House Committee on Public Health
Texas House of Representatives
Interim Report 2000

A Report to the
House of Representatives
77th Texas Legislature

Patricia Gray
Chair

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House Committee on Public Health

January 17, 2001

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

The Honorable James E. "Pete" Laney
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 House Committee on Public Health of the Seventy-Sixth Legislature submits this report on our interim charges to the Seventy-Seventh Legislature. The policy options outlined in this report were developed by the leaders of each charge. The options presented are not all inclusive, but do reflect testimony taken from stakeholders at our committee hearings. The committee respectfully declines to adopt specific recommendations, but offers this report as a reference for discussion of these complex issues by the Seventy-Seventh Legislature.

We thank you for providing us the opportunity to study these important public health issues.

Respectfully submitted,

Patricia Gray, Chair

Garnet Coleman, Vice Chair

Jaime Capelo

Dianne White Delisi

Bob Glaze

Harvey Hilderbran

Ruth Jones McClendon

Vice-Chairman: Garnet Coleman

Members: Jaime Capelo, Dianne White Deilsi, Bob Glaze, Harvey Hilderbran
Ruth Jones McClendon, Glen Maxey, Carlos Uresti

Glen Maxey

Carlos Uresti

Vice-Chairman: Garnet Coleman

~~**Members:** Jaime Capelo, Dianne White Delisi, Bob Glaze, Harvey Hilderbran~~
Ruth Jones McClendon, Glen Maxey, Carlos Uresti

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CHARGE I *Review the role of the pharmaceutical industry in the delivery of health care in Texas. The review should identify pharmaceutical cost-drivers and opportunities to reduce costs, assess the role of pharmacy benefit managers and pharmacies, and address patient-specific issues, as well as other issues identified by the committee.*

LEAD MEMBER *Rep. Patricia Gray*

INTRODUCTION

The committee held a public hearing to address this charge on May 23, 2000. At this hearing the committee heard from panels that provided a general overview of the pharmaceutical industry. This overview included various state initiatives to contain cost, designs of pharmacy assistance programs for seniors, and a discussion of cross-border issues with Mexico and Canada. The committee also heard different perspectives on the rising cost of pharmaceuticals such as prescribing patterns, utilization, direct-to-consumer advertising and marketing. Finally, state agency staff presented the committee with the impact of the rising cost of pharmaceuticals on their budgets.

In addition, Representative Gray invited stakeholders to participate in a workgroup on pharmaceutical issues. Representatives Coleman and Capelo participated in these work sessions as well. Stakeholders included Ken Ardoin, Task Force President, PhRMA (Pfizer); Robert Jones, Task Force Vice-President, PhRMA (Novartis); Christi Davis-O'Brien, Task Force Vice-President, PhRMA (Bayer); Joe Bill Watkins, Barr Pharmaceutical Company; Connie Barron, Texas Medical Association; Dr. Jesse Moss, Lone Star Medical Association; Karen Reagan, Texas Pharmacy Association; David Gonzales, Legend Pharmacies; Hector Leal, United Drugs; Tom Kowalski, Texas HealthCare and Bioscience Institute; Marsha Jones, Vice President, Governmental Affairs, Texas Hospital Association; Mary Anderlik, University of Houston Health Law and Policy Institute; Patrick Donoho, Vice President, Government & Regulatory Affairs, Pharmaceutical Care Management Association (PCMA) Institute for Health Care; Sam Stone, Texas Wholesalers Druggist Association; William "Reyn" Archer, M.D., Commissioner, Texas Department of Health; Don Gilbert, Commissioner, Texas Health and

Human Services Commission; Eric Bost, Texas Department of Human Services; Karen Hale, Texas Department of Mental Health and Mental Retardation; Jose Montemayor, Texas Department of Insurance; Sheila Beckett, Executive Director, Employees Retirement System; Charles Dunlap, Teachers Retirement System; Phyllis Coombes, Comptroller's Office; Jerry Patterson, Executive Director, Texas Association of Health Plans; Lisa McGiffert, Consumer's Union; Lara Laneri Keel, Texas Association for Business and Chambers of Commerce; Candice Carter, American Association of Retired Persons; Scott Macanelly, Executive Director, Workers Compensation and Research Oversight Committee; and Rick Levy, AFL-CIO.

The group held meetings in February, March and May. At these workgroup sessions attendees discussed cost containment strategies and barriers in state and federal law to more effective cost containment. We discussed many trends impacting utilization, such as the aging population, technology, genetic research/genomics, consumer education, research and development, unhealthy lifestyles, greater availability of lifestyle drugs and industry consolidation. We also talked about the difference between "health-sustaining" and "health-maintenance" drugs and discussed cross-border issues with Mexico and Canada.

The committee worked to identify specific factors such as marketing practices and provider incentive arrangements that may have contributed to the rising cost of pharmaceuticals in Texas. We worked to evaluate whether the use of formularies, generic brands, or purchasing cooperatives could reduce pharmaceutical costs in Texas' public health programs. We also examined the role of pharmacy benefit management companies and considered patient-specific issues such as cost differentials for different patient populations, patient privacy and general access to affordable medications.

POLICY OPTIONS

Option I	Create a bulk purchasing program that takes into consideration the impacts on wholesalers, pharmacies, employers, research, hospitals and uninsured consumers.
Option II	Consider developing and implementing a mandatory state rebate program.
Option III	Review drug purchasing data from all state agencies and set a price range, including a maximum allowable cost.
Option IV	Include publicly funded insurance programs (i.e., cities, counties, municipalities, hospital districts, school districts, etc.) in any state bulk purchasing program.
Option V	Require full disclosure of pricing information from wholesalers who do business in Texas.
Option VI	Require all pharmaceutical manufacturers (including generic pharmaceutical manufacturers) to report pricing information filed with the Health Care Financing Administration (HCFA) to the state.
Option VII	Make unused prescription drugs available to bonafide charity care organizations.
Option VIII	Coordinate patient assistance programs that are funded by the pharmaceutical industry to make such programs more accessible to physicians and their patients.

Option IX Require the Texas Department of Insurance, the Attorney General's Office, and the Texas Department of Health to evaluate existing buying groups and advise consumers.

Option X Advise Congress about the impacts of barriers to obtaining and sharing federal drug pricing information.

Option XI Establish pharmaceutical coverage for specified low income senior populations.

Option XII Expand Medicaid coverage to include more adults in the near-senior and/or senior age groups.

Option XIII Examine insurance-based programs for seniors above the federal poverty level without prescription drug coverage.

BACKGROUND

Prescription drugs have become an increasingly important part of medical practice as well as in most Americans' lives. According to a recent Kaiser Family Foundation survey, more than 9 in 10 Americans report taking prescription drugs, over half take them on a regular basis, and one-third have more than five prescription drugs in their medicine cabinet.[1] They help to save and extend lives, shorten hospital stays and improve the quality of life by treating everything from heart disease to hair loss. However, rising costs have become a major concern not only for consumers, but also for employers, private insurers, and government programs. National spending on prescription drugs has increased at double digit rates in each of the past two years, and is expected to continue to do so.[2] Drug expenditures are the fastest growing component of health care in the nation.[3] For example, between 1995 and 1998, expenditures for physician services increased by 14% and those for hospital services increased by 10%, while expenditures for prescription drugs increased by 50%. Prescription drug expenditures amounted to $38 billion in 1990 and increased to $91 billion in 1998.[4]

Although most Americans are affected by these rising costs, the elderly population has most acutely felt the increase. According to the same survey, those over 65 are significantly more likely to be regular users of prescription drugs, to have more than five prescriptions in their medicine cabinet, and to spend more out-of-pocket on prescription drugs.[5] Conversely, older Americans are more likely to report that they lack prescription drug coverage and that paying for prescription drugs is a serious problem.[6] Seniors are seriously affected by the rising prices of drugs. Families USA reports that their average cost per prescription increased by 48% from 1992 to 2000, meaning that the average cost paid by seniors per prescription increased from $28.50 in 1992 to $42.30 in 1998.[7] The same report projects this cost to reach $72.94 by 2010, which would mean an increase of 156% since 1992.[8]

The combination of rising usage, prices and the significant increase in the elderly population has led to an increasing awareness and concern about prescription drug coverage. The topic has received widespread attention from the federal and state governments and the national and local media. More

than half of the public now realizes that Medicare does not cover prescription drugs (except those dispensed in in-patient facilities or those which cannot be self-administered), as compared to less than one-third two years ago.[9] While there are some existing programs that provide coverage for prescription drugs such as Medicare + Choice plans, Medigap, private health insurance for retirees, or Medicaid, an estimated 13 million seniors have no coverage. Meanwhile, those who do have coverage have seen some reductions in that coverage and are worried that more are on the horizon.[10]

Consequently, a growing number of states have created special pharmaceutical assistance programs for seniors and people with disabilities. As of October 2000, 22 states have passed some type of pharmaceutical assistance law. (See Appendix A - "State Senior Pharmaceutical Assistance Programs", the National Conference of State Legislatures) Other states have adjusted eligibility for Medicaid, with its prescription benefit, to cover additional people, and some are exploring broad-based, statewide programs aimed at achieving substantially lower pharmaceutical prices for the average consumer by using Medicaid-style rebates or discount rates as a basis for a retail price, instead of providing a direct state-funded subsidy. A new law in Maine and proposals in several additional states also call for state price controls on pharmaceuticals that would apply to public consumer purchases. The federal government has also tried to address elderly access to prescription drugs, with four major Medicare prescription drug proposals considered by the 106th Congress. (See Appendix B - "A Side-by-Side Comparison of Selected Medicare Prescription Drug Coverage Proposals", The Kaiser Family Foundation)

Texas, like the rest of the nation, has a growing elderly population and is feeling the financial burden from the rising costs of pharmaceuticals. Approximately 1.9 million people over the age of 65 live in Texas. Approximately 247,000 seniors live below 100% of the Federal Poverty Level (the Federal Poverty Level is approximately $8,410 for a family of one), and, of that number, approximately 64,000 qualify to have some of their Medicare premiums paid for but do not receive prescription drug coverage (See Appendix C - 1999 Poverty Level Populations of Age 65+ Chart and Average Monthly

Clients Table, HHSC). In addition to providing prescription drugs for those who qualify for Medicaid through the Medicaid Vendor Drug Program, the State of Texas buys hundreds of thousands of prescription drugs for other programs at the Texas Department of Mental Health and Mental Retardation and the Texas Department of Criminal Justice. (See Appendix D - "How Texas State Agencies Purchase Drugs") The state also indirectly purchases prescription drugs through its contributions to the Children's Health Insurance Program, health benefit plans for state employees, retired teachers and some university systems, and many other entities that receive state money purchase prescription drugs, such as hospitals, school districts, county indigent health care programs, and municipalities. Prescription drug expenditures by the Employees Retirement System are estimated to have more than doubled over the last six years, while the Texas Medicaid Vendor Drug Program absorbed a 46% increase in drug spending over the past three years.

As seniors and others without prescription drug coverage struggle to absorb the rising costs of pharmaceuticals, so do Texas state agencies, and, therefore, Texas taxpayers. Prescription drug coverage will be an important issue not only from a public health policy perspective, but also from an appropriations and financial perspective as well. As Texas prepares for the 77th Legislative Session it is important to recognize the needs of our constituents and to understand the limits of our resources.

How Prescription Drugs Are Priced

The way a price is determined for a prescription drug is a complex process because of intricate arrangements between all the entities involved in delivering the product to the consumer. The process is further complicated by the variations in price based on who the payer is and who the seller is. The words "price" and "cost" are often used interchangeably, but when used in the context of prescription drugs, their meanings are very different. "Price" is accompanied by many modifiers: "wholesale", "manufacturer", or "retail", and is part of acronyms such as AWP (Average Wholesale Price) or AMP (Average Manufacturer Price). Price usually represents what one entity (manufacturer, wholesaler or retailer) charges another entity in the distribution chain (wholesaler, retailer or consumer) for a drug.

"Cost" also represents different things to different entities in the distribution chain. For consumers, "cost" is largely dependent on who pays for the drug, i.e. whether the payer is a private or government sponsored heath plan or whether the consumer pays cash out-of-pocket for the full retail price of the drug. (See Glossary for definitions of these terms)

The net result of all of these factors is that it can be very complicated for the average consumer to determine an objective market price for a drug or for state regulators to determine whether state agencies are receiving the lowest prices for the same drugs. Although average wholesale price may represent a reference point for a particular prescription drug, it does not represent the actual transaction price.[11] The reality of the pharmaceutical marketplace is that these price reference points represent negotiation starting points. One report compared the average wholesale price to the sticker price on an automobile, where a certain price is suggested by the manufacturer, but is rarely ever paid.[12] Include in the mix variations on unit cost and pharmacy dispensing fees and the price charged for a drug and cost paid become even more complicated.

In studying this interim charge, the committee worked with agency staff to survey Texas state agencies on the top 200 drugs purchased, but couldn't get a completely accurate picture because of the complexity of the pricing structure. Variations in the units purchased and whether programs received discounts or rebates made a difference in cost to the agency.

How Prescription Drugs Are Sold

The distribution channel for prescription drugs consists of three primary entities:

- the **Pharmaceutical Manufacturers,** that produce drugs;
- the **Wholesalers,** that distribute drugs obtained from manufacturers; and
- the **Pharmacies,** that dispense drugs to patients.

The interactions and arrangements between each of these entities determine the final cost of prescription drugs to the final entity in the chain, the **consumer**.

Manufacturers

Manufacturers produce and market prescription drugs. The term includes both major pharmaceutical manufacturers and generic pharmaceutical manufacturers.

Major pharmaceutical manufacturers identify and develop new prescription and/or nonprescription drugs through their research efforts. Typically these firms are large manufacturing companies. Sometimes they are referred as "innovator" pharmaceutical firms, "brand name" pharmaceutical manufacturers, research-based pharmaceutical manufacturers, or generally as the "pharmaceutical industry." These firms invest in new product research and development and support their products with extensive promotional efforts. Their trade associations include Pharmaceutical Research and Manufacturers' Association(PhRMA), the National Pharmaceutical Council (NPC), and the Consumer HealthCare Product Association (CHPA). Some major pharmaceuticals manufacturers also have generic manufacturing divisions or generic pharmaceutical manufacturer subsidiaries.

Generic pharmaceutical manufacturers produce and market generic prescription and/or nonprescription drug products. Some generic firms both manufacture and distribute drug products while others only repackage or distribute products manufactured for them by contract manufacturing firms (sometimes even a major pharmaceutical firm). Although all drug products must have FDA approval for sale, independent clinical trials are not required for generic drugs; the innovator's evidence of safety and effectiveness are accepted. Generic firms must show that their products are bio-equivalent, often through laboratory studies and assurances. Since generic firms often produce drugs identical to brand-name drugs, they generally compete on price to establish or gain market share.

The distinction between entities which produce brand name drugs and those which produce generic drugs is seen in their investments in research and development. The Pharmaceutical Research and Manufacturers of America (PhRMA) reports that the brand-name industry spent $24 billion in 1999 and expects to spend $26.4 billion this year.[13] These costs are generally recouped while the patent is

still in place, before other competitors enter the market and produce generic equivalents.

Manufacturers distribute their products predominately through drug wholesalers, but also sell directly to individual pharmacies, pharmacy chains, hospitals, HMOs and others.

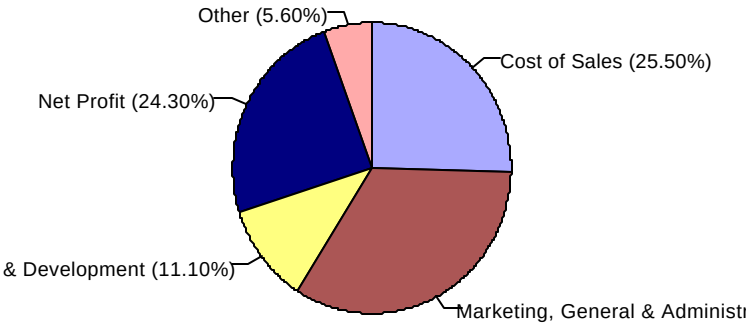
Their selling price, as mentioned before, is the AMP, which does not factor in after-market transactions such as rebates. Actual selling prices vary widely depending on the class of trade of the end user, market share arrangements, volume buying, and other factors.

Included on the next page are charts of the top 20 major and generic pharmaceutical companies and their respective financial operations.

Top 20 Major Pharmaceutical Companies Ranked by Prescription Sales

Company	1998 Sales (In Millions)
1. Pfizer, Inc.	$6,085
2. Merck & Company, Inc.	$6,076
3. Bristol-Myers Squibb Co.	$5,905
4. Glaxo-Wellcome, plc.	$5,376
5. Johnson & Johnson	$4,857
6. Eli Lilly & Company	$4,517
7. American Home Products Corp.	$4,334
8. Schering-Plough Corp.	$4,270
9. Novartis AG	$3,995
10. SmithKline Beecham, plc.	$3,815
11. Warner-Lambert Co.	$3,568
12. Abbott Laboratories	$3,111
13. Astra Merck, Inc.	$3,076
14. Hoffman-La Roche, Ltd.	$2,291
15. Amgen, Inc.	$2,261
16. TAP Pharmaceuticals	$1,945
17. Zeneca Pharmaceuticals	$1,879
18. Pharmacia & Upjohn, Inc.	$1,820
19. Hoechst Marion Roussel	$1,806
20. Bayer AG	$1,489
TOTAL	**$72,476**

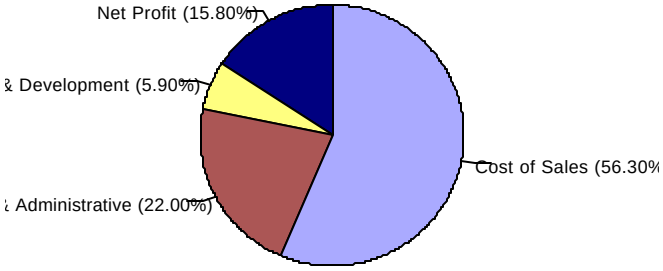
Financial Operations Summary: Top 10 Major Pharmaceutical Companies



Top 20 Generic Drug Manufacturers Ranked by Total Sales

Company	1998 Sales (In Millions)
1. Teva Pharm. Industries	$1,115.9
2. Perrigo, Co	$ 877.6
3. Mylan Labs., Inc.	$ 721.1
4. Ivax Corp.	$ 637.9
5. Forest Labs., Inc.	$ 624.0
6. Allpharma, Inc.	$ 604.6
7. Watson Pharm., Inc.	$ 556.1
8. Schein Pharm., Inc.,	$. 523.2
9. Barr Labs., Inc.	$ 444.0
10. Ranbaxy Labs., Inc.	$ 257.3
11. Copley Pharm., Inc.	$ 133.5
12. Jones Pharma, Inc.	$ 103.4
13. Taro Pharm. Indust., Inc.	$ 66.7
14. Warner Chilott, Plc.	$ 64.9
15. Pharm. Foundations, Inc.	$ 60.4
16. Akorn, Inc.	$ 56.7
17. Duramed Pharm., Inc.	$ 49.8
18. DynaGen, Inc.	$ 25.0
19. Hi-Tech Pharmacel Co., Inc.	$ 23.3
20. Bradley Pharm., Inc.	$ 15.9
Total	**$6,961.3**

Financial Operations Summary: Top 10 Generic Pharmaceutical Companies



**Source: Prescription Drug Trends - A Chartbook; The Kaiser Family*

Wholesalers

Wholesalers serve as the middlemen between manufacturers and pharmacies. Wholesalers can help pharmacies with inventory management by buying in large quantities and distributing in smaller allotments, thus relieving smaller pharmacies of costly inventory maintenance.

The wholesalers' cost to buy drugs from manufacturers is considered the Wholesaler Acquisition Cost (WAC) which is equal to the manufacturer's selling price.

Wholesalers may also broker deals with retailers and other third parties which involve bookkeeping and/or distribution of drugs without actually taking possession of and reselling the products.

A Wholesaler's selling price is determined using either a "cost plus" or "list less" approach, both of which may result in the same or similar price. "Cost plus" means the WAC plus a markup percent. "List less" means AWP minus a discount percent.[14]

Wholesalers sell or distribute their drugs to pharmacies and other retailers based on contracts or other agreements that may take into consideration factors such as volume, market share, prompt payment, class of trade or other competitive market factors. These prices may vary widely depending on the product, the manufacturer, and the retailer.

The drug wholesaler industry is a very concentrated market, with the top 5 firms achieving nearly the entire industry's sales in 1998. Mergers and acquisitions have contributed to this industry structure.

Top 10 Drug Wholesalers Ranked by Sales Activity, 1998

Company	1998 Sales (In Millions)	Market Share (% of Total Drug Wholesale Market)
1. McKesson HBOC Corp.	$21,484	28%
2. Bergen Brunswig Drug Corp.	$16,698	22%
3. Cardinal Health, Inc.	$14,928	19%
4. Amerisource Corp.	$ 8,669	11%
5. Bindley Western Drug	$ 7,623	10%
6. Neuman Distributors, Inc.	$ 1,668	2%
7. Kinray, Inc.	$ 905	1%
8. CD Smith Healthcare, Inc.	$ 798	1%
9. D&K Healthcare Resources, Inc.	$ 703	1%
10. Remo Drug Corp.	$ 508	1%

** Source: National Wholesale Druggists' Association (NWDA) Industry Profile, 1999, based on data from NWDA surveys of member wholesalers.*

There are two different types of wholesalers:

- *Wholesale Manufacturer*: a wholesaler who manufactures, prepares, propagates, compounds, processes, packages, repackages, or changes the container, wrapper, or labeling of any drug package.
- *Wholesale Distributor*: the traditional wholesale prescription drug distributor, not a manufacturer of drugs.

Federal and state laws regulate wholesaler procedures such as record keeping, security, temperature and humidity requirements, personnel training, returned goods and recall handling, emergency planning and receipts and distribution of products.[15] The licensing of wholesale distributors of drugs is the responsibility of the Texas Department of Health (TDH), Bureau of Food and Drug Safety, Drugs and Medical Devices Division.[16] Texas is served by eighteen prescription drug wholesale distributors, but only eight of these companies have facilities actually located in Texas. TDH licenses 2,035 separate wholesale drug locations in Texas and 720 out-of-state wholesale drug facilities that distribute drugs in Texas. TDH estimates that they inspect 1440 wholesale manufacturers and wholesale distributors annually, 65 of which are under an FDA/TDH partnership agreement. Non-manufacturing prescription drug wholesalers may be inspected by either TDH or the FDA.

Retailers/Pharmacies

Retailers (Pharmacies) dispense prescriptions to consumers and provide professional pharmacist services. This group includes independent and chain pharmacies, mass merchandise pharmacies, mail order houses and Internet web-based pharmacies.

The retailers cost to buy drugs from wholesalers or manufacturers is considered the Actual Acquisition Cost (AAC). Retailers may negotiate prices with wholesalers or manufacturers individually or through corporate management or buying groups. The actual cost to a retailer will vary widely depending on the terms of the negotiated arrangements.

Their selling price to uninsured and indemnity-insured consumers is the "usual and customary" (U&C) retail price - the cost of the drug plus the pharmacy's markup. To other insured consumers ("Service Benefit" Insurance Coverage), the selling price is the insurer's payment formula, typically including its determination of the cost of the drug dispensed ("ingredient cost") plus a professional dispensing fee. The pharmacy submits a claim to the insurer equal to the formula-based price less the consumer's cost-sharing amount (the co-payment or coinsurance).

There are different types of pharmacies:

- **Independent Pharmacies**, which are individual or small chains of pharmacies that are privately owned. These types of pharmacies have a greater reliance on prescription drug sales (70%-85%).
- **Traditional Chain Drug Stores** usually are defined as having 10 or more units under the same ownership. Traditional chains are "freestanding" retail outlets with prescriptions, nonprescription drugs, sundries, and general merchandise departments. The prescription department usually contributes more to total store sales than the other merchandise departments (e.g. gifts, sundries, photos, magazines, etc.). Examples include Walgreens, Eckerd, CVS, and

Rite Aid. These stores have a lesser reliance on prescription drug sales (about 50%).

- **Mass Merchandiser Pharmacies**, such as Wal-Mart and K-Mart are generally outlets in large multi-store chain operations or grocery stores. Prescription drug sales are a small portion (about 5%-10%) of their total business.
- **Franchise Pharmacies** are independently owned, but organized under a franchising umbrella organization that often provides management, marketing and purchasing support. These pharmacies share many similarities with independent pharmacies, but have a common name and identity logo. The majority of store sales are prescriptions. Examples include Medicine Shoppe International, etc.
- **Internet/Online Pharmacies** dispense prescriptions to consumers that contact the pharmacy via an Internet web site. Internet pharmacies are a relatively new phenomenon, first established in 1998 and starting sales in 1999. Although information about these pharmacies is sparse, due to their newness, they represent a small proportion of all prescriptions dispensed. Unlike traditional pharmacies, the pharmacies can serve more than the local market where the pharmacy is located. Since there typically is at least a short delay between ordering and receiving prescriptions, these pharmacies generally serve patients on long-term drug therapies and those without immediate drug needs.
- **Mail Order Pharmacies** dispense prescriptions to consumers who contact the pharmacy by mailing or faxing their prescriptions orders and then the prescription is mailed to the consumers. This can be an advantage for homebound patients or other patients without ready access to traditional community pharmacies. Unlike traditional pharmacies, the pharmacies can serve more than the local market where the pharmacy is located. Since there typically is at least a short delay between ordering and receiving prescriptions, these pharmacies usually serve patients on long-term drug therapies and those without immediate drug needs. The average size of prescriptions (number of capsules or tablets) dispensed in mail order pharmacies is larger than in local community pharmacies. Consequently, although mail order pharmacies represent less than 5% of all prescriptions dispensed, they compromise approximately 12% of total retail

prescription sales.

In the last ten years there has been a decrease in the total number of retail pharmacies in the United States. In 1990, there were approximately 59,000 retail pharmacies. By 1998, that number had declined to approximately 52,000 nationwide. In addition to this decline in the number of retail pharmacies, the market has shifted away from independently owned pharmacies to chain drug stores. From 1990 to 1998 there was an approximate 14% shift away from independent pharmacies (54% - 40%).[17]

In July 2000, the Kaiser Family Foundation reported that pharmacy gross margins as a percent of sales have decreased, even though the average retail prescription price has increased. The report notes while an increasing proportion of prescription expenditures are being paid by insurers, pharmacies are being affected by the cost management approaches of insurers, which have reduced dispensing fees and overall margins for pharmacies.[18]

Consumers

The majority of drugs sold to consumers are purchased through third party arrangements, including insurers, HMOs, and government programs such as Medicaid. Their cost to buy drugs depends primarily on whether they are insured or uninsured. If the consumer is uninsured, they pay the U&C cost. If the consumer is insured, they will pay the co-payment amount or the co-insurance amount.

