



# Louisiana Medicaid Preferred Drug List Program Overview and Results

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## **OVERVIEW**

The Louisiana Department of Health and Hospitals (DHH) 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 eighth 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 TOP\$ are Louisiana, Maryland, Delaware, Idaho, Pennsylvania, Wisconsin, Nebraska, and Connecticut.

This review summarizes the results of the PDL program for fiscal year 2011-2012 (FY2012) and the first two quarters of fiscal year 2012-2013 (FY2013).

### **I. MAJOR DEVELOPMENTS IN FY2012**

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. These regulations have not yet been clarified and implemented by the Centers for Medicare & Medicaid Services (CMS). CMS released their guidance in interpreting the ACA in February 2012 and allowed for a response period. This period ended in April 2012. CMS' final guidance on the effects of the ACA on the Medicaid marketplace is expected in 2013.

In 2012, ACA impact for Louisiana was seen in the partial movement of coverage for Medicaid pharmacy services from a fee-for-service (FFS) model to managed care organizations (MCOs). With MCO utilization eligible for the collection of federal rebates, several states have elected to employ MCOs for coordination of benefits and continue to collect federal rebates for this utilization. Utilization is not eligible for supplemental rebates, however, if the MCOs are permitted to use their own formularies. Louisiana elected for this option for a portion of Medicaid lives, decreasing the number of FFS lives to about 780,000.

For FY2013, the state altered their reimbursement methodology, which created a more aggressive pricing model for payments to pharmacies. This new formula for generic reimbursement is actual acquisition cost (AAC) + 10%; for brands, the formula is AAC + 1%. The dispensing fee has been increased to \$10.51. This enabled the state to take advantage of inexpensive generics and create the opportunity for significant switch savings. This is the savings associated with moving pharmacy utilization from more expensive products to less expensive products, provided that clinical effectiveness is similar. With this methodology in place, all PDL classes were re-evaluated for appropriate preferred products and the November TOP\$ review incorporated the new methodology in order to make projections under the new reimbursement model.

## Analysis

The 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. Also, expanded Medicaid enrollment encourages manufacturers to offer supplemental rebates to ensure the positioning of their drug products on Medicaid PDLs.

With the removal of nearly half of the Medicaid lives from the FFS group, overall spend will decline for the remaining lives, but federal and supplemental rebate collections by the state will also be reduced. .

## **II. SAVINGS METHODOLOGY**

There are two ways that Louisiana derives savings from the PDL: (1) supplemental rebates and (2) market shift savings. Both types of savings are listed in the PDL Supplemental Rebate & Market Shift Report that is sent quarterly to DHH.

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" (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 DHH 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.

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

The continuous cycle of patent expirations with the development of new PDL classes leaned more heavily on the patent expiration side for FY2013 in terms of determining the source of impact on the savings from the PDL program. Classes that historically have resulted in large savings for the state have seen generics cause them to move from supplemental rebate-driven savings to market shift savings. Examples include Antipsychotics and Leukotriene Modifiers. The following is a summary of the major therapeutic classes that generate a significant amount of savings for the PDL program.

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

Stimulants and Related Agents are used for the treatment of Attention Deficit/Hyperactivity Disorders and Narcolepsy. High amounts of supplemental rebates drive the significant savings in this class. Despite several products becoming available as generics in recent years, those generic costs remain high relative to the price of the brands, net of all rebates. Examples include Adderall XR and Concerta, two major brands that command high market shares.

SAVINGS: Total cost avoidance for the Stimulants and Related Agents for FY2012 was over \$21 million. The first two quarters of FY2013 have estimated savings for the Stimulants and Related Agents class of about \$8.9 million.

#### **Glucocorticoids, Inhaled**

Glucocorticoids, Inhaled, also called Inhaled Corticosteroids, are generally used in the management of asthma and chronic obstructive pulmonary disease (COPD). Over the last two years, Pulmicort Respules has had a generic product available. The shifting of market share from brand to generic resulted in increased costs due to the high cost of the generic. Otherwise, this class is a reliable source of supplemental rebates on most products.

