

UNIVERSITY OF ARKANSAS
FOR MEDICAL SCIENCES
COLLEGE OF PHARMACY

ARKANSAS MEDICAID EVIDENCE-BASED PRESCRIPTION DRUG PROGRAM (EBR_x)

QUARTERLY REPORT - FOURTH QUARTER 2005



4301 W. MARKHAM SLOT 522-9
LITTLE ROCK, ARKANSAS 72205
501-526-4200

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 percent. 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 October 1, 2005 through December 31, 2005.

PROGRESS OF COMMITTEES

DRC & DUCC MEETING UPDATES

DRUG REVIEW COMMITTEE (DRC) UPDATE

The Drug Review Committee held three public meetings in the fourth quarter of calendar year 2005. During these meetings the committee made recommendations to the DUCC and to DHHS. Drug classes reviewed were: Anti-migraine 'Triptans', Angiotensin II Receptor Blockers (ARBs), and the Skeletal Muscle Relaxants. 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

OCTOBER MEETING

Triptan migraine treatments were the subject of the October DUCC meeting. At the initial meeting, at DHHS, net cost bids from manufacturers were opened. The DUCC reviewed rebate bids submitted by the manufacturers of Maxalt, Axert, and Relpax. DHHS ruled Axert's bid as excluded for being a late submission. Additionally, the Relpax bid was excluded because of alterations to the contract language. EBRx staff learned that a bid submitted for Imitrex (the market leading product) was submitted, however, this bid was not presented at the DUCC meeting because of a problem with the outside envelope.

Despite the difficulties with the manufacturer bids, a DUCC motion was drafted November 1, 2005 after discussion among the four committee members. The motion was consistent with the DRC physicians' and pharmacists' recommendation (Appendix A), and provided for access to all dosing formulations and two different oral triptan medications without prior authorization. The DUCC motion would have reduced average per unit costs even without manufacturer supplemental rebates. This motion was seconded on November 8, 2005 and forwarded to DHHS.

On November 15, the Medicaid Pharmacy Program Director notified EBRx that DHHS had created their own recommendation for the triptans. EBRx was told that the DHHS Office of Chief Counsel suggests that a product not be given preferred status unless an acceptable supplemental rebate contract was submitted.

As a result, DHHS selected Maxalt and Maxalt MLT (rapidly dissolving tablets) as the sole preferred triptan agent. Other oral triptan products are available by prior authorization only after a documented trial of oral Maxalt in the past year. Injectable Imitrex and nasal spray formulations will also be available by prior authorization.

The Triptan preferred agent is scheduled for implementation on February 7, 2006.

NOVEMBER MEETING

The DUCC met in November at the DHHS offices to consider Angiotensin Receptor Blockers after the DRC Committee meeting. The DRC considered use of the Angiotensin Receptor blockers in five disease states. The DRC found limited data from direct comparisons of the agents to one another. None were considered to have significant safety issues. The DRC was able to make certain recommendations about specific agents in specific medical conditions. The complete DRC recommendation is attached as Appendix B.

The DUCC reviewed net price contract bids from several ARB manufacturers. EBRx staff received a report from the manufacturer of candesartan that they submitted a bid, but this bid was not seen by the DUCC. Candesartan is the one of the products which the DRC specifically stated should be available to patients with congestive heart failure.

The DUCC recommended placing losartan and valsartan on the PDL as preferred agents, and that candesartan be available with SmartPA point of sale prior authorization for patients with a diagnosis of congestive heart failure. DHHS elected to also include as preferred agents the losartan and valsartan products that are combined with the diuretic hydrochlorothiazide (HCTZ).

The Angiotensin Receptor Blocker PDL selections will be effective February 21, 2006.

DECEMBER MEETING

The DUCC acted on the DRC recommendations for Skeletal Muscle Relaxants in December, 2005. The DRC considered that these agents were used to treat two distinct conditions. The first condition, muscle spasm, is an intermittent or relapsing/remitting problem which may be experienced by any person. Muscle spasm may be associated with overuse, injury, or chronic neck or back issues. The second condition, spasticity, is a chronic condition affecting the muscles of individuals with brain or spine injury. Spasticity is associated with constantly increased muscle tone in one or several large groups of muscles. The full DRC recommendation for this class is attached as Appendix C.

