HOUSE COMMITTEE ON PUBLIC HEALTH
TEXAS HOUSE OF REPRESENTATIVES
INTERIM REPORT 2006

A REPORT TO THE
HOUSE OF REPRESENTATIVES
80TH TEXAS LEGISLATURE

DIANNE WHITE DELISI
CHAIRMAN

COMMITTEE CLERK
TOM A. MCCARTY

Committee On
Public Health

November 15, 2006

Dianne White Delisi
Chairman

P.O. Box 2910
Austin, Texas 78768-2910

The Honorable Tom Craddick
Speaker, Texas House of Representatives
Members of the Texas House of Representatives
Texas State Capitol, RM 2W.13
Austin, Texas 78701

Dear Mr. Speaker and Fellow Members:

The Committee on Public Health of the Seventy-Ninth Legislature hereby submits its interim report including recommendations for consideration by the Eightieth Legislature.

Respectfully submitted,

Dianne White Delisi

Jodie Laubenberg

Vicki Truitt

Garnet Coleman

Jim McReynolds

Jim Solis

Glenda Dawson

Jim Jackson

Bill Zedler

Jodie Laubenberg
Vice-Chairman

Members: Vicki Truitt, CBO, Garnet Coleman, Glenda Dawson, Jim Jackson, Jim McReynolds, Jim Solis, Bill Zedler

This report is dedicated to the memory and public service of
Representative Glenda Dawson

1941-2006

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INTRODUCTION

At the beginning of the 79th Legislature, the Honorable Tom Craddick, Speaker of the Texas House of Representatives, appointed nine members to the House Committee on Public Health. The committee membership included the following: Chairman Dianne White Delisi, Vice-Chairman Jodie Laubenberg, CBO Vicki Truitt, Garnet Coleman, Glenda Dawson, Jim Jackson, Jim McReynolds, Jim Solis, and Bill Zedler.

Pursuant to House Rule 3, Section 34, the Committee has jurisdiction over all matters pertaining to:

> (1) the protection of public health, including supervision and control of the practice of medicine and dentistry and other allied health services;
>
> (2) mental health and the development of programs incident thereto;
>
> (3) the prevention and treatment of mental illness;
>
> (4) oversight of the Health and Human Services Commission as it relates to the subject matter jurisdiction of this committee; and
>
> (5) the following state agencies: the Department of State Health Services, the Anatomical Board of the State of Texas, the Texas Funeral Service Commission, the State Committee of Examiners in the Fitting and Dispensing of Hearing Instruments, the Texas Optometry Board, the Radiation Advisory Board, the Texas State Board of Pharmacy, the Board of Nurse Examiners, the Texas Board of Chiropractic Examiners, the Texas Board of Physical Therapy Examiners, the Texas State Board of Podiatric Medical Examiners, the Texas State Board of Examiners of Psychologists, the State Board of Dental Examiners, the Texas State Board of Medical Examiners, the Advisory Board of Athletic Trainers, the Dental Hygiene Advisory Committee, the State Board of Barber Examiners, the Texas Cosmetology Commission, the Texas Cancer Council, the Texas State Board of Acupuncture Examiners, the Health Professions Council, the Office of Patient Protection, the Texas Board of Occupational Therapy Examiners, the Texas State Board of Examiners of Perfusionists, and the Texas Health Care Information Council.

During the interim the Committee was assigned five charges by the Speaker:

- Examine the selected scope of practice issues related to health professions which maintain the safety of patients through demonstrated competency and education, and balance improved cost efficiency within the health care system.
- Consider the state's role and approach to Medicare Part D, and evaluate the impact to Texas Medicaid clients.
- Study emerging practices for the prevention of hospital-acquired infections, and develop effective policies for incorporating these best practices into the delivery of health care in Texas.

- Review issues relating to Chapter 166.046 of the Texas Health & Safety Code, and assess if patients and/or their loved ones have a sufficient opportunity to obtain transfer to an alternate facility and subsequent care in end-of-life situations.
- Evaluate the need for regulation of laser hair removal facilities in Texas and the need for certification of individuals performing laser hair removal procedures.
- Examine the compliance of cigarette manufacturing companies with the 1998 Tobacco Settlement with reference to sales to minors and progress toward meeting the state's tobacco use goals, and the cost of tobacco use to the state. (Joint Interim Charge with the House Committee on State Affairs)
- Monitor the agencies and programs under the committee's jurisdiction.

The Committee has completed their hearings and investigations. The Committee on Public Health has adopted and approved all sections of the final report.

Finally, the Committee wishes to express appreciation to the agencies, associations and citizens who contributed their time and effort on behalf of this report.

HOUSE COMMITTEE ON PUBLIC HEALTH

INTERIM STUDY CHARGES

CHARGE Examine the selected scope of practice issues related to health professions which maintain the safety of patients through demonstrated competency and education, and balance improved cost efficiency within the health care system.

CHARGE Consider the state's role and approach to Medicare Part D, and evaluate the impact to Texas Medicaid clients.

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CHARGE

SCOPE OF PRACTICE

Examine the selected scope of practice issues related to health professions which maintain the safety of patients through demonstrated competency and education, and balance improved cost efficiency within the health care system.

BACKGROUND

During the 79th Legislative Session, the House Committee on Public Health received testimony and eventually passed fifteen "sunset bills" that were referred to the committee. During the hearing process, the debate to amend the bills for various scope of practice[1] issues emerged.

HB 2706 by Representative Dianne White Delisi would have established a Health Professions Scope of Practice Review Commission. The bill was considered in the 79th Regular Session in 2005, voted out of committee, and placed on the General State Calendar in the House on May 12, 2005. No further action was taken.

- The proposed Health Professions Scope of Practice Review Commission would have researched scope of practice issues at the written request of a member of the Texas Legislature. The commission was to consist of the commissioner of the Department of State Health Services (DSHS), an employee of the Legislative Budget Board in the Texas Performance Review section, a representative of the Office of Patient Protection, a representative of the Health Law and Policy Institute, an employee of the Texas Legislative Council with expertise in scope issues, an employee of the Texas Higher Education Coordinating Board with expertise in health care education issues, the director of the Sunset Advisory Commission, and two representatives of the public.

- By December 31 of each even-numbered year, the commission was to report the results of their reviews to the Governor, Lieutenant Governor, Speaker of the House of Representatives, and House and Senate standing committees that deal with financial and health and human services issues. A member of the legislature who proposed change in a scope of practice was authorized to request the commission to analyze the bill. The report was to include evidence-based analysis of changes submitted to the commission by a member of the legislature by August 31 of each even-numbered year. The analysis was to be provided before the second reading of the bill, and the analysis was to be made available to the public.

INTERIM STUDY

The Texas House Committee on Public Health was issued the "Scope of Practice" interim charge on October 19, 2005, by Speaker Tom Craddick. The committee held a two-day public hearing to receive testimony on this charge. On June 15, 2006, the committee heard invited testimony, followed by public testimony from interested stakeholders on June 16, 2006.

Prior to the committee hearing, the committee identified twenty health professions with a combined forty-five identified scope of practice issues. This list was compiled through review of legislation filed in previous legislative sessions and staff meetings with various health professions' associations.

Dr. Ben Raimer, Chair of the Statewide Health Coordinating Council (SHCC), provided testimony to the committee on the demographics of the state and the pressures affecting Texas' health system. Dr.

[1] Scope of Practice defines health care services that a particular health profession is authorized to perform through licensure, registration, or certification.

Raimer highlighted the fact that Texas' population is increasing at twice the rate of the U.S. population in general. Dr. Raimer, referring to the pressures affecting the health system as "the perfect storm[2]", presented data highlighting workforce shortages in various professions dealing with healthcare delivery. According to Dr. Raimer, a common theme among these professions is that, over the past six years, Texas saw a leveling off of the number of healthcare professionals[3] per 100,000 of Texas population. An example can be seen in Figure 1, which demonstrates the leveling off of Registered Nurses (RNs).

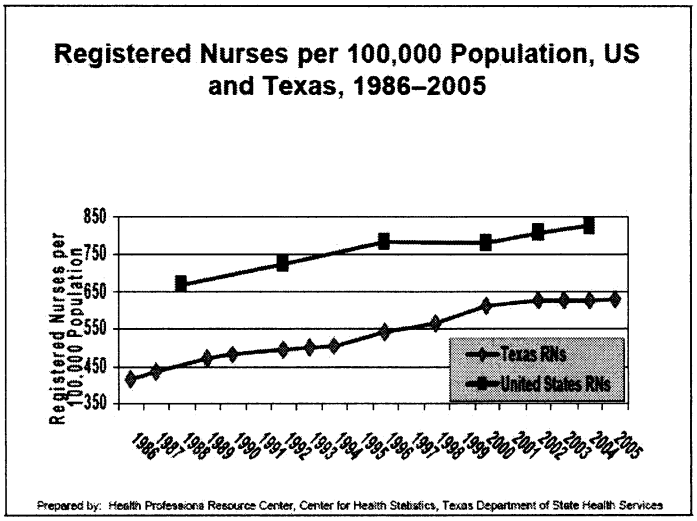


Figure 1

In 2005, there were 144,602 active RNs working in Texas. The data shows the number of RNs per 100,000 people rose significantly from 1988 to 1996 and then leveled off from 2001 to 2005. Dr. Raimer noted that supply ratios have been below the U.S. supply ratios for decades. Metropolitan counties had higher ratios than non-metropolitan counties, and border counties had much lower supply ratios than the rest of Texas. Four Texas counties did not have an RN in 2005. Median age of RNs in 2005 was 46, compared to 44 in 2000. According to Dr. Raimer, the only profession that did not see this leveling off trend was the Physician Assistant (PAs). The PAs have seen their number per 100,000 people rise steadily since 1991. (See Figure 2).

According to testimony provided by Dr. Raimer, 52 counties that did not have a PA in 1995 had at least one PA in 2005. However, in 2003 the metropolitan ratios surpassed the non-metropolitan ratios. The ratios of PAs per 100,000 people in border and non-border counties were similar. U.S. supply ratios have been consistently higher than Texas ratios. (See Figure 3).

[2] Raimer testimony to the Committee on Public Health, June 15, 2006, page 6.

[3] The health professions referenced in Dr. Raimer's testimony, as used in this interim report, are Direct Patient Care Physicians, Primary Care Physicians, Physician Assistants, Registered Nurses, Advanced Practice Nurses, Nurse Practitioners, Certified Nurse-Midwives, Certified Registered Nurse Anesthetists, Clinical Nurse Specialists, Licensed Vocational Nurses, Dentists, Dental Hygienists, Optometrists, Chiropractors, and Pharmacists.

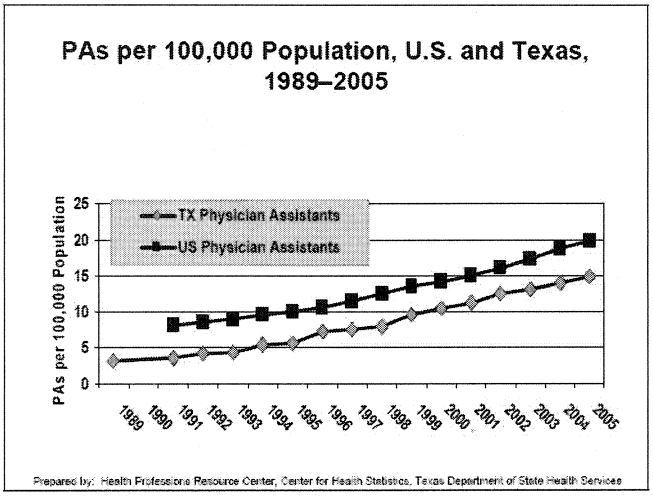


Figure 2

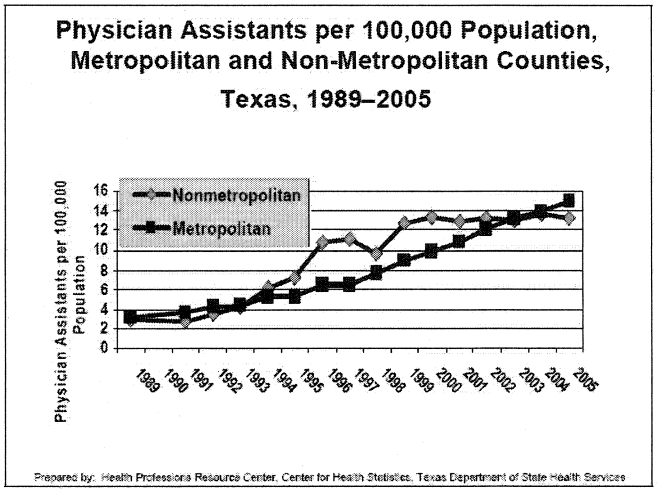
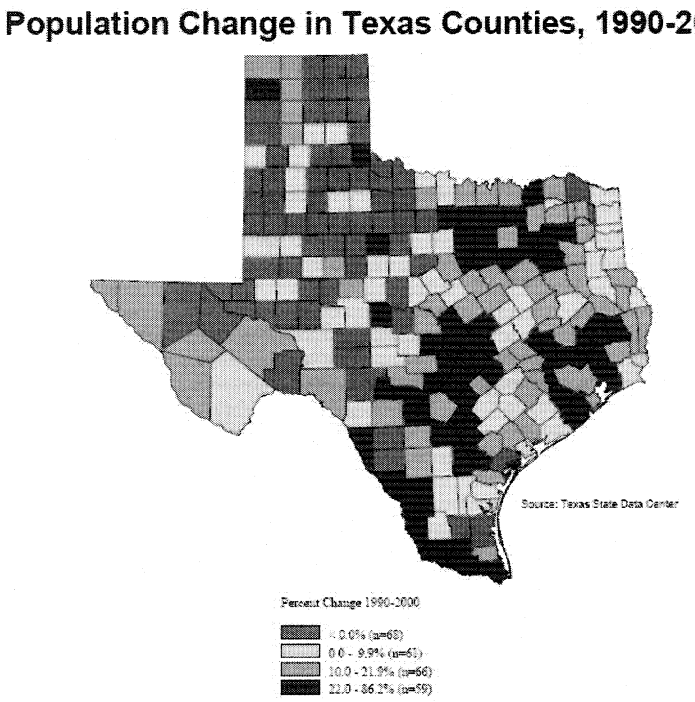


Figure 3

Figure 4



The Texas population has changed from 1990-2000. In the 1990s, Texas had more population in rural areas, as shown in Figure 4. As Texas' population increased, a shift from rural areas to urban areas occurred. According to state demographer Steve Murdock, the state's changing demographics directly affects the demand for health care services. From 1990 to 2000, Texas' population grew 22.8 percent, or 3.8 million.

