

UNIVERSITY OF ARKANSAS  
FOR MEDICAL SCIENCES  
COLLEGE OF PHARMACY

# ARKANSAS MEDICAID EVIDENCE-BASED PRESCRIPTION DRUG PROGRAM (EBR<sub>x</sub>)

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QUARTERLY REPORT – FOURTH QUARTER 2006



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# INTRODUCTION

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## OVERVIEW OF THE EVIDENCE-BASED PRESCRIPTION DRUG PROGRAM

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The Evidence-Based Prescription Drug Program (EBRx) came into existence in November 2004. The program is a collaboration between the University of Arkansas for Medical Sciences (UAMS) College of Pharmacy and the Arkansas Department of Health and Human Services (DHHS) Medicaid Program, with the support and input of the Arkansas Medical Society and the Arkansas Pharmacist's Association. The primary role of EBRx for DHHS is to facilitate development of an Evidence-based Preferred Drug List and provide related Prior Authorization review services for Medicaid and ARKids recipients.

Medicaid is an entitlement program for individuals and families with low-income or disabilities. Prior to January 1, 2006, the Medicaid program provided prescription benefits for qualifying elderly patients whose primary insurance was through the Federal Medicare program. With the availability of Medicare Part D prescription drug coverage, the Arkansas Medicaid enrollee population is now predominantly children. In fact Arkansas' Medicaid and ARKids programs are estimated to provide healthcare coverage to approximately half of all Arkansas children.

In the years before development of the Evidence-based Preferred Drug List, medication cost growth was a major contributor to increased costs of the Arkansas Medicaid program. In the nine years before EBRx began, Medicaid prescription drug spending grew at a compound annual growth rate exceeding 16 percent. This growth was due to increases in the costs of medications as well as increases in the numbers of enrollees. The largest contributor to the increase in total medication expenditures was increases in average medication costs. The rate of medication cost growth far exceeds state revenue growth, and jeopardizes continuation of the optional Medicaid drug benefit, or other benefits at current levels.

The goals of the EBRx program are to: identify differences between medication options; recommend inclusion on the PDL of superior medications, if they exist; enhance predictability and reduce costs of medications whenever possible; and to provide access to medications not on the PDL through Prior Authorization Call Center activities. These efforts are hoped to ensure the continued ability of the state to provide appropriate medical coverage for Arkansas' Medicaid and ARKids recipients.

# Preferred Drug List Summary

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## PDL CATEGORIES, SELECTIONS, RATIONALE, AND SPECIAL CONSIDERATIONS

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Medication Class	Medicaid Preferred Agents (Brand Name Agents in Bold)	Drug Review Committee Recommendation Summary	Special Considerations
Less Sedating Antihistamines	Loratadine	No difference in patient total symptom scores	Patients under age 2 years
Proton Pump Inhibitors	<b>Prevacid capsules</b> <b>Nexium capsules</b> <b>Prevacid Solutabs</b>	No difference in outcomes with equipotent dosing	Patients under age 7 Patients with feeding tubes
HMG-CoA Reductase Inhibitors (statins)	<b>Zocor (generic products are now also available)</b>	Three agents superior to others based on prevention of heart attacks	Need for more potent agent
Calcium Channel Blockers	Diltiazem ER capsules (equiv to Dilacor XR) <b>Dynacirc CR</b> <b>Norvasc (removed after PDL contract expired)</b> Nifedipine ER tablets Verapamil SR tablets	At least 1 product from each of the three sub-classes of calcium channel blockers should be available, no significant difference in outcomes with equipotent dosing.	Dosage strengths of extended release diltiazem
Beta Blockers	Atenolol Metoprolol tartrate Propranolol IR Bisoprolol (only for CHF) <b>Toprol XL (only for CHF)</b>	3 agents superior for treatment of congestive heart failure, few advantages for one agent over another for all other uses.	Diagnosis of symptomatic Congestive Heart Failure
Long-Acting Opioids	Methadone Morphine sulfate ER tablets	No clinical advantage for one agent over another for treatment of chronic pain.	Terminal cancer diagnosis. Patients that are long-term care eligible Patients unable to swallow
Angiotensin-Converting Enzyme (ACE) Inhibitors	<b>Altace</b> Captopril	No significant differences among the agents for most indications although there are differences in approved indications and data supporting use of specific products in specific conditions.	Patients under age 18 years
Serotonin 5-HT <sub>1</sub> Receptor Agonists (triptans)	<b>Maxalt</b> <b>Maxalt MLT</b>	No significant difference among 5 of the 7 agents that any one agent is clinically superior to another agent.	Nasal spray and injectable formulations
Angiotensin II Receptor Blockers	<b>Cozaar, Hyzaar</b> <b>Diovan, Diovan HCT</b>	No significant advantage or disadvantage among the agents.	Congestive heart failure.

