote their enrollment."[16]

Vaccine Funding

Children who are eligible to participate in the VFC program receive vaccines at no cost. This program can save parents and enrolled providers approximately $335 per child in out-of-pocket expenses.[17] It is important to note, however, that the average cost of a vaccination has risen dramatically over the last five years. In Texas alone, the average cost in 1994 was $6.79 per dose, compared to $13.23 in 1999.[18] The VFC program achieves savings by utilizing negotiated federal vaccine contracts at lower prices, which, in turn, standardizes vaccine costs for all states. Funding for the VFC program is transferred annually from the Health Care Financing Administration (HCFA) to the CDC. The CDC then awards funds to 61 immunization projects.

Vaccine funding, awarded three times annually, is projected to total $115,543,147 for Texas in fiscal year 2000.[19] Funding is generated from three sources:

- The VFC entitlement, which pays for vaccines and for some infrastructure;
- Monies from the Centers for Disease Control (CDC), which pay for specific vaccines for eligible children not covered through the VFC program and provide partial funding for vaccine delivery and quality assurance programs; and
- State general revenue, which is used to supplement federal funding.[20]

VFC funds are used to purchase vaccines for routine childhood vaccinations such as diphtheria, pertussis, tetanus, rubella, measles, mumps, Haemophilus influenza type B, hepatitis B, and

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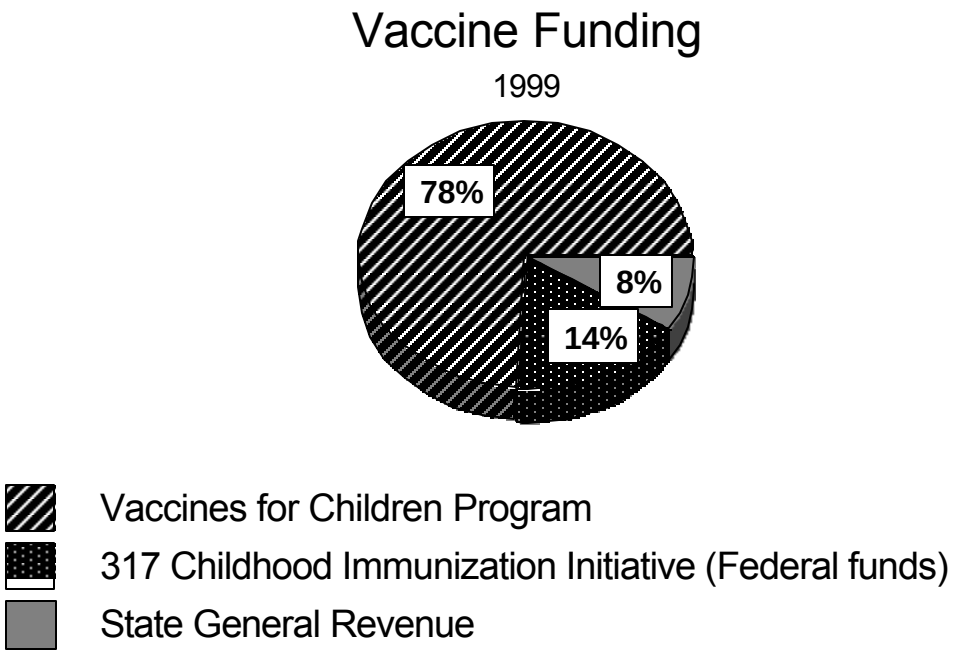
[16] Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, *Vaccines for Children Program Technical Support Visit Report*, 5 (June 27-28, 1996).

[17] Centers for Disease Control and Prevention , *National Immunization Program--Vaccines for Children* (visited June 2000) <http://www.cdc.gov/nip/vfc>.

[18] Texas Department of Health Immunization Division, Vaccines for Children Program.

[19] *Id.*

[20] Letter from Sharilyn K. Stanley, MD, *Texas Department of Health*, to the Senate Health Committee (May 5, 2000) (on file with the *Senate Health Committee*).



chickenpox.[21] The following chart illustrates vaccine funding by amount and source.[22]

Vaccines for Children Program	**317 Funds Childhood Immunization Initiative**	**State General Revenue**
Vaccines: Eligibility criteria: 0-18 years old CMedicaid CUnderinsured CNative American and Native Alaskans CNo Health Insurance Infrastructure: CDistribution of Vaccines CRecruitment and enrollment of VFC providers CVaccine ordering and accountability	Vaccines: CPortion of 0-18 not eligible for VFC Infrastructure: CVaccine-preventable disease surveillance, epidemiology, and outbreak control CService delivery products COutreach CTraining/education CQuality assurance CEvaluation CPolicy development CVaccine ordering, distribution, and accountability	Vaccines: CAdults CPortion of 0-18 not eligible for VFC CRabies CMeingococcal CImmune Globuline Infrastructure: CVaccine-preventable disease surveillance, epidemiology, and outbreak control CService delivery products COutreach CTraining/education CQuality assurance CEvaluation CPolicy development CVaccine ordering, distribution, and accountability

[21] Texas Department of Health Immunization Division, Vaccines for Children Program.

[22] *Id.*

Source: Texas Department of Health

Vaccine Choice

The issue of vaccine choice involves two primary components. The first of which is the selection from different formulations of essentially the same product. The second involves the decision to allow for products that are combination products to decrease the number of needlesticks an infant must endure in the vaccination process.

In April 1999, the CDC dealt with the first component by implementing a new contracting process to purchase vaccines that will open competition and better ensure the ability of states and individual providers to choose from all brands of a licensed vaccine recommended by the Federal Advisory Committee on Immunization Practices (ACIP). As evidenced by the letter in Appendix G, the CDC strongly recommends that the standard for vaccine distribution in states be based on individual provider choice unless there is a compelling reason for alternative choices.[23]

In response to the CDC's directive that states offer choice in vaccines, TDH conducted a pilot project in Public Health Region 8 from April 1999 through April 2000.[24] This pilot project is based in Seguin, which is located in Guadalupe County. The pilot allowed 150 providers in Region 8 to choose between four different formulations of DTaP vaccine. Each of the vaccines is equivalently priced and considered equally effective in protecting children.[25] Using the current complex pharmacy distribution system, the TDH pharmacy spent an additional $30,000 to ship these various vaccines to the 150 providers.[26] This increased cost is due to larger inventories necessary to allow for responsiveness to choice, inability to predict physician choices, and an increased staff to effectively handle the direct

[23] Letter from The Department of Health and Human Services, *Centers for Disease Control and Prevention* (December 16, 1998) (on file with the *Senate Health Committee*).

[24] *Vaccines for Children, 2000: Hearings on Vaccines for Children Program Before the Senate Health Committee*, 76th Legislature Interim (Apr. 11, 2000) (statement of Sharilyn K. Stanley, MD).

[25] Letter from Sharilyn K. Stanley, MD, *Texas Department of Health*, to the Senate Health Committee (May 5, 2000) (on file with the *Senate Health Committee*).

[26] *Id.*

shipping load.[27] TDH contends that the complexity of shipping vaccines to the more than 7,000 VFC providers across the state would be increased considerably if each provider is allowed to choose between similar products over a wide range of vaccines. In addition, TDH asserts that choice will not provide a public health benefit since the vaccines in the program are considered equally efficacious.[28]

In order to determine the economic impact of allowing for choice of vaccines, the Senate Health Services Committee requested that the Legislative Budget Board (LBB) prepare a cost analysis. The LBB determined that allowing for physicians to choose between equivalently priced vaccines is unlikely to have a significant fiscal impact on the state. The LBB identified two issues in implementing physician choice of equivalently priced vaccines: 1) potential increase in vaccine cost, and 2) an increase or decrease in the distribution cost.

The LBB asserts that vaccine cost may increase because physicians may select the higher priced vaccines from the CDC's National Vaccine List and because the initial vaccine inventory supply will need to be greater in order to respond to physician preferences. The LBB notes that the CDC has indicated that the VFC grants would continue to fund the purchase of vaccines under physician choice even if physicians were to select higher priced vaccines from the National Vaccine List.

The LBB also anticipates an increase in distribution costs since Texas may need additional storage space to maintain adequate inventories of all vaccines included on the national list. In addition, the processing time may increase due to the corresponding increase in the number of tracked vaccines. At the same time, the LBB asserts that redesigning the current distribution system will offset any increased program costs. TDH estimates that implementing provider choice could result in additional expenditures of $3.5 million (in all funds).[29] The TDH estimate is based upon the assumption that 8 percent of all immunization expenditures will be paid with State General Revenue.[30] Therefore,

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[27] *Id.*

[28] Texas Department of Health Immunization Division, Vaccines for Children Program.

[29] TEXAS LEG. BUDGET BD., COST ANALYSIS: PHYSICIAN CHOICE UNDER THE VACCINES FOR CHILDREN PROGRAM (Apr. 19,2000).

[30] *Id.*

$284,000 per year in General Revenue may be needed if physician choice in vaccine selection is implemented.[31] The LBB asserts that TDH can assume this additional cost within its current budget.[32] Additionally, the LBB indicates that the CDC allows states to request additional VFC monies to cover the cost of additional vaccine purchases if states' initial estimates of need is too low.[33]

The LBB reports that TDH currently holds inventory for longer than two months and may need to alter its current practices. The CDC suggests that maintaining a two-month supply in vaccine inventories will be sufficient to minimize or eliminate any increased costs associated with implementing physician choice. In response, TDH has successfully strengthened efforts to ensure that inventory does not exceed a two-month supply. In addition, Texas operates a multi-level distribution system. Under this system, TDH ships vaccines from its central depot or warehouse in Austin to regional depots, which then ship vaccines to local depots (city and county health departments). Private providers visit the local depots to collect their vaccine shipments. TDH is currently implementing changes that will eventually eliminate the regional depot level, allowing for direct shipment from the central depot to the 58 local health departments and seven regional sites. (see Appendix H)

The second component of vaccine choice, the use of combination vaccines, involves the bundling of several individually required vaccines into one vaccination. Combination vaccines offer several benefits to the child. Primarily, the child receives fewer injections, which means that medical visits are reduced and compliance with the recommended immunization schedule (located in Appendix I) is likely increased. Critics of including combination vaccines as a provider option in the Texas VFC program cite the fact that such formulations will require increased expenditure by TDH's immunization division.[34] While this is true, it is important to note that combination vaccines do offer a cost savings potential. When making economic forecasts, it is necessary to review the costs and potential savings from a statewide perspective, rather than focusing specifically on the immunization division budget. Currently,

[31] *Id.*

[32] *Id.*

[33] *Id.*

[34] Texas Department of Health Immunization Division, Vaccines for Children Program.

Medicaid pays immunization providers a $5 administration fee per injection. Since combination vaccines reduce the number of injections, administration fee cost would be reduced. Although the administration fee savings are not returned to TDH, Texas would save the state's match portion ($2.00) for each injection not administered.[35]

State Distribution Methods

Under contract with the CDC, the Logistics Management Institute (LMI) issued a report entitled *State Vaccine Distribution Systems: A Study of Their Cost and Risk*. The CDC requested that LMI identify:

- methods that each state uses and the costs that it incurs in distributing vaccines to its providers;
- methods to identify states needing assistance with program functions; and
- practical benchmarks to establish future reimbursements to states for their distribution of vaccines.[36]

The report consisted of state survey responses and LMI recommendations for improvements in vaccine distribution and total cost reduction. The report outlines the various distribution methods and systems used to deliver vaccines to providers in the 48 states, not including Texas, that participated in the study. Those methods generally involve the shipment of large vaccine orders from a manufacturer to a state-run or contractor-run distribution depot. That facility holds the vaccine and then ships it to providers in smaller quantities, as necessary. The LMI found that state distribution methods range from state-run operations to those operated entirely by a contractor or a combination of both. State-run operations ranged from single depots that ship vaccines directly to providers to multi-level systems that store, ship, and handle vaccines several times before shipping them to the provider. According to the LMI report, 35 states, including Texas, operate their own facility, six use a contractor, and twelve use a combination of state-run and contractor-run facilities.[37] Of the 35 states that operate a state-run

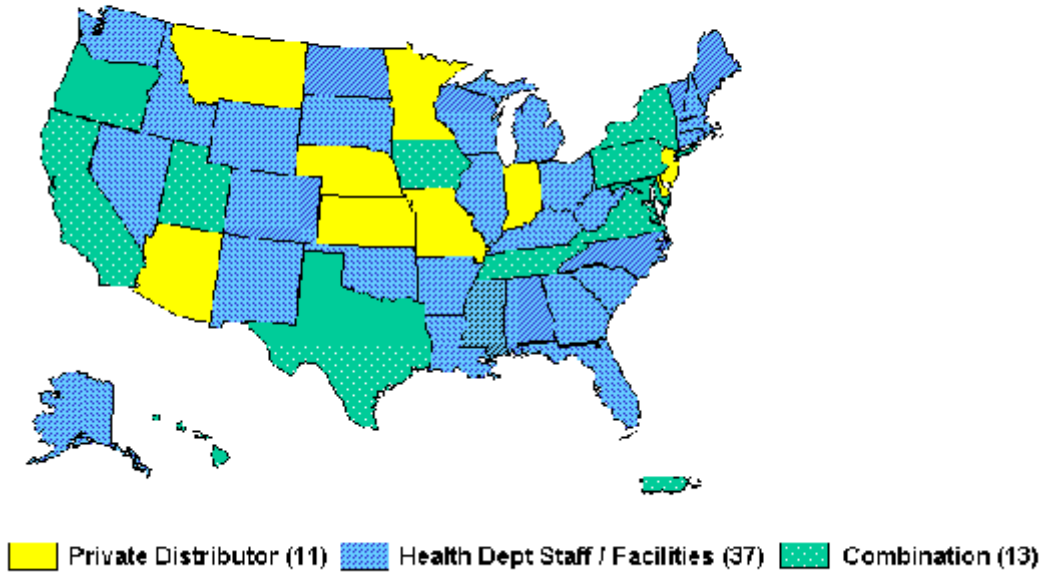
[35] Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, *Vaccines for Children Program Technical Support Visit Report*, at 5, (June 27-28, 1996).

[36] RICHARD NOLAN ET AL., STATE VACCINE DISTRIBUTION SYSTEMS: A STUDY OF THEIR COSTS AND RISKS, (1999).

[37] *Id.*

facility, seven, including Texas, indicated that they transship vaccines multiple times before finally delivering them to providers.[38] Since several states are currently revamping their distribution and storage systems, statistics revealing the different states' distribution and storage systems are ever-changing. The following map is the most recent depiction of states' distribution methods.

State Distribution Methods



Source: Centers for Disease Control and Prevention, http:www.cdc.gov/nip/vfc

The LMI study found that the average cost incurred by states to distribute each dose of vaccine was $0.64, including $0.40 in expenses related to holding the inventory and $0.22 in other delivery related expenses.[39] Currently, TDH does not maintain data regarding Texas' distribution costs or the average value of vaccines maintained as inventory.[40] However, the agency is compiling this information to

[38] *Id.*

[39] RICHARD NOLAN ET AL., STATE VACCINE DISTRIBUTION SYSTEMS: A STUDY OF THEIR COSTS AND RISKS, (1999).

[40] Texas Department of Health Immunization Division, Vaccines for Children Program.

enable more informed decisions when grappling with the responsibility of operating the storage and distribution system in the most efficient and effective manner.

The LMI study also shows that contracted operations are not always more efficient than in-house state operations, but that costs were far less variable. The study clearly shows that states, such as Texas, with multi-level distribution systems have much higher distribution costs and higher risks of spoilage from cold chain failures due to increased handling.[41] Although costs are a significant factor, integrity of the vaccine is critical to ensure that safety is not compromised and a child receives a viable vaccine.

Based on these findings and consistent with CDC's continuing effort to improve VFC program management, the LMI report recommends that the CDC do the following:

- Use another method for state justification of annual request for VFC and "317" grant funds that would allow state-to-state comparison of distribution efficiency and provide support in determining grant awards;
- Use a national benchmark, median cost per birth cohort, to standardize reimbursement of states' vaccine distribution expenses;
- Work with states that deviate significantly from the national benchmark to improve the accuracy of their data and reduce their distribution cost, including limiting state vaccine inventories to two month's usage or less and requiring single-level distribution systems that operate from one state depot or contracted facility;
- Approach contracts with vaccine manufacturers in a way that results in minimizing total cost and vaccine distribution costs, instead of minimizing vaccine cost only; and
- Modify software.[42]

Through the course of this study, the Committee has remained focused on the goal of improving childhood immunization rates. In order to achieve this goal, it is necessary to ensure that the Texas

[41] RICHARD NOLAN ET AL., STATE VACCINE DISTRIBUTION SYSTEMS: A STUDY OF THEIR COSTS AND RISKS, (1999).

[42] *Id.*

Vaccines for Children Program is operating in the most effective and efficient manner. Although interim charge #4 requesting this report only speaks to the issue of vaccine choice, the committee feels that there are several related issues that must be reviewed in order to fully address the choice issue from a statewide perspective. In order to achieve a system that enables providers to choose equivalently priced vaccines, TDH must reconstruct and refine the current vaccine storage and distribution systems to accommodate such a drastic systems change.

Based on the finding of this report, the committee makes the following recommendations.

Recommendations

1. By January 1, 2002, the Texas Department of Health shall allow all providers participating in the Vaccines for Children program choice among all vaccines that are recommended and approved by the Federal Advisory Committee on Immunization Practices and under contract with the CDC. Choice should be offered for different formulations of essentially the same product as well as combinations of individual products.

   Rationale: *The Texas Department of Health is currently weighing the benefits and costs of moving toward a choice system. It is necessary to expand choice incrementally so that the state can phase-in choice while concurrently moving to a private contractor for its distribution and storage systems.*

2. Develop and release a Request for Information (RFI) to private entities to assess their ability to assume the vaccine storage and distribution function currently operated by TDH.

