



# Louisiana Medicaid Preferred Drug List Program Overview and Program Results

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## **OVERVIEW**

The Louisiana Department of Health and Hospitals (LDHH) preferred drug list (PDL) program has been in operation since 2002 by Provider Synergies, L.L.C. Provider Synergies is an affiliate of Magellan Medicaid Administration, Inc.

Louisiana is entering the sixth year as one of eight states participating in the multi-state purchasing program, The Optimal PDL Solution (TOP\$). Louisiana was one of three states that initially participated in the multi-state purchasing pool, TOP\$, in 2005. The eight states now participating in the multistate purchasing program (TOP\$) are Louisiana, Maryland, Delaware, Idaho, Pennsylvania, Wisconsin, Nebraska, and Connecticut.

This review summarizes the results of the PDL program for fiscal year 2010-2011 and the first two quarters of fiscal year 2011-2012.

### **I. MAJOR DEVELOPMENTS IN FY 2010-2011**

In March 2010, President Obama signed the Patient Protection and Affordable Care Act and the Health Care and Education Affordability Reconciliation Act of 2010, together known as the Affordable Care Act (ACA), into law. The ACA included stipulations that had a significant impact on both Federal and Supplemental Medicaid drug rebates.

#### **Background**

- Provider Synergies' and Magellan Medicaid Administration clients use a wholesale average cost (WAC)-based Guaranteed Net Unit Price (GNUP) formula for the calculation of supplemental rebates

$$\text{WAC} - \text{Federal Rebate} - \text{GNUP} = \text{Supplemental Rebate}$$

- In this formula, there is an inverse relationship between the Federal and supplemental rebates.
  - As the Federal rebate rates increase, the Supplemental rebate rates decrease by an equal but opposite amount.
- Our model focuses on the net/net cost of drugs (net of both Federal and Supplemental rebates) in order to provide the most cost-effective Preferred Drug List (PDL) to our clients.
  - Our supplemental rebate contracts afford price protection to States against manufacturer's price increases over time via the guaranteed net unit price (GNUP) contract.
  - Fluctuations in drug prices then only affect how the total rebate is divided between the Federal and State governments.

The following changes mandated by the ACA are effective retroactive to January 1, 2010:<sup>1</sup>

- The minimum Federal Rebate for single source and innovator multiple source drugs increases from 15.1 to 23.1 percent.
- The Federal Rebate for generic drugs increases from 11 to 13 percent.
- The minimum Federal Rebate for clotting factors and outpatient drugs approved exclusively for pediatric indications increases to 17.1%.<sup>2,3</sup>

- The Federal Rebate for line extensions of oral solid dosage forms (such as extended release versions) will now be set at the highest Federal Rebate of any strength of the original dosage form.
- The Federal Rebate is now capped at 100% of AMP (average manufacturer's price).
- ACA states that the additional Federal rebates for branded drugs and generic drugs are returned to the Federal government without sharing with the states.

### Analysis

Due to the increase in the CMS base rebate, Supplemental Rebates have declined. This decline in Supplemental Rebates is due to the inverse relationship between Federal and Supplemental Rebates in our Guaranteed Net Unit Price (GNUP) contracts.

Despite increases in CMS rebates, due to the reduction in supplemental rebates and the offset of Federal rebates, states have experienced an estimated total reduction in rebates of approximately 4.8%.

ACA initially had a significant and immediate impact on states' shares of rebates. Magellan Medicaid Administration and Provider Synergies have observed that the negative impact on supplemental rebates has been somewhat negated by competition in the pharmaceutical marketplace and expanded Medicaid enrollment encourages manufacturers to offer Supplemental Rebates to ensure the positioning of their drug products on Medicaid PDLs.

CMS initially released Federal Rebates values under ACA in May 2011. Prior to that time, manufacturers performed their own estimated calculations and submitted estimated payments for Federal and Supplemental rebate amounts.

## II. SAVINGS METHODOLOGY

There are two ways that Louisiana derives savings from the Preferred Drug List: (1) Supplemental Rebates and (2) Market Shift savings. Both types of savings are listed in the quarterly savings reports that are sent to LDHH.