<b>Medication Class</b>	<b>Medicaid Preferred Agents (Brand Name Agents in Bold)</b>	<b>Drug Review Committee Recommendation Summary</b>	<b>Special Considerations</b>
Skeletal Muscle Relaxants	Chlorzoxazone Cyclobenzaprine 10mg Methocarbamol Baclofen (spasticity only) Tizanidine (spasticity only)	Muscle spasms and spasticity disorders have different preferred agents, no advantage of one product over another.	None
Systemic Estrogens	Estradiol 0.5mg,1mg,2mg Estropipate	No difference in the products at equipotent doses. At least one oral and one topical product should be available	None
Non-Benzodiazepine Sedative Hypnotics	<b>Ambien CR</b> <b>Rozerem</b> <b>Sonata</b>	No significant differences among the agents.	None
Targeted Immune Modulators	<b>Enbrel</b> <b>Humira</b>	No differences found, but generally lacking comparative data for analysis.	Subject to previous DUR clinical edits
Inhaled Corticosteroids	<b>Asmanex</b> <b>Azmacort</b> <b>Flovent (only to age 12)</b>	No significant differences among the products at equipotent doses	Patients under age of 12 years
Anticholinergics for Overactive Bladder	<b>Detrol LA</b> Oxybutinin syrup,5mg tablet <b>Vesicare</b>	No significant differences among the products at equipotent doses. None particularly effective	Patients under age of 18 years with spina bifida diagnosis
Antiemetics 5-HT3 and NK1 Receptor Antagonists	ondansetron	No significant differences among the products at equipotent doses.	None
Antidiabetics-meglitinides	<b>Starlix</b>	At least one agent from each of the sub-classes of antidiabetics should be included. No significant differences in efficacy among the agents.	None
Antidiabetics-First Generation Sulfonylureas	Chlorpropamide Tolazamide		
Antidiabetics-Second Generation Sulfonylureas	Glimepiride Glipizide Glyburide Glyburide micronized Metformin Metformin/glipizide Metformin/glyburide		
Antidiabetics-thiazolidinediones	<b>Actos 30mg,45mg</b> <b>Actosplus Met</b> <b>Avandamet</b> <b>Avandaryl</b> <b>Avandia</b>		
Nasal Corticosteroids	<b>Nasacort AQ</b> <b>Nasonex</b>		

# FINANCIAL IMPACT OF PDL SELECTIONS

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## COST SAVINGS TO THE STATE RESULTING FROM THE PDL

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### **METHOD OF ESTIMATING COSTS AVOIDED/SAVINGS**

Products placed on the Preferred Drug List (PDL) represent therapies with proven advantages over other alternatives, or cost-effective selections in categories where no important differences between products can be found. Even though the foundation of the PDL is clinical, it has impacted the net medication costs for Arkansas Medicaid. Estimates of the cost impact of PDL selections are presented in this section. The costs for a medication category could be either increased or decreased as a consequence of the PDL.