   Rationale: *It is possible that Texas' multi-tiered storage and distribution system is less efficient than some privately operated systems. A detailed RFI would be an effective tool to survey the private market to determine whether or not a private entity would have the capacity to effectively accommodate the storage and delivery of the millions of vaccinations that are delivered to Texas children. The RFI could serve as the basis for a subsequent Request for Proposal (RFP) in the event that a private entity displays their*

ability to deliver and store vaccines in a more effective and efficient manner.

3. Enhance collaboration with private health care providers, especially managed care organizations, to promote and increase participation in the VFC program. TDH must contact Medicaid providers who are not enrolled in the VFC program to promote their enrollment and participation.

Rationale: *Although Texas has successfully recruited VFC providers, the CDC has repeatedly requested that TDH increase provider enrollment to increase Texas' immunization rates.*

INTERIM CHARGE 5

Health Care Workforce

Health Care Workforce
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Health Care Workforce

Interim Charge #5

Assess the preparedness of the Texas health care workforce to meet the health care needs of Texans beyond the year 2000, including methods to retain Texas-trained medical personnel. The Committee shall evaluate the availability of health care providers in rural and urban areas. The Committee shall also review the oversight of medical procedures performed by medical residents and disclosure provided to patients prior to treatment.

Introduction

Texas' population exceeded 20 million in 1999.[1] As the second most populated state and boasting the second largest geographic area, Texas is growing at a pace almost double the growth rate of the United States as a whole.[2] Poverty, economics, employment, and ethnic mix differ in each region of the State and affect access, cost, and quality of health care in numerous ways.

Current projections reveal that Texas' population will increase by nearly 29 percent over the next 15 years and is anticipated to increase 99 percent from the time of the 1990 census to the year 2030.[3] In contrast, the population of the United States is projected to increase by only 41 percent between 1990 and 2030.[4] This astounding growth rate is not novel: Texas' population growth had, in fact, almost doubled the growth rate of the rest of the country for many years. High birth rates, immigration from other states and countries, longer life expectancy, and medical advances are all responsible for these significant increases. Texas' population growth during the 1990s resulted primarily from a natural increase (based on historical birth rates) through the birth of 1,183,025 persons representing

[1] U.S. Census Bureau, U.S. Census 2000, (visited July 1, 1999) <http://www.census.gov/population/www/methodep.html>. Population (Estimate) - The estimated population is the computed number of persons living in the area (resident population) as of July 1, 1999. The estimated population is calculated from a demographic components of change model that incorporates information on natural change (births and deaths) and net migration (net domestic migration and net movement from abroad) that has occurred in the area since the reference date of the 1990 census.

[2] LEGISLATIVE BUDGET BD., TEXAS FACT BOOK 2000, 15 (2000).

[3] Texas State Data Center, Dept. of Rural Sociology, Texas A&M University, *Texas Population Projections for the Years 1990 to 2030*, (Aug. 1999).

[4] *Id.*

55.2 percent of all growth occurring between 1990 and 1996. International immigration accounted for 491,931 new residents (23 percent of the growth between 1990 and 1996), and domestic immigration from other U.S. states accounted for 466,970 new Texans (21.8 percent of 1990 to 1996 population growth).[5] These numbers reflect that a larger proportion of growth in the 1990s is attributable to migration than during the 1980s, when a natural increase accounted for roughly two-thirds of all growth. From 1990 to 1996, the number of persons age 65 and older, living in rural and frontier areas, increased by 7.3 percent. Frontier areas differ from rural areas in that they are characterized by more extreme remoteness and isolation. The growth in rural and frontier elderly, ages eighty-five and older, was even more dramatic, increasing more than 20 percent during the same period. Texans must make preparations to ensure that an adequate health infrastructure will be capable of accommodating Texas' burgeoning population.

Texas has a unique and diverse population, with a high concentration of agricultural communities and 1,248 miles of shared border with Mexico.[6] This population, burdened by high incidence of poverty, inadequate transportation, large geographic distances between population centers, and an aging population, does not have the same level of access to basic health care services that is available to Texans in other parts of the State. In addition, rural and frontier residents of all ages are more likely to be uninsured: studies indicate a 19.8 percent uninsured rate compared with 16.3 percent for those in urban areas of the State. This is attributable, in part, to the fact that health insurance coverage is often not provided by rural and frontier workers' employers. In addition, farming families are less likely than other working families to have employers who contribute to health insurance premiums.

The changing demographics of rural and frontier Texas exert pressure on the limited range of existing health care services. Of Texas' 254 counties, 196 are considered rural and nearly all either are medically underserved or have an insufficient number of health care professionals. (see Appendices J and K) Approximately 2.9 million, or 15 percent of the State's population, live in rural counties. Texas has the largest number of frontier counties in the nation with 61 of the counties having a population density of seven persons or less per square mile.
Texas' rural and frontier areas suffer from a shortage of available health care providers. In this respect, Texas falls far below the national average. Exacerbating the problem, 62 rural counties do not even have a hospital. Twenty-

[5] Texas State Data Center,(last modified Dec. 09,1999)<http://txsdc.tamu.edu/rbsp971.html>.

[6] LEGISLATIVE BUDGET BD., TEXAS FACT BOOK 2000, 23 (2000).

six of Texas' 196 rural counties had no primary care physician in early 1998. An additional 13 counties had only one health care practitioner.[7] As a result of this "access to care" dilemma, 172 (88 percent) rural counties are designated as medically underserved areas (MUAs).[8] The shortage of health care providers is not unique to rural areas; there are also underserved pockets within urban centers. This reality is intensified by an increasing number of providers declining to serve the Medicaid population. These characteristics, coupled with a fragile or nonexistent health care infrastructure in many parts of the State, complicate the delivery of health care services in rural Texas and create a formidable challenge for policymakers.

Workforce

As recently as a decade ago, Texas suffered from a severe shortage of health care providers. In response, Texas took successful steps to increase the number of trained professionals, yet gaps remain in certain areas. Current data reveal that there are an adequate number of primary care providers statewide. However, there exists a maldistribution of these professionals, with a concentration of the professionals residing in and around urban centers. The availability of health care providers can be accurately viewed only in relation to the distribution of the population. When creating solutions, it must be noted that access to care is not necessarily achieved by assigning a specific ratio of health care providers to the population if other barriers exist that prohibit an individual's access. Although rural counties are doing a better job of recruiting primary care professionals, they have a difficult time retaining them. Young people from rural and frontier communities continue to relocate to the urban centers, which makes filling professional and voluntary health care positions from within the community more difficult.

Recruitment and Retainment of the Health Care Workforce

There is a shortage of certain health care professionals in both rural areas and specific sections of urban areas. In urban areas, especially near health care training facilities, a concerted recruiting effort is not necessary, since these areas are generally preferred by most professionals. The urban areas in need are primarily the densely populated inner-city areas not located near training facilities. Such inner-city, rural, and frontier areas face a common barrier to recruiting and retaining health care professionals because the financial base for the workforce is harder to maintain.

[7] CENTER FOR RURAL HEALTH INITIATIVES, RURAL HEALTH IN TEXAS, 1999.

[8] *Id.*

In rural areas, a professional and his or her family must consider factors such as the potential isolation from their former community. Successful underserved area recruitment programs have focused on identifying persons who have spent time in such areas and encouraging their return through residency placement programs. Research has shown that the best indicator of an inclination toward practice in such a community is a professional's previous life experience in a rural community as a child or youth, or the existence of a spouse or partner who has previous life experience in a rural community. The State has established several programs (as seen in the following chart) which focus on recruitment and retention in underserved areas, but additional efforts are needed.

The general lack of available providers in all health care categories, relative to the population, has numerous negative implications for rural Texas. Decreased access to care results in less preventive treatment for those in rural Texas, which in turn decreases the likelihood of early detection of health problems. This delayed intervention ultimately increases health care costs. In addition, ancillary services, such as emergency medical services (EMS), must be utilized at a higher rate, further burdening a system already plagued by an insufficient number of providers and resources.

Current Recruitment and Retention Programs

Provided By	Programs/ Services	Specifics of Services Provided	Impacted/ Awarded	Rural	HPSA	Under-served
Center for Rural Health Initiatives	Texas PRAIRIE DOC Program	Comprehensive recruitment and retention program with emphasis on community-based efforts, including Job Opportunity Registry, Locum Tenens Job Opportunity Registry, HealthFind, Primary Care Resident Practice Evaluation Training, Primary Care Provider Practice Site Evaluation Checklist, and other services.	New program	X		
Center for Rural Health Initiatives	Outstanding Rural Scholar Recognition Program	Loan forgiveness, 50 percent of loan from community and 50 percent State match; assists communities to "grow their own." Student provides year of health care in their sponsoring community for each year a loan is received.		X		
Center for Rural Health Initiatives	Medically Underserved Community - State Matching Incentive Program	Matching grant of up to $25,000 to a community to assist in establishing a new primary care practice site in the community.	FY 1999 7 awards	X		
Center for Rural Health Initiatives	Texas Health Services Corp.	Stipend to residents enrolled in an accredited family practice, general internal medicine, general pediatrics, or general obstetrics/gynecology residency program who contracts to provide services in a medically undeserved area for at least one year for each year that stipend was received.	FY 98 2 awards	X	X	X
Center for Rural Health Initiatives	Locum Tenens: Clearinghouse	Parallel list of practices/communities looking for locum tenens coverage and of physicians willing to work in locum tenens agreements.	List averages, 2 comm. and 4 providers.	X		
Center for Rural Health Initiatives	Visiting Physician (locum tenens) study	Legislatively mandated study to determine feasibility of a rural locum tenens program; study to include medical schools (AHSC), professional physician associations, and rural physicians.	New program	X		

Center for Rural Health Initiatives	HealthFind	Annual forum for interested communities to market themselves to residents and physicians; also includes physician assistants and nurse practitioners.	1997 & 1998; 62 comm. 119 physicians., 64 mid-level practitioners.	X		
Center for Rural Health Initiatives	Community Scholarship Program	Provides scholarships in rural Health Professional Shortage Areas to fund the health professional education of 3rd and 4th year medical students, physician assistants, and nurse practitioners that commit to practice in the sponsoring community.		X	X	
Center for Rural Health Initiatives	Physician Assistant Loan Reimbursement Program	Loan reimbursement up to $5,000 for Physician Assistants who work in rural area for at least 12 months; maximum of 18 awards per year.	FY 98 - 17 awards	X	X	X
Department of Health and Human Services (federal)	Nursing Education Loan Repayment Program	Eligible registered or advanced practice nurses (nurse practitioners, nurse midwives, nurse anesthetists). Payment of 60 percent of principal and interest of qualifying nursing loans for a 2-year commitment of full time clinical services in a public hospital, community health center, rural health clinic, or public or nonprofit health facility determined to have a critical shortage of nurses.				
National Library of Medicine, Houston	National Network/Library of Medicine Outreach & Training Services	Outreach for training, Grateful Med software and demonstration, document delivery through Lonesome Doc, Internet connectivity training				
Texas Department of Health	Clearinghouse for Health Professions	Clearinghouse for physicians, physician assistants, and nurse practitioners seeking collaborative practice opportunities; information kept active for four months.	7 health professionals currently on list (August 1999)			

Texas Department of Health Community Health Provider Resources provides info; waivers administered through the United States Department of Agriculture.	J-1 Visa Waiver Program	Foreign physicians may remain in the United States after completion of their training under a J-1 visa. The waiver permits the non-immigrant to remain and convert the temporary visa into an occupational visa. Sites must be in a rural, whole county HPSA or MUA; providers must practice primary care at the site for a three-year period.	1998: 39 J-1 Visa Waivers	X	X	X
Texas Department of Health through a cooperative agreement with Health Services Resources Administration (federal)	National Health Services Corp	Scholarship and Loan forgiveness for primary care providers (physicians, physician assistants, nurse practitioners, certified nurse midwives, dentists, dental hygienists, and mental health professionals). Sites must be located in a Health Professional Shortage Area. Providers are obligated for a two-year period, renewable by one year increments after the first two-year period. Up to $25,000 per year for up to five years, plus 39 percent of the award amount for tax liability.	1998: 62 awards		X	
Texas Higher Education Coordinating Board	Professional Nurses' Student Loan Repayment Program	Eligible licensed nurse who has practiced in Texas for at least one year in a position which requires the services of a licensed professional nurse; priorities based on criteria including geographical area of nursing practice, practicing in an area with an acute nursing shortage, and others, maximum of $2,000 annual repayment.	16 awards per year, equaling $32,000			

Texas Higher Education Coordinating Board	Physician Education Loan Repayment Program for Residents & Faculty of Texas Family Practice Residency Training Program	Loan repayment for undergraduate, graduate, or medical education: cannot be a loan from a relative's or physician's insurance company or pension plan; must have unrestricted license to practice in Texas, be second or third year Family Practice resident in an approved Residency Training Program or be a full time faculty member in a Texas Family Practice Residency Program, or be a full time faculty member who completed a Texas Family Practice Training Program on or after 7/1/95; must show strong commitment to practice medicine in a Texas HPSA or rural community.	38 awards for 1999	X	X	
Texas Higher Education Coordinating Board	Physician Loan Education Repayment Program	Loan repayment for undergraduate, graduate, or medical education, must be licensed to practice in Texas, and have had no disciplinary action, have completed one year of medical practice in an economically depressed or rural medically undeserved area; maximum total repayment is $18,000 (half state, half federal), maximum of five years (see below for more details).	FY 1999 113 awards	X	X	
Texas Higher Education Coordinating Board	Statewide Medical Student Preceptorship Program	$500 stipend to a medical student who completes a 4-week preceptorship in primary care (Family Medicine, General Pediatrics, General Internal Medicine).	Approx. 600 students/year			
Texas Higher Education Coordinating Board, Medical School Primary Care Depts.	Primary Care Residency Programs	Reimbursement to departments for one-month rotation time a resident spends in an approved off-campus site; Family Medicine site must be in a rural area, with population less than 30,000.	FY 1999: 205	X		
Texas State Board of Medical Examiners	Rural Physician Registry	Working collaboratively with the Center for Rural Health Initiatives' Texas Prairie DOC program through respective medical specialty societies.	New program	X		

Texas State Board of Medical Examiners	Texas Physician Placement Service	Community profile (of community seeking a physician) matched with a physician (seeking practice opportunity) profiles; profiles then sent to opposite parties to facilitate contract.				
AHEC, Tech-Prep	Pre-Medical Rural Training	Exposure to various aspects of the medical fields through classes, camps, and on-site visits for high school students.	Difficult to quantify, each AHEC unique.			
Office of Primary Care Education, UTMB	Generalist Physician Initiative (Robert Wood Johnson Foundation)	Administers program promoting substantial increase in number of resident and medical student graduates who can choose primary care careers; emphasis on placing at least 15 percent of these individuals in rural and undeserved communities; required of all UTMB medical students. CCE - all 1st and 2nd year medical students spend ½ day per month in community primary care practice. Multidisciplinary Ambulatory Clerkship requires 12-week community-based rotation in primary care during third year of medical school.				
Primary Care Departments	Resident Rural Rotations	Off-campus, community-based clinic experience; stipend provided by the Texas Higher Education Coordinating Board.	FY 1999: 205	X		
Telecommu-nications Infrastruc-ture Fund (TIF)	Telecommunicat-ions/ Telemedicine	Electronic link to medical school campus physicians; features e-mail connections to departments, and access to medical library CD ROMS.	Approx. 4,301 sites served in one year.			
Texas Prairie DOC Program	Physician Availability Subscription Service	Subscribers receive monthly lists of physicians/residents seeking medical practice opportunities in Texas (fee based).	71 subscribers currently (Aug. 1999)	X		
Texas Prairie DOC Program, Texas Medical Association Seminars, Professional Association continuing education materials	Practice Management Assessment & Assistance	Technical assistance for practice operations, personnel management, finances, legal, contracting, managed care, billing/coding, etc.	Partially available since Feb. 1999	X		

Center for Rural Health Initiatives; Texas Prairie DOC Program	Effective Matching of Physician & Community	Training for community/practice leaders on realistic evaluation of potential of recruitable physicians and how to match physician, spouse, family with community and its cultural, financial, educational, professional, social, religious and other components of daily life.	Available since Feb. 1999; 2 communities to date.	X		
Center for Rural Health Initiatives; Texas Prairie DOC Program	Community Recruiter Program	Empowering and training a local resident to be responsible to coordinate community recruiting and retention efforts to recruit and retain a physician, and to target community resources for the financial survival of the health care practice.	New program for CRHI.	X		
Center for Rural Health Initiatives; Texas Prairie DOC Program	Provider Spouse & Family Recruitment and Retention	Training of community personnel on techniques for working with the spouse/partner and family of the physician for recruitment and then ongoing involvement for retention.	Available through CRHI since Feb. 1999	X		
Center for Rural Health Initiatives; Texas Prairie DOC Program	Recruitment & Retention Training	Intensive, on-site training in effective recruitment and retention techniques for communities; also regional training workshops for community personnel; ongoing support through other services. Example: Specific assistance and material for effectively organizing and maintaining a Recruitment Committee.	Available since Feb. 1999; 2 communities.	X		
Center for Rural Health Initiatives; Texas Prairie DOC Program	Community "Encourager" Health Promotion Program (promoting use of local health services)	Utilization of a community resident to develop strategies and coordinate the development of local health promotion and utilization for increased community self-reliance on, and retention of, its health care services.	X		New program.	
Center for Rural Health Initiatives; Texas Prairie DOC, AHEC	Rural Site Visit Program	Community-sponsored opportunities for physician/spouse/family to assess the community and practice as well as for community to assess physician, for purposes of an effective match.	Available since Feb. 1999, currently still evolving.	X		

Center for Rural Health Initiatives; Texas Prairie DOC Program and R.W. Johnson Foundation	Community Health Services Development	Organizes local health care professionals and community individuals to determine their own realistic health care needs and develops strategies for supporting a health care delivery system in response to those needs. Example: needs assessment checklist and formula under development.	New program.	X		

Source: Center for Rural Health Initiatives, July 2000

Workforce Supply Numbers, Need Projections, and Profiles

The Center for Rural Health Initiatives (CHRI) has compiled information on the supply of various types of health care professionals in rural Texas. The Center's study, a crucial component of this report, also examines policy considerations that could potentially increase and preserve access to health care for rural Texas. When conducting its study, CHRI used standards established by the Federal Office of Management and Budget (OMB) to delineate between urban and rural areas. According to these standards, urban counties are the 58 Texas counties classified as metropolitan by the OMB, and rural counties are the 196 other counties classified as non-metropolitan. (see Appendix L) The Area Health Education Center (AHEC), the CRHI, and the Health Education Training Centers Alliance of Texas (HETCAT) have developed a directory of health careers to educate and recruit students into specific health related professions. Their information serves as a foundation for detailing the specific job descriptions for each health professional. The directory includes a compilation of various methods to inventory and calculate provider workforce data. The Integrated Requirements Model (IRM), discussed in the following sections of this report, has been applied to 27 different medical specialties. The physician IRM data is contained within the text of this study; the additional IRM results are located in Appendix M. A supply data table is provided for those professionals not included in the IRM model and in which appropriate data was available. It is important to note that every reasonable attempt was made to include every health care providers' workforce data in this report; however, useful data is not currently available for several professions. A comprehensive list of sources used as background information for the IRM and supply data tables is contained in Appendix N.