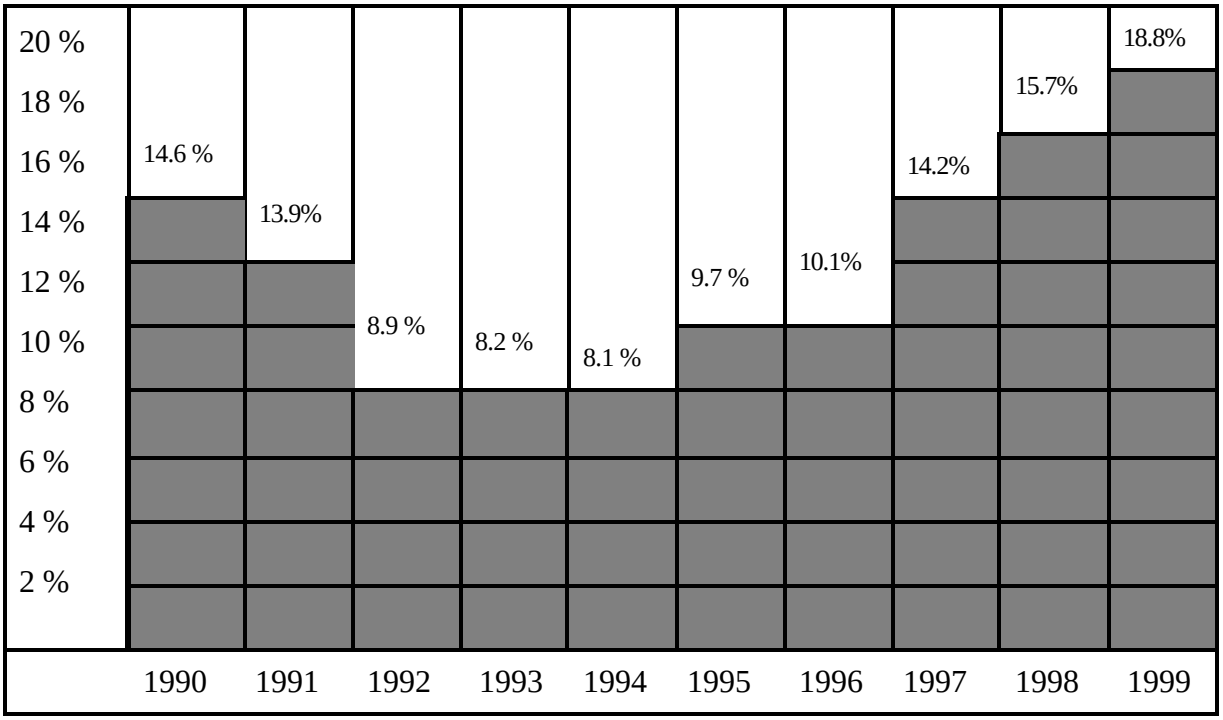
Why Drug Expenditures are Rising

As seen from the chart below, pharmaceutical sales have more than doubled in the last five years. National expenditures on pharmaceuticals have increased $10 billion annually from 1995 to 1998, culminating in a total of $91 billion in 1998, and expected to reach about $243 billion in 2008.[19] There are many reasons that contribute to this sharp increase in total expenditures, but increased utilization,

increased drug promotion and newer drugs with higher prices are the principal reasons drug expenditures are going up.

The US Prescription Pharmaceutical Market

Total Sales Growth Rates



*Source: *Prescription Drugs in the Health care system:* www.phrma.org

Utilization

Utilization of prescription drugs is one of the primary factors contributing to drug expenditure increases. In some sense, increased utilization is driven by a circular proposition: more people are taking more and improved drugs, thereby living longer and taking more drugs. The number of dispensed prescriptions has increased steadily since 1992. The total number of dispensed prescriptions increased by 37% from 1992 to 1998, and the number of prescriptions per capita increased by 32% from 1992 to 1998, while

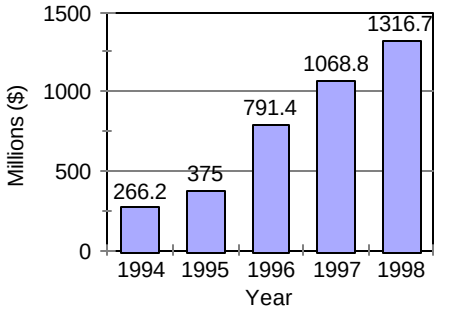
the national population growth was just 6%.[20] Other factors that have driven the increase in utilization include an increased number of prescribers and an increasing reliance on prescriptions in medical treatment and therapy.

Drug Product Promotion

A major factor affecting the use of prescriptions (particularly the use of new prescriptions) as well as the price of pharmaceuticals is the promotion of drug products by pharmaceutical manufacturers. The pharmaceutical industry promotes prescription drugs in several ways, including:

- Detailing: sales calls by company representatives to physician offices and hospitals, which often include providing samples;
- Displays and presentations at professional meetings and events; and
- Direct-to-Consumer advertising (DTC): "any promotional effort by a pharmaceutical company to present prescription drug information to the general public in the lay media"[21]

Direct-to-Consumer Advertising spending by Pharaceutical Companies



Although detailing continues to be the largest and most traditional type of promotion, the growth in direct-to-consumer advertising has been remarkable. Spending on DTC more than tripled from 1995 to 1998 (from $ .4 billion to $1.3 billion) and reached 16% of total promotional spending in 1998.[22] This growth in DTC advertising is due to two factors: increased competition among manufacturers and a need to be more aggressive in marketing their products and a relaxation of some of the regulatory standards for broadcast advertising of pharmaceuticals by the FDA in 1997.[23] In 1990, 10 different

medicines were advertised directly to consumers. That number grew to 79 in 1997.[24] Today, pharmaceutical advertising is one of the fastest growing categories of advertising.[25]

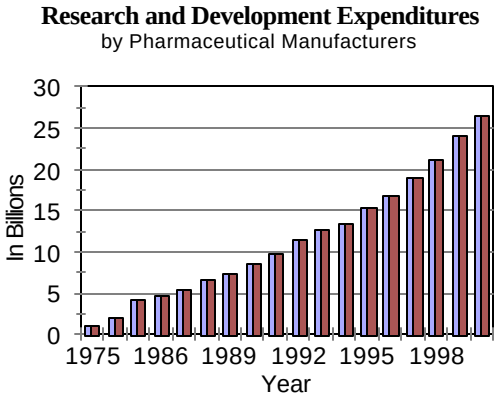
Prescription Drugs with the most DTC Advertising

Drug	Indication	DTC Advertising (In Millions)	Top 200 Ranking
Claritin	antihistamine	$150.2	11
Propecia	hair loss	$91.0	N/A
Zyrtec	antihistamine	$75.2	48
Pravachol	cholesterol-lowering	$59.6	29
Zyban	smoking cessation	$54.6	N/A
Allegra	anti-histamine	$52.5	59
Prilosec	anti-ulcer	$49.7	5
Zocor	cholesterol-lowering	$41.6	15
Evista	osteoporosis	$38.9	N/A
Prozac	anti-depressant	$37.5	8
Premarin	hormone replacement	$37.0	1
Imitrex	migraine	$36.4	79

Newer drugs on the market

According to PhRMA, the pharmaceutical industry developed 370 new medications in the last decade, up from 239 in the previous decade.[26] Not coincidentally, the timeline for FDA review and approval of new drugs has been cut in half in the last decade.[27] The new drugs on the market have the potential to save lives, reduce other health care costs and improve the quality of life. The industry reports that in

1999, 40 new medicines were introduced on the market, including "a new twice-a-day protease inhibitor for AIDS, the first in a new class of antibiotics, two new treatments for breast cancer, the first new medicine for a certain type of brain tumor in 20 years, two new medicines for Type II diabetes, and a breakthrough medicine for osteoarthritis" and that "more than 1000 new drugs are in development to treat hundreds of serious diseases, including Alzheimer's, Parkinson's, cancer, stroke, depression, and arthritis." [28] While the impact of these new medications on health and quality of life should not be underestimated, their impact on expenditures is a clear increase. The higher prices of these newer medications is attributable in large part to the amount the industry spends on research and development (R&D) for new medications. This year alone, the industry expects to spend $26.4 billion on R&D.[29]



The costs for research and development are factored into the price of the drug and projected to be recovered during the life of the patent for the drug. A patent provides exclusivity for a product in the market place. The patent life is the time during which a patent is in force and the product's manufacturer has exclusive marketing rights. The length of a patent for a drug is 20 years and is longer for other products. The effective patent life for a drug may actually be shorter than 20 years depending on the time between discovery and market launch that is needed for safety and efficacy testing, clinical trials and FDA approval for marketing. After a patent for a drug expires, generic pharmaceutical manufacturers can produce and distribute the drug. While the number of generic drugs has increased as a percentage of all prescriptions since 1991 (from 35% to 45%), their percentage of total prescription sales has declined in recent years to less than 20% of all prescription sales.[30]

The interplay between utilization, promotion and newer drugs in the pharmaceutical industry is complex;

changes in one factor impact another, and it's difficult to determine which came first: the high prices or the new ads, the new drugs or the new drug users. The pharmaceutical marketplace is extremely dynamic and these factors are constantly pushing one another. As newer drugs are developed, older drug therapies are displaced. The new drugs represent therapeutic advances, but are also are accompanied by higher prices. To recover costs spent on R&D, the manufacturers charge higher prices and increase drug promotion efforts. Because of greater name recognition due to drug promotion efforts, consumers are using more of the newer, higher priced drugs. When the patents expire on the new drugs, generic drugs are developed, but their sales don't increase at the same rate as the brand-name drugs and the promotional efforts aren't made as extensively. Continuing research and development produces new drugs, the older drugs are displaced, and the cycle begins again.

Reactions to Rising Expenditures

Increasing Access to Prescription Drug Coverage

Recognizing the growing burden that the costs for pharmaceuticals has become, many states have created different options to provide prescription drug coverage for their residents. Most programs are directed at low-income seniors or persons with disabilities, but some are open to anyone without a third-party source for coverage. Some of the options include:

- Pharmaceutical Assistance Programs: These programs use state funds to subsidize prescription drug costs for a defined population with certain eligibility criteria. The National Conference of State Legislatures reports that as of August 2000, 22 states had developed some form of pharmacy assistance program. (See Appendix A)
- Expansion of Medicaid Eligibility: These programs expand eligibility for the Medicaid program, with its prescription drug benefit, to a broader population.
- Discount prices: Other states have elected to make the elderly or disabled eligible for lower prices on prescription drugs, based either on the Medicaid rate or the Federal Supply Schedule. Similar proposals encourage broader use of Federally Qualified Health Centers because they sell drugs at discounts similar to those in the Medicaid program.
- Coordination of pharmaceutical charity programs: The pharmaceutical industry has many

programs that offer drugs free of charge to physicians whose patients do not have coverage and cannot afford them. Each manufacturer has different eligibility requirements for their programs and each program is administered separately. The industry has reportedly donated millions to needy patients through these programs.

Cost Containment Options

Other states have explored ways to control costs of pharmaceuticals directly, either for state purchases of pharmaceuticals or for consumer purchases. These options include:

- State bulk purchasing: the object in these programs is to negotiate lower prices based on bulk purchasing arrangements

- Price controls or state maximum prices: some states have imposed regulations setting the maximum price at which particular drugs can be sold in their state. One such law in Maine has been challenged by the pharmaceutical industry on grounds of interference with interstate commerce.

Managing Prescription Drug Benefits

Private health plans and managed care organizations have also undertaken efforts to control prescription drug expenditures. Several plans have instituted the use of formularies to control which drugs are prescribed by dictating which drugs the plan will pay for. Others use enrollee cost-sharing approaches such as tiered co-payments. Perhaps one of the largest efforts to control costs has been the creation of pharmacy benefit managers (PBMs), which are private firms that manage drug coverage programs for health plans, insurers, and many employers. These organizations provide administrative services in processing and analyzing prescription claims and can include other services such as contracting with a network of pharmacies, establishing payment levels for provider pharmacies, negotiating rebate arrangements, developing and managing formularies, preferred drug lists, and prior

authorization programs and operating disease management programs. Many PBMs also operate mail order pharmacies or have arrangements to include prescription availability through mail order pharmacies. In 1998, PBMs processed about 40% of all prescriptions dispensed.[31]

The next chart provides details about the largest **Pharmacy Benefit Managers** (PBMs), their prescription volume and market share.

PBMs	**1998 Prescription Volume (Million)**	**Market Share of All Prescriptions**
Merck-Medco Managed Care (PAID Prescription, Inc.)	252.4	9.8 %
PCS Health Systems	251.8	9.7 %
Express Scripts	196.3	7.6 %
Wellpoint Pharmacy Management	45.4	1.8 %
Advance Pharmacy Services/Paradigm	35.5	1.4 %
Caremark Prescription Services	33.7	1.3 %
Aetna Pharmacy Management	30.0	1.2 %
National Prescription Administration	28.0	1.1 %
Preferred Solutions	26.4	1.0 %
Provantage RX Management Services	19.5	0.8 %
Other	172.6	6.7 %
Total:	**1,091.7**	**42.2 %**

* *Note: Prescription Volume is the number of prescription claims processed by the PBMs. Market share is based on a total of 2.59 billion prescriptions dispensed in 1998.*

* *Source: National Association of Chain Drug Stores (NACDS.). The Chain Pharmacy Industry Profile, 1999.*

Currently, PBMs manage an estimated 71 % of the volume of prescription drugs dispensed through retail pharmacies that are covered by private third party payers. The PBM industry is highly concentrated. In 1998, the PBM market was dominated by 3 firms, Merck-Medco Managed Care, PCS Health Systems, and Express Scripts, Inc., which represented 64.2 % of the PBM prescriptions processed and 27.1 % of all US prescriptions dispensed that year.[32] No other PBM has more than

2% of the market.[33]

PBMs never take possession of a drug. Rather, they develop relationships with retail pharmacies, drug manufacturers, doctors and patients. A primary function of a PBM is claims processing, but it may utilize a variety of cost containment strategies, including any of the strategies listed below:

- **Formularies:** lists of preferred drugs within each therapeutic class, usually combined with financial or other incentives to steer patients toward the listed drugs, such as using differential levels of co-payment;
- **Generic Substitution Policies:** encouraging use of available generics in place of brand name drugs (also by using different levels of co-payment);
- **Management and Compliance:** selecting drugs for coverage;
- **Pharmacy Network and Payment Administration:** maintaining a panel of pharmacy providers which establishes payment rates;
- **Rebate Negotiations and Management:** contractually negotiated discounts, typically based on the ability of the PBMS to increase utilization for a particular drug by switching patients away form therapeutically similar alternatives (also referred to as moving market share);
- **Disease Management Programs:** educating patients about their illness and promoting compliance with drug regimens;
- **Drug Utilization Reviews (DUR):** reviews which are either concurrent (checking for drug interactions before the prescription is dispensed) or retrospective (reporting on the rate of formulary compliance across doctors or patients). Retrospective DUR can also be used to check for contradictions or other factors related to the quality of pharmaceutical care;
- **Lower Retail Pharmacy Prices:** negotiations with a network of retail pharmacies;
- **Therapeutic Interchange Programs:** obtaining the doctor's permission to substitute one brand-name drug for another with a different chemical composition that is in the

same therapeutic class and is included on the formulary;

- **Prior Authorization Programs:** requiring special permission be obtained before dispensing certain types of drugs; and
- **Mail Order Programs:** many PBMs have their own mail-order pharmacy, which can help to contain costs by dispensing drugs in larger quantities to consumers and requiring lower inventory control costs. (Mail-order drug sales grew to $11.2 billion in 1998, reaching about 12 percent of total prescription drug sales)[34]

GLOSSARY OF TERMS

Actual Acquisition Cost (AAC): The net cost at which the pharmacy acquires a drug. It varies with the size of container purchased (e.g., ten bottles of 100 tablets typically cost more than one bottle of 1,000 tablets) and the source of purchase (manufacturer or wholesaler).

Average Manufacturer Price (AMP): The price at which drugs are sold by the manufacturer to purchasers. For sales to wholesalers, AMP represents the Wholesaler Acquisition Cost (WAC) after all discounts; for sales directly to pharmacies, AMP represents the net "direct" price after discounts.

Average Wholesale Price (AWP): A national average of list prices charges by wholesalers to pharmacies. With few exceptions, the AWP is the manufacturer's suggested list price for a wholesaler to charge a pharmacy for a drug. It typically is higher than the pharmacy's actual acquisition cost (in 1997, the Office of Inspector General, Department of Health and Human Services, reported that pharmacies paid 18.3% less than AWP for brand name drugs and 42.5% less than AWP for generic drugs.)

Brand Name Drug: Generally, a drug product that is covered by a patent and is manufactured and sold exclusively by one firm. Cross licensing occasionally occurs, allowing an additional firm to market the drug. After the patent expires, multiple firms can produce the drug product, but the brand name remains with the original manufacturer's product.

Cash Prescription: A prescription purchased in a retail pharmacy where the consumer pays the pharmacy's usual and customary (U&C) charge entirely out-of-pocket when the prescription is dispensed.

Chain Pharmacy: A corporate organization with multiple pharmacy store outlets under common ownership. Traditional chain pharmacies such as Walgreens, Eckhard, Rite Aid, and CVS have

approximately 50% of their sales in other merchandise.

Coinsurance: A cost-sharing requirement under a health insurance policy that requires the patient to pay a percentage of costs for covered services/prescriptions (e.g., 20%of the prescription).

Co-payment: A cost-sharing requirement under a health insurance policy that requires the patient to pay a specified dollar amount for each unit of service (e.g. $10.00 for each prescription dispensed).

Cost of Goods Sold: For retail or wholesale firms, the cost of merchandise that was acquired with the intent of re-sale to the firms' customers. For a drug wholesaler, the cost of goods sold is the net price paid to the manufacturer for the drugs the wholesaler subsequently sells to pharmacies (wholesale acquisition cost, WAC). For a pharmacy, the cost of goods sold is the net price paid to the wholesaler (or manufacturer, if purchasing directly from the manufacturer) for the drugs sold to consumers (actual acquisition cost, AAC).

Direct-to-Consumer Advertising/Promotion: Advertising for prescription drugs in print, radio, and television media targeted directly to consumers by pharmaceutical manufacturers. Consumers are the targeted audience, even though the drugs require a prescription order from a prescriber in order to be dispensed.

Dispensing Fee: An amount added to the prescription ingredient cost by a pharmacy to determine a prescription price. The dispensing fee represents the charge for the professional services provided by the pharmacist when dispensing a prescription (including overhead expenses and profit). Most direct pay insured prescription programs use dispensing fees to establish pharmacy payment for prescriptions.

Drug: A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of a disease.

Drug Wholesaler: A firm involved in the logistics function (assembling, sorting, and redistributing) in the channel of distribution for pharmaceuticals. They purchase goods from manufacturers and redistribute them to pharmacies based on the needs and orders of the pharmacies.

Estimated Acquisition Cost (EAC): An estimate of the price at which most pharmacists can purchase a drug from a wholesaler or manufacturer. These estimates are developed by pharmacy benefit managers (PBMS's) or prescription insurance program administrators in order to establish payment of amounts to pharmacies for the drug costs of prescriptions dispensed (prescription ingredient cost) to covered individuals . An EAC is used in setting reimbursement rates for certain single source drugs (i.e., brand name drugs for which no generic equivalents exist).

Food Store/Supermarket Pharmacies: Pharmacy departments within chain grocery store outlets. The prescription department generates a small proportion of total store sales, but used to draw customers and build a "full service" image for the supermarket. Examples include Kroger, Albertsons, Sav-On/Tom Thumb, etc.

Formulary: A listing of drug products that may be dispensed or reimbursed (positive formulary) or that may not be dispensed or reimbursed (negative formulary). A government body, third-party insurer or health plan, or an institution may compile a formulary. Some institutions or health plans develop closed (i.e., restricted) formularies where only those drug products listed can be dispensed in that institution or reimbursed by the health plan. Other formularies may have higher patient cost-sharing requirements for off-formulary drugs.

Generic Drug: A drug product that is no longer covered by patent protection and thus may be produced and/or distributed by many firms.

Health Care Financing Administration Federal Upper Limit (HCFA FUL): Amount established

by HCFA of the US Department of Health and Human Services as a target amount of payment for a drug in a state Medicaid Program. States establish their own Estimated Acquisition Cost (EAC) and Maximum Allowable Cost (MAC) payment levels, but a state's total drug program payments cannot exceed what would be determined as the state's aggregate drug payments if the FUL amounts were used for payments. A state may pay above the HCFA FUL for some individual products as long as the aggregated payments are within the total amount determined using the FULs (e.g., the state may establish lower MACs than the FUL amounts to balance higher EACs for brand name drugs).

Indemnity Prescription Coverage: An insurance plan where the insured pays for the covered prescription and then is reimbursed or indemnified by the plan Often these plans first require the insured to pay a deductible and then the insurer covers a percent (e.g., 80%) of the cost of the prescriptions used by the insured. The insured pays the full retail price (Usual and Customary charge) when obtaining the prescription. Only a small percentage of consumers (5-10%) has this kind of insurance for prescriptions. Most insured consumers have service benefit coverage for prescriptions.

Independent Pharmacy: An independent entrepreneur or small chain (fewer than 10 units under one ownership) pharmacies, often viewed as the traditional "corner drug store." These pharmacies range from prescription-dominated clinic and apothecary pharmacies to pharmacies with the traditional mix of prescriptions, over-the-counter drugs, sundries, and general merchandise. For most independent pharmacies, prescriptions are the dominant share of total store sales (typically, 70% to 80% of sales or more).

Ingredient Cost: The cost of the drug product that is dispensed in a prescription. This can refer to the actual acquisition cost (AAC) or cost of goods sold for a pharmacy, or to the amount that an insurer would use in determining payment to a pharmacy for the drug dispensed in a covered prescription, i.e., Estimated Acquisition Cost (EAC) or Maximum Allowable Cost (MAC).

Legend Drug: a drug that is restricted to sale only after issuance of a prescription order by a licensed prescriber. Referred to as a "legend" drug because the label on the prescription package includes the legend,"Caution: Federal law prohibits dispensing without a prescription order."

Maximum Allowable Cost (MAC): the upper limit of ingredient cost for which a third party payer will reimburse a pharmacy for dispensing certain multiple source drugs (i.e., drugs for which generic equivalents exist). MAC's are used by public programs such as Medicaid and by private prescription insurance plans. Although there is no standard list of MAC drugs, often lists for different insurers of prescriptions include many of the same drugs and similar payment limits.

National Health Expenditures (NHE): amounts of spending for health care in the United States by type of service delivered and source of funding for those services. The Health Care Financing Administration (HCFA) collects and publishes NHE data annually. The following are definitions used by HCFA in determining expenditures:

> *Prescription Drugs*: includes spending for prescription drugs purchased in retail outlets. The value of prescription drugs used or provided by hospitals, nursing homes, or health professional is not included in prescription drugs, but is included in spending for these providers' services. Research and development expenditures of drug companies are included in the prescription drug category and not in the overall Research category (they are integral to the price manufacturers charge for their goods, and thus are incorporated into sales to and by pharmacies).
>
> *Drugs & Non-Durables:* includes spending for prescription drugs, over-the-counter medicines, and sundries purchased in retail outlets.
>
> *Physician Services:* Includes revenues/receipts in physician offices. NHE category includes

both taxable and tax-exempt physicians (medical doctors and doctors of osteopathy), as well as employer and non-employer physicians.

Hospital Care: includes hospital revenues from inpatient and outpatient services rendered.

Personal Health Care: includes spending for hospital care, physician services, dental services, other professional services, home health care, drugs and other medical non-durables, vision products and other medical durables, nursing home care, and other personal health care. Does not includes program administration and net cost of private health insurance, government and public health activities, or research and construction.

New Drug Approval: the process required by the Food and Drug Administration (FDA) before a drug can be marketed in the U.S. Approval for marketing is based on information submitted by manufacturer's research and clinical trials (e.g. in an application for an Investigational New Drug, IND, or New Drug Application, NDA). FDA approval is also required for generic versions of drugs already marketed, but the emphasis is on the generic drugs already marketed, but the emphasis is on the generic drug's equivalency with the originator's version of the drug; safety and efficacy is determined primarily by relying on the first approval.

New Molecular Entity: a unique new drug or drug compound that has not been previously approved by the Food and Drug Administration (FDA).

Nonprescription Drug: a drug product that can be purchased without a prescription order.

Over-the Counter Drug (OTC): a nonprescription drug.

Pharmaceutical: a prescription or nonprescription drug. General reference to pharmaceuticals (such

an industry or firm sales figures) sometimes include diagnostic agents and sterile solutions.

Preferred Drug: a drug designated "preferred" if the manufacturer agrees to make the drug available to a private insurer, health plan, or public program at a reduced price compared to other drugs that are considered therapeutic alternates. Health plan enrollees may pay lower cost-sharing amounts for preferred drugs, and pharmacists may be encouraged to dispense the preferred drug through higher reimbursement amounts (dispensing fees).

Prescriber: a health care provider licensed to prescribe drugs. Primary prescribers are physicians, but others may have prescriptive authority, depending on states' statutes and laws. For example dentists, physician assistants, nurse practitioners, optometrists, and others may have authority to prescribe, typically within limits.

Rebate: an amount that the manufacturer of a drug pays to an insurer or health plan for each unit of drug dispensed. Rebate arrangements exist between manufacturers and Medicaid agencies, HMOs, and other insurers or drug plans, and generally bypass the pharmacy. Rebates are referred to as "after market" arrangements because they do not affect the prices paid at the time of service, but are implemented later, ultimately reducing the payer's expenditures or program costs. The Omnibus Budget Reconciliation act of 1990 (OBRA '90) requires pharmaceutical firms to give a rebate to the Health Care Financing Administration (HCFA) for distribution to the States for all drugs covered under State Medicaid drug programs. Within the private insurance market, rebates often are associated with preferred drugs, and the rebate or level of rebate is contingent upon achieving market share goals.

Retail Prescription Price: the price charged by a pharmacy for prescriptions and related services provided. For cash (self-pay), uninsured patrons (and usually for those with indemnity insurance), it also is referred to as the "Usual and Customary (U&C)" charge, and is determined by the pricing policies of the pharmacy. For insured patients, it is the third party payment usually is established as an

amount determined by the insurance plan's payment formula and agreed to in the contract with the pharmacy. Third party payment usually is established as an amount for the prescription ingredient (cost of the drug dispensed) plus a professional dispensing fee (to cover dispensing and professional service costs of the pharmacist).

