

UNIVERSITY OF ARKANSAS
FOR MEDICAL SCIENCES
COLLEGE OF PHARMACY

ARKANSAS MEDICAID EVIDENCE-BASED PRESCRIPTION DRUG PROGRAM (EBR_x)

QUARTERLY REPORT - THIRD QUARTER 2005



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INTRODUCTION

OVERVIEW OF THE EVIDENCE-BASED PRESCRIPTION DRUG PROGRAM

Prescription medications are important tools in treatment and prevention of medical problems. Prescription drug coverage is an optional component of the Medicaid benefit, but Arkansas along with most other state Medicaid programs, extends some coverage to enrollees. Arkansas Medicaid drug expenditures exceeded \$400 million dollars in the last fiscal year. Spending for prescription drugs is budgeted to exceed one-half billion dollars in the current fiscal year. Over the past nine years Medicaid prescription drug spending has grown at a compound annual growth rate exceeding 16%. This growth has been due only in part to increases in the number of Medicaid and ARKids enrollees. The largest contributor to the increase in total medication expenditures has been increases in average medication costs. The medication cost growth rate far exceeds state revenue growth, and jeopardizes continuation of the drug benefit, or other Medicaid benefits at current levels.

The prescription benefits available under Arkansas Medicaid currently provide no limits on the number of prescription medicines per month for individuals under age 18, or in nursing homes. For other adults eligible for full Medicaid benefits, three prescription products per month are covered. With an Extension of Benefits, Medicaid covered individuals may receive up to six medications per month paid for through the Medicaid program. With each prescription dispensed, Medicaid recipients are expected to contribute a minimal co-payment, ranging between fifty cents and three dollars.

The State of Arkansas can not ensure continued access to medications for the Medicaid population if costs continue to rise at their current annual rate. Consequently, the Arkansas Department of Health & Human Services' (DHHS) Division of Medical Services and the University of Arkansas for Medical Sciences (UAMS) College of Pharmacy created the Arkansas Medicaid Evidence-based Prescription Drug Program. The major goals of this program are to create an evidence-based Preferred Drug List, to manage its implementation through a Prior Authorization (P.A.) Call Center operated by the College of Pharmacy, and to track the long term outcomes of these decisions through evaluation of medical and pharmacy claims.

After many months of planning, the program was approved by the state legislature, and authorized by the Governor. A contract between DHHS and the College of Pharmacy was executed, and the program began November 1, 2004. This report details the progress of the program from July 1, 2005 through September 30, 2005.

PROGRESS OF COMMITTEES

DRC & DUCC MEETING UPDATES

DRUG REVIEW COMMITTEE (DRC) UPDATE

The Drug Review Committee held three public meetings in the third quarter of calendar year 2005. During these meetings the committee made recommendations to the DUCC and to DHHS. Drug classes reviewed were: Long-Acting Opioids, ACE inhibitors, and antiplatelet medications. Summary recommendations of those meetings are attached at the end of this report (Appendices A, B, and C). Full meeting minutes are available through EBRx.

DRUG UTILIZATION AND COST COMMITTEE (DUCC) UPDATE

JULY MEETING

The DUCC met in July at the DHHS offices in Little Rock and again by phone and through e-mail correspondences to arrive at our decision. The committee reviewed the DRC recommendations on the Long-Acting Opioid class of medications. The committee opened the sealed supplemental rebate information for the Long-Acting Opioids. After review of the final Medicaid drug costs, the committee considered which products should be recommended as preferred. Because the DRC reported that all five long-acting opioids that were reviewed were efficacious, the DUCC made our recommendations based on the potential financial impact. The DRC did ask that a transdermal product be made available for patients who could not tolerate oral medications. As a result of these recommendations and in consideration of cost and utilization data, the DUCC issued the following recommendations:

After thorough review of the DRC recommendations and the net-net pricing, the following recommendations were made by the DUCC:

1. For all patients with an active malignant disease, any long acting opioid should be available.
2. For all patients with chronic, non-malignant pain, the following products should be preferred: methadone and generic morphine sulfate extended-release tablets
3. Transdermal fentanyl should only be available via SmartPA for patients with chronic, non-malignant pain who are unable to take oral medications and/or who have a PEG tube.

These recommendations for the Long Acting Opioids were then forwarded to DHHS. DHHS elected partial implementation of the recommendation. The Department chose to exempt patients eligible for long term care from this PDL recommendation.

The Long Acting Opioids are scheduled for implementation on October 26, 2005.

AUGUST MEETING

The DUCC met in August at the DHHS offices in Little Rock to consider Angiotensin Converting Enzyme (ACE) Inhibitors. The DRC recommendations covered the use of ACE inhibitors in six disease states. The DRC found few significant differences between the products, but identified two agents as having greater evidence supporting their use in two specific conditions. As a result of these recommendations and in consideration of cost and utilization data, the DUCC issued the following recommendations:

1. Generic captopril tablets and Altace (ramipril) capsules should be preferred.
2. All of other ACE inhibitors should be non-preferred

These recommendations for the ACE inhibitors were then forwarded to DHHS. Again, DHHS elected partial implementation of the evidence-based recommendations. The Department elected to exempt patients who they have identified as being Medicare-Medicaid Dual Eligibles from the PDL recommendation.