Methodology Used in the IRM and Supply Projections

The Texas Legislative Council's Department of Statistical and Demographical Research compiled the data for the IRM and supply tables. They used the following methodology in computing the Texas-specific projections. The tables compare the projections of needed health practitioners with the projected supply of health practitioners for each year of the 2000-2005 period and for 2010. Projections are shown for each of 18 physician specialties and 9 non-physician specialties for the State and for urban and rural areas. The projections of needed practitioners were derived from the latest beta test version of the IRM being developed for the Bureau of Health Professions of the U.S. Department of Health and Human Services. The supply projections were developed by legislative staff using the most current data from state licensing agencies.

IRM Projections

The IRM was originally developed to forecast specific national requirements for physicians and non-physician clinicians. However, it can be adapted to individual states, counties, or any area of interest by adjusting the model's parameters to match the demographic and health characteristics of the defined area. The IRM uses the following three components to project the number of health practitioners required to meet the health needs of a particular population for each year of a projection period:

- Age-gender distribution of the population;
- Insurance coverages of the population; and
- Staffing ratios for each physician and non-physician specialty.

The IRM was adapted to Texas by adjusting the parameters of these components to fit Texas in the year 2000. The year 2000 was selected as the base year on the basis of data availability.

Texas population projections for the years 2000-2005 and 2010 were obtained from the State Data Center at Texas A&M University and incorporated into the model. These population projections are for both males and females in each of the following eight age groups in both urban and rural areas counties: ages 0 to 4, 5 to 17, 18 to 24, 25 to 44, 45 to 64, 65 to 74, 75 to 84, and 85 and above.

Available estimates concerning the insurance coverage of the population in the year 2000 were then incorporated into the IRM. These estimates are for the number of uninsured, the number of Medicaid

recipients, the number of individuals with managed care coverage, and the number of individuals covered by traditional fee-for-service insurance plans.

The staffing ratios for each of the 18 physician specialties in the IRM were adjusted to fit the physician supply as of May 2000. The staffing ratios built into the IRM were derived from national data. (A "staffing ratio" is defined as the number of practitioners per 100,000 population. In May 2000, for example, the Texas staffing ratio for general internal medicine physicians was 22.9, meaning there were 22.9 licensed general internal medicine physicians practicing in Texas for each 100,000 persons.) Use of the national ratios without adjustments would have produced physician requirements projections that were well in excess of the current supply of physicians in Texas. Consequently, the staffing ratios for each of the 18 physician specialties defined in the IRM were adjusted downward so that the IRM projections for the year 2000 matched physician supply. For all physician specialties, supply was defined as the number of licensees with a Texas address as reported by the Texas State Board of Medical Examiners for May 2000. The licensee data are not adjusted to full time equivalents (FTEs).

The staffing ratios for the nine non-physician specialties in the IRM were not adjusted to equate projected needs and available supply for the year 2000. Since the IRM's projected needs exceed available supply for most of the non-physician specialties, especially nurses, this deficit provides a numerical estimate of the extent of potential shortages in these professions.

After the components of the IRM were adjusted to the Texas situation, as explained above, legislative staff used the model to project the required numbers of health practitioners at the state level. IRM projections for each specialty group were allocated to urban and rural areas based on population.

Supply Projections

The supply projections for the 18 physician specialties and 9 non-physician specialties were derived by holding the current ratio of practitioners to population constant for each specialty group in both urban and rural areas and using this ratio to project the practitioner supply for each year of the projection period. The supply data and supply projections were not adjusted to full time equivalents [FTEs], and supply projections were not available for psychologists and social workers. For example, the urban and rural staffing ratios for

general internal medicine physicians were 25.0 and 10.9, respectively, in 2000. These staffing ratios were applied to the respective urban and rural population projections for each year of the projection period (2001-2005 and 2010) to estimate the supply of general internists for both urban and rural areas for each year of the projection period. Use of this methodology to project supply assumes that the supply will increase at the same rate as population growth.

Since practitioner supply projections are calculated on the basis of the current number of licensees in urban and rural areas, while the practitioner needs projections are calculated on the basis of population, these tables illustrate the extent of geographic maldistribution of health practitioners between urban and rural areas. These tables reflect that, with one notable exception, health personnel are concentrated in the urban areas. In regard to general pediatricians, for example, the statewide staffing ratio is 12.8 pediatricians per 100,000 population. The urban and rural staffing ratios for pediatricians are 14.3 and 4.3, respectively. This means that urban areas have more than three times as many general pediatricians as rural areas relative to their respective populations. The exception to the geographic maldistribution of health practitioners is general/family practice physicians. In summary, more than 90 percent of many specialties practice in urban areas, which comprise approximately 85 percent of the State's population.

Supply Projections for Health Practitioners Not Included in the IRM

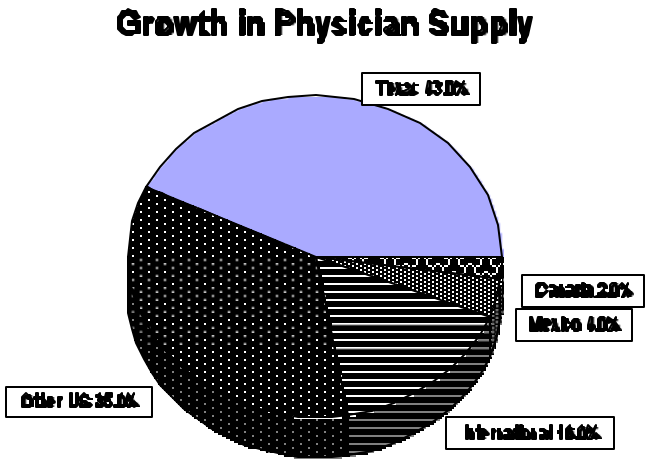
The supply projections for the health practitioners not included in the IRM were produced using the same methods as those used for the practitioners included in the IRM.

For each specialty, the ratio of practitioners to population in both urban and rural areas in base year 2000 was assumed to remain constant during the projection period and supply projections were calculated separately for urban and rural areas. The base year was the year for which the most recent licensee data were available. The urban and rural supply projections for each specialty group were combined to generate the statewide supply projection for each year.

Health Professionals

Primary Care Physicians: MDs and DOs

Texas' physician workforce is influenced by a number of different factors. For instance, the majority of the growth in the physician workforce stems from practitioners arriving from out of state. Graduates of schools outside of Texas make up 57 percent of the physician workforce; 22 percent of those are from other countries, as illustrated in the following chart.[9]



Source: Texas State Board of Medical Examiners, Licensure Masterfile, June 1998

In recent years, trends reflect an increased interest in practicing primary care. The Texas Medical Association (TMA) reported that in 1998, 44 percent of licensed physicians practiced in one of the four primary fields. In most rural areas of Texas, the only available health provider is a primary care professional. These professionals include physicians (MDs and DOs) in general and family practice, general internal medicine, general pediatrics, obstetrics/gynecology, physician assistants, and advanced practice nurses. These professionals serve as the first line of care for illness and injury and help reduce health care costs by providing a continuum of care from health education to medical intervention.

Rural Texas trails the urban areas of the State in availability and proportion of practicing primary care physicians. Of the 12,805 primary care physicians in direct patient care in Texas, only 1,443 (11 percent)

[9] THE TMA COUNCIL ON MEDICAL EDUCATION, THE PHYSICIAN WORKFORCE IN TEXAS: IMPLICATIONS FOR MEDICAL EDUCATION (1998).

practice in rural Texas, while approximately 15 percent of the State's population reside in rural Texas. Although there is concern about unequal distribution, the Texas Medical Association (TMA) reports that the projected number of physicians, from a statewide perspective, is expected to meet projected requirements when applied to the forecasted demand for the year 2005.

SUMMATION OF ALL PHYSICIAN SPECIALTIES (MDs & DOs)
PRIMARY AND NON PRIMARY CARE
for the years 2000-2005, 2010
Comparison of Integrated Requirements Model (IRM)
Requirement Projections With Supply Projections

IRM Requirements Projections				**Supply Projections**			Supply as a % of IRM Requirements
Year	Ratio per 100,000 Pop.	Requirements	% of Total	Ratio per 100,000 Pop.	Supply	% of Total	
2000	164.0	33,371	100.0%	164.0	33,371	100.0%	100.0%
2001	164.5	34,046	100.0%	164.0	33,944	100.0%	99.7%
2002	164.7	34,687	100.0%	164.0	34,526	100.0%	99.5%
2003	165.0	35,353	100.0%	163.9	35,115	100.0%	99.3%
2004	165.4	36,029	100.0%	163.9	35,712	100.0%	99.1%
2005	165.7	36,729	100.0%	163.9	36,316	100.0%	98.9%
2010	168.0	40,548	100.0%	163.7	39,503	100.0%	97.4%

However, only 8 percent (2,324) of all physicians licensed in Texas presently report a rural county as their place of residence. As of March 1998, 38 percent (74) of rural counties in Texas had two or fewer practicing primary care physicians, with 25 counties having no primary care physicians. Of those 25 counties, 17 have populations greater than 1,500 people, and one (Zavala) has a population of more than 12,000 people. Twenty-nine rural counties have only one primary care physician providing patient care, and 20 rural counties have two physicians. Of the 108 counties with fewer than five practicing primary care physicians, only three are designated metropolitan counties (Archer, Chambers, and Waller). One such county, Archer, has no practicing primary care physician.

In addition to being in short supply, rural physicians also tend to see more patients than their urban counterparts. Rural physicians had an average of 143 patient visits per week in 1993, as compared to 100

patient visits for urban physicians. This is partially a result of the physician shortage and is also attributable to the shared alliance these providers have with their local community.

Among the primary care specialists in rural Texas:

- 47 percent are family practitioners;
- 16 percent are general practitioners;
- 21 percent are internal medicine specialists;
- 8 percent are obstetricians/gynecologists; and
- 8 percent are general pediatricians.

Location	Primary Care MDs	Percentage	Primary Care DOs	Percentage
Urban Counties	10,532	89%	859	82%
Rural Counties	1,247	11%	193	18%

Source: Texas Department of Health, Health Professions Resource Center, January 1999

Another important consideration is that rural physicians are disproportionately older than their urban counterparts. Texas Medical Association's Medical Education Policy Department report (February 1999) showed that 36.4 percent of all rural physicians are at least 55 years of age and comprise 10 percent of all physicians in that age group. These numbers are even more alarming when one considers that rural physicians aged 65 and greater represent 17.5 percent of rural physicians and rural physicians that are at least 75 years old represent 4.7 percent of all rural physicians. The following charts show physician projection and physician distribution based on the practitioner's age.

Projections of Physician Surpluses/Deficits in Rural Areas, by Specialty, Years 2000, 2005, and 2010

Physician Specialty	Physician Supply, May 2000	IRM Projections of Physicians Needed	Projected Physician Deficits		
			Year 2000	Year 2005	Year 2010
Primary Care Physician Totals	**1,489**	**2,281**	**-792**	**-836**	**-883**
General Internal Medicine	335	701	-366	-395	-431
General Pediatrics	131	392	-261	-257	-252
ObGyn	99	333	-234	-243	-246
General/Family Practice	924	856	68	60	47

Non Primary Care Physician Totals	**898**	**2,748**	**-1,850**	**-1,952**	**-2,066**
Other Specialty Physicians	65	315	-250	-260	-271
Other Internal Medicine	46	294	-248	-267	-385
Anesthesiology	77	323	-246	-262	-277
Psychiatry	103	274	-171	-175	-180
Other Surgical Specialty	14	178	-164	-171	-178
Radiology	104	253	-149	-157	-166
Orthopedic Surgery	58	186	-128	-135	-142
Pathology	36	138	-102	-109	-116
Cardiovascular Diseases	25	124	-99	-107	-116
Ophthalmology	59	141	-82	-88	-95
Emergency Medicine	79	141	-62	-61	-61
Ear, Nose & Throat	27	82	-55	-57	-60
General Surgery	168	217	-49	-55	-63
Urology	37	83	-46	-49	-53

Age Group	**Rural Counties**	**Urban Counties**	**Total**	**Percentage**
Under 55	1,460	18,213	19,673	70%
55-59	233	2,727	2,960	10%
60-64	202	1,918	2,120	8%
65-69	154	1,394	1,548	6%
70-74	140	848	988	3%
75+	107	637	744	3%
TOTAL	2,296	25,737	28,033	100%

Source: Texas State Board of Medical Examiners Licensure Masterfile, July 1997

These practitioners are generally long-time providers in their communities and would be difficult to replace even if the supply of willing practitioners was more plentiful. Communities must make preparations to maintain providers in order to continue the same level of health care services they have had in the past. If no concerted effort is made to maintain providers, the access to care dilemma will be more acute when these older physicians retire from practice, with no replacement available to assume the responsibility of caring for their patient base.

Description	**Outlook**	**Training and Requirements**
Physicians		
Physicians care for healthy people and for those who are ill or injured. They perform physical examinations and diagnose and treat illnesses, injuries, and other disorders. They prescribe and administer medications and treatments, provide immunization services, care for pregnant women and deliver babies, perform surgery, and conduct research to aid in disease control or the development of new	Salary: $125,000 The demand for physician services will continue to increase in the future, especially in rural areas where many physicians are nearing retirement age. Primary care physicians are increasingly in demand under current health care delivery systems.	Physicians must train for 11 or more years after high school before they are qualified to practice medicine. Individuals may apply for medical school after three years of college. Applicants also must take the Medical College Admission Test (MCAT). Since admission to medical school is highly competitive, with more applicants than there are class positions, interested students should have high grade-point

treatments. Managed care and health maintenance organizations are creating an increased demand for primary care physicians who provide most health care needs for their patients and refer them to other specialists as needed. Primary care physicians may manage patient care and coordinate and direct the health care team.		averages and high MCAT scores. Individuals considering medicine should begin preparing in high school by taking a wide range of science, math, and liberal arts courses. Medical school consists of two years of basic medical science study (anatomy, biochemistry, microbiology, physiology, ethics, and law). During the last two years of medical school, students apply their classroom knowledge to the art of patient care. They rotate through medical specialties and may take electives in areas of special interest.

