Preferred Drug List Annual Report

Prepared by the Texas Health and Human Services Commission

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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 for a total of 60 drug classes. These 60 drug classes represent almost 70 percent of the Medicaid pharmacy expenditures, which totaled approximately $2.4 billion in fiscal year 2005.

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 2005 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 2005.
- Statistical information related to the PA process and the number of approvals granted and denied in fiscal year 2005.
- Potential impact from the implementation of Medicare Rx.
- A basic health outcomes analysis, including an analysis of the utilization trends for certain medical services for two drug classes.

Following is a brief summary of key sections discussed in detail in the annual report for fiscal year 2005.

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 $4.4 million in fiscal year 2005. In addition to the two contracts' costs, state staff time and resources have been provided within HHSC's existing budget.

Savings from the PDL in 2005

HHSC estimates the PDL has resulted in savings of approximately $143 million general revenue for the 2004-05 biennium on an incurred basis before administrative costs. On a cash basis, HHSC estimates savings of approximately $105 million general revenue for the 2004-05 biennium. Cash savings are lower than incurred savings because several months are required to invoice and collect supplemental rebates from drug manufacturers at the end of each quarter.

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 2005, monthly PDL PA requests varied from a low of 39,155 to a high of 72,453. PA requests through the call center peaked in January and July 2005 when HHSC implemented significant changes to the PDL. 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.

Health Outcomes Analysis

In April 2006, HHSC conducted two analyses of the effect of PDL and PA policies on health outcomes for certain Medicaid clients. The studies utilized data from a group of Medicaid clients with asthma and a second group of Medicaid clients with schizophrenia or affective psychosis who were receiving certain drugs affected by PDL implementation. HHSC information on Medicaid patient health is limited to claims data; therefore staff analyzed service utilization data from Medicaid claims as a proxy for health outcomes.

Given the limited available data for analysis, implementation of PA and the PDL does not appear to have a significant negative effect on health outcomes for subjects with asthma, schizophrenia, or affective psychoses, as measured by Medicaid service utilization. HHSC recognizes, however, that there are several limitations to the analyses.

Impact of Medicare Rx on 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 will be reduced by $616.9 million in calendar year 2006 as a result of the loss of Medicaid drug coverage of this client population. The associated loss of PDL savings is estimated to total about $28.6 million (all funds) in fiscal year 2006 over eight months, and about $72.7 million (all funds) in fiscal year 2007.

When actual utilization data is available for the therapeutic classes currently reviewed by the Pharmaceutical and Therapeutics (P&T) Committee, HHSC may decide to discontinue review of some of the current classes or add other therapeutic classes to the PDL.

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 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; and
- statistical information related to the number of prior approvals granted or denied.

Section 16(l), S.B. 1188, 79th Legislature, Regular Session, 2005, amended the Government Code, Chapter 531, Subchapter B, Section 531.070, by adding the requirement for the report to include an analysis of the impact of the Medicare prescription drug program, Medicare Rx, on the PDL. While it is too early to analyze the actual impact of this new benefit, which was effective January 1, 2006, information concerning some of the potential impacts is included in this report.

While H.B. 2292 required the implementation of a PDL in both Medicaid and CHIP, HHSC implemented the Medicaid program 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 has added drug classes to the PDL periodically during fiscal years 2004 and 2005 for a total of 60 drug classes. These 60 drug classes represent approximately 70 percent of all Medicaid pharmacy expenditures, which totaled $2.4 billion in fiscal year 2005. 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.
- Strategy for development of the CHIP PDL.
- PDL program benefit proposals.
- The cost of administering the PDL.
- Savings from the PDL in 2005.
- Statistical information related to the prior authorization (PA) process and the number of approvals granted and denied in fiscal year 2005.
- Potential impact from the implementation of Medicare Rx.

- A basic health outcomes analysis, including an analysis of the utilization trends for certain medical services, for two drug classes.