Service Benefit: insurance coverage where payment for services is made directly to the provider pharmacy via a claims process. The provider payment will be at a level of formula specified in the provider's contract, less any cost-sharing amounts required to be paid by the patient. Most consumers with prescription drug coverage are covered by service benefit plans.

Therapeutic Alternative/Equivalent: drugs that differ from one another, but are of the same pharmacological of therapeutic class and can be expected to have a similar ("equivalent") therapeutic effect when administered to patients in therapeutically equivalent dosages.

Third-Party Insurer: an entity (a public or private program, health plan, or insurer) that pays or reimburses the patient or pharmacy for all or part of the services provided.

Third Party Payment: payment or reimbursement amounts established by third-party drug programs for prescription and services dispensed to beneficiaries. Payment formulas typically specify an amount for the prescription ingredients to which is added a dispensing fee (e.g., EAC or MAC plus a dispensing fee) for calculating the total prescription "price" or payment from the third party program.

Usual and Customary (U&C) Charge: the amount a pharmacy or other provider charges self-pay (cash) patients. Some insurance programs dictate that a pharmacy's claim may not exceed its usual and customary charge for the prescription dispensed.

Wholesale Acquisition Cost (WAC): the price paid by the wholesaler for drugs purchased from the

wholesaler's suppliers (manufacturers). On financial statements, the total of these amounts equals the wholesaler's cost of goods sold. Publicly disclosed or listed WAC amounts may not reflect all available discounts.

Appendix A

Appendix B

Appendix C

Appendix D

How Texas State Agencies Purchase Drugs

Texas Department of Health

Program	Pharmaceutical Expenditures FY 99	Number of Recipients FY 99 * Number of unduplicated clients receiving at least one prescription in FY99.	Who is Eligible for this Program?	Pricing Structure Used by this Program?
Medicaid Vendor Drug*	$ 947,600,000	1,790,637	• Any Texas resident eligible for Medicaid (see Appendix A)	Rebates on all drugs (19%)
Kidney Health Care	$ 12,041,000	13,866	• KHC recipients with Medicaid after they have met their Medicaid prescription limit • KHC recipients with unlimited Medicaid drug coverage do not qualify for KHC drug benefits • KHC recipients with drug coverage under an HMO and Group/Private insurance plan are not eligible for KHC drug coverage, unless they have met their yearly maximum insurance drug benefits.	Some Rebates
Children with Special Health Care Needs* (CSHCN)	$ 5,478,000	6,100	• Children with special health care needs and adults with cystic fibrosis	

Tuberculosis*	$1,629,396	965,121	• All persons diagnosed with TB or who are suspected of having TB, and persons who have contacts to active cases of TB	
Immunizations	$ 56,637,592	2,174,624	• Infants, children, adolescents and adults.	
Sexually Transmitted Disease (STD)*	$ 411,196	Not available	• Any individual who has contracted a sexually transmitted disease (STD), other than HIV, or the partner of an individual who has been diagnosed with a STD who accesses care in a regional health department, local health department or private physicians office.	Public Health Service Pricing No Rebates
HIV*	$ 36,360,017	9,127	• Any individual who is a resident of Texas, has a physician diagnosis of the HIV disease, has no health insurance, and is below 200% of the federal poverty level.	Public Health Service Pricing No Rebates
Primary Health Care*	$ 2,742,995	91,723	• Someone who is at or below 150% of the federal poverty level, a Texas resident and not eligible for the same or similar benefits through other state, federal, or local programs.	
South Texas Hospital (STH)*	$795,063	16,885 (Estimated)	• Any person treated as an inpatient or outpatient at STH.	
Texas Center for Infectious Disease (TCID)*	$ 676,157	2,374	• Any person treated as an inpatient or outpatient at TCID.	

Hansen's Disease	$ 42,777	347	• Any Texas resident with physician diagnosed Hansen's disease.	
Refugee Health Screening	$ 8,378	6,000	• Official Refugees, Amerasian-Immigrants, Cuban and Haitian Parolees, and Asylees, whose date of arrival in the United States, or date they are granted asylum, is within 90 days prior to initiation of refugee health screening.	
Family Planning	$ 5,842,915	454,000	• Low-income Texas residents receive family planning services and pharmaceuticals through a network of contracted local health care providers and TDH public health regional clinics around the state.	
Total:	$1,070,265,486	5,530,804		

Texas Department of Mental Health and Mental Retardation

Program	**Pharmaceutical Expenditures FY 99**	**Number of Recipients FY 99**	**Who is Eligible for this Program?**
State Schools	$ 10,599,262	5,200	• Priority population residing in state mental retardation facilities.
State Hospitals	$ 10,796,217	12,525	• Priority population screened and admitted to state mental health facilities.

CMHMRC's	N/A	89,140	• Priority population (mental health or mental retardation)
Total:	$21,395,479	106,865	

Texas Department of Criminal Justice

Program	**Pharmaceutical Expenditures FY 99**	**Number of Recipients FY 99** (134, 184 patient years*)	**Who is Eligible for this Program?**
HIV	$12,286,050 (47%)	2,700	All TDCJ patients are eligible based on standard clinical criteria.. Every prescription that is filled, is paid for by the system.
Hep C	$239,554 (0.92%)		All TDCJ patients are eligible based on standard clinical criteria.. Every prescription that is filled, is paid for by the system.
Hep B	$183,595 (0.7%)		All TDCJ patients are eligible based on standard clinical criteria.. Every prescription that is filled, is paid for by the system.
Psych	$3,425,777 (13.1%)		All TDCJ patients are eligible based on standard clinical criteria.. Every prescription that is filled, is paid for by the system.
Other	$9,971,151 (38.3%)		All TDCJ patients are eligible based on standard clinical criteria.. Every prescription that is filled, is paid for by the system.
Total	$23,022,927	NA	

*Patient days are the total number of patient days for FY99 divided by the number of days in a year.

Texas Employees Retirement System

Program	**Pharmaceutical Expenditures FY 99**	**Number of Recipients FY 99**	**Who is Eligible for this Program?**
HealthSelect*	**Member Co-Pay** $33,719519 **Plan Cost** $151,920,934 **Total** $ 185,641,453	261,558	HealthSelect is the self-funded, basic health plan offered through the Uniform Group Insurance Program (UGIP). It is a managed care plan with networks of providers. It does provide out-of-network benefits. State employees, retirees and dependents, and Employees, retirees and dependents of institutions of higher education, excluding UT & A&M, including junior and community colleges.

Please Note: The UGIP also had a self-insured HMO look-alike, HealthSelect Plus, and 12 HMOs under contract for FY99. There were 256,441 participants in these programs. Their pharmacy costs are not included.

Texas Teacher's Retirement System

Program	**Pharmaceutical Expenditures FY 99**	**Number of Recipients FY 99**	**Who is Eligible for this Program?**
TRS-Care	$ 93,459,890	127,318	TRS retirees and their dependents with 10 years of service if not eligible under other state plans. TRS-Care 1 and 2 coverage pays like medical (80/20). TRS-Care 3 coverage has copays of $8 generic/$16 brand, plus a mail order feature of up to 90-day supply for same copay amounts.

Appendix E

Summary of Public Health Service 340b Drug Pricing Program

BACKGROUND

The Congress introduced drug pricing controls in 1990 with the passage of the Omnibus Budget Reconciliation Act (OBRA 1990) which provided a foundation for Public Law 102-585 (the Veterans Health Care Act of 1992), including enactment of section 340b of the Public Health Service (PHS) Act (Limitation On Prices Purchased By Covered Entities).

Section 340b of the PHS Act requires the Secretary of the Department of Health and Human Services (DHHS) to enter into pharmaceutical pricing agreements with manufacturers that sell covered outpatient drugs to covered entities. An agreement stipulates that a manufacturer will charge covered entities prices for covered outpatient drugs that will not exceed ceiling prices as specified in section 340(a)(1) and (2) of the law. A manufacturer can also negotiate with individual "covered entities" to achieve lower prices than those negotiated with DHHS. A manufacturer has the option of dealing directly with covered entities or through a wholesaler.

The Department of Health and Human Services Health Resources and Services Administration established the 340b program to implement the provisions of this section of the PHS Act. A manufacturer's decision to participate in the 340b program is voluntary. However, if the manufacturer does not participate, it will not receive Federal Medicaid matching funds for covered outpatient drugs in the Medicaid program. Entity participation in the program is also voluntary at this time.

Entities Which Are Eligible for the Program

Primarily certain grantees of the PHS and "eligible disproportionate share" hospitals. For example,

- Federally qualified health centers (migrant, community, homeless);
- Family planning projects receiving grants or contracts under section 1001, 42 U.S.C. 256a;

- State operated AIDS Drug Assistance Programs receiving financial assistance under section 2616 of the Act, 42 U.S.C. 300ff-26;
- An entity receiving a grant for outpatient early intervention services for HIV disease under subpart II of part C of title XXVI, 42 U.S.C. 300ff-51 et seq.
- An entity certified by the Secretary as receiving funds relating to the treatment of STD or the treatment of tuberculosis under section 318, 42 U.S.C. 247c.

(*the above list is not inclusive).

Calculation of the Drug Price

C The price of the drug is determined on a quarterly basis by the Federal Office of Pharmacy Affairs in a negotiation with the manufacturer. The discount appears in the initial price, varies according to the type of drug purchased and is held confidential.

Prohibitions under the Act

- Drug pricing information must be held confidential
- Covered entity may not re-sell medications
- Use of both discounted price and rebate is prohibited
- Vaccines are not included as drugs

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CHARGE II *Review issues related to the increased use of new technologies in the delivery of health care. The review should identify opportunities and risks associated with the sale of medical devices and drugs over the Internet, and feasibility of expanding telemedicine to improve care in underserved areas, and regulatory and privacy issues presented by these new technologies.*

LEAD MEMBER *Rep. Glen Maxey*

INTRODUCTION

The committee held a public hearing to address this charge on April 25, 2000. This hearing was divided into two parts; the first half of the day the committee addressed issues related to the Internet and its impact on the delivery of health care. The latter part of the day, the committee addressed the telemedicine portion of the charge. Five panels comprising various stakeholders that were invited to brief the members of the committee regarding the use of new technologies in the delivery of health care. These panels provided a general overview of on-line issues such as privacy, purchasing, prescribing patterns and accuracy of information. In addition, in-depth discussion of state considerations regarding the regulation of the delivery of health care on-line also took place.

Five panels briefed the committee regarding the feasibility of expanding telemedicine to improve health care in underserved and rural areas of the state. These panels provided a general overview of federal laws that pertain to telemedicine; the status of Texas laws that pertain to the use of telemedicine and current initiatives in Texas relating to telemedicine and teledentistry.

Rep. Maxey developed a list of stakeholders, and held four workgroup sessions that addressed both the delivery of health care on-line, as well as the use and feasibility of telemedicine. Stakeholders invited to participate in the workgroup were Ron Scott with the University of Houston Health Law and Policy Institute; Bruce Levy with the Board of Medical Examiners; Tom Gallo with the E-Health Care Association; Carmine Catizone with VIPPS; Gay Dodson with the Texas Board of Pharmacy; Karen

Reagan with the Texas Pharmacy Association; Sharon Hull and Cathy Steward with Rx.Com; Lisa McGiffert, Kathy Mitchell and Reggie James with Consumer's Union; Kay Ghahremani with the Texas Health and Human Services Commission; Linda Wertz, State Medicaid Director; Patti Paterson with the Texas Tech Health Science Center; Deborah Seale, Interim Director for the Center for Telehealth and Distance Education at the University of Texas Medical Branch at Galveston; Kim McPherson with the Mental Health Association; Eva Munoz with Southwestern Bell; Diana Prachyl with the Texas Dental Hygienists' Association; Sam Tessen and Nora Cox Taylor with the Texas Center for Rural Health Initiatives; Heather Vasek with the Texas Association Home Health Care; and Marc Samuels with Samuels Health Strategics.

The committee worked to identify risks and opportunities associated with the sale of durable medical equipment, contact lenses, and drugs through the Internet. We worked to identify federal and state regulations affecting providers with respect to emerging medical technologies, including the Internet. Additionally, we worked to evaluate the feasibility of expanding telemedicine to improve access to health care in medically underserved and rural areas of the state, including identifying quality and cost-effectiveness aspects. Finally, we worked to identify patient and provider acceptance of different technology applications and what impact the increasing uses of technology has on patient privacy.

POLICY OPTIONS

Policy Option I Allow hub sites that are not affiliated with a medical or osteopathic school located in Texas, or an affiliated entity with a written contract or agreement with an accredited medical or osteopathic school in Texas, to be reimbursed for telemedical consultations through Medicaid. Allow physicians not associated with a health science center to bill for services.

Policy Option II Continue the **Telemedicine Advisory Council**. Include additional members to the council such as members of the Texas Infrastructure Fund (TIF) and other state agencies as well as consumer advocates. Add tracking the expansion of telemedicine and monitoring the appropriate development and use of telemedicine to the responsibilities of the Telemedicine Advisory Council.

Policy Option III Expand reimbursement in Medicaid for additional health services including dental consultations and mental health professional consultations.

Policy Option IV Remove barriers that prohibit physicians to be reimbursed by Medicaid if the patient is presented by their registered nurses.

Policy Option V Expand access to teledentistry. Allow a dental hygienist with an Access to Care (ATC) permit to perform preventive care and assist in locating a dentist for patients in rural and underserved areas.

Policy Option VI Expand the Texas Infrastructure Fund (TIF) Grants to allow for-profit health facilities to receive TIF funding.

Policy Option VII Require the Health and Human Services Commission (HHSC) and TIF Board to develop minimum standards for operating telemedicine systems in Texas. HHSC and TIF should consider the following when developing standards:

1. Authorization of access;
2. Integrity, including data integrity, program integrity, system integrity and network integrity, which ensures system security;
3. Audit trails; and
4. Data storage and transmissions.

Policy Option VIII Update the appropriate statutes to clarify current laws that a regulatory authority granted to state agencies also applies to the Internet.

Policy Option IX Monitor the impact of new technologies on privacy.

Policy Option X Examine the various definitions of telemedicine in state law, and establish a single definition.

BACKGROUND

The Internet has revolutionized communications worldwide. The Internet is changing how people receive and give their health information and health care. In the field of medicine, the Internet has permitted physicians, nurses, physical therapists, occupational therapists, other healthcare professionals, pharmaceutical manufacturers, patients and other consumers to quickly access medical information in unprecedented volume and speed. Such access has the potential to transform the patient-physician relationship from that of physician authority ministering advice, care and treatment to that of shared decision making between the patient and the physician. However, there are several substantial barriers impeding this refinement in the patient-physician relationship that include wide variations in quality of content on the Web, no available standardization procedures, potential for commercial interests to influence online consent, and uncertain preservation of personal privacy.

The Internet has also enabled the distribution of prescription drugs through anonymous, electronic, and large volume means. By virtue of a personal computer and Internet service providers, the Internet has placed access to distribution centers in the homes and offices of millions of U.S. consumers.[1] There are two separate issues when discussing prescription drugs and the Internet: online prescribing and online pharmacies. Online prescribing is when a physician who has not established a proper physician-patient relationship issues a prescription to a consumer through the Internet. An online pharmacy is a pharmacy that verifies and fills a prescription via the Internet. The Internet, with all of its benefits, has also provided unscrupulous individuals with immense new opportunities to unlawfully promote and sell drugs to patients searching for lower prices and convenience. Some illegal pharmacy activities consist of providing direct links to pornographic sites and improving the Website appearance to present a professional and trustworthy appearance.

Advancement of technological tools has led to the provision of medical services and support to people over distances. "Telemedicine" can be broadly referred to as the transmission of medical information between health care professionals and patients, generally by means of computers, video equipment,

satellites, phone lines, or high-speed transmission lines. Transmission may occur over long distances, such as between Texas Tech University Medical School and a hospital in Alpine, or over shorter distances, such as between a clinic and a specialist's office within the same urban area.[2] Telemedicine does not have a universally acceptable definition. Some limit the definition to the interactive communication between health care professionals involved in diagnosing and treating patients. Other definitions encompass the long-distance education of health professionals and the use of electronic medical databases and websites, e-mail, and other software.[3] This technology holds tremendous promise for expanding access and guaranteeing quality care to underserved areas of Texas. Nevertheless, telemedicine's growth also raises critical issues for state lawmakers, including protection of public health and safety, the extent of public and private financing of infrastructures and services, health care providers' roles and liabilities, confidentiality of consumers' medical information, and competition in the medical marketplace.[4]

Texas has been among the leading states in establishing telemedicine programs and networks because of:

- Availability of federal and state grants;
- Issues of health care access and cost in rural areas and Texas prisons;
- Marketing of new software and hardware technologies by emerging high-tech industries;
- Formation of online businesses by traditional health care providers and payers; and
- Research interests of medical centers.[5]

Telemedicine:

The rapid development of technology, infrastructure, and global connectivity is impacting the ongoing technological advancement ranging from individual lifestyle modifications to the amount of information available at one's finger tips. Increased access to technology will fundamentally change the way people view the world and provide health care. The new technological advances are tools to use so that

healthcare can be delivered efficiently and with increased accessibility.

In light of technological advancements, and given the important impact that telemedicine has had on the delivery of health care, telemedicine could be re-defined as a health service between licensed professionals such as medical consultation, dental consultation, mental health professional consultation, diagnostic ultrasound, and antepartum services. The definition could also extend to providing health services such as preventive medicine services, case management services and nursing facility services to rural and/or underserved areas. In addition, an expansion of the term could include the transfer of medical, dental or mental health data, which requires the use of advanced telecommunications technology including:

- compressed digital interactive video, audio, or data transmission and clinical data transmission via computer
- imaging by way of still image and capture.

Currently, in Texas, there are no physicians in the counties of Archer, Armstrong, Bandera, Briscoe, Cochran, Dickens, Foard, Glasscock, Hartley, Hudspeth, Kenedy, Kent, King, La Salle, Lipscomb, McMullen, Oldham, Presidio, Roberts, Shackelford, Sherman, Sterling, Stonewall, and Throckmorton.[6] Meanwhile, there is only one physician in the counties Carson, Coke, Cottle, Edwards, Fisher, Irion, Jeff Davis, Kinney, Lynn, Mason, Menard, Rains, and Terrell.

Many Texans lack access to health care because the county in which they live has difficulty recruiting doctors. In the last year, 44 health clinics have closed in rural Texas.[7] In attempts to attract health care professionals, some areas are advertising generous salaries and startup bonuses. Similar incentives are being offered to physicians' assistants and nurse practitioners. For instance, in 1999, a 15-bed hospital in Morton, Texas, (a town with a population of 2,600 located 57 miles west of Lubbock) offered $150,000 salary plus $30,000 toward medical school loans as an incentive for a second doctor. Problems facing counties in regards to recruiting doctors include professional isolation, lack of big city

amenities and resistance to country living.

Recently a number of factors have converged to facilitate the coming of age of telecommunication in clinical practice. These factors include heightened consumer awareness, technology and infrastructure sophistication, state and federal policy changes and increased marketplace demand.[8] The purpose of telemedicine is not to replace doctors who are currently practicing in underserved areas but to enhance the quality of care that a patient receives.

Prescription Drugs and the Internet:

Long before the Internet, Congress and state legislatures enacted safeguards to protect patients from harms resulting from the use of unsafe drugs, counterfeit drugs, and the improper practice of medicine and pharmacy. In order to receive a prescription drug for the first time, a patient must be examined by a state licensed health care practitioner.

Traditionally, a patient had no other means than to have an established relationship with a physician to receive a prescription. A proper physician-patient relationship, requires at a minimum[9]:

- Verifying that the person requesting the medication, is in fact, who they claim to be;
- Establishing a diagnosis through the use of accepted medical practices such as a patient history, mental status exam, physical examination and appropriate diagnostic and laboratory testing;
- Discussing with the patient the diagnosis and the evidence for it, the risk and benefits of various treatment options; and
- Insuring availability of the physician or coverage for the patient for appropriate follow-up care.

The Occupations Code Chapter 157 § 157.101 (c) (2) states that it is unprofessional conduct for a physician to initially prescribe any dangerous drugs or controlled substances without first establishing a

proper physician-patient relationship.

Providing prescription drugs through the Internet is a positive development because it helps consumers who have transportation barriers and those who are seeking convenience in their busy lives. With the explosion of the Internet, a consumer has to do no more than fill out a questionnaire to receive a prescription. However, the Internet has provided a medium for abuse in prescribing FDA approved drugs. Prescribing over the Internet or any other electronic means only poses a problem of abuse when there is not an existing physician-patient relationship. Therefore, online practitioners and pharmacies must meet the above requirements to ensure a safe environment for consumers.

There are many misconceptions about online pharmacies that need to be clarified. An online pharmacy is a brick and mortar place that has a Website to reach out to consumers. It uses the Internet as a communication tool and allows the consumer to receive large volumes of information about drugs and their interactions. It also improves the communication between a pharmacist and the consumer by allowing the consumer to ask questions. The Internet pharmacy must comply with current laws and rules as traditional pharmacies. The online pharmacy must have a current Class "A" license for in-state pharmacies and/or Class "E" for an out-of-state pharmacy.[10]

How does an online pharmacy work? According to Rx.Com, the pharmacist can obtain a prescription several ways. The pharmacist may call the prescribing doctor, who phones or faxes the prescription, or the pharmacist may call an existing pharmacy to transfer a prescription, or the patient may mail an original prescription to the online pharmacy. For the patient to order a prescription off the Website, the patient must register and provide pertinent health information and provide proof of prescription information when applicable. The customer makes a choice of a child safety cap or non safety cap and has an option to choose a generic drug substitution. Once a pharmacist receives the order, then appropriate action is taken to obtain the prescription. The prescription is obtained and entered into the automated dispensing system. Once in the automated dispensing system, the prescription undergoes its

first pharmacist verification for accurate data entry. The error rate on automation is .001% compared to 5% in a traditional setting. A second pharmacist verification occurs when automated dispensing units are filed. Once the prescription is filled, it must undergo a third pharmacist verification. The order is then packaged and either shipped, delivered, or picked up by the patient.

There have been several attempts by online pharmacy to self regulate themselves. One voluntary process is call VIPPS (Verified Internet Pharmacy Practice Sites). This program was developed and is currently administered by the National Association of Boards of Pharmacy. In order for an online pharmacy to join the program, the online pharmacy first completes the VIPPS application, which can be found at www.nabp.net. Next, the online pharmacy must comply with a stringent set of criteria. The VIPPS criteria include questions in 17 Internet and practice-based areas, such as how the patient or care giver's identity is verified; communication with consulting physicians, patients or care givers; the steps that are taken to ensure the patient's confidentiality; how medications are dispensed; and how those medications are secured and tracked when shipped to the patient.

Even with programs such as VIPPS, the consumer must understand that when he or she voluntarily gives personal information there are risks associated. The state must set the minimum standards for identifiable patient health information. These protections are currently found in the Occupations Code Title 3. Health Professions § 560.051-565.054.

With an understanding of what an online pharmacy is and how it works, the committee is concerned about the ability for the online pharmacy to keep confidential information secure and the maintenance of privacy for personal identifiable medical information. The committee received many comments on allowing the industry to self regulate vs. state regulation.

Regulation: Federal vs. State Role:

At both the federal and state level, the government is alternatively a payer, provider, and regulator of

various aspects of health care. In its role as regulator, the federal government has primary responsibility for Medicare, Medicaid, drugs and medical devices, and employment benefits through the Employee Retirement Income Security Act (ERISA) which can preempt some attempted state regulation of employer health care plans. The states have primary responsibility for insurance, licensors of health care facilities and health care professionals, and public health. The states have overlapping jurisdiction with the federal government for Medicaid and regulation of drugs and medical devices.

Continuance of the Telemedicine Advisory Council:

The Telemedicine Advisory Council, established at § 531.07(h) of the Texas Government Code, could coordinate all the various state agency efforts on telemedicine. This council could track what types of telemedicine programs Medicaid was reimbursing. The council could include agency representatives (i.e., Center for Rural Health Initiatives, Texas Infrastructure Fund, Texas Department of Insurance, Texas Department of Health, Health and Human Services Commission, Board of Medical Examiners, Board of Nursing Examiners, Board of Pharmacy, Health Science centers), as well as outside telemedicine experts, and consumer advocates, to assist in evaluating existing programs and policy. The council could also evaluate and ensure the appropriate development and use of telecommunications and technology in health care settings.

Expand Medicaid Reimbursement:

The state currently reimburses for certain Evaluation and Management consultation codes. These limited codes only allow for reimbursement for an existing patient. Expanding reimbursement would allow a physician to perform an examination with a new or established patient through telemedicine. The state could expand Medicaid to reimburse for dental consultation and mental health professional consultation. Expansion of Medicaid could also occur for providing health services such as preventive medicine, case management and nursing facility services to an underserved or rural area. Diagnostic ultrasound, antepartum services or transfer of medical, dental or mental health data, that requires the use of advance telecommunications technology, including compressed digital interactive video, audio, or

data transmission and clinical data transmission via computer imaging by way of still image and capture should also be reimbursed in Medicaid.

Suggestions for new codes include:

- Office or other outpatient visits, 99201-99205 and 99211-99215. The above codes are used to report evaluation and management services provided in the physician's office or in an outpatient or other ambulatory facility;
- Preventive Medicine Services, 99381-99387 and 99391-99397. The above codes are used to report the preventive medicine evaluation and management of infants, children, adolescents, and adults;
- Counseling and/or risk factor reduction intervention, 99401-99412 and 99420-99429. The above codes are used to report services provided to individuals at a separate encounter for the purpose of promoting health and preventing illness or injury;
- Case Management Services (Team Conferences), 99361-99362. Physician case management is a process in which a physician is responsible for direct care of a patient, and for coordinating and controlling access to or initiating and/or supervising other health services needed by the patient;
- Nursing Facility Services - The following codes are used to report evaluation and management services to patients in Nursing Facilities (formerly called Skilled Nursing Facilities (SNFs), Intermediate Care Facilities (ICFs) or Long Term Care Facilities (LTCFs));
- Comprehensive Nursing Facility Assessments, 99301-99303. When the patient is admitted to the nursing facility in the course of an encounter in another site of service (e.g., hospital emergency department, physicians' office), all evaluation and management services provided by that physician in conjunction with that admission are considered part of the initial nursing facility care when performed on the same date as the admission or admission;

- Diagnostic Ultrasound (Pelvis), 76805, 76825, 76827;
- Antepartum Services 59020, 59025, 59050, 59051.[11]

Allow Registered Nurses as Telemedicine Presenters:

In 1997, the Texas Legislature passed House Bill 2386, which expanded Medicaid reimbursement for telemedicine consultations between academic health centers and rural communities. HB 2386 allowed for certain defined "Health Professionals" to present patients to physicians for a telemedicine consultation. In many rural and underserved clinics, nursing homes and rural school settings, an R.N. is frequently the only available health care provider. Moreover, they are the only competently trained people available to present a patient to a physician for a telemedicine consultation. Precluding a physician from receiving reimbursement from Medicaid for a telemedicine consult merely because the presenter is an R.N. can deny access to the benefits of telemedicine to many of our most needy citizens.