Nursing

Advanced practice nurses (APNs) include various types of nurse practitioners (NPs), certified nurse midwives (CNMs), certified registered nurse anesthetists (CRNAs), and clinical nurse specialists (CNSs). Although there are more certified registered nurse anesthetists than nurse practitioners, nurse practitioners (NPs) are the most common type of APN delivering primary care in rural Texas. While the number of NPs in rural Texas increased 35 percent from 1996 to 1998, only 11 percent, or 330, of the 3,059 nurse practitioners in the State report a rural Texas county as their place of residence. As with physicians, Texas has not been wholly successful in recruiting NP's to practice in rural Texas. Of the 196 rural counties in Texas, 78 (40 percent) do not have a nurse practitioner licensed in the county (down from 93 in 1995), while 50 rural counties (26 percent) have only one.[10]

Description	**Outlook**	**Training and Requirements**
Advance Practice Nurse		
Advanced practice nurses (APNs) are registered nurses approved by the board to practice as advanced practice nurses on the basis of completion of an advanced educational program. The APN acts independently and/or in collaboration with the health team in the observation, assessment, diagnosis, intervention, evaluation, rehabilitation, care and counsel, and health teachings of persons who are ill, injured or infirm or experiencing changes in normal health processes; and in the promotion and maintenance of health or prevention of	Salary: Unavailable	All advanced practice nurses must meet the requirements of the Board of Nurse Examiners for the State of Texas. All APNs must be licensed as registered nurses in the state of Texas and must have completed a post-basic advanced educational program of study acceptable to the board. Where required by rule, APNs must hold current certification in the authorized specialty area from a national certifying body recognized by the Board of Nurse Examiners. When certification in a particular

[10] Health Professional Resource Center of Texas, Bureau of State Health Data and Policy Analysis. Texas Department of Health, *Licensed RNs Recognized as APNs*. (1998).

illness. APNs provide a broad range of personal health services, the scope of which is based upon educational preparation, continued experience and the accepted scope of professional practice of the particular specialty area. APNs possess knowledge and skills which have prepared them to practice in an expanded role. The term APN includes the nurse practitioner, nurse midwife, nurse anesthetist, and clinical nurse specialist.		specialty is unavailable, other requirements must be met. All APNs must be recognized by the board to practice in a particular role and specialty. APNs have the option of applying to the Board of Nurse Examiners for limited prescriptive authority if all requirements for such authority have been met.
Certified Nurse-Midwife (CNM)		
A certified nurse-midwife (CNM) is a registered nurse with advanced education and clinical training, usually at the master's level, in midwifery. This additional training classifies the CNM as an advanced practice nurse. A certified nurse-midwife's focus is on women's wellness and consumer choice. Safe, sensitive, confidential personal care is the hallmark of the CNM's unique attention to the special primary care and reproductive needs of women.	Salary: $40,000 to $70,000 A national shortage of qualified nurse-midwives has created excellent work opportunities for certified nurse-midwives that should continue to increase.	Completion of registered nurse training is a prerequisite for entering a midwifery program. There are both certificate and master's-level programs for certified nurse midwives. Certificate programs are open to nurses with associate or bachelor's degrees and usually take nine to 12 months to complete. The master's program requires 16 to 24 months of study, and some require an additional year of clinical experience.
Certified Registered Nurse Anesthetists		
Anesthesia is a safe and effective method of alleviating pain during a medical procedure. Nurse anesthetists are registered nurses with advanced educational preparation in nurse anesthesia. Nurse anesthetists must be authorized by the Board of Nurse Examiners as advanced practice nurses. Nurse anesthetists are educated to provide anesthesia via different techniques during surgical procedures, labor and childbirth, and special medical procedures. They are responsible for pre-anesthetic care as well as for maintaining the patient in sound physiologic status during and after the procedure.	Salary: $46,500 to $56,500 The job outlook for certified registered nurse anesthetists is excellent. According to a study by the National Center for Nursing, there is a 13.6 percent shortage of CRNAs nationally. The study projected that there will be a need for 30,000 more CRNAs nationally by the year 2001. The recent acceleration of managed care services will provide additional opportunities and new challenges for these advanced practice nurses.	Applicants for this advanced training must hold a bachelor's degree in nursing or the equivalent, be licensed as a registered nurse, and have at least one year of critical-care nursing experience. Nurse anesthesia education programs consist of 25 to 36 months of graduate work including both classroom and clinical experiences.
Clinical Nurse Specialists		
Clinical nurse specialists are advanced practice nurses who hold the minimum of a master's degree. Clinical nurse specialists have specialized knowledge and skills within their chosen specialty area. Many clinical nurse specialists practice within hospital settings, but they are not limited to this clinical setting. These nursing professionals have	Salary: $33,016 to $50,264 Unavailable	Clinical nurse specialists must complete a post-basic educational program that is at the master's level in nursing. The program must be accredited by an accrediting agency recognized by the board and must be at least one academic year in length. Clinical nurse specialists have advanced education in a health care

responsibilities which include direct patient care, education of staff and patients, consultation with other health professionals, and provision of leadership and supervision within the workplace. Some clinical specialists may be granted limited prescriptive authority based on meeting the requirements for such authority.		specialty area that is population based such as gerontology or setting based such as critical care.
Nurse Practitioner		
Nurse practitioners are registered nurses with specialized advanced education who work as primary health care providers to diverse patient populations in a variety of ambulatory, acute and long term care settings. They provide care to individuals, families, and groups. Nurse practitioners provide nursing and medical services, including diagnosis and management of acute and chronic illness, with an emphasis on health promotion and disease prevention.	Salary: $37,000 A nurse practitioner (NP) is an advanced practice nurse with additional education and clinical training in a health care specialty area. They obtain medical histories, perform physical examinations, monitor patients with chronic diseases, assess and track acute and chronic illnesses, order and interpret lab tests and x-rays as needed, provide health education and disease prevention information to children and adults, and discuss disease prevention strategies with the public. Nurse practitioners also provide prenatal care and family planning. They recommend medications and medical treatments and are allowed by many states to prescribe medications.	Applicants must hold current licensure as registered nurses. Advanced educational programs may be at either the certificate or master's level, with the majority being at the master's level. Nurse practitioners have advanced education in a clinical specialty area. Nurse practitioner programs must be at least one academic year in length.

PROJECTIONS OF
ALL ADVANCED PRACTICE NURSES
(includes Certified Nurse Anesthetists, Certified Nurse Midwives,
Clinical Nurse Specialists, and Nurse Practitioners)
for the years 1999-2005, 2010
Comparison of Integrated Requirements Model (IRM)
Requirement Projections With Supply Projections

IRM Requirements Projections				**Supply Projections**			Supply as a % of IRM Requirements
Year	Ratio per 100,000 Pop.	Requirements	% of Total	Ratio per 100,000 Pop.	Supply	% of Total	
1999	40.1	8,012	100.0%	33.6	6,725	100.0%	83.9%
2000	40.1	8,166	100.0%	33.6	6,845	100.0%	83.8%
2001	40.2	8,327	100.0%	33.7	6,966	100.0%	83.7%
2002	40.3	8,486	100.0%	33.7	7,089	100.0%	83.5%
2003	40.4	8,651	100.0%	33.7	7,213	100.0%	83.4%
2004	40.5	8,817	100.0%	33.7	7,340	100.0%	83.2%
2005	40.6	8,991	100.0%	33.7	7,468	100.0%	83.1%
2010	41.2	9,932	100.0%	33.8	8,144	100.0%	82.0%

Physician Assistants (PAs)

A physician assistant (PA) is a licensed health professional trained to provide medical care under the supervision of a physician. The physician assistant profession was founded in the mid-1960s. There are four programs in Texas accredited by the Commission on Accreditation of Allied Health Education Programs and a military physician assistant education program, which now accepts civilian students. Programs are generally two years in length, with one year devoted to academics and one to clinical practice. Degrees are offered at the certificate, bachelor's, and master's level.

Physician assistants are one of the few health professions which report a slightly higher proportion of providers practicing or residing in rural areas when compared to the corresponding rural population. In 1998, approximately 18 percent, 317 of 1,768, licensed physician assistants reported a rural Texas county as their practice location, while about 15 percent of Texans reside in those counties. More than 80 percent (156) of the 196 rural counties in Texas have two or fewer practicing PAs. Sixty-nine rural counties (35 percent of rural Texas counties) have no PAs. This represents an improvement from 1996 when 80 rural counties had no PA.[11]

Description	Outlook	Training and Requirements
Physician Assistant		
Physician assistants (PAs) work directly under a doctor of medicine or osteopathy and perform a wide variety of state regulated health care services. Their duties may include: taking medical histories, performing physical examinations, ordering laboratory tests and x-rays, assisting in surgery, applying casts and bandages, making tentative diagnoses, directing treatments, recommending medications, treating minor injuries, and giving pre- and postoperative care. PAs also provide patient education when appropriate.	Salary: $42,000 to $59,000 Employment opportunities for physician assistants are excellent through the year 2000. An average of 200 to 300 openings is anticipated every year in Texas from 1996 to 2001.	Most physician assistant programs require applicants to have previous health care experience and some college education. Physician assistants are educated in programs lasting about 108 weeks. PA students are taught to diagnose and treat medical problems. Education consists of classroom and laboratory instruction in the basic medical and behavioral sciences followed by clinical rotations.

[11] Telephone interview with Gunn, Bruce A., PhD, Director: Health Professional Resource Center of Texas. Bureau of State Health Data and Policy Analysis. Texas Department of Health. (September 1998).

PROJECTIONS OF PHYSICIAN ASSISTANTS for the years 1999-2005, 2010 Comparison of Integrated Requirements Model (IRM) Requirement Projections With Supply Projections							
IRM Requirements Projections				**Supply Projections**			Supply as a % of IRM Requirements
Year	Ratio per 100,000 Pop.	Requirements	% of Total	Ratio per 100,000 Pop.	Supply	% of Total	
1999	9.5	1,902	100.0%	9.5	1,893	100.0%	99.5%
2000	9.5	1,938	100.0%	9.5	1,925	100.0%	99.3%
2001	9.5	1,976	100.0%	9.5	1,957	100.0%	99.0%
2002	9.6	2,013	100.0%	9.5	1,990	100.0%	98.9%
2003	9.6	2,052	100.0%	9.4	2,023	100.0%	98.6%
2004	9.6	2,091	100.0%	9.4	2,056	100.0%	98.3%
2005	9.6	2,132	100.0%	9.4	2,090	100.0%	98.0%
2010	9.8	2,355	100.0%	9.4	2,268	100.0%	96.3%

Dentists

In 1998, 69 counties in Texas were designated by the U.S. Department of Health and Human Services as experiencing a shortage of dentists. The population-per-dentist ratio was 2,636:1 in urban areas of the State in 1998. This ratio was 65 percent greater in rural areas of Texas.[12]

Location	**Population to Dentist Ratio**
Statewide	2,806:1
Urban Counties	2,636:1
Rural Counties	4,342:1

Source: Texas State Board of Dental Examiners, October 1998

Description	**Outlook**	**Training and Requirements**
Dentist		
A dentist has earned a degree as either a doctor of dental surgery (D.D.S.) or a doctor of dental medicine (D.D.M.). Dentists examine and treat diseases,	Salary: $53,000 The need for dentists and their services continues to grow.	Admission to dental schools requires a minimum of 90 semester hours of credit from an accredited college. Ninety-five percent of applicants have a bachelor's

[12] TEXAS STATEWIDE HEALTH COORDINATING COUNCIL, TEXAS STATE HEALTH PLAN 1999-2004, 2.17 – 2.19 (1998).

injuries, and malformations of teeth, gums, and mouth. They can enhance the appearance of their patients through dental techniques such as braces, dentures, or dental surgery. Ninety percent of dentists are general practitioners and are usually self-employed. Dentists supervise the work of the dental health care team and have final responsibility for all dental services being provided.	Successful preventive dentistry has resulted in a population that retains its teeth longer and therefore requires more dentists to continue its care. According to the Bureau of Labor Statistics, the field will experience a national growth rate of 5 percent through the year 2005.	degree in a scientific field. Graduation from an accredited school of dentistry usually takes about four years. Specialization requires additional years of training.

Supply Projections of Primary Care Dentists

Texas Totals				**Urban (Metro) Totals**				**Rural (Non-Metro) Totals**			
Year	Ratio per 100,000	Supply	% of Total	Year	Ratio per 100,000	Supply	% of Total	Year	Ratio per 100,000	Supply	% of Total
1999	40.6	8,109	100.0%	1999	42.7	7,241	89.3%	1999	28.5	868	10.7%
2000	40.6	8,255	100.0%	2000	42.7	7,381	89.4%	2000	28.5	874	10.6%
2001	40.6	8,403	100.0%	2001	42.7	7,524	89.5%	2001	28.5	880	10.5%
2002	40.6	8,554	100.0%	2002	42.7	7,668	89.6%	2002	28.5	885	10.4%
2003	40.6	8,706	100.0%	2003	42.7	7,815	89.8%	2003	28.5	891	10.2%
2004	40.7	8,861	100.0%	2004	42.7	7,964	89.9%	2004	28.5	897	10.1%
2005	40.7	9,018	100.0%	2005	42.7	8,116	90.0%	2005	28.5	902	10.0%
2010	40.8	9,845	100.0%	2010	42.7	8,917	90.6%	2010	28.5	928	9.4%

Dental Hygienists		
Dental hygienists are trained to evaluate a patient's dental health. Their duties include taking x-rays, cleaning patients' teeth, and applying fluorides and sealants to teeth. They may also apply temporary fillings at the request of the dentist. Dental hygienists are responsible for providing dental health education, including topics such as oral hygiene, selecting appropriate toothbrushes, the use of dental floss, and how diseases such as diabetes affect a patient's oral health.	Salary: $28,000 The demand for dental hygienists will continue to increase as the population ages and new treatments and technologies become available for the treatment of dental hygiene problems.	Two years of college at an accredited school is necessary to become a dental hygienist. There are some university-based dental hygiene programs that offer bachelor's and master's degrees.

Pharmacists

An extreme shortage of pharmacists exists in Texas and across the nation. This is due to several factors, including:

- an aging population that will require more prescription drugs;
- the introduction of more effective drug treatment options to keep patients out of hospitals and nursing homes;
- a requirement by the national accrediting body that all accredited colleges of pharmacy eliminate the Bachelor of Science degree, and only offer a Doctor of Pharmacy degree, increasing the educational requirements for pharmacy graduates from a five-year program to a six-year degree program;
- an increase in the number of Texans covered by insurance programs that offer prescription drug benefits; and
- pharmacy graduates leaving Texas to participate in out-of-state residency programs (pharmacists tend to remain in states where they conduct their residencies).

Although 15 percent of Texas' population lives in rural counties, only 11.9 percent of the active pharmacists were licensed in a rural county. Of the 196 rural counties, 19 have no active pharmacists.[13] In recent years, the role of the local pharmacist has been transformed. Pharmacists are accepting greater responsibility for the education of and care for their patients. The use of Internet pharmacies by patients and the increased use of technology in the pharmacy has contributed to changes in this profession. There are differing theories purporting to analyze the effect these changes have had on the access to, and provision of, quality health care. While home delivery of pharmaceuticals may increase access for home-bound patients, there are no assurances that the education needed to ensure proper utilization of medications can be provided under these new delivery systems.

Location	**Active Pharmacists**	**Percentage**
Statewide	14,687	100%
Urban Counties	12,939	88.1%
Rural Counties	1,748	11.9%

Source: Texas State Board of Pharmacy, December 1998

[13] Letter from the Texas State Board of Pharmacy to the Senate Health Committee, (Dec. 1998) (on file with the *Senate Health Committee*).

Description	Outlook	Training and Requirements
Pharmacist		
The role of the pharmacist has evolved from one who simply fills prescriptions to that of an active member of the primary health care team. Not only are pharmacists often the first health professional consulted by patients, they are also likely to be the final health care team member with whom the patient consults before taking a prescription drug. Since the pharmacist interacts with patients at such crucial times, they play a vital role in patient education and must be able to communicate effectively with individuals from all social and economic backgrounds.	Salary: $37,600 to $59,500 The demand for skilled pharmacists is increasing because of an increase in human life span, increased incidence of chronic diseases, and the complexity, number, and sophistication of medications and related products. An emphasis on primary and preventive health services and home health care is also increasing the need for more pharmacists.	Pharmacy programs currently offer the bachelor of science (B.S.) or the bachelor of pharmacy (B.Pharm.) degrees and the doctor of pharmacy (Pharm.D.) degree. The trend is for institutions to offer the Pharm.D. as the entry-level degree to the profession
Pharmacy Technician		
Pharmacy technicians work under the supervision of licensed pharmacists to perform technical and clerical duties in the systematic operation of the pharmacy. Their duties may include but are not limited to: 1) compounding (measuring, weighing, and mixing) medicinal drugs, 2) preparing and labeling medicines, 3) filling bottles and capsules with the correct quantity of medicine, 4) issuing medicines to the customers, 5) maintaining inventory, and 6) keeping patients' medication profiles on specified records or forms under the direct supervision of a pharmacist.	Salary: $12,400 to $19,900 According to the 1996-1997 Occupational Outlook Handbook, employment opportunities in this field are increasing faster than average.	Pharmacy technology programs teach the knowledge and skills needed to prepare, distribute, label, and package drugs, and to keep records. Formalized educational programs range from an eight-month certificate program to a two-year associate degree, which is usually obtained through a community college. Some pharmacy technicians learn their skills on the job. Because pharmacy technicians deal with controlled substances, they must submit to a background check.

Supply Projections of Pharmacists

Texas Totals				**Urban (Metro) Totals**				**Rural (Non-Metro) Totals**			
Year	Ratio per 100,000	Supply	% of Total	Year	Ratio per 100,000	Supply	% of Total	Year	Ratio per 100,000	Supply	% of Total
1999	74.7	14,931	100.0%	1999	77.9	13,199	88.4%	1999	56.9	1,732	11.6%
2000	74.7	15,199	100.0%	2000	77.9	13,454	88.5%	2000	56.9	1,744	11.5%
2001	74.7	15,470	100.0%	2001	77.9	13,714	88.7%	2001	56.9	1,756	11.3%
2002	74.8	15,745	100.0%	2002	77.9	13,978	88.8%	2002	56.9	1,767	11.2%
2003	74.8	16,024	100.0%	2003	77.9	14,245	88.9%	2003	56.9	1,778	11.1%
2004	74.8	16,307	100.0%	2004	77.9	14,517	89.0%	2004	56.9	1,789	11.0%
2005	74.9	16,594	100.0%	2005	77.9	14,794	89.2%	2005	56.9	1,800	10.8%

2010	75.0	18,105	100.0%	2010	77.9	16,254	89.8%	2010	56.9	1,852	10.2%

Nurses

Texas and the rest of the nation are faced with warnings of a nursing shortfall. To better assess the shortage, the Texas Nurses' Foundation has contracted with The University of Texas Health Science Center at San Antonio to collect information and analyze the current status of the nursing workforce data in Texas. This project, the Nurse Workforce Data System Project, reported that approximately 39,000 more RNs were needed in 1998 for Texas to match the national average of RNs per 100,000 population. Moreover, the national nursing workforce is aging rapidly; in 1998, the average employed RN was 44 years old. To add to this dilemma, almost 20 percent of RNs continue to renew their license each year, but do not work as a practicing nurse in a patient care arrangement. Ensuring an adequate nursing supply in rural areas is of paramount importance since these professionals are a vital component of health care facilities. State licensure for hospitals requires that the nursing staff provide around-the-clock services every day. Compounding the demand is the fact that an RN is required for each shift, unless the state licensure authorities allow waivers and such waivers are accepted by Medicare surveyors.