In the last fifteen years, the population of Texas has been moving into major urban areas of the state. The Dallas/Ft. Worth Metroplex, the Houston area, Austin, San Antonio, and the border region have seen a continued increase in population (Figure 5).

In 2003-2004, the population distribution revealed that 86 percent of Texans lived in metropolitan areas, while 14 percent lived in non-metropolitan areas.[4]

From 2000 to 2005, Texas' population growth rate was double that of the nation. Future population growth in Texas is expected to outpace the nation, and in 40 years, the state is projected to grow by 71 percent.

[4] Kaiser State Health Facts. *Texas: Population Distribution by Metropolitan Status, states (2003-2004), U.S. (2004).* http://www.statehealthfacts.org.

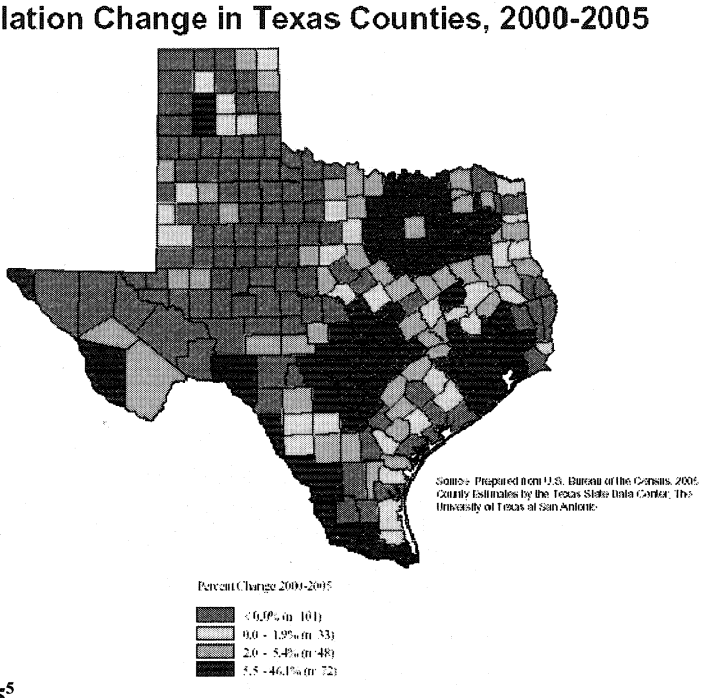


Figure 5[5]

Dr. Murdock testified that the demographics of Texas are changing, and that over 59 percent of our population will be of Hispanic descent by 2040. During that same time, aging of our "baby boomers" will result in twice as many Texans over age 65 by 2030 as in 2000.

Current health workforce resources are not keeping up with either the size or the diversity of the population.[6] Dr. Raimer described some unique challenges:[7]

- Aging of the workforce (physicians, nurses, etc.)
- Decreases in enrollment in health professional schools (largely due to a lack of professors and the lack of salary support)
- Although the increased number of women in the health professional fields is "good," one of the outcomes has been an actual decrease in the number of available practitioners as these individuals take time off to raise families or work "short weeks" to pursue other interests.
- The lack of aggressive promotion of career opportunities in the health professional arena has resulted in a generalized lack of interest in these careers, especially in the minority community.
- The actual supply of the workforce is impacted by age; as practitioners age, more are seeking early retirement and/or reduced hours.

Dr. Raimer cited some difficulty in collecting demographic data on healthcare professionals. He indicated that many health professional licensing boards still do not collect a "minimum data set"

[5] Dr. Murdock, written testimony to Committee on Public Health, June 15, 2006, page 14.
[6] Dr. Raimer, written testimony to Committee on Public Health, June 15, 2006, page 19.
[7] Ibid, page 10.

that enables the SHCC to adequately analyze and project workforce needs. [8]

In addition to overall population growth, Texas' population is also getting older and baby boomers are 25 percent of the state's population. This factor will increase the demand for healthcare services.. "Medical care will be driven faster than the overall population growth because of the aging population," Murdock said. In 2000, 81,000 Texans lived in nursing homes. At the projected rate of growth, this number is expected to be 309,000 in 2040.

Dr. Raimer testified that "as we all enjoy a longer life, our health issues become more complex, requiring additional access to care, more complicated technologies to address those problems, more medications, and a greater use of rehabilitative and long term care facilities." In order to address this trend, Dr. Raimer stated that an endless array of professional care-givers will be needed and that medical advances will require professionals who do not currently exist. He said that "we will need broadly trained professionals capable of multidisciplinary team work, and career matrices that permit professionals with basic training to move quickly and competently from one arena of health care to another as these systems develop."[9]

According to Dr. Raimer, "we may never catch up with the demand for these rapidly increasing health service requirements, [and] we need to think 'out of the box' and encourage pilot or demonstration projects that bridge these gaps." Dr. Raimer added, "since teaching faculty shortages in graduate health professional programs is such a difficult issue to address, perhaps financial incentives should be directed to those schools who merge faculty to provide instruction for duplicative courses. For instance, pharmacology, anatomy, physiology, etc., for medical students, nursing students, PA students, et. al. may be provided by common professors in campus or even regional groups. And, the use of distance education should be encouraged when faculty shortages are evident."[10]

The committee also heard testimony from Dr. Francisco Cigarroa, president of the University of Texas Health Science Center at San Antonio. Regarding the issue of scope of practice, he believes the patient should be the central focus in any decision or action that is made. Dr. Cigarroa stressed that one person needs to be in charge of determining a patient's treatment, but that a team of people is needed to provide complete care. He believes that there is adequate need for allied health professionals due to the shortage of physicians that many rural areas face.

COMMITTEE FINDINGS

The findings of the committee conclude that the legislature must develop both policy and budgetary initiatives in order to meet the changing demographics and pressing healthcare needs of Texas.

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[8] Ibid; page 12.
[9] Raimer, page 11.
[10] Raimer, page 14.

CHARGE

MEDICARE PART D

Consider the state's role and approach to Medicare Part D, and evaluate the impact to Texas Medicaid clients.

BACKGROUND

Introduced in June, 2003, and signed into law by the president in December of that year, the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 is an extensive reform measure affecting several portions of the Medicare program, including rural hospitals, inpatient services, preventive care services, graduate medical education, disproportionate share hospital allotments, and tax incentives for health and retirement security. The primary purpose of the legislation was the creation of two basic prescription-drug-related benefits: a temporary prescription drug discount card program with additional assistance for eligible low-income seniors, and the permanent, voluntary prescription drug benefit program. The prescription drug discount cards principally served as a transitional tool to assist seniors with outpatient prescription drug expenses in 2004 and 2005, until the permanent prescription drug benefit took effect. The discount cards were not available for Medicare beneficiaries who qualified for prescription drug coverage under Medicaid.

Effective January 1, 2006, the principal benefit established by the MMA, the voluntary prescription drug benefit program, represents the single largest expansion of the public health care system since Medicare was created in 1965. Under the program, Medicare's elderly and disabled beneficiaries can enroll in private plans that contract with the United States Department of Health and Human Services to provide outpatient prescription drug coverage. The new program also shifts responsibility for the prescription drug coverage of millions of low-income and disabled Medicare beneficiaries who also receive services through the Medicaid program (known as "dual eligibles") from the states to the federal government.

There are two types of plans available. Medicare Part D is the new stand-alone prescription drug plan (PDP) that provides only drug coverage, with all other Medicare benefits delivered through the traditional fee-for-service program, and Medicare Part C, renamed Medicare Advantage, delivers all of its benefits through a health maintenance organization or regional preferred provider organization. The prescription drug benefit is to be administered through 34 PDP regions and 26 Medicare Advantage regions nationwide (Texas constitutes its own PDP and Medicare Advantage region). Plans can operate in one or more regions.

The Medicare prescription drug benefit operates much like a typical insurance program. Beneficiaries pay a monthly premium, an annual deductible, and a copayment for each prescription filled. The amount of the deductible, monthly premium, and copayment depends on the specific plan chosen. The standard benefit, with a $250 deductible, will pay 75 percent of an enrollee's drug costs up to $2,250. There is a gap in coverage between $2,251 and $5,100 where the beneficiary is responsible for 100 percent of all prescription expenses. Medicare coverage resumes when an enrollee's out-of-pocket prescription costs total $3,600.[1] From that point forward, Medicare will cover 95 percent of an enrollee's prescription drug costs until the following year.

Each plan provider must design its drug benefit plan to meet certain minimum requirements

[1] Annual deductibles, monthly premiums, and the coverage gap (the difference between the initial coverage limit and the catastrophic threshold) are all indexed to rise between 2006 and 2014 with the growth in per capita Medicare drug benefit spending. In August, 2005, CMS estimated the average monthly premium will increase from $32.20 in 2006 to $64.26 in 2014, and the coverage gap from $2,850 in 2006 to $4,984 in 2014.

established by the Centers for Medicare and Medicaid Services (CMS). A plan's drug formulary must include at least two drugs from each therapeutic category covered under Medicaid and substantially all the drugs in certain categories, including antidepressants, antipsychotics, anticonvulsants, anticancer drugs, and immunosuppressants and antiretrovirals for treating HIV/AIDS. Plans must also provide in-network coverage to all enrollees who live in any nursing home in its region and follow guidelines that guarantee minimum access to retail pharmacies. Plan providers are given flexibility to employ cost management measures, such as preferred pharmacies and pharmacy networks, tiered cost-sharing, prior authorization, and quantity limits.

Another feature of the prescription drug benefit program is additional assistance for certain beneficiaries with limited incomes and resources. Medicare will provide partial subsidies to enrollees with incomes from 135 percent to 150 percent of the federal poverty level (FPL). Those beneficiaries who qualify for the partial subsidy will pay their premiums on a sliding scale and be responsible for 15 percent of their drug costs up to $5,100 with a copayment of $2 to $5 for each prescription thereafter. Enrollees with incomes between 100 percent and 135 percent FPL will have the same coverage but will not have to pay a premium. Full subsidies will be available for dual eligibles. Dual eligibles with an income below 100 percent FPL will not pay a premium or deductible and will have a copayment of $1 to $3 for each prescription. Dual eligibles with an income at or below 135 percent FPL who meet certain asset requirements will have the same coverage but will pay slightly higher copayments of between $2 and $5 per prescription. Dual eligibles in long-term care facilities will be exempt from premiums, deductibles, and copayments.

The benefit functions slightly differently under Medicare Advantage. Although the majority of Medicare Advantage beneficiaries already have prescription drug coverage, 26 percent were enrolled in plans that did not provide coverage in 2005. The MMA requires Medicare Advantage plan providers to offer at least one plan with a basic drug benefit like that featured in the stand-alone PDP. Alternatively, Medicare Advantage plans can offer enhanced drug coverage without charging an additional premium.

The complex policy interactions between Medicaid and Medicare wield significant influence over the federal-state fiscal relationship. Clearly, the implementation of the Medicare outpatient prescription drug benefit represents a significant change in that relationship. With Medicare, not Medicaid, paying for the drug coverage of dual eligibles, state Medicaid programs no longer receive federal matching funds that had previously reimbursed the states for expenses related to providing these prescriptions. Instead, the states now finance a majority of the Medicare benefit through "phased-down state contributions" or "clawback" payments. Each state is required to make a monthly payment to the Medicare program equal to a percentage of the amount the state would previously have spent to cover outpatient drugs for dual eligibles through Medicaid. The percentage "phases down" from 90 percent in federal fiscal year (FFY) 2006 to 75 percent in FFY 2015 and onward. The formula for determining a state's clawback payment for any given year is the product of (1) the state's 2003 monthly per capita drug spending for dual eligibles (adjusted for rebates and managed care) trended forward to 2006 by the estimated growth in overall per capita drug spending nationally as reflected in the CMS National Health Expenditure Accounts (NHE), (2) the number of full-benefit dual eligibles reported by the state in the preceding month, and (3) the phase-down

percentage specified by statute for that year.[2] Texas' 11 scheduled clawback payments for calendar year 2006 will total $274,067,264.[3]

The clawback provision has emerged as a subject of acrimony between the federal government and a number of states. Texas Governor Rick Perry has become a vocal critic of this policy and has taken a prominent role in seeking to have it changed.

Perry's first action, taken on June 5, 2005, was to veto the $444,255,834 in funds set aside in Senate Bill 1, the General Appropriations Act for fiscal years 2006-2007, to cover the state's clawback payments. The governor's reason's for doing so are stated in the veto proclamation:[4]

> "I continue to object to the Center for Medicare and Medicaid Services' interpretation of the state payment formula (i.e., clawback) and believe it penalizes states like Texas that have taken innovative steps to provide Medicaid drug benefits, control drug cost increases, and manage overall program costs trends. I am also concerned about new state administrative costs associated with the Medicare benefit and believe the federal government must clarify the federal-state roles and responsibilities in providing eligibility determination. Therefore, it is my intention to seek further changes at the federal level as soon as possible to ensure that the calculation of the clawback amount appropriately recognizes the aggressive efforts by Texas to reduce the rate of growth on prescription drug spending."

On May 3, 2006, Gov. Perry announced in a media release that Texas, joined by Kentucky, Maine, Missouri, and New Jersey, had filed a lawsuit with the U. S. Supreme Court over the clawback provisions.[5] Perry stated in the media release that nine other states had joined a friend-of-the-court brief filed by Arizona in support of the states filing the litigation.

At issue, Perry stated, was that the mandated clawback payments to the federal government established an unconstitutional direct tax levied upon the states "which usurps their sovereign powers and interferes with essential state business."

Perry also stated that Texas Attorney General Greg Abbott had estimated the mandated clawback payments could create a net loss for the state of $100 million over the next four years.

The lawsuit raises three specific questions to be examined by the Court regarding the constitutionality of the clawback.[6] They are:

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[2] The United States Secretary of Health and Human Services is required by statute to use the most recent NHE data to formulate states' clawback payments. In accordance with the February 2006 NHE revision, Texas is scheduled to pay $78.44 per dual eligible in FFY 2006 and $78.20 during the first quarter of FFY 2007. Texas' March 2006 full-benefit dual eligible count as reported by the Texas Health and Human Services Commission to CMS was 325,087.

[3] Kaiser Commission on Medicaid and the Uninsured, "An Update on the Clawback: Revised Health Spending Data Change State Financial Obligations for the New Medicare Drug Benefit." March 2006.

[4] Governor Rick Perry's Veto Proclamation, Health and Human Services Commission, B.2.3. Medicare Federal Give Back, June 18, 2005.

[5] "Texas Sues Federal Government Over Unfair Medicare Policy", Governor Rick Perry Press Release, March 3, 2006.