SAVINGS: In FY2012, the cost avoidance total for the Glucocorticoids, Inhaled was \$1.1 million. The first two quarters of FY2013 have estimated savings for the Glucocorticoids, Inhaled class of about \$707,000.

#### **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 Suprax and and Cedax. Utilization of these brands resulted in significant accumulation of supplemental rebates.

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 FY2012, cost avoidance due to market shift savings and supplemental rebates totaled \$8.3 million for the Cephalosporins and Related Agents. The first two quarters of FY2013 have estimated savings for the Cephalosporins and Related Agents class of \$4.5 million.

#### Proton Pump Inhibitors (PPI)

The proton pump inhibitor class has generated the most savings to date of any of the classes reviewed. In previous years, these savings have been due to high supplemental rebate amounts as brands fought for market share versus omeprazole, the first generic in the class. In 2012, the preferred solid dosage forms became generics, so savings associated with this class are now due to market shift savings.

SAVINGS: For FY2009, the savings for the PPI category were \$8 million. Following patent expirations and declining generic prices, the total cost avoidance for the Proton Pump Inhibitors in FY2012 was \$1.4 million. The first two quarters of FY2013 have estimated savings for the Proton Pump Inhibitors class of \$240,000 as utilization in this class becomes further driven by inexpensive generics.

#### Beta Agonist Bronchodilators

The Beta Agonist Bronchodilators are important in the management of acute symptoms of asthma and asthma control. Supplemental rebate savings continue to be high based on the volume of utilization of albuterol inhalers.

SAVINGS: For FY2012, the cost avoidance savings totaled \$1.6 million due to an optimized PDL selection of inhalers. However, the lack of movement in market share for Xopenex nebulizers contributed to a market shift savings that was less than projected. The first two quarters of FY2013 have estimated savings for the Beta Agonist Bronchodilators class of nearly \$141,000.

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

Antidepressants classes have experienced major patent expirations over the past couple of years that have impacted the source of savings within these classes. This began with the expiration of Effexor XR's patent, followed by Lexapro's patent expiration in 2012, and will continue with the expiration of the Cymbalta patent in 2013. Supplemental rebates were gathered on Lexapro utilization through its patent expiration in March, at which time savings became associated with market shift savings as utilization moved from the brand to the generic.

SAVINGS: The total cost avoidance savings for FY2012 was \$1 million for the Antidepressants, SSRIs class. The first two quarters of FY2013 have estimated savings for this class of \$795,000.

### Growth Hormone

Savings projections are consistently met for this class due to constant utilization and a relatively static list of preferred agents. For several years, this class has been set at three preferred options and market shares tend to fall in line accordingly, as providers are pleased with the selections made by the P&T Committee and the state.

SAVINGS: For FY2012, the cost avoidance totaled \$1.2 million in this class. Savings for the first two quarters of FY2013 are projected to be \$948,000.

### Lipotropics, Statins

A former class for high savings, patent expirations have lessened the impact of reviewing this class in the past year. Following the expiration of the patent on Zocor, the generic simvastatin took away market share from brand products. Lipitor's patent expiration in November 2011 will have the same impact at the expense of Crestor utilization. The federal rebate on Crestor increased significantly, decreasing the supplemental rebate amounts collected.

SAVINGS: For FY2012, the cost avoidance totaled \$1.3 million in this class. Utilization moved to lower-cost products and generics. Supplemental rebates were decreased as the federal rebate on Crestor increased. The expiration of the Lipitor patent will further market shift savings in FY2013. Savings for the first two quarters are projected to be negligible as utilization continues to transition to generics from brands with high federal rebates.

### Number of Therapeutic Classes Reviewed

The number of PDL classes reviewed has nearly doubled since the inception of the TOP\$ program, culminating with the review of 79 classes during the FY2013 P&T 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 FY2012, the PDL Compliance average rate was 90.3 percent. FY2013's rate was the same through the first two quarters.