Several factors make it likely that medication costs in a drug category will decrease after preferred agents are selected. First, manufacturers of patent-protected, single source products offer supplemental rebates to Arkansas Medicaid in consideration of inclusion on the Preferred Drug List. Selection as a preferred agent has significant impact on product sales and market share, and manufacturers often generate higher sales from Arkansas Medicaid if their products are selected as preferred agents. These supplemental rebate offers ensure Arkansas Medicaid lower net costs than without the PDL. Second, there are situations where no important clinical differences exist among the medications in a category. In many cases there are less expensive, equally effective generic medications available at lower costs than single source agents in a drug category. Where there is the opportunity to gain all important clinical benefits offered by a group of drugs, while using a lower cost agent, these agents are selected for the PDL.

These estimates of medication costs avoided are calculated with estimates of the Medicaid net cost per prescription. Two estimates of net costs are made. One value is based on the weighted average net cost per prescription in a drug category immediately prior to the preferred drug selection. This average net cost per prescription represents the expected Medicaid net cost which would have been incurred without the PDL. It is important to remember that the estimated expected Medicaid net cost is not adjusted for price increases imposed after the PDL effective date for the category. Multiplying the expected net cost per prescription by the total number of prescriptions dispensed in the current period yields the Estimated Expected Costs. The second estimate is based on current Medicaid net costs for preferred agents. These costs are multiplied by the prescription volumes for each preferred drug. The total net costs estimated for each of the non-preferred drugs currently used is added to this result. This estimate is called the Post-PDL Net Cost Estimate. The difference between the Estimated Expected Costs and the Post-PDL Net Cost Estimate is our estimate of costs avoided (or incurred) as a consequence of the PDL.

The reported savings or costs avoided do not consider the impact of PDL decisions on total care costs. There may be either increases or decreases in others categories of Medicaid spending as a result of the PDL. There may also be shifts to or from particular drug categories as a consequence of the PDL recommendations. Along with the EBRx staff, UAMS' College of Pharmacy, Pharmaceutical Evaluation and Policy Division conducts ongoing analyses and reviews of the impact of the PDL on total Medicaid costs.