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.

While prescription drug costs continue to be among the fastest growing elements of state Medicaid budgets in recent years, drug spending increases have averaged between 15 to 20 percent per year between 2000 and 2003 to 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 on the market. Non-preferred drugs, which are drugs reviewed but not selected to be on the PDL, require PA. Unless Texas Medicaid has historical paid claim 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 Program

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 or 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
- 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 and at least quarterly thereafter. The committee continued to meet one time each quarter after fiscal year 2005.

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, 2006.

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, 2006.

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 clinical efficacy, safety, and cost-effectiveness information on each product in each drug class. 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 60 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.

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 60 drug classes during fiscal year 2005 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 will only implement major PDL changes once yearly. The annual PDL changes will be effective in July of each year, beginning with July 2006. 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.

PA 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 SmartPA.

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 has allowed 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, then 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, then 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. HHSC instructed the PA call center to approve non-preferred prescriptions if the patient met one of these three general criteria or if the physician provided 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 2006.

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.

Provider Synergies is currently soliciting new contracts with generic manufacturers and is encouraging them to submit proposals or strategies for larger rebate proposals.

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. Approximately 54 percent of the brand name companies and 43 percent of the generic companies already provide CHIP rebates for over 79 percent of the total drug spend.

The first draft of a CHIP PDL was presented to the P&T Committee at their August 2004 meeting. The committee decided to defer action on the CHIP PDL until the 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 with potential discrepancies between the Medicaid and CHIP PDLs.

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 is currently

negotiating with manufacturers for best rebate offers for CHIP. The CHIP PDL will be treated as a "closed formulary." Manufacturers of brand name and single source products who do not sign a CHIP rebate agreement with HHSC may not have outpatient drug coverage for their products in the CHIP program.

By adopting this strategy, HHSC will treat the CHIP outpatient drugs similarly to the Medicaid outpatient drugs under the basic federal rebate requirements and should ensure the maximum availability of medically necessary drugs for CHIP recipients.

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 $1,000,000 either in cash, program benefits, or a combination of the two. Six program benefit agreements with a total annual value of less than $5 million per year are in negotiation or have been negotiated with HHSC.

Cost of PDL Administration

Costs for PDL administration include both the Provider Synergies and ACS/Heritage contracts, which totaled $4.4 million (all funds) for fiscal year 2005. 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 2004 through August 2005, Provider Synergies provided HHSC $1.3 million 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 2004 through August 2005, ACS/Heritage provided a total of $3.1 million in PA services to HHSC related to the 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. In the fiscal year 2004-05 biennium HHSC has invoiced manufacturers for supplemental rebates for seven calendar year quarters beginning with the first quarter 2004. The following table reports the estimated savings to the state from the PDL and supplemental rebate program on both an incurred and a cash basis.

December 2005 Estimated Medicaid PDL Savings

(Estimates with Provider Synergies data through 09/2005)

	FY 04		FY 05		FY 04-05	
	Rebates Collected	**Rebates Billed**	**Rebates Collected**	**Rebates Billed**	**Rebates Collected**	**Rebates Billed**
Number of Rebate Quarters	1	2.667	4	4	5	6.667
Supplemental Rebates	$13,642,998	$71,689,355	$120,138,102	$157,973,038	$133,781,100	$229,662,393
Market Shift Savings	$33,203,328	$33,203,328	$101,057,186	$101,057,186	$134,260,514	$134,260,514
Total Savings	$46,846,326	$104,892,683	$221,195,288	$259,030,224	$268,041,614	$363,922,907
State Match %	39.80%	39.80%	39.18%	39.18%		
State general revenue Dollars (Savings)	**$18,644,838**	$41,747,288	**$86,664,314**	$101,488,042	**$105,309,152**	$143,235,329
PDL Savings as a Percent of Total Drug Expenditures						
Estimated Medicaid Total Drug Spend	$2,202,164,358	$2,202,164,358	$2,414,686,554	$2,414,686,554	$4,616,850,912	$4,616,850,912
PDL Savings (all funds) as % of Total Expended	2.13%	4.76%	9.16%	10.73%	5.81%	7.88%
PDL Savings Breakdown						
Supplemental Rebates	29.12%	68.35%	54.31%	60.99%	49.91%	63.11%
Market Shift	70.88%	31.65%	45.69%	39.01%	50.09%	36.89%

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.