- a. **Supplemental Rebates = (Supplemental Rebate Per Unit x Number of units dispensed)**

Supplemental Rebate per Unit is calculated in accordance with the supplemental rebates offered for products (identified by 11 digit NDC) that are included on the PDL.

The predominant calculation type that manufacturers may use is called a "Guaranteed Net Unit Price" or "GNUP." GNUP calculations are different from total percent offers because they protect the state from price increases through manufacturer price guarantees. If the manufacturer increases its price, it makes up the price increase penny for penny in additional rebates. For example, if the manufacturer offered a GNUP of \$0.60 per unit, its federal rebate was \$0.25 and the AWP of the product was \$1.00, the manufacturer would pay a \$0.15 supplemental rebate. Should the manufacturer then increase its price to \$1.10, the rebate

liability would also increase, from \$0.40 to \$0.50 (i.e. \$1.10 - \$0.60). The supplemental rebate would increase from \$0.15 to \$0.25.

**b. Market Shift Savings = Total Savings – Supplemental Rebates**

“Market Shift Savings” occur when a patient on a product not included on the PDL changes therapy to a preferred medication that is less expensive. Essentially, this is a measure of cost avoidance for the Medicaid program.

For example, suppose that a non-preferred medication costs the Louisiana Medicaid program \$40 per prescription (after all rebates are applied), and the physician changes a recipient’s drug regimen to replace that medication with one on the PDL that costs \$30 per prescription (again, after application of all rebates). As a result of the change, the Medicaid program saves \$10 each time the recipient receives the new prescription versus incurring the additional cost had the patient not changed drugs.

In some cases, products are placed on the PDL and generate savings even without offering a supplemental rebate. This situation occurs either because the product is less expensive or because it has a large federal rebate that renders the net price paid by LDHH lower than the cost of competing therapies.

Market Shift Savings for each class are calculated for each drug name in the class, and then summed for the class total. Total Savings is the sum of Market Shift Savings and Supplemental Rebate Savings.

**c. PDL Performance report (cost avoidance) for the LDHH PDL Program**

Starting with FY 2009, Provider Synergies began a new methodology of reporting cost avoidance or PDL performance for the Preferred Drug List (PDL) Program. This change enabled us to provide reporting capability in reconciling cost avoidance projections made in our bi-annual Pharmaceutical and Therapeutics committee PDL review process.

The cost sheets are developed for the scheduled therapeutic categories prior to each Pharmaceutical and Therapeutics (P&T) meeting. Each therapeutic category is reviewed annually at one of two meetings. Cost sheets incorporate actual utilization of prescriptions, total cost paid by state, federal rebate amounts, maximum allowable cost (MAC) pricing, Federal Upper Limit (FUL) pricing, and offers for supplemental rebates. Estimation of market share shifts and the impact of drugs being ON the PDL or requiring prior authorization are included in the analysis.

The PDL Performance report derives cost avoidance from calculating the projected spend without the PDL for each therapeutic category (from the cost sheet) minus the sum of cost avoidance from market shifts and savings from supplemental rebates. The difference between the projected spend without the PDL and the projected spend with the PDL results in Total Savings with Recommendations; this is calculated for each therapeutic category. The Total Savings with Recommendations represents the projected cost avoidance from both the market share shifts and the supplemental rebates.

Variances between the projected savings on the cost sheets and the actual savings may include changes in volume, differences in market share shifts than expected, changes in manufacturer pricing not guaranteed by contract and adjustments to maximum allowable cost (MAC) program, clinical issues that develop with one or more products within a class, and launch of new branded or generic products, or removal of drugs from the market. New drugs, both branded and generic products, are incorporated into the report as utilization occurs, because they can have considerable impact on market share.

In summary, savings from the PDL program are generated through supplemental rebates and the movement of market share from higher cost products to lower cost, preferred products.

### **III. REVIEW OF MAJOR THERAPEUTIC CLASSES**

The following is a summary of the major therapeutic classes that generate a significant amount of savings for the PDL program. Hepatitis C Agents are included also.