No manufacturer rebate bids were presented by DHHS for review among this group of medicines. DHHS informed the DUCC that a bid for Skelaxin was submitted; however it was not presented to the DUCC because of a problem with the outside envelope. All of the agents in this category are available generically with the exception of the highest dose strength of Skelaxin. Considering the DRC findings, the DUCC was able to recommend three agents for the treatment of muscle spasm (chlorzoxazone, cyclobenzaprine, and methocarbamol), and two agents for spasticity (baclofen and tizanidine). The agents for muscle spasticity will approve only for patients with a corresponding diagnosis of a spasticity-related condition. These criteria will ensure easy access to the spasticity treatments for smaller number of patients with this condition, while maintaining appropriate controls on prescription drug cost growth.

One of the Skeletal Muscle Relaxants currently widely used is carisoprodol (Soma). Because of its cost compared to the other agents and because its metabolite has potential for dependency and abuse, carisoprodol will no longer be paid for by Medicaid without Prior Authorization. The EBRx

Prior Authorization Call Center will make outbound phone calls to the prescribers of carisoprodol to alert them of the need to taper their patients from this medication.

The Skeletal Muscle Relaxant PDL recommendation will begin March 20, 2006.

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.

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 inflation that would have occurred in prescription drug prices.

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.

As a result of the PDL implementation, the average cost per non-sedating antihistamine prescription has been reduced by 57 percent. Table 1 demonstrates estimated savings based on the method described above.

TABLE 1

NON SEDATING ANTIHISTAMINE ARKANSAS MEDICAID COSTS

	October	November	December	Total
Actual Volume times pre PDL Cost per Rx	\$416,000	\$383,000	\$343,000	\$1,142,000
Post PDL Net Cost	\$175,000	\$165,000	\$151,000	\$491,000
PDL Savings	\$241,000	\$218,000	\$192,000	\$651,000

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 has been reduced by 74 percent. Table 2 demonstrates estimated savings based on the method previously described.

TABLE 2

PROTON PUMP INHIBITORS ARKANSAS MEDICAID COSTS

	October	November	December	Total
Actual Volume times pre PDL Cost per Rx	\$1,178,000	\$1,232,000	\$1,299,000	\$3,709,000
Post PDL Net Cost	\$303,000	\$316,000	\$339,000	\$958,000
PDL Savings	\$875,000	\$916,000	\$960,000	\$2,461,000

HMG COENZYME-A REDUCTASE INHIBITORS (THE STATINS)

The PDL recommendation for cholesterol reducing ‘statin’ 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 has been reduced by 30 percent. Table 3 demonstrates estimated savings based on the method previously described.

TABLE 3

STATINS ARKANSAS MEDICAID COSTS

	October	November	December	Total
Actual Volume times pre PDL Cost per Rx	\$739,000	\$753,000	\$775,000	\$2,267,000
Post PDL Net Cost	\$503,000	\$503,000	\$533,000	\$1,539,000
PDL Savings	\$236,000	\$250,000	\$242,000	\$728,000

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 products. As a result of the PDL implementation, the average cost per calcium channel blocker prescription has been reduced by 11 percent. Table 4 demonstrates estimated savings based on the method previously described.

TABLE 4

CALCIUM CHANNEL BLOCKERS ARKANSAS MEDICAID COSTS

	October	November	December	Total
Actual Volume times pre PDL Cost per Rx	\$462,000	\$468,000	\$499,000	\$1,429,000
Post PDL Net Cost	\$383,000	\$389,000	\$419,000	\$1,191,000
PDL Savings	\$79,000	\$79,000	\$80,000	\$238,000

BETA BLOCKERS

The beta blocker recommendations became effective October 5, 2005 with generic atenolol, metoprolol tartrate, and propranolol immediate-release being selected as preferred products. Additionally, generic bisoprolol and Toprol XL® (metoprolol succinate) were selected as preferred agents for patients with Congestive Heart Failure. All other beta blockers now are denied at the point of sale and require prior authorization for Medicaid coverage of these medications.

The manufacturer of Toprol XL 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 beta blocker prescription was reduced by 55 percent. Table 5 demonstrates estimated savings based on the method previously described.

TABLE 5

BETA BLOCKERS ARKANSAS MEDICAID COSTS

	October*	November	December	Total
Actual Volume times pre PDL Cost per Rx	\$248,000	\$244,000	\$252,000	\$744,000
Post PDL Net Cost	\$160,000	\$109,000	\$113,000	\$382,000
PDL Savings	\$88,000	\$135,000	\$139,000	\$362,000

* Implementation on October 5th

LONG ACTING OPIOIDS

The long-acting opioid recommendations became effective October 26, 2005 with generic methadone and generic extended-release morphine sulfate tablets being selected as preferred products. Additionally, DHHS chose to make exempt from this implementation all patients that were eligible for long term care and patients who had a diagnosis of metastatic cancer. All other long-acting opioids now are denied at the point of sale and require prior authorization for Medicaid coverage of these medications.