October 2005 VDP actuarial estimates used.

HHSC estimates PDL savings of approximately $143 million general revenue in the 2004-05 biennium on an incurred basis before administrative costs. On a cash basis, HHSC estimates savings of approximately $105 million general revenue for the 2004-05 biennium. Cash savings are lower than incurred savings because several months are required to invoice and collect supplemental rebates from drug manufacturers at the end of each quarter.

Estimated savings are lower than the fiscal note amount for several reasons. First, the fiscal note assumed a full PDL implementation by March 1, 2004. HHSC set an ambitious PDL phase in timeline and worked to implement the first phase of the PDL for 15 drug classes on February 23, 2004. HHSC implemented 45 additional PDL drug classes in later phases, so HHSC did not begin to generate savings for these drug classes until after March 1, 2004.

Second, the fiscal note savings estimate assumed that under the PDL, Texas prescribers would shift their prescribing patterns toward less expensive preferred drugs. Since the implementation of the Medicaid PDL, prescribing patterns have shifted toward preferred products, however Texas has not experienced as high a shift in prescribing patterns as projected, compared to other states' experience with PDLs. This may be attributable to HHSC's broad PA criteria, the fact that HHSC does allow a physician's staff member to request a PA, and high PA approval rates. HHSC continues to work with the DUR Board on the PDL PA criteria and will continue to educate physicians and other prescribers about the goals of the PDL program.

Statistics on Prior Authorizations

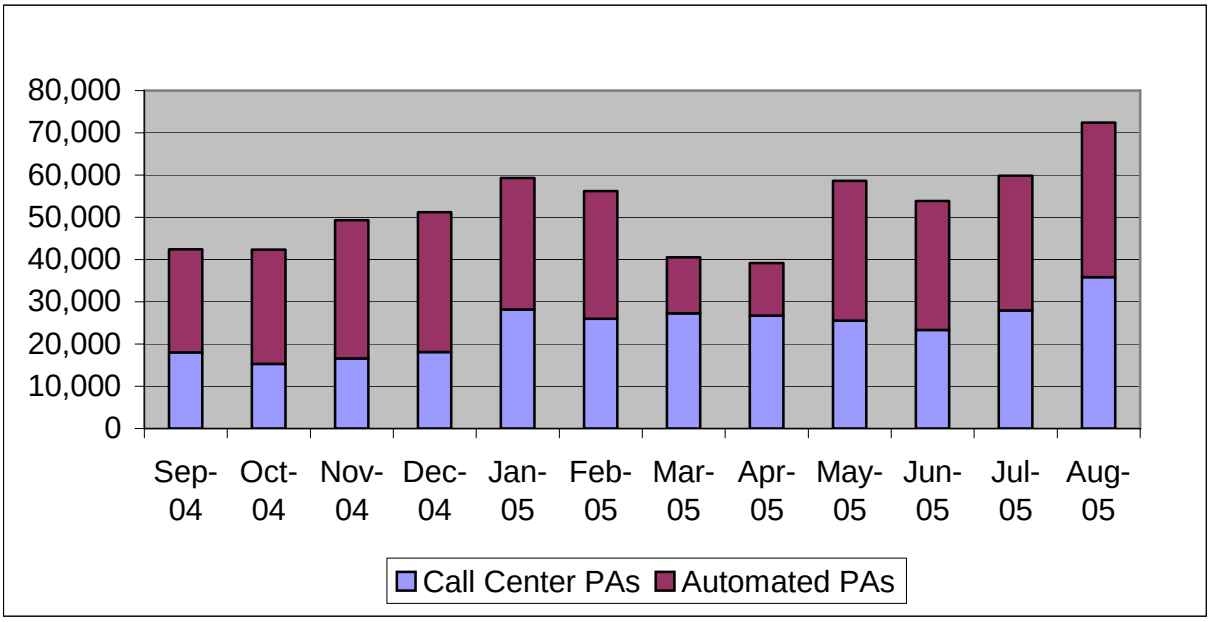
Table 1 and Chart 1 show the trend in PA transactions from September 2004 through August 2005 for non-preferred drugs. Automated PAs are approved through the Smart PA system at the pharmacy point of sale without the need for a phone call if the patient's Medicaid medical and pharmacy claims histories 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 2004 – August 2005

