Colorado Medicaid Preferred Drug List Program

Annual Report

January 1, 2008 – December 31, 2008

Prepared by the Colorado Department of Health Care Policy and Financing

September 2009

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Executive Summary

Background

In January of 2007, the Governor of Colorado signed an executive order to implement a Preferred Drug List (PDL) for Colorado Medicaid. Since that time, the Department of Health Care Policy & Financing (Department) began creating a PDL with the intention to promote clinically appropriate utilization of pharmaceuticals in a cost-effective manner. The current PDL has been developed based on safety, effectiveness, and clinical outcomes from classes of medications where there are multiple drug alternatives available and supplemental rebates from drug companies, allowing Colorado the ability to provide medications at the lowest possible costs. Rules for the PDL were presented to the Medical Services Board over several months in the second half of 2007. As required in the PDL rules, this report serves to publicly post an estimate of cost savings generated by the PDL program.

PDL Program Process Overview

The PDL controls increases to pharmacy benefit expenditures by encouraging prescribers to utilize safe and efficacious medications, which are more cost effective compared to their competitors. Prescriptions for Preferred Drugs are reimbursed immediately upon submission, whereas Non-preferred Drugs require prior authorization (PA) for coverage, which can be obtained by calling or faxing the Prior Authorization Helpdesk through the state's fiscal agent. The PA process is utilized to manage access to medications with safety issues, abuse potential and public health concerns, while ensuring that the prescribing is medically appropriate. Under the PDL, Medicaid clients continue to have access to all the drugs required under federal law (including the medications covered prior to the PDL's inception).

The Pharmacy and Therapeutics (P&T) Committee is an advisory board, which was set up pursuant to 10 C.C.R. 2505-10, Section 8.800.17 to perform reviews and make recommendations to facilitate the development and maintenance of the PDL. The P&T Committee is a group of actively practicing physicians, pharmacists, and client representatives that provide expertise in diverse areas such as mental health, pediatric medicine, health care consumer advocacy, drug use review, and pharmacology. The P&T Committee reviews drug information to make recommendations to the Department regarding the comparative safety and effectiveness of medications within a therapeutic drug class (without regard to cost). The P&T Committee meets in a public forum quarterly and public notice of the meeting time and agenda is posted at least 30 days prior to each meeting.

The recommendations of the P&T Committee on safety and effectiveness are then considered by the Department with respect to cost effectiveness looking at potential savings for products

considered equivalent in safety and effectiveness. This is achieved through generic drug utilization and collection of manufacturer submitted supplemental rebates. Department suggestions for the PDL are then presented to the Medicaid Director for determination of Preferred Drug or Non-preferred Drug status. After the Medicaid Director designates a drug as Non-preferred, the Department then refers that drug to the Drug Utilization Review (DUR) Board for recommendations on prior authorization criteria.

Prior authorizations are set up by information exchange between the Prior Authorization Helpdesk and the authorizing prescriber. This exchange can be processed by phone call or by fax submittal. If a client is found to have met the predetermined PA criteria, then the PA is approved by the Helpdesk staff. In some cases, issues of medical necessity outside of the PA criteria are appealed to the Department for review. All requests for PA are reviewed and answered within 24 hours from receipt. The Prior Authorization Helpdesk can also authorize an emergency seventy-two hour supply of a drug in instances where the prescriber cannot be contacted to set up the necessary PA.

PDL Benefit Overview

The positive effects of the Colorado Medicaid PDL are far-reaching. In the first 11 months after its inception, it is estimated that the PDL saved over $4 million in cost avoidance over nine selected drug classes. By incorporating the Drug Effectiveness Review Project from the Oregon Evidence-based Practice Center and two expert panels (Pharmacy &Therapeutics Committee and Drug Utilization Review Board) the PDL selections are making the Colorado Medicaid Fee-for-Service Pharmacy Benefit increasingly more efficient and evidence-based.

Colorado Medicaid PDL Program

What is a Preferred Drug List (PDL)?

A PDL is a tool to manage the price increase in drug expenditures for state Medicaid programs while also keeping safe, effective, and medically necessary medications available to clients. It is a listing of clinically effective medications for which the Medicaid Fee-for-Service Program allows coverage without prior authorization. These medications are selected as Preferred Drugs within a given therapeutic drug class. The Non-preferred Drugs are still available as covered pharmacy benefits once prior authorization is obtained by the prescriber. For drugs belonging to therapeutic classes not addressed by the PDL, coverage is determined by the Colorado Department of Health Care Policy and Financing and is primarily unrestricted.

By establishing and maintaining a PDL, a Medicaid Fee-for-Service program is able to collect supplemental rebates from pharmaceutical manufacturers for brand name drugs. This helps to ensure that the program can provide high quality medication at the lowest possible costs. Another benefit of the PDL on cost savings is that in many cases it encourages the prescribing of generic medications when clinically appropriate.

Under PDL programs, Medicaid clients retain access to all of the drugs previously covered (per requirements determined by federal law). By increasing the utilization of safe, clinically effective, and cost effective preferred drugs, the state Medicaid programs have some control over the rising cost of medications.

Pharmacy and Therapeutics Committee (P&T Committee)

In order to establish a PDL, states create a Pharmacy and Therapeutics (P&T) Committee. Although the exact duties of P&T Committees vary state to state, the P&T Committees are usually responsible for comparing drugs on a clinical basis and recommending which drugs should be preferred agents on the PDL. The Pharmacy and Therapeutics Committee typically consists of medical professionals who review evidence-based clinical data to make their recommendation.