Because the preferred products, methadone and extended-release morphine sulfate, are both generic, there are no supplemental rebates for these products. As a result, cost savings will be solely from moving patients from higher cost medications to equally effective, less expense medications. As a result of the PDL implementation, the average cost per long-acting opioid prescription was reduced by 53 percent. Table 6 demonstrates estimated savings based on the method previously described.

TABLE 6

LONG ACTING OPIOIDS ARKANSAS MEDICAID COSTS

	October*	November	December	Total
Actual Volume times pre PDL Cost per Rx	\$563,000	\$482,000	\$474,000	\$1,519,000
Post PDL Net Cost	\$497,000	\$224,000	\$222,000	\$943,000
PDL Savings	\$66,000	\$258,000	\$252,000	\$576,000

* Implementation on October 26th

ACE INHIBITORS

The ACE Inhibitor recommendations became effective November 16, 2005 with generic captopril and Altace® (ramipril) being selected as preferred products. Additionally, DHHS chose to make exempt from this implementation all Medicaid/Medicare Dual Eligibles. All other ACE Inhibitors now are denied at the point of sale and require prior authorization for Medicaid coverage of these medications.

The manufacturer of Altace provided a supplemental rebate bid. 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 ACE Inhibitor prescription has been reduced by 13 percent. Table 7 demonstrates estimated savings based on the method previously described.

TABLE 7

ACE INHIBITORS ARKANSAS MEDICAID COSTS

	October	November	December	Total
Actual Volume times pre PDL Cost per Rx	\$410,000	\$386,000	\$377,000	\$1,173,000
Post PDL Net Cost	\$407,500	\$372,000	\$328,000	\$1,107,500
PDL Savings	\$2,500	\$14,000	\$49,000	\$65,500

TOTAL ESTIMATED PDL SAVINGS

FOURTH QUARTER 2005

PRESENTED BY DRUG CLASS AND MONTH

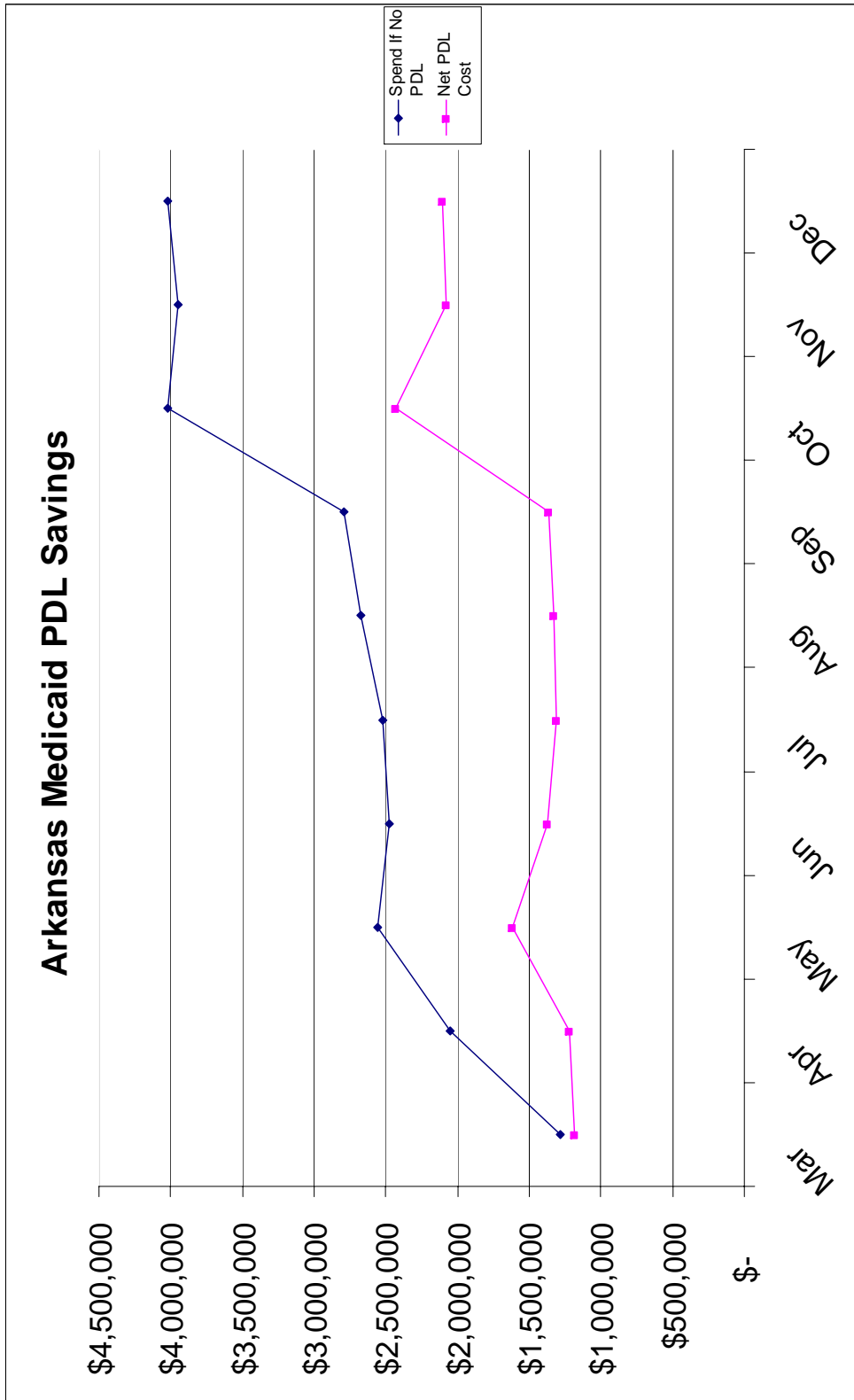
The table below (Table 8) demonstrates the cost savings by drug class and month for the fourth quarter of 2005. The estimated total cost savings for the entire fourth quarter of 2005 is \$5,371,500. Graph 1 illustrates what the cost for these medications would have been, assuming the same utilization, if there had not been a PDL in place.