The ACE Inhibitor PDL recommendations will become effective November 16, 2005.

SEPTEMBER MEETING

The DUCC communicated through telephone and e-mail to determine that additional information was required prior to a recommendation on the newer antiplatelet agents. This drug class review was limited to the FDA approved uses of the newer antiplatelet products. The DRC recommendations covered the use of the newer antiplatelet agents for four different disease states.

Analysis of Medicaid claims data by EBRx revealed that the majority of the 8600 patients receiving these medicines were over age 65 and therefore eligible for Medicare Part D benefits. Of the 3000 patients less than age 65, only 2000 had medical diagnoses that supported use of the newer antiplatelet agents. These findings imply that as many as one third of the patients using these expensive agents may be receiving these medications without an appropriate indication

The average annual per patient spending for these medications is approximately \$500. By naming these agents as preferred drugs only within their approved indications, Medicaid drug costs could be reduced by approximately \$500,000 annually. This savings would come exclusively from appropriate utilization and not from supplemental rebates.

This information was presented to Arkansas Medicaid pharmacy officials. At this time, DHHS has taken no action on this class of medications.

No implementation date is scheduled.

FINANCIAL IMPACT OF COMMITTEE'S DECISIONS

COST SAVINGS TO THE STATE BECAUSE OF THE PDL

This report provides estimated cost savings to the State of Arkansas using available claim and rebate data. Please note that the cost savings presented in this section attempt to include the CMS rebates that are a part of all state Medicaid prescription drug programs. The CMS rebate data that was used in the calculation of each of these drug classes comes from the information provided to the DUCC by DHHS.

SECOND GENERATION ANTIHISTAMINES

The second generation antihistamines were fully implemented on March 25, 2005 with loratadine products (tablets, reditabs, and syrups) as the preferred products. In addition, Zyrtec Syrup® and Clarinex Syrup® are available for children ages six to 24 months of age through the SmartPA system. All other second generation antihistamine claims now are denied at the point of sale and must have a prior authorization for Medicaid to cover these medications.

Because the preferred product, loratadine, was a generically available medication that did not offer any supplemental rebates, the cost savings in this category are obtained by moving market share from the more expensive non-sedating antihistamines to the equally effective, less expensive loratadine products.

To standardize the computation of savings among all the classes we will utilize the following method: average net prescription price for the quarter immediately preceding the implementation of that class on the PDL will be multiplied by the actual prescription volume experienced post PDL implementation, finally this amount will be subtracted by the net amount actually spent following the implementation of the PDL. This provides a conservative estimate of savings based on actual prescription volume. From time to time, the average prescription price prior to the PDL implementation will be adjusted to reflect increases in prescription drug prices.

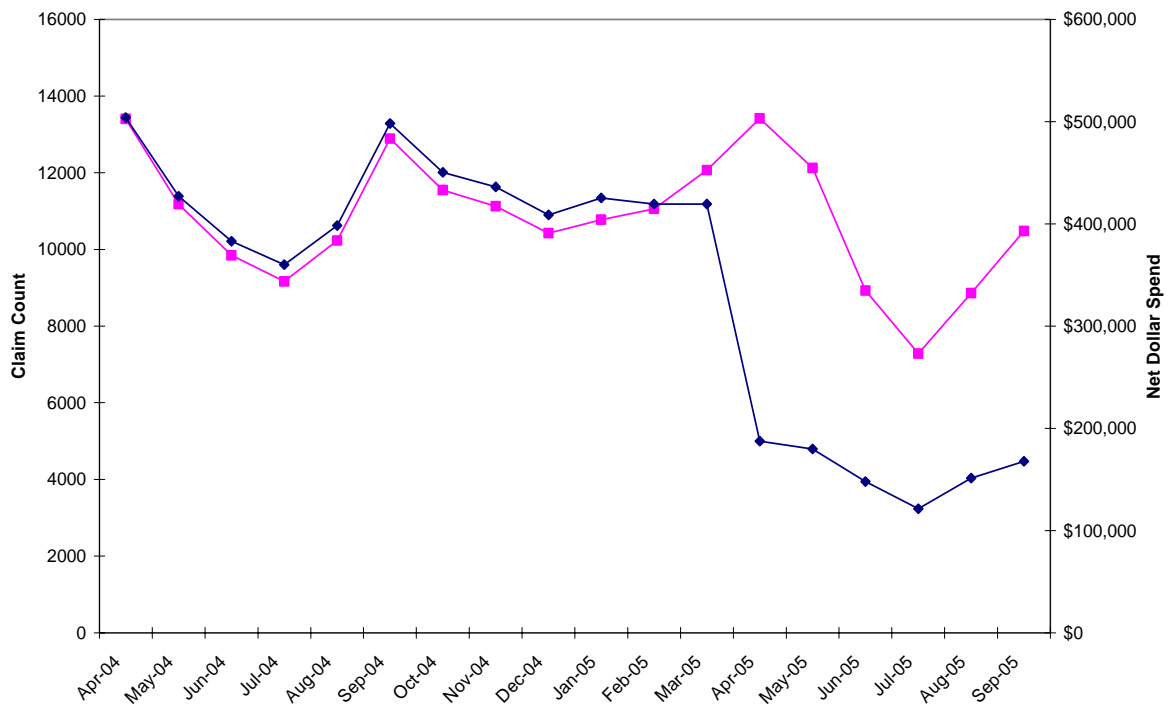
As a result of the PDL implementation, the average cost per non-sedating antihistamine prescription was reduced by 57 percent. The chart on the next page (Chart 1) illustrates prescription volume and net cost trends for non-sedating antihistamines in the Arkansas Medicaid Program over the last 18 months as well as the average cost per prescription. Table 1 demonstrates estimated savings based on the method described above.