The Colorado P&T Committee was created pursuant to Executive Order D004-07 to serve as an advisory board to the Department by performing reviews and making clinical recommendations (based on drug safety and efficacy) which facilitate the development and maintenance of the PDL. The P&T Committee also considers public comments and testimony related to the drug classes being reviewed or other PDL-related agenda items. At least 30 days prior to the meeting, the Department will post a meeting agenda inviting public participation through comments submitted to the Department or presentation at the P&T Committee meeting. All meetings are open to the public. If circumstances require an executive session be held pursuant to state or federal law, it must be conducted after conclusion of the open meeting.

The P&T Committee consists of 7 physicians, 4 pharmacists and 2 client representatives, who are appointed by the Department's Executive Director. The physicians must include: one physician who specializes in the practice of psychiatry; one physician who specializes in the practice of pediatrics; one physician who specializes in the treatment of clients with disabilities; and four physicians from any other medical specialty. Each physician and pharmacist must be licensed and actively practicing in the state of Colorado while a member of the P&T Committee. Candidates for P&T Committee positions are required to disclose any conflicts of interest before they can be appointed as members. The members are also required at the beginning of any meeting to disclose any conflicts of interest, which could interfere with their ability to perform P&T Committee duties objectively.

Colorado Medicaid P&T Committee Members

November 2007 – December 2008

- Michael H. Allen, M.D. (Chairperson)
- Patricia M. Lanius, R.Ph.
- Barry Martin, M.D.
- Michael F. McGuire, MPA
- Linda L. Mulka, M.D.
- Mark H. Pearlman, M.D
- Robert L. Page II, Pharm.D., BCPS, FASCP, CGP

- Beth Chester, PharmD, BCPS
- Thomas Reiley, MD, MHS-via phone
- Kyle Mills, PharmD, BCPS
- Tamara Chambless, MD
- Dale Reid, MSN, APN
- Ricardo Velásquez, MD

Colorado Medicaid P&T Committee History

The P&T Committee held its first meeting on December 4th, 2007. Upon the approval of Colorado State Plan Amendment (SPA) 07-002 by the Centers for Medicare & Medicaid Services (CMS), the Department was authorized to initiate their first drug class for the Colorado PDL. The first class on the PDL was the Proton Pump Inhibitors (PPIs). Effective February 1, 2008, Nexium capsules, Prevacid capsules and Prevacid solutabs were considered Preferred Drugs on the PDL. The P&T Committee met monthly for the first five months of its existence before going to a quarterly meeting schedule in July of 2008. They reviewed a total of 11 drug classes for their addition to the Colorado PDL during the period of December 2007 – December 2008.

Cost Effectiveness Review

Following a P&T Committee meeting, the Pharmacy Benefit Section of the Department compiles the safety and effectiveness recommendations of the P&T Committee and begins to analyze the P&T Committee recommendations along with utilization and safety data. It is at this point that the manufacturer submitted supplemental rebate offers become a consideration. While manufacturers are mandated to give a federal rebate on all drugs covered by a state Medicaid program, one of the biggest savings of a PDL is the potential for manufacturers to supply an additional or "supplemental" rebate in exchange for Preferred Drug status on the PDL. Comparing drug class market-share and current drug costs, the Department is able to determine potential cost savings that may be obtained from the recommendations of the P&T Committee. Taking into account the total patients that would be affected and clinical recommendations from the P&T Committee; the Department presents the results of its analysis to the Medical Director for the determination of Preferred Drug status. The Preferred Drug selection must then meet the approval of the Medicaid Director and the Executive Director. Once the Preferred Drugs have been selected, the Pharmacy Benefits section of the Department begins to evaluate the Non-preferred Drugs for prior authorization criteria.

The Prior Authorization Process

In order for a Medicaid client to receive a Non-preferred Drug, the client's prescriber must submit a request for PA. This request can be submitted either via phone or by fax and it gets processed through the Department's Prior Authorization Helpdesk. The Prior Authorization Helpdesk is available for questions or submissions 24 hours-a-day, seven days-a-week. The submitted requests give background information with respect to the client's medical necessity for a Non-preferred Drug. If the request fulfills the PA criteria, the PA is approved and the client is

allowed coverage for the requested medication. If the criteria are not met, the prescriber is allowed to re-submit with updated information, or appeal the decision to the Department's Pharmacy Benefit Section for further review.

Each request is processed within 24 hours, and most phone requests are given the approval/denial decision immediately upon submission. For emergency situations where a Non-preferred Drug is needed and the prescriber is not available to request the required PA, the client's pharmacy can get approval to provide an emergency 72-hour supply of medication. Following the processing of a PA, both the client and the prescriber are notified by mail or fax of the decision to approve or deny.

The established PA criteria generally fall into one of five categories: (1) treatment failure with one/two preferred product(s); (2) drug allergy to the Preferred Drug(s); (3) contraindication to therapy with the Preferred Drug(s); (4) clinical guidelines for safety or monitoring have been established; and occasionally (5) the client is stable on a Non-preferred Drug and therapeutic switch would be detrimental to that client. Specific PA criteria can be set up for certain high risk medications to ensure appropriate prescribing/ monitoring is taking place. In some drug classes, clients stable on a Non-preferred Drug are authorized to continue taking that medication after its class is added to the PDL. This is referred to as "grandfathering".

