# Preferred Drug List Annual Report
## Fiscal Year 2006

**Prepared by the Texas Health and Human Services Commission**

**August 2007**

# TABLE OF CONTENTS

# Preferred Drug List Annual Report

## Executive Summary

In recent years, prescription drug costs have contributed in a major way to the growth of state Medicaid expenditures with increases averaging 15 to 20 percent per year from 2000 through 2003, and approximately 11 percent from 2004 to 2005. In response to this rapid growth in prescription drug expenditures, the 78th Legislature directed the Texas Health and Human Services Commission (HHSC) in 2003 to implement a Preferred Drug List (PDL) for the Medicaid Program and the Children's Health Insurance Program (CHIP).

A PDL controls spending growth by increasing the use of preferred drugs, which are selected prescription drugs that are safe, clinically efficacious, and cost-effective compared to other similar drugs on the market. Non-preferred drugs require prior authorization (PA), but are still available through the Medicaid Program. With a PDL, Medicaid clients have access to all of the drugs that Medicaid is required to cover under federal law, including those covered before the PDL was established.

The first phase of the Medicaid PDL, representing 15 therapeutic drug classes, was implemented on February 23, 2004. HHSC added drug classes to the PDL periodically during fiscal years 2004 and 2005, and the current PDL now consists of 56 drug classes. These 56 drug classes represent approximately 66 percent of all Medicaid pharmacy expenditures, which totaled $1.9 billion in fiscal year 2006.

Government Code, Chapter 531, Subchapter B, Section 531.070, requires HHSC to provide a written report on the PDL program to the Legislature and the Governor each year. HHSC has included the following information in the 2006 PDL Annual Report.

- background information on preferred drug lists;
- the Medicaid PDL process;
- the PDL process for generic drugs;
- strategy for development of the CHIP PDL;
- PDL program benefit proposals;
- the cost of administering the PDL,
- savings from the PDL in 2006;
- statistical information related to the PA process and the number of approvals granted and denied in fiscal year 2006; and
- impact from the implementation of Medicare Rx.

The following is a brief summary of key sections discussed in detail in the annual report for fiscal year 2006.

## The PDL Process

The PDL process generally continues to operate as it has in previous years. One recent enhancement is that the PDL is now available to prescribing practitioners and pharmacists through the Epocrates drug information system. Epocrates is a web-based tool that provides instant access to information on the drugs covered on the Texas Medicaid formulary and PDL. The formulary information in Epocrates can also be downloaded to a handheld device.

## Cost of Administering the PDL

Costs for PDL administration include a contract to assist the state in supplemental rebate negotiations with drug manufacturers and a contract to provide PA services. Administrative costs for PDL related services provided under the two contracts totaled $4.31 million in fiscal year 2006. In addition to the costs of the two contracts, state staff time and resources have been provided within HHSC's existing budget.

## Savings from the PDL in 2006

HHSC estimates the PDL has resulted in savings of approximately $109 million general revenue in fiscal year 2006 on a cash basis. PDL savings for the 2006-07 biennium are expected to be approximately $220 million in general revenue.

## PA Process and Statistics

PAs include both automated PAs and PAs requested through the PA call center. The automated process, Smart PA, uses a computer system with patient information on file from paid Medicaid pharmacy and medical claims to determine if a patient's medical history indicates that a PA should be approved. If the claims history does not demonstrate that a patient meets the PA criteria, the prescriber or his representative must request a PA through the call center.

During fiscal year 2006, monthly PDL PA requests varied from a low of 38,957 to a high of 72,453. PA requests through the call center peaked in August 2006 after HHSC implemented significant changes to the PDL in mid-July 2006. As prescribers became familiar with the changes to the PDL and adjusted prescribing patterns, requests for PAs again declined. Since the implementation of the Medicaid PDL, denied PA requests have been below 10 percent each month.

## Impact of Medicare Rx on the Texas Medicaid PDL

Effective January 1, 2006, approximately 320,000 to 340,000 Medicaid recipients, who are also eligible for Medicare, became eligible for drug coverage through the Medicare prescription drug program, Medicare Rx. These dual-eligible recipients no longer receive prescription drug

coverage under Texas Medicaid's Vendor Drug Program, except for a very limited number of drugs excluded from the Medicare Rx program. HHSC estimates that drug expenditures were reduced by $489.9 million (all funds) in calendar year 2006 as a result of the loss of Medicaid drug coverage of this client population.

While total drugs expenditures in the Medicaid Program decreased by 20 percent from fiscal year 2005 to fiscal year 2006, the PDL savings as a percent of total expenditures actually increased from 9.16 percent in 2005 to 14.34 percent in fiscal year 2006 on a cash basis.

## Introduction

House Bill (H.B.) 2292, 78th Legislature, Regular Session, 2003, directed the Texas Health and Human Services Commission (HHSC) to implement Preferred Drug Lists (PDLs) for Medicaid and the Children's Health Insurance Program (CHIP) by March 1, 2004.

Government Code, Chapter 531, Subchapter B, Section 531.070, requires that HHSC provide a written report on the PDL program to the Legislature and the Governor each year. The report is to include the following.

- the cost of administering the PDLs;
- an analysis of the utilization trends for medical services provided by the state and any correlation to the PDLs;
- an analysis of the effect on health outcomes and results for recipients;
- statistical information related to the number of prior approvals granted or denied; and
- an analysis of the impact of the Medicare prescription drug program, Medicare Rx, on the PDL.

The Medicare Rx program became effective January 1, 2006. Information concerning the impact of Medicare Rx for the eight months it was in place during fiscal year 2006, is included in this report.