	Sep-04	Oct-04	Nov-04	Dec-04	Jan-05	Feb-05	Mar-05	Apr-05	May-05	Jun-05	Jul-05	Aug-05
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	24,432	27,038	32,686	33,111	31,153	30,232	13,298	12,422	33,066	30,510	31,856	36,637
Total PAs	**42,447**	**42,359**	**49,281**	**51,182**	**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 13, 2005.

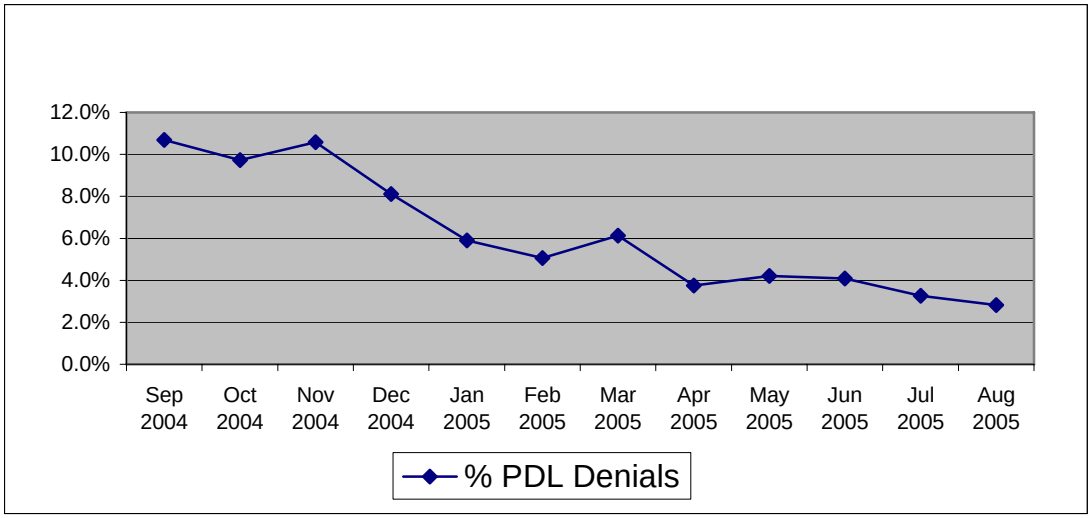
Chart 1 - Medicaid Preferred Drug List Prior Authorization Transactions



HHSC implemented changes to the PDL in January 2005 and mid-July 2005. As prescribers became familiar with the changes to the preferred drug list and adjusted prescribing patterns, requests for PAs again declined.

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 2004 through August 2005.

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 overall stabilized at a fairly consistent rate of approximately 4 percent in the last three months of the fiscal year 2005.

Potential 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. HHSC estimates that drug expenditures will be reduced by $616.9 million in calendar year 2006 as a result of the loss of Medicaid drug coverage of this client population. The associated loss of PDL supplemental rebates is estimated to total about $28.6 million (all funds) in fiscal year 2006 over eight months and about $72.7 million (all funds) in fiscal year 2007 over twelve months.