To establish appropriate PA criteria, the Pharmacy Benefit Section of the Department takes the list of Non-preferred Drugs and considers the above criteria with respect to each given drug. A list of recommended criteria is established and then presented to the Drug Utilization Review (DUR) Board.

Drug Utilization Review (DUR) Board

The DUR Board serves in an advisory capacity to the Department and makes recommendations regarding issues of drug utilization, provider education interventions, and application of standards. The DUR Board meets once quarterly. The DUR Board consists of nine members appointed by the Executive Director; four physicians, four pharmacists licensed and actively practicing in Colorado, and one non-voting pharmaceutical industry representative. The quarterly meetings have a regular session, which is open to the public and an executive session, which must be a closed session to conduct review of selected client profiles. Agenda item additions and requests to present at the meeting must be received and approved by the Department prior to the day of the meeting.

The DUR Board also recommends the prior authorization criteria for drugs with special prescribing guidelines as well as the prior authorization criteria for Non-preferred Drugs.

Colorado Medicaid DUR Board Members

April 2007 – March 2008

- Robert McCartney, MD
- James Regan, MD

- Terrie Sajbel, PharmD
- James 'Rick' Kant, RPh
- Jeff Almony, MD
- Robert Lee Page II, PharmD
- Mary Newell, RPh
- Edra Weiss, MD
- Kristen Andrews, PhRMA Representative

All PA criteria recommendations and approvals from the DUR Board meeting are then presented to the Department Medical Director for final approval. When final approval is obtained the PA criteria are updated in the Appendix P. This publicly posted document contains all of the Colorado Medical Assistance Program Prior Authorization Procedures and Criteria for Physicians and Pharmacists. It lists the categories of covered and non-covered pharmaceuticals and outlines the process for submitting the Prior Authorization Request.

Community Outreach

In order for a PDL to be a success, it is essential that the various stakeholders involved support the process. Public information and feedback was an important part of the overall PDL planning. In an effort to obtain positive and negative feedback as well as to gain public support for the program various members of the Department were active in traveling throughout the state, speaking at various public functions and conducting "town hall meetings". Meetings were held in Denver, Colorado Springs, Greeley, Grand Junction, Montrose, Durango, Pueblo and Fort Morgan in an effort to cover the entire state. At each public meeting, a high level overview of the PDL program and prior authorization process was presented in a forum open to public discussion. The Department contacted various advocacy groups and interested parties to stimulate comments at the meetings and/or written comments. An additional meeting was held with area pharmaceutical manufacturer representatives to discuss their concerns and involvement in the PDL process. Once the PDL was established, the Department began informing Medicaid providers on PDL issues and updates via the Provider Bulletin, which is distributed among all registered Medicaid providers. This outreach provided a voice for the community in the PDL process, and it allowed the Department an opportunity to address public concerns and create a more effective process.

Provisions to Protect Vulnerable Clients

In an attempt to protect the patients most vulnerable to PDL related therapy changes in our population, provisions were written into the Department's rules. Pursuant to 10 CCR 2505-10, Section 8.800.16.G, a drug moratorium was placed on six drug classes determined to represent highly critical disease states. Included in the list are: (1) atypical and typical antipsychotic drugs; (2) drugs used for the treatment of HIV/AIDS; (3) anticonvulsant drugs; (4) immunosuppressants; (5) drugs used for the treatment of hemophilia; and (6) drugs used for the treatment of cancer. This drug moratorium protected high risk clients from drug therapy changes until the Department was able to implement its Global PA program. The original moratorium

lasted through December 31, 2008. At that point it was revised to remove both the anticonvulsant and immunosuppressant categories and to extend the date until December 31, 2009.

The "Global PA" program provides an opportunity for a prescriber to exempt selected high risk clients from all prior authorization criteria for Non-preferred Drugs, as well as, for non-PDL drugs with prior authorization criteria. This program is aimed to help our most vulnerable clients. In order to qualify, a prescriber must state that the client has a focal point of care, is at high risk for drug-drug interactions, and has one of the following diagnosis: HIV/AIDS; severe chronic schizophrenia or severe bipolar disorder; traumatic brain injury; or developmental disability. The registration process for this program is very simple, only requiring the submission of a one page form indicating that the eligibility requirements are met.

Contractors Involved in the PDL Process

Prior to the establishment of the Colorado PDL, at least 44 other states had indicated their participation in a PDL. The multitude of predecessors developed their PDLs in a variety of different ways. Two popular options are: to contract with a Pharmacy Benefit Manager (PBM) to administer the PDL; and/or to join a purchasing pool, which represents multiple states and handles manufacturer rebate negotiations for the group as a whole.

Following extensive research, it was determined that several factors opposed the contracting of a PBM. Researched showed that several states paid over $800,000 per year for a PBM, which would be a similar cost to Colorado. Additionally, Colorado could have lost some control over the selection of Preferred Drugs with a PBM and would have had to wait for approval from the Centers for Medicare and Medicaid Services (CMS) before contracting with the PBM, which would have delayed the implementation of the PDL.

The purchasing pool option could offer supplemental rebate negotiation along with increased purchasing power afforded by the other states in the pool. It could also lessen the personnel needed to handle rebate agreements. For similar cost issues as stated in the PBM argument and the issue of PDL delay while waiting for CMS and purchasing pool approval, the Department selected to manage its own rebate negotiation. It was felt that our state's purchasing power might be too small to gain approval of the other pool members, and also that our specific needs in terms of therapeutic classes for savings could be significantly different from many of the larger states driving the purchasing pools. In addition, it was felt that in highly competitive therapeutic classes, many manufacturers would compete for preferred drug status independent of purchasing pool status.