Expand Access to Oral Health:

Currently § 262.151 of the Occupations Code authorizes a licensed dentist to delegate orally or in writing a service, task, or procedure to a dental hygienist who is under the supervision and responsibility of the dentist. This prevents a hygienist from conducting oral preventive care in schools or nursing homes without the patient seeing a dentist within a 12-month prior period. With legislative authorization, a dental hygienist could perform preventive care and assist in locating a dentist for the patient who accepts Medicaid, third party insurance, or could provide care if payment is not obtainable. In this case, the law could state that telemedicine is an appropriate form of supervision. This change would only apply to that hygienist with an Access to Care (ATC) permit who is treating patients in underserved areas. A dental hygienist working with underserved populations could be required to complete 12 hours of continuing education each year in addition to the 12 hours already required by the statute. The 12 additional hours of continuing education could be in the following areas: General Medicine, Pharmacology, Medical Emergencies, Oral Pathology and Management and Psychology of geriatric and disabled patients.

Expand the Texas Infrastructure Fund Grants:

Statutes could direct the Texas Infrastructure Fund (TIF) to develop policies and procedures on expanding TIF grants to for-profit health practices. Currently there are 1,130 Public, not-for-profit health care facilities that are available for TIF funding, and 761 have received grants. The 10 health science centers that are qualified for the grants have all received funding. Expanding the TIF to for-profit providers would encourage new physicians and dentists to underserved areas, fight the feeling of professional isolation and allow consumers to access specialty care without traveling long distances to metropolitan medical centers. The benefits of assisting private physicians in getting telemedicine technology are endless to the consumer:

- By increasing provider access to medical specialists and needed information, telemedicine has the potential to improve patient diagnosis and treatment;
- Consumers in urban or suburban areas who are unable to travel long distances will receive specialty care and have access through their local provider;
- Oversight of health care decision making can be improved;
- Consumers who do not have access to regular health care are normally only seen when a condition is at a complicated state in a hospital emergency room. Telemedicine could reduce costly usage patterns, thus providing the consumer access to primary, specialty and preventive health care.

There should be a clear and concise definition of exactly who or what for profit entities are eligible for TIF funding. A priority determination should be developed to assist those for profit entities that serve indigent patients.

The HHSC and the TIF Board could be instructed to collaborate and develop minimum standards for operating systems, telemedicine software and hardware and electronic transmission standards. TIF

currently has minimum standards for wireless systems, workstations, servers, connectivity hardware, video conferencing systems and addition equipment/software/systems. TIF and HHSC could consider the following when developing standards[12,13,14]:

- *Authentication of users* - Providing assurance regarding the identity of a subject or object. For example, ensuring that a particular user is who the user claims to be (authentication of users) and corroboration that the source of data is received as is claimed (authentication of data origin);
- *Authorization* - Granting of rights, which includes granting of access based on access rights;
- *Integrity* - Providing the information is changed only in a specified and authorized manner. Data integrity, program integrity, system integrity, and network integrity are all relevant to consideration of computer and system security;
- *Audit Trails* - Monitoring each operation on information;
- *Data Storage and Transmission* - The physical location and maintenance of data. Transmission of data is the exchange of data between person and program, or program and program, when the sender and receiver are remote from each other.

Appendix A

Federal Legislation Affecting Telemedicine

104th Congress 1995-1996:

Health Insurance Portability and Accountability Act of 1996	[H.R. 3103] [Public Law 104-191]	Amended the Internal Revenue Code of 1986 to improve portability and continuity of health insurance coverage in the group and individual markets, to combat waste, fraud, and abuse in health insurance and health care delivery, and to promote the use of telemedicine.
Telecommunications Act of 1996	[S.652] [Public Law: 104-104]	Focused on deregulating the telecommunication marketplace to increase competition that would inevitably benefit consumers. Also made possible a telecommunication discount program, called Universal Service, for rural health care providers, schools, and libraries.

105th Congress 1997-1998:

Balanced Budget Act of 1997		Provided for Informatics, Telemedicine and Education Demonstration Project Medicare Reimbursement for Telehealth Services. In addition to budgetary language, this bill focused on numerous health care issues, including two major sections on telemedicine. First, Medicare was directed to approve reimbursement of teleconsultations in health professional shortage areas including retroactive payment for services rendered as of Jan 1, 1999. Second, the Department of Health and Human Services was directed to fund a telemedicine demonstration project in urban setting.

Next Generation Internet Research Act of 1998	(Enrolled Bill (Sent to President)) [H.R.3332] [Public Law 105-305]	Amends the High-Performance Computing Act of 1991 to authorize appropriations for fiscal years 1999 and 2000 for the Next Generation Internet program, to require the Advisory Committee on High-Performance Computing and Communications, Information Technology, and the Next Generation Internet to monitor and give advice concerning the development and implementation of the Next Generation Internet program and report to the President and the Congress on its activities.

1999-2000 Bills Focusing on Telemedicine:

Telehealth Improvement and Modernization Act of 2000	(Introduced in the Senate) [S.2505.IS]	Would revise and expand reimbursement under the Medicare program for telehealth services, as well as direct the Secretary of Health and Human Services to permit reimbursement of facility fees and home telehealth care.
Comprehensive Telehealth Act of 1999	(Introduced in the Senate) [S.770.IS]	Would provide reimbursement under the Medicare program for telehealth services, and directs the Secretary of Health and Human Services to study interstate licence for physicians.
Health Care Restoration Act of 1999, § 223	(Introduced in the House) [H.R.3146.IH]	Would amend Titles XVIII, XIX, and XXI of the Social Security Act to adjust the Medicare, Medicaid, and children's health insurance programs, as well as refine Medicare telemedicine reimbursement rules in the Balanced Budget Act of 1997.

Medicare, Medicaid, & SCHIP Balanced Budget Refinement Act of 1999, § 512(c)	[H.R.3075.EH]	Would amend Title XVIII of the Social Security Act to make corrections and refinements in the Medicare Program as revised by the Balanced Budget Act of 1997.
Promoting Health in Rural Areas Act of 1999, Title III	(Introduced in the Senate) [S.980.IS]	Would make certain technical amendments with regard to reimbursement under the Medicare program for telehealth services by making technical amendments to the Balanced Budget Act of 1997. Additionally, this bill makes technical amendments to the 1997 Act to improve Medicare payment rates to health care facilities.

Schools and Libraries Internet Access Act of 1999	(Introduced in the House) [H.R.1746.IH]	Affects Universal Service by amending the Communications Act of 1934 to reduce telephone rates, provide advanced telecommunications services to schools, libraries, and certain health care facilities. To accomplish this goal, it would use a portion of the current federal excise tax and create a new telecommunication fund for rural areas.
Triple-A Rural Health Improvement Act of 1999	(Introduced in the House) [H.R.1344.IH]	Would adjust Medicare payments to rural hospitals as well as refine Medicare telemedicine reimbursement rules by adjusting provisions in the Balanced Budget Act of 1997.

1999-2000 Bills Mentioning Telemedicine:

Access to Quality Care Act of 1999, § 103 (a)	(Introduced in the House) [H.R.216.IH]	Would amend the Public Health Service Act and the Employee Retirement Income Security Act of 1974 to protect consumers in managed care plans and preserve against preemption of certain State causes of action.
Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act 2000, Title 3	(Enrolled Bill (Sent to President)) [H.R.1906.ENR]	Appropriated funds for Agriculture, Rural Development, Food and Drug Administration, and related agencies for the fiscal year ending September 30, 2000.
Clinical Research Enhancement Act of 1999, § 409C	(Introduced in the House) [H.R.1798.IH]	Would amend the Public Health Service Act to provide additional support for and to expand clinical research programs' development of telemedicine use.
Comprehensive Managed Health Care Reform Act of 1999, § 4 (a)(2)	(Introduced in the House) [H.R.1133.IH]	Would require specific standards for managed care organizations, such as coverage for prescription drugs, and support the use of telemedicine in underserved areas.

Conquering Pain Act of 1999, § 201(c)	(Introduced in the Senate) [S.941.IS]	Would amend the Public Health Service Act, responding to the public health crisis of pain management, as well as establish telemedicine links to provide education and for the delivery of services in pain and symptom management.
Critical Care Spectrum Act of 1999, § 3	(Introduced in the House) [H.R.2379.IH]	Would ensure that adequate frequencies of the electromagnetic spectrum are available for biomedical telemetry.
Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act, 2000, § 622	(Enrolled Bill (Sent to President)) [H.R.2670.ENR]	Made appropriations for the Departments of Commerce, Justice, and State, the Judiciary, and related agencies for the fiscal year ending September 30, 2000. Including a significant appropriation to develop telemedicine services at a southern medical college.

Department of Defense Appropriations Act, 2000, § 8141 (a)	(Enrolled Bill (Sent to President)) [H.R.2561.ENR]	Made appropriations for the Department of Defense for the fiscal year ending September 30, 2000. Additionally, permitted the Department to enter into contracts that used telemedicine to serve the health care needs of native Hawaiians.
Emergency Medical Services Efficiency Act of 1999, § 201, 202	(Introduced in the Senate) [S.911.IS]	Would amend Title XVIII of the Social Security Act to ensure Medicare reimbursement for certain ambulance services, and to improve the efficiency of the emergency medical system, and for other purposes.
Healthcare Research & Quality Act of 1999, § 6	(Engrossed in Senate) [S.580.ES]	Would amend Title IX of the Public Health Service Act to revise and extend the Agency for Health Care Policy and Research, and would mandate that a federal study on the state of telemedicine be conducted.

National Defense Authorization Act for Fiscal Year 2000, § 724	(Enrolled Bill (Sent to President)) [S.1059.ENR]	Appropriated funds for fiscal year 2000 for military activities of the Department of Defense, for military construction, and for defense activities of the Department of Energy, and included the development of a joint telemedicine and telepharmacy demonstration project by the Department of Defense and Department of Veterans Affairs.
National Institute of Biomedical Imaging and Engineering Establishment Act, § 2	(Introduced in the House) [H.R.1795.IH]	Would amend the Public Health Service Act to establish the National Institute of Biomedical Imaging and Engineering. This bill also proposes that the National Institutes of Health support telemedicine with basic research focused on the acquisition, transmission, processing, and optimal display of images.

Other States Past Legislation:

Arkansas S.B.417 Creates the Joint Committee on Advanced Communications and Information Technology	Signed by the Governor 3/22/95, Act 737 of 1995. The	Would create the Joint Committee on Advanced Communication and Information Technology. The bill also establishes the Distance Learning and Telemedicine Network Advisory Board.

Arkansas S.B. 769 Makes an appropriation for the development of a strategic plan for the establishment of a statewide Distance Learning and Telemedicine Network for the Office of the Governor	Signed by the Governor 4/10/95, Act 1069 of 1995	Calls for the appropriation of $200,000 for the biennial period beginning July 1, 1995 and ending June 30, 1997.
Arkansas S.B. 770 Makes an appropriation for the development of a strategic plan for the establishment of a statewide Distance Learning and Telemedicine network for the Office of the Governor	Signed by the Governor 4/10/95, Act 1070 of 1995.	Calls for the appropriation of $2,000,000 for the biennial period beginning July 1, 1995 and ending June 30, 1997.
Arkansas S.B. 771 Appropriates $886,493 to the Office of the Governor to provide grants for the development of a statewide Distance Learning and Telemedicine Network	Signed by the Governor 4/10/95, Act 1071 of 1995.	Calls for the appropriation of $4,000,000 for the biennial period beginning July 1, 1995 and ending June 30, 1997.

California A.B. 667 Creates a University of California Regents Telemedicine Task Force	Pending in the Senate. (Adjournment date 9/15/95)	Would require the regents to provide the resources to establish the task force to study and report, by July 1, 1997, on the use of telemedicine technology to improve health care for rural and urban medically underserved populations. The task force would consist of 16 members appointed by the Governor, Senate Committee on Rules, Speaker of the Assembly and the Regents of the University of California.

Colorado H.B. 1272 Establishes minimum standards for radiologists practicing telemedicine	Failed to pass the House. (Adjourned 5/8/95).	States that any person, regardless of location, who practices medicine or another healing art on a person located in Colorado is deemed to be practicing in Colorado. The bill also defines the practice of telemedicine as the performance using the aid of any telecommunication medium, of an act for which a license, registration or certification is required under the health care licensing statutes. The bill sets out minimum standards to be met by radiologists practicing telemedicine.
Iowa SCR. 15 and H.C.R. 19 Resolutions requesting that the Congress direct the Health Care Financing Administration to establish a national policy	SCR. 15 passed the House and the Senate (Does not need to be signed by the Governor). H.C.R. 19 was withdrawn from consideration. (Adjourned 5/14/95).	

Services rendered to individuals located in this state.	Kansas Register 100-26-1	Requires out-of-state physicians who provide telemedical consultations to be licensed by the state board of the healing.
Louisiana S.R. 16	Passed the Senate 4/3/95. (Adjourned 6/19/95).	Urge the Senate Committee on Commerce and Consumer Protection to study the areas of telemedicine and distance learning.
Louisiana S.B. 618		States that a health care provider participating in the originating terminus of a telemedicine transmission will be reimbursed. The provider will be reimbursed at a rate of not less than 75 percent of the amount of reimbursement for an office visit. The bill also provides that provisions in a health and accident policy that discriminate against payments for telemedicine shall be prohibited.

Louisiana S.B. 773	Signed by the Governor 6/16/95, Act 391 of 1995.	States that a health care provider participating at the originating terminus of a telemedicine transmission shall be reimbursed. The provider will be reimbursed at a rate of not less than 75 percent of the amount of reimbursement for an office visit. The bill also provides that provisions in a health and accident policy that discriminate against payments for telemedicine shall be prohibited.

Louisiana S.B. 774	Signed by the Governor 6/17/95, Act 464 of 1995.	States that the Coordinating Council on distance learning education will promote and ensure communications between public agencies in the area of telecommunications application and planning, advancements and technology as they apply to telemedicine and distance education. The Council shall consist of seven members to be appointed by the Secretary of the Department of Health and Hospitals, the Director of the Office of Telecommunications Management, the Chancellor of the Louisiana State University Medical Center, the Executive Director of Louisiana Public Broadcasting, the Chairman of the Public Service Commission, the superintendent of Education and the Governor. By March 1 of each year the Council would be required to submit a report

New Mexico H.B. 142	Pending in Committee. (Adjourned 3/18/95).	Would establish the "Office of Telemedicine Research" at the University of New Mexico. $1,320,000 would be appropriated to the Board of Regents of the University of New Mexico for fiscal year 1996. $74,000 would be appropriated to the Department of Health for fiscal year 1996.
Oregon S.B. 463	Referred to Committee. (Adjourned 6/10/95).	Would establish the "Office of Telemedicine Research" at the University of New Mexico. $1,320,000 would be appropriated to the Board of Regents of the University of New Mexico for fiscal year 1996. $74,000 would be appropriated to the Department of Health for fiscal year 1996.

South Dakota S.B. 116	Signed by the Governor 2/24/95	Would consider a person who is physically located in another state to be engaged in the practice of medicine in South Dakota if they provide diagnostic or treatment services through electronic means.

South Dakota H.B. 1150	Signed by the Governor 3/3/95	Allows the Board of Medical and Osteopathic Examiners to give licensure reciprocity if the legal requirements of the licensing board were not less than those of South Dakota at the time the license is presented for registration.
Virginia H.J.R. 455	Does not need to be signed by the Governor. (Adjourned 2/25/95)	Requests the Joint Health Care Commission to study the use of telemedicine technology. Provides instant consultation and diagnostic evaluation for patients in another location with the use of computers, television, cameras and phone lines.

Texas Legislation:

Texas H.B. 2128	Signed by the Governor 5/29/95. (Adjourned)	Deregulates the telecommunications industry; and Section 3.606 establishes a telecommunications infrastructure fund, which would provide money to interconnect public entities via broad band digital services for voice, video and data. Non-profit telemedicine centers of academic health centers, hospitals or state-licensed practitioners listed in Section 3.359 and are considered public entities for purposes of the act.

Texas H.B. 2669	Signed by the Governor 6/16/95.	Modifies the Medical Practice Act to consider a person who is physically located in another jurisdiction to be engaged in the practice of medicine in Texas if they are treating a patient via an electronic medium.
Texas S.B. 673	(Enrolled)	Section 106.025(a)(8)(A) and Section 106.025(a)(15) - (17), Health and Safety Code, relating to the requirements specified for the Center for Rural Health Initiatives (Center), as follows: Subsection (a)(8)(A) requires the Center to promote telemedicine and distance learning through a transmission rate structure which accommodates rural needs and through the improvement of the telecommunications infrastructure in rural areas.

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CHARGE III *Evaluate the role and potential of disease management in public health programs that serve chronically ill populations.*

LEAD MEMBERS *Reps. Ruth Jones McClendon and Carlos Uresti*

INTRODUCTION

The committee held a public hearing to address this charge on February 29, 2000. At this hearing, members of the committee heard from five panels that addressed the role and potential of disease management in public health programs that serve chronically ill populations in Texas. Specifically, the panels provided the committee with a general overview of disease management; various disease management perspectives; current disease management initiatives, including private disease management initiatives; and possibilities within Texas' Medicaid program for disease management.

On August 11, 2000, Rep. McClendon and a subcommittee composed of Reps. Capelo, Coleman, Delisi, and Uresti, held a public hearing in San Antonio, Texas. The subcommittee heard from four panels that provided the subcommittee with an overview of data collected at the Texas Department of Health regarding disease management; a briefing regarding some specific public, as well as private, disease management projects in Texas for asthma, congestive heart failure and diabetes; various perspectives from stakeholders regarding the use of disease management; and public testimony from Community First Health Plan.

In addition, Rep. McClendon developed a list of stakeholders and invited them to participate and bring ideas to the table in an effort to begin understanding the complexity and importance of the role of disease management in Texas. Stakeholders that were invited to participate in the work sessions were Joe da Silva and Marsha Jones with the Texas Hospital Association; Lillie Gilligan and Bert Jones with Glaxo Wellcome Pharmaceutical Company; Marc Samuels with Samuels Health Strategies; Tom Banning with the Texas Academy of Family Practitioners; Jo Anne Hargraves with Schering-Plough Pharmaceutical Company; Beverly Koops, MD, with the Texas Department of Health; David Gonzales

with Legend Pharmacy Group; Chuck Courtney with the Texas Federation of Drug Stores; Brad Shields with the Texas Society of Health System Pharmacists; Hector Rivero with Humana; Don Gilbert, Commissioner, Texas Health and Human Services Commission; Reyn Archer, Commissioner, Texas Department of Health; Sheila Beckett, Executive Director, Employees Retirement System; Linda Wertz, State Medicaid Director, Texas Health and Human Services Commission; and Cathy Rossberg with the Health and Human Services Commission.

The workgroup held three different meetings in February, April and June. At these meetings, attendees discussed what the critical components are for a successful disease management program, as well as who should comprise and lead the health care team and what their respective roles are. The group discussed appropriate short and long term clinical outcomes and how they could be measured and tracked. The group also identified data sources and other tools currently available for outcomes tracking. Additionally, the workgroup discussed systems that are needed to initiate, implement and evaluate disease management in Texas' Medicaid program, and identified health conditions that were most prevalent and costly among Medicaid clients. Finally, the group discussed incentives that are appropriate for patients and providers and addressed issues related to enrollment, including ways to simplify the enrollment process in an effort to avoid additional administrative burdens for patients and providers.

The committee and subcommittee members worked with legislative staff, state agency representatives and many stakeholders to identify the prevalence of specific diseases such as asthma, congestive heart failure, kidney and liver diseases and diabetes in Texas' public health programs, and to identify cost savings opportunities, such as reduced hospital admissions and/or emergency room use. The subcommittee also assessed the roles of different health care providers, the role of cultural competency in disease management, and the emergence of pharmacogenomics. We also worked to identify disease management issues in specialized populations, such as women, minorities and infants, while maintaining a focus on measurement outcomes for determining whether disease management improves the health

status for population served.

POLICY OPTIONS

Policy Option I Rural Study. Develop an asthma disease management program in Bell and surrounding counties for patients, who receive health care through the Scott and White (S&W) Health Care Delivery System, including the Hospital, the Clinic in Temple and the 18 satellite S&W Clinics (in rural counties of Central Texas). The pilot participants should include Medicaid eligible school age children. The following steps should be taken in the implementation of the disease management pilot program:

- The first step in the Scott and White service area will be to begin the intervention with physicians through expansion of the Physician Education Program to provide information regarding the Medicaid (and possibly the CHIP) population(s). The consulting physician(s) for the Asthma Pilot will design articles for the educational newsletters, which pertain to the management of pediatric asthma, with a specific emphasis on the unique problems of the Medicaid patients. The newsletters would continue to have the scientific data and recommendations on asthma management from the nationally published standards/guidelines of care.
- A second step will be to evaluate the roles of school nurses and pharmacists, where the real-time clinical observation of children's symptoms and/or the dispensing of clusters of reliever asthma medications, may be a sentinel event as to children who are not being adequately managed. The study may include evaluation of telephone, electronic, fax and e-mail communications between these providers and the primary care providers (PCPs).
- Third, the project will study the effectiveness of case management by

the case managers or health plan care coordination staff. Scott and White has both clinical case managers and health plan care coordinators currently involved in facilitating access to physician visits and follow-up, patient education appointments.

- Fourth, the pilot will test the effectiveness of patient education through consumer surveys. An external quality monitor will be contracted to look at the effectiveness of a variety of providers, including office nurses, clinic patient educators, school-based nurses, respiratory therapists, social workers, pharmacists, and possibly other consumers, i.e., asthma patients/families in the community.
- Fifth, the program should have a control group, so that meaningful comparisons of outcomes can be made between those who use disease management and those who use traditional care methods.
- Sixth, the program should use disease management techniques that can be easily duplicated in private practices and other parts of the State. A study that uses unique resources and local conditions that cannot be duplicated easily will not have value to the State as a whole.
- Seventh, the following outcomes should be measured:
  - School absenteeism
  - Hospitalization and emergency room utilization
  - Frequency of asthma symptoms
  - Impact of illness on the family
  - Economic effects, including the cost to parents from missed work days and the cost to the school system from student absenteeism
- Finally, it is essential that the program guarantee eligibility for at least twelve months for Medicaid enrollees regardless of changes in income

over the enrollment period.

Policy Option II Urban Study. Develop an asthma disease management program in Bexar and surrounding counties for patients, who receive health care through the Medicaid Managed Care and Medicaid Fee For Service health care delivery systems. The pilot participants should be Medicaid eligible school age children. The following steps should be taken in the implementation of the disease management pilot program:

- The first step in the Bexar County Service Area will be to determine with medical directors and administrative leaders of the Medicaid Managed Care Organizations (MCOs) what is the care coordination role, which the plans are required by contract to provide to their enrolled Members and families. In addition to the care coordination provided by their staff, MCOs are also required to make good faith efforts to communicate with the non-capitated, Medicaid-funded case managers and any other community-based case managers who assist their Members with asthma in accessing health and health related services. A major focus of the Bexar project may be to clarify these care coordination/case management functions, and to document the appropriate interactions among these providers.
- Second, the Bexar service area may wish to test the physician education component of disease management. The consulting physician(s) for the Bexar Asthma Pilot may also design articles for the educational newsletters, which pertain to the management of pediatric, with a specific emphasis on the unique problems of the Medicaid

patients. The newsletters would also have scientific data and recommendations on asthma management from nationally published standards/guidelines of care.

- Third, the project may include the evaluation of the use of reliever and controller asthma medications. The Bexar MCOs have already participated in focused studies on asthma patients in the past several years. The State plans on an external quality monitor of the Medicaid managed care program and may wish to formalize another continuous quality improvement study.
- Fourth, the Bexar pilot will also evaluate the effectiveness of patient/family health educators, such as physicians, nurse practitioners, physician assistants, clinic or school nurses, pharmacists, and respiratory therapists, through surveys, similar to those mentioned under the Bell County service area.
- Fifth, the program should have a control group, so that meaningful comparisons of outcomes can be made between those who use disease management and those who use traditional care methods.
- Sixth, the program should use disease management techniques that can be easily duplicated in private practices and other parts of the State. A study that uses unique resources and local conditions that cannot be duplicated easily will not have value to the State as a whole.
- Seventh, the following outcomes should be measured:
    - School absenteeism
    - Hospitalization
    - Frequency of asthma symptoms
    - Impact of illness on the family
    - Economic effects, including the cost to parents from missed

work days and the cost to the school system from student absenteeism

- Finally, it is essential that the program guarantee eligibility for at least twelve months for Medicaid enrollees regardless of changes in income over the enrollment period.

BACKGROUND

Health care for patients with chronic diseases consumes a vast majority of all health care expenditures in the United States. As we are faced with ways to provide high-quality, cost-efficient care, certain chronic diseases such as diabetes, hemophilia, depression, hypertension, arthritis, congestive heart failure and asthma are increasing in prevalence, consuming a disproportionate amount of health care resources, and are very difficult to manage in the individual provider's office. As a result, health care providers are examining strategies to better manage patients with chronic diseases and to improve clinical outcomes. This is especially true for health care payers, both public and private, who are searching for ways to reduce expenditures in treating patients with chronic diseases. Disease management is the latest innovation in health care cost containment and several State Medicaid agencies have begun to study its potential for public health programs that serve chronically ill populations.

Disease management has become a growing phenomenon in both public and privately funded health care delivery systems. Since the early 1990's disease management programs, techniques and methods have been designed by the pharmaceutical industry, managed care organizations, pharmacy benefit managers (PBMs) and most recently by state Medicaid programs. The focus of disease management is on improving quality and containing total cost, and the purpose is to provide a more effective and systematic approach to managing patients with chronic illnesses. The techniques emphasize a more patient-focused approach to providing all components of care, including the psychological aspects and dealing with care giver issues. Therefore, all stakeholders in health care want to be involved including

providers, patients, managed care organizations, insurance companies, government agencies, PBMs, and employer purchasing coalitions.

