



Louisiana Medicaid Preferred Drug List Program Overview and Results

January 9, 2015

Table of Contents

- 1.0 Overview3**
- 2.0 Major Developments in FY2014.....4**
 - 2.1 Analysis 4
- 3.0 Savings Methodology.....5**
- 4.0 Review of Major Therapeutic Classes.....6**
 - 4.1 The Top Five Classes 6
 - 4.2 Number of Therapeutic Classes Reviewed 7
 - 4.3 PDL Compliance 8
 - 4.4 Reported Savings FY2013 through FY2014 8
- 5.0 Estimated Savings for FY201510**
 - 5.1 Factors That Affected the PDL Program in FY2014..... 10
 - 5.2 Projected Savings for FY2015..... 10
- 6.0 Features of the Louisiana Medicaid PDL that Impact Savings12**
 - 6.1 Strengths..... 12
 - 6.2 Weakness 12
- 7.0 Summary13**

1.0 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., a Magellan Rx Management company (“Magellan”).

Louisiana is entering the tenth 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 2013-2014 (FY2014) and the first two quarters of fiscal year 2014-2015 (FY2015).

2.0 Major Developments in FY2014

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 went into effect October 1, 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 this option for a portion of Medicaid lives, decreasing the number of FFS lives to about 630,000.

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 was 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 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.

NOTE: Effective January 1, 2015, the dispense fee will decrease to \$10.13.

For SFY15, the state is projecting a significant decrease in the FFS population; this movement of lives to MCOs will impact the FFS pharmacy program savings/spend numbers.

2.1 Analysis

The ACA initially had a significant and immediate impact on states' shares of rebates. Magellan has observed that the negative impact on supplemental rebates has been somewhat negated by competition in the pharmaceutical marketplace. Also, expanded Medicaid enrollment across participating states 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.

3.0 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 and Market Shift Report that is sent quarterly to DHH.

1. 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.

2. 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.

4.0 Review of Major Therapeutic Classes

The continuous cycle of patent expirations with the development of new PDL classes such as Hypoglycemics, SGLT2s, and Hepatitis C treatment agents, leaned more heavily on the patent expiration side for FY2014 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 Neuropathic Pain.

The following is a summary of the major therapeutic classes that generate a significant amount of savings for the PDL program.

4.1 The Top Five Classes

4.4.1 Group One: 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. For 2014, the majority of supplemental savings comes from Adderall XR, Vyvanse, Focalin XR, and Intuniv. The positive market share savings comes from the continued shift from higher-cost Concerta to its generic.

SAVINGS: Total supplemental and market shift savings for the Stimulants and Related Agents for FY2014 was over \$5 million. The first two quarters of FY2015 have estimated savings for the Stimulants and Related Agents class of about \$2 million.

4.4.2 Group Two: Cephalosporins and Related Agents

The Cephalosporins and Related Agents treat a number of common infections. The 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 Cedax. Utilization of these brands resulted in significant accumulation of supplemental rebates. The bulk of the supplemental savings comes from the higher cost Suprax suspension shifting to the lower cost generics in the class.

SAVINGS: The supplemental plus market shift savings total 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 FY2014, cost avoidance due to market shift savings and supplemental rebates totaled approximately \$4.7 million for the Cephalosporins and Related

Agents. The first two quarters of FY2015 have estimated savings for the Cephalosporins and Related Agents class of \$1.8 million.

4.4.3 Group Three Antipsychotics

The Antipsychotics are important in the management of symptoms of bipolar mania and schizophrenia. Supplemental rebate savings continue to be high, based on the volume of utilization of these agents. Latuda, Fanapt, and Seroquel XR are generating the supplemental savings. The market share shift savings is coming from Geodon, Seroquel, Invega Sustenna, and Abilify shifting to less costly products in the class.

SAVINGS: For FY2014, the supplemental plus market shift savings totaled \$3 million due to an optimized PDL selection of preferred agents. The first two quarters of FY2015 have estimated savings for the Antipsychotics class of nearly \$2.3 million.

4.4.4 Group Four: 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. The positive savings comes mostly from large supplemental rebates from Norditropin and Norditropin AQ. The negative savings is a result of lower cost Saizen shifting to Norditropin.

SAVINGS: For FY2014, the supplemental plus market shift savings totaled \$1.8 million in this class. Savings for the first two quarters of FY2015 are projected to be \$1 million.

4.4.5 Group Five: Various Classes

The above four classes were in the top five savings each quarter, the fifth group for each quarter varied by quarter.

- For SFY 2Q14: **Bronchodilators, Beta-agonists** rounded out the top five with a savings of \$352,341.
- For SFY 3Q14: **Hepatitis C Agents** were the fifth category with a savings to the state of \$308,958.
- For SFY 4Q14: **Anticoagulants** has a savings of \$192,194.
- For SFY 1Q15: **Opiate Dependence Treatments** had a savings of \$267,578.