Although the determination was made that purchasing pools and PBM contracts were not cost effective for the Colorado Medicaid program, there were contractors that specialized in clinical drug information and P&T Committee assistance that could bring in experience and efficiency to the new program.

PDL and P&T Committee Support - Health Information Designs (HID)

HID is an over 30 year old company that specializes in the conversion of drug data and clinical pharmaceutical information into tools that can be used to solve the issues facing the physicians, pharmacists, and drug benefit program administrators in the 21st century. Their vast experience in PDL and P&T Committee management made them a key factor in the establishment of the Colorado Medicaid PDL. HID offers recommendations for: PDL inclusion/exclusion of drugs; which drugs should be considered; projected cost savings of PDL additions; new drug information; clinical and informational support; and P&T Committee meeting support. Especially important is their experience in PDL management, and how similar PDL developments have been effective or ineffective in other states (including ways to earn physician support). Their contracted services were very important in establishing a new PDL with an inexperienced state such as Colorado.

Clinical Resources - Oregon Health & Science University's Drug Effectiveness Review Project (DERP)

The DERP project originated when the state of Oregon was creating its PDL. The state of Oregon collaborated with the Oregon Evidence-based Practice Center (EPC) to produce systematic reviews of their drug classes for effectiveness. The idea was to consider drug effectiveness first and then make decisions regarding cost. Idaho and Washington had an interest in this evidence-based approach toward a PDL, so the three states decided to collaborate with the EPC. Eventually, the efforts were expanded to a national level, and additional states and non-profit entities joined DERP as well.

The benefits that DERP provides for a PDL program solidify P&T Committee decisions by providing comprehensive, updated and unbiased systematic reviews regarding drug effectiveness and safety. When a state becomes a member of the DERP project, they obtain the ability to help select the drug classes for review, and they help to decide when updates are needed to existing reports. The state representatives for the DERP project are able to interact directly with the authors of individual reviews, proposing key questions for the review and submitting comments that guide the review. In this respect, all members have an equal voice in determining where the efforts are focused. Furthermore, many reviews also have summary documents to aid individual P&T Committees with drug class overviews.

Clinical Outcomes

A couple of clinical issues were identified that could be addressed by the PDL, where it was determined that inappropriate prescribing was causing excessive expenditures, specifically in the long-acting oral opioid class and the respiratory inhalant class. The efforts taken to control inappropriate prescribing of respiratory inhalants may have resulted in reduced supplemental rebates taken in that category, but it was successful in reducing the prescribing for non-approved indications. While future efforts will remain to concentrate on clinically appropriate, FDA approved prescribing, there is room for additional savings in that class upon further review. The

efforts to control overprescribing/inappropriate prescribing in the long-acting oral opioids class had negligible effect on overall costs (due to our grandfathering policy for patients stabilized on the Non-preferred drug), but they showed benefits in clinical outcomes (fewer overall claims), appropriate utilization, and will have an effect on future expenditures by encouraging the use of more cost effective alternatives.

The clinical outcomes data in Figures 1 and 2 provided a comparison of the incidence and cost of claims for varying healthcare settings after the implementation of the drug class. The control group includes clients stabilized on the Preferred drug prior to implementation, as well as those who remain on the Non-preferred drug which they had been stabilized on (via grandfathering PA). The switched group data could contain any client taking this drug class who was switched following PDL implementation. It is useful to verify that the PDL is not causing an additional burden in other healthcare expenditures.