[6] Motion for Leave to File Bill of Complaint, Supporting Brief, and Bill of Complaint, Cause No. 135, Original In Case Styled, State of Texas, et al. v. Leavitt.

- Is the "clawback" an unconstitutional tax against the States in their sovereign capacities?
- Does the clawback impermissibly commandeer state legislatures to fund the federal Medicare program?
- Does the clawback violate the Constitution's Guarantee Clause by improperly usurping control of essential functions of state government?

The U. S. Supreme Court has declined to hear the case. The State of Texas is currently in consultation with the other states involved in the clawback litigation to determine their next course of action.

Federal Preparation for Implementation

Certain provisions of the MMA were specifically designed to facilitate the transition of dual eligibles and prevent interruption of prescription drug coverage. First, the legislation provided for automatic enrollment, effective January 1, 2006, in a drug plan for full-benefit dual eligibles who were not enrolled by December 31, 2005. Notifications of automatic plan assignments were sent in November, 2005. Plan assignments were based on criteria intended to minimize the disruption of the beneficiaries' current care, but full-benefit dual eligibles are permitted to switch plans at any time. Second, the MMA provided for automatic enrollment in the low-income subsidy for full-benefit dual eligibles. These beneficiaries, along with certain other groups that qualified for the assistance but who are required to apply, were notified of their enrollment or eligibility between May and October, 2005.

Texas Preparation for Implementation

Texas' preparation for Medicare Part D followed a similar approach to that of the federal government. The state first worked to identify dual eligibles and their specific needs, then planned for providing continuity of coverage, coordinating affected state agencies for the transition, and developing an outreach and education strategy to inform beneficiaries and appropriate health care professionals. Medicare beneficiaries who receive financial assistance from the State of Texas (full- and partial-benefit dual eligibles) fall into three categories: (1) those who get their prescriptions through Medicaid, (2) those who receive Medicaid assistance for Medicare-related expenses, and (3) those who receive aid for certain prescriptions from one of the Department of State Health Services' pharmaceutical assistance programs (the Kidney Health Care Program and Mental Health Medications Program). Combined, these populations represent approximately 500,000 Texans. Much of the challenge in preparing for the prescription drug benefit transition, however, is in the fact that these populations are fluid, often moving from one category to another and in and out of eligibility for certain benefits while remaining qualified for others. As a result of this crossover, several state agencies were affected by the implementation of the new benefit, demanding extensive coordination to meet federal expectations.

Recognizing this need, the Texas Health and Human Services Commission (HHSC) assembled an interagency team to devise the state's strategy to transition Texas' dual eligibles into Medicare. The team began its work in 2004, reprogramming agencies' computer systems to aggregate the state's dual eligibles and categorize them according to their coverage needs in anticipation of the monthly reports to CMS required by the MMA. This process also aided the state in developing its plan to maintain

continuity of coverage: Medicaid continues to pay for cost sharing for Medicare Part B covered drugs and to cover certain categories of drugs that are excluded from Medicare Part D formularies ("wrap-around" coverage).

The state's outreach was accomplished in three phases: research, information and awareness, and informing beneficiary of plan selection. The state conducted surveys and organized focus groups in an effort to pattern the state's outreach materials and techniques. These surveys revealed important information about the most effective methods for educating dual eligibles about the prescription drug benefit and the low-income subsidy. HHSC learned that most respondents preferred to receive communication about the benefit via mail and that community educational events were more likely to reach only certain constituencies. Armed with this feedback and with the help of a private public relations firm, Enviromedia, HHSC commenced its information and awareness campaign by launching a comprehensive Medicare Part D website and, beginning in July, 2005, with direct mailings to target populations introducing the new prescription drug benefit. This initial mailing announced the enrollment timeline and prepared beneficiaries for forthcoming correspondence from HHSC. The commission then hosted statewide stakeholder education sessions and training and, based on these engagements, further developed the agency's message for targeted mailings to inform specific beneficiary populations. The final stage of the state's transition plan took the form of a November 2005 mailing to inform beneficiaries of their plan selection options. The mailing included information on how to enroll or change prescription benefit plans and how to select the plan that best met the beneficiaries' needs. Full-benefit dual eligibles received individualized prescription match information detailing the drugs they required and the corresponding subsidized PDPs that covered those drugs. Texas was nationally regarded by a number of organizations for its preparation for the Medicare Part D implementation, and the state's information and awareness effort, Medicare Rx "Helping Texas Get It," was awarded the highest honor for a marketing campaign by the Texas Public Relations Association.

Nonetheless, throughout the enrollment period Texas beneficiaries experienced their share of the well-publicized imperfections in the Medicare Part D transition. Mailed notices of auto-enrollment were not always reliable, contributing to confusion among dual eligibles and caretakers. Beneficiaries were auto-assigned drug plans as of January 1, 2006, in spite of the fact that formulary matches were not available for evaluation because many PDP plans had not been finalized. Additionally, retail pharmacists, long-term care pharmacists, facility staff, and caseworkers were not immediately able to identify assigned plans, causing further uncertainty for enrollees. State facilities were also dealing with implementation issues. Under provisions of MMA, the large mental health and mental retardation facilities with in-house pharmacies are required to bill outside PDPs for prescriptions, but even after the implementation date, the PDP contracts were not yet in place. In response to these challenges, CMS announced a waiver program to extend federal reimbursement for prescription drug coverage provided under state Medicaid programs until the transition to Medicare was completed successfully. To further ease the transition and avoid disruptions in treatment, CMS required Medicare Part D plan providers to cover a 90-day supply of beneficiaries' existing prescriptions even if they were not included in the plan's Part D formulary. In April 2006, the Department of Health and Human Services (HHS) also announced that beneficiaries who qualify for the low-income subsidy will be allowed to enroll in a benefit plan beyond the May 15 deadline. Seniors who are otherwise eligible but do not qualify for this subsidy and who miss the enrollment

deadline will have to wait until 2007 to enroll and will be assessed a penalty in the form of an additional percentage applied to the cost of their prescriptions for the entire duration of their participation in the program. The amount of the penalty increases monthly until enrollment.

Many of the well-publicized difficulties with the Medicare Part D drug benefit can be attributed to the magnitude of enrolling so many people in a new program. However, the United States Government Accountability Office (GAO) was asked to review the quality of CMS's communications with potential enrollees relating to the benefit and reported that the material lacked clarity and was written at a reading comprehension level too high for many seniors.[7] This could explain early reluctance among seniors to enroll in the program, especially in light of the facts that many Medicare beneficiaries do not have a caretaker to guide them through the process and that the information available to pharmacists was limited as a result of the delayed development of PDP formularies.

Even so, on April 18, 2006, HHS reported that nearly 19.7 million beneficiaries were enrolled in a Medicare Part D prescription drug plan, and the Secretary of Health and Human Services predicted that, at that rate of enrollment, as many as 90 percent of eligible seniors could be enrolled by the deadline. The 19.7 million figure included 6.4 million beneficiaries dually eligible for Medicare and Medicaid, 594,000 of whom were enrolled in Medicare Advantage.[8] Twenty-seven percent of Medicare beneficiaries in Texas were without an identified source of creditable drug coverage as of that same date. The remaining 73 percent who do have creditable coverage in Texas comprised beneficiaries enrolled in stand-alone PDPs, beneficiaries enrolled in Medicare Advantage with prescription coverage, beneficiaries in employer plans with retiree drug subsidies, federal government retirees, and auto-enrolled dual eligibles. HHSC reported 325,087 full dual eligibles and 160,636 partial dual eligibles to CMS for the monthly count due March 1, 2006.[9]

Likewise, to account for the fluctuations in the dual-eligible population, determining a more precise fiscal impact of the Medicare prescription drug benefit to the state's Medicaid program will require data covering a longer period of time.

INTERIM STUDY

On February 15, 2006, the House Committee on Public Health held a public hearing to take invited testimony on the impact of the Medicare Part D interim charge. The committee received stakeholder input on the implementation and its impact on various stakeholders.

One issue of concern is the delayed enrollment of beneficiaries who expect to have their coverage available at the first day of the next month. A.J. Patel, a pharmacist speaking on behalf of the Texas Federation of Drug Stores, stated that CMS and the various Part D plans do not always have sufficient time to "process the application, confirm eligibility, and provide information to the plan and the TrOOP facilitator so that the information is in the pharmacy's system when the beneficiary comes into the pharmacy." The pharmacists report that it usually takes ten days to two weeks from

[7] The United States Government Accountability Office, Highlights of GAO-06-654, "Medicare: Communications to Beneficiaries on the Prescription Drug Benefit Could Be Improved." May 2006.
[8] The Henry J. Kaiser Family Foundation, "Medicare Prescription Drug Coverage Enrollment Update." April 2006.
[9] Texas Health and Human Services Commission, Texas Dual Eligible MMA Monthly Counts April 2005-February 2006.

the time of enrollment until the pharmacy has access to the beneficiary's information. However, the MMA of 2006 allows for enrollments submitted by the end of a given month to be effective the first of the following month.

A second concern raised by Larry Cowen, an independent community pharmacist, is that persons residing in assisted living facilities or group homes who were allowed an unlimited number of prescriptions under Medicaid are now having to pay co-pays under Medicare Part D. These co-payments, though only between one and five dollars, can cause a financial burden for these beneficiaries. Often these beneficiaries are unaware that they will be responsible for paying a co-pay for their prescriptions when they come into the pharmacy. A.J. Patel noted, "Many patients who are Medicare/Medicaid dual eligible or low income subsidized (LIS) are not classified as such by the plans, and their co-payment amounts are being returned to the pharmacy at the standard benefit level. Which means that the patient is listed in the plan's database, but coded incorrectly, so the co-payment message to the pharmacy far exceeds the patient's ability or obligation to pay."

A third concern introduced by the pharmacists is that low income Medicare eligibles who enter a long-term care facility without previously having a Medicare Part D plan in place have to wait until the first day of the next month to receive prescription drug coverage. However, individuals in this situation often need prescription drugs immediately. These individuals under Medicaid would have been put on a "Medicaid Pending" status, ensuring the facility and pharmacy that they would be reimbursed. This assurance of reimbursement does not exist under Medicare Part D.

A fourth concern is that not all Part D Plans are complying with CMS expectations. Pharmacies have encountered problems in obtaining approval from some Part D plans to override the formulary and provide a transitional supply of drugs to Medicare beneficiaries. CMS has an expectation that plans will provide the transitional supply, but do not require them to do so. Also, Larry Cowen stated that "coverage for drugs that are covered under Part B for beneficiaries residing at home, but not for those residing in long term care settings are expected by CMS to be covered under Part D for long term care residents. However, some Part D plans are still rejecting payment for these drugs." The American Society of Consultant Pharmacists (ASCP) were concerned that many of the Part D plans were, "rejecting claims for injectibles with incorrect messages that the medication claim should be submitted to Medicare Part B." Pharmacists are unclear whether there is widespread confusion among plans about Part B payment policies, or there is an unwillingness to pay for these more expensive medications and dosage forms. ASCP is concerned, as well, that many "plans are not abiding by prescription claim processing guidance published by the National Council for Prescription Drug Programs." This is causing many claims from the pharmacies to be rejected initially.

A fifth concern raised by ASCP is that, "although Drug Enforcement Administration regulations permit long-term care pharmacies to provide several partial fills of Schedule II controlled substance prescriptions, to help reduce waste and diversion, Part D plans are generally refusing to permit pharmacies to submit more than one claim per month for these medication." Also, the plans' other "quantity limit restrictions are incompatible with some drug distribution systems currently used in long-term care and assisted living."

Another concern is that CMS policy allows for large variability among the many Medicare Part D

plans. ASCP stated that the plans have "different approaches, forms, or requirements related to areas such as:

- Formularies
- Injectable medications and intravenous infusion solutions
- Prior authorization procedures
- Quantity limit requirements
- Initial fill policies
- Transition policies related to new admissions, hospital transfers, etc
- Customer service hours of operation and call volume capacity
- Payment policies for emergency box medications, leave medications, medication doses that are dropped by the nurse or spit out by the resident, etc."

This variability causes many operational challenges for long-term care pharmacies.

Another big concern for pharmacists is the financial burden they are experiencing while CMS is working out the initial problems with the system. Many pharmacies have covered the costs of supplying drugs to many long-term care residents expecting that CMS will require the Part D plans to work through all of the problems in a timely manner. A lack of reimbursement to these pharmacies is causing them cash flow problems because they are still having to pay their suppliers.

Dr. James Farris, the Regional Administrator for Centers for Medicare and Medicaid Services (CMS) testified before the committee on CMS' concerns and problem-solving activities associated with Medicare Part D. Farris first addressed the problems faced by dual-eligible beneficiaries who enrolled or switched plans late in the month when they tried to fill prescriptions at the beginning of the next month. In order to help with this problem, Farris said CMS encourages "beneficiaries to enroll or switch by the fifteenth of the month, and to try to enroll several weeks before they start using their coverage." Also, to help with the information lag time he said they have "contracted with Electronic Data Systems (EDS) to help CMS work together with the plans, states, and pharmacies to resolve challenging data translation issues." According to Farris, the goal of CMS "is to achieve, by ten days before a new coverage month begins, at least a 95 percent match for enrollment and co-pay information for dual eligible beneficiaries between Medicare and the plans."

The second concern CMS acknowledged was the initial, long wait times at CMS call centers for both beneficiaries and pharmacists. In order to reduce wait times, they have hired more customer service representatives and updated their scripts with more information to help callers. CMS is also monitoring the customer service lines of the various plans to assure that beneficiaries and pharmacists are receiving timely and accurate responses.

Also, to help pharmacists, Farris indicated that CMS established a "point-of-sale mechanism whereby pharmacists could obtain payment for medications dispensed to beneficiaries demonstrating coverage under Medicare and Medicaid, but for whom plan information could not be obtained." CMS, according to Farris, has "established a demonstration project to reimburse states for the costs they incur by covering drugs that should be covered by the appropriate plan. [They] will also reimburse states for appropriate administrative costs for providing these services and for connecting beneficiaries who are having difficulty, to their Medicare drug plan."

HHSC followed up with the committee on outstanding issues that may be adversely impacting the individuals that are participating in the Medicare Part D program. HHSC provided the following information:

- New dual eligibles continue to have a one to two-month "gap" in which neither they nor their pharmacy have information on their assigned Medicare drug coverage. Medicaid continues to pay for prescription drug coverage for clients until the state has verification that they are enrolled in a Medicare Part D plan. However, states cannot draw down federal funds for these medications after the date the client is eligible for Medicare Part D. States also may not be informed of the eligibility date until after that date has passed, and a client might be eligible but not enrolled in a Medicare Part D plan. CMS' contingency plan for these clients does not work consistently at the point of sale.

