
PREFERRED DRUG LIST

Annual Report to the Texas Legislature

As Required by Texas Government Code § 531.070

Texas Health and Human Services Commission

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Executive Summary

In response to rapid growth in prescription drug expenditures, H.B. 2292, 78th Legislature, Regular Session, 2003, directed the Texas Health and Human Services Commission (HHSC) to implement a preferred drug list (PDL) for the Medicaid program and the Children's Health Insurance Program (CHIP).

HHSC implemented a Medicaid PDL in early 2004. The 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 has periodically added drug classes to the PDL. The current PDL consists of 66 drug classes, which represented approximately 71 percent of the total \$2.12 billion in Medicaid pharmacy expenditures in fiscal year 2009.

Government Code, Chapter 531, Subchapter B, Section 531.070, requires HHSC to provide a yearly written report on the PDL program to the Legislature and the Governor. HHSC has included the following information in this year's report:

- Background information on PDLs.
- Medicaid PDL process.
- PDL process for generic drugs.
- Strategy for the development of the CHIP PDL.
- PDL program benefit proposals.
- Cost of administering the PDL.
- Savings from the PDL.
- Statistical information related to the PA process and the number of approvals granted and denied.
- Impact from the implementation of Medicare Rx.
- A basic health outcomes analysis, including an analysis of the utilization trends for certain medical services for one drug class.

The following is a brief summary of key sections discussed in detail in this year's report.

The PDL Process

The Medicaid PDL process generally continues to operate as it has in previous years. In June 2007, the PDL was made 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. In November 2009,

HHSC implemented an additional formulary search application on the HHSC website. With this application, providers and stakeholders can search for drugs that are on the Medicaid formulary and get important information about the current PDL.

Cost of Administering the PDL

Costs for Medicaid 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 \$3.73 million in fiscal year 2008 and \$3.67 million in fiscal year 2009 (all funds).

Savings from the PDL

HHSC estimates the Medicaid PDL has resulted in savings of approximately \$115 million general revenue in fiscal year 2009 on a cash basis. PDL savings for the 2008-09 biennium are estimated to be approximately \$246 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 2008, monthly PDL PA requests ranged from a low of 35,088 to a high of 54,251. In fiscal year 2009, monthly PDL PA requests ranged from a low of 37,034 to a high of 55,216. HHSC implemented significant changes to the PDL in mid January and mid July of each fiscal year. PA requests will typically increase in the first few months following changes to the PDL, and as prescribers become familiar with the changes to the PDL and adjust prescribing patterns, requests for PAs will decline. Since the implementation of the Medicaid PDL, denied PA requests have been below 13 percent each month.

Impact of Medicare Rx on the Medicaid PDL

Effective January 1, 2006, approximately 320,000 to 340,000 Medicaid recipients who were also eligible for Medicare, also known as dual-eligibles, became eligible for drug coverage through the Medicare prescription drug program, Medicare Rx. These dual-eligible recipients stopped receiving prescription drugs through the Medicaid Vendor Drug Program, except for a very limited number of drugs excluded from the Medicare Rx program.

While total drug expenditures in the Medicaid program decreased from fiscal year 2005 to fiscal year 2009, the PDL savings as a percent of total expenditures actually increased from 9.16 percent in fiscal year 2005 to 17.24 percent in fiscal year 2009 on a cash basis.

Health Outcomes Analysis

Since the implementation of the Medicaid PDL in 2004, HHSC has performed three studies to determine if client health outcomes have been negatively impacted by the PDL or PA process. In November 2007, HHSC staff conducted an analysis of health outcomes for Medicaid clients diagnosed with migraine headaches. Staff reviewed Medicaid claims data to observe any changes in frequency of utilization of emergency department services or utilization of short-acting narcotics after the PDL status changed for certain drugs used to treat migraine headaches. In addition to the 2007 study, two other studies were performed in 2005 to evaluate drugs used in the treatment of asthma and schizophrenia or affective psychosis. All three studies included drugs used in the maintenance and treatment of chronic conditions where the lack of treatment could be expected to result in acute exacerbations. All three studies yielded similar results, with no adverse health outcomes due to the adoption of and/or changes to the PDL.