TABLE 8

Fourth Quarter 2005 PDL Cost Savings by Class

	October	November	December	4Q 2005 Total
Non-Sedating Antihistamines	\$241,000	\$218,000	\$192,000	\$651,000
Proton Pump Inhibitors	\$875,000	\$916,000	\$960,000	\$2,751,000
Statins	\$236,000	\$250,000	\$242,000	\$728,000
Calcium Channel Blockers	\$79,000	\$79,000	\$80,000	\$238,000
Beta Blockers	\$88,000	\$135,000	\$139,000	\$362,000
Long-Acting Opioids	\$66,000	\$258,000	\$252,000	\$576,000
ACE Inhibitors	\$2,500	\$14,000	\$49,000	\$65,500
TOTAL				\$5,371,500

Graph 1



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 prescriptions that were filled for preferred product in each of the therapeutic categories reviewed and implemented to date. This percentage is commonly called market share in the pharmaceutical industry. Outcomes and cost savings are maximized as market share approaches 100 percent 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	Mar	Apr	May	June	July	Aug	Sep	Oct	Nov	Dec
NSAs	17.6%	93.4%	91.3%	88.0%	87.4%	87.5%	88.0%	87.4%	86.3%	85.2%
PPIs	64.7%	67.1%	81.0%	99.8%	99.8%	99.8%	99.8%	99.7%	99.8%	99.7%
Statins	23.8%	23.9%	25.6%	62.1%	98.7%	98.6%	98.7%	98.6%	98.6%	98.6%
CCBs	76.7%	76.8%	76.8%	76.8%	84.7%	96.1%	95.9%	96.2%	93.8%	96.1%
Beta Blockers	74.7%	74.2%	74.8%	74.9%	74.9%	74.8%	75.4%	86.1%	91.7%	91.5%
Long-acting Opioids	27.2%	27.4%	26.2%	27.0%	28.1%	27.8%	32.2%	37.4%	68.9%	69.6%
ACE Inhibitors	14.2%	13.9%	13.9%	14.0%	14.0%	13.9%	14.6%	17.2%	23.6%	39.7%

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	Oct 2005	Nov 2005	Dec 2005	Total 4Q 2005
Incoming Calls from Healthcare Professionals	1512	1741	1013	4266
Number of SmartPA Tickets Created	1527	1800	1004	4331
Total Number of P.A. Request at the Call Center	816	1004	543	2363
Total Number of P.A. Requests Approved at the Call Center	558	691	344	1593
Call Center P.A. Approval Percentage	68.4%	68.8%	63.4%	67.4%
Point of Sale SmartPA Requests	7545	9722	9664	26,931
Point of Sale SmartPA Approvals	2294	3701	4025	10,020
Point of Sale SmartPA Approval Percentage	30.4%	38.1%	41.7%	37.2%
Average Call Duration	2 min 58 sec	3 min 16 sec	2 min 57 sec	3 min 4 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 December 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 second quarter of SFY 06, the program is approximately \$875,000 under budget from July 1, 2005 through December 31, 2005.