While H.B. 2292 required the implementation of a PDL in both Medicaid and CHIP, HHSC implemented the Medicaid PDL first because the opportunity for savings to the state is much larger in the Medicaid program. CHIP total drug expenditures for fiscal year 2005 totaled $80.5 million, while the total drug expenditures in the Medicaid prescription drug program exceeded $2.4 billion. The result is a potential for much larger supplemental rebates in the Medicaid program than in the CHIP rebate program.

The first phase of the Medicaid PDL, representing 15 therapeutic drug classes, was implemented on February 23, 2004. HHSC added drug classes to the PDL periodically during fiscal years 2004 and 2005. The PDL currently consists of 56 drug classes. These 56 drug classes represent approximately 66 percent of all Medicaid pharmacy expenditures, which totaled $1.9 billion in fiscal year 2006.

HHSC has included the following information in this report.

- background information on preferred drug lists and the H.B. 2292 PDL requirements;
- the Medicaid PDL process;
- the PDL process for generic drugs;
- CHIP PDL;
- PDL program benefit proposals;
- the cost of administering the PDL;
- savings from the PDL in 2006;
- statistical information related to the prior authorization (PA) process and the number of approvals granted and denied in fiscal year 2006; and
- impact from the implementation of Medicare Rx.

The fiscal year 2005 annual report included an initial analysis of the effect of the PDL on health outcomes, and additional information on health outcomes will be included in the next annual report.

## Background Information on the PDL and H.B. 2292 Requirements

### What is a Preferred Drug List?

A PDL is a tool used by many states to control growing Medicaid drug costs while also ensuring that program recipients are able to obtain medically necessary medicines.

The Federal Omnibus Budget and Reconciliation Act of 1990 (OBRA 90) requires that state Medicaid outpatient drug programs cover all products for which a manufacturer has signed a Medicaid rebate agreement with the federal government. As a result of this requirement, state Medicaid outpatient drug programs cover a broad array of drugs and drug classes.

Prescription drug costs have been among the fastest growing elements of state Medicaid budgets in recent years with drug spending increases averaging between 15 to 20 percent per year between 2000 and 2003, and around 11 percent per year in 2004 and 2005. To help curb growing drug costs, many states have developed and implemented PDLs.

With a PDL, Medicaid clients have access to all of the drugs that Medicaid is required to cover under federal law, including those covered before the PDL was established. The PDL controls spending growth by increasing the use of *preferred drugs* – selected prescription drugs that are safe, clinically effective, and cost-effective compared to other drugs in the same therapeutic class on the market. Non-preferred drugs, which are drugs reviewed but not selected to be on the PDL, require prior authorization (PA). Unless the Texas Medicaid paid claims database contains information that indicates a patient meets the state's PA criteria, a physician's office must call to obtain prior approval before a non-preferred drug can be reimbursed. By containing drug costs, the PDL will help to preserve Medicaid's ability to meet clients' increasing prescription drug needs as well as other health care needs.

### Overview of H.B. 2292 PDL Requirements

States have taken different approaches to developing PDLs based on federal and state law. In Texas, H.B. 2292 provided direction to HHSC on how to implement PDLs for Medicaid and CHIP. H.B. 2292 required that HHSC implement PDLs for Medicaid and CHIP, and allowed for the adoption of PDLs for other state programs.

Below is a summary of the major PDL provisions from H.B. 2292.

- The PDL may contain only drugs for which the drug manufacturer or labeler has reached a supplemental rebate agreement or program benefit agreement with HHSC.
- HHSC or its designated contractor is to negotiate with manufacturers and labelers of both brand name and generic products for supplemental rebates.
- A governor-appointed Pharmaceutical and Therapeutics Committee (P&T) consisting of physicians and pharmacists makes recommendations to HHSC about which drugs to place on the PDL based on clinical efficacy, safety, cost-effectiveness, and other program benefits.
- HHSC decides which drugs go on the PDL based on the recommendations of the P&T Committee, safety, clinical efficacy, the net price of competing drugs to the state, and program benefit offers.
- HHSC must protect the confidentiality of drug pricing information.
- The physician or other prescriber must obtain PA for non-preferred drugs, which are drugs reviewed by the P&T Committee but not selected to be on the PDL.

## Medicaid PDL Process

### Texas Pharmaceutical and Therapeutics (P&T) Committee

Governor Rick Perry appointed six physicians and five pharmacists to the Texas P&T Committee in November 2003. Committee members were reappointed in March 2006 for a term of service through August 2007. The P&T Committee provides recommendations to HHSC on which drugs to place on the PDL based on clinical efficacy, safety and cost-effectiveness. The 11 committee members represent diverse specialties, geographic areas, and practice settings.

*P&T Committee Members*

- Harris Hauser, M.D., Chairman, Psychiatrist and Neurologist
- Donna Rogers, R.Ph., Vice Chair, Hospital Pharmacy Services Consultant
- Richard Adams, M.D., Developmental Pediatrician
- Anthony Busti, Pharm.D., Assistant Professor at Texas Tech University Health Sciences Center School of Pharmacy
- Melbert "Bob" Hillert, M.D., Cardiologist
- J.C. Jackson, R.Ph, Retail Pharmacy Manager, Kelsey-Seybold Clinic
- David King, R.Ph, Community Pharmacy.
- Julie Lewis-Crozier, R.Ph, Lead Consultant Pharmacist at PharMerica (resigned effective April 2007, position currently vacant)
- Valerie Robinson, M.D., Pediatric Psychiatrist
- Guadalupe Zamora, M.D., Family Practitioner
- Mario R. Anzaldua, M.D., Family Practitioner (appointed March 30, 2006)

H.B. 2292 required that the P&T Committee meet monthly for the first six months after creation of the committee and at least quarterly thereafter. The committee met five times in fiscal year 2006.