Activities to Address the Shortage

A number of regions, including DFW, Houston, East Texas, Laredo, and San Antonio have made efforts to address the nursing shortage. Employers and nursing education programs are identifying and implementing local strategies to increase enrollments, graduates, and applicants. For example, the Dallas-Fort Worth Hospital Council has provided funds to local nursing schools to produce more nursing graduates. Unfortunately, this shortage is not only a local issue; its complexity requires both local and state level responses.

The Nurse Workforce Data System Project, discussed previously, is initiated and coordinated by the Texas Nurses Foundation, supported in part by the Texas Institute for Health Policy Research, and produced by the Center for Health Economics and Policy at UTHSC in San Antonio. The project is addressing the immediate need for data and information regarding nurse supply and demand. The report, published earlier this year, identified available data on the nursing workforce and highlighted the supply side of the nursing shortage.

The Texas Nurses' Foundation will also coordinate project reports and activities planned prior to the 2001 Legislative session, including:

- Career Fulfillment of Texas RNs - a report on the work, job satisfaction, health, education, and personal background of Texas' RNs;
- The Demand for Nurses in Texas - a summary report of employer demand for nurses in hospitals, nursing homes, home health, public health nursing, mental health and mental retardation care settings, physician practice groups; and
- Data for Action - a monograph on the status of Texas' nurse workforce, dynamics, and expected future trends including a major chapter evaluating the capacity of the nursing education pipeline.

In addition, a conference on the nursing workforce is scheduled for October 2000, in San Antonio. This conference will bring together national and state health economists, researchers, and workforce experts to recommend how best to predict nurse demand for Texas given the information and resources now available. They will also make recommendations for a model and methodology for managing future nurse supply and demand in Texas.

Total Number of Registered Nurses			
Location	**RNs**	**Percentage**	**Population to RN Ratio**
Statewide	150,817	100%	130:1
Urban Counties	133,061	88%	125:1
Rural Counties	17,756	12%	170:1

Source: Texas Department of Health, Health Professions Resource Center of Texas, April 1998

Description	**Outlook**	**Training and Requirements**
Licensed Vocational Nurse		
Licensed vocational nurses (LVNs) help care for ill or injured people and perform health maintenance duties under the direction of physicians, osteopathic physicians, dentists, and registered nurses. Most LVNs provide basic bedside care to patients such as taking vital signs, applying dressings, helping patients with bathing and personal hygiene, and administering prescribed medications. LVNs observe and report on patients' symptoms, reaction to treatment and medication, and progress.	Salary: $26,000 According to the Bureau of Labor Statistics, the demand for licensed vocational nurses in Texas is projected to grow by 24 percent, with 13,600 new job openings from 1993 to 2005.	Vocational nursing training programs usually require one year of study that is generally offered in community colleges, technical and vocational centers, and hospitals.
Nursing Assistant/Patient Care Assistant		
Nursing assistants perform simple, basic patient care under the supervision of registered nurses and	Salary: $5.37 to $7.68 an hour	Many programs require that the applicant be at least 16 years of

licensed vocational nurses. They have a broad range of duties including bathing, walking, and feeding patients; making beds; assisting patients in and out of bed; dressing and shaving patients; and taking vital signs such as blood pressure, pulse, and temperature.	An aging population is increasing the need for nursing assistants.	age and a high school graduate. Training programs provide instruction and supervised clinical experience related to basic patient care, medical terminology, nutrition, taking patient vital signs, interpersonal/communication skills, basic anatomy, safety measures, infection control, assisting with therapies, and employability skills. The patient care assistant program is about 300 hours (15 weeks) long.
Registered Nurse		
Registered Nurses (RNs) observe, assess, provide therapeutic interventions for, evaluate, rehabilitate, counsel, and educate persons who are ill, injured, infirm, experiencing changes in normal health processes, or who need assistance in maintaining wellness and preventing illness. Professional nursing practice includes the supervision and teaching of nursing, nursing administration, and the conduct of research as well as providing patient care. RNs may practice independently or in collaboration with other members of the health care team. RNs supervise other registered nurses, licensed vocational nurses (LVNs), and unlicensed health care personnel such as nursing assistants/aides. RNs use a systematic approach to health care management by performing nursing assessments, developing plans of care, implementing and directing the implementation of that care, and evaluating patients' responses to nursing interventions.	Salary: $38,500 to $48,000 The Bureau of Labor Statistics projects the demand for registered nurses in Texas will grow more than 25 percent, with 25,300 new job openings predicted from 1993 to 2005.	Prospective nurses may choose a diploma program, an associate degree in nursing (A.D.N.), the bachelor's of nursing degree (B.S.N.), or a master's degree in nursing (M.S.N.).

Supply Projections of Registered Nurses

Texas Totals				**Urban (Metro) Totals**				**Rural (Non-Metro) Totals**			
Year	Ratio per 100,000	Supply	% of Total	Year	Ratio per 100,000	Supply	% of Total	Year	Ratio per 100,000	Supply	% of Total
1999	594.8	118,929	100.0 %	1999	627.8	106,413	89.5%	1999	411.1	12,516	10.5%
2000	595.1	121,076	100.0%	2000	627.8	108,472	89.6%	2000	411.1	12,604	10.4%
2001	595.5	123,253	100.0%	2001	627.8	110,566	89.7%	2001	411.1	12,686	10.3%

2002	595.8	125,459	100.0%	2002	627.8	112,691	89.8%	2002	411.1	12,768	10.2%
2003	596.2	127,698	100.0%	2003	627.8	114,849	89.9%	2003	411.1	12,850	10.1%
2004	596.5	129,971	100.0%	2004	627.8	117,041	90.1%	2004	411.1	12,930	9.9%
2005	596.8	132,279	100.0%	2005	627.8	119,270	90.2%	2005	411.1	13,009	9.8%
2010	598.5	144,421	100.0%	2010	627.8	131,039	90.7%	2010	411.1	13,382	9.3%

Physical Therapists

As with other medical professions, the demand for Physical Therapists (PTs) and Physical Therapy Assistants (PTAs) continues to rise in rural areas. This demand is driven by shortened hospital stays and an aging population. In 1996, 537 licensed PTs reported a rural Texas county as their place of residence; that number increased to 583 in 1998. About 8.3 percent of the 6,771 licensed PTs report a rural county as their place of residence. This is compared to a rural population of 15 percent. Physical Therapy Assistants must practice under the supervision of a PT. In 1998, 345 (13 percent) of the 2,647 PTAs reported a rural county as their place of residence.

Description	**Outlook**	**Training and Requirements**
ALLIED HEALTH: Physical Therapist		
Physical therapists work with patients who have lost certain physical abilities through injury or illness to relieve their pain, help them regain physical strength, help them recover the use of an affected limb, or relearn how to perform the activities of daily living. They confer with the patient's physician prior to initiating treatment and evaluation. Evaluating a patient's physical ability through testing, which includes range-of-motion tests, manual-muscle tests, gait and functional analysis, and other diagnostic tools, helps the therapist establish a program for the patient, teach the patient the techniques they need to use, and monitor their progress. Physical therapists work in rehabilitation, community health, industry, sports, research, education, and administration. They also perform patient evaluations.	Salary: $35,000 to $40,000 According to the March 1995 issue of Money, physical therapy is the third-fastest growing career in the nation. The demand for physical therapists far exceeds the available supply. An aging population, the general population's growing participation in sports and fitness activities, and technology and medical advances are contributing to the increased need for physical therapists. In Texas, the limited number of accredited programs also contributes to the shortage of these professionals.	The American Board of Physical Therapy Specialties certifies qualified physical therapists in seven areas of specialty (cardiopulmonary, clinical electrophysiology, neurology, orthopedics, pediatrics, geriatrics, and sports physical therapy). Certified specialists are denoted by the letters CS, which appear after their area of specialty. In Texas, physical therapists must receive a four-year bachelor's degree from an accredited university and then enroll in a master's-level program.

ALLIED HEALTH: Physical Therapy Assistant/Aide		
Physical therapy assistants implement treatment programs for patients under the supervision of a physical therapist. Their duties may include training patients in exercises, helping them relearn the daily living skills, using special equipment and prostheses, reporting patients' progress to the physical therapist, and other treatment procedures.	Salary: $24,000 to $28,000 As with physical therapists, physical therapy assistants are in high demand and will continue to be so into the next century.	Physical therapy assistants must complete a two-year accredited program offered at community colleges and universities. The course of study for a physical therapy assistant differs greatly from that of a physical therapist. The curriculum includes one year of general study and one year of technical courses that focus on physical therapy procedures and clinical experience. Upon completion, graduates receive an associate degree.

Supply Projections of Physical Therapists

Texas Totals				**Urban (Metro) Totals**				**Rural (Non-Metro) Totals**			
Year	Ratio per 100,000	Supply	% of Total	Year	Ratio per 100,000	Supply	% of Total	Year	Ratio per 100,000	Supply	% of Total
1999	35.5	7,095	100.0%	1999	38.1	6,461	91.1%	1999	20.8	634	8.9%
2000	35.5	7,224	100.0%	2000	38.1	6,586	91.2%	2000	20.8	638	8.8%
2001	35.5	7,356	100.0%	2001	38.1	6,713	91.3%	2001	20.8	643	8.7%
2002	35.6	7,489	100.0%	2002	38.1	6,842	91.4%	2002	20.8	647	8.6%
2003	35.6	7,624	100.0%	2003	38.1	6,973	91.5%	2003	20.8	651	8.5%
2004	35.6	7,761	100.0%	2004	38.1	7,106	91.6%	2004	20.8	655	8.4%
2005	35.6	7,901	100.0%	2005	38.1	7,242	91.7%	2005	20.8	659	8.3%
2010	35.8	8,634	100.0%	2010	38.1	7,956	92.1%	2010	20.8	678	7.9%

Supply Projections of Physical Therapist Assistants

Texas Totals				**Urban (Metro) Totals**				**Rural (Non-Metro) Totals**			
Year	Ratio per 100,000	Supply	% of Total	Year	Ratio per 100,000	Supply	% of Total	Year	Ratio per 100,000	Supply	% of Total
1999	14.2	2,832	100.0%	1999	14.3	2,426	85.7%	1999	13.3	406	14.3%
2000	14.2	2,882	100.0%	2000	14.3	2,473	85.8%	2000	13.3	409	14.2%
2001	14.2	2,932	100.0%	2001	14.3	2,521	86.0%	2001	13.3	412	14.0%
2002	14.2	2,983	100.0%	2002	14.3	2,569	86.1%	2002	13.3	414	13.9%
2003	14.2	3,035	100.0%	2003	14.3	2,618	86.3%	2003	13.3	417	13.7%
2004	14.2	3,088	100.0%	2004	14.3	2,668	86.4%	2004	13.3	419	13.6%
2005	14.2	3,141	100.0%	2005	14.3	2,719	86.6%	2005	13.3	422	13.4%

2010	14.2	3,422	100.0%	2010	14.3	2,987	87.3%	2010	13.3	434	12.7%

Speech Pathologists and Audiologists

Speech/language pathologists are health care professionals educated and trained to evaluate and treat children and adults with speech, language, and swallowing problems. Audiologists specialize in the diagnosis, prevention, and treatment of patients, ranging from infants to the elderly, who suffer from hearing, central auditory processing, and balance disorders. By the year 2005, the demand for speech/language pathologists and audiologists is expected to grow at a rapid rate of 46 percent nationwide, increasing the new job openings by almost 40,000. Projections indicate that there will be a 30 percent growth in demand for these occupations.[14]

The following table shows the distribution of Speech/Language Pathologists and Audiologists in the State of Texas. The current shortage may become more acute as demand increases, especially if a disproportionate number of graduates choose to practice in metropolitan rather than rural counties.

Location	**Licensed Speech Language Pathologists and Audiologists**	**Percentage**
Statewide	8,054	100%
Urban Counties	7,314	91%
Rural Counties	740	9%

Source: Texas Department of Health, Professional Licensing and Certification Division, January 1999

Description	**Outlook**	**Training and Requirements**
ALLIED HEALTH: Speech/Language Pathologist and Audiologist		
Speech/language pathologists are health care professionals educated and trained to evaluate and treat children and adults with speech, language, and swallowing problems. They help children and adolescents with language disorders to give directions, convey ideas, and improve language skills that lead to better academic performance. They also evaluate and treat persons with swallowing disorders that may result from illness, surgery, stroke, or injury. Audiologists specialize in the diagnosis, prevention, and treatment of patients, ranging	Salary: $38,500 to $41,500 By the year 2005, the demand for speech/language pathologists and audiologists is expected to grow at a rapid rate of 46 percent nationwide, increasing the new job openings by almost 40,000. In Texas, it is estimated that the growth will be 30 percent for these occupations.	The minimum requirement is a master's degree.

[14] THE CENTER FOR RURAL HEALTH INITIATIVES, H.O.T. JOBS! A COOL GUIDE TO HEALTH CAREERS, 11 (1997).

from infants to the elderly, who suffer from hearing, central auditory processing, and balance disorders.		

Supply Projections of Speech-Language Pathologists											
Texas Totals				**Urban (Metro) Totals**				**Rural (Non-Metro) Totals**			
Year	Ratio per 100,000	Supply	% of Total	Year	Ratio per 100,000	Supply	% of Total	Year	Ratio per 100,000	Supply	% of Total
1999	19.1	3,821	100.0%	1999	20.2	3,423	89.6%	1999	13.1	398	10.4%
2000	19.1	3,890	100.0%	2000	20.2	3,489	89.7%	2000	13.1	401	10.3%
2001	19.1	3,960	100.0%	2001	20.2	3,557	89.8%	2001	13.1	403	10.2%
2002	19.1	4,031	100.0%	2002	20.2	3,625	89.9%	2002	13.1	406	10.1%
2003	19.2	4,103	100.0%	2003	20.2	3,694	90.0%	2003	13.1	409	10.0%
2004	19.2	4,176	100.0%	2004	20.2	3,765	90.2%	2004	13.1	411	9.8%
2005	19.2	4,250	100.0%	2005	20.2	3,837	90.3%	2005	13.1	414	9.7%
2010	19.2	4,641	100.0%	2010	20.2	4,215	90.8%	2010	13.1	426	9.2%

Occupational Therapists

Occupational therapy (OT) is one of the fastest growing health professions in the nation. The job market for OTs is expected to increase dramatically. Community settings and geographic areas that are underserved by occupational therapists offer the greatest job opportunities.[15]

In the State of Texas, there are both Occupational Therapists (OT) and Registered Occupational Therapists (OTRs). An OT holds a temporary license and is under continuing supervision of an OTR until passing the national certification examination and receiving a regular license. An OTR holds a regular or provisional license from the Texas Board of Occupational Therapy Examiners.

There are also Certified Occupational Therapy Assistants (COTA) and Occupational Therapy Assistants (OTA). A COTA holds a regular or provisional license to practice occupational therapy and is under general

[15] THE CENTER FOR RURAL HEALTH INITIATIVES, H.O.T. JOBS! A COOL GUIDE TO HEALTH CAREERS, 7 (1997).

supervision of an OTR. An OTA holds a temporary license and is under the continuing supervision of an OTR until passing the national certification and achieving licensure.[16]

The table below contains the approximate number of OTRs and OTs in the State of Texas. The statistics were only available by city and zip code and were manually added and split into rural and metro counties.

Location	Licensed Occupational Therapists	Percentage
Statewide	4,202	100%
Urban Counties	3,830	91%
Rural Counties	372	9%

Source: Texas State Board of Occupational Therapy Examiners, January 1999

Description	Outlook	Training and Requirements
ALLIED HEALTH: Occupational Therapist		
Occupational therapists provide services to individuals whose ability to cope with the activities of daily living are impaired by physical illness or injury, congenital or developmental disability, or the aging process. The goal of the therapist is to help their patients regain their independence and good health. Therapists use several types of activities to evaluate and treat patients. With children, they may use toys and games. In treating adults, the therapists may use computers, work simulation, leisure activities, self-care tasks, and other methods. Adaptive equipment such as wheelchairs, splints, and eating and dressing aids are provided by the therapist when needed. The effectiveness of the activity and progress of the patient are carefully monitored and recorded by occupational therapists.	Salary: $32,000 to $40,000 Occupational therapy is one of the fastest growing health professions in the nation. The job market is expected to increase dramatically through the end of the 1990s and into the next century. Community settings and geographic areas that are underserved by occupational therapists offer the greatest job opportunities.	Three routes are offered: a bachelor's degree, a post-baccalaureate certificate program, or a professional master's degree program. All OT education programs include a period of supervised clinical experience.
ALLIED HEALTH: Occupational Therapy Assistant/Aide		
The occupational therapy assistant/aide works with the occupational therapist to treat the patient who has a disability resulting from physical injury or trauma, disease, aging, mental illness, or alcohol/substance abuse. They may assist the patient with exercises, work with artificial limbs, provide therapeutic massage, or perform any other activities directed by the occupational therapist.	Salary: $25,000 to $30,000 The job outlook for occupational therapy assistants is excellent. There are not enough certified personnel to meet the current demand. More jobs are expected to be created by new rehabilitation centers, schools, and work sites.	To become an occupational therapy assistant, you must complete either a two-year associate degree or one of a limited number of certificate programs. These programs also include supervised clinical experience.

[16] Letter from Joy L. Vaughn, Acting Coordinator. Texas State Board of Occupational Therapy Examiners. Austin, TX, to the Senate Health Committee (on file with the *Senate Health Committee*).