#### **Antipsychotics**

The year 2005 marked the first time that LDHH selected preferred drugs within the atypical antipsychotic medications. This class represents the largest single class of expenditures within the Medicaid drug budget. The majority of the cost avoidance for this class is generated by the market share shift to the lower cost preferred agents.

At the P&T meeting in August 2009, the first generation antipsychotics and the injectable antipsychotics were reviewed within the PDL program for the first time. The preferred agents for the PDL published October 1, 2009 were the generic first generation antipsychotics, Fazaclor<sup>®</sup>, Seroquel<sup>®</sup>, Seroquel<sup>®</sup> XR, risperidone, oral Geodon<sup>®</sup> and injectable Geodon<sup>®</sup>. Overall utilization increased for this category due to the expanding FDA-approved indications and populations eligible for treatment with the Antipsychotics. In 2010, Saphris<sup>®</sup> and Risperdal<sup>®</sup> Consta were added to the PDL. At the April 2011 P&T meeting, Latuda<sup>®</sup> was reviewed as a new drug and was listed as non-preferred.

SAVINGS: In FY 2010-2011, the net price of risperidone generic fell significantly and was the lowest cost atypical antipsychotic in the class. The estimated average cost per prescription has been trending downward steadily to \$150 per prescription in the last quarter of FY 2010 and trending downward to \$130 per prescription in early 2011. Total cost avoidance for this class in FY2010-2011 was approximately \$90,000 due to the negative impact of the high cost of risperidone generic in the first two quarters of the fiscal year. The first two quarters of FY 2011-2012 have estimated savings for the Antipsychotics class of about \$8,000.

#### **Stimulants and Related Agents**

Stimulants and Related Agents are used for the treatment of Attention Deficit/Hyperactivity Disorders and Narcolepsy. New entries to the market over the past two years included Nuvigil<sup>®</sup> (armodafinil), Kapvay<sup>™</sup> (clonidine extended release), and Intuniv<sup>®</sup> (guanfacine ER). At the February 2010 P&T meeting, Intuniv<sup>®</sup> (guanfacine ER) was recommended as preferred; market share has quickly grown to over 8 percent of the class. High cost generics for Adderall XR<sup>®</sup> (amphetamine salt combo extended release) continue to increase the cost of treatment for

ADHD. Drug shortages with the generic amphetamine salt combo extended release occurred during 2010 while brand Adderall XR<sup>®</sup> remained available.

SAVINGS: Total cost avoidance for the Stimulants and related agents for FY 2010-2011 was over \$12.5 million. The first two quarters of FY 2011-2012 have estimated savings for the Stimulants and Related Agents class of about \$9.56 million.

#### Glucocorticoids, Inhaled

Glucocorticoids, Inhaled, also called Inhaled Corticosteroids, are generally used in the management of asthma and chronic obstructive pulmonary disease. The class included only branded agents until the sporadic release of the generic for Pulmicort<sup>®</sup> Respules over the last couple of years.

Over the last two years, Pulmicort<sup>®</sup> Respules, a product exclusively for children ages 1 to 8 years, had a generic product enter and leave the US market. Pulmicort<sup>®</sup> Respules are available to children 8 years and younger without prior authorization in Louisiana. Pulmicort<sup>®</sup> Respules or the generic equivalent require prior authorization for patients ages 9 years and older. The shifting of market share from brand to generic resulted in increased costs due to the high cost of the generic; most recently, the utilization is mostly the brand Pulmicort<sup>®</sup> Respules rather than the generic product. For the PDL published in October 2009, the preferred agents were Qvar<sup>®</sup>, Symbicort<sup>®</sup>, Aerobid<sup>®</sup> and Aerobid<sup>®</sup> M, Flovent<sup>®</sup> and Flovent<sup>®</sup> HFA, Advair<sup>®</sup> Diskus and HFA, and Azmacort<sup>®</sup>. Non-preferred agents were Asmanex<sup>™</sup> and Alvesco<sup>®</sup>, a new market entry. In FY 2010-2011, the preferred medications included Qvar<sup>®</sup>, Symbicort<sup>®</sup>, Aerobid<sup>®</sup> and Aerobid<sup>®</sup> M, Flovent<sup>®</sup> and Flovent<sup>®</sup> HFA, Advair<sup>®</sup> Diskus and HFA, and Asmanex<sup>™</sup>. Azmacort left the market. Aerobid<sup>®</sup> and Aerobid<sup>®</sup> M also left the market in June 2011. Dulera, a new combination product similar to Advair<sup>®</sup> Diskus / Advair<sup>®</sup> HFA and Symbicort<sup>®</sup>, was reviewed at the April 2011 meeting and was recommended as non-preferred.