TABLE 1

NON SEDATING ANTIHISTAMINE ARKANSAS MEDICAID COSTS

	July	August	September	Total
Actual Volume times pre PDL Cost per Rx	\$283,000	\$344,000	\$407,000	\$1,034,000
Post PDL Net Cost	\$121,000	\$151,000	\$167,000	\$439,000
PDL Savings	\$162,000	\$193,000	\$240,000	\$595,000

**Chart 1
Non Sedating Antihistamine Trends**



PROTON PUMP INHIBITORS

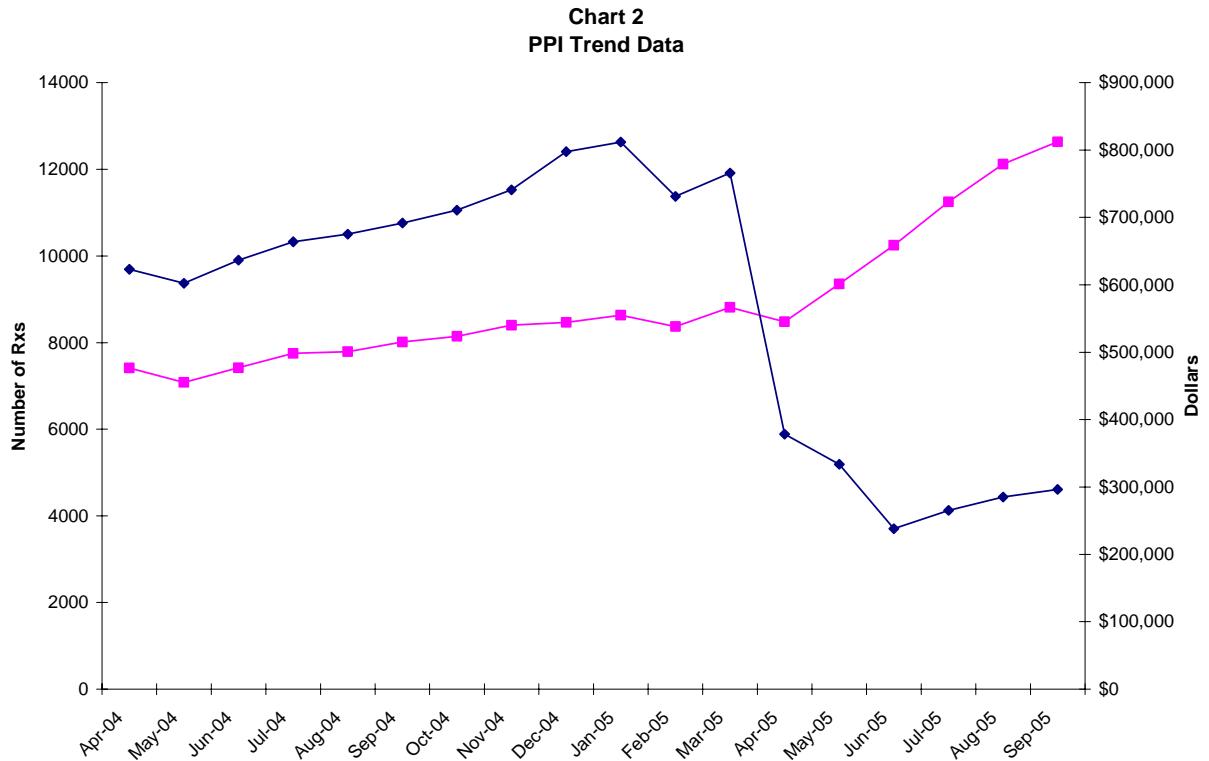
The proton pump inhibitor PDL recommendations became effective May 18, 2005 with Prevacid® (lansoprazole) capsules and Nexium® (esomeprazole) capsules as preferred products. In addition, Prevacid SoluTabs® gained preferred status for children under the age of seven and for patients with nasogastric tubes. All other proton pump inhibitor claims now require a prior authorization for Medicaid to purchase these medications.