Figure 1

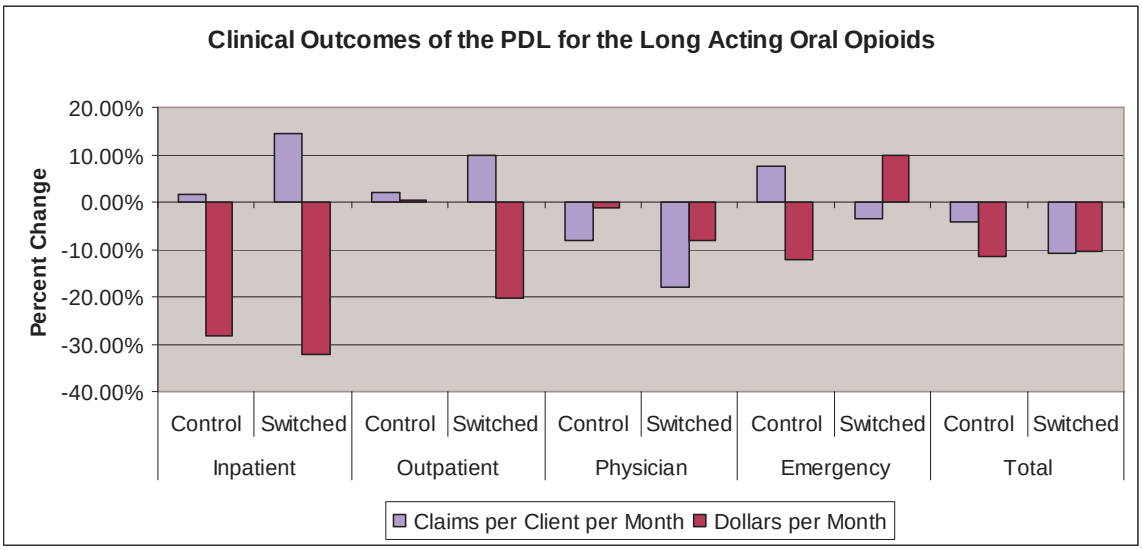
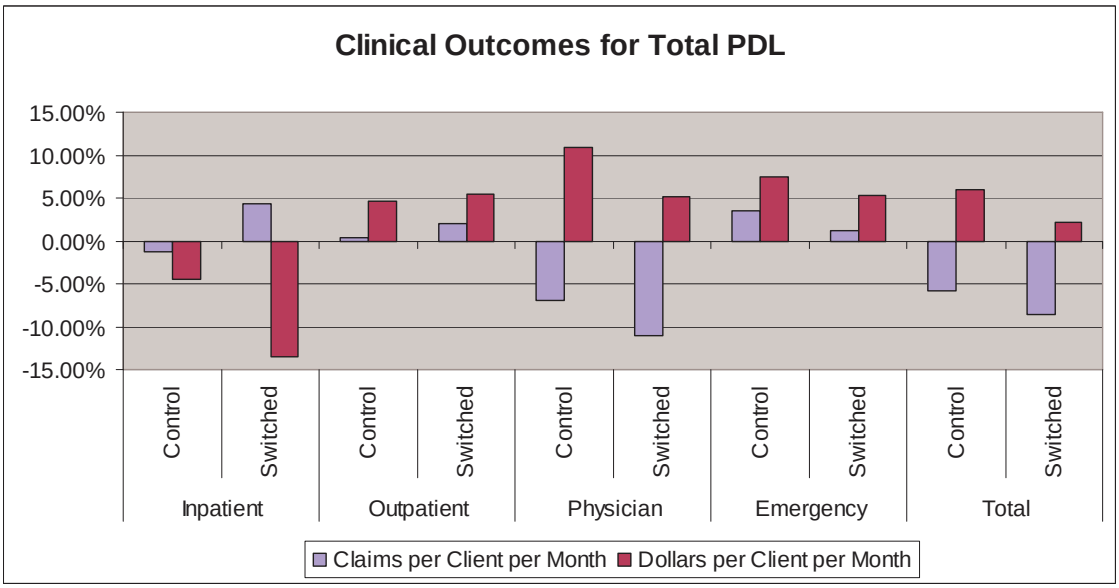


Figure 2



Costs of PDL Implementation

The PDL implementation was not without expense. In all, three full-time positions were added to the Department to accommodate the additional workload of the PDL process. The cost of adding those positions along with their benefits was $341,471 over three different fiscal years to cover the preparation, establishment and implementation for the first year of the PDL. There was also an initial, one-time cost to implement the PDL within the pharmacy claims portion of the Medicaid Management Information System (MMIS). The cost for this project was originally estimated to be $170,371; however, the project was accomplished at a substantial savings for only $57,866. The current MMIS contract allows for the necessary system revisions and quarterly drug class updates to be administered within the contract's fixed costs. A common cost factor among other PDL programs is related to the increased cost for PA processing. In the case of the Colorado PDL, a majority of the PA costs were managed within the existing appropriation for Pharmacy Benefit PAs. In an isolated incident following the PDL's July 2008 implementation, the number of PAs exceeded the monthly allotment resulting in an additional cost of $12,043. Following the incident, the PA contract was renegotiated to prevent future occurrences. The Department also incurred costs from contracts with HID (who provided P&T Committee services) and with DERP (who provided unbiased information on drug efficacy and safety). A total of the contractor associated costs was $390,520. An estimation of all the costs incurred with starting the PDL and managing it for year one totals $801,900. Looking ahead, an annual cost estimate to continue the PDL would be $306,570.

PDL Associated Costs

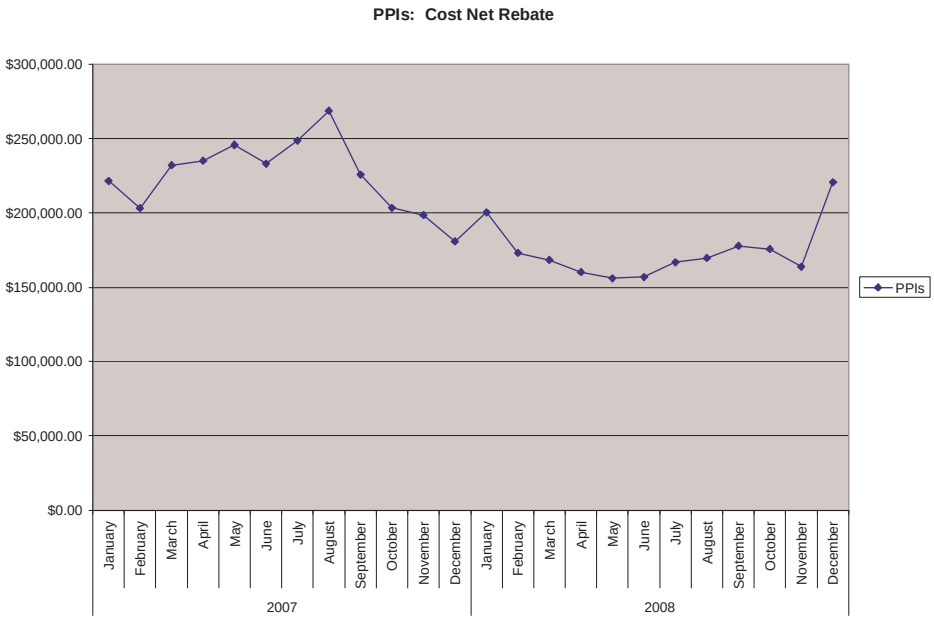
	Implementation and Year One	Ongoing Annual
Staff Salary and Benefits	$341,471	$195,230
Contractors (DERP and HID)	$390,520	$111,340
Actual MMIS Implementation and Prior Authorization Costs	$69,908	$0.00
Totals	$801,900	$306,570