## **IV. REPORTED SAVINGS FY2011 THROUGH FY2012**

### a. Factors affecting the PDL program: United States Health Care Reform

As referred to in Section I (Major Developments in FY2011-2012), the ACA results in an 8% increase in the federal rebate on the majority of single source brand (SSB) drugs and 2% on generics, an increase that is exempted from State FMAP (Federal Medical Assistance Percentage) regulations. This act reduced State Medicaid supplemental rebate dollars initially for those drugs under contract starting in January 1, 2010.

### b. Savings Results

In FY2011, the cost avoidance savings with the PDL program totaled \$40.5 million. This number was \$42.2 million in FY2012.

The ACA changes to the Federal Rebate program have negatively affected the accrual of supplemental rebates since its effective date in FY2010.

**Table 1: Reported Savings by Quarter FY2011, FY2012**

Savings Results FY 2011			
Calendar Qtr	LA Fiscal Qtr	Quarterly Reported Savings	Comment
2Q10	Q111	\$ 11,014,745	Actual 2Q2010 (reflecting CMS federal rebates amounts under rebate rules established by ACA.)
3Q10	Q211	\$ 12,197,274	Actual 3Q2010 (reflecting CMS federal rebates amounts under rebate rules established by ACA.)
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		<b>\$ 40,497,020</b>	

Savings Results FY 2012			
Calendar Qtr	LA Fiscal Qtr	Quarterly Reported Savings	Comment
2Q11	Q112	\$ 10,251,080	Actual 2Q2011 (reflecting CMS federal rebates amounts under rebate rules established by ACA.)
3Q11	Q212	\$ 10,564,139	Actual 3Q2011 (reflecting CMS federal rebates amounts under rebate rules established by ACA.)
4Q11	Q312	\$ 11,748,842	Actual 4Q2011 (reflecting CMS federal rebates amounts under rebate rules established by ACA.)
1Q12	Q412	\$ 9,680,080	Actual 1Q2012 (reflecting CMS federal rebates amounts under rebate rules established by ACA.)
Total		<b>\$ 42,244,140</b>	

#### **V. ESTIMATED SAVINGS FOR FY2013**

##### a. Factors affecting the PDL program in FY2013

##### i. New generic medications

The pharmaceutical market is entering a period of high occurrences of patent expirations of blockbuster drugs. Examples of this impact on the PDL program could be seen in the past year with Lipitor, Plavix, and Singulair. 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 (usually about six months). Price

erosion typically occurs over one year. The coming year will not see the same large number of blockbuster patent expirations, but there will be several significant expirations such as that for Cymbalta.

- b. Savings estimates for FY2013 are a total of \$38 million.

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.

**Table 2: Estimated Savings by Quarter FY2013**

Savings Projections FY 2013				
Calendar Qtr	LA Fiscal Qtr	Estimated Supplemental	Estimated Switch	Comment
2Q12	Q1 13	\$ 10,608,291	\$ (2,040,080)	Actual 2Q2012 (reflecting CMS federal rebates amounts under rebate rules established by ACA.)
3Q12	Q2 13	\$ 12,297,051	\$ (2,418,781)	Actual 3Q2012 (reflecting CMS federal rebates amounts under rebate rules established by ACA.)
4Q12	Q3 13	\$ 11,805,169	\$ (2,191,612)	<b>Estimated 4Q2012. Projections may be impacted by list of factors below.</b>
1Q13	Q4 13	\$ 10,034,394	\$ (2,463,550)	<b>Estimated 1Q2013. Projections may be impacted by list of factors below.</b>
Totals		<b>\$ 44,744,905</b>	<b>\$ (9,114,022)</b>	

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## **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.

The change to the reimbursement formula in 2012 will allow Louisiana to better take advantage of low prices on generics and not rely so heavily on supplemental rebates for program savings.

**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 FY2012 were \$42.2 million. For the first two quarters of FY2013, the savings are \$18.4 million with the estimated year-end savings of \$35.6 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\$ multi-state program accelerated this trend.