Both manufacturers of the preferred products submitted supplemental rebate bids. As a result, cost savings will be from supplemental rebates *and* moving market share to the preferred products. As a result of the PDL implementation, the average cost per proton pump inhibitor prescription was reduced by 74 percent. The chart on the next page (Chart 2) illustrates prescription volume and net cost trends for the proton pump inhibitors in the Arkansas Medicaid Program over the last 18 months as well as the average cost per prescription. Table 2 demonstrates estimated savings based on the method previously described.

TABLE 2

PROTON PUMP INHIBITORS ARKANSAS MEDICAID COSTS

	July	August	September	Total
Actual Volume times pre PDL Cost per Rx	\$1,033,000	\$1,113,000	\$1,161,000	\$3,307,000
Post PDL Net Cost	\$265,000	\$285,000	\$296,000	\$846,000
PDL Savings	\$768,000	\$828,000	\$865,000	\$2,461,000



HMG COENZYME-A REDUCTASE INHIBITORS (THE STATINS)

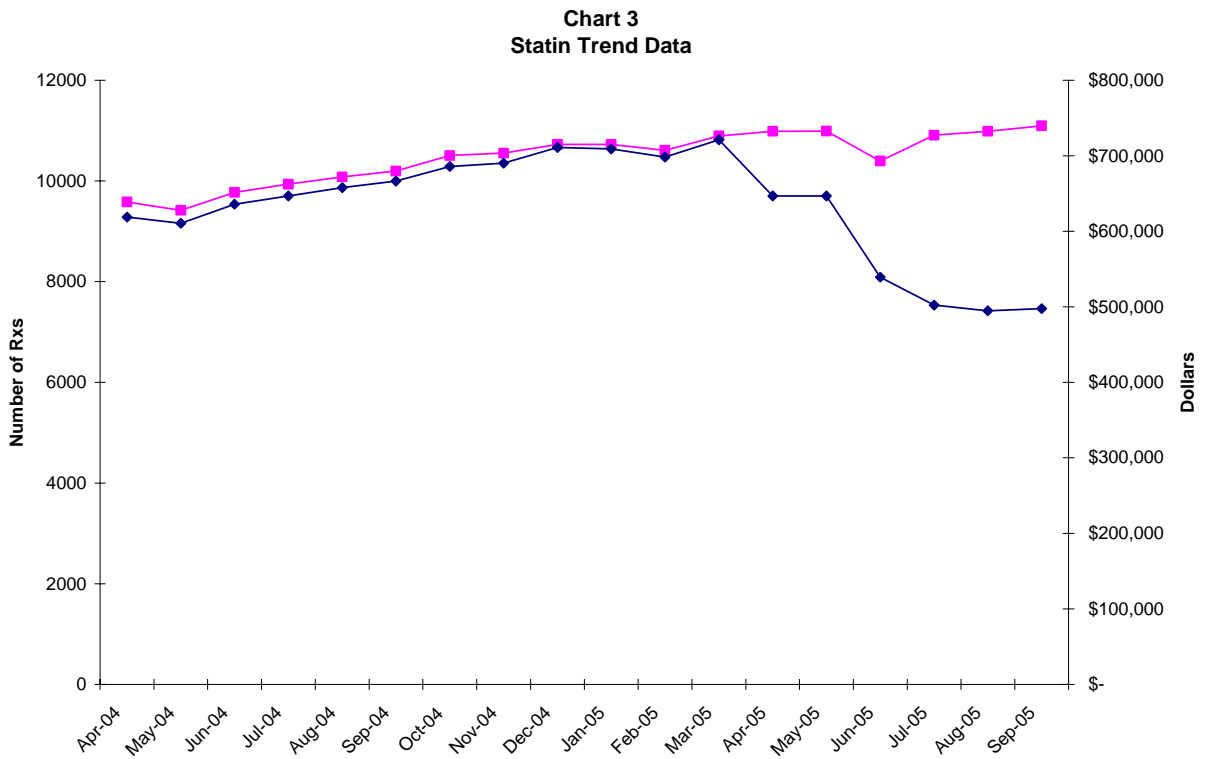
The PDL recommendation for cholesterol reducing products was implemented on June 8, 2005 with Zocor® (simvastatin) tablets being selected as the preferred product. Lipitor® 80mg tabs are also available to patients previously treated with that product who consistently adhered to their treatment regimen. All other statins now are denied at the point of sale and require a prior authorization to authorize Medicaid payment for these medications.