Supply Projections of Occupational Therapists											
Texas Totals				**Urban (Metro) Totals**				**Rural (Non-Metro) Totals**			
Year	Ratio per 100,000	Supply	% of Total	Year	Ratio per 100,000	Supply	% of Total	Year	Ratio per 100,000	Supply	% of Total
1999	21.6	4,319	100.0%	1999	23.7	4,022	93.1%	1999	9.8	297	6.9%
2000	21.6	4,399	100.0%	2000	23.7	4,100	93.2%	2000	9.8	299	6.8%
2001	21.6	4,480	100.0%	2001	23.7	4,179	93.3%	2001	9.8	301	6.7%
2002	21.7	4,562	100.0%	2002	23.7	4,259	93.4%	2002	9.8	303	6.6%
2003	21.7	4,646	100.0%	2003	23.7	4,341	93.4%	2003	9.8	305	6.6%
2004	21.7	4,731	100.0%	2004	23.7	4,424	93.5%	2004	9.8	307	6.5%
2005	21.7	4,817	100.0%	2005	23.7	4,508	93.6%	2005	9.8	309	6.4%
2010	21.8	5,270	100.0%	2010	23.7	4,953	94.0%	2010	9.8	318	6.0%

Supply Projections of Occupational Therapist Assistants											
Texas Totals				**Urban (Metro) Totals**				**Rural (Non-Metro) Totals**			
Year	Ratio per 100,000	Supply	% of Total	Year	Ratio per 100,000	Supply	% of Total	Year	Ratio per 100,000	Supply	% of Total
1999	7.0	1,401	100.0%	1999	7.2	1,217	86.9%	1999	6.0	184	13.1%
2000	7.0	1,426	100.0%	2000	7.2	1,241	87.0%	2000	6.0	185	13.0%
2001	7.0	1,451	100.0%	2001	7.2	1,264	87.1%	2001	6.0	187	12.9%
2002	7.0	1,477	100.0%	2002	7.2	1,289	87.3%	2002	6.0	188	12.7%
2003	7.0	1,502	100.0%	2003	7.2	1,313	87.4%	2003	6.0	189	12.6%
2004	7.0	1,529	100.0%	2004	7.2	1,339	87.6%	2004	6.0	190	12.4%
2005	7.0	1,555	100.0%	2005	7.2	1,364	87.7%	2005	6.0	191	12.3%
2010	7.0	1,695	100.0%	2010	7.2	1,499	88.4%	2010	6.0	197	11.6%

Behavioral Medicine

The lack of behavioral medicine professionals, such as psychiatrists, licensed psychologists, and licensed or certified social workers, is significant in rural areas. It is difficult to find a certified rural health clinic that provides the services of a psychologist or social worker, even though reimbursement is available for these services.

Location	Population to Psychiatrist Ratio
Statewide	14,076:1
Urban Counties	12,721:1
Rural Counties	43,201:1

Source: Texas Statewide Health Coordinating Council, October 21, 1998

Location	Active Psychiatrists	Percentage
Statewide	1,341	100%
Urban Counties	1,253	93%
Rural Counties	88	7%

Source: Texas Department of Health, Bureau of State Health Data and Policy Analysis, 1998

Location	Active Licensed Psychologists	Percentage
Statewide	3,120	100%
Urban Counties	3,004	96%
Rural Counties	116	4%

Source: Texas State Board of Examiners of Psychologists, 1998

Description	Outlook	Training and Requirements
Psychologist		
Psychologists study the behavior of people and animals in an effort to understand, compare, and explain the ways they act and respond. They collect and apply knowledge related to the mental, emotional, and behavioral characteristics of individuals and groups.	Salary: $18,000 to $75,000 Employment opportunities for psychologists in Texas are estimated to increase by 16 percent annually.	Training for a psychologist varies from a four-year, bachelor's degree to an eight-year, doctoral degree.

PROJECTIONS OF PSYCHOLOGISTS for the years 1999-2005, 2010
Comparison of Integrated Requirements Model (IRM) Requirement Projections With Supply Projections

IRM Requirements Projections				Supply Projections			Supply as a % of IRM Requirements
Year	Ratio per 100,000 Pop.	Requirements	% of Total	Ratio per 100,000 Pop.	Supply	% of Total	
1999	24.9	4,986	100.0%	N/A	N/A	N/A	N/A
2000	24.9	5,066	100.0%	N/A	N/A	N/A	N/A
2001	24.9	5,147	100.0%	N/A	N/A	N/A	N/A
2002	24.8	5,230	100.0%	N/A	N/A	N/A	N/A
2003	24.8	5,313	100.0%	N/A	N/A	N/A	N/A
2004	24.8	5,399	100.0%	N/A	N/A	N/A	N/A
2005	24.8	5,487	100.0%	N/A	N/A	N/A	N/A

2010	24.7	5,966	100.0%	N/A	N/A	N/A	N/A

Location	**Licensed Social Workers**	**Percentage**
Statewide	14,398	100%
Urban Counties	12,808	89%
Rural Counties	1,590	11%

Source: Texas Department of Health, Professional Licensing and Certification Division, 1998

Description	**Outlook**	**Training and Requirements**
MENTAL HEALTH: Social Worker		
Social workers assist individuals and groups with problems such as poverty; illness; substance abuse; child, spouse, or elder abuse; lack of financial management skills; emotional and mental health disorders; and inadequate housing. There are five types of certified/licensed social workers: social work associate, licensed social worker, advanced practice social worker, licensed master's social worker, and advanced clinical practice social worker.	Salary: $20,900 to $31,400 The demand for social workers in Texas is expected to increase by 26 percent annually, while opportunities for social workers are projected to grow by 34 percent at the national level.	Training for social workers ranges from an associate degree to a doctoral degree. The bachelor of social work degree (B.S.W.) prepares students for general practice. Students wishing to specialize must earn a master of social work (M.S.W.) degree.

PROJECTIONS OF
CLINICAL SOCIAL WORKERS
for the years 1999-2005, 2010
Comparison of Integrated Requirements Model (IRM)
Requirement Projections With Supply Projections

IRM Requirements Projections				**Supply Projections**			Supply as a % of IRM Requirements
Year	Ratio per 100,000 Pop.	Requirements	% of Total	Ratio per 100,000 Pop.	Supply	% of Total	
1999	24.6	4,927	100.0%	na	na	na	na
2000	24.6	5,006	100.0%	na	na	na	na
2001	24.6	5,086	100.0%	na	na	na	na
2002	24.5	5,168	100.0%	na	na	na	na
2003	24.5	5,250	100.0%	na	na	na	na
2004	24.5	5,335	100.0%	na	na	na	na
2005	24.5	5,422	100.0%	na	na	na	na
2010	24.4	5,895	100.0%	na	na	na	na

Other Potential Behavioral Medicine Resources

Location	Licensed Professional Counselors	Percentage
Statewide	9,194	100%
Urban Counties	8,822	96%
Rural Counties	372	4%

Source: Texas Department of Health, Professional Licensing and Certification Division, 1998

Description	Outlook	Training and Requirements
MENTAL HEALTH: Marriage and Family Therapist		
Marriage and family therapists address a wide array of relationship issues and diagnose and treat mental and nervous disorders and problems within families. These therapists deal with a wide variety of issues, including those that stem from couple relationships, children, step-families, and caring for elderly parents. They also treat and help families cope with specific disorders such as substance abuse, eating disorders, prolonged underachieving, depression, and other mental and emotional problems. The marriage and family therapist consults with all those involved in the problem, including parents, spouses, children, friends, school personnel, social services, community agencies, and the courts.	Salary: $35,000 to $53,300 The job outlook for this field is mixed. As more consumers, health professionals, and employers understand the skills, educational and training standards, and effectiveness of marriage and family therapy, the profession will gain clients.	A six-year, master's level degree is the minimum education required to enter this field. Doctoral education in family therapy emphasizes the training of supervisors, teachers, researchers, and clinicians in the discipline.

Supply Projections of Marriage and Family Therapists

Texas Totals				Urban (Metro) Totals				Rural (Non-Metro) Totals			
Year	Ratio per 100,000	Supply	% of Total	Year	Ratio per 100,000	Supply	% of Total	Year	Ratio per 100,000	Supply	% of Total
1999	17.1	3,419	100.0%	1999	19.2	3,252	95.1%	1999	5.5	167	4.9%
2000	17.1	3,483	100.0%	2000	19.2	3,315	95.2%	2000	5.5	168	4.8%
2001	17.1	3,548	100.0%	2001	19.2	3,379	95.2%	2001	5.5	169	4.8%
2002	17.2	3,614	100.0%	2002	19.2	3,444	95.3%	2002	5.5	170	4.7%
2003	17.2	3,681	100.0%	2003	19.2	3,510	95.3%	2003	5.5	171	4.7%
2004	17.2	3,749	100.0%	2004	19.2	3,577	95.4%	2004	5.5	173	4.6%
2005	17.2	3,818	100.0%	2005	19.2	3,645	95.5%	2005	5.5	174	4.5%
2010	17.3	4,183	100.0%	2010	19.2	4,005	95.7%	2010	5.5	179	4.3%

Description	Outlook	Training and Requirements
ALLIED HEALTH: Recreational Therapist		
Recreational therapists, also known as therapeutic recreational specialists, use medically approved recreational programs to physically and socially rehabilitate patients who have chronic physical,	Salary: $31,472 The U.S. Department of Labor Statistics predicts that the field will grow by 40	Individuals who wish to be considered for jobs in clinical settings, such as hospitals or community mental health facilities, must obtain a degree in therapeutic recreation. They also require

psychological, and social handicaps. Activities may include sports, games, dance, drama, arts and crafts, music, and field trips. The recreational therapist encourages patients to develop interests and skills to assist them in recovering from and coping with illness or disability. They may also treat individuals with specific medical problems in these environments.	percent through the year 2005 because of the increasing need for long-term care, rehabilitation, and services for the developmentally disabled.	a minimum of 360 hours of internship under the supervision of a certified therapeutic recreational specialist.
ALLIED HEALTH: Respiratory Care Technician/ Therapist		
Respiratory care therapists and respiratory care technicians, referred to as respiratory care practitioners (RCPs), treat patients who have difficulties with breathing because of cardiopulmonary (heart-lung) problems. They conduct diagnostic tests of patients' cardiopulmonary functions and give patients appropriate treatment, as ordered by a physician.	Salary: Unavailable The field of respiratory care is growing rapidly. This career is expected to grow 36 percent by the year 2005 because of the growing middle-aged and elderly population.	Training for respiratory care technicians ranges from 12 to 18 months, respiratory care therapists require a two-year associate degree or a four-year bachelor's degree.
MENTAL HEALTH: Licensed Professional Counselor		
Licensed professional counselors help people deal with problems or conflicts they are unable to solve alone, including substance abuse; family, parenting, and marriage conflicts; managing stress; depression; suicidal thoughts; career concerns; and problems with self-esteem. Mental health counselors collect information through interviews, observations, and tests, and then decide how best to treat patients. The counselor may work with individuals, couples, families, or in group sessions of people with similar problems. They work closely with other mental health professionals, such as psychiatrists, psychologists, and social workers, to care for patients.	Salary: $35,000 to $48,900 Growth in this field is faster than average. These professionals may be in even greater demand if present trends such as high divorce rate, alcoholism, drug abuse, and child abuse continue.	The minimum education requirement is a master's degree of arts or sciences. A doctoral degree is rapidly becoming required in the field. After completing course requirements, individuals must complete an internship beforegraduating.

Supply Projections of Licensed Professional Counselors

Texas Totals				**Urban (Metro) Totals**				**Rural (Non-Metro) Totals**			
Year	Ratio per 100,000	Supply	% of Total	Year	Ratio per 100,000	Supply	% of Total	Year	Ratio per 100,000	Supply	% of Total
1999	32.6	6,512	100.0%	1999	35.1	5,957	91.5%	1999	18.2	555	8.5%
2000	32.6	6,631	100.0%	2000	35.1	6,072	91.6%	2000	18.2	559	8.4%
2001	32.6	6,752	100.0%	2001	35.1	6,189	91.7%	2001	18.2	563	8.3%

2002	32.6	6,875	100.0%	2002	35.1	6,308	91.8%	2002	18.2	566	8.2%
2003	32.7	6,999	100.0%	2003	35.1	6,429	91.9%	2003	18.2	570	8.1%
2004	32.7	7,125	100.0%	2004	35.1	6,552	92.0%	2004	18.2	573	8.0%
2005	32.7	7,254	100.0%	2005	35.1	6,677	92.0%	2005	18.2	577	8.0%
2010	32.9	7,929	100.0%	2010	35.1	7,336	92.5%	2010	18.2	593	7.5%

Chiropractors

Doctors of Chiropractic (DC) base their treatment upon a foundation of diagnostic information gathered through physical examination, patient history, clinical laboratory results (blood chemistries, urinalysis, etc.), diagnostic imaging (X-rays, MRIs, etc.), and other diagnostic measures in addition to evaluations unique to chiropractic.[17] In Texas, there is a total of 4,240 licensed chiropractors. At this time, the statistical data is in city and zip code order, so a comparison between rural and metro counties is not available.[18]

Description	**Outlook**	**Training and Requirements**
Chiropractor		
Chiropractors, or doctors of chiropractic (D.C.), are concerned with the proper function of the nervous system as it relates to the body as a whole. This approach to health care stresses the patient's overall health and well-being. Chiropractors use natural, nonsurgical health treatments such as heat, ultrasound, massage, light, diet, water, exercise, and rest. Postural and spinal analysis, involving correct alignment of the vertebrae, is unique to chiropractic. Chiropractors are not permitted to prescribe drugs or use surgery to treat their patients. Chiropractors may take diagnostic x-rays as a part of their treatment methods, but Texas law prohibits their use of x-ray or radium therapy.	Salary: $30,000 to $40,400 Texas employment is estimated at 3,600 jobs by the year 2000. There are approximately 200 additional job openings in Texas each year.	To become a licensed chiropractor in Texas, an applicant must graduate from a college that is accredited by the Council on Chiropractic Education (CCE). The educational requirements call for a minimum of two years of college-level study in an accredited institution of higher learning and graduation from a four-year college of chiropractic that meets the standards of professional education. Before graduating, a chiropractic student must also complete a program in clinical experience.

Source: East Texas AHEC, http://www.etxahec.org/hcp/index.htm; and, Texas Board of Nurse Examiners. Modified by: Texas Department of Health, Health Professions Resource Center, July 13, 2000

Supply Projections of Chiropractors											
Texas Totals				**Urban (Metro) Totals**				**Rural (Non-Metro) Totals**			
Year	Ratio per 100,000	Supply	% of Total	Year	Ratio per 100,000	Supply	% of Total	Year	Ratio per 100,000	Supply	% of Total

[17] The National College of Chiropractic, *Definition of Chiropractic*. (visited January 1999) <http://www.national.chiropractic.educ/gen/chirodef/html>.

[18] Letter from Joyce Kershner, Licensing Division. Texas State Board of Chiropractic Examiners. Austin, TX, to the Senate Health Committee (January 1999)(on file with the *Senate Health Committee*).

1999	15.6	3,124	100.0%	1999	16.4	2,782	89.1%	1999	11.2	342	10.9%
2000	15.6	3,180	100.0%	2000	16.4	2,836	89.2%	2000	11.2	344	10.8%
2001	15.6	3,237	100.0%	2001	16.4	2,891	89.3%	2001	11.2	347	10.7%
2002	15.6	3,295	100.0%	2002	16.4	2,946	89.4%	2002	11.2	349	10.6%
2003	15.7	3,354	100.0%	2003	16.4	3,003	89.5%	2003	11.2	351	10.5%
2004	15.7	3,413	100.0%	2004	16.4	3,060	89.6%	2004	11.2	353	10.4%
2005	15.7	3,474	100.0%	2005	16.4	3,118	89.8%	2005	11.2	355	10.2%
2010	15.7	3,791	100.0%	2010	16.4	3,426	90.4%	2010	11.2	366	9.6%

Medical Radiologic Technologists

In 1995, the 74th Texas Legislature enacted H.B. 1200, which amended the Medical Radiologic Certification Act with the intent of ensuring that radiologic procedures being performed by persons other than certified Medical Radiologic Technologists are done in a safe and knowledgeable manner. Specifically, the bill addressed minimum training standards for Non-certified Radiologic Technicians (NCTs), minimum standards for NCT's curricula and education programs, and the creation of hardship exemptions for physicians and hospitals that employ NCTs.

In many rural areas, NCTs are providing the majority of radiologic procedures. According to the Texas State Board of Medical Examiners, there are more than 600 registered NCTs under physician supervision. The hardship exemption specified in the law was to exempt these providers from being required to attend additional training. If NCTs practicing in rural communities do not receive the exemption, they would have to leave their practices to complete the educational requirements. As a result, a community may be left with no local access to radiologic services.[19]

Telemedicine

Technology is rapidly changing the way Texans do business. The health care industry welcomes and will benefit from these technological advancements. Telemedicine is a new, innovative method to solve some of

[19] Texas Department of Health., *Medical Radiologic Technologist Certification Program, Roster Medical Radiologic Technologists. Professional Licensing and Certification Division.*(visited January 1999) <http://www.tdh.state.tx.us/hcqs/plc/mrtrost.txt.>.

the problems facing many providers throughout health care communities. The availability of this technology could prove invaluable to addressing some of the serious issues affecting both rural and inner-city Texans.

Telemedicine enables patients and providers to interact with health care professionals located miles apart. It increases patients' access to specialists through video-imaging and real-time collaboration using computer and telecommunications technology. Telemedicine also brings continuing medical education and training to isolated providers. "Access to quality health care has a major influence on quality of life, and this is a significant issue for rural communities...new technology offers great hope for helping us deal with this challenge," said North Dakota Governor Edward T. Schafer at a rural health roundtable.