In conducting the 2007 study, researchers found it difficult to evaluate the impact the PDL may have had on health outcomes. This difficulty was due to the fact that it was no longer possible to compare pre-PDL and post-PDL subject groups, since a significant amount of time had passed since the PDL was initially implemented in early 2004. The lack of a pre-implementation control group and the myriad of factors influencing recipient health status did not allow for a true evaluation of the impact of the PDL changes on health outcomes.

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:

- Cost of administering the PDL.
- Analysis of the utilization trends for medical services provided by the state and any correlation to the PDL.
- Analysis of the effect on health outcomes and results for recipients.
- Statistical information related to the number of prior authorizations (PAs) granted or denied.
- Analysis of the impact of the Medicare prescription drug program, Medicare Rx, on the Medicaid PDL.

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 was much larger in Medicaid than in CHIP. CHIP total drug expenditures for fiscal year 2005 totaled \$80.5 million, while Medicaid total drug expenditures exceeded \$2.4 billion. Thus, there was potential for much larger supplemental rebates in Medicaid than in CHIP.

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 since that time. The Medicaid PDL currently consists of 66 drug classes. These 66 drug classes represent approximately 71 percent of all Medicaid pharmacy expenditures, which totaled \$2.12 billion in fiscal year 2009.

HHSC has included the following information in this report.

- Background information on PDLs and the H.B. 2292 PDL requirements.
- Medicaid PDL process.
- PDL process for generic drugs.
- CHIP PDL.
- PDL program benefit proposals.
- Cost of administering the PDL.
- Savings from the PDL.
- Statistical information related to the PA process and the number of approvals granted and denied.
- Impact of the implementation of Medicare Rx.
- Basic health outcomes analysis, including an analysis of the utilization trends for certain medical services for one drug class.

Background Information on PDLs 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. 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 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 PA before a non-preferred drug can be reimbursed. By containing drug costs, the PDL will help to preserve Medicaid's ability to meet clients' prescription drug needs as well as other health-care needs.

Overview of 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 to place 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.

H.B. 2030, 81st Legislature, Regular Session, 2009, modified several of the PDL requirements. Under H.B. 2030, a drug may be added to the PDL without a supplemental rebate or program benefit agreement if there is no negative cost impact to the state. This change will be implemented in the summer of 2010 contingent upon approval from the Centers for Medicare & Medicaid Services. In addition, H.B. 2030 requires that HHSC allow PA requests to be submitted by facsimile or electronic communications through the Internet. This change will be implemented in December 2010.

H.B. 2030 also requires that HHSC post to its website a summary of any clinical efficacy and safety information that is provided to the P&T Committee by any entity contracted with HHSC to provide the information. HHSC must also post to its website the P&T Committee recommendations and HHSC's decision for each specific drug reviewed for inclusion on the PDL. The postings must include the general basis for each recommendation and decision and whether or not a supplemental rebate agreement or program benefit agreement was reached for each reviewed drug. These changes to the PDL process were implemented in October 2009.

Medicaid PDL Process

Texas Pharmaceutical and Therapeutics (P&T) Committee

The P&T Committee provides recommendations to HHSC on which drugs to place on the Medicaid PDL based on clinical efficacy, safety and cost effectiveness. The eleven committee members, appointed by the Governor, 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
- Daniel R. Hernandez, R.Ph, Community Pharmacy Oncology Pharmacy
- Melbert "Bob" Hillert, M.D., Cardiologist
- J.C. Jackson, R.Ph, Retail Pharmacy Manager, Kelsey-Seybold Clinic
- Dorinda Martin, R.Ph, Community Pharmacy, Long-Term Care Pharmacy
- Valerie Robinson, M.D., Pediatric Psychiatrist
- Guadalupe Zamora, M.D., Family Practitioner
- Mario R. Anzaldúa, M.D., Family Practitioner
- Vacant pharmacist position

H.B. 2292 required that the P&T Committee meet monthly for the first six months after the creation of the committee and at least quarterly thereafter. The committee met four times in fiscal years 2008 and 2009.

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 contracted 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 the identification of drug classes the state may want to include on the PDL. HHSC's contract with Provider Synergies is a fixed-fee contract effective through December 31, 2010.

HHSC has also contracted with Affiliated Computer Systems, Inc./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 effective through December 31, 2010.