The manufacturer of Zocor provided a supplemental rebate bid. As a result, cost savings will be from supplemental rebates *and* moving market share to the preferred product. As a result of the PDL implementation, the average cost per statin prescription was reduced by 30 percent. The chart on the next page (Chart 3) illustrates prescription volume and net cost trends for the statins in the Arkansas Medicaid Program over the last 18 months as well as the average cost per prescription. Table 3 demonstrates estimated savings based on the method previously described.

TABLE 3

STATINS ARKANSAS MEDICAID COSTS

	July	August	September	Total
Actual Volume times pre PDL Cost per Rx	\$720,000	\$725,000	\$732,000	\$2,177,000
Post PDL Net Cost	\$502,000	\$495,000	\$497,000	\$1,494,000
PDL Savings	\$218,000	\$230,000	\$235,000	\$683,000



CALCIUM CHANNEL BLOCKING AGENTS

The calcium channel blocker recommendations became effective July 12, 2005 with Norvasc® (amlodipine) tablets, Dynacirc CR® (isradipine) tablets, generic nifedipine extended-release tablets, generic verapamil extended-release tablets, and generic diltiazem capsules (AB rated to Dilacor XR only) being selected as the preferred products. All other calcium channel blockers now are denied at the point of sale and require prior authorization for Medicaid coverage of these medications.

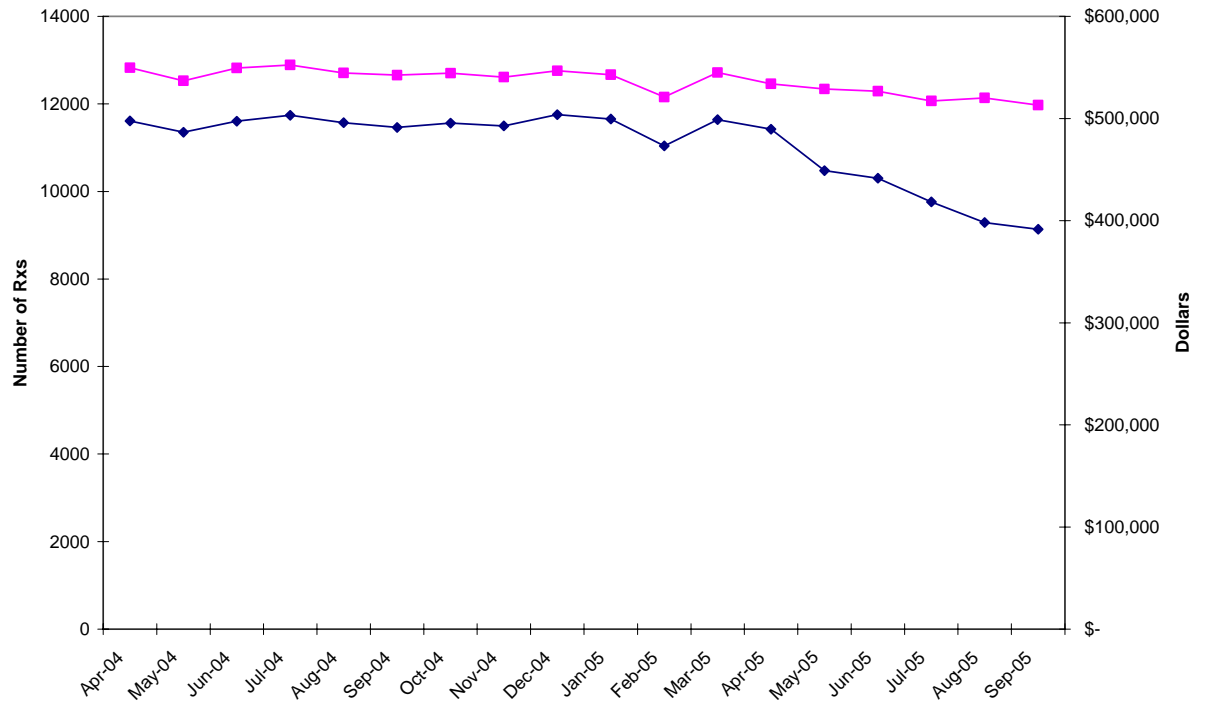
The manufacturer of Norvasc and Dynacirc CR provided supplemental rebate bids. As a result, cost savings will be from supplemental rebates *and* moving market share to the preferred product. As a result of the PDL implementation, the average cost per calcium channel blocker prescription was reduced by 11 percent. The chart on the next page (Charts 4) illustrates prescription volume and net cost trends for calcium channel blockers in the Arkansas Medicaid Program over the last 18 months as well as the average cost per prescription. Table 4 demonstrates estimated savings based on the method previously described.