The approach includes coordination of physician care with pharmaceutical, home health and institutional care, and addresses the various aspects of a disease state. A successful and well coordinated disease management program is intended to provide chronically ill patients with access to the latest advances in treatment and to teach them how to be active participants in their health care through patient education and self management. Using scientific evidence to establish the baseline for appropriate patient care, providers and patients can work together to tailor treatment regimens that improve outcomes in sub-populations which share common diseases and in individual patients. A disease management approach should take into account co-morbidities and psychological factors, and aim to increase the quality of care while overall costs are managed. In general, disease management programs:

- Identify best scientific evidence about diagnostic and therapeutic processes, which are most likely to achieve optimal patient outcomes;
- Set goals and validate outcome measures with stakeholders;
- Develop teams that may include physicians, pharmacists, nurses and case managers, who participate in patient communication and education;
- Identify the sub-populations of patients with chronic conditions for whom a disease management strategy may work best;
- Enhance communication between practitioners and patients;
- Generate feedback necessary for behavior modification and reinforce the new behaviors learned by patients and practitioners; and
- Measure the effectiveness of the interventions.[1]

Several State Medicaid agencies have begun to put disease management programs into place. Both empirical data and clinical information are used when comparing attributes of diseases which are candidates for intervention. Selection of a chronic condition to target for disease management includes

consideration of the following criteria:

- Existence of treatment guidelines with the consensus about the level of appropriateness and effectiveness of care;
- Presence of generally recognized interventions that are well documented in the medical literature;
- Evidence of large practice variation and a wide range of drug treatment modalities;
- Presence of a large number of patients with the disease whose therapy can be improved;
- Preventable secondary conditions that are often associated with the chronic disease;
- Measurable outcomes that can be agreed upon and measured in standardized and objective ways, and that can be improved by application of appropriate therapy;
- The potential for cost savings within a short period of time less than two years.[2]

Asthma is often selected as a disease for intervention because there is a great opportunity to treat this disease more effectively and to develop programs that will help providers, payers and health plans manage the high costs associated with it, as well as improve the quality of care. Following is a list of reasons as to why asthma is often selected for state Medicaid disease management programs:

- High-cost patients can be identified based on the clusters of reliever drugs used;
- Consistent clinical practice guidelines are available with core recommendations that apply to both children and adult sub-populations;
- Validated outcome measures are available that can help measure the effectiveness of the interventions;
- Communication programs are available and have been shown to work in the treatment of asthma;
- Patient education materials are plentiful;
- Feedback and information necessary for patient and provider behavior changes can be generated easily. [3]

National asthma health goals for the year 2000 are:

- To increase formal patient education;
- Reduce hospitalizations;
- Reduce activity limitations associated with asthma;
- Monitor health status in patients with asthma;
- Monitor associated respiratory symptoms triggered by environmental factors. [4]

In most of the patients, the symptoms of asthma can be prevented and/or controlled, and intervention programs have the potential to improve health outcomes. Asthma appears to be an ideal target for disease management as it has the potential for cost effectiveness while improving patient morbidity and mortality. In addition, disease management for asthma motivates patients to manage their own condition and to improve their own health outcomes through active participation in health education and healthy lifestyle choices.

About Medicaid:

Title XIX of the Social Security Act, commonly referred to as Medicaid, is a program which provides medical assistance for certain individuals and families with low incomes and resources. The program became law in 1965 as a jointly funded cooperative venture between the Federal and State governments to assist States in providing medical care to eligible persons. Medicaid is the largest program funding health and health-related services to America's poorest people. Currently Medicaid covers approximately 36 million individuals including children, aged, blind, disabled, and people who are eligible to receive federally assisted income maintenance payments. Within broad national guidelines that the Federal government provides, each of the States:

- establishes its own eligibility standards;
- determines the type, amount, duration, and scope of services;
- sets the rate of payment for services; and
- administers its own program. [5]

The Role of Medicaid in the Delivery of Health Care in Texas:

As in many other states, Medicaid is the dominant health care program in Texas for children and pregnant women. Table I shows the number of Texas Medicaid recipients and their associated provider reimbursements for treating five chronic diseases, namely, diabetes, asthma, congestive heart failure, hepatitis C and hemophilia in Fiscal Year (FY) 1999.

Table 1: **A summary of the unique Medicaid clients in fee for service (FFS) and primary care case management (PCCM), including total amount paid by selected disease conditions**

Disease	Number of Patients	Total Amount Paid
Asthma	123,243 patients	$41,642,180
Congestive Heart Failure	54,491 patients	$31,706,285
Diabetes	123,945 patients	$45,671,660
Hemophilia	2,857 patients	$1,567,621
Hepatitis C	4,327 patients	$1,709,012
Total	308,863 patients	$122,386,758

Source: The Texas Department of Health

The estimates for the number of patients and costs in each disease category only include Medicaid clientele whose care is reimbursed via the State's claims administrator, the National Heritage Insurance Company (NHIC). These are the fee-for-service (FFS) and primary care case management (PCCM) clients, and do not include the clients who participate in the Medicaid health management organizations (HMOs) health care delivery system.

From Table 1, it is clear that Diabetes has the highest number of Medicaid patients and the highest cost associated with treating this disease. However, the 75th Texas Legislature introduced SB 162 that mandated a pilot study be conducted for Diabetes in Bexar County for patients in Medicaid Managed Care, to observe if health outcomes could be improved through disease management strategies.

The second largest number of Medicaid recipients and associated costs can be seen for Asthma. Thus, Asthma was chosen for the new disease management study in Texas. The study will include both rural (Bell county area), and urban (Bexar county area) sites.

Congestive heart failure (CHF) was not chosen because the number of affected Medicaid clients was small even though the associated costs are high. Moreover, there are many complications and disabilities associated with CHF that may not be observed in Asthma patients. Hemophilia and Hepatitis C did not make good candidates for disease management since the Medicaid patient populations, as well as the financial burdens, are small.

Disease management for Asthma, in the selected regions of Bell and Bexar counties and their surrounding counties, will yield favorable and statistically significant results, since they have large populations of children in the Medicaid fee for service and managed care programs, respectively.

Table 2 further justifies why asthma was chosen as the condition for the disease management study compared to the other chronic disease conditions.

Table 2: A summary of the number of Texas Medicaid patients with asthma (counted by diagnoses codes), total amount paid by NHIC (FFS and PCCM), and the percentage of cost by category of service (professional, outpatient hospital, inpatient hospital and vendor drug) for FY 1999.

Asthma	Number of Patients	Total Amount Paid	Percent
Professional Visits	136,773 patients	$12,245,271	19.82 %
Outpatient Hospital	36,252 patients	$6,916,460	11.20 %
Inpatient Hospital	7,033 patients	$22,465,648	36.37 %
Vendor Drug	105,755 patients	$20,140,767	32.61 %
Total:	**180,119 patients**	**$61,768,146**	**100.00 %**

Source: The Texas Department of Health

In table 2, professional visits include primary care physician visits, specialty physician consultations, and respiratory therapists' services. Outpatient hospital represents primarily emergency room visits, but also includes the smaller costs of hospital outpatient clinic visits. Inpatient hospital represents the facility costs for inpatient services. The claims payment administrator for professional, outpatient and inpatient services is the National Heritage Insurance Company (NHIC). However, NHIC only reimburses providers in the fee-for-service and the primary care case management health care delivery models.

The total number of patients with Asthma (more than 180,000) does not represent an unduplicated count because there is overlap of patients utilizing the four benefit categories, i.e., professional visits, outpatient visits, inpatient hospital and vendor drug program.

In table 2, vendor drug represents the outpatient pharmaceutical services and costs for drugs which are specifically used only for asthma. Additional costs for other drugs, such as steroids and antibiotics, that are not used exclusively for treatment of asthma, are not included. Therefore, the associated drug costs are clearly underestimating the true cost for pharmaceuticals Medicaid patients who have Asthma. These data were obtained from the Vendor Drug Program at the Texas Department of Health, because it is responsible for claims processing and not NHIC.

It should be noted that the Texas data comparing physician, emergency room, inpatient hospital, and drug expenditures for Asthma do not coincide with the data from other states such as Virginia and Florida. In the data from these states, they have reported that disease management has been a cost-efficient method of treating asthma because it has increased drug utilization and expenditures but greatly reduced the costs of inpatient hospital stays and emergency room services. The data in table 2 demonstrate that there is already a much higher ratio of expenditures for asthma drugs in comparison to inpatient hospital and emergency room services visits in Texas. The conclusion is that the Texas disease management study on Asthma regarding Medicaid expenditures may show savings in the vendor drug costs as well as in the other service categories.

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CHARGE IV *Study issues arising from hospital system sales, conversions, partnerships and mergers, including the impact on health care in medically underserved and rural communities and on the level of charity care provided.*

LEAD MEMBERS *Reps. Bob Glaze and Garnet Coleman*

INTRODUCTION

The committee held a public hearing to address this charge on June 28, 2000. At this hearing, the committee heard from two panels that provided us with a general overview and history of Texas' charity care law, as well as an overview of issues arising from hospital system sales, conversions, partnerships and mergers, including the impact on health care in medically underserved and rural communities and on the level of charity care provided. The second panel covered provider and consumer perspectives of the charity care law, as well as issues set forth in the charge.

The committee worked with state agency personnel and others to identify and assess the impacts that the changes in the charity care law have on the amount of charity care provided by hospitals, as well as on the availability and quality of health care in medically underserved and rural communities in Texas. Additionally, the committee worked to identify the impacts of hospital system sales, conversions, partnerships and mergers on the level of charity care provided by hospitals.

POLICY OPTIONS

Policy Option I	Request the Texas Department of Health to publish annually an "Access Manual" that lists the nonprofit hospitals in Texas with brief summaries of their charity care policies and community benefits work.
Policy Option II	Create new incentives for access expansion by linking reimbursement from the Tertiary Care Fund to the provision of charity care and community benefits by nonprofit hospitals.
Policy Option III	Create new incentives for nonprofit hospitals to contract with local counties, with special focus on rural and underserved counties, for provision of county indigent health care services to local residents.
Policy Option IV	Allow nonprofit hospitals to receive credit towards meeting their charity care and community benefits obligations by contributing to a new "State Access Fund," which will be used to finance access expansion initiatives in underserved areas.
Policy Option V	Initiate an "access levy" on certain inpatient hospital revenue that goes into the new State Access Fund, which will be used to finance access expansion initiatives in underserved areas.
Policy Option VI	Improve accountability to communities served by asking nonprofit hospitals to publish summary notice of their charity care policies and community benefits work in local publications.
Policy Option VII	Commission an independent appraisal of a representative sample of

nonprofit hospitals to determine the value of their state tax exemptions.

Policy Option VIII Streamline standards in the charity care law to improve accountability and ensure maximum access to health care services, especially for the uninsured and underinsured.

BACKGROUND

There is a long history of partnership between the State of Texas and nonprofit health care organizations to keep our population healthy and improve access to health care, especially for those who are uninsured and underinsured. Texas has encouraged charitable organizations that promote health by exempting these organizations from taxation, because it believes that healthy people are productive people that drive the engine of the state's economy. Health-related charities assist the state with its responsibility to promote the health of its citizens, thus helping to reduce the general tax burden on the public.

Nonprofit hospitals are a particularly vital part of this network of health charities that partner with the state to keep its population healthy and productive. In fact, it is estimated that nonprofit hospitals alone contribute more than $1.5 billion of the $4.7 billion in charity care provided in 1998.[1] Most of that care is provided to people who are uninsured and underinsured, making nonprofit hospitals a fundamental component of the health care safety net. But with the number of uninsured Texans at about 4.8 million[2] and rising, working to improve this public-private partnership, ensuring the viability of the health care safety net, and increasing access to health care will be among the key health care policy challenges in Texas over the next several years.

In recognition of these challenges, Speaker Pete Laney in 1999 asked the House Committee on Public Health to evaluate Texas' charity care statute, with a focus on the level of charity care being provided in the state by nonprofit hospitals, especially in rural and underserved communities. The review was conducted with the broad policy challenges outlined above in mind -- and the options developed are intended to improve the partnership between the state and its nonprofit hospitals, strengthen the health care safety net for the uninsured and underinsured, and increase access to health care.

The committee held one public hearing focusing on this charge on June 28, 2000, and solicited written input from interested parties. Representative Garnet Coleman and Representative Bob Glaze also held

several meetings with stakeholders throughout the interim to collect information and discuss options. The committee used this input to develop a set of policy options for consideration by the 77th Legislature.

Charity Care Statute Overview

The Texas charity care law (Subchapter D, Chapter 311, Health and Safety Code), was passed by the 73rd Legislature in 1993 as Senate Bill 427 by Senator Rodney Ellis and Representative Glen Maxey. It requires nonprofit hospitals to annually satisfy one of the three requirements below to qualify as a charitable organization under the Tax Code. Nonprofit hospitals that are part of a hospital system and that are located within a radius of 125 miles or less may elect to satisfy the charity care requirements on a consolidated basis:[3]

REASONABLENESS STANDARD	Provide charity care and government-sponsored indigent health care at a level reasonably relating to community needs.
100% OF TAX-EXEMPT BENEFITS STANDARD	Provide charity care and government-sponsored indigent health care in an amount equal to 100 percent of the hospital's tax-exempt benefits, excluding federal income tax.
CHARITY CARE AND COMMUNITY BENEFITS MIX STANDARD	Provide charity care, community benefits and government-sponsored indigent health care in an amount equal to at least five percent of the hospital's net patient revenue, of which charity care and government-sponsored indigent health care must be at least four percent.[4]

Charity care is defined by the statute as the unreimbursed cost to the hospital of (1) providing health care services to people classified by the hospital as financially or medically indigent; and/or (2) providing, funding or otherwise financially supporting health care services provided to financially

indigent persons through other nonprofit or public outpatient clinics, hospitals or health care organizations.[5] Who is classified as "financially indigent" varies from hospital to hospital; each is required to set an eligibility standard based on its assessment of community need, but it can be no lower than 25 percent of the federal poverty level (FPL) and no higher than 200 percent of FPL.[6]

Government-sponsored indigent health care is defined by the statute as the unreimbursed cost to the hospital of providing health care services to recipients of federal, state or local indigent health care programs, eligibility for which is based on financial need.[7] This includes programs such as Medicaid and the County Indigent Health Care Program. Medicare is not included in this category because eligibility for Medicare is not based on financial need. Basically, this category is the difference between the amount it costs the hospital to provide health care services to recipients of programs like Medicaid, and the amount that Medicaid pays for those health care services. For example, if it costs a hospital $60 to do an X-ray on a Medicaid patient, but Medicaid only pays the hospital $17, the $43 difference would be counted as government-sponsored indigent health care.

Community benefits is defined by the statute as activities that benefit the community, including government-sponsored program unreimbursed costs, donations, education, research and subsidized health services like community clinics.[8] Government-sponsored program unreimbursed costs primarily is the difference between the amount it costs to provide health care services to people on Medicare, and the amount that Medicare pays for those services.

All non-profit hospitals, hospitals that qualify to receive Medicaid disproportionate share hospitals (DSH) funds, and public hospitals owned or operated by a political subdivision of the state are required to report the amount of charity care they provide, but certain hospitals are exempt from meeting one of the above requirements:

- Hospitals that are located in counties with population of 50,000 or less and where

the county is designated as a health professional shortage area;

- Hospitals that do not charge patients nor receive payment for providing health care services, such as Shriner's Hospitals and Scottish Rite Hospitals; and

- Hospitals that are designated as Medicaid disproportionate share hospitals in either the current fiscal year or in either of the previous two years is "deemed" to be in compliance with the statutory standards.[9]

The first two categories of hospitals also are exempt from the reporting requirements of the law described below. Medicaid DSH hospitals still must comply with the reporting requirements.

Once a year, each nonprofit hospital that is required to meet one of the above standards must file a form with the Texas Department of Health (TDH) that tells which standard the hospital chose to comply with in the preceding fiscal year. The hospital must submit this form no later than April 30 of the following year.

Along with this form, before April 30 of each year a hospital must submit its "Community Benefits Plan." This plan must include the hospital's mission statement, a description of the health care needs of the community it serves, and a list of the charity care and community benefits the hospital provided in the previous year. It also must include an audited statement of the hospital's total operating expenses from the most recent year available, as well as a calculation of the hospital's "cost-to-charge ratio" for that year (for more detail on cost-to-charge ratios, see below). The statute also requires each hospital to post notice in conspicuous places throughout the hospital that the community benefits plan is completed and available to the public upon request to TDH.[10]

By July 1 of each year, TDH is required to submit a report to the attorney general and the comptroller

listing each nonprofit hospital or hospital system that did not meet the charity care and community benefits requirements. By November 1 of each year, TDH must submit another report to the attorney general and the comptroller showing the amount of charity care and community benefits provided by each hospital or hospital system.[11]

Cost-to-Charge Ratios

A cost-to-charge ratio is a percentage that is calculated and used to determine whether or not a nonprofit hospital met its charity care and community benefits obligation. Roughly speaking, a cost-to-charge ratio is calculated by dividing a hospital's total operating expenses by its total patient revenue. Once the ratio is calculated, it is applied to the hospital's total billed **charges** for charity care to come up with the actual **cost** of providing that charity care. The hospital then subtracts any third-party or patient revenue it received for that care, and then that final number is used to determine whether the hospital met its chosen charity care standard.

The two key factors in calculating the cost-to-charge ratio for a hospital are the hospital's total operating expenses and its total patient revenue. Under current law, these numbers must come from the hospital's audited financial statement, which uses so-called generally accepted accounting principles (GAAP) to determine what qualifies as "operating expenses" and what qualifies as "patient revenue."[12] When determining operating expenses, GAAP requires the inclusion of "bad debt," which is billed charges for which the hospital expects but has not received payment. This amount is included in the numerator of the original calculation of a hospital's cost-to-charge ratio.

This is important to note because under the original charity care law passed in 1993, the numbers for a hospital's total operating expenses and total patient revenue were required to come from the hospital's Medicare cost report. The Medicare cost report is an annual report to the federal government by each hospital that describes the hospital's costs of providing health care services to Medicare patients, and it does not include bad debt. This means that under the Medicare cost report method, the numerator in

the cost-to-charge ratio is smaller, resulting in a smaller cost-to-charge ratio. The practical effect comes when that cost-to-charge ratio is applied to the hospital's billed charity care charges; the smaller ratio means the hospital will have to do more charity care to meet its chosen standard.

As a side note, bad debt does eventually get included under the Medicare cost report method, but only after the cost-to-charge ratio is calculated without it. The amount of bad debt reported by the hospital gets multiplied by the cost-to-charge ratio, and the resulting number is added to the hospital's cost of providing charity care.

Senate Bill 1190 by Senator Ellis in 1995 changed the statute to allow hospitals to use audited financial statements rather than Medicare cost reports to calculate cost-to-charge ratios and the amount of charity care provided. Concern about whether or not the change affected the amount of charity care provided by nonprofit hospitals led to the passage of SB 788 by Senator Ellis in 1997, which required hospitals to report using both methods so that comparisons could be made between the two. Preliminary reports from TDH indicate that in 1998, the amount of charity care provided by nonprofit hospitals was $87.2 million higher under the audited financial statement method than under the Medicare cost report method.[13]

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CHARGE V *Examine the requirements imposed on emergency medical service providers in rural areas. Determine whether individual requirements encourage or hinder the provision of services.*

LEAD MEMBERS *Rep. Bob Glaze and Rep. Carlos Uresti*

INTRODUCTION

The committee held a public hearing to address this charge on June 28, 2000. At this hearing, the committee heard from two panels that provided an overview of current requirements and perspectives imposed on emergency medical services providers in rural areas, and whether individual requirements encourage or hinder the provision of services.

The committee worked with state agency personnel and others to assess the number of personnel, firms and equipment for emergency medical services (EMS) as well as the type and level of EMS services provided in Texas' urban, rural and frontier areas. Additionally, the committee identified funding issues and current requirements for EMS providers in rural areas of Texas that might be an impediment to the provision of services. The committee also monitored and participated in the work group sessions of the Advisory Council at the Department of Health.

POLICY OPTIONS

Policy Option I

Allow the **Advisory Council**, which was established under **HB 2085** to advise the Texas Department of Health on emergency issues:

a. Assess the need for EMS provision and service coverage in all rural and frontier areas of Texas.

b. Develop specific proposals that deal with subject of EMS provision and service coverage.

c. Ensure adequate rural and frontier representation on the council to the Board of Health.

d. Construct a strategic plan for educational levels and systems development.

Policy Option II

Develop strategies to improve initial and continuing training and certification requirements for rural and frontier areas. Some issues include:

a. Require urban, hub, medical and/or lead trauma facilities to provide educational opportunities to the rural providers in their Trauma Service Areas (TSAs).

b. Specify requirements for trauma system participation for health care entities.

c. Stipulate training requirements for hospitals with regard to EMS clinical training and/or require hospitals that receive any state funds to provide such training.

d. Allow community colleges to extend their educational offerings into another district if the college in that district does not provide the services.

e. Create strategies for scholarships and receipt of college credit to increase EMS staffing in rural and frontier areas.

Policy Option III Allow counties to reimburse EMS providers under the Indigent Health Care Act at the Medicaid rate.

Policy Option IV Consider the standardization and simplification of EMS terminology and classification of providers.

Policy Option V Allocate resources for the biennium in state funds to the TDH for its EMS Local Projects Grants program.

TIME LINE

1943 Texas regulates ambulances. A first aid kit and a person with a "Red Cross" certificate is required.

1947 Vernons Annotated Civil Statute (VACS) 4590b mandated minimum standards and permitting for emergency ambulance operators.

1966 National Highway Safety Act set forth criteria to improve quality of care for persons injured in highway accidents.

1973 **VACS 4447-o** provided for the development of a coordinated EMS system in accordance with the federal EMS Act of 1973.

SB 855 created the Coordinated EMS Division in TDH which was charged with

1. Developing a state plan to deliver EMS to high risk neonatal infants and other acutely ill persons, and
2. Establishing EMS delivery areas with at least one hospital designated as a trauma center.

1983 **VACS 4447-o** amended to mandate minimum requirements for training, staffing, vehicles, equipment and licensing of EMS providers.

SB 385, the EMS Act established a comprehensive regulatory program for EMS. SB 385 repealed the 1943 ambulance law and amended the 1973 law removing the neonatal care and trauma designation provisions.

SB 385 established the 18 member **Emergency Medical Services Advisory Council** which was appointed by the Board of Health consisting of 3 physicians (one board certified in emergency medicine); two municipal officials; two county officials; one hospital representative; one private EMS provider; one volunteer EMS provider; one local government provider; one EMS educator; one paramedic EMT; one EMT; one emergency nurse; one fire department representative; and two consumers.

1987 **VACS 4447-o** re-codified to Chapter 773, Texas Health and Safety Code.

1989 **HB 18**, the Omnibus Rural Healthcare Act, established a program to designate trauma facilities and authorized a grant program. The Bureau of Emergency Management was required to develop and monitor a statewide EMS and trauma care system and develop and maintain a trauma reporting and analysis system.

HB 18 established a 12 member **Trauma Technical Advisory Committee** which was appointed by the Board of Health. Appointees included hospital administrators from rural and urban facilities; emergency nurses; physicians who were board certified in neurosurgery, surgery, and anesthesiology; family practice physicians; and a trial lawyer who represented claimants.

1993 **Chapter 773** amended to allow the Texas Board of Health to determine criteria for personnel re-certification.

HB 2835 established the EMS for children program and a seven member **Pediatric Emergency Medical Services Advisory Committee** appointed by the Commissioner of Health. Appointees consisted of individuals who were clinical management, clinical education, and administration experts in the areas of pre-hospital

care, emergency room care, acute care, children's hospital care, and rehabilitation of pediatric patients.

SB 383 abolished all advisory committees effective September 1, 1997 unless

1. The governing body established a different sunset date; or
2. The duration of the advisory committee was prescribed by law.

This bill included new requirements for the composition, duration, and operation of advisory committees.

1994 TDH staff reviewed all advisory committees and recommended consolidating the three EMS-related committees. Board of Health proposed rules establishing the **Emergency Health Care Advisory Committee**.

1995 Board of Health adopted rules to establish a 14 member **Emergency Health Care Advisory Committee** composed of one emergency physician; one provider of pre-hospital EMS; one EMT, EMT-I, or EMT-P; one emergency nurse; one pediatrician; one trauma surgeon; one trauma nurse; one facility administrator; one fire department provider; one EMS medical director; and four consumers. Sunset date was set at May 1, 1999.

1997 **Chapter 773** amended to create Licensed Paramedics.

SB 1517 repealed the advisory committee provisions in **SB 385, HB 18 and HB 2385** which were not in effect since the passage of **SB 383** in 1993.

First funding was appropriated by the Texas Legislature. **SB 102** created the Emergency Medical Services (EMS) and Trauma System Fund.

1999 **Chapter 773** amended to create a Governor appointed advisory council, to change late fee structures, and provide a certification process and immunity for emergency medical dispatchers.

Board of Health adopted rules to continue **Emergency Health Care Advisory Committee** until May 1, 2003. Committee was increased to add one additional consumer member.

HB 2085 abolished the **Emergency Health Care Advisory Committee** effective September 1, 1999 and established a 15 member **advisory council** to the Board of Health. Members are appointed by the Governor to include one board certified emergency physician; one physician who is an EMS medical director; one fire chief for a municipality; one officer or employee of a private EMS provider that is involved in trauma system development; one EMS volunteer; one EMS educator; one member of an EMS air medical team; one fire department representative; one hospital representative who is affiliated with a designated trauma center in an urban area; one hospital representative who is affiliated with a designated trauma center in a rural area; one representative of a county EMS provider; one pediatrician with trauma or emergency medicine expertise; one trauma surgeon or registered nurse with trauma expertise; and two consumers. The provisions of SB 383 (Govt. Code §2110) concerning the size, composition, and duration of an advisory committee **do not** apply.

BACKGROUND

A milestone was reached for the Texas Emergency Medical Systems (EMS), when the first funding was appropriated by the Texas Legislature for systems development. In May 1997, Senate Bill (SB)-102 created the Emergency Medical Services (EMS) and Trauma System Fund. Allocation of four million dollars to the fund occurred for the 1998/99 biennium.[1] Statewide trauma care professionals were delighted as they were able to fund more services in trauma systems with the available resources.

However, the attainable funding was unable to relieve the state's already taxed EMS and trauma systems. A few factors that increase the demands on our trauma systems include an expanding and mobile population, the large tourism trade and a growing economy.[2] Approximately 30 Texans die every day from injuries; over 10,000 each year. Since trauma is the leading cause of death in persons aged 1-44 years, the years of potential life lost are staggering: ~290,000 in 1993.[3]

Trauma is a "disease" that can occur anywhere at any time. Critical trauma victims must reach definitive care within a short period of time, often called the "golden hour," to prevent death or disability. Trauma systems coordinate all the necessary resources such as communication systems, pre-hospital care providers, multi disciplinary trauma teams, prevention activities, public information and rehabilitation required to prevent impairment and mortality.