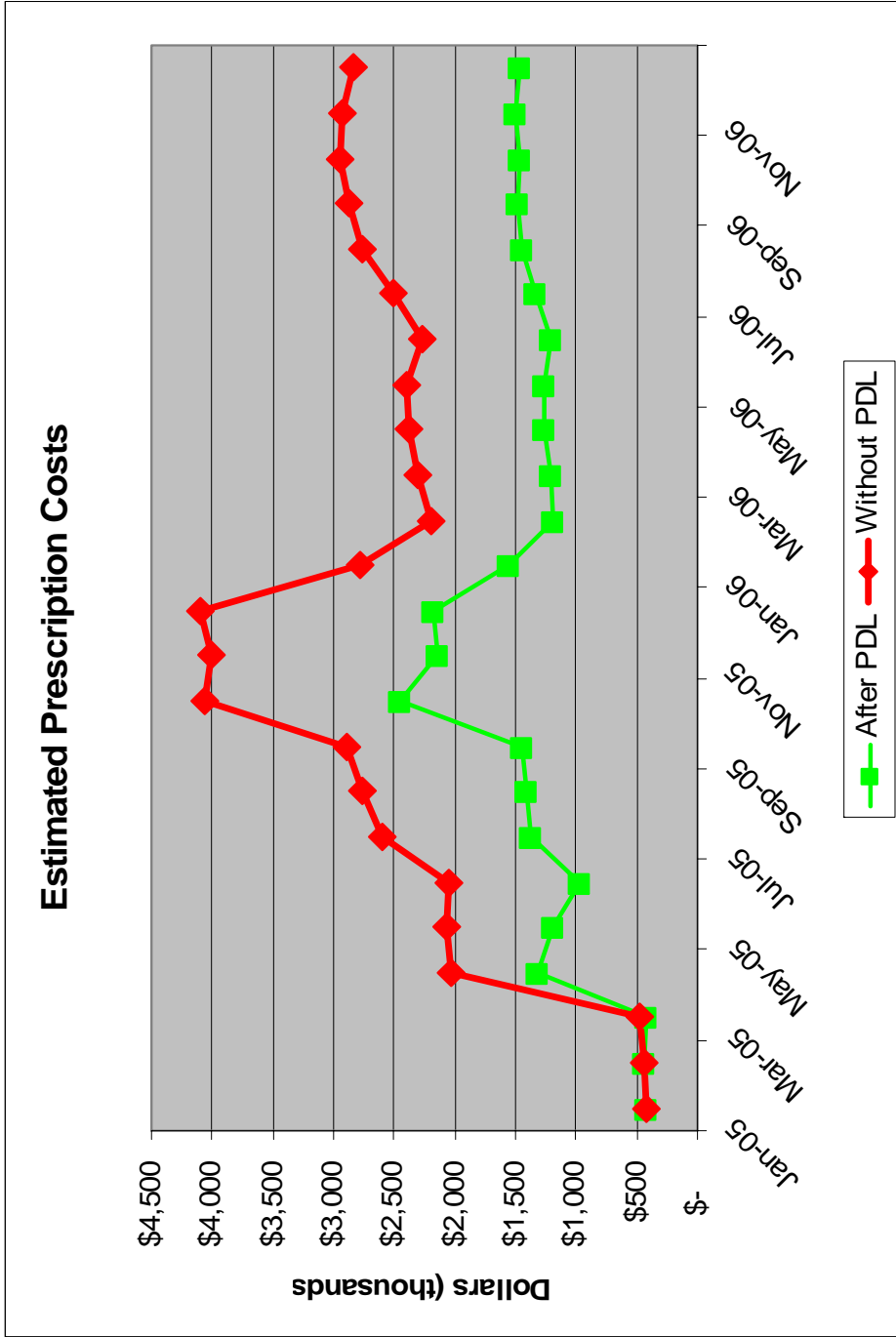
**OVERALL RESULTS**

The first PDL selection became effective March 25, 2005. By the end of December, 2006 preferred drugs had been selected in eighteen drug classes. Since the first PDL selection, EBRx estimates that the PDL process has yielded potential savings/excess costs avoided of at least \$27 million. Table I shows implementation dates, and costs avoided or incurred for each category reviewed.

TABLE 1 – Summary of Estimated Prescription Costs Avoided to Date by Category

Drug Category	PDL Effective Date	Costs Avoided/Potential Savings or Costs Incurred Estimates		
		State Fiscal Year 05	State Fiscal Year 06	State Fiscal Year 07 (to date)
Less Sedating Antihistamines	3/25/05	\$ 810,000	\$ 2,340,000	\$ 1,120,000
Proton Pump Inhibitors	5/18/05	\$ 1,680,000	\$ 8,540,000	\$ 3,191,000
“Statin” Cholesterol Agents	6/8/05	\$ 240,000	\$ 1,940,000	\$ 1,300,000
Calcium Channel Blockers	7/12/05	\$ -	\$ 580,000	\$ 128,000
Beta Blockers	10/5/05	\$ -	\$ 650,000	\$ 263,000
Long-Acting Opioids	10/26/05	\$ -	\$ 1,240,000	\$ 754,000
ACE Inhibitors	11/16/05	\$ -	\$ 320,000	\$ 150,000
“Triptan” Antimigraine Agents	2/7/06	\$ -	\$ 120,000	\$ 129,000
Angiotensin Receptor Blockers	2/21/06	\$ -	\$ 140,000	\$ 151,000
Skeletal Muscle Relaxers	3/20/06	\$ -	\$ 100,000	\$ 199,000
Estrogens	4/17/06	\$ -	\$ 20,000	\$ 60,000
Sedative Hypnotics (Sleep Aids)	5/9/06	\$ -	\$ 100,000	\$ 267,000
Targeted Immune Modulators	6/13/06	\$ -	\$ (20,000)	\$ 4,100
Inhaled Corticosteroids	7/11/06	\$ -	\$ -	\$ 391,000
Overactive Bladder Agents	8/15/06	\$ -	\$ -	\$ 79,000
Newer Antiemetics	10/10/06	\$ -	\$ -	\$ (4,900)
Oral Diabetes Agents	11/28/06	\$ -	\$ -	\$ 128,000
Nasal Steroids	11/28/06	\$ -	\$ -	\$ 179,000
<b>Grand Total</b>		<b>\$ 2,730,000</b>	<b>\$ 16,070,000</b>	<b>\$ 8,488,000</b>