TABLE 4

CALCIUM CHANNEL BLOCKERS ARKANSAS MEDICAID COSTS

	July	August	September	Total
Actual Volume times pre PDL Cost per Rx	\$472,000	\$475,000	\$468,000	\$1,415,000
Post PDL Net Cost	\$418,000	\$398,000	\$391,000	\$1,207,000
PDL Savings	\$54,000	\$77,000	\$77,000	\$208,000

Chart 4
Calcium Channel Blockers



TOTAL ESTIMATED PDL SAVINGS

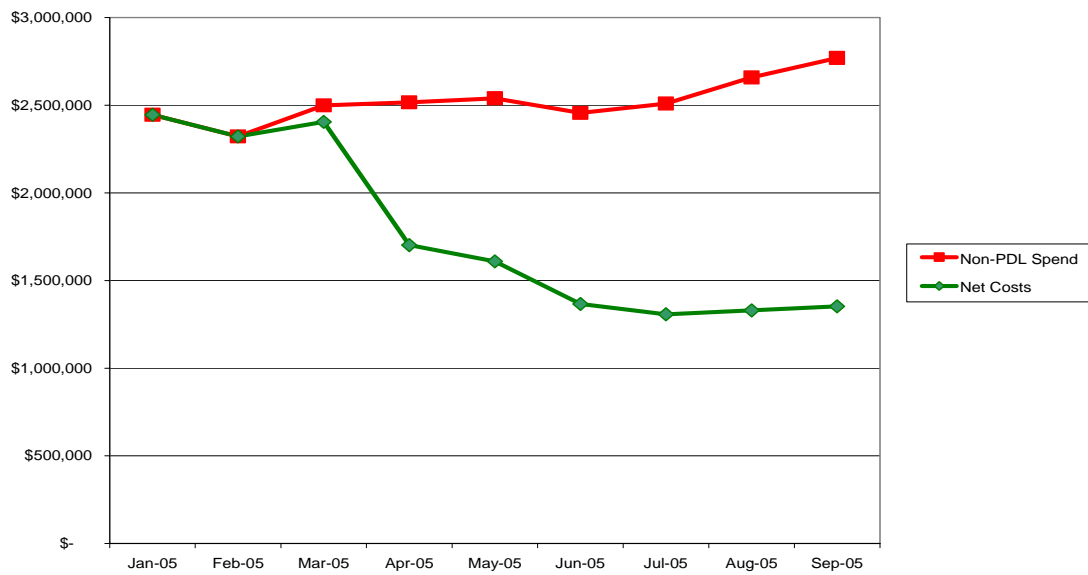
THIRD QUARTER 2005

PRESENTED BY DRUG CLASS AND MONTH

The chart below demonstrates the cost savings by drug class and month for the third quarter of 2005. The estimated total cost savings for the entire third quarter of 2005 is \$3,947,000.

	July	August	September	3Q 2005 Total
Non-Sedating Antihistamines	\$162,000	\$193,000	\$240,000	\$595,000
Proton Pump Inhibitors	\$768,000	\$828,000	\$865,000	\$2,461,000
Statins	\$218,000	\$230,000	\$235,000	\$683,000
Calcium Channel Blockers	\$54,000	\$77,000	\$77,000	\$208,000
				\$3,947,000

Medicaid PDL Costs and Savings



MARKET SHARE IMPACT OF PDL RECOMMENDATIONS

PRESCRIBER AND PATIENT COMPLIANCE WITH PDL SELECTIONS

The success of the PDL depends in large part on participation by prescribers with the recommendations of the Drug Review and Drug Utilization and Cost Committees. Prescribing compliance with the Preferred Drug List is monitored by EBRx. The following table presents data on the percentage of patients receiving a preferred product in each of the therapeutic categories reviewed and implemented to date. This percentage is commonly called market share in the pharmaceutical industry. Optimal outcomes and or cost savings are maximized as market share approaches 100% compliance with the Preferred Drug List recommendations. However, it should be noted that complete compliance with the Preferred Drug List is unlikely as there remains individual variation in response to any medicine.

Market Share of PDL Preferred Agents by Drug Class and Month

2005	Jan	Feb	Mar	Apr	May	June	July	Aug	Sep
NSAs	2.6%*	5.1%	17.6%	93.4%	91.3%	88.0%	87.4%	87.5%	88.0%
PPIs	63.4%	64.0%	64.7%*	67.1%	81.0%	99.8%	99.8%	99.8%	99.8%
Statins	24.1%	24.0%	23.8%	23.9%*	25.6%	62.1%	98.7%	98.6%	98.7%
CCBs	76.8%	76.7%	76.7%	76.8%	76.8%*	76.8%	84.7%	96.1%	95.9%

* indicates month providers were notified of PDL selection for the drug class

Data in bold highlight the month PDL recommendations for the drug class became effective.

Prior Authorization Call Center Statistics

P.A. CALL CENTER OPERATIONS AS A RESULT OF THE PDL

The PDL Call Center approves or denies prior authorization requests from physicians for products that have been placed in non-preferred status. The approval, denial, and appeal of denials are handled by the clinical pharmacists and medical directors of the EBRx Program. The statistics below represent the Call Center's activity for the second quarter 2005, which includes April 1st through June 30th 2005.