- Long-term care pharmacies report that many institutional clients are being incorrectly charged a co-payment. A recent definition change by CMS will reduce the number of people with institutional status.

- If Medicare eligibility is lost, a manual process is required to allow the Medicaid program to resume payment of medications.

- CMS procedures for auto-enrollment may override the Medicare Part D plan that the client enrolled in proactively.

COMMITTEE RECOMMENDATIONS

It is recommended that the Texas Legislature continue to monitor the implementation of the MMA of 2003, particularly in regard to the "clawback" provisions. A large budgetary implication to the State of Texas involves the dispute with the federal government over the "clawback" provision. Prudent contingency planning regarding the eventual outcome of the "clawback" provision dispute should be factored into the State of Texas' budget process.

The Texas Legislature should also consider passage of a formal resolution urging the Congress of the United States to make substantial revisions to the "clawback" provision. This should include ensuring that the "clawback" formulas do not unfairly penalize states such as Texas that had efficient drug purchasing procedures in place prior to the passage of Medicare Part D.

The Texas Legislature should consider passage of a formal resolution urging the Congress of the United States to make the pharmacist whole for their contribution to the implementation of Medicare Part D.

CHARGE

HOSPITAL ACQUIRED INFECTIONS

Study emerging practices for the prevention of hospital-acquired infections, and develop effective policies for incorporating these best practices into the delivery of health care in Texas.

BACKGROUND

In 2005 the Texas Legislature enacted SB 872 by Senator Jane Nelson to establish a 14-member Advisory Panel on Health Care-Associated Infections (APHCAI) to determine how hospitals and ambulatory surgical centers (ASCs) should report hospital-acquired infections (HAI, also referred to as hospital-acquired infections, nosocomial infections, and hospital infections) to the Texas Department of State Health Services (DSHS). The advisory committee is charged with developing recommendations for reporting hospital-acquired infection information to the public.

Legislation to establish reporting requirements was filed in 2005 (HB 734 by Representative Yvonne Davis), received a hearing in the House Committee on Public Health, and was left pending. An amendment offered on the House floor by Representative Yvonne Davis to SB 872 was also adopted to establish mandatory infection reporting requirements for niche hospitals. This niche hospital reporting language was later removed and replaced with language that established an advisory panel to create reporting recommendations for all hospitals and ASCs.

SB 872 requires the Commissioner of State Health Services to file a report with the Texas Legislature by November 1, 2006, with a recommendation for legislation. The deadline for hospitals and ASCs to comply with the collection and reporting of infection rates and/or process measures is September 1, 2007.

INTERIM STUDY

The House Committee on Public Health held public hearings on January 25, 2006, and heard testimonies from representatives from the HAI Advisory Panel and other stakeholders.

- **Panel 1** was comprised of Dr. Jan Patterson, MD, FACP and Rick Danko, Dr. PH, Director of Department of State Health Services (DSHS) Center for Policy and Innovation. Dr. Patterson testified on behalf of the HAI Advisory Panel and discussed emerging and best practices involved with the control and reporting of HAI. She described the need for evidence-based recommendations grounded in public health/medical best practices as the requisite components for the development of effective public policy. Dr. Patterson stressed the benefits of good reporting systems, while also noting the risks of bad reporting systems. Good reporting systems accurately identify infections, use rates of infections (the number of infections divided by the number of operations expressed as a percentage), and use multivariate risk indices to deal with the differences of intrinsic risk of the patient mix in different hospitals.

- **Panel 2** was comprised of Matt Wall and Star West, both representing the Texas Hospital Association. They spoke about federal and state laws and initiatives which encourage voluntary reporting of HAI to patient safety organizations. Mr. Wall described HAI federal legislation as "the carrot vs. the stick approach," where the "carrot" serves as an award of confidentiality and immunity for hospitals reporting HAI. Mr. Wall cited Illinois legislation as a good example of the use of this approach as it has immunity written into the law (and also requires reporting of nurse staffing ratios). The "carrot" promotes purported care of

patients, while encouraging reporting which provides feedback in a non-punitive way. This reduces fear of punishment to healthcare providers while allowing for institutional accountability and improvements in quality. Mr. Wall and Ms. West also spoke of consumers and how they should be involved in their healthcare and aware of the choices available to them. The website http://www.hospitalcompare.hhs.gov/ was cited as an innovative tool that assists patients, families, and communities in making informed health care decisions. Duplication and conflict between state and federal laws was a major concern of this panel.

- The THA and the Texas Medical Association are both actively participating in the Institute for Healthcare Improvement's 100,000 Lives Campaign. The 100,000 Lives Campaign is the first-ever national campaign to promote saving a specified number of lives in hospitals by a certain date through the implementation of proven, evidence-based practices and procedures.[1] The interventions include deploying rapid response teams at the first sign of patient decline; implementing medication reconciliation, which includes listing and evaluating all of a patient's drugs to prevent adverse effects; preventing central venous catheter-related bloodstream infection and related deaths by implementing a set of recommended interventions in all patients requiring a central line; preventing surgical site infection and related deaths by reliably implementing a set of recommended interventions in all surgical patients; preventing ventilator-associated pneumonia and related deaths and other complications in patients on ventilators by reliably implementing a set of recommended interventions; and delivering evidence-based care for patients with acute myocardial infarction.[2] Phase II of the 100,000 Lives campaign is currently underway, focusing upon documenting and sharing best practices, spreading the interventions, and building systems for sustaining progress.

- **Panel 3** was comprised of Brenda Foster, RN, Permian Regional Medical Center and Jay Haynes, MD, Chief Medical Officer at JPS Health Network. Nurse Foster detailed her role as an infection control supervisor in a busy rural hospital. She expressed concern for small facilities, where many staff members have multiple responsibilities. She spoke of the meetings she attends each week and how they impact the time available to provide direct patients care. She emphasized that many rural facilities are understaffed.

Dr. Haynes was joined by Adonna Lowe, RN, MA, VP of Patient Care and Chief Nursing Officer at JPS. They highlighted the various types of healthcare facilities and populations in Texas and they contrasted the rural hospital Nurse Foster described with the urban JPS Health Network in Tarrant County.

- Dr. Haynes and Nurse Lowe described a "very active infection control" program at JPS where "quality is the strategic overarching strategy." Dr. Haynes and Nurse Lowe spoke about "good healthcare, good patient care, good infection management" and stressed the need for "good hand washing" by all doctors, nurses, and other hospital staff.

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[1] Smith, D. (2006, May/June). 100 K Taking Patient Safety to a New Level. *Texas Hospitals*, 14-17.

[2] 100k Lives Campaign. Institute for Healthcare Improvement. 17 Sep. 06. <http://www.ihi.org/IHI/Programs/Campaign/Campaign.htm?TabId=1>

- Dr. Haynes and Nurse Lowe discussed concerns about what data would be collected from the hospitals for state HAI reporting purposes, specifically whether each hospital would have enough surveillance staff (ICP's) to report the data and whether there would be one set of guidelines on how data is collected. Dr. Haynes and Nurse Lowe spoke of the role of surveillance officers and the JCAHO recommendation of *one ICP/100 hospital beds* and how this staffing recommendation affects different reporting outcomes for rural hospitals and large, urban teaching hospitals.

- Dr. Haynes and Nurse Lowe also brought up the topic of guidelines for outcome measures. The issue of how this data will be reported (monthly/quarterly, admission vs. patient days vs. device days) and stratified (bed size, location, teaching, non-teaching, etc.) was also discussed.

The hearing highlighted the various concerns that stakeholders have regarding the issue of effective HAI legislation and regulation. While consensus existed regarding the need for legislation, the THA expressed concern about Federal/State duplication, Nurse Foster spoke on behalf of overburdened staff, and all who testified expressed concern regarding the public's ability to access accurate, comprehensive, and comprehensible multivariate data. Dr. Robert W. Haley, in his testimony to the U.S. House of Representatives (March, 2006), said, "What gets measured gets controlled." [3] Requiring the collection and public reporting of HAI data are two steps in measuring the extent of the problem and identifying solutions.

The committee also reviewed how the subject of HAIs was being addressed by other entities, both within government and the private sector. The specific examples cited within this report contain information presented by the HAI Advisory Panel, and gathered through independent committee research.

FEDERAL LEVEL ACTIVITY

Centers for Disease Control (CDC)

Denise Cardo, director of the CDC's Division of Healthcare Quality Promotion states that national priorities regarding HAI should be "data collection, developing sustainable protocols, adoption of new technology, new research -- and incentives for hospitals to adopt best practices...Within hospitals, the goal of not just managing, but eliminating the infections needs to be a priority, and everyone from the CEO to housekeeping staff needs to be involved."[4]

Congressional Investigation into Public Reporting Standards

The U.S. House Committee on Energy and Commerce's Subcommittee on Oversight and Investigations conducted an investigation into public reporting standards for HAI in hospitals. In support of this investigation, the Subcommittee sent a letter to eight of the largest hospitals in the nation requesting information on how those hospitals detect, monitor and report HAI rates. On March 29, 2006, the subcommittee held a hearing titled: Public Reporting of Hospital–Acquired

[3] Haley, R. W., *Public Reporting of Hospital-Acquired Infection Rates: Empowering Consumer, Saving Lives.* Testimony to Subcommittee on Oversight and Investigations, The Committee on Energy and Commerce, U.S. House of Representatives, pg 5. March 29, 2006.

[4] Analysis: Rx for hospital infection rates, UPI, June 7, 2006 Wednesday, 11:33 PM EST, 881 words, WASHINGTON, June 7, 2006, Olga Pierce.

Infection Rates: Empowering Consumers, Saving Lives. The archived hearing can be listened to at http://energycommerce.house.gov/108/Hearings/03292006hearing1821/hearing.htm#Webcast.

Deficit Reduction Act of 2005

The Deficit Reduction Act of 2005, signed by President Bush on February 8, 2005, included significant hospital quality provisions related to infection reporting. Sec. 5001 amends title XVIII of the Social Security Act (SSA) to require that subsection (d) hospitals[5] that do not submit certain required data to the Secretary of Health and Human Services in FY2007 and each subsequent year will have the applicable market basket percentage reduced by two percentage points. It requires each "subsection (d) hospital" to submit data on measures selected by the Secretary in the established form, manner, and specified time. It also requires the Secretary to expand the set of measures appropriate for the measurement of the quality of care furnished by hospitals in inpatient settings.[6] It directs the Secretary, in expanding the number of such measures, to: (1) begin to adopt the baseline set of performance measures as set forth in the November 2005 report by the Institute of Medicine of the National Academy of Sciences under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003; and (2) subsequently add other measures that reflect consensus among affected parties, including measures set forth by one or more national consensus building entities.

Patient Safety and Quality Improvement Act of 2005

S. 544 known as the "Patient Safety and Quality Improvement Act of 2005" sponsored by Sen. James M. Jeffords (VT) and signed into law by President Bush on July 29, 2005, requires the Department of Health and Human Services to establish a process for the voluntary and confidential reporting of medical errors to "patient safety organizations (PSOs)," which would develop ways to improve patient safety and reduce medical errors. The Secretary of Health and Human Services is required to develop rules regarding the establishment and certification of PSOs. These organizations will be responsible for receiving confidential, voluntary reports from hospitals and other providers relating to such things as medical errors and near-misses. A network of PSOs sharing information regarding best practices and quality issues is envisioned. There is no measurement of outcomes in this legislation.

Registered Nurse Safe Staffing Act of 2005

The Registered Nurse Safe Staffing Act of 2005, S. 71, amends part D (Miscellaneous) of title XVIII (Medicare) of the Social Security Act (SSA) to: (1) require each participating hospital to adopt and implement a staffing system that ensures a number of registered nurses on each shift and in each unit of the hospital to ensure appropriate staffing levels for patient care; (2) provide for the public reporting of certain staffing information, including a daily posting for each shift in the hospital of the current number of licensed and unlicensed nursing staff directly responsible for patient care; (3) prescribe recordkeeping, data collection, and evaluation requirements for participating hospitals; (4) specify civil monetary penalties for violations of such requirements; and (5) provide whistleblower protections. This bill was introduced by Sen. Daniel K. Inouye (HI) on January 24, 2005, and

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[5] Subsection d hospitals are defined as short term acute care general hospitals reimbursed under the Medicare prospective payment system

[6] In 2005, CMS began to link payment with performance by requiring hospitals to submit data on 10 quality measures. These 10 performance indicators measured processes of healthcare such as "pneumonia patients who receive their first dose of antibiotics within 4 hours after arrival at the hospital." Hospitals were to submit this data by July 1, 2004 to comply with the Medicare Prescription Drug, Improvement and Modernization Act. CMS states that "hospitals that do not submit performance data for the 10 quality measures will receive 0.4 percent smaller Medicare payments in fiscal year 2005 than hospitals that do report quality data." Currently there are 20 quality measures listed on the CMS Hospital Compare website, http://www.hospitalcompare.hhs.gov/Hospital/Static/About-HospQuality.asp?dest=NAV|Home|About|QualityMeasures#TabTop.

referred to the Senate Committee on Finance.

Quality Nursing Care Act of 2005
Similar to the Registered Nurse Safe Staffing Act of 2005, HB 1372 aims to amend title XVIII of the Social Security Act to impose minimum nurse staffing ratios in Medicare participating hospitals, and for other purposes. This bill was introduced by Rep. Lois Capps (CA) on March 17, 2005 and was referred to the House Ways and Means Subcommittee on Health on March 24, 2005.

VA Hospital Quality Report Card Act of 2006 (S.2358)
A bill to amend title 38, United States Code, it directs the Secretary of Veterans Affairs to establish and implement a Hospital Quality Report Card Initiative to report on health care quality in Department of Veterans Affairs (VA) hospitals. It requires the Secretary, at least semiannually, to publish reports on VA hospital quality, including assessments of effectiveness, safety, timeliness, and efficiency. S.2358 was authored by Sen. Barack Obama (IL) on March 2, 2006. It has been read twice and referred to the Committee on Veteran's Affairs.

Hospital Quality Report Card Act of 2006 (S.2359)
A bill to amend title XVIII (Medicare) of the Social Security Act to direct the Secretary of Health and Human Services, acting through the Administrator of the Centers for Medicare & Medicaid Services, to establish a Hospital Quality Report Card Initiative under the Medicare program to report on health care quality in subsection (d) hospitals. It directs the Administrator to establish the Hospital Quality Advisory Committee to advise on the submission, collection, and reporting of quality measures data. S.2359 was authored by Sen. Barack Obama (IL) on March 2, 2006. It has been read twice and referred to the Senate Committee on Finance.