Medicare Rx Impact on PDL Rebate Revenues		
	FY 2006 (8 Months)	**FY 2007 (12 Months)**
Projected PDL Rebates including Dual Eligibles (All Funds)*	$168.60	$193.90
Projected PDL Rebates without the Dual Eligibles (All Funds)*	$140.00	$121.20
Decrease in PDL Rebates due to Medicare Rx (All Funds)*	($28.6)	($72.7)
% Decrease in PDL Rebates	17.0	37.50
State Match Percent	39.32	39.23
Decrease in State general revenue Dollars*	($ 11.2)	($ 28.5)

** Millions*

When actual utilization data is available for the therapeutic classes currently reviewed by the P&T Committee, HHSC may decide to discontinue review of some of the current classes or add other therapeutic classes to the PDL. Since Medicare drug coverage began January 1, 2006, initial implementation issues have delayed full federal drug coverage for some of the dual-eligible population. As a result of these delays, it may be several months before accurate projections of costs and savings can be prepared based on actual utilization data.

The current PDL classes expected to be most impacted by loss of the dual eligibles include are listed below.

- Alzheimer's agents – Drugs used in the treatment of Alzheimer's disease.
- Bone resorption suppression and related agents – Drugs to treat osteoporosis (thinning bones).
- Hypoglycemics, Meglitinides – Drugs used in the treatment of diabetes.
- Opthalmics, Glaucoma agents – Drugs used to treat glaucoma.
- Platelet aggregation inhibitors – Drugs used to prevent platelets in the blood from sticking together and forming clots.

Health Outcomes Analysis

H.B. 2292 required that the PDL annual report contain an analysis of the effects of the PDL and PA on health outcomes. In April 2006, HHSC conducted two analyses of the effect of PDL and PA policies on health outcomes for certain Medicaid clients. The studies utilized data from one group of Medicaid clients with asthma and a second group with schizophrenia or affective psychosis who were receiving certain drugs affected by PDL implementation. HHSC information on Medicaid patient health is limited to claims data; therefore staff analyzed service utilization data from Medicaid claims as a proxy for health outcomes. Specifically, staff reviewed Medicaid claims data to observe any changes in frequency of utilization of inpatient hospital services, emergency department services, and outpatient services after the PDL status changed for certain drugs used to treat the conditions specified above. Drug utilization data was also analyzed to determine any changes or trends in prescribing practices.

Study Conclusions and Limitations

Given the available data for analysis, implementation of PA and the PDL does not appear to have a significant negative affect on health outcomes, as measured by Medicaid service utilization, for subjects with asthma, schizophrenia, or affective psychoses. HHSC recognizes, however, that there are several limitations to the analyses presented here.

- Health outcomes are most accurately assessed by a study of individual case records, including diagnoses, treatments, medications, progress notes, and other measures of a patient's current physical and mental health. A retrospective analysis based on claims data is of limited utility in understanding the day-to-day well being of the subjects studied.

- The studies could not control for patients who may have had multiple diagnoses and/or may have received multiple drugs for the studied illness. Patients may also have been taking drugs prescribed for other illnesses not included in the studies. This makes it difficult to draw conclusions about any cause-and-effect relationship between PA policies and health outcomes.

- Patients enrolled in Medicaid managed care were not included in the analyses because detailed claims data from managed care organizations (MCOs) is not readily available.

- In the psychotropic drug study, the data does not represent a static group of patients over the two-year study period, but rather may include different patients at different points in time as some patients leave Medicaid and new patients are enrolled. This makes it difficult to accurately compare changes in outcomes over time, since patient needs (and hence service utilization) could be changing from month to month as the patient population changes.

- Also, the fact that patients receiving treatment with Zyprexa® and clozapine when the PDL was implemented were allowed to continue that therapy without going through a PA process presents a limitation in accurately assessing the full impact of the PDL policy. These clients were exempt from the PA requirements.