**PDL and PA Contractors**

HHSC has contracted with external vendors for both PDL related services and PA services through a competitive bidding process as allowed by H.B. 2292.

HHSC has a contract with Provider Synergies, LLC, to negotiate rebates on behalf of the state, to provide information to the P&T Committee on the clinical efficacy, safety, and cost-effectiveness of products in each drug class, and to assist HHSC and the P&T Committee with PDL development and maintenance, including PDL communications to stakeholders and identification of drug classes the state may want to include on the PDL. HHSC's contract with Provider Synergies is a fixed-fee contract through August 31, 2009.

HHSC has also contracted with Affiliated Computer Systems, Inc. (ACS)/Heritage Information Systems (ACS Heritage) for the provision of PA services. ACS/Heritage provides both a PA call center with a toll free number and an automated PA system called Smart PA. The contract with ACS/Heritage is a transaction-based contract through August 31, 2008.

**The PDL Process**

The P&T Committee reviews drugs for the PDL by pharmacologically determined drug classes. HHSC determines which drug classes will be reviewed at each P&T Committee meeting and notifies the PDL contractor. The contractor then solicits rebate offers from drug manufacturers and labelers on HHSC's behalf. After receipt and review of all rebate offers, the PDL contractor provides HHSC and the P&T Committee with information on each product in each drug class, as it relates to clinical efficacy, safety, and cost effectiveness. Additionally, drug manufacturers, labelers, and other interested parties may submit written evidence to the P&T Committee supporting the inclusion or exclusion of a drug on the PDL in advance of the meeting.

The P&T Committee accepts public testimony at each meeting on the drug products being reviewed at that meeting. Some committee meetings have had testimony from as many as 80 individuals. Following the public testimony, the PDL contractor provides the P&T Committee and the audience a verbal summary of the clinical and safety information provided to the P&T Committee in advance of the meeting.

Since HHSC and the P&T Committee must protect confidential pricing information, the P&T Committee then adjourns to a working session to decide which products in each drug class it will recommend be placed on the PDL. The committee takes into account three factors in its deliberations – the clinical efficacy, safety, and cost-effectiveness of each drug product. The P&T Committee then returns to the public meeting and announces its recommendations for each drug class.

Following the P&T Committee meeting, HHSC reviews the committee's recommendations and makes a final decision as to which drugs will be included on the PDL. HHSC posts this decision on its website, followed by the posting of the updated Medicaid PDL with PA criteria. HHSC must provide a minimum of 30 days public notice before implementing new PDL PA requirements.

HHSC notifies stakeholders via e-mail about P&T Committee meetings and changes to the PDL or PA criteria. A hard copy of the PDL is available to provider physicians and pharmacies upon request. The PDL is also now available to prescribing practioners and pharmacists through the Epocrates drug information system. Epocrates Rx is a web-based tool that provides instant access to information on the drugs covered on the Texas Medicaid formulary and PDL. The formulary information in Epocrates can also be downloaded to a Palm or Pocket PC handheld device.

As required in H.B. 2292, the P&T Committee reviews PDL drug classes at least once a year to the extent feasible. The committee reviewed 56 drug classes during fiscal year 2006 for the Medicaid PDL. Drug products that are new to the market place are not subject to prior approval until the P&T Committee has reviewed them. New products are reviewed as soon as possible once they become available in the market.

**The PDL Update Process**

In response to feedback from providers, HHSC modified the PDL update process to only implement major updates to the Medicaid PDL two times per year in 2005. Major changes to the PDL occurred in January 2005 and July 2005. In 2006, HHSC only implemented major PDL changes one time in July 2006. Based on input from the P&T Committee, HHSC plans to return to making PDL updates twice a year. HHSC may make other minimal changes to the PDL throughout the year for products new to the marketplace or in the event of new clinical or safety information.

**Prior Authorization Process**

H.B. 2292 required that the prescribing physician or other prescribing practitioner obtain PA for non-preferred drugs before the drug can be dispensed. Non-preferred drugs are drugs that have been reviewed by the P&T Committee, but were not selected for placement on the PDL. PDL-related PA is *not* required for drugs in drug classes that the P&T Committee has not reviewed. These drugs continue to be available to Medicaid clients according to HHSC Vendor Drug Program policies.

HHSC contracted with ACS-Heritage to provide PA services. ACS/Heritage provides PA services both through a PA call center with a toll-free number and through an automated PA system called Smart PA.

When a pharmacy submits a Medicaid claim for a drug that is subject to PA, the Smart PA system checks the patient's available medical and prescription drug claim histories to determine whether the information in the system indicates that the patient's condition meets the state's

established criteria for approval. If the patient's medical and prescription claim histories demonstrate the criteria are met, the pharmacy claim will be approved in seconds at the pharmacy point of sale and no PA phone call is required. If the patient's claims histories do not demonstrate that the patient meets the criteria, the pharmacy will receive a message indicating that the prescriber needs to call the Texas PA call center at 1-877-PA-TEXAS. HHSC allows the prescriber or a representative, such as a staff nurse, to request a PA.

In compliance with federal law, ACS-Heritage must respond to PA requests within 24 hours, and a 72-hour supply of a drug must be provided in an emergency or if a response to a PA request cannot be provided within 24 hours. The call center is open Monday through Friday, from 7:30 a.m. to 6:30 p.m., Central Time. If a patient goes to the pharmacy to pick up a non-preferred drug outside of call center hours and a PA call is required, the pharmacy can provide a 72-hour emergency supply of the drug to give the physician's office time to request the PA.