SAVINGS: In FY 2010, the cost avoidance total for the Glucocorticoids, Inhaled was \$1.3 million. The first two quarters of FY 2011-2012 have estimated savings for the Glucocorticoids, Inhaled class of about \$460,000.

#### Cephalosporins and Related Agents

The Cephalosporins and Related Agents treat a number of common infections, and selection of a particular agent to treat a specific infection is often empirical and without the availability of microbiology culture and sensitivity data of the pathogen. The cephalosporins class consists of mostly generic products with a few branded exceptions including Ceftin<sup>®</sup> suspension, Suprax<sup>®</sup>, and Cedax<sup>®</sup>. At the August 2010 P&T meeting, preferred agents included cephalexin, cefuroxime tablets, cefadroxil, amoxicillin/clavulanate tablets and suspension, cefprozil, and Suprax<sup>®</sup>. Non-preferred agents included high cost generics such as cefdinir, cefpodoxime, cefaclor, cefditoren (new generic for Spectracef<sup>®</sup>), and amoxicillin/clavulanate XR (the new generic for Augmentin<sup>®</sup> XR).

SAVINGS: Savings for the Cephalosporins and Related Agents class consist of both market share movement to lower cost generic preferred agents and from the accrual of supplemental

rebates. For FY 2010-2011, cost avoidance due to market shift savings and supplemental rebates totaled \$9.6 million for the Cephalosporins and Related Agents. The first two quarters of FY 2011-2012 have estimated savings for the Cephalosporins and Related Agents class of \$3.68 million.

### Proton Pump Inhibitors (PPI)

The proton pump inhibitor class has generated the most savings to date of any of the classes reviewed. At the start of FY 2009, Nexium<sup>®</sup> and Prevacid<sup>®</sup> were the two preferred PPIs. The generic for Prevacid<sup>®</sup> (lansoprazole) entered the market in November 2009. The cost of the new Prevacid<sup>®</sup> generic, lansoprazole, was much higher than the other products in the class and was recommended as non-preferred at the February 2010 P&T meeting. Omeprazole, the generic for Prilosec<sup>®</sup>, was added to the preferred drug list at the February 2010 meeting. Omeprazole generic historically had a high cost, but pricing has significantly decreased. Nexium<sup>®</sup> remained a preferred agent in FY 2010-2011. At the April 2011 P&T meeting, the preferred agents for this class remained omeprazole and Nexium<sup>®</sup>.

SAVINGS: For FY 2009, the savings for the PPI category were \$8 million. In FY 2010, the savings for the PPI category totaled \$4.7 million. Prevacid<sup>®</sup> became available as a generic in November 2009; savings were negatively impacted in the third and fourth quarter of FY 2010 because of the arrival of the higher cost generic, lansoprazole, for Prevacid<sup>®</sup>. Additionally, the market share shifted to higher cost generic lansoprazole which negatively impacted savings. Total cost avoidance for the Proton Pump Inhibitors in FY 2010-2011 was \$1.5 million. The first two quarters of FY 2011-2012 have estimated savings for the Proton Pump Inhibitors class of \$678,000.