# Graph 1



# MARKET SHARE IMPACT OF PDL RECOMMENDATIONS

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(s) 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.

**Percent Market Share of PDL Preferred Agents by Drug Class and Month**

	Jan 06	Feb 06	Mar 06	Apr 06	May 06	Jun 06	July 06	Aug 06	Sept 06	Oct 06	Nov 06	Dec 06
<b>Less Sedating Antihistamines</b>	86	86	86	87	86	82	82	84	85	84	84	83
<b>Proton Pump Inhibitors</b>	100	100	100	100	100	100	99	100	100	100	100	100
<b>Statins</b>	99	99	99	99	99	99	99	98	98	98	98	99
<b>Calcium Channel Blockers</b>	96	96	97	96	97	97	96	95	95	96	96	96
<b>Beta Blockers</b>	91	91	92	91	92	91	91	92	91	91	91	92
<b>Long-acting Opioids</b>	77	83	81	81	83	82	83	80	81	83	83	81
<b>ACE Inhibitors</b>	77	78	78	77	78	79	79	78	78	78	78	79
<b>Triptans</b>	33	<b>72</b>	89	90	85	88	86	88	87	87	88	88
<b>ARBs</b>	72	<b>75</b>	100	100	100	100	100	100	100	100	100	100
<b>Skeletal Muscle Relaxers</b>	58	59	<b>68</b>	99	99	99	99	99	99	99	99	99
<b>Estrogens</b>	16	15	17	<b>32</b>	93	93	92	91	93	92	91	93
<b>Newer Sleep Aids</b>	21	23	28	27	<b>60</b>	100	99	100	100	99	100	100
<b>Targeted Immune Modulators</b>	78	83	86	91	84	<b>87</b>	85	81	86	82	77	88
<b>Inhaled Corticosteroids</b>	62	63	67	67	70	72	<b>80</b>	84	83	84	83	82
<b>Overactive Bladder Agents</b>	56	55	53	54	54	56	55	<b>71</b>	89	89	89	93
<b>Newer Antiemetics</b>	89	85	87	89	94	90	89	88	86	<b>93</b>	96	98
<b>Oral Diabetes Agents</b>	70	67	66	66	66	65	66	67	66	66	<b>67</b>	66
<b>Nasal Steroids</b>	38	39	39	39	40	36	36	37	38	46	<b>53</b>	100

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

# Prior Authorization Call Center Statistics

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

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“Non-preferred” medications continue to be available to Medicaid recipients, but require prior authorization. Two processes are in place to provide prior authorization. The first is a computer-based system called Smart-PA. If the patient meets predetermined authorization guidelines, Smart-PA can grant an instantaneous prior authorization at the pharmacy counter with no additional effort by the provider or pharmacist. This occurs as a prescription claim is processed at the pharmacy

The second prior authorization process is the PDL Call Center. This 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 FY 2006, which includes January 1<sup>st</sup> 2006 through December 31, 2006.