PDL Cost Avoidance

Savings benefits generated from the PDL are derived from both supplemental rebate agreements for brand name drugs with pharmaceutical manufacturers and market shift towards the prescribing of more cost effective brand name and generic Preferred Drugs.

When the PDL was initiated February 1, 2008, immediate savings were realized as shown in Figure 3. The majority of cost savings in this class came through the negotiation of supplemental rebate contracts with PPI manufacturers. Please note that the rebates from a portion of December 2008 claims are not received until 2009. This explains why the figure shows a spike in cost net rebate for that month. Overall for 2008, it is estimated that this class (PPIs) was able to provide over $1.7 million in cost avoidance.

Figure 3



Over the next several months, seven additional drug classes were selected for their cost avoidance potential and were brought before the P&T Committee for review of safety and effectiveness. The classes selected gave the most potential because they had high expenditures and/or generic options. On April 1, 2008, statin drugs (HMG co-A reductase inhibitors) and non-benzodiazepine sedative-hypnotic drugs were both added to the PDL. On July 1, 2008, newer generation anti-histamines, anti-hypertensives, long-acting oral opioids, and respiratory inhalant categories were also added. The final PDL class addition for 2008 was the Attention Deficit Hyperactivity Disorder (ADHD) and Stimulant class, which was added October 1, 2008. Most classes showed an effective shift toward the Preferred Drug in the class (as shown in figures 4, 5,

and 6), which was achieved through effective outreach and education by the Department as well as prescriber and pharmacist support of the PDL process in Colorado.