### Analgesics, Narcotics

Narcotic Analgesics category consists of agents which are long-acting for chronic pain management and short-acting analgesics which are typically used for acute pain. At the February 2010 meeting, fentanyl transdermal (generic) was recommended as preferred; Duragesic<sup>®</sup> branded product was recommended as non-preferred in the Long-Acting Narcotic Analgesics class. Embeda<sup>®</sup>, a morphine ER product with features to reduce abuse, was first reviewed at the February 2010 meeting; however, it was not been proven to reduce abuse. The P&T committee reviewed Embeda and recommended Embeda to be non-preferred. In March 2011, Embeda<sup>®</sup> was removed from the market. Ryzolt<sup>™</sup>, a new long acting form of tramadol, was also recommended as non-preferred. At the April 2011 P&T meeting, both fentanyl transdermal generic and Duragesic<sup>®</sup> branded were preferred with morphine ER, methadone, and Kadian<sup>®</sup>. Despite the large number of preferred products, PDL compliance rates for the long-acting narcotics analgesics remain relatively low compared to many other PDL classes. Oxycontin<sup>®</sup> continues to maintain significant market share despite the non-preferred status.

For the February 2010 review of the short-acting Narcotic Analgesics, all generic agents are recommended as preferred with the exception of fentanyl buccal (for Actiq<sup>®</sup>). Branded short-acting narcotic analgesics were recommended as non-preferred with the exception of Replexain<sup>™</sup>. At the April 2011 P&T meeting, additional non-preferred agents included several

branded products (Zolvit™, Reprexain™, Hycet®, Abstral®) and oxymorphone (a new generic for Opana®).

SAVINGS: The cost avoidance savings generated for FY 2010-2011 were over \$211,000.

While switching among brand and generic forms of a drug moves market share, the goal and desired result is to maintain costs as low as feasible for similar products. Very little has changed in the PDL recommendations for the Short Acting Narcotics since most products are generic. The PDL has effectively limited the growth in market share of the expensive brand products for the last three years. For the Short-Acting Narcotic Analgesics, the average net cost per prescription was \$22 for FY 2009 and dropped to under \$16 for FY 2010-2011.

The first two quarters of FY 2011-2012 have estimated savings for the Narcotic Analgesics class of \$550,000.

#### Leukotriene Modifiers

The National Asthma Education and Prevention Program (NAEPP)\_ and Global Initiative for Asthma (GINA) guidelines recommend inhaled corticosteroids as the cornerstone for the treatment of asthma while leukotriene modifiers are included as potential alternatives or add-on therapy in patients with mild persistent asthma and in some patients with aspirin-sensitive asthma.<sup>4</sup> Leukotriene Modifiers are also used as add-on therapy in patients receiving inhaled corticosteroids to reduce the dose of the inhaled corticosteroids in patients with moderate to severe asthma and to potentially improve asthma control in patients whose asthma is not controlled with low or high doses of inhaled corticosteroids. In the NAEPP and GINA guidelines, leukotriene modifiers may be used as controller treatment in asthma, particularly in children ages zero to four years.<sup>5,6</sup> However, in adults and adolescents over 12 years of age and children ages five to 11 years, leukotriene modifiers are not the preferred adjunctive therapy to inhaled corticosteroids compared to the addition of long-acting inhaled beta<sub>2</sub>-agonists according to NAEPP. Leukotriene Modifiers consist of Singulair®, Accolate®, and Zflo CR. Preferred agents for the past several years are Singulair® and Accolate®. Zflo® CR is non-preferred. Despite the Leukotriene Modifiers being second or third line in the management of asthma, utilization has risen over the last two years.

SAVINGS: In FY 2010, total cost avoidance savings for the Leukotriene Modifiers was \$57,000. The first two quarters of FY 2011-2012 have resulted in an increased net spend for the Leukotriene Modifiers class of about \$7,000.

#### Beta Agonist Bronchodilators

The Beta Agonist Bronchodilators are important in the management of acute symptoms of asthma and asthma control. At the August 2010 P&T meeting, the recommended preferred agents included albuterol (oral and nebulizer inhalation solution), Maxair®, ProAir® HFA, Proventil® HFA, Ventolin® HFA, terbutaline (oral), and Xopenex® nebulizer solution.

SAVINGS: For FY 2010-2010, the cost avoidance savings totaled \$3.8 million. The first two quarters of FY 2011-2012 have estimated savings for the Beta Agonist Bronchodilators class of nearly \$814,000.

### Antidepressants, Others and Selective Serotonin Reuptake Inhibitors (SSRIs)

Antidepressants includes two major subclasses – the Selective Serotonin Reuptake Inhibitors (SSRIs) and the Other Antidepressants.