Approved requests for PA are valid for one year. If the call center denies the PA request, the prescriber can either prescribe a preferred product or request reconsideration. If the prescriber's request for reconsideration is denied, ACS-Heritage sends the client a letter notifying them of their right to appeal that decision.

**PA Criteria**

Each public or private insurance program that has a drug PA program establishes PA criteria that are used to determine whether a PA request is approved or denied. Some states have fairly specific Medicaid PDL PA criteria, while others have more general criteria. The PA criteria provide physicians and other providers with information when writing prescriptions. For instance, if a physician knows that his Medicaid patients must try and fail on Drug A before Medicaid will pay for Drug B, the physician may prescribe Drug A first unless he knows of a clinical or safety reason why the patient cannot take Drug A, such as a drug allergy or a drug interaction with another drug the patient is already taking.

For most of the drug classes on the PDL, HHSC has established three general PA criteria: (1) therapeutic failure with a preferred drug; (2) an allergy; or (3) contraindication to preferred product(s). HHSC selected these three criteria based on other states' PDL experience and general medical practice guidelines. The PA call center approves non-preferred prescriptions if the patient meets one of these three general criteria or if the physician provides another appropriate clinical reason why the patient needed to receive a non-preferred product instead of a preferred product.

For three mental health drug classes – Atypical Antipsychotics, Selective Serotonin Reuptake Inhibitors (SSRI) Antidepressants, and Atypical Antidepressants – HHSC allows an exception to the PA requirements to maintain continuity of care. For these three drug classes, Medicaid patients who are stable on a non-preferred drug are allowed to continue receiving that drug without a PA phone call. For clients new to Medicaid or in cases where HHSC is not aware that a patient is stable on a non-preferred drug, the physician's office must call one time to receive PA for a non-preferred drug.

The HHSC Drug Utilization Review (DUR) Board, which like the P&T Committee is comprised of Texas physicians and pharmacists, has the responsibility for making recommendations to HHSC on possible changes to PDL PA criteria. HHSC has implemented PA criteria that are more specific than the general PA criteria discussed above for four drug classes and will continue the process of customizing PA criteria for other drug classes during fiscal year 2007.

## Generic PDL Strategy

H.B. 2292 required that the PDLs contain only drugs for which the drug manufacturer or labeler reaches a supplemental rebate agreement or program benefit agreement with HHSC. HHSC or its designated contractor is to negotiate with manufacturers and labelers of both brand name and generic products for supplemental rebates.

Texas is the first state to require that generic manufacturers and labelers sign supplemental rebate agreements for their drugs under the PDL program. HHSC has worked with generic manufacturers and labelers to comply with H.B. 2292, taking into account that generics may usually be, but are not always, less expensive than brand name products.

Generic drugs are different than brand name drugs in that the dispensing pharmacist, rather than the prescribing physician, decides which specific generic drug a patient receives. If a physician writes a prescription for a drug and does not specify that the patient receive the brand name product, then the pharmacist fills the prescription with a generic version of the drug that the pharmacy stocks. Pharmacy A might fill a prescription with a generic product from Generic Manufacturer C while Pharmacy B would fill the same prescription with a generic product from Generic Manufacturer D.

In a few cases, the Texas P&T Committee recommended, and HHSC concurred, that certain generic drugs should be non-preferred and require PA for clinical, safety, or cost effectiveness reasons. For all other generics, HHSC has asked that generic manufacturers and labelers offer HHSC a supplemental rebate of some value in order for their products to be classified as Premium Preferred Generics. Effective December 1, 2004, pharmacies that dispense Premium Preferred Generics receive a 50 cent increase in the pharmacy dispensing fee for those specific products.

## Children's Health Insurance Program (CHIP) PDL

H.B. 2292 required HHSC implement PDLs for both Medicaid and CHIP. HHSC requested that the P&T Committee focus initially on the Medicaid PDL, because the Medicaid PDL is expected to generate most of Texas' PDL savings. HHSC expects minimal savings from the CHIP PDL for three reasons. First, Texas' CHIP drug expenditures represent less than 5 percent of the Medicaid drug expenditures ($80.5 million for CHIP in fiscal year 2005 vs. $2.4 billion for Medicaid). Second, HHSC cannot receive the same level of rebates for CHIP drugs as it does for Medicaid drugs. Federal regulations require a drug manufacturer to include rebates paid to the CHIP program in that company's calculation of their national "best price". A manufacturer's "best price" is used to determine their federal Medicaid rebate liability for all 50 states, which effectively limits the maximum rebate available to the CHIP program at an amount not to exceed

the basic federal Medicaid rebate amount. Finally, HHSC already had a voluntary CHIP drug rebate program in place before the passage of H.B. 2292.

The first draft of a CHIP PDL was presented to the P&T Committee at the August 2004 meeting. The committee decided to defer action on the CHIP PDL until November 2004 to allow the CHIP review to coincide with the re-review of drugs on the Medicaid PDL. In November 2004, the committee again deferred action on the CHIP PDL because of concerns that different PDLs in Medicaid and CHIP could have a negative impact on children, who frequently move between the two programs. The committee also had concerns that children and adults have significantly different drug utilization patterns and needs and that a Medicaid similar PDL may not be clinically appropriate for a pediatric population.