In addition to trauma service, EMS personnel also perform life-saving tasks for medical emergencies such as cardiac arrest, stroke, gun violence, infectious disease outbreaks and more. These professionals are also able to deliver children and are an important factor in stabilizing the patient before they reach the hospital.

Urban areas have the means and the size to provide a full continuum of above mentioned resources. In

comparison, rural and frontier areas may not have the means to provide all the necessary resources; therefore, death rates due to trauma in these areas are considerably higher. For instance, critically injured patients in rural areas are three to four times more likely to die of their injuries than similarly injured patients in urban areas. In addition, the types of trauma that rural and frontier areas confront significantly differ from trauma incidences that occur in urban areas.

Vehicle collisions and crashes are the main trauma response calls made by rural EMS teams.[4] Motor vehicle crashes in rural Texas often occur in isolated areas, and the great distances that primarily volunteer emergency medical services have to travel often complicate the treatment of injuries received in such crashes. Moreover, many rural areas lack EMS units and designated trauma facilities to supply needed emergency care during a patient's critical 'golden hour' after the injury which may make the difference between life and death for the victim.

Staffing volunteer services and funding for these services in rural areas are two of the most important challenges facing EMS today. Volunteer staff make up approximately half of the EMS firms in Texas and most of those volunteer services are situated in rural areas. Proper training for these volunteers is an important issue as these volunteers practice the same professional standards of career EMS personnel. At present, only two methods of additional training opportunities are available to rural EMS personnel namely distance learning and mobile training units.

In regards to funding, according to the Texas Department of Health (TDH), Texas does not have a law requiring that county governments provide funding for EMS. This leads to a lack of resources being allocated from the counties for these essential services. The 75th Texas Legislature allocated $3.1 million for the biennium in state funds to the TDH for its EMS Local Projects Grants program. The funding is apportioned based on need for equipment, education and services. Approximately $1.5 million of the resources have been used to fund many meritable projects. However, many well deserving projects and ideas remain unfunded as the need exceeds availability.

In addition, unlike police and fire control, EMS has not been classified as an essential service. This has lead to a variety of methods in which EMS is provided especially in rural and frontier areas that causes large disparities and inconsistencies in the quality and level of services accessible. According to TDH's Bureau of Emergency Management, this is termed as the "Patchwork Quilt of EMS in Texas".[5]

In conclusion, EMS is still a young profession as legislation for coordinated EMS service was established in 1973 with comprehensive regulatory programs being mandated in 1983. Thus, the EMS system has only been established for the last 17 years. As such there are many issues that need to be carefully evaluated and assessed especially in relation to rural and frontier EMS. This report outlines the interim charge of rural EMS and the policy options for consideration.

History of Emergency Medical Services:

From the mid 1930s through 1970, emergency ambulance service in Texas was provided primarily by funeral homes. The hearse was designed to transport a human body, albeit deceased, in a horizontal position, and the mortuary staff were accustomed to handling bodies. It became simply a matter of convenience and economy that funeral homes began to provide ambulance service for the ill and injured.

Ambulance operators were not regulated until the Texas Legislature passed Vernons Annotated Civil Statute 4590b in 1947, which required emergency ambulances to be permitted and to carry a minimum amount of first aid equipment, a traction splint and oxygen. The law also required the ambulance personnel to have theoretical and/or practical knowledge of first aid as certified by the American Red Cross.

The National Highway Safety Act of 1966 set forth criteria for adoption and implementation by all states and local governments to focus on standards for the quality of emergency care for persons injured on the highway. As a result, the department charged the Civil Defense and Traffic Safety

Program with the implementation of the guidelines and criteria for this act.

In the late 1960s, there were significant advances in trauma research that proved well-trained non-physicians are capable of saving lives. The American College of Surgeons jointly with the American Academy of Orthopedic Surgeons, acting on a federal grant, developed an 80 hour comprehensive emergency pre-hospital training program called the Emergency Medical Technician (EMT) Course for ambulance attendants. New federal laws governing the pay of ambulance attendants made it difficult for the funeral home provider to make a profit. In addition, competition among private ambulance operators in the metropolitan areas was out of control with squads racing their rivals to scenes of accidents with little regard for public safety. As a result, funeral homes began to pass the responsibility for ambulance service to city fire departments, hospitals, private and volunteer ambulance operators, and county governments.

In 1973, the Texas Legislature enacted VACS 4447-o in accordance with a federal mandate, which created the EMS Division within the Texas Department of Health and provided for the development of a coordinated EMS system in Texas. The department established guidelines for training, staffing, vehicles and equipment, but compliance was voluntary and not enforced.

Chapter 4447-o was amended in 1983 by the 68th Legislature mandating minimum requirements for training, certification, staffing, vehicle design, equipment standards, and licensing of ambulance operators. The provision for minimum staffing required two persons, trained for 40 hours and certified as Emergency Care Attendants, for each ambulance. Standards for higher levels of certification were also established including EMT, EMT- Intermediate and EMT- Paramedic. The National Standard Curricula guidelines for each training program were adopted and requirements for maintenance of certification at each level were specified. The EMS Act was re-codified in 1987 as Chapter 773 of the Texas Health and Safety Code. The code was amended in 1997 to create the licensing of Paramedics.

Current Status of Emergency Medical Services in Texas:

A table depicting the number of EMS personnel in Texas from 1984 through 2000 is given below.

Table 1: EMS Personnel in Texas from 1984 through 2000

	ECAs	EMT	EMT-I	EMT-P*	Totals
FY 1984	10798	17144	861	3571	32374
FY 1986	10708	19788	1386	4579	36461
FY 1988	12872	20809	1812	5479	40972
FY 1992	9750	26633	2939	7620	46942
FY 1994	8772	25472	3277	8704	46225
FY 1996	8282	25520	3496	10067	47365
FY 1998	5860	21740	3595	11669	42864
FY 1999	5341	21749	3649	12379	43118
FY 2000	4922	21693	3738	13082	43435

*Licensed paramedics (LPs) have been combined with certified paramedics (EMT-Ps).

Table 1 shows that the number of Emergency Care Attendants (ECAs) has decreased dramatically to 54.4% from 1984 to 2000. This ECA downturn that was seen in 1992 can possibly be attributed to volunteer firms upgrading ECA personnel to Emergency Medical Technicians (EMTs). An approximate decrease of 18.5% in the number of EMT personnel is noticeable from fiscal year 1992 to 2000. A possible explanation for this downturn is that the implementation of emergency suspensions led to a failure to report continuing education (CE). This explanation is also applicable to the total downturn experience from 1996 to 2000 of 8.3%. On the other hand, the number of EMT - Intermediates and EMT - Paramedics have increased rapidly from 1984 to 2000.

The graphs in Appendix A show the same trends experienced by the EMS industry in relation to the total number of personnel and for each of the EMS speciality personnel.

With regard to personnel, the state has given some added benefits to EMS personnel who are volunteers if they are located in rural areas. One of the benefits is an exemption from state license fees for personnel and firms providing EMS service. A provider is **exempt** if he or she recruits or intends to

staff personnel of whom 75% are volunteers. Another requirement for the exemption is that the provider should have no more than five full time staff or their equivalent to provide emergency pre-hospital care.

Table 2 and Figure 1 show the number and percentage of firms with exempt and non-exempt status in frontier, rural and urban areas respectively. **Frontier areas** are defined as counties with populations that average less than six people per square mile. **Rural areas** are counties with a population of less than 50,000 but averages more than six people per square mile. Finally, counties that have a population of 50,000 or more are considered to be **Urban areas**.

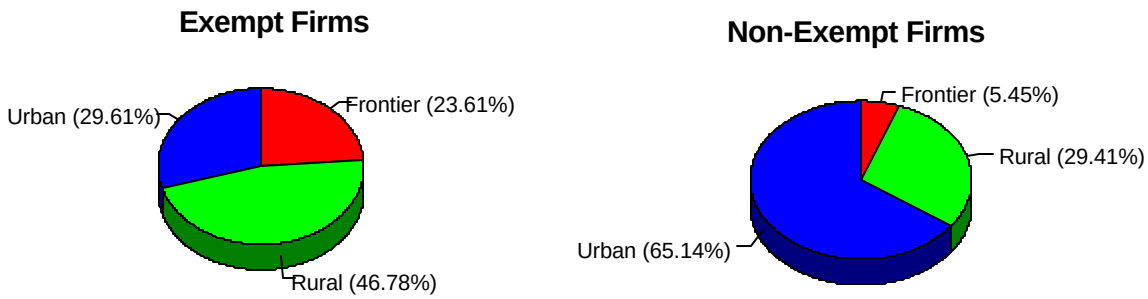
Table 2: Exempt and Non-exempt Firms in Frontier, Rural and Urban Areas

	Frontier	**Rural**	**Urban**	**Total**
Exempt	55	109	69	233
Non-exempt	25	135	299	459
Total	80	244	368	692

Figure 1: Percentage of Exempt and Non-exempt Firms in Frontier, Rural and Urban Areas

Table 2 and Figure 1 depict that approximately 70.4% or 164 firms are exempted from state license fees in rural and frontier areas compared to only 29.6% or 69 urban firms. Most of the non-exempt firms are located in the urban area with rural and frontier areas making up only 34.9% of these firms. The rural and frontier firms that provide pre-hospital EMS care can be inspected by the various levels of service. Figure 2 and Table 3 present the numbers and percentages of firms by the level of service.

Figure 2: Rural and Urban Frontier Firms by Level of Service



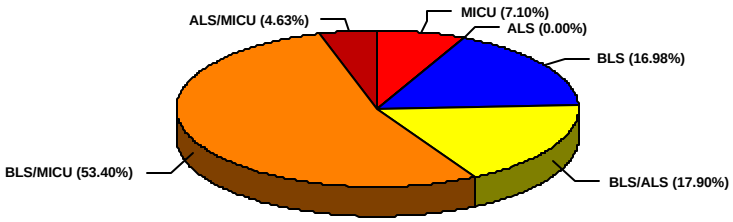


Table 3: Rural and Frontier Firms by Level of Service

	Frontier	Rural	Total
Mobile Intensive Care Unit (MICU)	0	23	23
Advanced Life Support (ALS)	0	0	0
Basic Life Support (BLS)	16	39	55
BLS/ALS	17	41	58
BLS/MICU	46	127	173
ALS/MICU	1	14	15
Total	80	244	324

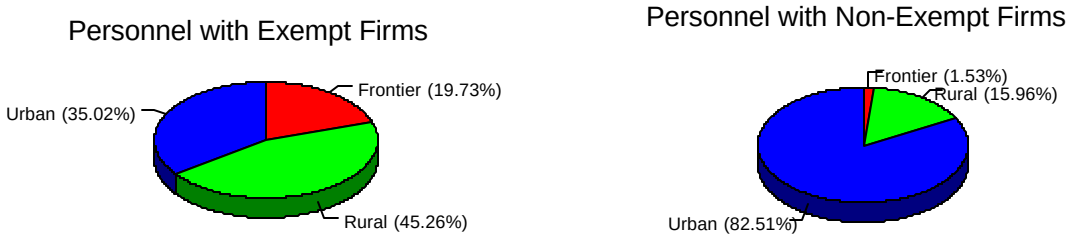
The numbers above are based on January 2000 data. According to the Bureau of Emergency Medicine, ECAs and EMTs can carry out medical care that deals with basic life support while the EMT-Is are responsible for medical tasks involving both basic and advanced life support. In order to utilize the mobile intensive care unit, a paramedic needs to be on board the vehicle. However, the bureau feels that the combination of levels such as BLS/ALS, BLS/MICU and ALS/MICU are capable of providing higher levels of care intermittently with proper staffing. From the pie chart and table, it is clear that nearly 54% or 173 firms in total, provide most of the BLS/MICU services. This service would incorporate basic life support that can be conducted by ECAs and EMTs who are mostly volunteers in a vehicle that is equipped with specialized services and staffed with a paramedic. At a close second are firms that provide BLS/ALS and BLS levels at about 17% each. These are the types of levels that are required in rural and frontier trauma cases.

After looking at the exempt and non-exempt firms and the level of service that they provide, it is important to consider the number of personnel working for the rural and frontier firms in comparison to the urban firms. Table 4 and Figure 3 present the number of personnel working for exempt and non-exempt firms.

Table 4: Personnel with Exempt and Non-exempt Firms in Frontier, Rural and Urban Areas

	Frontier	**Rural**	**Urban**	**Total**
Exempt	915	2099	1624	4638
Non- Exempt	314	3272	16921	20507
Total	1229	5371	18545	25145

Figure 3: Percentage of Personnel with Exempt and Non-Exempt Firms in Frontier, Rural and Urban Areas



The same definitions for exempt, urban, rural and frontier apply to Table 4 and Figure 3. Approximately 65% of the EMS personnel work for exempt firms in rural and frontier areas compared to 35% of personnel in urban areas. In rural and frontier areas, about 17.5% of the personnel are engaged with non-exempt firms compared to 82.5% of urban personnel. However, the total number of personnel in rural and frontier areas is remarkably low at 26.2% or 6600 personnel compared to 73.8% or 18545 personnel in urban areas. Thus, there is a shortage of EMS personnel in rural and frontier areas to provide essential pre-hospital care.

Traumas and trauma service areas (TSAs) in rural and frontier areas significantly differ from those situated in urban centers. Additionally, types of EMS providers and their quantity in a particular region is different for both areas. Table 5 and Figure 4 indicate the various EMS providers and the numbers for rural and urban areas.

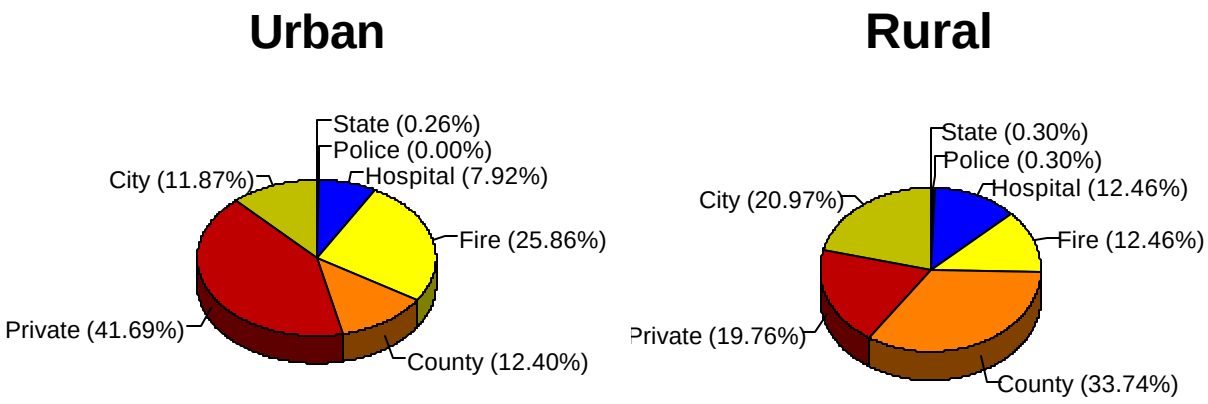
Table 5: EMS Providers in Rural and Urban Areas

	Rural	Urban	Total
State	1	1	2
Police	1	0	1
Hospital	41	30	71
Fire	41	98	139
County	111	47	158
Private	65	158	223
City	69	45	114
Total	329	379	708

Figure 4: Percentage of Rural and Urban EMS Providers

As can be seen from Table 5 and Figure 4, most of the EMS providers in rural areas are from the counties, while in urban areas private entities are responsible for EMS services. The type of EMS provider can determine the level of expertise the particular firm and its personnel will possess. For instance, in urban centers, due to private entities providing EMS service, specialized services with well-trained staff can be offered. In contrast, rural areas that depend on county funding for EMS services may not have the volunteers or means to provide specialized services. In addition, for rural areas approximately 20% of the EMS providers are the city and private health care facilities. Fire stations seem to be a close second after private facilities for urban centers at around 26% of all EMS providers.

Today, of the 724 EMS providers in Texas, 50% are municipal operations, 20% are private



enterprises, 12% are hospital-affiliated services and the rest are county, emergency service district, non-profit associations and volunteer organizations. There are currently still two funeral homes in Texas providing emergency ambulance service. In conclusion, rural and frontier areas face different EMS and trauma issues compared to urban centers. These areas have a different composition in regards to

exempt and non-exempt firms and the personnel associated with each type of firm. These areas also differ on the basis of the types of EMS providers and levels of service provided by each type of firm. EMS is a young profession that still is developing especially in rural and urban areas.

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GLOSSARY OF TERMS

ADVANCED CARDIAC LIFE SUPPORT (ACLS): Training provided by American Heart Association for Paramedics.

AUTOMATIC EXTERNAL DEFIBRILLATOR (AED): An electronic medical device capable of determining whether defibrillation should be performed.

ADVANCED LIFE SUPPORT (ALS): Emergency pre-hospital or interfacility care that uses invasive medical acts. The provision of advanced life support must be under the medical supervision and control of a licensed physician.

ADVANCED LIFE SUPPORT (ALS) VEHICLE: A vehicle that is designed for transporting the

sick and injured and that meets the requirements of a basic life support vehicle and has sufficient equipment and supplies for providing intravenous therapy and endotracheal or esophageal intubation or both.

ADVANCED TRAUMA LIFE SUPPORT – (ATLS): National training program for Paramedics.

BASIC LIFE SUPPORT (BLS): Emergency pre-hospital or interfacility care that uses noninvasive medical acts. The provision of basic life support must be under the medical supervision and control of a licensed physician.

BASIC LIFE SUPPORT (BLS) VEHICLE: A vehicle that is designed for transporting the sick or injured and that has sufficient equipment and supplies for providing basic life support.

BASIC TRAUMA LIFE SUPPORT (BTLS): National training program for basic emergency medical technicians.

CONTINUING EDUCATION (CE): Minimum requirements necessary for EMS personnel to maintain certification or licensure.

CISD - critical incident stress debriefing.

DNR - Do not resuscitate.

EMERGENCY CARE ATTENDANT (ECA): An individual who is certified by the department as minimally proficient to provide emergency pre-hospital care by providing initial aid that promotes comfort and avoids aggravation of an injury or illness.

EMERGENCY MEDICAL SERVICES (EMS): Services used to respond to an individual's perceived need for immediate medical care and to prevent death or aggravation of physiological or psychological illness or injury.

EMERGENCY MEDICAL SERVICES (EMS) OPERATOR: A person who, as an employee of a public agency receives emergency calls and may provide emergency medical information.

EMS-C: Emergency Medical Services For Children.

EMERGENCY SUSPENSION: Emergency suspension of licensed or certified personnel when there is cause to believe the individual creates a public danger.

EMERGENCY MEDICAL SERVICES (EMS) PROVIDER: A person who uses, operates or maintains EMS vehicles and EMS personnel to provide EMS.

EMERGENCY MEDICAL SERVICES (EMS) VOLUNTEER PROVIDER: An EMS which has at least 75% of the total personnel as volunteers and is a nonprofit organization.

EMERGENCY MEDICAL SERVICES (EMS) VOLUNTEER: EMS personnel who provide emergency pre-hospital or interfacility care in affiliation with a licensed EMS provider or a registered First Responder organization without remuneration, except for reimbursement for expenses.

EMERGENCY MEDICAL TECHNICIAN (EMT): An individual who is certified by the department as minimally proficient to perform emergency pre-hospital care that is necessary for basic life support and that includes the control of hemorrhaging and cardiopulmonary resuscitation.

EMERGENCY MEDICAL TECHNICIAN-INTERMEDIATE (EMT-I): An individual who is

certified by the department as minimally proficient in performing skills required to provide emergency pre-hospital or interfacility care by initiating and maintaining under medical supervision certain procedures, including intravenous therapy and endotracheal or esophageal intubation or both.

EMERGENCY MEDICAL TECHNICIAN - PARAMEDIC (EMT-P): An individual who is certified by the department as minimally proficient to provide emergency pre-hospital or interfacility care by providing advanced life support that includes initiation and maintenance under medical supervision of certain procedures, including intravenous therapy, endotracheal or esophageal intubation or both, electrical cardiac defibrillation or cardioversion, and drug therapy.

EMERGENCY PRE-HOSPITAL CARE: Care provided to the sick and injured before or during transportation to a medical facility, including any necessary stabilization of the sick or injured in connection with that transportation.

EMERGENCY SERVICE DISTRICT – ESD: Taxing district combining fire and EMS.

FIRST RESPONDER: Certified individuals or organizations which routinely respond to medical emergency situations but do not transport patients.

GOVERNOR'S EMS AND TRAUMA ADVISORY COUNCIL – GETAC: An advisory council appointed by the governor to advise the Texas Board of Health concerning rules relating to EMS/Trauma systems.

HAZMAT: Hazardous materials.

LICENSED PARAMEDIC – LP: An individual who is certified by the department as minimally proficient to provide emergency pre-hospital or interfacility care by providing advanced life support that

includes initiation and maintenance under medical supervision of certain procedures, including intravenous therapy, endotracheal or esophageal intubation or both, electrical cardiac defibrillation or cardioversion, and drug therapy. The individual must hold a college degree or possess a minimum of 60 academic credit hours from an accredited college.

MCI - Multiple casualty incident.

MEDICAL CONTROL: The supervision of pre-hospital emergency medical service providers by a licensed physician. This encompasses on-line (direct voice contact) and off-line (written protocol and procedural review).

MEDICAL DIRECTOR: The licensed physician who provides medical supervision to the EMS personnel of a licensed EMS provider under the terms of the Medical Practices Act (Chapter 6, Texas Civil Statutes 4495b) and rules promulgated by the Texas State Board of Medical Examiners. May also be referred to as off-line medical control.

MOBILE INTENSIVE CARE UNIT (MICU): a vehicle that is designed for transporting the sick or injured and that meets the requirements of the advanced life support vehicle and has sufficient equipment and supplies to provide cardiac monitoring, defibrillation, cardioversion, drug therapy, and two-way communication.

OSHA: Occupational Safety and Health Administration.

PROTOCOL: Standing delegated written orders for patient treatment issued by the physician medical director.

REGIONAL ADVISORY COUNCIL – RAC: A group formed to develop a system plan and to

help trauma service areas reach system status.

RE-CERTIFICATION: The procedure for renewal of emergency medical services certification.

RECIPROCITY: The recognition of certification or privileges granted to an individual from another state.

RE-LICENSURE: The procedure for renewal of a paramedic license and EMS provider license as described in the Emergency Medical Services Act, Chapter 773 of the Texas Health and Safety Code, Sub Chapter C Licenses, Certification, and Qualifications

RESPONSE READY: All EMS vehicles in the provider's fleet which are not transporting a patient or which have not been taken out of service are considered response ready. Response ready vehicles are subject to unannounced inspection. They must have on board or immediately available, correct and complete equipment consistent with the provider's staffing plan and vehicle designations.

RUN REPORT: Patient care and treatment record completed by an EMS provider for all emergency calls.

SOLE PROVIDER: The only licensed emergency medical service provider in a geographically contiguous service area and in which the next closest provider is greater than 20 miles from the limits of the area.

SPECIALIZED EMERGENCY MEDICAL SERVICES VEHICLE: A vehicle that is designed for responding to and transporting sick or injured persons by any means of transportation other than by standard automotive ground ambulance or rotor or fixed wing air craft and that has sufficient staffing, equipment and supplies to provide for the specialized needs of the patient transported. This category

includes, but is not limited to, water craft, off-road vehicles, and specially designed, configured or equipped vehicles used for transporting special care patients such as critical neonatal or burn patients.

STANDARD OF CARE: Care equivalent to what any reasonable, prudent person, of like certification (license) level would have given in a similar situation based on local or regionally adopted standard emergency medical services curricula.

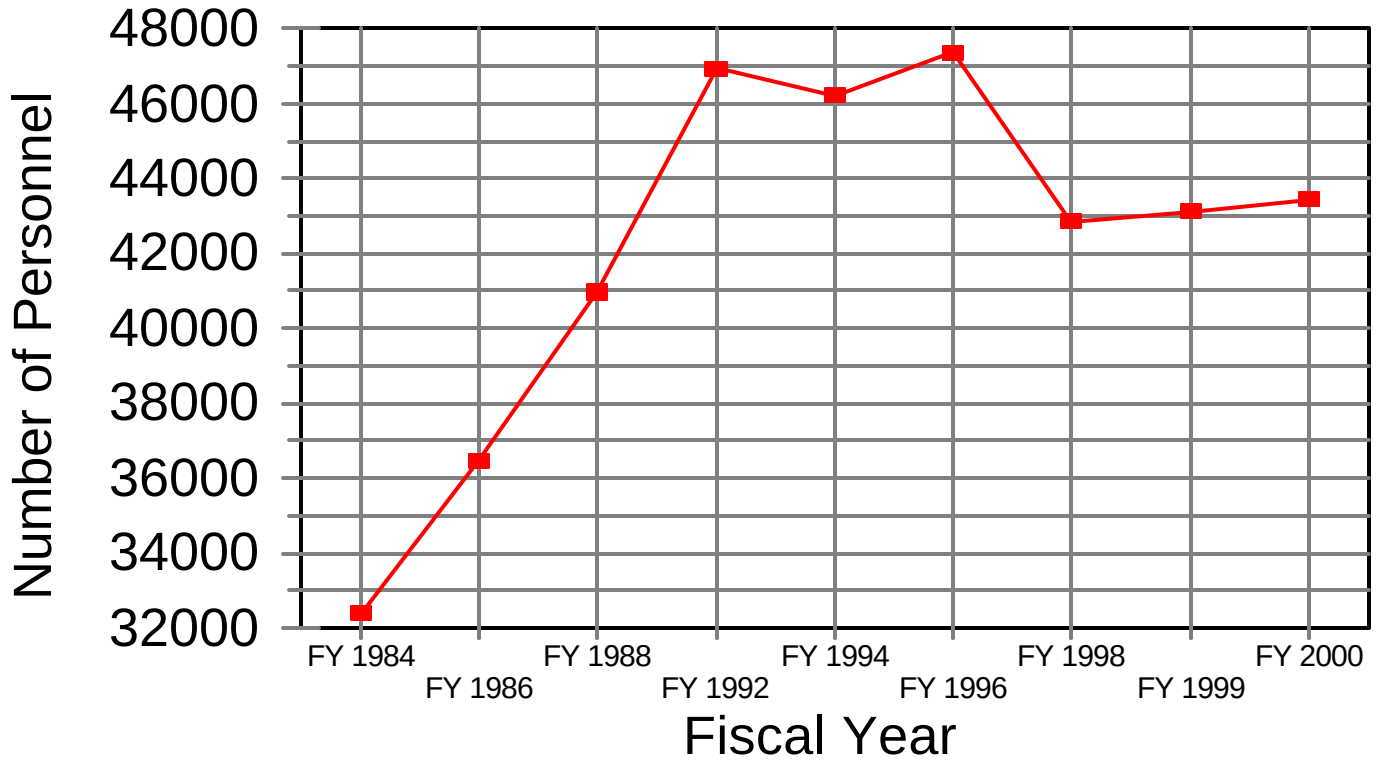
TRAUMA SERVICE AREA – (TSA): TSAs are established for descriptive and planning purposes and not for the purpose of restricting patient referral.