STATE LEVEL ACTIVITY

Legislation regarding HAI reporting varies significantly among the fifty states. The Association for Professionals in Infection Control and Epidemiology website[7] provides detailed information regarding each state's status in development of HAI legislation. Figure 1 shows states with study bills, states with 2006 legislative activity, states that mandate public reporting of infection rates, and a state that mandates reporting only to state government.

[7] http://www.apic.org/Content/NavigationMenu/GovernmentAdvocacy/MandatoryReporting/state_legislation/state_legislation.htm

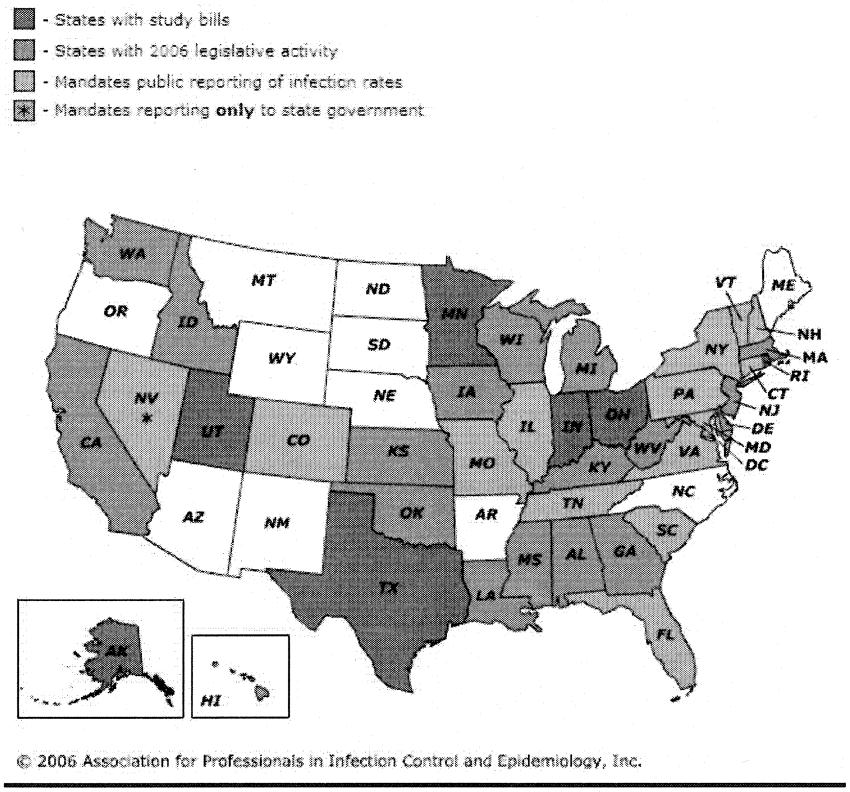

Figure 4

TEXAS LEGISLATIVE HISTORY

SB 872 was amended by Representative Vicki Truitt on the house floor during third reading. The amendment established the 14 member HAI Advisory Panel. The HAI Advisory Panel was charged with using nationally accepted measures to study and recommend definitions and methodologies for collecting and reporting evidence-based data on:

- infection rates;
- process measures; or
- both infection rates and process measures.

In developing the recommendations the HAI Advisory Panel is charged to consider:

1. adjusting the reported infection rates to account for the differences in patient populations and for factors outside the control of the health care facility;
2. standardizing data collection methodology and reporting;
3. reviewing data collection and reporting systems of other entities related to infection rates, such as the National Nosocomial Infections Surveillance System of the federal Centers for Disease Control and Prevention;
4. reviewing data collection and reporting systems of other entities related to process measures, such as the Joint Commission on Accreditation of Healthcare Organizations or the Centers for Medicare and Medicaid Services;
5. maximizing the efficient use of the resources required for health care facilities to conduct required surveillance and reporting;

6. recognizing the potential unintended consequences of public reporting that is poorly designed or executed and that may diminish the overall quality of this state's health care or mislead or fail to protect health care consumers who use the data; and
7. providing additional benefits to health care consumers.

The findings of the two year study conducted by the APHCAI are due on November 1, 2006.

COMMITTEE FINDINGS

The House Committee on Public Health recommends to the Texas Legislature that requirements for reporting HAI should take into account best practices in infection identification and reporting. Infection reporting should utilize data that is verifiably accurate and include infections that are associated with substantial cost, morbidity and mortality.

The House Committee on Public Health recommends to the Texas Legislature that requirements for reporting HAI should carefully consider the HAI Advisory Panel's recommendations and findings from interim studies.

CHARGE

CHAPTER 166.046

Review issues relating to Chapter 166.046 of the Texas Health & Safety Code, and assess if patients and/or their loved ones have a sufficient opportunity to obtain transfer to an alternate facility and subsequent care in end-of-life situations.

BACKGROUND

The Texas House Committee on Public Health was directed on October 19, 2005, by Speaker Tom Craddick to examine the following interim charge: "Review issues relating to Chapter 166.046 of the Texas Health & Safety Code, and assess if patients and/or their loved ones have a sufficient opportunity to obtain transfer to an alternate facility and subsequent care in end-of-life situations."

This report provides an overview of the legislature's prior actions on this subject to give historical context for the committee's current charge. The legislative history demonstrates that the core of this issue is rooted in the limits of both human mortality, and those of medical science when faced with it. Conflicts arise when the judgment of those in the medical field cannot be reconciled with the desires of a patient or his family members regarding whether care sustains life or prolongs dying. Chapter 166.046 details how the State of Texas has established procedures to try to resolve this conflict.

The specificity of the committee's interim charge regarding Chapter 166.046 was used as primary guidance during its review. Other items related to the Advance Directives Act were presented to the committee. The report seeks to stay within the bounds of the speaker's charge.

TEXAS LEGISLATIVE HISTORY

Texas has a relatively short statutory history involving end-of-life care decisions and advance medical directives. The Natural Death Act (Chapter 398, 65th Texas Legislature, Regular Session, 1977), which took effect August 29, 1977, first authorized a person to execute a written directive for the withholding or withdrawal of life-sustaining procedures in the event of a terminal condition. The bill prescribed the form of a directive and defined such terms as "life-sustaining procedure," "qualified patient," and "terminal condition." The Natural Death Act was amended by the 68th Texas Legislature to remove the requirement that a person's advance directive be notarized.

The first significant changes to the law came in 1985 with the passage of HB 403 by Representative Bob Bush (Chapter 870, Acts of the 69th Legislature, Regular Session, 1985). This bill authorized a person to issue an advance directive by a non-written form of communication in the presence of the person's attending physician and two witnesses; removed the requirement that an advance directive follow a statutorily prescribed form; and provided that a directive could include other directions, including the designation of another person to make a treatment decision if the person making the advance directive was comatose, incompetent, or otherwise mentally or physically incapable of communication. The bill also established the order of priority for individuals legally authorized to make end-of-life health care decisions for a person in the event a surrogate decision maker was not designated.

Further changes were proposed in the 75th Legislature, Regular Session, 1997, in SB 414 by Senator Mike Moncrief. While the bill was approved by both chambers of the Texas Legislature, it was vetoed by then-Governor George W. Bush. The governor's veto proclamation stated:

> SB 414 contains several provisions that would permit a physician to deny life-

sustaining procedures to a patient who desires them. Additionally, the Bill eliminates the objective negligence standard for reviewing whether a physician properly discontinued the use of life-sustaining procedures and replaces it with a subjective "good faith" standard. While this Bill contains a number of commendable measures that would streamline Texas' law on advanced directives, these benefits are outweighed by the Bill's potentially dangerous defects.

SB 1260 by Senator Moncrief (Chapter 450, Acts of the 76th Legislature, Regular Session, 1999) enacted the Advance Directives Act, Chapter 166, Health and Safety Code, amended provisions of the Natural Death Act, and consolidated those with other provisions concerning medical powers of attorney (previously durable power of attorney for health care decisions) and out-of-hospital do-not-resuscitate orders. The bill required health care providers to reevaluate policies and procedures relating to directives, clarified who qualified as a witness to the execution of a written advance directive or the issuance of a non-written advance directive, and established the order of priority for persons qualified to serve as a surrogate health care decision maker.

The most recent changes to the Advance Directives Act were made in 2003 by SB 1320 by Senator Jane Nelson (Chapter 1228, Acts of the 78th Legislature, Regular Session, 2003). This bill specified language explaining a patient's right to transfer to another physician or health care facility when there is disagreement about medical treatment, and required the Texas Health Care Information Council to maintain a registry for health care providers and referral groups that may consider accepting, or may assist in locating a provider willing to accept, a patient's transfer.

In the 79th Regular Session in 2005, two amendments were offered on the House floor to SB 1188 by Senator Nelson. The first amendment that was offered on second reading by Representative Bryan Hughes, amendment #26, was withdrawn. The second amendment offered, amendment #28, also by Representative Hughes, was adopted by the House onto the bill. This amendment would have made two changes to the Advance Directives Act regarding Medicaid patients. The amendment established that the state would pay costs associated with Medicaid patient transfers under Chapter 166.046 and that life-sustaining treatment must be continued until a transfer occurred. The amendment was later removed in a House and Senate conference committee.

CURRENT LAW

The Texas Advance Directives Act establishes a set of procedures for physicians and health care providers to follow in cases where there is disagreement with patients or their surrogate decision makers on the futility of continued treatment. The following is a summary of the statute's provisions.

When an attending physician refuses to honor a patient's decision to continue life-sustaining treatment that the physician believes is futile, an ethics committee must review the physician's decision, and life-sustaining treatment may not be withdrawn during such review. The patient or his representative must be advised about the ethics committee review process at least 48 hours before the committee meets to consider the case. The patient or his representative is entitled to attend the meeting and receive a written explanation of the ethics committee's decision.

The patient must also be provided "a copy of the registry list of health care providers and referral groups that have volunteered their readiness to consider accepting transfer or to assist in locating a provider willing to accept transfer."1 The *Registry of Health Care Providers and Referral Groups* is available on the Texas Department of State Health Services website. This registry lists "providers and groups that have indicated . . . their interest in assisting the transfer of patients in the circumstances described."2 There are two categories for providers who wish to register. "In cases in which the attending physician refuses to honor a patient's advance directives or a health care or treatment decision made by or on behalf of a patient requesting the provision of life-sustaining treatment, the registry lists health care providers and referral groups that have volunteered their readiness to consider accepting the transfer of the patient or to assist in locating a provider willing to accept the transfer of a patient."[3] The registry has five entries in this category.

"In cases in which the attending physician refuses to comply with an advance directive or treatment decision requesting the withholding or withdrawal of life-sustaining treatment, the registry lists health care providers and referral groups that have volunteered their readiness to consider accepting the transfer of the patient or to assist in locating a provider willing to accept the transfer of the patient."[4] There are currently no entries in this registry.

If the patient or his representative requests life-sustaining treatment deemed inappropriate by the attending physician and ethics committee, the physician and health care facility must attempt to transfer the patient to a physician and/or facility that is willing to comply with the patient's wishes. The patient must be provided life-sustaining treatment for a period of 10 days pending transfer to another physician or facility.

Under current law and absent court intervention, the physician and the health care facility are not obligated to provide life-sustaining treatment after 10 days from the time the patient or patient's representative is provided the ethics committee's written decision. A district or county court may extend the 10 day period at the request of the patient or his representative "only if the court finds, by a preponderance of the evidence, that there is a reasonable expectation that a physician or health care facility that will honor the patient's directive will be found if the time extension is granted."[5] The court considers whether another provider who will honor the patient's directive is likely to be found; it does not address the issue of whether the decision to withdraw life support is valid.[6]

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[1] University of Houston Health Law and Policy Center briefing.
[2] ibid.
[3] ibid.
[4] *Registry of Health Care Providers and Referral Groups,* Texas Department of State Health Services. Updated 14 April 2006. <http://dshs.state.tx.us/THCIC/AdvanceDirectivesRegistry.shtm>
[5] University of Houston Health Law and Policy Center briefing.
[6] Summary from a briefing by The University of Houston Health Law and Policy Center, provided for the committee as a resource document on August, 4, 2006.

The committee was asked to examine whether there is "sufficient opportunity" to find a transfer to an alternate facility willing to provide treatment.

The committee held a public hearing on August 9, 2006, in which a total of 79 witnesses either offered testimony or registered opinions with the committee. A majority favored substantial changes to the statute regarding provisions relevant to this charge.

The Texas Advanced Directives Act Coalition, an ad hoc organization with current membership from at least 24 distinct organizations, worked on the original law and is now deliberating proposed revision. Its membership ranges from pro-life organizations such as Texas Right to Life and the Texas Alliance for Life, to the medical groups Texas Hospital Association and Texas Medical Association. The group's chairman, Greg Hooser, and representatives from a number of the coalition's individual member groups, appeared at the hearing to detail the issues under discussion and policy options. The total list of possible revisions to Chapter 166.046 being evaluated is extensive. The original legislation from the 74th Regular Session in 1995, SB 1161 by Senator Peggy Rosson, was later amended onto Senator Frank Madla's SB 673 in the House by Representative Hugo Berlanga, and was a consensus document.

Mr. Hooser's written testimony states that a review of nine hospitals with a total of 4,613 beds found a total of 2,842 formal ethics consultations regarding withdrawal of treatment over the last five years, with 57 cases reaching the ten-day notice. In his testimony, Mr. Hooser estimated that these same facilities had seen about 36,000 deaths within this same period.

As a result of the committee's testimony and research, the interim charge was organized into two categories. These were:

1. Procedural matters related to Chapter 166.046 and the "sufficient opportunity" question. These are ways in which the law could be revised to make the ten-day period to seek a transfer (or any other set number of days) easier for families to navigate.
2. The larger policy question regarding whether Chapter 166.046 should have a set deadline at all. This is the key point upon which most of the debate occurs- whether treatment should be required until transfer.

The procedural matters were the subject of committee testimony and discussion by the Texas Advanced Directives Act Coalition in its meetings. There is general agreement by stakeholders that sections of the law regarding an appeal to the court system need clarification. The Chapter 166.046 case most frequently cited to highlight procedural difficulties is *Nikolouzos v. St. Luke's Episcopal Hospital.* The Court of Appeals of Texas, Fourteenth District, Houston, denied an appeal to intervene in a lower court decision on the case, citing a lack of jurisdiction. The concurring opinion registered by Justice Wanda McKee Fowler in this case suggests clarifications of the statute that would make it easier for families to navigate. Justice Fowler cited a "lack of specificity in the statute" as the root of the problem.[7]

[7] *Nikolouzos v. St. Luke's Episcopal Hosp.*, 162 S.W.3D 678 (Tex. Civ. App.-Houston [14th Dist.] Mar. 17, 2005).