Over the past three regular legislative sessions of the Texas Legislature (1995-1999), Texas lawmakers have passed laws which authorized:

- Medicaid to reimburse for telemedicine (contingent upon certain criteria);
- private insurance (state regulated health benefit plans) to pay for telemedicine consultations;
- a "special" physician license for out-of-state physicians to provide telemedicine services;
- grants to not-for-profit health facilities and academic health science centers to develop telemedicine networks;
- an interstate compact for registered nurses using telecommunications; and
- the creation of a Medicaid telemedicine consultation advisory committee.

Following implementation of these state laws related to telemedicine, numerous state agencies have been regulating certain telemedicine activities. For example, the State Board of Medical Examiners and the State Board of Nurse Examiners regulate the scope of practice of their respected medical professions related to telemedicine. While the Texas Department of Insurance, Texas Department of Health, and the Health & Human Services Commission regulate the types of telemedicine services eligible for reimbursement, several of these agencies have developed standing committees to prevent fraud and abuse and evaluate appropriate telemedicine use throughout the State. Although each regulatory body effectively governs entities under their purview, there is little coordination between the separate governing bodies and programs.

Since the passage of the federal Balanced Budget Act of 1997 (BBA), which has adversely impacted hospitals and clinics throughout the country, Texas has experienced a loss of more than 57 rural clinics and 5 rural health hospitals. As these facilities closed, the citizens traditionally in their care have been forced to travel to larger, urban hospitals to receive services. However, many of the urban hospitals are not equipped to absorb this increase in their patient base. This is alarming considering that only 30 percent of Texas' acute care hospitals are in rural counties.[20]

Studies and pilot projects around the country are currently underway to analyze the potential cost savings and practicality of incorporating telemedicine services into different settings. Telemedicine could aid in preserving the patient's medical home in the rural communities, especially since many of the clinics are in a tenuous state. When determining the role that the State should play in encouraging the use of telemedicine, there are a number of issues that should be considered by policymakers. Telemedicine should complement, not replace, existing provider-patient relationships and recognize and promote coordination with traditional providers.

Benefits of Telemedicine for Rural Providers

Rural Provider and Community Support

The most frequent challenges experienced by rural providers are the lack of opportunity to interact with their peers and consult with other providers, and the lack of access to continuing education opportunities and other professional resources. Telemedicine has the potential to provide methods for isolated providers to connect, network, and consult with their peers and access resources that would otherwise be unavailable. Electronic access to reference materials in medical libraries would also benefit rural providers. These resources would not only benefit the health care providers, but may also aid the patient education process. Current health care information could be made available via telecommunication systems in waiting rooms, senior centers, local pharmacies, schools, and libraries. This increased access could be used to promote prevention, provide social services, and make local citizens aware of health care resources in their area and across the State.

Access to Referrals and Tertiary Care

[20] CENTER FOR RURAL HEALTH INITIATIVES. RURAL HEALTH IN TEXAS, 1999: A REPORT TO THE GOVERNOR AND THE 76TH TEXAS LEGISLATURE. TEXAS (1999).

Specialty health care facilities in Texas tend to be located predominantly in urban areas. The ability of health care providers and medical specialists to consult through the use of telemedicine technology can be an important tool for increasing access to specialty health care services to residents of small towns and rural communities across the State. This issue will become critical as our rural physician population continues to age. Currently, 35 percent of rural physicians are over the age of 55. A survey by Merritt, Hawkins & Associates, recently published in the *Wall Street Journal*, reports that 38 percent of the surveyed physicians over 50 years of age and older planned to retire in the next five years. As these physicians retire, recruiting strategies will become increasingly more important to maintain the same level of care to which communities are accustomed. Smaller communities may be unable to financially support a full-time physician practice, but a mid-level practitioner could be a potential acceptable alternative. Since mid-level practitioners are required to work under the supervision of a physician, telemedicine can be a valuable tool in facilitating that supervision and communication. A telecommunications infrastructure must continue to evolve in a way that ensures the patient population and the practitioner in each rural community have access to the broadest array of referral, consultation, and support services possible.

Home Health

The expansion of home health services through telemedicine holds a great deal of promise for patients and providers. Many rural home health agencies have closed as a result of the Balanced Budget Act of 1997, leaving rural patients with limited access to home health services. Using telemedicine to monitor homebound patients and to assist home health staff in the delivery of services to remote areas is a concept that can and should be explored.

Mental Health

As previously noted, rural Texas is faced with a critical shortage of behavioral health providers. Telemedicine is considered an effective tool in the delivery of mental health services and could be used to improve access to mental health services for rural communities. This would benefit local providers as well as those in need of services by allowing patients to stay in their community and continue to receive services.

Barriers to Telemedicine

Telecommunication Infrastructure

Rural communities differ in the services that are available, therefore, they may differ in the type of telemedicine services that can be offered. Local Internet Service Providers (ISPs) are not available in all rural communities. Rural systems range from large established telephone providers to very small independent telephone companies and telephone cooperatives. These differences can affect the availability of telecommunication lines and the ability to monitor and upgrade equipment and all the ancillary components (i.e. switches) that are required for telemedicine. While some rural areas do have the option of an ISP, those that do not are required to pay long-distance charges for basic Internet connectivity, which can make connecting frequently or for long periods of time cost-prohibitive. In order to utilize telemedicine effectively, a connection such as a DSL line, cable modem, or other access to a high-speed line, such as a T-1 or ATM, is necessary to transmit large amounts of data, such as video, quickly. Establishing a local dial-up in a rural area is not a financially attractive situation for many ISPs, since rural areas may not have the number of potential customers that would be needed to support such a venture.[21]

Costs for Telemedicine Providers

Geographic distance plays a tremendous role in both the type of communication links possible and the cost of transmitting data over that link. Types of telecommunication links include everything from local telephone lines to satellite links, with costs generally increasing in relation to the distance and sophistication of the link. For providers, this cost is in addition to all other costs, such as labor and equipment. Some first year implementation costs are covered through various grants. For instance, one of the State's programs, the Telecommunications Infrastructure Fund (TIF), covers costs for the first year. Beyond the first year, the provider must absorb the costs, which are often not recouped in the patient visit charges.

The definition of acceptable equipment and method of transmission that is needed to qualify for reimbursement for telemedicine services under payors such as Medicare and Medicaid does not match the telecommunications infrastructure of rural areas. Full-motion interactive telemedicine requires a high speed transmission line such as a T1, ISDN, fiber optic, or cable modem. Yet alternative models of telemedicine technology, such as store-and-forward, that do not require high speed lines are not currently reimbursable. Still image capture or store-and-forward technology allows a provider to capture an image from a video

[21] CENTER FOR RURAL HEALTH INITIATIVE'S REPORT ON RURAL TELEMEDICINE ISSUES FOR THE HOUSE SELECT COMMITTEE ON RURAL DEVELOPMENT, (June 13, 2000).

stream and forward the electronic image or documentation to a specialist for review and consultation, rather than relaying the image in real time.

Technical Support and Training Issues

An additional barrier for rural providers is the lack of availability of a technical workforce in rural areas. Technical assistance is readily available in the metropolitan areas from vendors that sell and install systems, but rarely available in remote areas. National vendors who offer technical help via 1-800 numbers often charge for that assistance. This raises a particular concern for medical providers who need their telemedicine equipment repaired quickly in order to prevent disrupting patient care. If there are no professionals available locally to perform upgrades and maintenance, not to mention emergency repairs, rural health care providers are forced to assume the responsibility and risk for their equipment without access to adequate support. In addition to a lack of a technical workforce, rural areas do not have the same level of access to technical training as urban or suburban areas. While the Internet has made online training widely available, it is not always the best method to deliver training. Hardware training, for example, is best done on-sight so the user becomes familiar with the equipment. In other cases, providers may not feel comfortable with online learning and may need to be trained in a one-on-one situation to become comfortable with both hardware and software.

Access to TIF Resources

The Telecommunications Infrastructure Fund Board (TIF) is a Texas state agency responsible for disbursing approximately $1.5 billion in grants and loans. The creation of TIF, in 1995, provided an unprecedented amount of funding to develop connectivity for rural health care providers. Due to the limitations inherent in the use of public funding, for-profit entities are ineligible for TIF funding.[22] The TIF Board reported funding $20.1 million for public health technology advancements from 1996- 2000. Unfortunately, many private physician practices and clinics in rural areas are technically considered "for-profit" and have not been able to access this funding stream. (see Appendix O for the public health grants funded by TIF) Many of these providers are located in communities that have been wired for access for their libraries and schools. However, at this time, that infrastructure is inaccessible to local providers that are not "non-profit." In

[22] The Texas 75th Legislature created the Telecommunications Infrastructure Fund in H.B. 2128. It authorized funding Internet connectivity, telemedicine and distance education to public schools, public libraries and not-for-profit hospitals, clinics and academic health science centers.

addition, TIF has focused on providing Internet connectivity for health care providers, but connectivity alone does not provide the necessary components needed to utilize telemedicine services.

Support for Telemedicine at the Federal Level

Medicare Reimbursement

As part of the Balanced Budget Act of 1997, the Health Care Financing Administration opened up a pilot project to provide reimbursement for telemedicine for patients and providers in Health Professional Shortage Areas. To qualify for reimbursement, the initiating practitioner must initiate a referral, the patient must be present, and the consultation must be done live. Under the current methodology, the consulting physician bills for the consultation and shares the reimbursement on a 75 percent/25 percent basis with the initiating physician.

Universal Service Fund

The Rural Health Care Division (RHCD) is a Universal Service support program authorized by Congress and designed by the Federal Communications Commission (FCC). RHCD's mission is to provide support to rural health care providers for telecommunications services related to the use of telemedicine/telehealth through Universal Service support. This program supports monthly telecommunications service charges and installation charges, but not terminal equipment costs. The Universal Service Support Program established a fund to make up to $400 million available annually to rural health care providers who will then pay no more than their urban counterparts for telecommunication services.

As of November 12, 1999, the Universal Service Administrative Company (USAC) had made its initial commitments to eligible health care providers totaling $1,281,174.50 for the first program year, January 1, 1998 to June 30, 1999. Texas received only thirteen of USAC's 290 first round commitments, for a total of $12,278.68. Other disbursements include (but are not limited to):

State	# of Commitments	Dollar Amount
Hawaii	8	$91,612.44
Minnesota	26	$113,793.17
Montana	28	$114,133.61

North Dakota	14	$158,054.44
New York	12	$124,386.36
Texas	13	$12,278.68

The RHCD began accepting applications for the 1999 Funding Year on March 1, 1999. The 1999 Funding Year started July 1, 1999 and ended June 30, 2000.

Some of the eligible telecommunication services include: T1, Fractional T1, ISDN (BRI and PRI), Frame Relay, ATM, Off-premise, Extension, Satellite service, Centrex, Dedicated Private Line, Foreign Exchange Line, Network Reconfiguration Service, Direct Inward Dialing, and xDSL (when the bandwidth is less than 1.544 Mbps).

Eligible health care providers (HCPs) must be:

- a health care provider;
- part of a not-for-profit organization; and
- located in a rural area (The one exception to this rule is the Internet provision).

Not-for-profit health care providers located in a rural or urban area may qualify for Internet access assistance if the organization pays toll charges (long distance) in order to access an Internet Service Provider. In this case, the health care provider may qualify to receive up to 30 hours or $180.00 per month, whichever is less, to pay for the toll charges. Internet providers are not part of the agreement and thus are not eligible for the program in any form. Service must be provided by telecommunications companies, all of which are eligible.

Support is also available for limited long distance charges for accessing the Internet. The level of support depends on the HCP's location and the type of service chosen, which is calculated individually for each HCP. An HCP can find out its level of support and total service charge prior to committing to a telecommunications service when it applies for assistance from USAC.

Support for Telemedicine at the State Level

Legislation

Three pieces of legislation specifically pertaining to telemedicine reimbursement were passed during Texas' 75th Legislative Session (1997):

- House Bill (H.B.) 2017 addressed the need for provider reimbursement by all payors, not just Medicaid, for telemedicine services. For example, the Texas Tech University Health Science Center provides a variety of telemedicine services ranging from teleradiology to health care consultations to prisons, yet receives no reimbursement for these services. H.B. 2017 requires the Health and Human Services Commission (HHSC) to develop and implement a system to reimburse providers for services performed using telemedicine. The bill also directs HHSC to encourage university affiliated teaching hospitals, small rural hospitals, federally qualified health centers, and state-owned health care facilities to participate as telemedicine service providers in the health care delivery system.

- H.B. 2033 prohibited health benefit plans from excluding a service from coverage under the plan solely because the service was provided through telemedicine and not a face-to-face consultation. The bill also covered informed consent and confidentiality issues by requiring providers to ensure that informed consent is obtained before telemedicine services are provided and that providers take steps to protect the patient's confidentiality under the Medical Practice Act.

- H.B. 2386 directs the Health and Human Services Commission to require, by rule, agencies administering a part of the Medicaid program to provide Medicaid reimbursement for certain telemedical consultations. The bill allowed health professionals who practice in a rural health facility and who conduct a telemedicine consultation for a Medicaid patient to be reimbursed under certain circumstances. The health professional must be an advanced nurse practitioner, an allied health professional, a mental health professional, a physician, or a physician assistant who is licensed in this State.

Despite the passage and implementation of the above-referenced legislation, expansion of telemedicine services by rural providers has been slow. Telemedicine is successfully being utilized in the State's correctional managed care program through the academic health science centers; however, this system does not always utilize local providers. Likewise, increasing access to reimbursement is only a part of the solution

for optimum utilization of telemedicine. Without infrastructure and appropriate support, the potential of telemedicine will not be realized.

Additional Policy Considerations

Telemedicine and Local Service Delivery

It has become increasingly evident that the only way to keep rural health care providers viable is to ensure that local dollars are directed to local and regional practices. Traditional referral patterns must be protected whenever possible to support the economic contribution of health care providers to local economies. The rural health infrastructure is extremely fragile and easily disrupted. The development of an infrastructure to support telemedicine should include components to recognize and support local providers, avoid short and long-term negative consequences for the local economy, and ensure the sustainability of the local health care infrastructure.

Provider Licensure

Often, a medical provider who consults via telemedicine lives in a different state and is not licensed to practice outside that state. This may cause a problem in paying the out-of-state provider for his or her services and may raise questions about whether state licensing regulations are being violated.

Malpractice Liability

The use of telemedicine complicates the determination of the responsible party when an error occurs. An example is the difficulty of determining which state has jurisdiction to hear complaints when parties are located in different states. It is also possible that malpractice suits related to the use of telemedicine will increase because of the impersonal nature of the service. Conversely, malpractice suits may decrease because videotapes of the encounter would offer fairly definitive proof of whether malpractice has occurred.

Patient Confidentiality

Privacy and confidentiality of health care information is an issue that is receiving increased attention at both the state and federal level. It is imperative that any telemedicine policy deliberations include the critical need

to protect the privacy of patient specific health information. As standards for physical security and transmissions of electronic data are set, the cost of complying with those standards may increase.

Insurance Reimbursement

Medicare and most insurance carriers are accustomed to traditional face-to-face encounters between physicians and patients and are hesitant to accept telemedicine encounters as reimbursable services. However, some progress has been made in recent years. The Balanced Budget Act of 1997 now allows Medicare to reimburse for telehealth services. During the past several years, Medicaid regulations also have afforded states greater flexibility in this area.

Through telemedicine, unnecessary patient travel to tertiary care facilities can be avoided. However, for telemedicine to reach its full potential, states will need to incorporate health care applications into their telecommunications planning and develop interconnection capabilities among and within states.

Conclusion

Texas policymakers recognize that the rural and frontier health infrastructure must be strengthened to develop and maintain a sufficient statewide health care delivery system. Texas has taken steps to address significant barriers to rural and frontier health care delivery. Implementing approaches to address the unique challenges that rural and frontier communities face cannot be done through a singular effort or in a haphazard fashion. Texas is facing opportunities through new technology that will build and support the health care capacity and infrastructure in its communities. As we continue to explore methods to ensure an adequate number and mix of rural and underserved area health professionals, an emphasis should be placed on recruitment and retention of health care providers and the promotion of the appropriate use of telemedicine.

Recommendations

1. Require the Center for Rural Health Initiatives to coordinate with various agencies to assist in evaluating existing telemedicine programs and policy. The Center shall also ensure the appropriate development and use of telecommunications and technology in health care settings.

   Rationale: *Currently, there is no single entity charged with collecting information on existing telemedicine projects, assessing current programs, or predicting the feasibility of proposed projects.*

2. Expand TIF fund eligibility to include for-profit physicians in rural or underserved areas.

   Rationale: *For-profit physicians practicing in rural and underserved areas are often unable to incorporate telemedicine into their practices since they are excluded from receiving TIF funds.*

3. Require the Center for Rural Health Initiatives to develop a uniform definition for telemedicine.

   Rationale: *Currently, State law and agency regulations include differing definitions for telemedicine. A uniform definition is necessary to facilitate consistency in reimbursements and rulings. In addition, the current definitions are so narrowly written that they cannot adapt to the ever-changing technology industry, i.e., "still image capture" (or store/forward) and audio/video clip.*

4. Direct the Legislative Budget Board to prepare a cost analysis projecting the cost of including pharmacists, occupational therapists, physical therapists, and mental health providers in the list of health professionals eligible to receive Medicaid reimbursement for telemedicine services.

   Rationale: *These professionals are recognized as providers under Medicaid, but are not reimbursed for telemedicine services.*

5. Modify definition of "HUB" site facility/provider in the State Medicaid code to remove the requirement that the "HUB" site facility/provider must be affiliated with an accredited allopathic or osteopathic medical school.