<b>PA Call Center Statistics</b>	<b>1Q 2006</b>	<b>2Q 2006</b>	<b>3Q 2006</b>	<b>4Q 2006</b>	<b>Total 2006</b>
Incoming Calls from Healthcare Professionals	<b>2182</b>	<b>3080</b>	<b>2940</b>	<b>2939</b>	<b>11141</b>
Number of SmartPA Tickets Created	<b>2221</b>	<b>3972</b>	<b>2928</b>	<b>2226</b>	<b>11347</b>
Total Number of P.A. Request at the Call Center	<b>1323</b>	<b>2806</b>	<b>1649</b>	<b>1473</b>	<b>7251</b>
Total Number of P.A. Requests Approved at the Call Center	<b>835</b>	<b>2114</b>	<b>1153</b>	<b>1014</b>	<b>5116</b>
Call Center P.A. Approval Percentage	<b>63%</b>	<b>75%</b>	<b>70%</b>	<b>68%</b>	<b>71%</b>
Point of Sale SmartPA Requests	<b>26260</b>	<b>28511</b>	<b>36736</b>	<b>40527</b>	<b>132034</b>
Point of Sale SmartPA Approvals	<b>9961</b>	<b>13714</b>	<b>23389</b>	<b>27393</b>	<b>74457</b>
Point of Sale SmartPA Approval Percentage	<b>38%</b>	<b>48%</b>	<b>64%</b>	<b>68%</b>	<b>56%</b>
Average Call Duration	<b>2 min 46 sec</b>	<b>3 min 04 sec</b>	<b>2 min 14 sec</b>	<b>1 min 57 sec</b>	<b>2 min 30 sec</b>

# Budget Update

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## A GENERAL OVERVIEW OF THE PROGRAM BUDGET

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The Arkansas Medicaid Evidence-based Prescription Drug Program budget and expenditures to date are presented below. There remain a number of personnel positions initially budgeted, but not filled. If needs for additional program personnel arise, the program will work within the existing budget to ensure that service obligations are met. At the end of the second quarter of SFY 07, the program is approximately \$1,000,000 under budget from July 1, 2006 through December 31, 2006.

	<b>SFY07 Budget</b>	<b>SFY07 Expenditures To Date</b> <small>(through Dec. 31, 2006)</small>
<b>Personnel –(Salary and Fringes, includes DRC stipends)</b>	\$2,341,514	\$588,461.00
<b>Miscellaneous – (Supplies, Travel, etc)</b>	\$160,750	\$13,183.79
<b>Equipment – (computers, phones, furniture, renovation)</b>	\$0	\$0
<b>Indirect Costs</b>	\$1,351,223	\$324,888.19
<b>TOTAL</b>	<b>\$3,856,487</b>	<b>\$926,532.98</b>

# Data Evaluation

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## TRACKING OUTCOMES OF THE PDL DECISIONS

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### **PEP Division Activities**

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 is analyzed to determine impacts to the Medicaid program, beyond potential changes in medication costs.

The PEP division has produced analyses of the impact of four PDL category decisions. These categories are Less Sedating Antihistamines for allergy, Proton Pump Inhibitors for acid reflux, "Statin" cholesterol medicines and Calcium Channel Blocker blood pressure medications. These analyses are detailed and scientifically rigorous. All of these analyses have been prepared as scientific posters and have either been presented or were submitted for inclusion at scientific conferences relating to outcomes research. To date, none have revealed significant negative impacts on access to care, outcomes or total Medicaid costs. In each case analyzed to date, the supposition that Medicaid has reduced medication costs without leading to increases in other Medicaid costs has been supported. The estimated savings for Medicaid found in these analyses are comparable to the estimates obtained with the methods in this report.