PA Call Center Statistics	July 2005	August 2005	September 2005	Total 3Q 2005
Incoming Calls from Healthcare Professionals	837	954	714	2505
Number of SmartPA Tickets Created	846	977	609	2432
Total Number of P.A. Request at the Call Center	442	510	437	1389
Total Number of P.A. Requests Approved at the Call Center	286	355	290	931
Call Center P.A. Approval Percentage	64.7%	69.6%	66.4%	67.0%
Point of Sale SmartPA Requests	1616	1752	2363	5731
Point of Sale SmartPA Approvals	846	1008	1090	2944
Point of Sale SmartPA Approval Percentage	52.4%	57.5%	46.1%	51.4%
Average Call Duration	2 min 48 sec	2 min 40 sec	2 min 49 sec	2 min 46 sec

Budget Update

A GENERAL OVERVIEW OF THE PROGRAM BUDGET

The current budget status for the Arkansas Medicaid Evidence-based Prescription Drug Program is presented below. The second column in the table shows total State Fiscal Year budget allocation, and the third column shows program expenditures for July 2005 through September 2005. There are a number of personnel positions which remain empty; however, if demand arises the program will work within its budget to ensure that it can meet the demand. At the end of the first quarter of SFY 06, the program is approximately \$400,000 under budget from July 1, 2005 through September 30, 2005.

	SFY06 Budget	SFY06 Expenditures To Date <small>(through September 30, 2005)</small>
Personnel –(Salary and Fringes, includes DRC stipends)	\$2,183,719	\$301,558
Miscellaneous – (Supplies, Travel, etc)	\$157,650	\$10,141
Equipment – (computers, phones, furniture, renovation)	\$0	\$0
Indirect Costs	\$1,264,339	\$168,318
TOTAL	\$3,605,708	\$480,017

Provider Outreach

EBRX EFFORTS TO EDUCATE PROVIDERS ON THE PROGRAM

The most challenging aspect of any new program is educating the parties involved about the process. This has been one of the highest priorities for the EBRx Program. Recognizing that there are many stakeholders, we have actively pursued educating physicians, nurses, physician office staff, pharmacists, and pharmaceutical manufactures.

As part of our efforts, we have done live presentations to the following groups:

- Arkansas Foundation for Medical Care – Medicaid Managed Care Conference – Monticello
- Arkansas Foundation for Medical Care – Medicaid Managed Care Conference – Harrison
- Boehringer Ingelheim
- AstraZeneca
- Schering Plough
- Multiple presentations to medical staffs at hospitals throughout the state

Additional outreach efforts are planned for the upcoming quarter, including meetings with medical staff at hospitals around the state, talks at AFMC Managed Care Conference, and lectures at Area Health Education Centers around the state.

Data Evaluation

TRACKING OUTCOMES OF THE PDL DECISIONS

One of the most important aspects of the EBRx program is the evaluation of Medicaid data to determine what the long term ramifications of the PDL decisions are. Through the College of Pharmacy's Pharmaceutical Evaluation and Policy (PEP) Division, the Medicaid claims database will be analyzed to determine impact to the Medicaid program, beyond simply the cost of the medications.

Programmers have been hired to help facilitate the evaluation of the data. It is our hope to begin providing some initial outcome data during the last quarter of SFY 06 or early SFY07.

Appendix A

Date: July 18, 2005

Subject: DRC Recommendations to DCC and DHS

To: DHS, DCC, Dean's Office

From: Henry F. Simmons, Jr., MD, Ph.D.
Chairman DRC

At its 07/14/05 meeting, the Drug Review Committee considered the potential toxicity and therapeutic roles of the long acting opioids in the management of patients with chronic pain of non cancer origin.

Based upon the bulk of the best available evidence concerning fentanyl, hydromorphone, methadone, morphine, and oxycodone the Committee concluded the following:

- There is insufficient evidence to conclude in general that one agent is safer or has fewer adverse effects than another.
- There is sufficient evidence to conclude in general that all five agents are efficacious.
- There is insufficient evidence to conclude in general that one agent is more efficacious based upon demographics, comorbidities or adverse drug interactions.

In a discussion of problems that might arise in prescribing the aforementioned five agents, the committee noted the following:

- A transdermal preparation should be available for patients who cannot tolerate oral medication;
- Methadone should be available;
- Elderly patients taking one opioid who have secondary constipation should have an alternative;
- Kadian may pose special problems for patients who are taking H2 blockers or proton pump inhibitors due to potential problems with release of the drug.