   Rationale: Currently the HUB site must be affiliated with a medical school. This designation has deterred other providers from utilizing telemedicine.

6. Create a Rural Community Investment Program to allow communities, through a newly created state loan repayment or stipend program, an opportunity to recruit health care professionals who are willing to locate in their rural or underserved community.

   Rationale: Rural communities suffering from a health provider shortage struggle to recruit and retain health care professionals.

INTERIM CHARGE 6

Children’s Health Insurance Program (CHIP) Implementation

CHIP Implementation
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Children's Health Insurance Program

Interim Charge #6

Monitor the implementation of S.B. 445, 76th Legislature, Regular Session relating to the Children's Health Insurance Program.

Background

The Federal Balanced Budget Act (BBA) of 1997 established the State Children's Health Insurance Program (Title XXI of the Social Security Act), making $48 billion (over a period of 10 years) in federal grants available to states to provide health care coverage. The grants are available to Texas at a better match rate than previously given under Medicaid. The federal government matches the state dollars 74 percent to 26 percent respectively. This past legislative session, Texas utilized a portion of the tobacco settlement dollars to fund the State's share, which totaled $179.6 million in Article XII of the General Appropriations Act.

States were given the option of either expanding Medicaid, creating or expanding a non-Medicaid children's health insurance program, or implementing a combination of both options.[1] (see Appendix P) Texas chose a combination of both options, but in order to secure the State's allotment of funds for the first year of the program, Texas submitted a proposal to implement Phase I of the CHIP in March 1998. The first phase of the CHIP plan extended Medicaid coverage to children between the ages of 15 and 18 in families with incomes below 100 percent of the federal poverty level (FPL) ($16,700 for a family of four), making coverage available to 56,000 children.

In 1998, Lieutenant Governor Bob Bullock appointed the Texas Senate Interim Committee on Children's Health Insurance to review Texas' options and provide policy direction. The committee recommended that the Legislature authorize and fund a state-designed CHIP plan. In 1999, the Legislature responded and passed S.B. 445, which created the Children's Health Insurance Program (CHIP). The second phase of CHIP creates a separate children's health insurance program for children through age 18 whose families have

[1] Health Care Financing Administration, *Children's Health Insurance Program*, (visited June 200)< http://www.hcfa.gov/init/chip-map.htm>.

incomes up to 200 percent of FPL and who do not qualify for Medicaid ($34,100 for a family of four).[2] Approximately 478,000 children are estimated to be eligible for CHIP Phase II. The families are required to cost-share at certain income levels; these levels are based on a federal formula using the family's income and a portion that has been deemed an appropriate and affordable percentage. (see Appendix Q)

Senate Bill 445 directs the HHSC to develop and conduct an education and outreach program, utilizing community-based organizations. In response, a generic outreach campaign was developed to encompass CHIP Phase II, Medicaid, and the Texas Healthy Kids Corporation (THKC). The TexCare Partnership is the umbrella outreach campaign targeted to all families with uninsured children, regardless of income or citizenship status. When a family applies to the TexCare Partnership, they will be linked to the appropriate children's health insurance program based on family size, income, and citizenship status. The bill requires coordination between the Medicaid program, CHIP, and the Texas Healthy Kids Corporation so that health insurance coverage is sustained regardless of fluctuations in income. Some families will be referred to Medicaid, some will be determined eligible for CHIP, and others will be referred to the Texas Healthy Kids Corporation. It is important to note that S.B. 445 does not include a mandate for the CHIP program to be administered by the Texas Healthy Kids Corporation, but the bill clearly states that it is the intent of the Legislature that the CHIP program utilizes private resources to the greatest extent possible.

Families with CHIP-eligible children must complete an enrollment form in which they choose a health plan and Primary Care Provider (PCP) and pay the applicable cost-sharing obligation. In areas covered by the EPO (Exclusive Provider Organization), the children will be enrolled in the EPO without any PCP selection (EPO coverage is primarily for families that reside in the rural areas). Senate Bill 445 includes waiting periods for enrollment to help deter crowd-out; however, exceptions were included for those who lose insurance because of unforeseen events such as business closures and layoffs. Health care providers may undertake a variety of activities designed to encourage families to apply to the TexCare Partnership. Examples include, but are not limited to: displaying posters, brochures, or other written materials, distributing application booklets to families with uninsured children, and playing a video that promotes the TexCare Partnership and informs the patients of the toll-free hotline. Providers may distribute or display written health educational materials or health-related posters, provided it is done for all plans in which the providers participate. These materials may

[2] Children up to 100 percent of federal poverty are already covered by traditional Medicaid and the Medicaid expansion authorized under CHIP Phase I.

include the health plan's name, logo, and phone number. Providers are one of the main avenues by which the program is being marketed to the uninsured. The TexCare Partnership has also contracted with community-based organizations (CBOs) to aid in recruitment and education. Families that have not had private coverage in the past often do not know how to effectively utilize the system.

In order to implement the program, HHSC procured contractors for: health plan services, administrative services, marketing and media services, community-based organization outreach services, dental services, and quality monitoring and assurance services. While all of the CHIP procurements were important, the procurement for comprehensive administrative services was particularly critical, given the key functional responsibilities assigned to this contract. Many of the statutory requirements inherent in S.B. 445 are implemented through this contract, including the following:

- Cost-sharing;
- The 90-day waiting period as well as the exceptions to the waiting period;
- Referrals to Medicaid, Texas Healthy Kids, and the Employees Retirement System (per S.B. 1351);
- Identification and tracking expenditures for state-funded immigrant children; and a
- Toll-free hotline.

Implementation of S.B. 445

The following is a chronological summary of the primary events surrounding the implementation of S.B. 445. The chronology is grouped by events as they occurred within each month. Within each monthly group, the order of the events is not necessarily a reflection of the order in which the events occurred, since many of the events within a month occurred simultaneously. The timeline begins with events that occurred in June 1999 and ends with events through June 2000. The seminal CHIP event, the final passage and signing of S.B. 445, is not indicated here because it occurred in May 1999.

June 1999

- Submission of Title XXI state plan amendment to HCFA;
- Release for public comment of draft Requests for Proposal (RFPs) for comprehensive administrative services, media/marketing services, and health plans;
- Beginning of initial set of focus groups to test outreach themes, outreach approaches, application design, and attitudes toward health insurance; and
- Completion of work on initial draft of joint application.

July 1999

- Revisions based on public comment of the draft RFPs for comprehensive administrative services, media/marketing services, and health plans;
- Release of final RFPs for comprehensive administrative services and media/marketing services;
- Proposers' conferences for comprehensive administrative services and media/marketing services procurements;
- Completion of initial set of focus groups to test outreach themes, outreach approaches, application design, and attitudes toward health insurance; and
- Initial interagency work on revisions to the joint application based on focus group research.

August 1999

- Release of final RFP for management services and health plans;
- Proposers' conference held for health plans' procurement;
- Public comment taken on draft joint application; and

- Release for public comment of draft RFP for community-based organization (CBO) outreach.

September 2000

- Proposals due and evaluations begin for administrative services, media/marketing services, management services, and health plans;
- Public comment ends on draft joint application;
- Application undergoes considerable revision based on public comment and interagency vetting;
- Public comment period ends on draft RFP for CBO outreach; and
- RFP is subsequently revised to reflect public input.

October 1999

- Contract tentatively awarded to Sherry Matthews Advertising for media/marketing services;
- Contract tentatively awarded to Birch & Davis Health Management Corporation for comprehensive administrative services;
- Contract tentatively awarded to THKC for management services covering every primary contract area except dental services;
- Evaluations of health plans' proposals continue;
- Release of final RFP for CBO outreach; and
- Conducted regional CBO outreach proposers' conferences (eight in all).

November 1999

- HCFA approves CHIP Phase II state plan amendment;
- Next round of focus group testing occurs with an emphasis on the draft joint application and possible TV and/or radio themes;
- Contracts for health plans tentatively awarded to FirstCare, Texas Universities Health Plan, Americaid, Parkland, Cook Children's, UTMB, Texas Children's, Driscoll, Mercy, Superior, and Valley Baptist;
- Release of final RFPs for quality monitoring, Exclusive Provider Organization (EPO), and dental services; and
- Proposals due for CBO outreach.

December 1999

- Joint application finalized;
- Regional evaluations of CBO proposals (eight different interagency teams evaluate proposals divided up by public health region);
- Contracts executed with Sherry Matthews Advertising and Birch & Davis; and
- Toll-free hotline activated initially as a roll-over from the national "Insure Kids Now" hotline (until April 3, all calls to the hotline were handled through an automated voice system).

January 2000

- Third round of focus group testing occurs with an emphasis on the draft written material, TV and radio concepts, and branding of the campaign;
- "TexCare Partnership" is designated as the outreach campaign's generic identity;

- Contracts for health plans are executed with FirstCare, Texas Universities Health Plan, Americaid, Parkland, Cook Children's, UTMB, Texas Children's, Driscoll, and Mercy;
- Valley Baptist withdraws from the health plan procurement;
- Vista/El Paso First is tentatively awarded a health plan contract;
- Contract tentatively awarded to Clarendon National Insurance Company for EPO services and USA-MCO is tentatively awarded the bid for network management services (as a Clarendon subcontractor);
- Superior Health Plan withdraws its HMO bid to cover the El Paso area;
- Contract tentatively awarded to Safeguard Health Enterprises for dental services;
- Contracts for community-based outreach are tentatively awarded to 50 CBOs;
- Regional negotiations take place with each CBO; and
- HHSC withdraws the quality monitoring procurement based on cost and indicates intent to re-issue a modified RFP.

February 2000

- Initial printing of application booklets (300,000), brochures (two million), and posters (240,000) with all materials printed in English and Spanish;
- THKC is authorized to begin hiring CHIP-dedicated staff and incurring costs in advance of contract execution; initial regional and Austin-based staff are hired;
- Birch & Davis begins regional-based training of CBOs;
- Employees Retirement System (ERS) and HHSC agree to develop a stand-alone application for the State Kids Insurance Program;

- Program SKIP, is also known as the enhanced subsidy program;
- Health plan contract is executed with Vista/El Paso First; and
- CBO contracts are executed.

March 2000

- Production of TV and radio ads;
- Revised quality monitoring RFP is released;
- THKC continues hiring regional and Austin-based staff and provides implementation support, particularly in areas pertaining to the CBOs and health plans;
- THKC, with the support of staff from several state agencies, begins readiness reviews of health plans, Birch & Davis, and Sherry Matthews Advertising;
- Birch & Davis completes the initial round of staff training and tests, and installs the CHIP automated system, completes the call center infrastructure, prints enrollment materials, and awards subcontracts for mail-house operations, premium collections, printing, and other services;
- CBOs begin their community-based outreach efforts; and
- THKC mails application booklets to families on THKC waiting lists.

April 2000

- "Kick-off" news conference events are held throughout the state;
- Birch & Davis begins accepting and processing applications and distributing enrollment materials;
- With the assistance of the Office of the Attorney General, application booklets are mailed to custodial parents with children who are the objects of a medical support order;

- DHS mails a TexCare Partnership tri-fold brochure to families who are on food stamps and who have at least one uninsured child not eligible for Medicaid;
- Broad-based outreach partnership with the Texas Workforce Commission (TWC) begins;
- THKC continues readiness reviews of the health plans and completes initial reviews of Birch & Davis and Sherry Matthews Advertising;
- Ongoing THKC implementation support;
- Proposals due and evaluations begin for quality monitoring;
- Contract for quality monitoring services tentatively awarded to the Institute for Child Health Policy, which is affiliated with University of Florida in Gainesville;
- Second printing of application booklets (500,000);
- SKIP application is printed and distribution to state agency benefit coordinators; and
- Dental services contract award to Safeguard is withdrawn and a subsequent tentative contract award is made to United Concordia Companies of Pennsylvania.

May 2000

- Initial TV and radio media flight airs in 12 primary media markets;
- THKC completes initial readiness reviews of health plans;
- Ongoing THKC implementation support;
- Health plan coverage begins with the exception of dental services;
- Targeted CHIP application mailing to families with children who are enrolled in THKC; and
- Print-run of 5.3 million black-and-white “mini” application booklets (approximately three million were initially distributed to CBOs).

June 2000

- More than 17,000 children are enrolled and able to access services;
- Dental services begin;
- Contract executed with United Concordia Companies;
- THKC Board of Directors votes and HHSC agrees not to execute the CHIP management services contract with HHSC; and
- Telethon concept piloted in conjunction with San Antonio station KSAT (an ABC affiliate).

CHIP Enrollment

The following chart depicts the current (as of August 14, 2000) CHIP enrollment as a percentage of estimated CHIP eligibles, comparing Texas' progress with other states. A graphic representation of these figures is located in Appendix S.

	Arizona	**California**	**Florida**	**Michigan**	**New York**	**Texas**
Month 1	2,252	4,600	1,526	5	200	30
% of est. eligibles	*3.57%*	*0.77%*	*0.59%*	*0.01%*	*0.05%*	*0.01%*
Month 2	3,710	10,500	2,088	27	2,250	17,032
% of est. eligibles	*5.88%*	*1.75%*	*0.81%*	*0.06%*	*0.58%*	*3.56%*
Month 3	5,283	20,200	10,949	62	3,118	36,164
% of est. eligibles	*8.37%*	*3.37%*	*4.23%*	*0.13%*	*0.80%*	*7.57%*
Month 4	8,149	32,400	16,566	96	5,784	59,819
% of est. eligibles	*12.91%*	*5.41%*	*6.40%*	*0.20%*	*1.49%*	*12.51%*
Month 5	10,578	43,900	20,514	182	7,704	80,000
% of est. eligibles	*16.76%*	*7.33%*	*7.92%*	*0.39%*	*1.98%*	*16.74%*
Month 6	11,458	54,800	23,316	3,401	10,327	*not*

% of est. eligibles	*18.16%*	*9.15%*	*9.00%*	*7.24%*	*2.65%*	*available*
Estimated eligibles	63,100	599,000	259,000	47,000	389,000	478,000

Source: Texas Health and Human Services Commission

Cost

The following table illustrates estimated state costs for the CHIP program.

LBB Cost Estimates (Dollars in Millions: GR and Tobacco)

Coverage Area	FY 2000	FY 2001	FY 2002	FY 2003	FY 2004
CHIP Phase I	$17.78	$10.98	$4.12	NA*	NA*
CHIP Phase II	$15.42	$80.76	$120.99	$131.73	$137.11
Medicaid Spillover**	$5.10	$18.71	$31.62	$34.17	$34.59
Legal Immigrants	$2.40	$4.63	$7.48	$7.95	$7.95
As a result of S.B. 445	$22.92	$104.1	$160.09	$173.85	$179.65
State Employees***	$0	$13.15	$14.20	$15.34	$16.57
Grand Total	$40.70	$128.23	$178.41	$189.19	$196.22

* CHIP Phase I caseload is eventually absorbed by the traditional Medicaid program.

** The original Health and Human Services Commission estimates of Medicaid spillover prepared in 1999 are roughly double those prepared by the LBB.

*** Coverage for state employee children begins September 1, 2000. No fiscal impact in FY 00.

Conclusion

The Texas Children's Health Insurance Program, TexCare Partnership, offers an unprecedented opportunity to Texas' families. CHIP has successfully made coverage available to children who lack health insurance. A projected 80,000 children (a number that is equal to 17% of the target CHIP population of 479,000) who were previously uninsured, will have quality health care coverage as of September 1, 2000, as will several thousand Medicaid eligible children. In the fourth month of implementation, August 2000, an estimated 71,271 children have been identified as enrolled in CHIP. (see Appendix R)

The Health and Human Services Commission in partnership with the Texas Department of Health, Department of Human Services, and Department of Insurance, implemented the program three months ahead of schedule and five months before the statutory deadline. This effort has been accomplished through various entities including: community-based organizations, health care providers, social workers, and state agencies. Consistent with the requirements of S.B. 445, HHSC has succeeded in maximizing private resources by contracting almost exclusively with private entities, with the exception of several community-based organizations and the quality assurance contractor.

Further implementation of S.B. 445 will reveal areas for continued refinement. CHIP alone cannot solve all of the systemic challenges in the State's health care system. For example, there are areas in the state, both rural and inner city, where an insufficient number of providers have decided to establish practice. With the waning federal commitment to encourage providers to practice in medically underserved areas, the State should explore creative ways of improving access to care in those areas. In addition, for many families who live and work in the cash economy, making payments by a check or cashier's check represents a genuine hardship. This impediment should be addressed to ensure that the State does not erect over-burdensome barriers to families seeking health care coverage for their children. With the CHIP program in operation for less than five months at the time that this report went to press, much of the available data is still preliminary. Further initiatives will become apparent with the accumulation of additional program data.

Recommendations

1. The Health and Human Services Commission shall continue to monitor the progress of the Children's Health Insurance Program and, as required by statute, report back to the 77th Legislature.

Rationale: *It is too early to make comprehensive policy recommendations based only upon the first four months of full implementation and coverage of CHIP.*

2. The Health and Human Services Commission shall investigate the benefits of reimbursing for telemedicine services under CHIP and also coordinate with the Legislative Budget Board to determine if the use of telemedicine could result in cost savings to the State. Telemedicine should complement, not replace, the existing health care provider infrastructure.

   Rationale: *In rural and underserved areas of the State, telemedicine could be an effective tool to deliver services to children who do not have adequate access to the appropriate health care provider.*

3. HHSC may adopt policies to allow families with children enrolled in CHIP to pay monthly or annual premiums with a cash payment.

   Rationale: *For some families, it is not possible to make payment by check or cashier's check. This recommendation is consistent with programs that allow families to pay their utility bills with cash at a designated location.*