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. 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 Medicaid 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 about P&T Committee meetings and changes to the PDL or PA criteria via notices on the agency website and e-mail. A hard copy of the PDL is available to provider physicians and pharmacies upon request. In June 2007, the PDL was made available to prescribing practitioners 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.

In November 2009, HHSC implemented an additional formulary search application on the HHSC website. With this application, providers and stakeholders can search for drugs that are on the Medicaid formulary and get important information about the current PDL. Within the application, there are links attached to non-preferred drugs that will guide prescribers to the preferred drugs in that therapeutic class. The tool also provides information on whether or not clinical or therapeutic PA edits exist for a specific drug.

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 66 drug classes during fiscal year 2009 for the Medicaid PDL. Drug products that are new to the market place are not subject to PA 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 in 2006 to only implement major updates to the Medicaid PDL once per year. Major changes to the PDL only occurred in July 2006 and July 2007. Based on input from the P&T Committee, HHSC, in 2008, returned to making PDL updates twice per year. In 2008 and 2009, HHSC implemented major PDL changes in January and July. 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 specific to a drug or drug class.

The PA Process

H.B. 2292 requires that the prescribing physician or other prescribing practitioner obtain PA for a non-preferred drug 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/she 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 to a preferred drug; or (3) contraindication to a preferred drug. HHSC selected these three criteria based on other states' PDL experience and general medical practice guidelines. The PA call center approves non-preferred drugs if the patient meets one of these three general criteria or if the physician provides another appropriate clinical reason why the patient needs to receive a non-preferred drug instead of a preferred drug.

For five drug classes – Atypical Antipsychotics, Selective Serotonin Reuptake Inhibitors (SSRI) Antidepressants, Atypical Antidepressants, Growth Hormone Injections and Hepatitis C treatments – HHSC allows an exception to the PA requirements to maintain continuity of care. For these five drug classes, Medicaid patients who are stable on a non-preferred drug are allowed to continue receiving that drug. 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 a number of drug classes and will continue the process of customizing PA criteria for other drug classes.

Generic PDL Strategy

H.B. 2292 required that the PDL 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 Medicaid 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 to implement PDLs for both Medicaid and CHIP. HHSC requested that the P&T Committee focus initially on the Medicaid PDL, because the Medicaid PDL was expected to generate most of Texas' PDL savings. HHSC expected minimal savings from the CHIP PDL for three reasons. First, Texas' CHIP drug expenditures in fiscal year 2005 represented less than 5 percent of the Medicaid drug expenditures (\$80.5 million for CHIP 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 CHIP 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 PDL similar to the Medicaid PDL may not be clinically appropriate for the CHIP 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 specifically 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:

- Do not implement a closed formulary for CHIP.
- Implement a preferred CHIP drug status categorization of medications for those drug products for which a manufacturer has offered a rebate.
- Implement a PA process, due to clinical issues for specific drugs.
- Implement an incentive process for the drugs manufactured by drug companies that have provided HHSC with a voluntary rebate.
- Leave the present formulary as is 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 enrolled in CHIP. The Committee's recommendation for development of a PA program in CHIP was an effort to ensure consistency between the Medicaid and CHIP programs. 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 believed those same restrictions should be implemented in CHIP. The Committee's final recommendation was that HHSC should 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 that offered rebates in CHIP, those companies' products are listed as preferred on the Epocrates web-based tool. HHSC determined that the 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. Table 1 shows CHIP expenditures and rebates for fiscal years 2005 - 2009.

Table 1 - CHIP Rebate Program

	FY 2005	FY 2006	FY 2007*	FY 2008	FY 2009
Rebates Collected					
<i>All Funds</i>	\$7,174,010	\$7,169,205	\$16,049,938	\$12,677,290	\$17,146,553
State Match Percent	27.43%	27.53%	28.49%	28.20%	28.71%
State General Revenue Dollars (Savings)	\$1,967,831	\$1,973,682	\$4,573,380	\$3,575,364	\$4,922,425
CHIP Drug Expenditures	\$84,482,388	\$79,979,490	\$85,165,772	\$111,375,724	\$136,767,153
Rebates (All Funds) as Percent of Total Expended	8.49%	8.96%	18.85%	11.38%	12.54%

* Rebate collection in 2007 included a one-time payment of \$6 million (all funds) from one manufacturer that included payments for several calendar quarters from previous fiscal years.