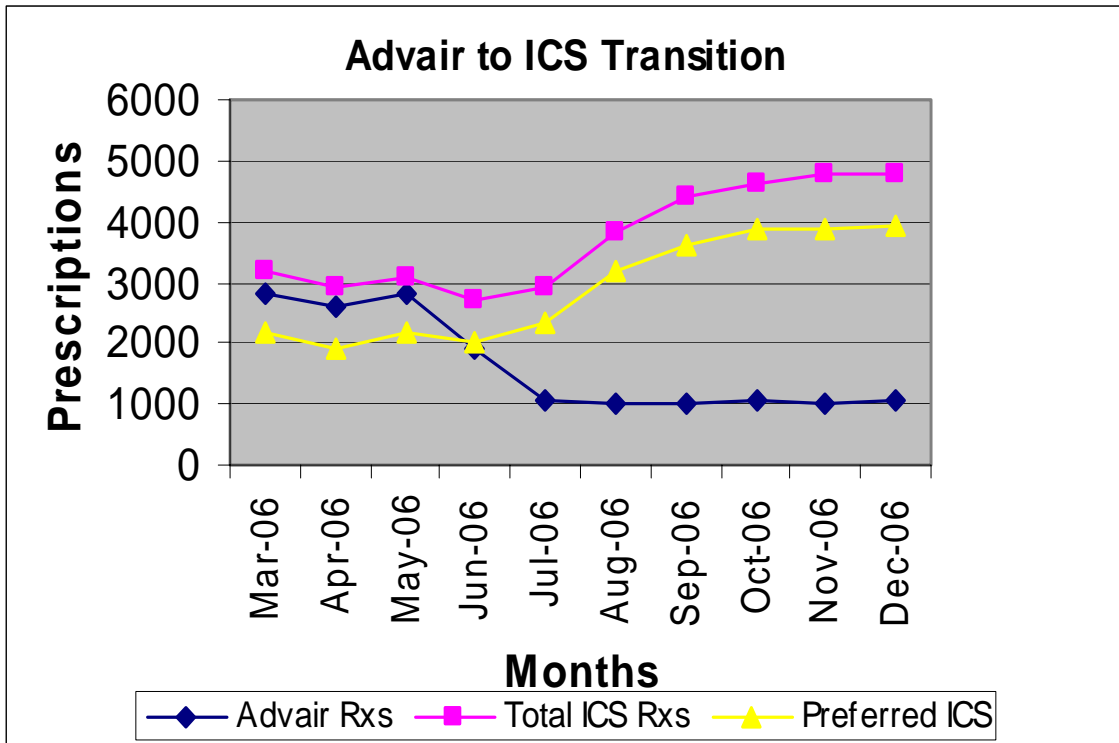
### **EBRx Activities**

EBRx staff has used access to Medicaid claims data to conduct additional analyses supporting DHHS policy development beyond the Preferred Drug List project. The most notable recent contribution was analysis of the use of products containing Long Acting Beta Agonists (LABAs). LABAs carry a risk of increases in deaths due to asthma compared to other asthma controllers. These agents are used in patients with asthma and with chronic lung disease usually associated with tobacco use (Chronic Obstructive Pulmonary Disease – COPD). The leading product among these is Advair Diskus marketed by GlaxoSmithKline. This product is an appropriate treatment for patients with COPD and the more severe persistently symptomatic patients with asthma. EBRx analysis revealed use patterns for Advair that were contrary to national asthma treatment guidelines, the manufacturer's prescribing information and the FDA safety advisory. This information was presented to the Medicaid Drug Utilization Review board and appropriate prior authorization controls on the use of LABAs were implemented in June 2006.

Since the LABA policy change, the Inhaled Corticosteroid (ICS) agents, the cornerstone agents for asthma preventive therapy, have been added as a PDL category. EBRx has monitored prescription dispensing of all inhaled asthma controllers since these policy changes. While Advair dispensing has fallen dramatically, ICS controllers are now dispensed much more frequently for the control of asthma. Advair use has stabilized over the past several months, and patients continuing on Advair appear to be using this product monthly. Through Point-of-Sale prior authorization edits, patients with moderate to severe persistent asthma who use their asthma controller consistently do not have barriers to receiving Advair. These policy changes have resulted in a much higher percentage of asthma patients being treated with an inhaled steroid as their only asthma control agent. This change is consistent with national asthma treatment guidelines. General dispensing patterns of asthma controlling agents are shown in Graph 2. With the completion of six months following the policy changes relating to asthma controller medications, EBRx will begin more comprehensive analysis of the impact on this policy change on patient care indicators.