The majority of the SSRIs Antidepressants are now available as generics. In August 2010, the preferred agents for the SSRIs included citalopram, fluoxetine, sertraline, paroxetine, fluvoxamine, and Lexapro<sup>®</sup>. Non-preferred SSRIs effective October 1, 2010 included paroxetine CR (for Paxil<sup>®</sup> CR), fluoxetine weekly (for Prozac<sup>®</sup> Weekly), Luvox<sup>®</sup> CR, and Pexeva<sup>™</sup>.

For the Other Antidepressants in FY 2010-2011, the preferred agents included bupropion immediate-release (IR) and sustained-release (SR), mirtazapine, trazodone, and venlafaxine ER tablets. Non-preferred antidepressants included Aplenzin<sup>®</sup>, bupropion XL (generic for Wellbutrin<sup>®</sup> XL), Pristiq<sup>®</sup>, Cymbalta<sup>®</sup>, nefazodone, Emsam<sup>®</sup>, Effexor<sup>®</sup> XR, and venlafaxine IR. PDL Compliance averages approximately 55-58 percent for the Other Antidepressants category.

SAVINGS: The total cost avoidance savings for FY 2009 was \$2 million for the Antidepressants. For FY 2010, the cost avoidance savings for Antidepressants classes was \$1.7 million. In the past year, Effexor XR became available as an expensive generic and negatively impacted savings for this class. The first two quarters of FY 2011-2012 have estimated savings for the Antidepressant classes of \$80,000.

### Hepatitis C Agents

In August 2005, the P&T committee first reviewed this class. In general, hepatitis C treatment requires combination therapy of a peginterferon and ribavirin for 24 to 48 weeks. Preferred agents since February 2007 have included PEG-Intron<sup>®</sup>, PEG-Intron<sup>®</sup> Redipen, Pegasys<sup>®</sup>, and ribavirin (generic). In February 2010, the preferred agents recommended were Pegasys<sup>®</sup>, which had the largest market share of the peginterferons, and ribavirin (generic). PEG-Intron<sup>®</sup> and PEG-Intron<sup>®</sup> Redipen required prior authorization effective April 1, 2010.

In the Spring of 2011, two new oral protease inhibitors, Incivek<sup>®</sup> and Victrelis<sup>®</sup>, were approved by the FDA. These two agents are used in combination with peginterferon and ribavirin for triple combination therapy.

SAVINGS: For FY 2009, the cost avoidance totaled \$387,000 for the Hepatitis C agents. For FY 2010, the cost avoidance was \$455,000. The first two quarters of FY 2011-2012 have estimated savings for the Hepatitis C Agents class of about \$210,000. Costs for this drug class will increase significantly as the cost of the new oral protease inhibitors can range from \$30,000 to \$40,000 per patient per treatment course.

### Number of Therapeutic Classes Reviewed

The Pharmaceutical and Therapeutics (P&T) Committee reviewed a total of 57 classes in FY 2008. In FY 2009 and FY 2010, the number of classes reviewed by the P&T committee was 68 classes each year. While the number remained constant, two new classes were the Antihyperuricemics and the Tetracyclines, Oral in 2009. For FY 2010-2011, the P&T Committee reviewed 73 classes at the August 2010 and April 2011 meetings.

### PDL Compliance

PDL Compliance is the percentage of the number of dispensed prescriptions that are preferred divided by the total number of dispensed prescriptions that are subject to the PDL. In FY 2009, the PDL compliance rate was 92.3 percent. For FY 2010-2011, the PDL compliance rate was 89.4 percent. For the first two quarters of FY 2011-2012, the PDL Compliance average rate was 90.3 percent.

## **IV. REPORTED SAVINGS FY 2009-2010 AND FY 2010-2011**

- a. Factors affecting the PDL program in FY 2009 – FY 2012: United States Health Care Reform

As noted in Section I (Major Developments in FY 2010-2011) on the first page, the 8% increase in the Federal rebate on the majority of single source brand drugs and 2% on generics, an increase that is exempted from State FMAP (Federal Medical Assistance Percentage) regulations, reduced State Medicaid supplemental rebate dollars initially for those drugs under contract starting in January 1, 2010.