Program Benefit Proposals

H.B. 2292 allows 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 approximately \$9.1 million were in place in fiscal year 2008. Three program benefit agreements with an annual value of approximately \$1.6 million were in place in fiscal year 2009.

Cost of PDL Administration

Costs for PDL administration include both the Provider Synergies and ACS/Heritage contracts, which totaled \$3.73 million (all funds) for fiscal year 2008 and \$3.67 million (all funds) for fiscal year 2009. In addition to these contract costs, HHSC 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. Provider Synergies provided HHSC with \$1.20 million (all funds) in services each year for fiscal years 2008 and 2009.

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 \$4.50 to \$5.15 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 fiscal year 2008, ACS/Heritage provided a total of \$2.53 million (all funds) in PA services to HHSC related to the Medicaid PDL. PA services provided by ACS/Heritage for fiscal year 2009 totaled \$2.47 million (all funds).

PDL Savings

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. Table 2 reports the estimated savings to the state from the PDL and supplemental rebate program on a cash basis.

Table 2 - Estimated Medicaid PDL Savings

	FY 2006 PDL Savings (Cash Basis)	FY 2007 PDL Savings (Cash Basis)	FY 2006-2007 PDL Savings (Cash Basis)	FY 2008 PDL Savings (Cash Basis)	FY 2009 PDL Savings (Cash Basis)	FY 2008-2009 PDL Savings (Cash Basis)
Supplemental Rebates Collected	\$145,775,370	\$119,874,451	\$265,649,821	\$106,208,879	\$123,348,177	\$229,557,056
Market Shift Savings	\$130,186,992	\$175,577,264	\$305,764,256	\$225,053,236	\$242,043,900	\$467,097,136
Total Savings	\$275,962,362	\$295,451,715	\$571,414,077	\$331,262,115	\$365,392,077	\$696,654,192
State Match %	39.32%	39.23%		39.42%	31.54%	
State General Revenue Dollars (Savings)	\$108,517,747	\$115,905,708	\$224,423,455	\$130,583,526	\$115,244,661	\$245,828,187

PDL Savings as a Percent of Total Drug Expenditures

Estimated Medicaid Total Drug Spend	\$1,924,356,864	\$1,763,137,198	\$3,687,494,062	\$1,971,196,788	\$2,120,014,650	\$4,091,211,438
PDL Savings as Percent of Total Expended (All Funds)	14.34%	16.76%	15.50%	16.81%	17.24%	17.03%

PDL Savings Breakdown

Supplemental Rebates	52.82%	40.57%	46.49%	32.06%	33.76%	32.95%
Market Shift	47.18%	59.43%	53.51%	67.94%	66.24%	67.05%

Notes: Estimates calculated using Provider Synergies' data.

PDL implementation was phased in. Rebates began to accrue effective January 1, 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 expenditure estimates were used.

HHSC estimates Medicaid PDL savings of approximately \$115 million general revenue in fiscal year 2009 with estimated savings of \$246 million general revenue for the 2008-09 biennium on a cash basis before administrative costs. The overall PDL savings for fiscal year 2009 represents 17.2 percent of the total Medicaid expenditures for prescription drugs and is estimated at 17.0 percent for the 2008-09 biennium.