In September 2005, HHSC decided to proceed with a mandatory CHIP rebate agreement for brand name and single source drugs in order for those drugs to be included on the CHIP formulary. To encourage all manufacturers to participate in the CHIP rebate program and to ensure that the rebate levels are at the maximum level possible, Provider Synergies conducted negotiations with manufacturers for best rebate offers for CHIP during fiscal year 2006. HHSC also worked with brand name manufacturers in an effort to ensure a comprehensive CHIP formulary and specifically worked with several key manufacturers to ensure the CHIP formulary contains products needed by CHIP recipients. At the conclusion of the negotiations, over 150 manufacturers had agreed to participate in the CHIP rebate program, but several major manufacturers as well as a number of smaller manufacturers had not agreed to participate.

In November 2006, the P&T Committee reviewed the potential composition of the CHIP formulary representing drug products from participating manufacturers as well as the list of drugs that would be excluded from the CHIP formulary. The Texas Medical Association and the Texas Pediatric Society provided written and public testimony in opposition to the CHIP closed formulary. The P&T Committee made the following recommendations to HHSC.

- The Committee is *not* in favor of recommending a closed formulary for the children in Texas covered under CHIP.
- The Committee does recommend that the following be implemented for CHIP.
  - A preferred CHIP drug status categorization of medications for those drug products for which a manufacturer has offered a rebate.
  - A prior authorization process, due to clinical issues for specific drugs.
  - An incentive process for the drugs manufactured from drug companies that have provided HHSC with a voluntary rebate.
- The Committee recommends the present formulary remain until the above or alternative directions are received from HHSC.

The Committee expressed concerns that a closed formulary would not provide an adequate selection of clinically effective and safe drugs to meet all the needs of the children in CHIP. The Committee's recommendation for development of a prior authorization program in CHIP was an effort to ensure consistency between the Medicaid and CHIP programs. Currently in Medicaid there are PA requirements and restrictions on a limited number of drugs that are specific to safety and efficacy issues regarding drug use in children. The Committee believes those same

restrictions should be implemented in CHIP. The Committee's final recommendation was that HHSC continue the current voluntary rebate program in CHIP and concurrently evaluate methods of encouraging the use of products from those manufacturers who have signed rebate agreements with HHSC.

HHSC considered the recommendations and concerns of the P&T Committee and decided to continue with the voluntary rebate program in CHIP. In order to specifically recognize the companies who offered rebates in CHIP, those products will be listed as preferred on the Epocrates web-based tool. Adoption of a closed formulary would not increase the rebate revenues in CHIP and could potentially jeopardize the health status and clinical needs of the children enrolled in CHIP. The following table shows CHIP expenditures and rebates for fiscal years 2005 and 2006.

## CHIP Rebate Program

| | FY 2005 Rebates Collected | FY 2006 Rebates Collected |
|---|---|---|
| **Rebates All Funds** | $7,174,010 | $7,169,205 |
| **State Match %** | 27.43% | 27.53% |
| **State General Revenue Dollars (Savings)** | **$1,967,831** | **$1,973,682** |
| **PDL Savings as a Percent of Total Drug Expenditures** | | |
| **CHIP Drug Expenditures** | $84,482,388 | $84,232,240 |
| **Rebates (All Funds) as % of Total Expended** | 8.49% | 8.51% |

### Program Benefit Proposals

H.B. 2292 allowed HHSC to sign a program benefit agreement with a drug manufacturer in lieu of a cash supplemental rebate agreement if the program benefit yields savings that are at least equal to the amount the manufacturer would have provided under a supplemental rebate agreement. Program benefits may include, but are not limited to, disease management, drug product donation, drug utilization control programs, and education and counseling.

In order to maintain a competitive supplemental rebate process for all drug manufacturers, HHSC requires that manufacturers who want to offer a program benefit proposal for a drug must first offer a cash supplemental rebate. The drug's net price after supplemental rebates can then be compared to competing drugs as the P&T Committee recommends, and HHSC decides which drugs to place on the PDL. If a product is placed on the PDL, then a manufacturer can work with HHSC to offer a program benefit with expenditures tied to the supplemental rebate amount offered. For instance, if a manufacturer signs a supplemental rebate agreement for $1 per unit, and Texas Medicaid pays for one million units of the drug during the supplemental rebate contract term, then the manufacturer must pay HHSC a total of $1 million either in cash,

program benefits, or a combination of the two. Five program benefit agreements with a total annual value of less than $5 million per year are currently in place.

## Cost of PDL Administration

Costs for PDL administration include both the Provider Synergies and ACS/Heritage contracts, which totaled $4.31 million (all funds) for fiscal year 2006. In addition to these contract costs, state staff time and resources have been provided within HHSC's existing budget.

HHSC's contract with Provider Synergies is a fixed-fee contract with options for additional services. From September 2005 through August 2006, Provider Synergies provided HHSC $1.32 million (all funds) in services.

The ACS/Heritage PA contract is reimbursed on a per-PA transaction basis with several options for additional services, such as targeted mail-outs to prescribers. HHSC pays $5.25 or less per PA transaction, with the cost per transaction decreasing as a higher percentage of PA requests are handled through ACS/Heritage's automated Smart PA system instead of through the PA call center. For September 2005 through August 2006, ACS/Heritage provided a total of $2.99 million (all funds) in PA services to HHSC related to the Medicaid PDL.

## PDL Savings

The fiscal note for H.B. 2292 assumed that Texas would save approximately $150 million general revenue (general revenue) in the 2004-05 biennium on an incurred basis through the implementation of the PDLs. PDL savings are generated from both supplemental rebates and from the shift in prescribing patterns toward less expensive preferred drugs.

HHSC invoices manufacturers for supplemental rebates approximately 60 days after the end of each calendar year quarter. HHSC's first supplemental rebate agreements took effect January 1, 2004. The following table reports the estimated savings to the state from the PDL and supplemental rebate program on a cash basis.