Appendix B

Date: August 18, 2005

Subject: DRC Recommendations to DCC and DHS

To: DHS, DCC, Dean's Office

From: Henry F. Simmons, Jr., MD, Ph.D.
Chairman DRC

At its 08/18/05 meeting, the Drug Review Committee considered the potential toxicity and therapeutic roles of the angiotensin converting enzyme inhibitor [ACEIs] class in the management of adult patients with hypertension, recent myocardial infarction, heart failure, diabetic nephropathy, non-diabetic nephropathy, and high cardiovascular risk. [For the purposes of the discussion, high cardiovascular risk was defined as CHD/CVD or a combination of other risk factors for CHD/CVD, such as diabetes, smoking, hyperlipidemia, or hypertension.]

The medications discussed included the following:

Benazepril (Lotensin)
Captopril (Capoten)
Enalapril (Vasotec)
Fosinopril (Monopril)
Lisinopril (Prinivil, Zestril)
Moexepiril (Univasc)
Perindopril (Aceon)
Quinapril (Accupril)
Ramipril (Altace)
Trandolapril (Mavik)

Based upon the bulk of the best available evidence pertaining to the aforementioned drugs the Committee concluded the following:

- There is insufficient evidence to conclude in general that one agent is safer or has fewer adverse effects than another.
- There is sufficient evidence to conclude that all of the listed ACEIs are efficacious for the treatment of hypertension. However, since captopril, enalapril and lisinopril have outcome data, at least one of these three should be available for this indication.
- There is sufficient evidence to conclude that captopril, ramipril, trandolapril and Lisinopril are efficacious for treatment of patients with recent myocardial infarction. However, since the first three have mortality outcome data, at least one of them should be available for this indication.
- There is sufficient evidence to conclude that captopril, enalapril, fosinopril, ramipril and trandolapril are efficacious for the treatment of heart failure outside the setting of recent myocardial infarction. Accordingly, at least one of the five should be available for this indication.
- There is sufficient evidence to conclude that captopril is efficacious for the treatment of diabetic nephropathy in type I diabetics. It should be available for

this indication.

- There is sufficient evidence to conclude that benazepril, captopril, enalapril and ramipril are efficacious for the treatment of non diabetic nephropathy. However, since the evidence is strongest for benazepril and ramipril, at least one of these two agents should be available.
- There is sufficient evidence to conclude that enalapril, perindopril, quinapril and ramipril are efficacious for patients at high risk of cardiovascular disease as defined above. However, since the evidence is strongest for perindopril and ramipril, at least one of these two should be available for this indication.
- There is insufficient evidence to conclude in general that one agent out of the group is either more efficacious or associated with more adverse effects based upon demographics, comorbidities or adverse drug interactions.

In a discussion of problems that might arise in prescribing the aforementioned five agents, the committee noted the following:

- Some patients might need a drug that could be taken once daily.
- At least two ACEIs should be available in the event that some patients may have an adverse reaction to the first one prescribed.

Appendix C

Date: September 15, 2005

Subject: DRC Recommendations to DCC and DHS

To: DHS, DCC, Dean's Office

From: Henry F. Simmons, Jr., MD, Ph.D.
Chairman DRC

At its 09/15/05 meeting, the Drug Review Committee considered the potential toxicity and therapeutic roles of three antiplatelet drugs in the management of adult patients with acute coronary syndromes, percutaneous coronary intervention, stroke/TIA and symptomatic peripheral vascular disease.

The medications discussed included the following:
Aspirin 25 mg/ extended release dipyridamole 200 mg [ERDP/ASA]
Clopidogrel
Ticlopidine

Based upon the bulk of the best available evidence pertaining to the aforementioned drugs the Committee concluded the following:

There is insufficient evidence to exclude completely any of the agents from therapeutic consideration. However, concerns about the potential for ticlopidine to cause neutropenia warrant extra caution.

There is sufficient evidence to conclude that clopidogrel should be available for the treatment of acute coronary syndromes. There was insufficient data to recommend the use of either ERDP/ASA or ticlopidine for this indication.

There is sufficient evidence to conclude that clopidogrel should be the preferred agent for the treatment of patients undergoing percutaneous coronary interventions. Ticlopidine is also efficacious but has a higher potential for toxicity than clopidogrel.

There is sufficient evidence to conclude that ERDP/ASA should be the preferred agent for treating patients with prior ischemic stroke who have TIA or recurrent stroke. Ticlopidine is also efficacious in that it is superior to aspirin. Clopidogrel is no better than aspirin. However, clopidogrel and ticlopidine should be available for patients who are sensitive to aspirin.

There is sufficient evidence to conclude that clopidogrel should be available for treating patients with symptomatic peripheral vascular disease. There was insufficient data to recommend the use of either ERDP/ASA or ticlopidine for this indication.

Patients who are pregnant or those who are sensitive to aspirin should have access to clopidogrel and ticlopidine. Aside from these two subgroups there is insufficient evidence to conclude in general that one agent is either more efficacious or associated with more adverse effects based upon demographics, comorbidities or adverse drug interactions.