PA Statistics

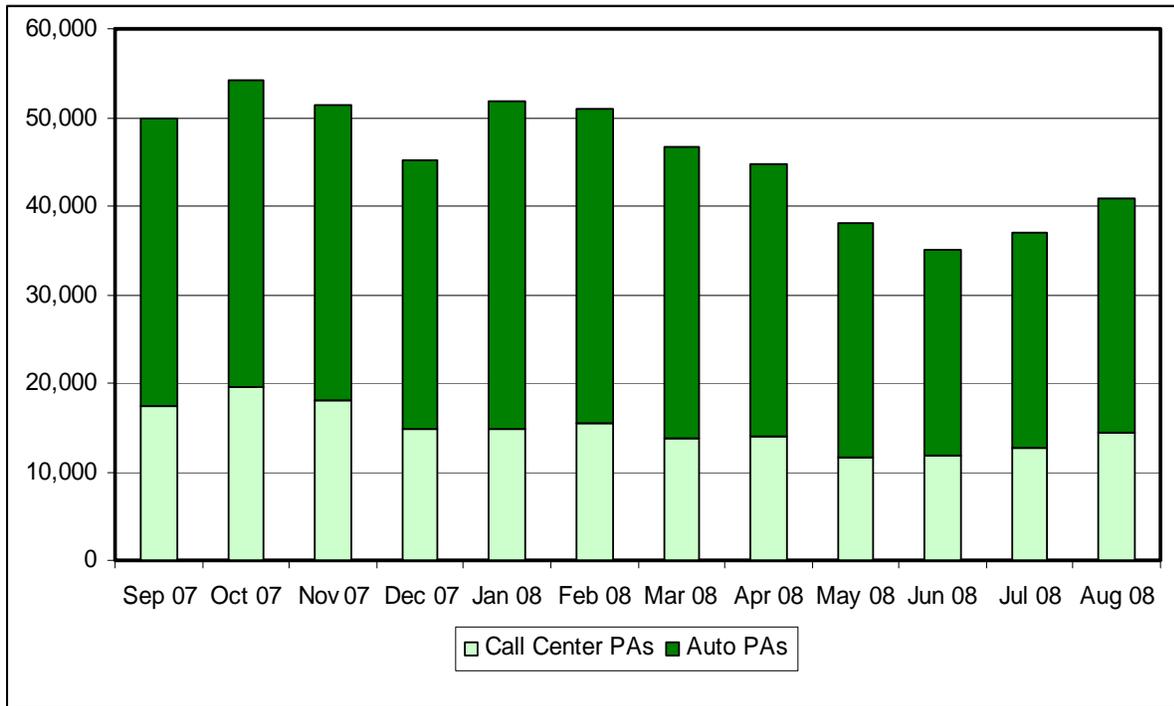
Table 3 and Charts 1 and 2 show the trend in PA transactions from fiscal year 2008 through fiscal year 2009 for non-preferred drugs. Automated PAs are approved through the Smart PA system at the pharmacy point of sale without the need for a phone call if the patient’s Medicaid medical and pharmacy claims 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 3 - Medicaid PA Transactions