# 2006 Estimated Medicaid PDL Savings

(Estimates with Provider Synergies data through 09/2006)

| | FY 04 | FY 05 | FY 04-05 | FY 06 | FY 07 (Projected) | FY 06-07 (Projected) |
|---|---|---|---|---|---|---|
| | **PDL Savings (Cash Basis)** | **PDL Savings (Cash Basis)** | **PDL Savings (Cash Basis)** | **PDL Savings (Cash Basis)** | **PDL Savings (Cash Basis)** | **PDL Savings (Cash Basis)** |
| **Number of Rebate Quarters** | 1 | 4 | 5 | 4 | 4 | 8 |
| **Supplemental Rebates** | $13,642,998 | $120,138,102 | $133,781,100 | $145,775,370 | $120,915,738 | $266,691,108 |
| **Market Shift Savings** | 33,203,328 | 101,057,186 | 134,260,514 | 130,186,992 | 163,149,987 | 293,336,979 |
| **Total Savings** | 46,846,326 | 221,195,288 | 268,041,614 | 275,962,362 | 284,065,725 | 560,028,087 |
| **State Match %** | 39.80% | 39.18% | | 39.32% | 39.23% | |
| **State General Revenue Dollars (Savings)** | **$18,644,838** | **$86,664,314** | **$105,309,152** | **$108,508,401** | **$111,438,984** | **$219,947,385** |
| | | | **PDL Savings as a Percent of Total Drug Expenditures** | | | |
| **Estimated Medicaid Total Drug Spend** | $2,202,164,358 | $2,414,686,554 | $4,616,850,912 | $1,924,750,864 | $1,773,369,423 | $3,698,120,287 |
| **PDL Savings (all funds) as % of Total Expended** | 2.13% | 9.16% | 5.81% | 14.34% | 16.02% | 15.14% |
| | | | **PDL Savings Breakdown** | | | |
| **Supplemental Rebates** | 29.12% | 54.31% | 49.91% | 52.82% | 42.57% | 47.62% |
| **Market Shift** | 70.88% | 45.69% | 50.09% | 47.18% | 57.43% | 52.38% |

**Notes:**

PDL implementation was phased in, beginning January 2004.

Cash flow is dependent on calendar year quarterly billing and collection cycles shown below:

Rebate billings normally occur in November, March, May, and August. The first supplemental rebate billing was June 2004, for $19.4 million (all funds).

The larger rebate collections normally occur in the months of October, January, April, and July. The first supplemental rebate collections began in July 2004.

VDP actuarial estimates used.

HHSC estimates PDL savings of approximately $109 million general revenue in fiscal year 2006 and projects estimated savings to be $220 million general revenue for the 2006-07 biennium on a cash basis before administrative costs. The PDL savings for fiscal year 2006 represents 14.3 percent of the total Medicaid expenditures for prescription drugs and is projected at 15.1 percent for the 2006-07 biennium.

## Statistics on Prior Authorizations

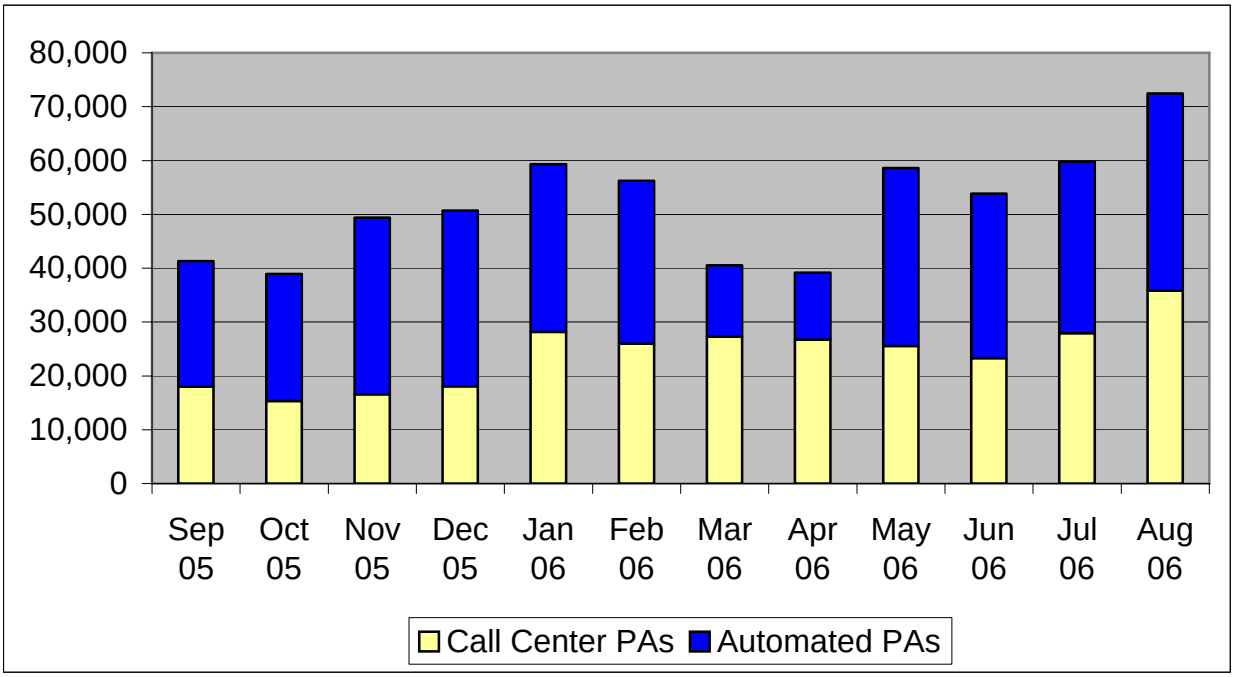
Table 1 and Chart 1 show the trend in PA transactions from September 2005 through August 2006 for non-preferred drugs. Automated PAs are approved through the Smart PA system at the pharmacy point of sale without the need for a phone call if the patient's Medicaid medical and pharmacy claims histories demonstrate the patient meets the PA criteria. If the claims history does not demonstrate the patient meets the PA criteria, then the prescriber or his representative must request a PA through the call center.