WHEN IN SERVICE: The period of time when an EMS vehicle is at the scene or when en route to a facility with a patient.

Appendix A

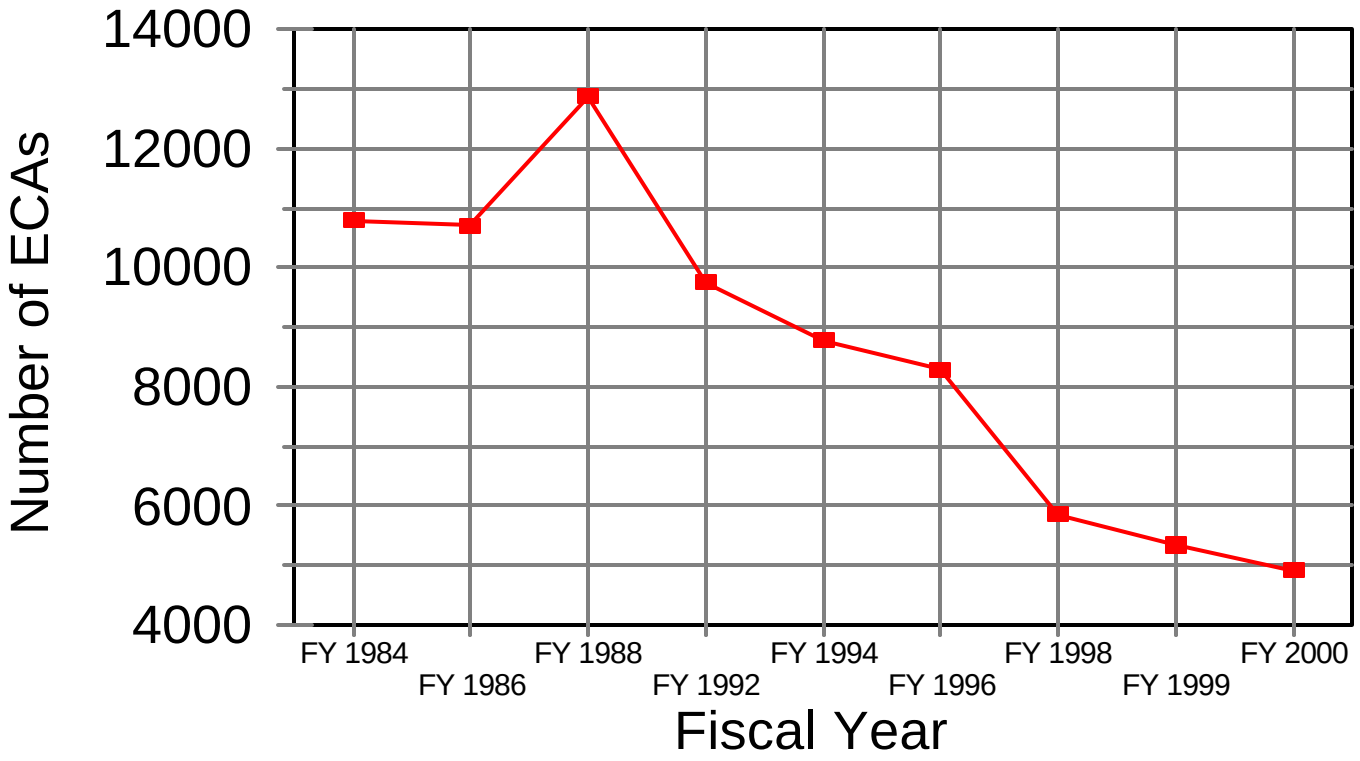
Total Number of Texas EMS Personnel

1984 through 2000



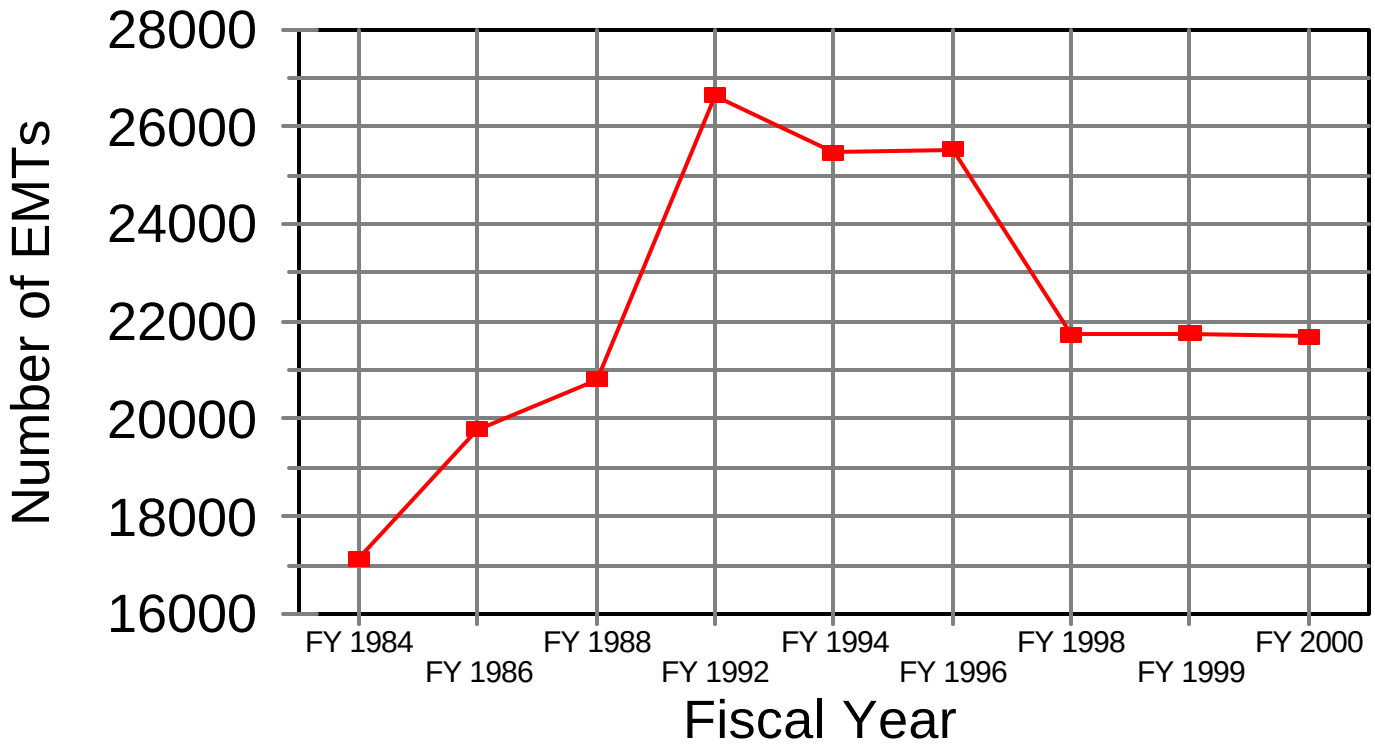
Number of Texas ECAs

1984 through 2000



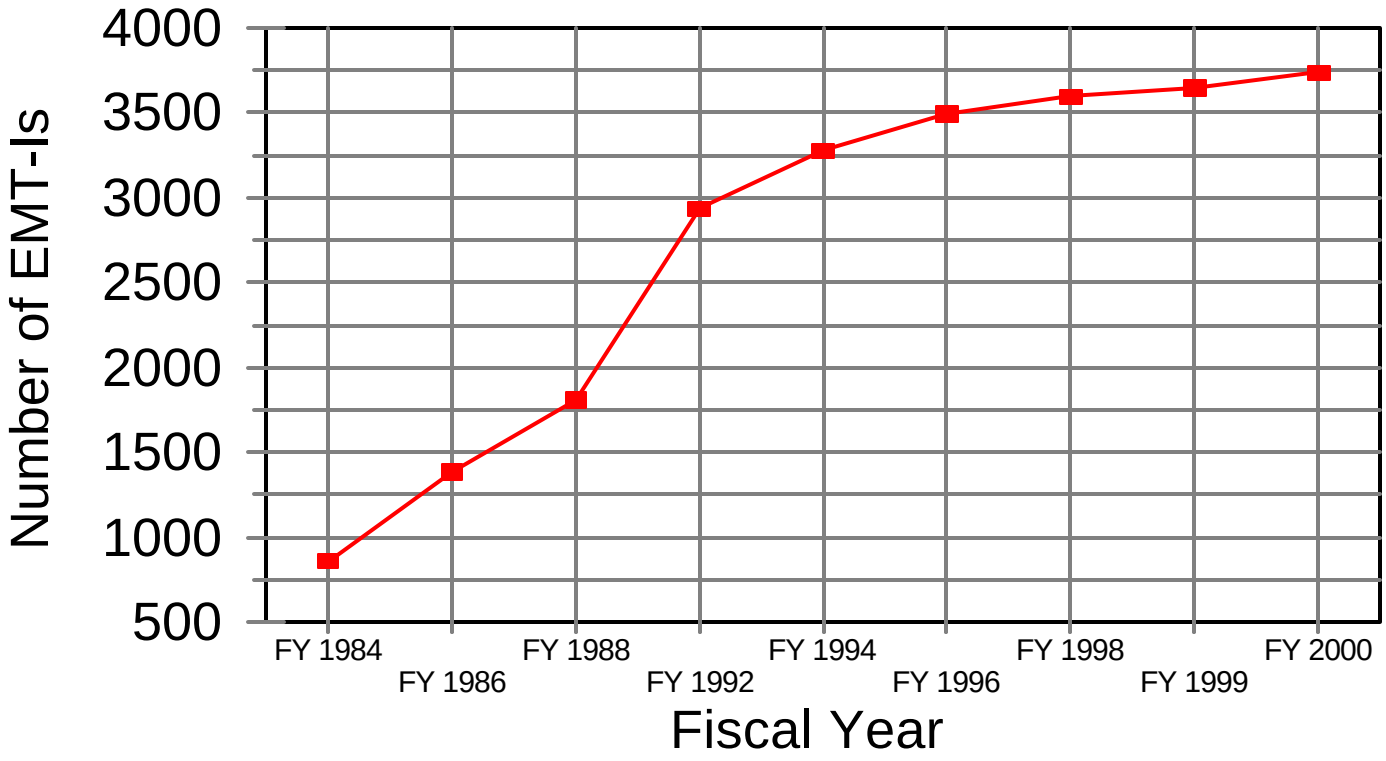
Number of Texas EMTs

1984 through 2000



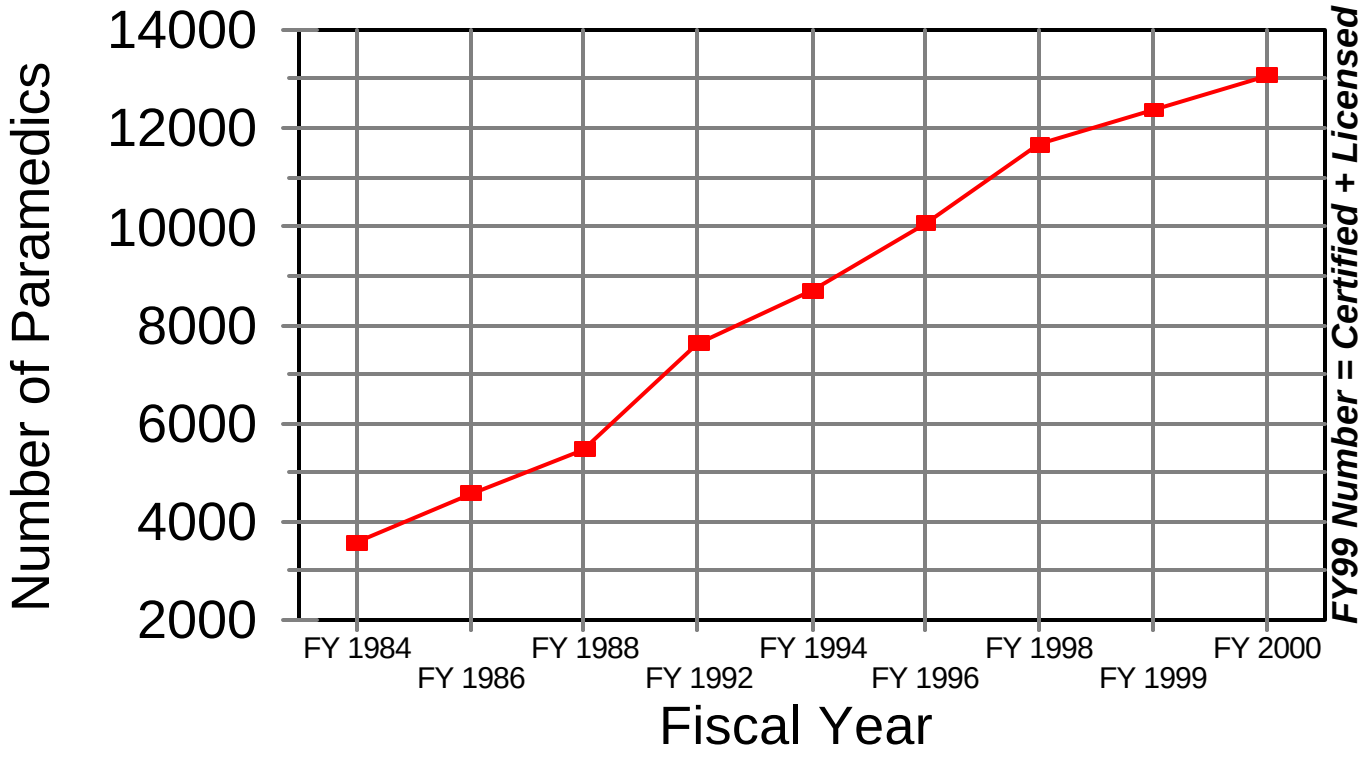
Number of Texas EMT-Is

1984 through 2000



Number of Texas Paramedics

1984 through 2000



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CHARGE VI *Conduct active oversight of the Medicaid Managed Care Program.*

LEAD MEMBER *Rep. Garnet Coleman*

INTRODUCTION

Texas began experimenting with managed care in its Medicaid program in 1993 with pilot programs in Travis County and the Tri-County (Jefferson, Chambers and Galveston) area in Southeast Texas. Senate Bill 10, passed by the Legislature in 1995, cemented Texas' commitment to Medicaid managed care. SB 10 required the Texas Health and Human Services Commission (HHSC) to submit a waiver request by August 31, 1995, to the federal government that would allow Texas to (1) move most of its Medicaid recipients into managed care; and (2) expand Medicaid to cover children with family incomes below 133 percent of the federal poverty level (FPL), and adults with or without children with family incomes below 45 percent of FPL. HHSC submitted the waiver on time and began negotiations with the federal government. Over the course of the next year, the adult expansion was removed from the waiver, leaving just the children's expansion. The federal government continued to have problems with Texas' proposed financing structure, however, and HHSC stopped negotiating in August 1997. This effectively killed the waiver request.

While the waiver discussions were going on, Texas continued to implement Medicaid managed care on a piecemeal basis around the state. Bexar, Tarrant, and Lubbock County (and their surrounding counties) were converted in the fall of 1996. After the waiver discussions stalled, Texas continued to implement Medicaid managed care around the state, region by region. Harris County was converted in December of 1997, with the surrounding counties coming on-line in the spring of 1998.

Although this rapid implementation schedule seemed to indicate that Medicaid managed care was working well, there were, in fact, significant problems. In 1997, the Legislature passed House Bill 2913, which tried to address the observed problems with the Bexar, Tarrant and Lubbock County conversions, before other areas like Harris County were converted.

Among other provisions, HB 2913 created protections for Medicaid significant traditional providers (STPs) by creating incentives for managed care organizations (MCOs) to contract with STPs. HB 2913 also required the state to contract with any MCO formed by a hospital district (or hospital district equivalent) in a particular region; toughened contract provisions for contracts between the state and MCOs by requiring payment of clean claims within 45 days; created a readiness review procedure for potential MCOs to ensure they were ready to accept Medicaid patients; improved the default procedure by which clients are assigned to MCOs; prohibited deceptive marketing practices by MCOs; and created a system of regional advisory committees to ensure local input into the decision-making process.

While the Legislature continued to conduct vigilant oversight of the Medicaid managed care system, HHSC planned for the continued expansion of Medicaid managed care into the Dallas and El Paso areas. These conversions were scheduled for July and December of 1999, respectively. Unfortunately, HHSC had entered into contracts with MCOs for these two regions before the Legislature was able to pass House Bill 2896 in 1999. This is important because HB 2896, like HB 2913 before it, attempted to address additional observed problems with Medicaid managed care before any more areas were converted. But because the state had already entered into contracts with the MCOs for Dallas and El Paso, the provisions of HB 2896 could not affect them without exposing the state to lawsuit risk.

HB 2896 made several technical changes to the Medicaid managed care program, including requiring annual independent financial audits of all Medicaid contractors; requiring MCOs to include specialized pediatric laboratories in their networks; requiring HHSC to develop and implement an expedited process for determining eligibility and enrolling pregnant women and newborns into MCOs; requiring HHSC to ensure that pregnant women and newborns receive immediate access to services; allowing HHSC to temporarily assign newborns to fee-for-service for a period of 60 days to ensure proper payment to providers; and creating a statewide advisory committee to ensure the flow of information of

local regional advisory committees to state-level decision makers.

More significantly and out of great concern about the impact of Medicaid managed care on the rural areas of the state, HB 2896 imposed an absolute moratorium on converting any additional areas of the state to Medicaid managed care until July 1, 2001. As noted above, this moratorium provision could not impact the Dallas and El Paso areas because of pre-existing contractual obligations. It also did not affect those other areas of the state that currently operate under Medicaid managed care (Travis, Harris, Bexar, Tarrant, Lubbock, and Tri-County areas). The moratorium did, however, keep Medicaid managed care from being implemented in the South Texas area, the Bell and McLennan County area, the East Texas area, the Midland/Odessa area, the Panhandle area, and the West Texas area, until at least July 1, 2001. If the Legislature wants to extend the moratorium, it must affirmatively act to do so.

In addition to imposing the moratorium, HB 2896 required HHSC to conduct a comprehensive study of Medicaid managed care in Texas. The purpose of the study was to review the impact of Medicaid managed care on access to services; quality of health care delivered; utilization patterns of recipients; statewide Medicaid costs; public hospitals and other significant traditional providers of care; coordination of care; level of administrative complexity for providers, recipients and MCOs; and competition in the marketplace. The report on the results of the study, which is due on November 1, 2000, will also include recommendations on how to improve the Medicaid managed care system and whether or not the moratorium on further implementation should be lifted.

The committee held two public hearings at which HB 2896 was discussed, January 31, 2000, and July 10, 2000, and solicited written input from affected stakeholders. The following is a sampling of some of the concerns the committee heard about Texas' Medicaid managed care system:

- < There are too many MCOs in some areas, which prevents some of these MCOs from succeeding financially or even breaking even;

- Premiums paid to MCOs are overly discounted and do not reflect reasonable administrative costs, whereas the state's PCCM contractor receives a separate payment for administrative costs;
- Many reporting and data requirements imposed on MCOs and other providers are duplicative and unnecessary;
- The Medicaid eligibility rules for children, who make up over 80 percent of MCO members, results in children rolling on and off the Medicaid program, which impedes continuity of care and prevents MCOs from achieving better health outcomes through the use of the medical home and preventive medical care;
- Administrative complexity and low reimbursement rates for providers are barriers to recruitment and retention, which negatively affects access for clients;
- Each MCO has its own set of administrative systems (preauthorization, referral requirements, credentialing, claims payment), which requires providers to spend a lot of time navigating bureaucracy rather than providing patient care;
- Accuracy and efficiency in claims processing has been complicated by multiple points of reimbursement -- NHIC, Birch and Davis, MCOs;
- Significant traditional providers are being leveraged by MCOs into accepting lower than usual rates;
- Significant traditional hospital providers are experiencing an adverse selection of patients as a result of competition created by Medicaid managed care;
- Participation in the Early Periodic Screening Diagnosis and Treatment (EPSDT) program is low in Medicaid managed care areas; and
- In STAR+PLUS in Harris County, providers have struggled to receive payment from MCOs for services provided.

The comprehensive study of Medicaid managed care in Texas conducted pursuant to HB 2896 identified many of these same concerns. It also described some additional issues:

- Data processing systems used for traditional Medicaid were designed to pay large volumes of claims and to audit billing patterns, not to examine issues of access and quality;
- The original encounter data system developed for the State does not meet current needs, with both the submission of encounter data and the encounter data system itself needing improvement;
- The State does not yet have a performance system capable of supporting value purchasing and quality improvement outcomes;
- Medicaid eligibility requires periodic recertification, making it more difficult for STAR and STAR+PLUS MCOs to affect outcomes;
- Primary care providers are dissatisfied with managed care overall, especially with the administrative complexity;
- No standard guidelines exist for identifying members with disabilities and chronic or complex conditions, which hinders the provision of proper care;
- Timeliness of claims payment is a significant issue for providers, with a claims study showing that some plans are not meeting the State's contract standard for prompt payment of clean claims; and
- Some providers report that their Medicaid clients seek information related to managed care processes from them, suggesting that some clients may benefit from additional education about managed care processes.

In addition to identifying areas of concern, the comprehensive study also identified the following areas of success:

- The majority of Medicaid managed care enrollees report having a usual source of care and being satisfied with the ease of finding a personal doctor;
- Managed care members have access to more supportive services, such as translation and interpreter services, health education, information about providers, cultural

competency, and monitoring for Americans with Disabilities Act (ADA) compliance, than traditional program clients have;

- < Surveys indicate that members are generally satisfied with quality in managed care; and
- < An HHSC clinical study of asthma showed a greater tendency for MCO members to receive prescription drugs that help prevent asthma attacks than PCCM members or traditional Medicaid clients.

The committee used input from stakeholders and the comprehensive study to identify issues regarding the implementation of HB 2896 and develop policy options relating to those issues for consideration by the 77th Legislature.

POLICY OPTIONS

Option I Extend the moratorium on Medicaid managed care rollouts until July 1, 2003. If the moratorium is not extended, direct HHSC, when planning for the implementation of managed care for the rural areas, to consider the unique issues rural areas face with an emphasis on local infrastructure and community interests.

Option II Require HHSC to convene a long-term workgroup of stakeholders to develop alternatives to current Medicaid managed care models, with the goal of developing new models that balance the need to manage costs with the need to improve quality and accessibility of services.

Option III Require state agencies involved in administering the Medicaid managed care program to engage in a coordinated effort to reduce administrative complexity for MCOs, providers and patients, including:

A. Improving the timeliness and ease of obtaining prior authorizations;

B. Implementing standard forms for all MCOs, PCCM and traditional fee for service processes, including referrals, credentialing and claims; and

C. Evaluating administrative requirements, reports, deliverables, and other requirements on MCOs and eliminating unnecessary requirements.

Option IV Improve enforcement of prompt pay contract requirements to ensure that Medicaid managed care providers are paid on time.

Option V Streamline eligibility and enrollment for Medicaid enrollees, including guaranteeing eligibility for 12 months for all Medicaid enrollees regardless of changes in income over that period.

Option VI Improve reimbursement rates for Medicaid MCOs and providers.

Option VII Improve the state's Medicaid managed care-related data systems, including:

A. Improving the encounter data system with the long-term goal of being able to use encounter data as the basis for rate setting and plan performance assessment;

B. Developing a managed care performance system capable of supporting value purchasing, quality improvement outcomes, and risk and acuity adjustment capability;

C. Developing an interagency managed care financial performance system, which should include analysis and regular reporting on cost-effectiveness and financial performance, Medicaid contractor goals and costs, and effects of capitation rates on MCO and state savings; and

D. Implement a uniform complaint reporting and tracking system.

Option VIII Reduce the number of MCOs in each area to a maximum of two MCOs.

Option IX Require HHSC and MCOs to work with stakeholders to improve member education, including providing data on MCO performance to consumers in an easy to understand format to assist them in MCO selection.

BACKGROUND

The Texas Medicaid program currently provides health care coverage to approximately 1.7 million Texans, or about nine percent of the total population. Of that 1.7 million, approximately 437,000 are enrolled in Medicaid managed care. Texas has a substantially lower percentage of its Medicaid population in managed care (25 percent) compared to the rest of the nation (54 percent).

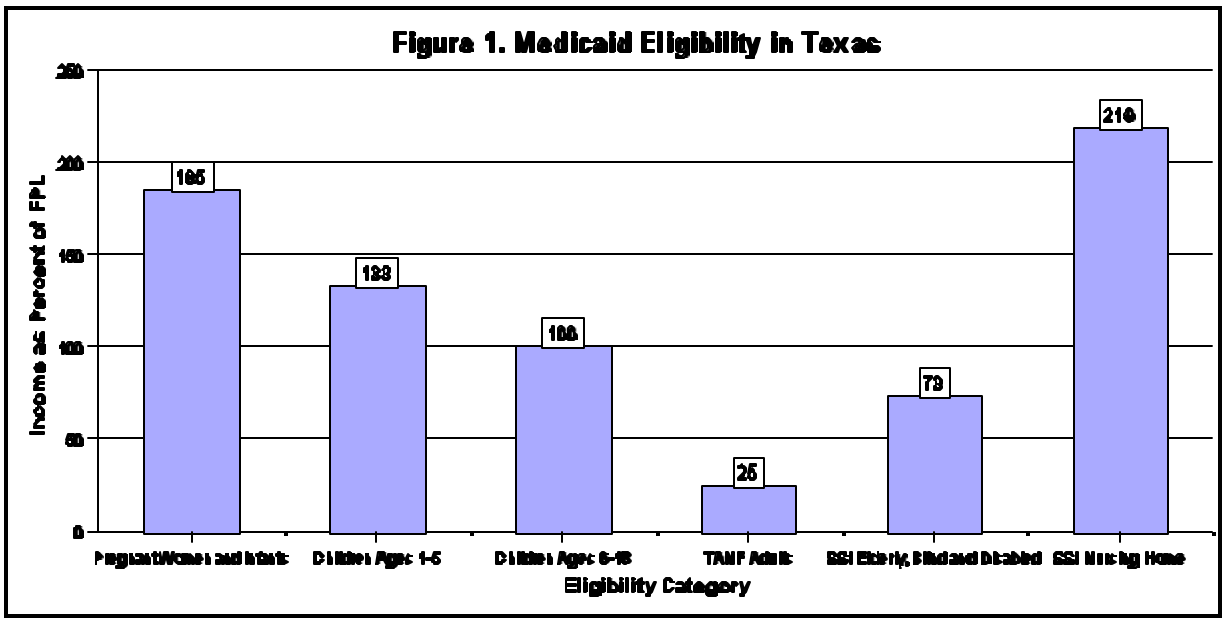
The Medicaid program is funded jointly by the state and federal government. Texas' annual Medicaid budget is approximately $9.6 billion in state and federal funds. As Figure 1 shows, Medicaid generally provides coverage for the following groups of people (this list is not inclusive of every possible eligibility category for Medicaid):

- Low-income children
- Low-income parents in families receiving cash assistance
- Low-income pregnant women
- Low-income adults and children with severe disabilities, including blindness
- Low-income elderly in need of nursing home care
- Low-income elderly in need of pharmaceuticals and other services not covered by Medicare

What is interesting to note are the groups that are not on the above list:

- Low-income adults without children and not elderly, blind or disabled
- Low-income adults with children, not receiving cash assistance and not elderly, blind or disabled

This should dismiss the common misconception that Medicaid provides coverage to everyone who is poor. The fact is, there are large gaps in the population that Medicaid covers, and those gaps primarily impact low-income non-disabled adults, both with and without children. Many of these adults (more than 300,000) would have been covered under the adult expansion that was included in the original 1995 waiver request and then subsequently removed.