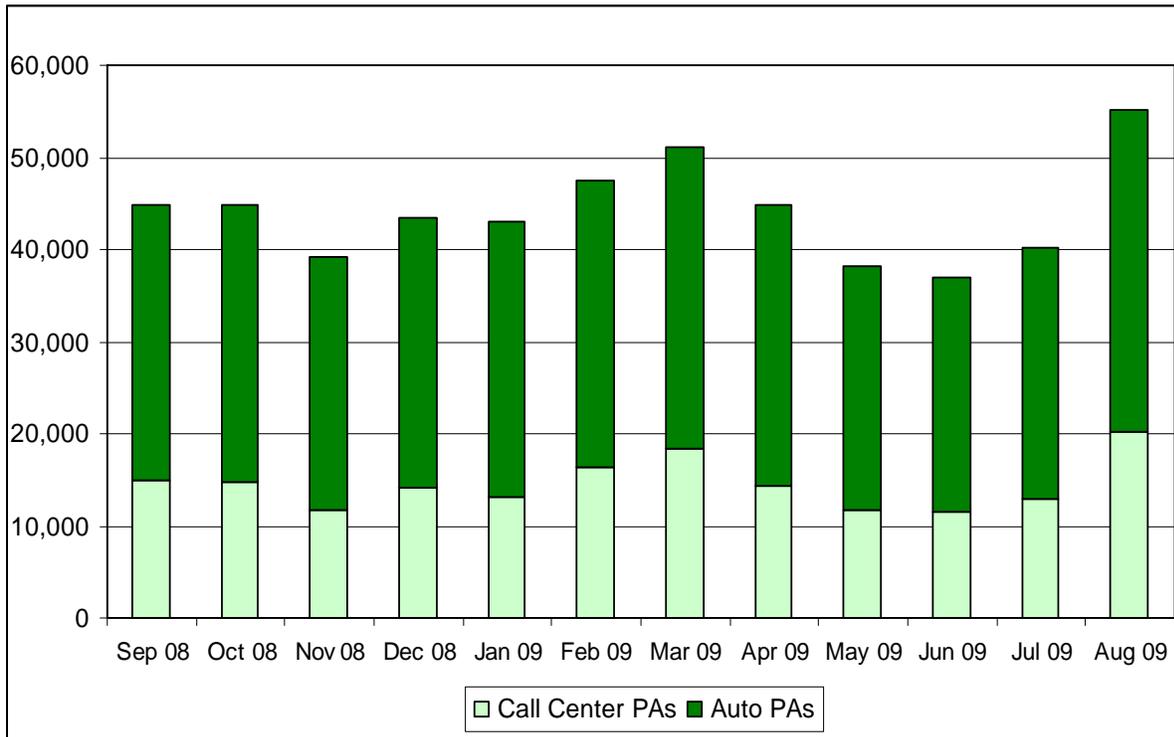
	Call Center PAs	Auto PAs	Total PAs		Call Center PAs	Auto PAs	Total PAs
Sep 07	17,314	32,518	49,832	Sep 08	14,912	29,957	44,869
Oct 07	19,469	34,782	54,251	Oct 08	14,787	30,058	44,845
Nov 07	17,984	33,408	51,392	Nov 08	11,762	27,450	39,212
Dec 07	14,939	30,115	45,054	Dec 08	14,116	29,353	43,469
Jan 08	14,856	36,901	51,757	Jan 09	13,063	29,996	43,059
Feb 08	15,381	35,634	51,015	Feb 09	16,362	31,064	47,426
Mar 08	13,867	32,768	46,635	Mar 09	18,287	32,813	51,100
Apr 08	13,975	30,720	44,695	Apr 09	14,263	30,626	44,889
May 08	11,642	26,429	38,071	May 09	11,675	26,554	38,229
Jun 08	11,782	23,306	35,088	Jun 09	11,465	25,569	37,034
Jul 08	12,741	24,228	36,969	Jul 09	12,862	27,301	40,163
Aug 08	14,462	26,348	40,810	Aug 09	20,278	34,938	55,216

Notes: Based on ACS/Heritage invoiced PAs as of December 2009.

**Chart 1 - Medicaid PDL PA Transactions
FY 2008**



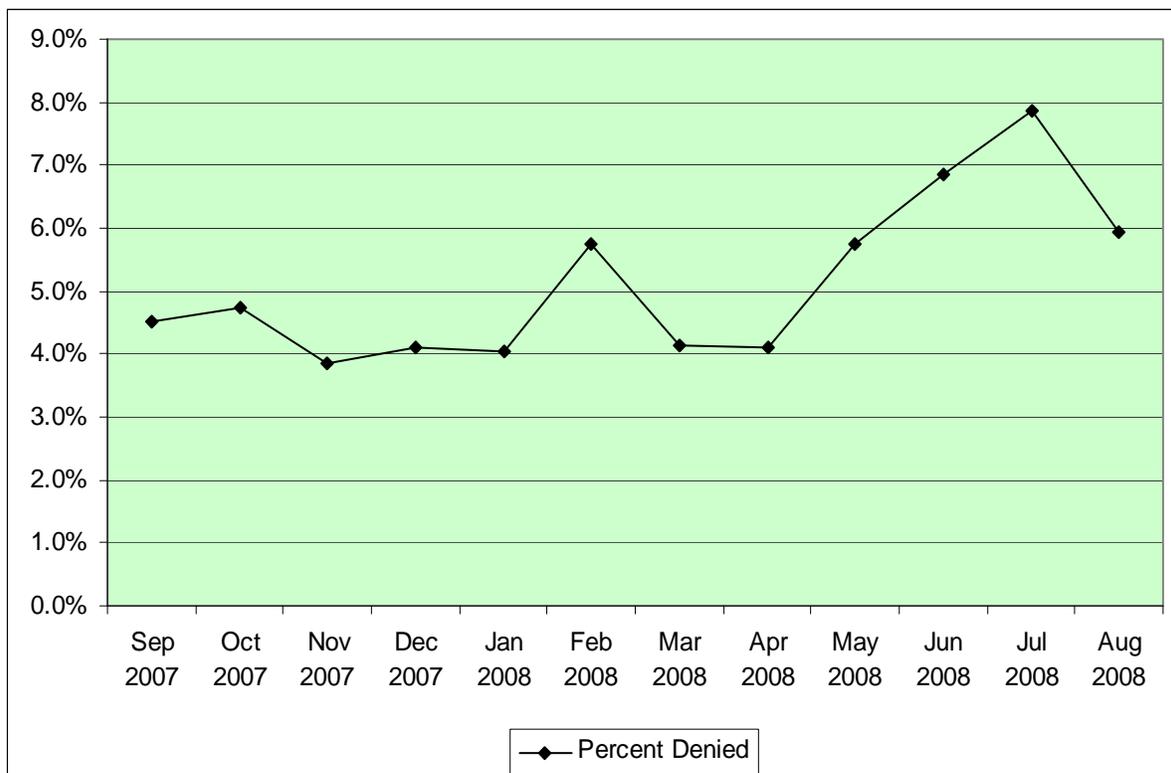
**Chart 2 - Medicaid PDL PA Transactions
FY 2009**