**Table 1 – Medicaid PA Transactions for September 2005 – August 2006**

| | Sep 05 | Oct 05 | Nov 05 | Dec 05 | Jan 06 | Feb 06 | Mar 06 | Apr 06 | May 06 | Jun 06 | Jul 06 | Aug 06 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Call Center PAs | 18,015 | 15,321 | 16,595 | 18,071 | 28,156 | 25,996 | 27,261 | 26,733 | 25,560 | 23,324 | 27,961 | 35,816 |
| Automated PAs | 23,280 | 23,636 | 32,780 | 32,605 | 31,153 | 30,232 | 13,298 | 12,422 | 33,066 | 30,510 | 31,856 | 36,637 |
| **Total PAs** | **41,295** | **38,957** | **49,375** | **50,676** | **59,309** | **56,228** | **40,559** | **39,155** | **58,626** | **53,834** | **59,817** | **72,453** |

Based on ACS/Heritage invoiced PAs as of December 2006.

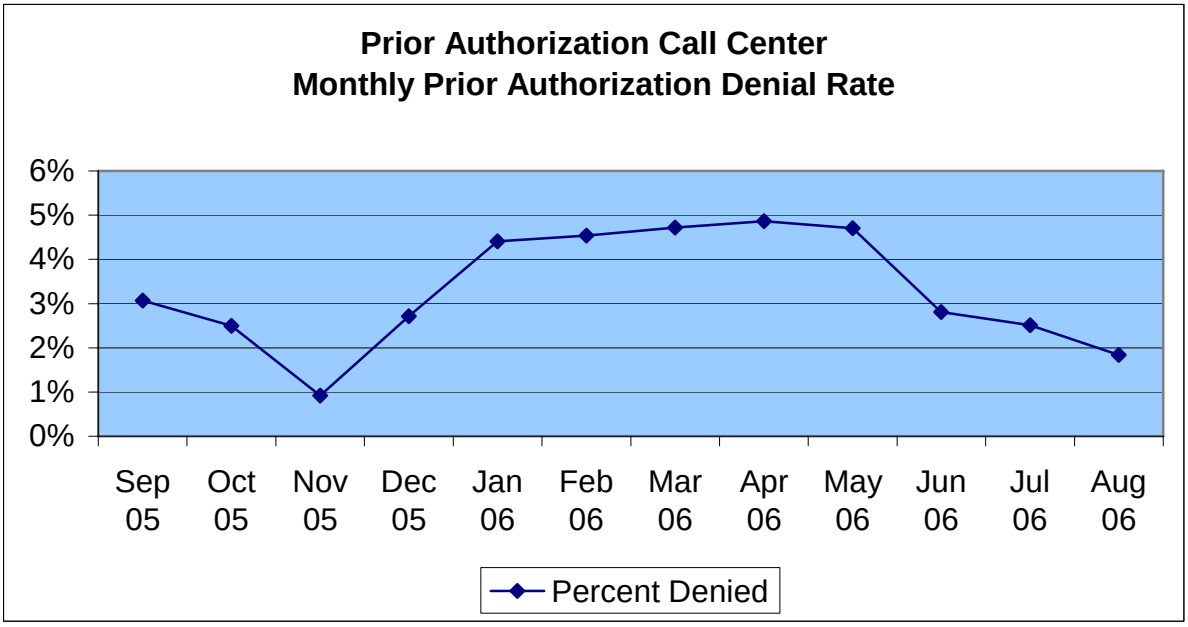
**Chart 1 - Medicaid Preferred Drug List Prior Authorization Transactions**



HHSC implemented changes to the PDL in mid-July 2006 resulting in a peak in PA requests in August 2006. As prescribers become familiar with the changes to the preferred drug list and adjusted prescribing patterns, requests for PAs typically decline.

Since the Medicaid PDL was implemented, the percent of PA requests denied by the PA call center has been below 10 percent each month. Chart 2 shows the estimated percent of PA requests for non-preferred drugs that were denied by the PA Call Center from September 2005 through August 2006.

**Chart 2 – Prior Authorization Call Center Monthly PA Denial Rate**




HHSC initially published the following three general PA criteria for most drug classes on the PDL: (1) therapeutic failure; (2) allergy; or (3) contraindication with preferred product(s). HHSC instructed the call center to approve non-preferred prescriptions if the patient met one of these three criteria, or if the prescriber provided another clinical reason why the patient needed to receive a non-preferred product instead of a preferred product.

Low call center PA denial rates since the beginning of the program are due in part to HHSC's fairly broad PA criteria. In addition, call center PA denial rates decrease as prescribers and their staff becomes more familiar with the information required to get an authorization request approved. Call center PA denial rates for fiscal year 2006 ranged from 1.8 percent to 4.9 percent and averaged 3.3 percent per month.

## Impact of Medicare Prescription Drug Benefit on the Medicaid PDL

Effective January 1, 2006, approximately 320,000 to 340,000 Medicaid recipients who are also eligible for Medicare became eligible for drug coverage through the Medicare prescription drug program, Medicare Rx. These dual-eligible recipients no longer receive prescription drug

coverage under Texas Medicaid's Vendor Drug Program, except for a very limited number of drugs excluded from the Medicare Rx program.