In those areas where Medicaid managed care is present, not all of the above groups of recipients are required to enroll in managed care. Only the first three groups – children, parents in families receiving cash assistance, and pregnant women – are required to enroll in managed care. The other groups – such as the elderly, blind and disabled – may enroll in a managed care plan on a voluntary basis. The

exception to this arrangement is in Harris County, where a pilot project called STAR+PLUS is underway that requires these traditionally exempted groups to participate in Medicaid managed care. The STAR+PLUS program only exists in Harris County; any further expansion of this initiative to other areas would be subject to the moratorium provisions of HB 2896.

The following areas and counties currently operate under Medicaid managed care:

AREA	COUNTIES
Southeast Texas	Chambers, Jefferson, Liberty, Hardin, Orange
Travis	Travis, Burnet, Blanco, Hays, Caldwell, Bastrop, Lee, Williamson
Bexar	Bexar, Kendall, Comal, Medina, Atascosa, Wilson, Guadalupe
Tarrant	Tarrant, Wise, Denton, Parker, Hood, Johnson
Lubbock	Lubbock, Lamb, Hale, Floyd, Crosby, Garza, Lynn, Terry, Hockley
Harris	Harris, Fort Bend, Montgomery, Waller, Brazoria, Galveston
Dallas	Dallas, Ellis, Kaufman, Rockwall, Hunt, Collin, Navarro
El Paso	El Paso, Hudspeth, Culberson

For more detailed information about the Texas Medicaid program and Medicaid managed care, please consult Texas Medicaid in Perspective: Third Edition, State Medicaid Division, Texas Health and Human Services Commission, February 1999.

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CHARGE VI *Conduct active oversight of the Children's Health Insurance Program.*

LEAD MEMBER *Rep. Patricia Gray*

INTRODUCTION

On May 28, 1999**,** Senate Bill 445, which authorizes state agencies to provide comprehensive health insurance to children from low-income families, was signed into law. The bill provides children, from birth to age 18, whose net family income is at or below 200 percent of the federal poverty level ($34,100 per family of four)[1] with a choice of health plans and guarantees 12 months' continuous coverage when enrolled. Requiring family co-pays (see Appendix A) at all income levels, it establishes a benefit package (see Appendix B) and makes the Texas Health and Human Services Commission (HHSC) responsible for overseeing the program. Prior to that, in July 1998, Texas implemented Phase I of the Children's Health Insurance Program (CHIP). It expanded Medicaid by making teens ages 15-18 years old, with family incomes under 100 percent of the federal poverty level, eligible for benefits.

Phase II of CHIP began on April 3, 2000 when Birch & Davis Health Management Corporation (operating under "TexCare Partnership"), the program's administrative contractor, began enrollment and eligibility determination, with actual CHIP coverage effective May 1, 2000. The program's launch was covered by extensive media attention and TexCare Partnership planned statewide outreach initiatives to create awareness and educate Texans about CHIP's services (see Appendix C). Currently, seven contracts have been procured: administrative, media, HMOs, exclusive provider organization (EPO), dental, health plan quality assurance, and 50 community based organizations (CBOs). (see Appendix D)

Application Information

To apply, a CHIP potential enrollee usually either submits a written application by mail or web site, applies through the hotline, or requests an application over the phone. (see Appendix E)

Total Application Contacts Via Mail or Phone (families, not children)[2]		**238,832**
Application Contacts Via Phone	163,773	
Application Contacts Via Mail	75,059	

Eligibility Information

A tentative eligibility determination is made when enough application information is received to determine whether the child is eligible for CHIP, Medicaid, or Texas Healthy Kids Corporation (THKC). Required information includes the child's name, date of birth, citizenship status, insurance status, family income, family size, and family expenses. The determination may be made pending receipt of a signed application or verifications.

When a CHIP-eligible child is actually enrolled and ready to begin receiving services, that child is deleted from the total of CHIP eligible children. To determine the total number of children who have been determined eligible for CHIP since the start of the program (including those currently enrolled), add the "Total CHIP Children" category in this section to the "Estimated Number of Children Currently Enrolled in CHIP" category found in the next section.

Total Children - Tentative Eligibility Determination[3]		**122,001**
Total Potential Medicaid Eligible Children	61,962	
Total CHIP Children	45,463	
Total THKC Referrals	14,576	

Total Potential Medicaid Eligible Children[4]		**61,962**
DHS Referrals (Passed Assets Test)	37,655	
Potentially Medicaid Eligible Children Awaiting Assets Test	24,307	

TexCare Partnership will refer the child to DHS if it determines, based on income, assets, family size, citizenship, and family expenses, that the child may be eligible for Medicaid. If the referral is made, TexCare Partnership may not act until DHS either determines the child eligible for Medicaid or CHIP.

Total CHIP Children[5]	**45,463**
Total CHIP Children Based on Income, Expenses and Family Size	42,226
Total CHIP Children Based on Denial of Medicaid Due to Assets	3,237

Enrollment Information

This number represents the children who are enrolled in CHIP and receiving services and an estimate of those who have completed the enrollment process. The figure is based on the number of enrollment forms that have been received and an assumption of an average of two children per family. (see Appendix F for enrollment by county).

Estimated Number of Children Enrolled in CHIP[6]	**100,033**
Actual number of children receiving services	83,538
Estimated number of enrollees not yet receiving services	16,495

Program Performance

CHIP has had strong enrollment numbers during its first six months. The enrollment goal for the program is 428,000 children enrolled by September 1, 2001. That translates to an average increase of 29,000 enrollees a month.

As of the end of the sixth months of operation, Texas' CHIP program has enrolled 20.9% of the target population of 478,000 or 100,033 children who previously were uninsured as defined by SB 445, 76th Texas Legislature. The following states have been selected for purposes of comparison because their underlying Medicaid income eligibility standards are similar to Texas' and because their demographics

in many ways are comparable to those of Texas.[7]

Six months after beginning operations, the percentage of the target population enrolled was:[8]

- 9.15% in CA
- 9.00% in FL
- 7.24% in MI
- 16.75% in NY

To achieve Texas' level of enrollment as a percentage of the target population, it took:[9]

- CA 11 months
- FL 13 months
- MI 13 months
- NY 8 months

During that same period, 4,767 Texas children were enrolled in Medicaid, entering through the TexCare Partnership/DHS eligibility process.[10]

Even though Texas' enrollment rate during the first six months has outstripped other states, the initial enrollment has not been consistent with the original projections. However, it is estimated that the projections will be achieved at a different rate over the same period.

The staff at CHIP theorize that there are several reasons for the discrepancy. First, the number of incomplete applications was unanticipated, even after focus group testing. Failure to sign and lack of income verification were the greatest causes of delay. These omissions result in delays in making an eligibility determination and full enrollment.

Second, there were many people who began the application process and then neglected to follow

through, despite receiving prompts in the form of follow-up letters or phone calls. This appears to be a reflection of the challenge of selling families on the need for children's health insurance. The fact that 75% of CHIP enrolled children come from families with income equivalent to 150% FPL or less suggests that the program faces a stiffer test in marketing to families at income levels where their financial obligation increases from the annual enrollment fee of $15, applicable to families between 100% and 150%, to $15 or $18 per month in the case of families between 150% and 185% and 186% and 200% respectively.[11]

Third, initial outreach expenditures were constrained by the federal and state statutory requirements limiting administrative outlays for the program which could be matched with federal dollars. As staff has gained experience with the program, they have been able to expand outreach efforts, including devoting additional funds, to levels which will more fully support the effort to meet the original projections.[12]

Finally, the original program design envisioned continuous, ongoing enrollment of children into the program. However, when it came time to procure health plan and administrative services vendors, the vendor community made it clear that that approach would entail major changes in their existing information systems and business processes, adding significantly to program costs. As a result, the program design was modified to be consistent with current private market practices of enrolling individuals up to a cutoff date each month effective the following month. Any enrollments occurring after that cutoff date are effective the next month. While this method does not effect the total number of children enrolled, it does slow its rate.[13]

Program Management

One of the challenges confronting the program in the early months had been managing the program's initial outreach success. With 22,000 application contacts, including more than 151,000 telephone contacts, the call center operation at times had been stretched to its limits, resulting in a lower level of responsiveness than desired. This challenge is magnified by the difficulty of maintaining call center

staffing in the tough Austin area labor market. In response, HHSC acted to institute a three-pronged strategy:[14]

- Immediate resolution of consumer-specific complaints
- Consultation with CBOs, advocates, contractors
- Identification and resolution of systems' shortcomings

The action plan implemented by the contractor at the direction of HHSC and under the oversight of the TDH CHIP Bureau included: the hiring of additional call center staff; introduction of a system for triaging calls to specialized groups of staff; enhancements to the call center's automation to improve efficiency; evaluation of the clarity and effectiveness of letters, forms, and other written material that is sent to applicant families; and improvement of call center contractor/community-based organizations' (CBOs) communication.[15]

The second early challenge to program management came with the decision by the Texas Healthy Kids Corporation Board late in June, not to execute a contract under which THKC would have provided management services to the program, in effect managing the bulk of day-to-day program operations on behalf of the state.[16]

In anticipation of that decision, HHSC had begun planning for the TDH CHIP Bureau to continue to manage CHIP vendor contracts at HHSC direction. The state had proceeded according to the plan in enhancing staffing in the regions and in central offices using existing FTEs. Hiring has begun on a incremental basis to ensure that at no time is the program overstaffed. The total number of projected CHIP FTEs at HHSC and TDH is 30.[17]

Outreach

As indicated earlier, outreach efforts are expanding as staff gains experience with the program. The focus continues to be on community-based outreach efforts such as:

- # Back-to-school activities underway across Texas, including as many as four million fliers going home with Texas school children.
- # Telethon planning underway in several communities
- # Applicant contact information being shared with contracted community-based organizations (CBOs) to conduct local follow-up on incomplete applications.[18]

The full media flight began in August and is running through September. HHSC has formed a TexCare Partnership Corporate Support Committee to design and carry out a targeted campaign to secure backing of the Partnership by corporate Texas. This will include the formation of Local Corporate Support Committees in communities across the state.[19]

Substantial new outreach spending of $4 million will be added to the $7 million already earmarked for 00-01. These new funds will be devoted to enhanced media buys, both statewide and locally developed, including additional Spanish-language radio in the Valley, providing additional funding to contracted CBOs for local application assistance and informing activities, and revision of printed materials based on input from CBOs.[20]

TIMELINE

August 1997	Congress enacted the Balanced Budget Act, which authorized the Title XXI Children's Health Insurance Program (CHIP).
Fall 1997	Speaker Laney charged the House Committee on Public Health to study the provisions of the Balanced Budget Act that relate to children's health.
October 1997	The House Committee on Public Health met jointly with the House Committee on Appropriations regarding the CHIP charge. The hospital districts presented a proposal to use hospital district funds to finance the state's matching portion under the CHIP program.
December 1997	Speaker James E. "Pete" Laney sent Chairman Berlanga a letter, which requested that the House Committee on Public Health review all options available to Texas under the new Title XXI CHIP program and give specific policy direction as the plan is developed.
January 1998	The House Committee on Public Health met jointly with the House Committee on Appropriations regarding the CHIP charge. The committees further considered the hospital district proposal to use hospital district funds to finance the state's matching portion under the CHIP program.
January 1998	Attorney General Morales announced the tobacco settlement which designated $151 million to fund the first year of the CHIP program.
March 1998	Chairman Berlanga resigned as a member of the Texas Legislature.

March 1998	Lt. Governor Bob Bullock appointed the Senate Interim Committee on Children's Health Insurance to study the relationship between the provisions of the federal Balanced Budget Act of 1997 and the Texas health care infrastructure, and to provide oversight for the efforts of the state health and human services agencies to develop a state children's health insurance program, which is chaired by Sen. Mike Moncrief. Other members of the committee include Senators Bill Ratliff and Eliot Shapleigh.
March 1998	Under Gov. George W. Bush's signature, Texas submits Phase I of the CHIP program in order to secure the state's allotment of funds for the first year of the program. Phase I accelerates the phase-in of teens (14-18 year olds) into the Medicaid program (these children would have become eligible for Medicaid under other existing federal law).
May 1998	Speaker Laney named Representative Jaime Capelo to serve as a member of the House Committee on Public Health and appointed Representative John Hirschi to serve as Chair of the House Committee on Public Health for the duration of the interim.
May 1998	Joint committee hearing of the House Committee on Public Health, House Committee on Appropriations and the Senate Interim Committee on CHIP regarding eligibility determination and enrollment and outreach efforts.
June 1998	Joint committee hearing of the House Committee on Public Health, the House Committee on Appropriations, and Senate Interim Committee on CHIP regarding the design of a benefits package relating to CHIP.

July 1998	Joint committee hearing of the House Committee on Public Health, the House Committee on Appropriations and the Senate Interim Committee on CHIP regarding the administrative structure relating to CHIP.
August 1998	Joint committee hearing of the House Committee on Public Health, the House Committee on Appropriations, and the Senate Interim Committee on CHIP regarding the costs associated with implementation of CHIP.
August 1998	Speaker Laney sent a letter to Chairman Hirschi extending the date of submission for the interim CHIP report to December 1, 1998.
November 1998	Joint committee hearing of the House Committee on Public Health, House Appropriations Committee and Senate Interim Committee on CHIP to have final discussions and consider recommendations regarding the development and implementation of Phase II of the CHIP program.
May 1999	SB 445, authored by Sen. Mike Moncrief, was signed by Governor George Bush. Relating to a child health plan for certain low-income children, it amended Subtitle C, Title 2 of the Health and Safety Code by adding Chapters 62 and 63. It became effective on August 30, 1999.
June 1999	Title XXI state plan amendment was submitted to HCFA. It was released for public comment of draft RFPs for comprehensive administrative services, media/marketing services, and health plans. Began initial set of focus groups to test outreach themes, outreach approaches, application design, and attitudes toward health insurance. Completed work on initial draft of joint application.

July 1999 — HHSC made revisions based on public comment of the draft RFPs for comprehensive administrative services, media/marketing services, and health plans. Released final RFPs for comprehensive administrative services and media/marketing services procurement. Completed initial set of focus groups to test outreach themes, outreach approaches, application design, and attitudes toward health insurance. Began inter-agency work on revisions to joint application based on focus group research.

August 1999 — Released final RFP for management services and health plans. Proposers' conference for health plans procurement was held. Public comment was taken on draft joint application. The draft RFP was released for public comment for community-based organization (CBO) outreach.

September 1999 — Proposals were due and evaluations began for administrative services, media/marketing services, management services, and health plans. Public comment ended on draft joint application; application underwent considerable revision based on public comment and inter-agency vetting. Public comment period ended on draft RFP for CBO outreach; the RFP was subsequently revised to reflect public input.

October 1999 — Contracts were tentatively awarded to:

- Sherry Matthews Advertising for media/marketing services
- Birch & Davis Health Management Corporation for comprehensive administrative services
- Texas Healthy Kids Corporation for management services covering every primary contract area except dental services

Evaluations of health plans proposals continued. Released final RFP for CBO

outreach. Regional CBO outreach proposers' conferences (8 in all) were held.

November 1999 — HCFA approved CHIP Phase II state plan amendment. Next round of focus group testing occurred with an emphasis on the draft joint application and possible TV/radio themes. Contracts for health plans tentatively awarded to:

- FirstCare
- Texas Universities Health Plan
- Americaid
- Parkland
- Cook Children's
- UTMB
- Texas Children's
- Driscoll
- Mercy
- Superior
- Valley Baptist

Released final RFPs for quality monitoring, Exclusive Provider Organization (EPO) and dental services. Proposals due for CBO outreach.

December 1999 — The joint application was finalized. Conducted regional evaluations of CBO proposals (8 different inter-agency teams evaluate proposals divided up by public health region). Contracts were executed with Sherry Matthews Advertising and Birch & Davis. A toll-free hotline was activated initially as a roll-over from the national "Insure Kids Now" hotline (until April 3, all calls to the hotline were handled through an automated voice system).

January 2000 — A third round of focus groups testing occurred with an emphasis on the draft

written material, TV and radio concepts, and branding of campaign. "TexCare Partnership" was designated as the outreach campaign's generic identity. Contracts for health plans were executed with:

- FirstCare
- Texas Universities Health Plan
- Americaid
- Parkland
- Cook Children's
- UTMB
- Texas Children's
- Driscoll

Mercy Valley Baptist withdrew from the health plan procurement. Vista/El Paso First was tentatively awarded a health plan contract. Contracts were tentatively awarded to:

- Clarendon National Insurance Company for EPO services
- Safeguard Health Enterprises for dental services

Contracts for community-based outreach were tentatively awarded to 50 CBOs; regional negotiations took place with each CBO. Superior Health Plan withdrew its HMO bid to cover El Paso area. HHSC withdrew quality monitoring procurement based on cost and indicated intent to re-issue modified RFP.

February 2000 — Initial print run of application booklets (300,000), brochures (2 million), and posters (240,000) with all materials printed in English and Spanish. THKC was authorized to begin hiring CHIP-dedicated staff and incurring costs in advance of contract execution; initial regional and Austin-based staff were hired. Birch & Davis began regional-based training of CBOs. ERS and

HHSC agreed to develop a stand-alone application for the State Kids Insurance Program (SKIP), also known as the enhanced subsidy program. Health plan contract was executed with Vista/El Paso First. CBO contracts were executed.

March 2000

TV and radio ads were produced. Revised quality monitoring RFP was released. THKC continued hiring regional and Austin-based staff and provided implementation support, particularly in areas pertaining to the CBOs and health plans. THKC, with the support of staff from several state agencies, began readiness reviews of health plans, Birch & Davis, and Sherry Matthews Advertising. Birch & Davis:

- # completed initial round of staff training
- # tested and installed CHIP automated system
- # completed call center infrastructure
- # printed enrollment materials
- # awarded subcontracts for mail-house operations, premium collections, printing, and other services.

CBOs began their community-based outreach efforts. THKC mailed application booklet to families on THKC waiting lists.

April 2000

"Kick-off" news conference events were held throughout the state. Birch & Davis began accepting and processing applications and distributing enrollment materials. With the assistance of the Office of Attorney General, application booklets were mailed to custodial parents with children who are the object of a medical support order. DHS mailed TexCare Partnership tri-fold brochure to families who are on food stamps and who have at lease one uninsured child not eligible for Medicaid. Broad-based outreach partnership with Workforce

	Commission began. THKC continued readiness reviews of health plans, completes initial reviews of Birch & Davis and Sherry Matthews Advertising. Ongoing THKC implementation support. Proposals were due and evaluations began for quality monitoring. Contract for quality monitoring services tentatively awarded to Institute of Child Health Policy, which is affiliated with the University of Florida in Gainsville. Second print-run of application booklet (500,000). SKIP application is printed and distribution to state agency benefits coordinators began. Dental services contract award to Safeguard was withdrawn and a subsequent tentative contract award was made to United Concordia Companies of Pennsylvania.
May 2000	Initial TV and radio media flights aired in 12 primary media markets. THKC completed initial readiness reviews of health plans. Ongoing THKC implementation support. Targeted CHIP application mailing to families with children who are enrolled in THKC. Print-run of 5.3 million black-and-white "mini" application booklets (around 3 million initially distributed to CBOs).
June 2000	Over 17,000 children enrolled and able to access services. Dental services began. Contract executed with United Concordia Companies. THKC Board of Directors voted and HHSC agreed not to execute the CHIP management services contract with HHSC. Telethon concept piloted in conjunction with San Antonio station KSAT (ABC affiliate).

BACKGROUND

According to Texas Health and Human Services Commission, approximately 1.4 million of Texas' 5.8 million children lack health insurance. It is estimated that 1.1 million of theses children are eligible either for Medicaid or CHIP, but the families are not aware of these services. Lower income families with children in Texas are potentially eligible for free or low cost health insurance through TexCare Partnership, an umbrella organization which provides assistance with three children's state health insurance programs: Medicaid, Children's Health Insurance Program, and Texas Healthy Kids.

The State Children's Insurance Program (SCHIP) was initiated in 1997 by Congress through the Balanced Budget Act. Title XXI of the Social Security Act (SSA) was created to expand health insurance for low-income uninsured children under 19 whose families do not qualify for Medicaid. States may expand Medicaid, create a separate program, or combine Medicaid and SCHIP for children in families with defined gross incomes of up to 200 percent of the federal poverty level ($34,100 per family of four) from birth through age 18. States that already provide coverage above 150 percent of the federal poverty level may expand coverage up to 50 percentage points higher than their current level. Like Medicaid, SCHIP requires a state match, but the federal match is at an enhanced rate, which is approximately 30% higher than the Medicaid match rate. Children who are eligible for Medicaid may not be enrolled in SCHIP. States that establish a separate program may establish eligibility based on geographic area, age, income, and resources, residency, disability status, access to other health coverage and duration of eligibility. The block grant appropriation to states is approximately $40 billion through 2007.[21] States are required to contribute money to receive the federal allotment. For every dollar spent by Texas, the federal government will match $3. Texas' source of the CHIP fund is the settlement money from lawsuits against the tobacco companies.[22]

REFERENCES

1.65 Fed. Reg., 7555 (2000).

2.TX HHSC, *Cumulative Application, Eligibility Determination, and Enrollment Activity 9-18-00,*<http://www.hhsc.state.tx.us/chip/Weekly SumRpt.pdf>

3.*See id*.

4.*See id*.

5.*See id.*

6.*See id*.

7.Cooke, Jason, Director of CHIP, HHSC, CHIP Update (Sept. 10, 00).

8.*See id*.

9.*See id*.

10.S*ee id.*

11.*See id*.

12.*See id*.

13.*See id*.

14.*See id*.

15.*See id*.

16.*See id*.

17.*See id*.

18.*See id*.

19.*See id.*

20.*See id.*

21.SCHIP; Final Allotments to States, the District of Columbia, and U.S. Territories and Commonwealths for Fiscal Year 2000, 65 Fed. Reg., 33638, (2000).

22.TexCare Partnership Application Assistance Training Program

CHIP Contractors

1. Birch & Davis Health Management Corporation - eligibility determination, health plan enrollment, and cost-sharing administration

2. Sherry Matthews Advertising - media campaign, printed materials

3. Clarendon National Insurance Company - exclusive provider organization (EPO) for counties not covered by the HMOs.

4. United Concordia Companies Incorporated - dental indemnity coverage

5. Institute for Child Health Policy - health plan quality assurance

6. 50 Community Based Organizations (CBOs) - see following document

7. Health Maintenance Organizations - see following document

ACKNOWLEDGMENTS

The House Committee on Public Health appreciates the opportunity provided by Speaker James E. "Pete" Laney to study and provide policy options to the 77th Legislature regarding public health issues that affect the lives of so many Texans. We also appreciate greatly the leadership and sentiments of all who devoted their time and expertise to preparing this interim report.

The committee would like to thank Caton Fenz, Legislative Director for Rep. Garnet Coleman, who was instrumental in the development of the charity care and Medicaid managed care reports; Brent Biggs, Legislative Aide for Rep. Glen Maxey, who was instrumental in the development of the telemedicine and internet medicine report; Anjali Chudasama, Public Policy Research Assistant for the Public Health Committee, who was instrumental in the development of the EMS and telemedicine and internet medicine reports; Tam Le, Public Policy Research Assistant for the Public Health Committee, who was instrumental in the development of the CHIP report; and Zoe Taylor, Legislative Director for Rep. Patricia Gray.

Our success reflects the impressive cooperation and dedication of our extended team of committee members, legislative staff, including staff members from the Speaker's office, the Legislative Budget Board and the House Appropriations Committee, state agency representatives, public health organizations, and many interested parties.

We are grateful for the support and guidance provided by Texas state agencies, including Don Gilbert, Commissioner, Health and Human Services Commission; Reyn Archer, MD, Commissioner, Texas Department of Health; Linda Wertz, State Medicaid Director; Jason Cooke, State CHIP Director; Karen Hale, Commissioner, Texas Department of Mental Health and Mental Retardation; Shelia Beckett, Executive Director, Employees Retirement System; Charles Dunlap, Executive Director, Teacher Retirement System of Texas; and Alan Hightower, Texas Department of Criminal Justice.

In addition to those who testified, the following state agencies, organizations and interested parties

submitted recommendations to the committee regarding our interim charges: the Texas Academy of Family Physicians; the Texas Department of Health; Seton Healthcare Network; the Texas Conference of Catholic Health Facilities; Americaid Community Care; Central Texas Pediatric Physician Alliance; the Texas State Employees Union; The North Texas Affiliated Medical Group-Department of Obstetrics and Gynecology; the Texas Medical Association; Life Ambulance Service, Inc.; Midwestern University-College of Pharmacy; the Texas Hospital Association; the Lone Star Medical Association; the Center for Public Policy Priorities; the Texas Speech-Language-Hearing Association; the National Council of La Raza; Providence Healthcare Network; Hillcrest Baptist Medical Center; the Texas Association of Community Health Centers, Inc.; DePelchin Children's Center; United Way; Children's Hospital and Related Institutions of Texas (CHARIOT); the Disability Policy Consortium; the Disease Management Association of America; the Healthcare Computer Corporation; Texas Tech University Health Sciences Center; Coalition for Nurses in Advanced Practice; the eHealthcare Association; and the Health Internet Ethics Association.

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