	SFY06 Budget	SFY06 Expenditures To Date (through December 31, 2005)
Personnel –(Salary and Fringes, includes DRC stipends)	\$2,183,719	\$583,692
Miscellaneous – (Supplies, Travel, etc)	\$157,650	\$16,157
Equipment – (computers, phones, furniture, renovation)	\$0	\$0
Indirect Costs	\$1,264,339	\$323,919
TOTAL	\$3,605,708	\$923,768

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:

- AHEC - Fayetteville
- Arkansas Foundation for Medical Care – Medicaid Managed Care Conference – Little Rock
- Arkansas Academy of Family Physicians
- Department of Family & Preventative Medicine – UAMS College of Public Health
- Pfizer
- Schering Plough
- Multiple presentations to medical staffs at hospitals throughout the state

Additionally, EBRx staff presented, in conjunction with DHHS staff, the progress of our program to the Interim Joint Public Health Committee in October.

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: October 20, 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 10/20/05 meeting, the Drug Review Committee considered the potential toxicity and therapeutic roles of seven triptans in the management of adult patients with headaches.

The medications discussed included the following:

Almotriptan [Axert]
Eletriptan [Relpax]
Frovatriptan [Frova]
Naratriptan [Amerge]
Rizatriptan [Maxalt]
Sumatriptan [Imitrex]
Zolmitriptan [Zomig]

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 on the basis of toxicity or increased frequency of adverse effects.

Almotriptan and frovatriptan should be not be considered at this time due to a relative paucity of data supporting their efficacy relative to eletriptan, naratriptan, rizatriptan, sumatriptan and zolmitriptan.

Rizatriptan should be available because there is some evidence that it is more efficacious than other available agents.

At least one nasal and one injectable dosage form should be available.

At least two oral formulations should be available.

There is insufficient evidence to conclude in general that any of the remaining five drugs [eletriptan, naratriptan, rizatriptan, sumatriptan and zolmitriptan] is either less efficacious or associated with more adverse effects than another based upon demographics, comorbidities or adverse drug interactions.

Appendix B

Date: November 17, 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 11/17/05 meeting, the Drug Review Committee considered the potential toxicity and therapeutic roles of seven angiotensin receptor blockers in the management of adult patients with various indications as listed below.

ARBs under consideration

Candesartan [Atacand]
Eprosartan [Teveten]
Irbesartan [Avapro]
Losartan [Cozaar]
Olmesartan [Benicar]
Telmisartan [Micardis]
Valsartan [Diovan]

Indications under consideration

Essential hypertension
High cardiovascular risk
Recent myocardial infarction
Heart failure
Nephropathy

Throughout its deliberations various Committee members remarked that there is a paucity of head to head data to use in making decisions regarding these drugs.

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 on the basis of either toxicity or an increased frequency of adverse effects.

All of the agents are efficacious in reducing blood pressure.

Losartan should be available to patients with left ventricular hypertrophy who are not African-American.

Valsartan should be available to patients who have sustained myocardial infarctions.

Candesartan and valsartan should be available to patients with congestive heart failure.

Either irbesartan or losartan should be available to patients with nephropathy, type unspecified. An alternative to losartan should be available to African-American patients.

Appendix C

Date: December 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 12/15/05 meeting, the Drug Review Committee considered the potential toxicity and therapeutic roles of the skeletal muscle relaxers listed below in the management of adult and pediatric patients with various indications as listed below.

Skeletal muscle relaxers under consideration

Baclofen (Lioresal)*
Carisoprodol (Soma)
Chlorzoxazone (Parafon)
Cyclobenzaprine (Flexeril)
Dantrolene (Dantrium)*
Metaxolone (Skelaxin)
Methocarbamol (Robaxin)
Orphenadrine (Norflex)
Tizanadine (Zanaflex)*
*FDA approved for spasticity

Indications under consideration for adults and children

Chronic neurological conditions associated with spasticity
Acute musculoskeletal conditions with or without muscle spasms
Chronic musculoskeletal conditions with or without muscle spasms

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

Either tizanadine or baclofen should be available to Arkansas Medicaid recipients for the treatment of spasticity due to the potential hepatotoxicity of dantrolene.

Dantrolene, baclofen, and tizanadine are efficacious for the treatment of spasticity disorders.

Carisoprodol, chlorzoxazone, cyclobenzaprine, metaxolone, methocarbamol and orphenadrine are efficacious for the treatment of spasm.

None of the aforementioned drugs that are efficacious for treatment of spasticity or spasm pose either a special risk or benefit for a particular group on the basis of demographics.