Since the Medicare Rx program was implemented in January 2006, it was only in effect for eight months of fiscal year 2006 and initial implementation issues delayed full federal drug coverage for some of the dual-eligible population until April 2006. In addition, the impact of Medicare Rx on drug utilization is only one of the variables that influence drug expenditures in the Medicaid program. Medicaid drug expenditures also are impacted by drug cost inflation, changes in utilization patterns for prescription drugs and variations in caseloads.

HHSC estimates that drug expenditures were reduced by $489.9 million (all funds) in calendar year 2006 as a result of the loss of Medicaid drug coverage for this client population. While total drugs expenditures in the Medicaid program decreased by approximately 20 percent from fiscal year 2005 to fiscal year 2006, the PDL savings as a percent of total expenditures actually increased from 9.16 percent in 2005 to 14.34 percent in fiscal year 2006 on a cash basis. Part of the increase in savings is due to the billing cycle for supplemental rebates. Rebates are billed based on a calendar quarter with actual receipt of payment occurring 60 to 90 days after the end of the calendar quarter. Therefore, collections for rebates billed at the end of fiscal year 2006 are not received until fiscal year 2007. However, the ratio of rebate savings to total drug expenditures does not appear to have declined as a result of the implementation of Medicare Rx as shown in the table below.

**Medicare Rx Impact on Medicaid PDL Savings**

| | **FY 05** | **FY 06** | **FY 07 (Projected)** |
|---|---|---|---|
| | **PDL Savings (Cash Basis)** | **PDL Savings (Cash Basis)** | **PDL Savings (Cash Basis)** |
| **Estimated Medicaid Total Drug Expenditures (all funds)** | $2,414,686,554 | $1,924,750,864 | $1,773,369,423 |
| **Supplemental Rebates Collected** | 120,138,102 | 145,775,370 | 120,915,738 |
| **Market Shift Savings** | 101,057,186 | 130,186,992 | 163,149,987 |
| **Total Savings** | 221,195,288 | 275,962,362 | 284,065,725 |
| **State Match %** | 39.18% | 39.32% | 39.23% |
| **State general revenue Dollars (Savings)** | **$86,664,314** | **$108,508,401** | **$111,438,984** |
| **PDL Savings Breakdown** | | | |
| **Supplemental Rebates as % of Total Expended (all funds)** | 4.97% | 7.57% | 6.82% |
| **Market Shift Savings as % of Total Expended (all funds)** | 4.19% | 6.77% | 9.20% |
| **Total PDL Savings as % of Total Expended (all funds)** | **9.16%** | **14.34%** | **16.02%** |

The Medicaid and Medicare dual-eligible population consists primarily of individuals who are aged or disabled. As a result, the impact of Medicare Rx varies across different therapeutic classes depending on their utilization by the dual-eligible population and the general Medicaid

population. The table below compares the utilization of drugs in specific therapeutic classes for the last three months of calendar year 2005 and the first three months of calendar year 2006. The table illustrates the variation in utilization changes over different therapeutic classes as a result of Medicare Rx.

**Medicare Impact on Specific Therapeutic Classes**

| Therapeutic Drug Class | | Oct/Nov/Dec 2005 | | Jan/Feb/Mar 2006 | | |
|---|---|---|---|---|---|---|
| | | Number of Rxs | Amount Paid (All Funds) | Number of Rxs | Amount Paid (All Funds) | % Change in Rxs |
| Drugs used primarily in elderly populations | Alzheimer's Agents | 80,202 | $12,144,757 | 11,067 | $1,532,899 | -86.2% |
| | Bone Resorption Suppression Agents (Osteoporosis) | 64,006 | 8,166,640 | 11,933 | 1,541,087 | -81.4% |
| | Glaucoma Agents | 49,424 | 3,828,815 | 10,571 | 794,596 | -78.6% |
| Drugs used equally in elderly and younger populations | Insulins And Related Agents (Diabetes) | 110,808 | 10,933,599 | 50,199 | 5,493,047 | -54.7% |
| | Antipsychotics, Atypical (Schizophrenia) | 225,879 | 72,489,512 | 127,714 | 43,226,794 | -43.5% |
| Drugs used primarily in younger populations | Bronchodilators, Beta Agonist (Asthma) | 309,611 | 7,339,724 | 256,484 | 6,475,967 | -17.2% |
| | Leukotriene Modifiers (Asthma) | 138,364 | 14,432,899 | 123,776 | 12,519,740 | -10.5% |
| | Stimulants And Related Agents (Attention Deficit Disorder) | 168,751 | 19,551,033 | 170,320 | 19,531,158 | 0.9% |
| | Ophthalmic Antibiotics (Eye infections) | 75,307 | $2,363,911 | 87,833 | $2,816,292 | 16.6% |

In therapeutic classes that are primarily utilized in the treatment of disease states that are more prevalent in elderly individuals, such as Alzheimer's disease, osteoporosis, and glaucoma, there was a significant decrease in the number of Medicaid prescriptions after the implementation of Medicare Rx on January 1, 2006. In drug classes that are utilized to treat conditions equally prevalent in both elderly and younger populations, such as schizophrenia and diabetes, there was approximately a 50 percent decrease in utilization. However, the utilization of drugs primarily used for the treatment of attention deficit disorder and eye infections actually increased after Medicare Rx because these conditions occur more commonly in the younger non-dual eligible population. Some of this increase also may be due to the fact that children tend to get sick more often during the winter months. Drugs used to treat asthma had a small decrease of 10-17 percent in utilization because in addition to asthma they may also be used in the treatment of chronic obstructive pulmonary disease, which occurs more commonly in the elderly population.