Figure 4

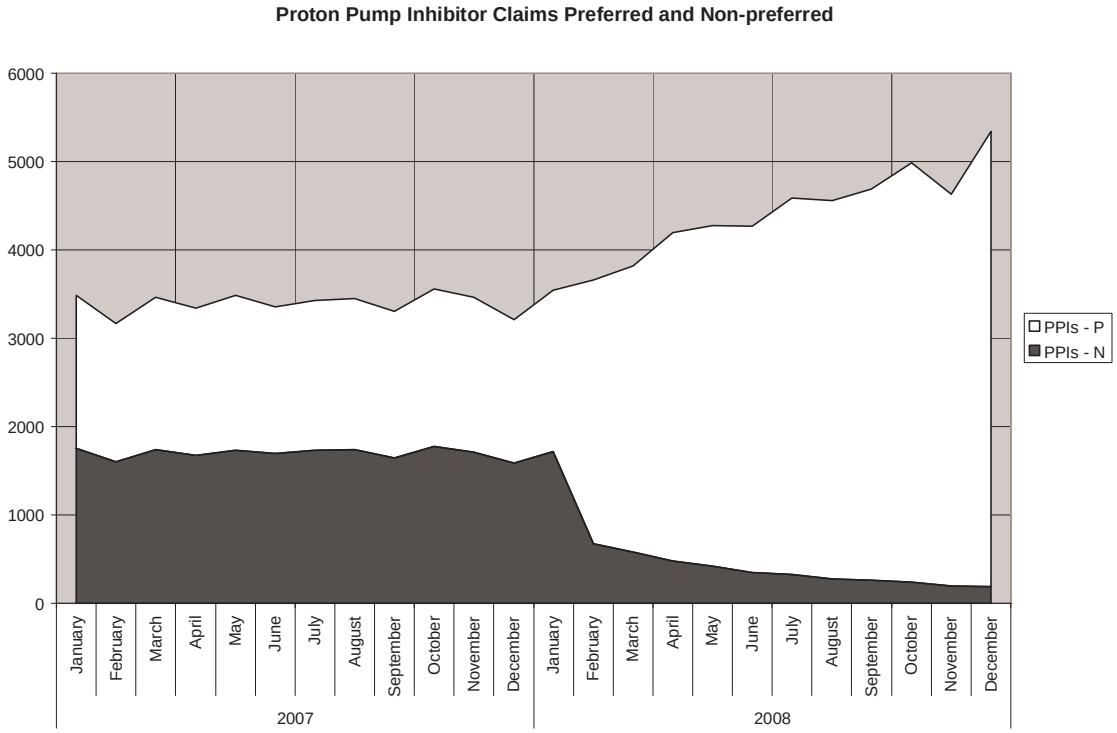


Figure 5

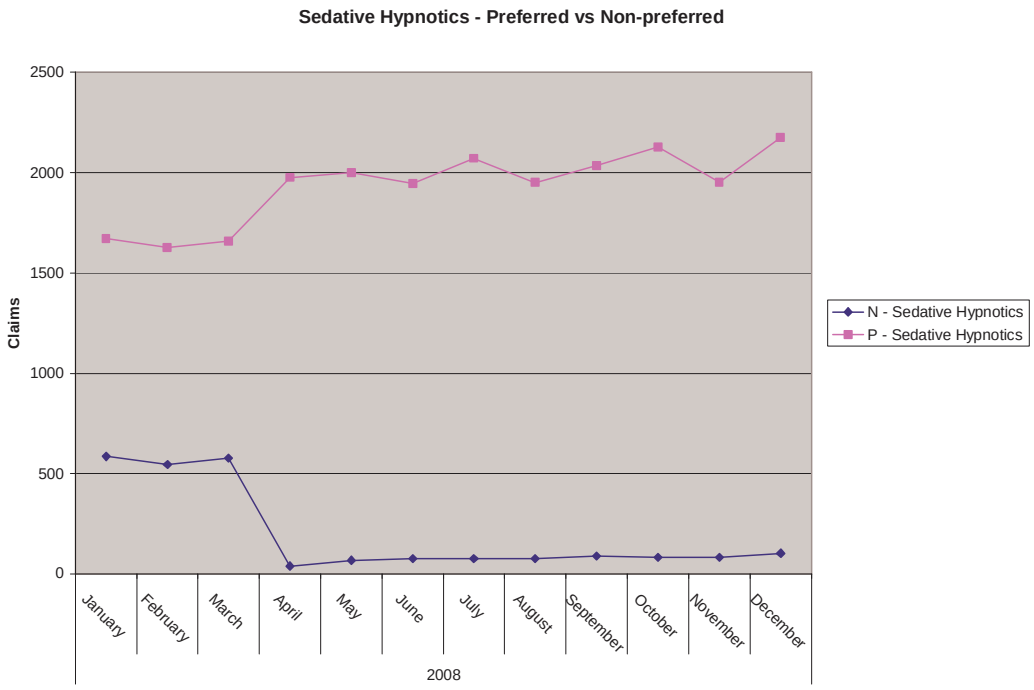
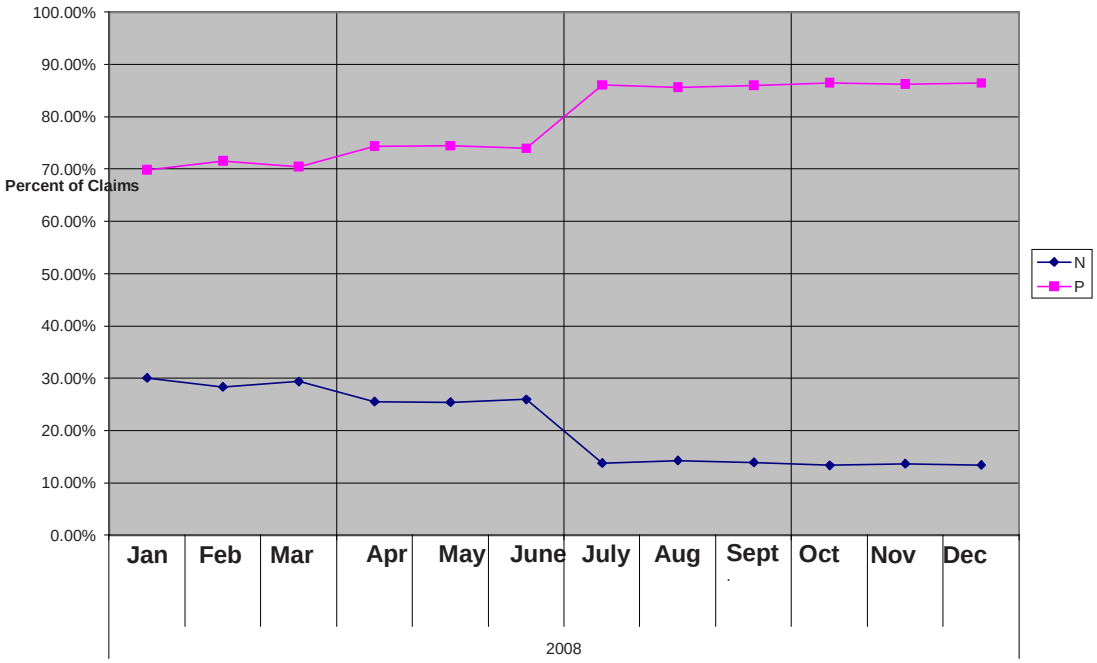


Figure 6

Preferred (P) vs. Non-preferred (N) Claims for 2008 PDL Classes



An examination of Figure 7 shows the current trends in Pharmacy Benefit expenditures. It is important to remember that the sharp decrease which occurred in early January 2006 was due to the implementation of Medicare part D. Starting that January, Medicare beneficiaries became eligible for a Medicare drug benefit which reduced the eligible population for Medicaid Fee-for-Service considerably. Prior to that decrease (and continuing after it) is a rapid increase in expenditures resultant from an increasing Medicaid Fee-for-Service eligible population and the constant rise in drug costs. Figure 8 gives a breakdown of the cost avoidance values for the 2008 PDL drug classes.