## Graph 2

### Prescription Trends of Advair and Inhaled Corticosteroid Agents



EBRx has leveraged the relationship with DHHS to win a \$373,000 two year research grant. This grant is funded through the Attorney's General Consumer and Prescriber Education Grant Program. This program was created as part of the national settlement of litigation relating to off-label promotion of the seizure medication Neurontin. The project title of the grant is Impacting Medication Prescribing for Arkansas Children Through Off-label Education (IMPACT Off-label Education). This grant will fund activities within the College of Pharmacy, as well as provide funding for some activities within the Arkansas Foundation for Medical Care. DHHS will provide access to prescriber data for the evaluation component of this project.

# Drug Review Committee

## Activities

- October 19, 2006 – DRC Meeting  
Meeting was cancelled
- November 16, 2006 – DRC Meeting  
Public Comment meeting was held on 2<sup>nd</sup> Generation Antidepressants
- Date: December 14, 2006

Subject: DRC Recommendations to DUCC and DHS

To: DHHS, DUCC, Dean's Office

From: Howell R. Foster, PharmD.

At its 012/14/06 meeting, the Drug Review Committee considered the potential toxicity and therapeutic role of second generation antidepressants.

### **Second generation antidepressants**

Bupropion (Wellbutrin)  
Citalopram (Celexa)  
Duloxetine (Cymbalta)  
Escitalopram (Lexapro)  
Fluoxetine (Prozac)  
Fluvoxamine (Luvox)  
Nefazodone (generic)  
Paroxetine (Paxil)  
Mirtazapine (Remeron)  
Sertraline (Zoloft)  
Venlafaxine (Effexor)

### **Indications for the initial use of antidepressants under consideration in adults and geriatric patients unless otherwise specified**

Major depressive disorder  
Major depressive disorder in children  
Dysthymic disorder  
Generalized anxiety disorder  
Obsessive compulsive disorders  
Panic disorder  
Post-traumatic stress disorder  
Social anxiety disorder

Premenstrual dysphoric disorder and late luteal phase dysphoric disorder

1. Based on failure rates with initial therapy, the DRC recommends at least three of the second generation agents should be available on the PDL.
2. None of the agents should be stricken for safety reasons, but the DUCC should consider the following:
  - A. Patients with hepatic dysfunction should have the opportunity to receive an agent other than nefazodone.
  - B. Patients with a seizure disorder should have the opportunity to receive an agent other than bupropion.
  - C. Venlafaxine may produce seizures in overdose.
  - D. Patients with hypertension should have the opportunity to receive an agent other than venlafaxine.
3. Based on the evidence fluoxetine should be available to pediatric patients 18 years of age or less.
4. In regards to concomitant medications, co morbidities, and pregnancy, the committee wishes to inform the DUCC of the following:
  - A. Bupropion appears to cause the least sexual dysfunction.
  - B. Fluoxetine has a very long half-life and it is a potent inhibitor of CYP2D6 and should be used with caution in patients taking other medications metabolized by this pathway.
  - C. Paroxetine is an inhibitor of CYP2D6 and should be used with caution in patients taking other medications metabolized by this pathway.
  - D. Paroxetine is a category D in pregnancy and a fetal echocardiogram should be performed when exposed to the drug in the first trimester.
  - E. Weight gain appears to occur more frequently with mirtazapine and paroxetine and may be desirable in emaciated patients.
  - F. Bupropion appears to lead to weight loss and may be desirable in obese patients.

Howell R. Foster, Pharm.D.  
December 14, 2006