Other procedural issues similar to those highlighted by *Nikolouzos* are cited by advocates for changes to Chapter 166.046 to grant more time to obtain a transfer.

A written summary of 16 cases in which Texas Right to Life (TRTL) participated in Chapter 166.046 proceedings, "Texas Right to Life's Experience in Assisting Families with Facing Futile Care Law", was presented to the committee. In TRTL'S testimony to the committee by Elizabeth Graham and others supporting the TRTL position, the following position statements were provided.

- "Once the futility review committee met, the clock started ticking and the family felt helpless. Upon calling the hospital to see how she might assist in trying to find a transfer, the mother was told that the hospital was handling any transfer attempts, and they did not need her assistance." The mother made several efforts to obtain medical records so she could better understand her daughter's condition and begin making her own transfer inquiry calls. The caseworker told the mother this was unnecessary and referred her to the medical records department, who then told her that records are not released until 30 days after the request. The medical records staff was unaware both of the nature of a futility review case, and the 10 day deadline associated with it. They referred the mother back to the caseworker. The family was initially told that they would have to pay for the medical records. "The hospital did ultimately provide these records at no cost to the family after external pressure... Texas Right to Life called the head of the Ethics Department at the hospital and communicated the medical records were being withheld unjustly from a family desperately trying to find a transfer before the 10 days expired. Within 24 hours of that call, the medical records were provided to the mother... Meanwhile, 4 days out of 10 days were lost."[8]

- The deadlines involved in Chapter 166.046 required the realistic involvement of medical or legal experts, or other entities such as courts, that were not available on weekends or holidays – yet the law does not specify business days in the given time limits. Therefore, multiple days might pass without action through weekends or holidays while the clock is ticking. One example cited was an out-of-town family who was notified of an ethics committee meeting at 4:00 p.m. on Good Friday, and the meeting was scheduled for 7:00 a.m. the Tuesday after Easter. This specific case was also referenced in the written testimony of Jerri Lynn Ward, an attorney who worked on this case. She was contacted for assistance on the weekend only because her office phone was forwarded to her house. Ward stated the short time "made it impossible for me to get the medical chart, get a second opinion, or to prepare for the ethics committee meeting."

- TRTL reported cases of families being confused about who was supposed to be contacting alternate facilities, or whether there was any mechanism to ensure that contacts were actually being made by facilities when promised. Families were often unable to get information on the status of facility transfer attempts. There were also

[8] From Case 7 in "Texas Right to Life's Experience in Assisting Families with Facing Futile Care Law."

numerous examples of families expressing confusion over what exactly was supposed to happen under the Chapter 166.046 process once it was initiated.

Testimony offered by Joe Pojman, executive director for the Texas Alliance for Life and a member of the Texas Advance Directives Act Coalition, stated that his board had articulated a number of principles and recommendations on Chapter 166.046. The Alliance's priority is that the presumption should be to err on the side of life. Mr. Pojman's testimony raised two points concerning physicians and health care providers:

- When someone is terminally ill, physiologically futile care may exist when the best medical care available will not change the patient's condition. Sometimes families can be unrealistic in asking for treatments that are difficult for the patient to endure and of no realistic physiological value to the patient.

- Physicians, and health care providers in general, have professional integrity that the law needs to respect if a physician's conscience does not allow him to provide treatment that significantly harms the patient while providing no realistic hope of saving the patient's life.

Mr. Pojman's testimony on behalf of the Texas Alliance for Life identified areas of concern with current law that the Alliance would like to see remedied.

- Families often have a difficult time obtaining their relatives' medical records.

- The length of time for the transfer can be short in some cases, and at a minimum should be based on business days rather than calendar days.

- The legal process for the patient to seek an alternate provider should be redefined and the procedural process should be clarified.

- Statute fails to define basic procedural issues, including venue, expedited timelines for court action, the manner and timeline for the appellate review, and even the manner in which the case is styled.

- The definition of types of treatments that can be withheld or withdrawn on Chapter 166.046 is broad. Food and water should not be considered life sustaining treatment that a provider can involuntarily deny a patient.

- Texas Alliance for Life states that, "It is our sincere hope that these problems and some of the others that have been raised, that have been very significant, can be addressed by making changes to Chapter 166.046 to both honor and balance both the professional integrity of the physicians and health care providers, while protecting the wishes of patients."

Testimony from Burke Balch, an attorney representing TRTL, stated that 11 states now operate

without a deadline in what is their equivalent of Chapter 166.046. The two views – limits or unlimited – were articulated by multiple witnesses in both written and oral testimony.

The Disability Policy Consortium, which represents 29 disability organizations, provided the following position statement:

> With respects to the value of all people, including those with disabilities, we oppose the premise of futility laws and legislation supporting involuntary euthanasia. The ability of the doctor and hospitals to overrule both the patient and their surrogate in withdrawing life-sustaining treatment is in conflict of the principle of patient autonomy.
>
> The Disability Policy Consortium recommends that revisions be made to Chapter 166.046 of the Texas Health & Safety Code to provide "treatment pending transfer" with no time limit which allows the individual or family the opportunity to find other treatment arrangements.

Dr. Robert Fine, Director of the Office of Clinical Ethics for the Baylor Health Care System and a member of the Texas Advance Directives Act Coalition, provided testimony on behalf of the Texas Medical Association.

> "We have an ability to prolong dying in almost any circumstance without the ability to make patients well in every circumstance," Fine stated. "Families, for all sorts of very human reasons, may have great difficulty with the advice to 'let go and let God' in circumstances in which recovery is no longer possible but the body can be maintained by the exceptional use of technology. The result is terrible suffering and chaos for all involved, including the medical and nursing staff that work so very hard to save lives when possible but do not wish to prolong dying or promote suffering without any chance of benefit to the patient."[9]

Pat Bissonet, a social worker on the ethics committee for St. Luke's Hospital, testified on behalf of the Texas Hospital Association.

- The typical patients who fall within Chapter 166.046 demand a level of care that does not exist in our society.

- This state of affairs may become more pronounced in the future as life-supporting technology improves and begins to take over for failed organs.

Ginny Gremillion, a clinical ethics specialist and vice-chairman of the ethics committee, testified on behalf of Memorial Hermann Hospital.

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[9] Text from letter provided to the House Committee on Public Health by Dr. Robert Fine on August 31, 2006, as follow-up to testimony given during the hearing.

- Ethics committees do not decide whether a certain treatment is "futile," they consider whether it is "medically inappropriate."

- Standards of evidence are necessary and must be put forth if treatment is to be declared medically inappropriate.

COMMITTEE FINDINGS

The Advance Directives Coalition met six times prior to the August 9, 2006, hearing held by the Committee on Public Health. Mr. Hooser indicated that he expects the coalition to meet an additional two to three times before the 80th Legislative Session convenes in January, 2007. The consensus reached by the coalition will inform the findings of this interim study. Based on the testimony from families who appeared before the Public Health Committee it is recommended that the Texas Legislature consider revisions to Chapter 166.046 of the Texas Health & Safety Code.

CHARGE

LASER HAIR REMOVAL FACILITIES

Evaluate the need for regulation of laser hair removal facilities in Texas and the need for certification of individuals performing laser hair removal procedures.

BACKGROUND

Laser hair removal has been a growing trend in the United States since 1997. This procedure is normally performed by individuals trained to use a laser or pulsed light device for the removal of hair. Most laser hair removal facilities in Texas have an oversight physician who ensures that protocols regarding these procedures are followed to promote and enhance client safety.

The Texas State Board of Medical Examiners (TSBME), now the Texas Medical Board (TMB), is the state agency charged with regulating the practice of medicine. In 2003, the TMB adopted Rule, Sec. 193.11, which outlines the use of lasers/pulsed light devices as the practice of medicine. They define laser hair removal as a non-ablative procedure, or a procedure which is not intended to remove, burn, or vaporize the epidermal surface of the skin. Sec. 193.11 specifies "that the use of lasers/pulsed light devices for non-ablative procedures cannot be delegated to non-physician delegates, other than an advanced health practitioner, without the delegating/supervising physician being on-site and immediately available."[1]

This rule was originally set to take effect in November, 2003. The effective date for enforcement was set for December, 2004. After this date, any non-physician laser hair removal practitioner could have been indicted for practicing medicine without a license, which is a third degree felony.

However, on December 2, 2004, the Laser Hair Removal Stakeholders Group and the Dr. Steven Finder, Dr. Kimberly Finder, & Smooth Solutions, LP group were granted a temporary restraining order and an injunctive relief from the state district court in Travis County that prevented the TMB from enforcing Rule 193.11. Subsequently the Board and the Stakeholders entered into an agreement to abate enforcement of Rule 193.11 to allow the Stakeholders to pursue legislation that would provide for licensing and certification requirements of laser hair removal practitioners under the auspices of the Texas Department of State Health Services (DSHS). The abatement agreement was recently extended until June 30, 2007, to allow the Texas Legislature time to address the issue in the upcoming Regular Session. H.B. 3178, by Representative Vicki Truitt, et al, was filed during the Regular Session of 79th Legislature, and the bill was heard by the House Committee on Public Health. H.B. 3178 called for laser hair removal facilities in Texas to be regulated by the Texas Department of State Health Services, since that agency presently regulates the laser/pulsed devices. The "public safety" issue that was raised by the TSBME was addressed in H.B. 3178 because operators of the laser/pulsed devices would be required to receive some type of certification and each facility would have a physician consultant. On May 4, 2005, the bill was heard and left pending in the committee. The abatement agreement was subsequently extended until March 16, 2006, and then once again extended until the end of September, 2006. Recently, the Stakeholders Group formed an association called Texas Association for Cosmetic Laser Education and Regulation (TACLER) to more formally organize their efforts.

INTERIM STUDY

[1] Texas Medical Board. Standing Delegation Orders Chapter 193.1-193.11 as of 25 Jan. 2006. http://www.tmb.state.tx.us/rules/rules/193.php#193.11.

Speaker of the House Tom Craddick issued an interim charge to the House Committee on Public Health to evaluate the need for regulation of laser hair removal facilities in Texas and certification of individuals performing laser hair removal procedures.

During the interim hearing on this charge held on June 15 and 16, 2006, the House Committee on Public Health heard testimony from Richard Ratliff of the Texas Department of State Health Services (DSHS) Radiation Control Program.

According to Ratliff, "Chapter 401 of the Health and Safety Code authorizes the DSHS to regulate the use of lasers and intense pulsed light sources (IPL's)."[2] Ratliff also stated that the DSHS requires that all laser hair removal registrants identify a physician as a medical director who oversees the use of the lasers or IPL devices. Investigations into incidents and complaints associated with laser hair removal devices are conducted by DSHS. There have been eighteen reports of alleged skin burns due to laser hair removal, seven of which have been verified.

The committee also heard testimony from Thomas Brinck, Manager of the Drugs and Medical Devices Group, a division of DSHS. Mr. Brinck's testimony made three points noted by the committee:

- "Laser and IPL devices intended for the removal of unwanted hair...are classified by the U.S. Food and Drug Administration (FDA) as Class II medical devices subject to general and special controls, including performance standards, pursuant to 21 Code of Federal Regulations (CFR), §878.4810...Laser and IPL devices used for hair removal are limited by FDA to prescription use and are required to bear the statement 'Caution: Federal law restricts this device to sale by or on the order of a ____.' Federal regulations require the blank to be filled in with the word 'physician', 'dentist', 'veterinarian', or with the descriptive designation of any other practitioner licensed to use or order the use of the device by the law of the state in which that individual practices."[3]

- "A prescription device is defined by 21 CFR, §801.109 to be a device which, because of any potentially harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe except under the supervision of a practitioner licensed by law to direct its use, and hence for which adequate directions for lay use cannot be prepared."[4]

- "DSHS relies on the authority granted by Chapter 483 of the Health and Safety Code to recognize the appropriate state medical licensing boards and those practitioners who can use or order the use of prescription devices such as lasers and IPL devices within their scope of practice. A person's misuse or failure to provide adequate supervision for the use of laser and IPL devices may cause the devices to be adulterated or misbranded within the meaning of Chapter 431 of the Health and Safety Code and subject that person to the enforcement provisions of the Chapter."[5]

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[2] Ratliff, Richard A., Testimony. Texas House of Representatives, *House Committee on Public Health--Laser Hair Removal Hearing.* June 15, 2006.
[3] Brinck, Thomas E., Testimony. Texas House of Representatives, *House Committee on Public Health--Laser Hair Removal Hearing.* June 15, 2006.
[4] Ibid.
[5] Ibid.

Dr. Dan McCoy, a practicing dermatologist, presented testimony to the committee on behalf of the Texas Dermatological Association[6]. His view is that lasers used for laser hair removal destroy the hair follicle, that this procedure causes a physical change and should be considered the practice of medicine. It is his opinion that physicians should supervise this procedure, and that their licenses should be at stake if the lasers are misused, thus being held accountable for supervision. He recommends that there be certified training and licensing for those performing laser hair removal, but they should still be under the supervision of a physician.

The committee heard testimony from both Dr. Kimberly Finder (K. Finder) and Dr. Steven Finder (S. Finder), who own Smooth Solutions, the largest hair removal facility in Texas. Dr. K. Finder is a dermatologist and Dr. S. Finder is a preventative health physician. Dr. S. Finder is also the president of TACLER, which formed to promote and encourage reasonable regulation of the laser hair removal industry. The Finders believe, based on their company's success with over 350,000 laser hair removal treatments, that laser hair removal can be safely delegated to non-physicians. The Finders developed a two week in-house training program to train their staff in laser hair removal because they believed the manufacturers' programs to be insufficient. It takes their nurses three months to complete the course, with three weeks of classroom instruction. They also implemented a continuous quality improvement (CQI) program to identify, track, evaluate, and learn from every negative outcome that they encounter. They also hold monthly CQI meetings attended by them and the senior nurses from all areas of the company.