4.2 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 84 classes during the FY2014 P&T meetings.

4.3 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 FY2014, the PDL Compliance average rate was 93.9 percent.

4.4 Reported Savings FY2013 through FY2014

4.4.1 Factors Affecting the PDL Program

There are two major factors that have affected the PDL Program in the past several years: (1) United States Health Care Reform and (2) a shift in population from FFS to MCOs.

1. United States Health Care Reform

As referred to in *2.0 Major Developments in FY2014*, the ACA results in an 8 percent increase in the federal rebate on the majority of single source brand (SSB) drugs and 2 percent 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.

2. Shift of Population from FFS to MCOs

The loss of lives from the FFS Pharmacy Program to the MCOs results in a loss of savings due to less utilization on medications with high federal and/or supplemental rebates. As the loss of lives continues, savings will also continue to decrease.

4.4.2 Savings Results

In SFY2013/14 the cost avoidance savings with the PDL program totaled \$23.2 million. This number was \$40.4 million in SFY2013.

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 for FY2013

Savings Results FY 2013			
Calendar Quarter	LA Fiscal Quarter	Quarterly Reported Savings	Comments
1Q13	Q313	\$9,820,689	Actual 1Q2013 (reflecting CMS federal rebates amounts under rebate rules established by ACA.)
2Q13	Q413	\$9,159,758	Actual 2Q2013 (reflecting CMS federal rebates amounts under rebate rules established by ACA.)
3Q13	Q114	\$9,701,738	Actual 3Q2013 (reflecting CMS federal rebates amounts under rebate rules established by ACA.)
4Q13	Q214	\$6,390,582	Actual 4Q2013 (reflecting CMS federal rebates amounts under rebate rules established by ACA.)
Total		\$35,072,767	

Table 2: Reported Savings by Quarter for FY2014

Savings Results FY 2014			
Calendar Quarter	LA Fiscal Quarter	Quarterly Reported Savings	Comments
1Q14	Q314	\$4,927,633	Actual 1Q2014 (reflecting CMS federal rebates amounts under rebate rules established by ACA.)
2Q14	Q414	\$2,186,278	Actual 2Q2014 (reflecting CMS federal rebates amounts under rebate rules established by ACA.)
3Q14	Q115	\$4,401,604	Actual 3Q2014 (reflecting CMS federal rebates amounts under rebate rules established by ACA.)
4Q14	Q215	Not yet available	Actual 4Q2014 (reflecting CMS federal rebates amounts under rebate rules established by ACA.)
Total		\$11,515,515 – NOT including 4Q14	

5.0 Estimated Savings for FY2015

5.1 Factors That Affected the PDL Program in FY2014

5.1.1 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 Cymbalta, Lidoderm, and Concerta. 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, however, some will continue to occur.

5.2 Projected Savings for FY2015

Savings estimates for FY2015 are a total of \$19 million.

Actual savings may be different from projections due to some or all of the following possibilities. Large population changes as a result of the economy and/or hurricanes or other natural disasters would have a potentially large effect on the population. Since the Pharmacy benefits program was placed into MCO 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 Average Manufacturer Price (AMP) and the changes in Federal Upper Limit (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. Federal Medical Assistance Percentage (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 also affect the savings estimates.

Table 3: Projected Savings by Quarter for FY2015

Savings Projections for FY2015				
Calendar Quarter	LA Fiscal Quarter	Estimated Supplemental	Estimated Switch	Comments
3Q14	Q115	\$4,401,604	\$1,332,610	Actual 3Q2014 (reflecting CMS federal rebates amounts under rebate rules established by ACA.)
4Q14	Q215	\$5,193,412	\$1,157,938	Estimated 4Q14 Projections may be impacted by list of factors below.
1Q15	Q315	\$2,838,892	\$754,060	Estimated 1Q2015. Projections may be impacted by list of factors below.
2Q15	Q415	\$2,666,479	\$517,951	Estimated 2Q2015. Projections may be impacted by list of factors below.
Totals		\$15,100,387	\$3,762,559	

Actual savings may be different from projections due to the 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. Population changes as a result of economic changes or natural disasters could have a significant impact on the pharmacy spend. 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 the pricing of drugs. The level of aggressiveness of a state MAC list can affect 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.

6.0 Features of the Louisiana Medicaid PDL that Impact Savings

6.1 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.

6.2 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 (both brand and generic) 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.

With the push to move ever more lives to MCOs, the savings will continue to trend downward for the FFS Pharmacy Program, but the good news is with appropriate PDL management, there is still relevant savings to be had.

7.0 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 expensive medications to less costly alternatives.

The LDHH PDL program continues to be extremely successful. Savings for FY2014 were \$23.2 million. For the first quarter of SFY2015, the savings are \$4.4 million with the estimated year-end savings of \$19 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.