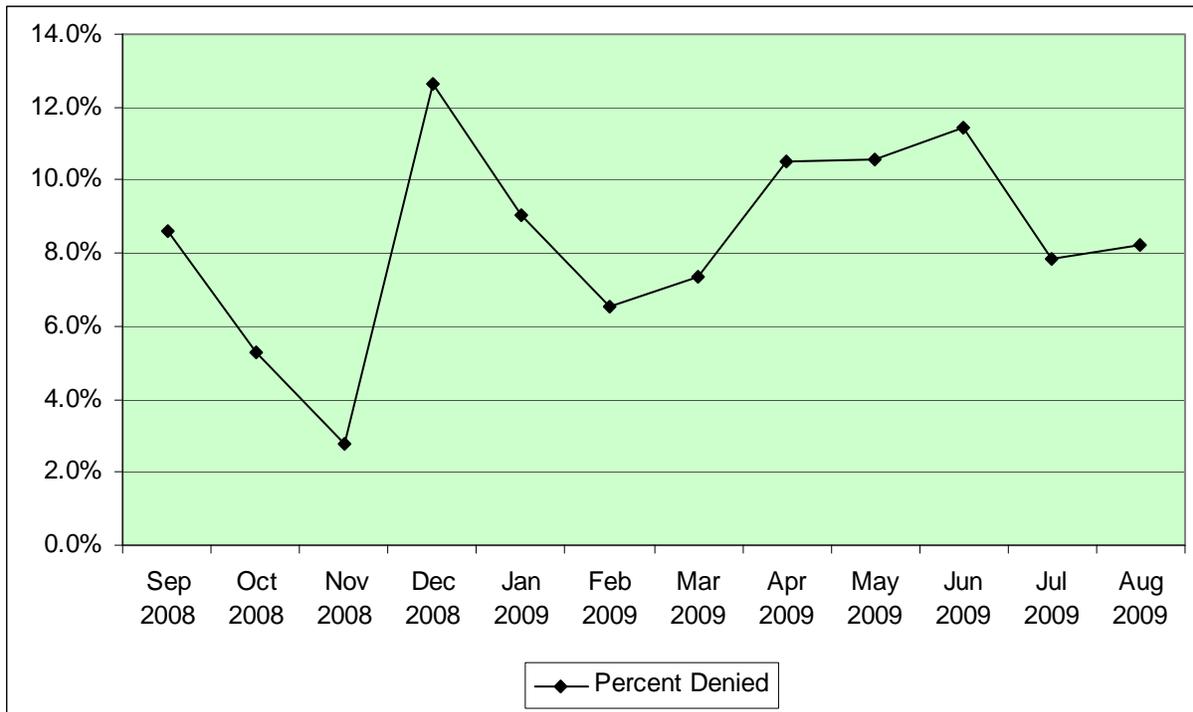
HHSC implemented changes to the PDL in late July and early February in 2008 and 2009, resulting in an increase in PA requests in the following 3 months. As prescribers become familiar with the changes to the PDL and adjust prescribing patterns, requests for PAs typically decline.

Since the Medicaid PDL was implemented, the percent of PA requests denied by the PA call center has been below 13 percent each month. Charts 3 and 4 show the estimated percent of PA requests for non-preferred drugs that were denied by the PA call center in fiscal years 2008 and 2009.