Figure 7
Total Pharmacy Expenditure and Expenditure less Rebate

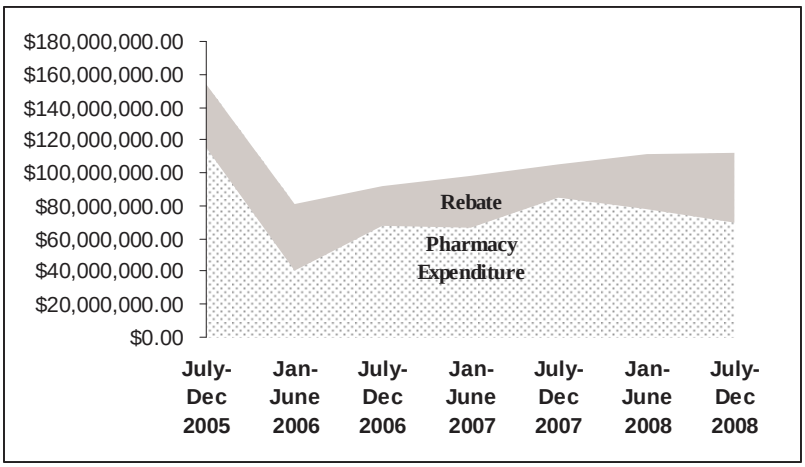
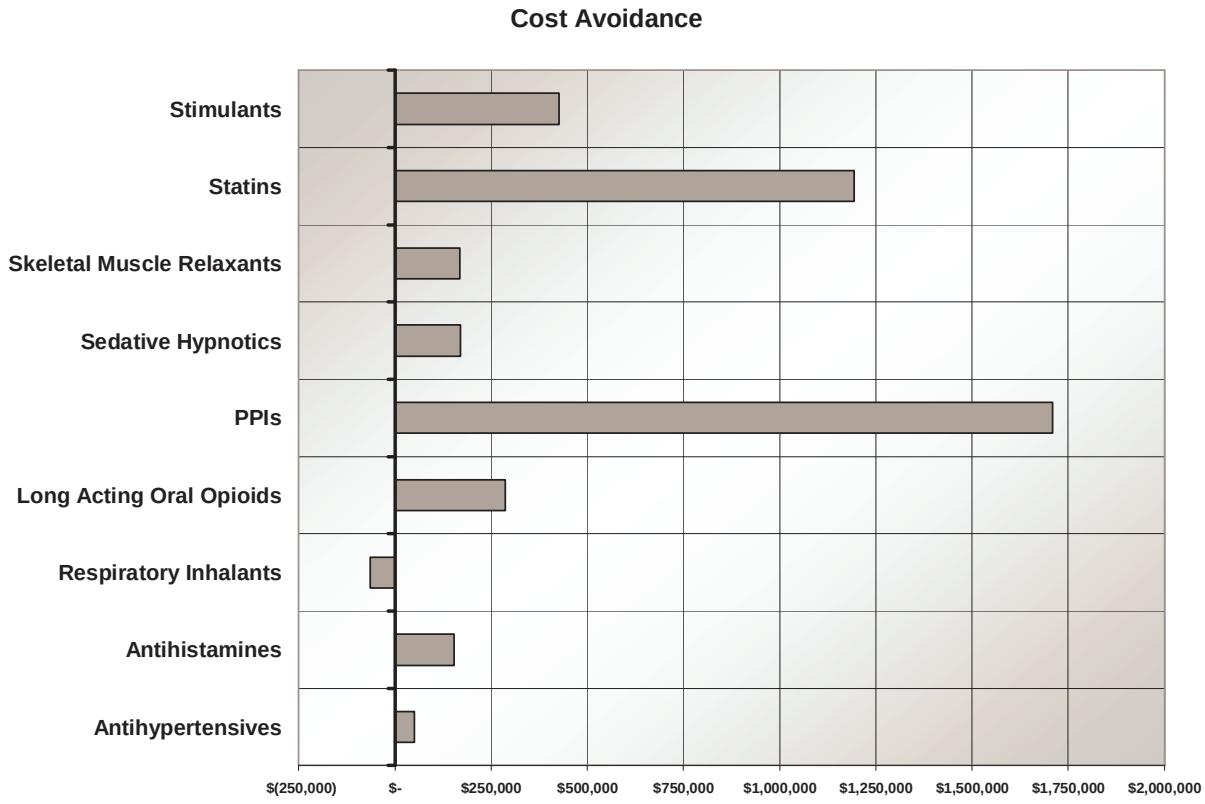


Figure 8


Cost Avoidance
Stimulants
Statins
Skeletal Muscle Relaxants
Sedative Hypnotics
PPIs
Long Acting Oral Opioids
Respiratory Inhalants
Antihistamines
Antihypertensives
$(250,000)
$-
$250,000
$500,000
$750,000
$1,000,000
$1,250,000
$1,500,000
$1,750,000
$2,000,000

Summary

Overall, the cost containment strategies set forth in the PDL process have been a success in cost avoidance without sacrificing clinical efficacy and safety. As a result, the State of Colorado Medicaid program has seen over $4 million in cost avoidance measures for February – December 2008. The results were greatest in the proton pump inhibitors, statins and stimulants classes which accounted for $3.3 million in cost avoidance together. Approximately 77% of the cost avoidance was obtained through supplemental rebate negotiations. This may indicate that additional savings from generic utilization could be pursued. At the same time, it shows the dedication of those involved with the PDL process to maintain safety and clinical effectiveness as the primary objectives and find cost savings only where clinically appropriate. The addition of approximately 12 new classes to the PDL will continue the savings in 2009. Future considerations to save on PDL associated costs include handling the P&T Committee and informational support from within the Department, and adding an automated prior authorization system to increase efficiency and reduce prior authorization processing fees.

Figure 9