Dr. K. Finder stated that complications from laser hair removal can initially look severe. She noted that "crusting of the skin and blister formation can occur with lasers, but these complications are almost always self limited and resolve completely, assuming proper care."[7]

"What can make laser hair removal complications so dramatic is the involvement of skin pigment due to the targeting of melanin by the laser energy," she added.[8] According to the Finders, the skin pigment alterations look terrible in the initial stage, but usually the skin recovers completely. "A few rare reactions have been reported that leave permanent sequelae, similar to a curling iron burn or small acne scar. These reactions will occur whether a physician is present or not," stated Dr. K. Finder.[9]

In the Finders experience, about 10% of treatments will have a reaction of some kind, but these reactions are usually minor and last only a few days. Symptoms include swelling, redness, and acne-like reactions. Dr. K. Finder stated, "In one in 1,000 treatments, we see a more significant reaction with blisters, swelling and pigment changes...Normally the blisters and swelling resolve in a week or so, but the pigment changes can take months to go away."[10]

In Dr. K. Finders opinion, "What increases the safety of laser hair removal is understanding laser

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[6] Dr. Dan McCoy's testimony before the Committee Public Health, June 15, 2006.
[7] Finder, Kimberly. Testimony. Texas House of Representatives, *House Committee on Public Health--Laser Hair Removal Hearing.* June 15, 2006.
[8] Ibid.
[9] Ibid.
[10] Ibid.

effects, knowledge of appropriate settings, the ability to properly assess a candidate, and experience. Though training is an important precondition, it is ultimately experience that really matters."[11] She believes that the medical judgment, knowledge, and experience required for laser hair removal are far less than that of a physician. However, she does think there is a role for physicians in laser hair removal.

"Physicians are essential in developing standards for evaluation potential candidates, in developing treatment algorithms, in ensuring the training of these standards, and most importantly, being available to evaluate and treat significant complications if they occur," Dr. K. Finder stated.[12] However, once a viable system and controls are established, Dr. K. Finder sees no reason for a physician to be involved or even present for the vast majority of treatments.

Dr K. Finder provided recommendations to the committee. First, she believes that the state should require that supervisors of laser hair removal have a certain standard level of experience and training necessary for certification that is higher than the training and experience necessary to perform the treatment. She also thinks that laser hair removal should not be performed without the presence of a qualified supervising provider, but not necessarily a physician. Finder stated, "Each organization providing laser hair removal services should have an ongoing relationship with a physician to provide pre- and post-treatment evaluation of laser hair removal clients when appropriate. And finally, there should be an ongoing reporting mechanism to ensure quality and safety."[13]

"We need regulations and standards to ensure fair competition, as well as safety and access for the public," Dr. S. Finder added. [14]

The committee was also provided testimony by Gregory Absten, the President and Executive Director of the non-profit Professional Medical Education Association (PMEA), which teaches laser applications through their Laser Training Institute Division. Mr. Absten states, "I am supportive of the credentialing of laser hair removal operators based upon established standards, and performed under indirect physician supervision."[15]

However, he believes that the supervising physicians should themselves be required to receive adequate training on laser hair removal procedures. Mr. Absten went on to say that complications arising from laser hair removal treatments did not occur "due to lack of physician supervision."[16] Rather, "they are due to lack of proper training and standardized documentation of this training through objective credentialing and certifications."[17]

Through his work with PMEA, Absten has found there to be a need for certifications in the support areas for laser hair removal. These certifications include the areas of Laser Repair Technicians, Medical Laser Safety Officers, and Laser Operations in the areas of Aesthetics, Laser Hair Removal,

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[11] Ibid.
[12] Ibid.
[13] Ibid.
[14] Finder, Steven. Testimony. Texas House of Representatives, *House Committee on Public Health--Laser Hair Removal Hearing.* June 16, 2006.
[15] Absten, Gregory. Testimony. Texas House of Representatives, *House Committee on Public Health--Laser Hair Removal Hearing.* June 16, 2006.
[16] Ibid.
[17] Ibid.

and Surgical Operators. Mr. Absten's belief is that academic training, in combination with clinical training, should be required for certification.

COMMITTEE RECOMMENDATIONS

Representatives of TDS and TACLER have been meeting to resolve the differences in their positions on this matter. The Committee anticipates receiving a report of the results of these discussions and will inform the legislature of the findings of any mutually acceptable recommendations made by these interested parties.

JOINT CHARGE

TOBACCO CHARGE

Examine the compliance of cigarette manufacturing companies with the 1998 Tobacco Settlement with reference to sales to minors, and the progress toward meeting the state's tobacco use goals and the cost of tobacco use to the state.

(Joint Interim Charge with the House Committee on State Affairs)

TOBACCO SETTLEMENT

In 1996, the State of Texas filed a federal lawsuit accusing five major tobacco companies - Philip Morris Incorporated, Lorillard Tobacco Company, Liggett & Myers, R.J. Reynolds Tobacco Company, and Brown & Williamson Tobacco Corporation (now owned by R.J. Reynolds Tobacco Company) - of violating conspiracy, racketeering, consumer protection, and other provisions of state and federal law. The state sought to recover billions of tax dollars it had spent to treat tobacco-related illnesses. Although the case was settled in January of 1998, a most favored nation clause allowed the state to improve its settlement. The State of Texas chose to accept the Minnesota settlement requiring the tobacco companies to pay $15 billion over 25 years and to pay an extra $2.3 billion to Texas counties and hospital districts.[1]

Actual payments by the industry are subject to adjustment formulas related to tobacco sales, inflation, and industry profitability. Under Texas' settlement terms, payments from the tobacco companies rise or fall in proportion to domestic consumption of cigarettes each year as compared to consumption in 1997.[2]

The 76th Legislature in 1999 used $1.5 billion of the initial receipts to create endowment funds for health and human services and higher education and created sources of ongoing program funding out of interest earnings.[3] The Texas Tobacco Prevention Initiative is funded by the interest proceeds generated from the $200 million Permanent Endowment for Tobacco Education and Enforcement that was one of several endowments established by the 76th Legislature.[4]

STATE'S TOBACCO USE GOALS

The Legislature has set specific goals for the Texas Department of State Health Services (or any other agency) to achieve when implementing state funded tobacco cessation programs.

> ***Tobacco Use Goals.***[5]
>
> *a. It is the intent of the Legislature that the Department of State Health Services (DSHS) or any other grantee or agency that receives funds for tobacco reduction or cessation in the State of Texas create the following goals;*
>
> *(1) In areas where the state funds tobacco cessation programs at a level of $3.00 per capita, there should be a demonstrated reduction in underage use of cigarettes, snuff, and smokeless tobacco of 60 percent by the year 2010 by all Texans 22 years and younger; and*
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> *(2) In areas where the state funds tobacco prevention and cessation*

[1] Texas. House Research Organization. *Securitizing Texas' Tobacco-Settlement Receipts.* February 4, 2002. Interim News. Number 77-5.
[2] Ibid. (footnote 106)
[3] Ibid. (footnote 106)
[4] Texas. Department of State Health Services. Email Response to Questions from the House Committee on State Affairs. Received August 11, 2006.
[5] Rider 67 under Article II of the General Appropriations Act, 2006-2007 Biennium, 79th Legislature; Rider 49 under Article II of the General Appropriations Act, 2004-2005 Biennium, 78th Legislature; and Rider 11 under Article XII of the General Appropriations Act, 2002-2003, 77th Legislature

programs at a level of $3.00 per capita, the use of cigarettes, snuff, and smokeless tobacco by all Texans 22 years and younger should be eliminated by the year 2018.

b. The agency should focus on achieving these goals by creating and using programs permitted under Government Code, §403.105.

c. The agency, or any other grantee or agency receiving funds for tobacco reduction or cessation in the state, shall prepare a report by December 1, 2006, on the agency's progress in achieving the above goals. The report shall include an evaluation of the agency's progress and recommendations on how to improve the programs. The report shall be submitted to the Eightieth Legislature.

AGENCY EFFORTS

Texas Department of State Health Services (DSHS)

In 2000 and 2001, an annual $10 million dollar appropriation to the Texas Department of Health legacy agency, now DSHS, funded a pilot study conducted in partnership with eight state universities in Southeast Texas known as the Texas Tobacco Prevention Initiative.[6] East Texas and Houston were identified as the primary sites for the initiative because the regions experience a high rate of lung cancer and other tobacco-related diseases and they contain demographically diverse populations that are heavily targeted by the tobacco industry.[7] Due to a funding increase during 2002 and 2003, the pilot area was expanded to be fully implanted in Harris, Fort Bend, Montgomery, and Jefferson Counties, thus reaching 20 percent of the state's population. A reduction in funding during 2004 and 2005 decreased the pilot area to include only the Beaumont-Port Arthur Metropolitan Statistical Area (includes Jefferson County). During this time, the surrounding communities of Harris, Fort Bend, and Montgomery counties did receive a lower intensity level of tobacco prevention methods. DSHS officially ended the pilot study in late 2005, but continues to support comprehensive programming in the Beaumont-Port Arthur area.[8] This programming includes two tobacco use public awareness campaigns aimed to reduce tobacco use by minors in the state and support youth groups that include components related to the reduction of tobacco use by the group's members. These campaigns are known as *Duck Texas - Tobacco is Foul* and *Worth It.*

[6] Texas. Department of State Health Services. *Southeast Texas Tobacco Prevention Program Frequently Asked Questions.* Provided to House Committees on Public Health and State Affairs Joint Hearing. April 18, 2006.

[7] Texas. Department of State Health Services. *Texas Tobacco Prevention Initiative Infrastructure and Baseline Data.* January 2001. E16-11186. Accessed July 31, 2006. http://www.dshs.state.tx.us/tobacco/pdf/finalrep.pdf

[8] Ibid. (footnote 111)

Cost of Comprehensive Programming Per Year[9]			
Fiscal Year	**Program Location**	**Total Population**	**Approximate Cost**
2002	Harris, Jefferson, Fort Bend, and Montgomery Counties	4,300,849	$9,848,944
2003	Harris, Jefferson, Fort Bend, and Montgomery Counties	4,156,575	$11,264,318
2004	Beaumont/Port Arthur MSA	386,848	$1,720,250
2005	Beaumont/Port Arthur MSA	386,848	$1,720,250
2006	Beaumont/Port Arthur MSA	385,090	$1,462,750

Youth Population within Comprehensive Programming Area[10]	
Location	**% Population Who Are Youth 0-19 yrs. (& Number of Youth)**
Montgomery County	32.1% (94,483)
Jefferson County	28.9% (72,924)
Harris County	31.9% (1,083,790)
Fort Bend County	34.7% (123,038)
Beaumont/Port Arthur MSA*	39.3% (113,315)
*Some overlap exists between Jefferson County and the Beaumont/Port Arthur MSA	

Funding at a level of about $3 per capita of programming that includes school, community, enforcement, cessation and mass media was shown to be effective in reducing tobacco use. Lower level media campaigns and single focus community programs did not have measurable effects on tobacco use among children and adults. For the Beaumont/Port Arthur area and Houston (where a comprehensive program was funded through fiscal year 2003)[11]:

- From 1998 to 2003, current use of any tobacco products showed a 32% reduction among middle school students (from 24.5% to 16.6%) and a 41% reduction among high school students (from 40.1% to 23.6%).
- The prevalence of adult smoking decreased 26.4% (from 21.6% in 2000 to 15.9% in 2004).

In the Beaumont/Port Arthur area only, where the comprehensive program continues to be provided[12]:

- From 2000 to 2005, current cigarette use among middle school students decreased 34% (from 17% to 11.2%) and among high school students decreased 46% (from 34.2% to 18.3%).

After the funding reduction in 2004 and resulting end to comprehensive programming in Harris County, smoking rates among middle school students began to rebound.[13]

[9] Texas. Department of State Health Services. Response to House Committees on Public Health and State Affairs Asked During Joint Hearing. April 18, 2006. Letter Dated May 26, 2006.
[10] Ibid. (footnote 114 - as ref: U.S. Census Bureau)
[11] Ibid. (footnote 111)
[12] Ibid. (footnote 111)
[13] Ibid. (footnote 109)

DSHS contracted with the Kaiser Permanente Center for Health Research to use a return on investment model to calculate the net annual medical care and productivity savings associated with 2003 program spending and smoking rate reductions from the Texas Tobacco Prevention Initiative. The Kaiser Permanente Center estimates that as a result of the 2003 single year investment of $11.3 million ($2.71 per person) in the pilot area only (Houston and Southeast Texas) there were 29,870 fewer smokers in 2003 and a five-year savings of over $252 million in total medical care and productivity costs.[14]

In addition to programming in the comprehensive area, DSHS supports tobacco prevention efforts across the state at a low intensity. For example, regional DSHS staff work with tobacco prevention coalitions, community-based organizations, and other interested entities to promote policies that discourage tobacco use.[15] Additionally, DSHS supports limited media activities such as billboards, print ads, promotional events, press releases, radio, and public service announcements.[16]

DSHS uses the best information and practices to make the best program intervention investments based on scientific, public health, and psychosocial science literature. Research shows that media messages need to reach at least 80 percent of the target audience a minimum of 6 times in order to change behavior. It is more practical to concentrate the high-intensity media in the comprehensive program area where it can have measurable impact and be reinforced with other program activities, because funds are not available to purchase this level of high-intensity media statewide and the desired result would not be achieved by placing low-intensity media throughout the state. Jefferson County is an advantageous media market because of the availability of local television and radio stations with low advertising rates, which are based on population and viewership levels. Additionally, some Houston stations reach this area as well as a large audience outside the area. However, Houston media is quite costly and is considered a supplement only.[17]

In fiscal year 2006, DSHS was able to extend some media buys to areas throughout the state through an agreement with the Texas Association of Broadcasters (TAB). TAB's member television and radio stations across the state agreed to run the placed advertisement a guaranteed number of times. Time slots and audiences are not guaranteed through the arrangement. Because the audience cannot be targeted with this type of placement, it is not considered a good investment for ads aimed at the relatively small age range for teens and pre-teens, which is also a very diverse audience with fragmented viewing habits. The larger adult audience is more suitable. Therefore, DSHS placed two ads aimed at an adult audience through the TAB. One ad focused on cessation and was placed during the end-of-year period when many smokers are preparing to quit for the New Year. The other ad focused on secondhand smoke education. Each placement cost $196,000, for a total of $392,000. The ads were purchased with the following funds: $301,000 from U.S. Centers for Disease Control and Prevention funds and $91,000 from settlement funds.[18]

Markets include: Amarillo, Dallas/Fort Worth, Houston, San Antonio, Austin, Texarkana, Waco,

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[14] Ibid. (footnote 109)
[15] Ibid. (footnote 109)
[16] Texas. Department of State Health Services. *Different DSHS Tobacco Prevention Efforts by Program.* Provided to House Committees on Public Health and State Affairs Joint Hearing. April 18, 2006.
[17] Ibid. (footnote 109)
[18] Ibid. (footnote 109)

Harlingen, El Paso, Tyler/Longview, Corpus Christi, Beaumont/Port Arthur, Wichita Falls, Lubbock, Odessa/Midland, Sherman, Abilene, Laredo, San Angelo, and Victoria[19]

Additionally, DSHS placed ads with an enforcement message in Abilene, Corpus Christi, Lubbock, Tyler/Longview, and Waco. These ad placements were made as part of an interagency contract and funded through the Comptroller's Office. Markets were determined based on feedback from the Comptroller's Office and available funding. The budget for this media buy was $206,500. The ads were purchased with the following funds: $180,000 from the Comptroller's Office and $26,500 from settlement funds.[20]

DSHS receives funding specifically for tobacco prevention and control from General Revenue, the Permanent Fund for Tobacco Education and Enforcement, the Comptroller of Public Accountants, and the U.S. Centers for Disease Control and Prevention. Also, DSHS receives Substance Abuse Prevention and Treatment Block Grant funds from the Substance Abuse and Mental Health Services Administration for prevention programming on alcohol, tobacco, and other drugs.[21]

DSHS Actual Expenditures[22]

Method of Finance	FY 02	FY 03	FY 04	FY 05	FY 06
General Revenue - 0001	121,115	122,868	122,869	109,739	266,695
Tobacco Settlement Receipts - 5040	5,000,000	5,000,000			
Tobacco Education/Enforcement - 5044	7,680,219	8,295,953	5,993,590	5,897,692	5,218,131
Federal Funds - 555	716,401	864,233	864,233	936,362	882,756
Appropriated Receipts - 666	865	34,238	105,160		
Interagency Contracts - 777	636,075	388,253	388,253	426,000	479,429
Total	**14,154,674**	**14,705,545**	**7,474,105**	**7,369,793**	**6,847,011**

Notes:
FY 02 - Travel, rent, and utilities are included in operating costs
FY 03 - Includes tobacco funds which were in a strategy entitled Tobacco Education/Enforcement
FY 06 - Budgeted amounts, not actual expenditures
These amounts do not include all DSHS funds spent on tobacco education/prevention.