- b. Savings Results

In FY 2009-2010, cost avoidance generated by the PDL program totaled \$46.4 million. For FY 2010 - 2011, the cost avoidance savings with the PDL program totaled \$40.5 million.

The ACA changes to the Federal Rebate program have negatively affected the accrual of supplemental rebates during years FY 2009-2010 and FY2010-2011.

**Table 1: Reported Savings by Quarter FY 2009 – 2010**

Savings Results FY 2009-2010			
Calendar Qtr	LA Fiscal Qtr	Quarterly Reported Savings	Comment
2Q09	Q110	\$ 12,408,970	Actual 2Q2009
3Q09	Q210	\$ 12,345,714	Actual 3Q2009
4Q09	Q310	\$ 13,893,704	Actual 4Q2009
1Q10	Q410	\$ 7,747,518	Reported 1Q2010 following use of mfg submitted estimated federal rebate amounts. Supplemental rebates were decreased due to changes in Federal Rebate amounts.
Totals		\$ 46,395,906	

**Table 2: Reported Savings by Quarter FY 2010 - 2011**

Savings Results FY 2010-2011			
Calendar Qtr	LA Fiscal Qtr	Quarterly Reported Savings	Comment
2Q10	Q111	\$ 11,014,745	Estimated 2Q2010 following use of mfg submitted estimated federal rebate amounts
3Q10	Q211	\$ 12,197,274	Estimated 3Q2010 following use of mfg submitted estimated federal rebate amounts
4Q10	Q311	\$ 8,979,028	Actual 4Q2010 (reflecting CMS federal rebates amounts under rebate rules established by ACA.)
1Q11	Q411	\$ 8,305,973	Actual 1Q2011 (reflecting CMS federal rebates amounts under rebate rules established by ACA.)
Totals		\$ 40,497,020	

**V. ESTIMATED SAVINGS FOR FY 2011-2012**

- a. Factors affecting the PDL program in FY 2011-2012
  - i. New generic medications

In the next year, several medications are expected to become available as generics. Typically, generics are thought to be lower cost than branded medications. More often, the newly released generics are priced at a premium to the net-net cost of the branded medications in Medicaid.

The new higher cost generics will likely negatively impact the savings of the PDL program in the short term. Price erosion typically occurs over one year. Generics that are expected to be launched in the next year include: Lipitor<sup>®</sup> (atorvastatin), Seroquel<sup>®</sup> (quetiapine), Zyprexa<sup>®</sup> (olanzapine), and Lexapro<sup>®</sup> (escitalopram).

ii. Sun setting of Average Wholesale Price (AWP)

On March 30, 2009, the US District court of Massachusetts entered a final order and judgment approving the class action settlement that involved two major publishers of drug pricing information, First Data Bank (FDB) and Medi-Span. FDB ceased publication of AWP in September 2011. It will be necessary for the State to evaluate an alternative pricing methodology. A decision would likely impact drug pricing and may offer the State an opportunity for additional savings.

b. Savings estimates for FY 2011 – 2012 are a total of \$37.7 million.

**Table 3: Estimated Savings by Quarter FY 2011 - 2012**

Savings Projections FY 2012			
Calendar Qtr	LA Fiscal Qtr	Estimated Savings	Comment
2Q11	Q112	\$ 10,251,080	Actual 2Q2011
3Q11	Q212	\$ 9,304,850	Estimated 3Q2011. Projections may be impacted by list of factors below.
4Q11	Q312	\$ 8,979,028	Estimated 4Q2011. Projections may be impacted by list of factors below.
1Q12	Q412	\$ 9,149,293	Estimated 1Q2012. Projections may be impacted by list of factors below.
Total		<b>\$ 37,684,251</b>	