- Finally, in the asthma study, some subjects may have been excluded if their treatment during the period before or after implementation of the PDL was limited to the use of alternate asthma drugs that were not included in the study.

Health Outcomes for Texas Medicaid Children with Asthma

Staff compared the utilization of inpatient, outpatient (office visits), and emergency department (ED) services before the PDL was implemented (pre-PDL) and after implementation (post-PDL). The study subjects included Medicaid recipients between 1 and 19 years of ages. Each study recipient had a primary diagnosis of asthma with at least one prescription filled for an asthma-related medication. The subjects were divided into three study groups: (1) subjects who only received preferred drugs (preferred); (2) subjects who only received non-preferred drugs (non-preferred); and (3) subjects who received both preferred and non-preferred drugs (mixed). The study covered the 12-month period prior to the implementation of the PDL for asthma drugs and the 12-month period following the implementation. There did not appear to be a negative effect due to the implementation of the PDL as observed in the number of asthma-related inpatient hospital admissions and office visits. There was a 29 percent overall decrease in the number of inpatient hospital admissions from the pre-PDL to the post-PDL period. There was virtually no change in the overall number of asthma-related office visits in the post-PDL period compared to the pre-PDL period, with the preferred and non-preferred groups showing small, statistically significant increases in utilization of office visits and the mixed group showing an almost 12 percent decrease in utilization in the post-PDL period.

ED utilization varied between the three study groups, resulting in an overall decrease in the number of ED visits from the pre-PDL to the post-PDL period. There did not appear to be a significant effect of the PA policy on ED utilization among the patients studied here. However, data restrictions and other limitations make it difficult to determine if variations in ED utilization between the groups are attributable to PA policies. HHSC will continue to monitor health outcomes and prescribing practices as they relate to the PDL in order to better understand possible impacts of PA policies.

Health Outcomes for Texas Medicaid Clients Diagnosed with Schizophrenia or Affective Psychosis

Schizophrenia affects approximately one percent of the U.S. population, and if untreated may cause disability from symptoms such as hallucinations, delusions, and social isolation or withdrawal. Affective psychoses include a number of depressive disorders as well as bipolar disorder. Over the past decade, a new generation of drugs, called atypical antipsychotics, has been introduced for the treatment of these potentially debilitating illnesses. In January 2004, the P&T Committee reviewed six drugs in the atypical antipsychotic therapeutic class. Upon review, the P&T Committee recommended that Zyprexa® (olanzapine) and clozapine (both brand name and generic) not be placed on the PDL. The four remaining drugs, Abilify® (aripiprazole), Geodon® (ziprasidone), Risperdal® (risperidone), and Seroquel® (quetiapine) were recommended to be placed on the PDL. The committee also recommended that all patients currently receiving treatment with either Zyprexa® or clozapine be allowed to continue that therapy without going through a PA process. This would ensure continuity of care for patients who were stable on their current therapy. The PA criteria for approval also allowed for an automatic approval for clients new to the Medicaid program, but currently stable on a non-preferred medication. HHSC agreed with the P&T Committee's recommendations, and on March 29, 2004, Zyprexa® and clozapine became non-preferred products.

HHSC staff conducted an analysis of health outcomes for Medicaid clients diagnosed with schizophrenia or affective psychosis. Medical service claims data from the Medicaid fee-for-service and Primary Care Case Management programs were used as a proxy for health outcomes. Staff compared the utilization of inpatient, ED, or outpatient hospital and doctor services for the two-year period of September 1, 2003 through August 31, 2005.

The implementation of PA for Zyprexa® and clozapine did not result in a significant change in the utilization of any of the service types studied. Utilization rates for impatient services, ED services, and outpatient hospital and physician services remained consistent over the two-year study period with only regular variation from month to month. There was no significant variation in trends for any of the service types studied following implementation of the PDL.