In 2006, DSHS appropriated $5.5 million specifically to tobacco prevention and control. An additional $1.7 million came from the U.S. Centers for Disease Control and Prevention allowing roughly $7 million to be aimed at these efforts. Although another $20 million was available from the Texas Commission on Alcohol and Drug Abuse legacy agency, the funds are universal in use covering alcohol, tobacco, and other drug prevention, intervention, and treatment. Only some of this money goes toward tobacco prevention and control.[23] For example, DSHS funds contract agencies

[19] Ibid. (footnote 109)
[20] Ibid. (footnote 109)
[21] Texas. Department of State Health Services. *DSHS Tobacco Prevention Efforts*. Provided to House Committees on Public Health and State Affairs Joint Hearing. April 18, 2006.
[22] Ibid. (footnote 109)
[23] Sanchez, Eduardo. Texas Department of State Health Services Commissioner. Testimony Before the House Committees on Public Health and State Affairs. April 18, 2006.

that serve more than 450 school districts with evidence based curriculum on alcohol, tobacco, and drug use.[24]

Texas Education Agency (TEA)

The Texas Essential Knowledge and Skills (TEKS) are the standards of instruction developed for every required foundation and enrichment content area from kindergarten through twelfth grade. When offering a course, teachers must provide instruction on all of the components of the TEKS for that class at that grade level, using the curriculum or curricula that their district deems appropriate. Substance abuse prevention, including tobacco use, is included in the TEKS for Health Education at every grade level. Instruction in Health Education must be provided within every grade level during elementary school and is also offered in the middle school setting. A half-credit must be earned for high school graduation.[25]

In addition, all elementary, middle, and junior high schools are required to implement a Coordinated School Health Program (CSHP) starting in the 2006-2007 school year. However, many school districts started a CSHP in their elementary schools after the passing of Senate Bill 19 in 2001. A CSHP requires that designated staff, especially those involved in school health issues (nurses, cafeteria staff, physical education teachers, counselors, etc.), align their efforts in developing healthier students and staff.[26]

TEA contracts with the DSHS to administer the Youth Risk Behavior Survey with a grant received from the U.S. Centers for Disease Control and Prevention. Tobacco use is one of many health issues addressed in this survey.[27] The survey measures behaviors that fall into five other categories including unintentional injuries and violence, alcohol and other drug use, sexual behaviors, dietary behaviors, and physical activity.

Each of the twenty regional education centers has a school health specialist and a Safe and Drug Free School Coordinator (SDFSC). These positions are funded from various funding sources including some federal government funding, a small amount from DSHS, and various others. Sometimes the same person will be the contact for both school health and the SDFSC programs. Any questions pertaining to or from school nurses are handled by the school health specialist. They stay in close coordination with the DSHS Division of School Health.[28] The school health specialist provides and promotes wellness information, materials and other resources to teachers, administrators, other school personnel, parents and community members within the school community through in-service training, workshops, and other technical assistance. The specialists, together with support and guidance from the Texas Cancer Council and DSHS, make up the Texas School Health Network.[29]

Although not required by statute, the Texas School Health Network has been in existence for 20

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[24] Ibid. (footnote 126)
[25] Rathbone, Marissa. Texas Education Agency Director of Health & Physical Education. Email Response to House Committee on State Affairs Information Request, August 9, 2006.
[26] Ibid. (footnote 130)
[27] Ibid. (footnote 130)
[28] Cowan, Tommy. Texas Education Agency Interagency Coordination Director. Email Response to House Committee on State Affairs Information Request. July 31, 2006.
[29] Texas. Department of State Health Services. *Texas School Health Network: School Health Specialists.* Accessed July 21, 2006. http://www.dshs.state.tx.us/schoolhealth/netlist.shtm

years and has received funding at different levels from a variety of agencies. In 1995, DSHS became the primary funding source for the network and currently funds 30% of a full-time school health specialist position within each educational service center. DSHS funding for the network comes from two sources: $210,000 from an inter-agency contract with the Texas Cancer Council to support cancer prevention activities and $802,132 from Maternal and Child Health (Title V) to provide primary prevention trainings, technical assistance and support to schools. For example, the network provides training on tobacco prevention and other coordinated school health programs.[30]

Comptroller's Office (CO)[31]

Senate Bill 55, relating to the regulation of the sale, distribution, and use of tobacco products by minors, enacted during the 75th Regular Session, charges the CO, along with Local Law Enforcement agencies, to enforce Subchapters H, K, and N of the Texas Health and Safety Code Chapter 161.

The Comptroller's primary enforcement efforts are carried out through inspections of tobacco retail establishments by staff of the Enforcement Division and the Criminal Investigation Division (CID). During inspections, staff ensures that retail establishments maintain appropriate employee notification forms and warning signs and are in compliance with youth access laws. Violations result in an assessment of a civil penalty and/or a criminal citation when deemed appropriate. A total of $108,000 in civil penalties has been assessed to date.

In addition to performing inspections, CID personnel often partner with local law enforcement agencies to assist in performing "controlled buy" stings where a minor, under the supervision of the law enforcement agency, is sent into a tobacco retail establishment in an attempt to purchase tobacco products. Employees of retail establishments that sell cigarettes or tobacco products to minors are issued criminal citations. CID personnel make follow-up visits to establishments that have been found in such violation to determine whether additional civil penalties should be applied.

Enforcement Activities from June 1, 2005 to May 31, 2006	
Comptroller's Office	
Retailer Inspections	5,304
Local Law Enforcement Report	
Retailer Inspections	6,181
"Controlled Buys"	7,292
• Violation to Buy Rate (10.33%)	
Retailers Educated on Tobacco Laws	3,567
Minors in Possession Citations	2,528
Children Educated on Tobacco Laws	348,196
Officers Trained on Tobacco Laws	1,307
Educators trained on Tobacco Laws	11,297
Court Personnel Trained on Tobacco Laws	235

[30] Ibid. (footnote 109)

[31] Texas. Comptroller of Public Accounts. Response to House Committee on State Affairs Information Request. Letter Dated August 8, 2006.

The CO also makes grant dollars available to local law enforcement agencies and school districts with on-campus police programs. These funds are appropriated by the Legislature specifically for the on-going administration of SB 55, and are not tied to the Tobacco Settlement payments. The grant dollars for Local Law Enforcement agencies are designated for:

- Educating tobacco retailers on the laws concerning minors access to tobacco;
- Educating local court personnel on the laws concerning minors access to tobacco;
- Inspecting tobacco retailers to ensure compliance with state laws;
- Performing "controlled buy" stings using minor decoys to test tobacco retailers on sales of tobacco products to minors.

The grant dollars available to school districts with on-campus police departments are designated for:

- Educating minors on the tobacco laws;
- Enforcing the tobacco laws concerning minors in possession of tobacco on and off campus at school-sanctioned events.

Through the use of an interagency contract for fiscal year 2006, the CO will pay DSHS $466,000 to provide the following services:

- DSHS shall subcontract with a toll-free phone service provider in order to receive, dispatch, monitor, and accommodate complaints, questions, reports of violations, requests for technical assistance, and any other incoming calls related to the sale and distribution of tobacco products to minors in Texas, or possession of tobacco products by minors in Texas (1-800-345-8647).
- DSHS shall continue the ongoing development and implementation of a statewide public awareness campaign designed to reduce tobacco use by minors.
- No later than January 5th of each odd numbered year, DSHS shall report to the Governor, Lieutenant Governor, and Speaker of the House on the status of smoking and the use of tobacco and tobacco products in compliance with all the legislative requirements per Section 1612.0901, Chapter 161, Texas Health and Safety Code.
- DSHS shall implement a revision of the statewide tobacco education program known as the Texas Youth Tobacco Awareness Program, for minors who are cited for possession of tobacco products.

In addition, the CO maintains a memorandum of understanding with DSHS. The agreement states that DSHS will:

- Contract with Texas State University to conduct the federally mandated Synar inspections, using CO's list of retail tobacco outlets. Submit the Synar report required by federal law and any implementing regulations adopted by the United States Department of Health and Human Services.
- Require that DSHS contact tobacco retailers to request voluntary compliance with the state law, participate in raising public awareness regarding minors and tobacco issues, and actively participate in community tobacco prevention coalitions and activities.

- Coordinate the enforcement of state and federal statutes to reduce availability of tobacco products to minors, conduct and report data from compliance inspections and purchase attempts.

Office of the Attorney General (OAG)[32]

In response to the problem of underage people trying to purchase cigarettes over the internet, many states have passed laws prohibiting minors from having cigarettes delivered to them. Also, the National Association of Attorneys General has entered into several "Assurances of Discontinuance" with United Parcel Service Inc., DHL Holdings USA, Inc. and Federal Express. These agreements prohibit the delivery of cigarettes to minors. The agreements which have been adopted by many states provide that the delivery company will not ship or deliver "cigarettes to individual consumers in the United States" unless the delivery of the cigarettes is authorized by law. Therefore, under the agreements, the delivery companies will not deliver cigarettes to persons who are under the legal age to purchase cigarettes, the delivery company promises to deliver cigarettes only when the delivery is a "properly labeled tobacco product" and the delivery company "obtains an in-person signature from a person who has reached such legal purchase age, pursuant to the respective laws of each state." Moreover, under the agreements, the delivery companies will train their employees and keep them informed about the restrictions on the delivery of cigarettes.

The following states or territories have all signed onto these agreements: American Samoa, Arizona, Arkansas, California, Colorado, Connecticut, Georgia, Hawaii, Idaho, Illinois, Iowa, Illinois, Kentucky, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Northern Mariana Islands, Nebraska, Nevada, New Jersey, New Mexico, New York, North Dakota, Oklahoma, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Washington, West Virginia, and Wisconsin.

In Texas, the Delivery Sales Restriction Statute requires that tobacco delivery sales not be made to an individual who is under the age of 18. Among other details, the delivery person must use a reliable source to verify the age of the person receiving the delivery and obtain the person's signature on a statement that certifies the person's address, date of birth, compliance with Texas law, and desire to receive tobacco products.[33]

COMMITTEE RECOMMENDATIONS

Alternative Delivery

In educating Texas minors, DSHS has isolated its tobacco prevention and education efforts to three counties. Out of the state's more than 4.5 million minors, DSHS only reached roughly 113,315 minors with the Texas Tobacco Prevention Initiative each year from 2004 to 2006.[34,35] Additionally, DSHS has limited resources available to deliver tobacco education to minors.

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[32] Texas. Office of the Attorney General. Email Response to House Committee on State Affairs Information Request. Received September 5, 2005.
[33] Texas Health & Safety Code, Sections 161.451 (2003) and 161.452 (2003)
[34] Texas. Education Agency. *2005-2006 Student Enrollment.* Accessed July 31, 2006.
http://www.tea.state.tx.us/cgi/sas/broker?_service=marykay&_program=adhoc.addispatch.sas&major=st&minor=e&endyear=06&format=W&linespg=60&charsln=120&selsumm=ss&key=TYPE+HERE&grouping=g
[35] Ibid. (footnote 114)

Therefore, it is the recommendation of the committee to consider changing the method of delivery used by DSHS to provide tobacco prevention education to minors throughout the state. The committee is aware of numerous options that could be the solution to the limited delivery system currently utilized by DSHS. However, the committee recommends that the Texas Legislature consider three of these possible changes. One, DSHS could be required to contract with TEA whenever DSHS is targeting minors with its tobacco prevention efforts. Two, DSHS and TEA could be required to work together through the Texas School Health Network when targeting minors with tobacco prevention efforts. Three, DSHS could be required to transfer its educational and monetary responsibility of tobacco prevention education to TEA, thereby making TEA the educational delivery system to educate minors throughout the state.

Lack of Information Exchange

The CO conducted 7,292 "controlled buys" from June 1, 2005, to May 31, 2006, and discovered a 10.33% violation to buy rate. Likewise, DSHS conducts an annual Synar survey to determine the rate of illegal sales to minors. This effort results in approximately 1,000 random, unannounced inspections of local tobacco retailers.[36] During fiscal year 2005, DSHS discovered a 12.4% violation to buy rate. Although, the discovered violation to buy rate is reasonably consistent, the information exchange is not. Even though DSHS uses the CO's list of retail tobacco outlets, DSHS claims that the Synar survey compliance inspections are never combined with law enforcement actions. This is to avoid jurisdictional and safety issues since Synar was strictly designed as a survey mechanism and not an enforcement tool.[37] This lack of communication inhibits the CO's enforcement abilities. Therefore, it is the recommendation of the committee to have DSHS conduct the federally required Synar survey as well as inform the CO of discovered violations so that the CO may enforce the Texas Tobacco Laws.

[36] Ibid. (footnote 121)

[37] Texas. Department of State Health Services. *Tobacco Retail Sales: Regulation, Enforcement & Education.* Received April 28, 2006.