**Chart 3 – PA Call Center Monthly PA Denial Rate
FY 2008**



**Chart 4 – PA Call Center Monthly PA Denial Rate
Fiscal Year 2009**



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 drug(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 drug instead of a preferred drug.

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 a PA request approved. Call center PA denial rates for fiscal year 2009 ranged from 2.8 percent to 12.6 percent and averaged 8.4 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 were also eligible for Medicare became eligible for drug coverage through the Medicare prescription drug program, Medicare Rx. These dual-eligible recipients stopped receiving prescription drugs through the Medicaid Vendor Drug Program, except for a very limited number of drugs excluded from the Medicare Rx program.

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. These complex and interacting variables make it difficult to isolate and measure any impact on expenditures, or the PDL, that can be tied specifically to Medicare Rx on an ongoing basis in the years after implementation. However, it does not appear that the implementation of Medicare Rx has significantly impacted the PDL program. While there has been a reduction in total Medicaid drug expenditures since 2005, the ratio of rebate savings to total drug expenditures increased from 9.16 percent in fiscal year 2005 to 17.24 percent in fiscal year 2009.

Table 4 - Medicare Rx Impact on Medicaid PDL Savings

	FY 2005 PDL Savings (Cash Basis)	FY 2006 PDL Savings (Cash Basis)	FY 2007 PDL Savings (Cash Basis)	FY 2008 PDL Savings (Cash Basis)	FY 2009 PDL Savings (Cash Basis)
Estimated Medicaid Total Drug Expenditures (All Funds)	\$2,414,686,554	\$1,924,356,845	\$1,763,149,406	\$1,971,196,788	\$2,120,014,650
Supplemental Rebates Collected	\$120,023,739	\$145,804,227	\$119,844,175	\$106,208,879	\$123,348,177
Market Shift Savings	\$101,057,186	\$130,186,992	\$175,577,264	\$225,053,236	\$242,043,900
Total Savings	\$221,080,925	\$275,991,219	\$295,421,439	\$331,262,115	\$365,392,077
State Match %	39.18%	39.32%	39.23%	39.42%	31.54%
State General Revenue Dollars (Savings)	\$86,619,506	\$108,519,747	\$115,893,831	\$130,583,526	\$115,244,661
PDL Savings Breakdown					
Supplemental Rebates as Percent of Total Expended (All Funds)	4.97%	7.58%	6.80%	5.39%	5.82%
Market Shift Savings as Percent of Total Expended (All Funds)	4.19%	6.76%	9.96%	11.42%	11.42%
Total PDL Savings as Percent of Total Expended (All Funds)	9.16%	14.34%	16.76%	16.81%	17.24%

Health Outcomes Analysis

Since the implementation of the PDL in 2004, HHSC has performed three studies to determine if client health outcomes have been negatively impacted by the PDL or PA process. Two studies were performed in 2005 to evaluate drugs used in the treatment of asthma and schizophrenia or affective psychosis and a third study was conducted in 2007 on drugs used to treat migraine headaches. All three studies included drugs used in the maintenance and treatment of chronic conditions where the lack of treatment could be expected to result in acute exacerbations. All three studies yielded similar results; with no adverse health outcomes due to the adoption of and/or annual changes to the PDL.

Given the available data for analysis, it does not appear that the PDL has had a negative affect on health outcomes, as measured by Medicaid service utilization, for clients reviewed. HHSC recognizes, however, that there are several limitations to its analysis.

- 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 health. A retrospective analysis based on claims data is of limited utility in understanding the day-to-day well being of the patients 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 analysis because detailed claims data from managed care organizations is not readily available.
- The PDL with PA requirements has been in place since early 2004 so a comparison between pre- and post-PDL is no longer possible.

In conducting the 2007 study, researchers found it increasingly difficult to evaluate the impact the PDL may have had on health outcomes. The reason for this is because it is no longer possible to compare pre-PDL and post-PDL subject groups, since we have moved farther away from the initial PDL implementation date. The PDL has now been in place for over six years, and the lack of a pre-implementation control group and the myriad factors influencing recipient health status does not allow for truly direct correlation between PDL changes and health outcomes.