Actual savings may be different from projections due to following various factors: Medicaid expansion with eligibility. The percent of Federal share of the newly eligible population changes over several years. Drug utilization may change depending on the health of the newly eligible population. Large population changes as a result of economy, hurricanes or other disasters would have a potentially large effect on the population. If Pharmacy benefits program is placed into CCN programs, the smaller population in FFS would accrue less supplemental rebates. New drugs will enter the market – unforeseen impact on drug utilization and unknown participation in supplemental rebate program. Drugs may enter the market for diseases that are currently not treated. Recalculation of AMP and the changes in FUL calculation may have significant impact on pricing of drugs. The level of aggressiveness of a state MAC list can impact the number of branded drugs listed on the PDL. Fewer branded drugs or lower utilization of branded products will result in lower supplemental rebates. Limiting the number of branded products in a class would likely lower supplemental rebates for some drug classes or potentially for the whole PDL program. Change in savings reporting methodology. FMAP changes will impact the state's share of all rebates. New changes in Federal Medicaid rules and regulations regarding drug coverage, drug pricing or rebate programs may impact the savings estimates.

**VI. FEATURES OF THE LOUISIANA MEDICAID PDL THAT IMPACT SAVINGS**

Strengths: Louisiana participates in the multi-state purchasing pool and benefits from volume purchasing but maintains autonomy in PDL decisions. States receive in some cases better

offers for supplemental rebates as a part of the TOP\$ program compared to other single states soliciting for supplemental rebates.

**Weakness:** The feature of Louisiana's program that possibly affects savings to the greatest extent is the statutorily mandated continuity of care process. Under the continuity of care program, a patient whose prescription medication is non-preferred may continue to take the non-preferred medication for up to six months or five refills. While this approach has minimized the initial impact of the PDL on patients, usage has not shifted as quickly to preferred medications, and savings have not been realized as quickly as would otherwise have been possible.

The current PDL program allows new drugs to process without prior authorization until reviewed by the Pharmaceutical and Therapeutics Committee. New drugs gain market share quickly before the P&T Committee has an opportunity to review the data on the new drug. An evaluation of this process should be considered to determine if new drugs should require prior authorization prior to the P&T Committee's review of the safety and efficacy data.

## **VII. SUMMARY**

The Preferred Drug List generates cost savings in two ways. First, supplemental rebates are collected from pharmaceutical manufacturers for their inclusion as a preferred product. Secondly, by requiring a prior authorization (PA) on non-preferred products, claims are shifted from more expensive medications to less costly alternatives.

The LDHH PDL program continues to be extremely successful. Savings for FY 2009-2010 were \$46.4 million. Savings for FY 2010-2011 were \$40.5 million. For the first two quarters of FY 2011-2012, the savings are \$21 million with the estimated year end savings of \$37.7 million.

Similar to other states with competitive selection based PDL models, prices have continued to drop or at worst stabilize in each subsequent review of each class. Louisiana's leadership in establishing the TOP\$<sup>SM</sup> multi-state program accelerated this trend.

## **VIII. REFERENCES**

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<sup>1</sup> Available at: <http://www.cms.gov/smdl/downloads/SMD10006.pdf>. Accessed November 17, 2011.

<sup>2</sup> Available at: <http://www.cms.gov/Reimbursement/Downloads/listofbloodclottingfactors.pdf>. Accessed November 17, 2011.

<sup>3</sup> Available at: <http://www.cms.gov/Reimbursement/Downloads/listofpediatricdrugs.pdf>. Accessed November 17, 2011.

<sup>4</sup> National Asthma Education and Prevention Program (NAEPP). Available at: [http://nhlbi.nih.gov/guidelines/asthma/08\\_sewwwc4\\_lt\\_0-11.pdf](http://nhlbi.nih.gov/guidelines/asthma/08_sewwwc4_lt_0-11.pdf). Accessed November 17, 2011.

<sup>5</sup> Global Initiative for Asthma (GINA) 2010. Available at: <http://www.ginasthma.com/>. Accessed November 17, 2011.

<sup>6</sup> National Asthma Education and Prevention Program (NAEPP). Available at: [http://www.nhlbi.nih.gov/guidelines/asthma/08\\_sec4\\_lt\\_0-11.pdf](http://www.nhlbi.nih.gov/guidelines/asthma/08_sec4_lt_0-11.pdf). Accessed November 17, 2011.