



Louisiana Medicaid Preferred Drug List Program Overview and Results

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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 twelfth year as one of six 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 six states now participating in TOP\$ are Louisiana, Maryland, Idaho, Wisconsin, Nebraska, and Connecticut.

This review summarizes the results of the PDL program for fiscal year 2015-2016 (FY2016) and the first quarter of fiscal year 2016-2017 (FY2017).

2.0 Major Developments in FY2016

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 has been increased to \$10.51 which includes a provider fee of \$0.10. This has enabled the state to take advantage of inexpensive generics and opportunity for significant switch savings. Switch savings are 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.

For SFY15, the state underwent a significant decrease in the FFS population; this movement of lives to MCOs severely impacted 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 about 90% of the Medicaid lives from the FFS group, overall spend has declined for the remaining lives, but federal and supplemental rebate collections by the state have also been 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 WAC 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

Savings from patent expirations, shifting of market share along with supplemental rebates leaned more heavily on supplemental rebates in terms of determining the source of impact on the savings from the PDL program for FY2016.

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 and market shifting 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.

SAVINGS: Total supplemental and market shift savings for the Stimulants and Related Agents for FY2016 was over \$440K. The dramatic loss of savings from last year is a direct result of the loss of lives to Managed Medicaid.

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.

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 FY2016, cost avoidance due to market shift savings and supplemental rebates totaled over \$371K for the Cephalosporins and Related Agents. Again, the trend of savings erosion is primarily due to the migration of lives to Managed Medicaid.

4.4.3 Group Three Anticoagulants

Anticoagulants are used to treat a variety of conditions such as deep vein thrombosis (DVT), pulmonary embolism (PE), and nonvalvular atrial fibrillation (NVAf). The newer direct oral anticoagulants have created additional competition in this space. They appear to be at least as effective as warfarin in preventing stroke or systemic embolism in patients, and they appear to be safer with less monitoring.

SAVINGS: For FY2016, the supplemental plus market shift savings totaled over \$229K. Due to decreased utilization as a direct result of the migration to Managed Medicaid, savings is less than the previous year.

4.4.4 Group Four: Growth Hormone

Growth hormone is used to treat a variety of disorders in which endogenous growth hormone is insufficient to meet the needs of the patient.

The class was reduced to two preferred options with the largest market share. The positive savings comes mostly from supplemental rebates and some market shifting.

SAVINGS: For FY2016, the supplemental plus market shift savings totaled \$184K in this class. The sharp decline of savings from last year is primarily due to the movement of lives to Managed Medicaid as stated above.

4.4.5 Group Five: Hepatitis C Agents

With the advent of new, oral Hepatitis C medications, patients are able to achieve sustained virologic response (SVR) rates greater than 90% where once this infection was very difficult to treat. Better efficacy does come at a hefty price tag. With limited resources, preferred medication(s) must be chosen very wisely. Fortunately, as more competitive products have come to market, the net cost of treatment is trending down.

SAVINGS: For FY2016, the supplemental plus market shift savings totaled just under \$140K in this class.

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 90 classes during the FY2016 Pharmaceutical and Therapeutics Committee (P&T) meetings. The following classes were added for review: Antivirals, Oral; GI Motility, Chronic; H.pylori Treatment; Hypoglycemics, Sulfonylureas; Immunosuppressives, Oral; Nitrofurantoin Derivatives; Vasodilators, Coronary

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 FY2016, the PDL Compliance average rate was 94%.

4.4 Reported Savings FY2015 through FY2016

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 FY2016*, 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.

2. Shift of Population from FFS to MCOs

The loss of lives from the FFS Pharmacy Program to the MCOs resulted in a loss of savings due to less utilization on medications with high federal and/or supplemental rebates. Between the last two quarters of FY2015, there was an 83% decline in supplemental rebates due the loss of population to the MCOs. There is a continual decline this year as well.

4.4.2 Savings Results

In FY2016 the cost avoidance savings with the PDL program totaled \$1.8 million. This number was \$14.2 million in FY2015.

The ACA changes to the Federal Rebate program have negatively affected the accrual of supplemental rebates since its effective date in FY2010. In addition, the shift to Managed Medicaid has heavily impacted supplemental rebate revenue in a negative manner.

Table 1: Reported Savings by Quarter for FY2015

Savings Results FY 2015			
Calendar Quarter	LA Fiscal Quarter	Quarterly Reported Savings	Comments
3Q14	Q115	\$4,401,604	Actual 3Q2014 (reflecting CMS federal rebates amounts under rebate rules established by ACA.)
4Q14	Q215	\$5,622,303	Actual 4Q2014 (reflecting CMS federal rebates amounts under rebate rules established by ACA.)
1Q15	Q315	\$3,451,877	Actual 1Q2015 (reflecting CMS federal rebates amounts under rebate rules established by ACA.)
2Q15	Q415	\$802,089	Actual 2Q2015 (reflecting CMS federal rebates amounts under rebate rules established by ACA.)
Total		\$14,277,873	

Table 2: Reported Savings by Quarter for FY2016

Savings Results FY 2016			
Calendar Quarter	LA Fiscal Quarter	Quarterly Reported Savings	Comments
3Q15	Q116	\$417,905	Actual 3Q2015 (reflecting CMS federal rebates amounts under rebate rules established by ACA.)
4Q15	Q216	\$498,952	Actual 4Q2015 (reflecting CMS federal rebates amounts under rebate rules established by ACA.)
1Q16	Q316	\$223,355	Actual 1Q2016 (reflecting CMS federal rebates amounts under rebate rules established by ACA.)
2Q16	Q416	\$653,924	Actual 2Q2016 (reflecting CMS federal rebates amounts under rebate rules established by ACA.)
Total		\$1,794,136	

5.0 Estimated Savings for FY2017

5.1 Factors That Affected the PDL Program in FY2016

5.1.1 High Cost Generic Medications

The generic pharmaceutical market has seen an influx of high cost generics. Examples of expensive generics include Abilify, Copaxone, 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. These generics have continued to maintain high pricing in FY2016 even after the six-month exclusivity period. Finally, in April 2016, the price of the generic Abilify dropped so the State was able to experience some relief. Various generic drugs that are not new to the market, and, in fact, have been available for a long time are also now outrageously priced including tetracycline. Factors that may dictate pricing of generics may be shortages, manufacturing issues, pharmaceutical company mergers and acquisitions, and competition.

5.2 Projected Savings for FY2017

Savings estimates for FY2017 are a total of \$2.3 million.

Table 3: Projected Savings by Quarter for FY2017

Savings Projections for FY2016				
Calendar Quarter	LA Fiscal Quarter	Estimated Supplemental	Estimated Switch	Comments
3Q16	Q117	\$419,153	\$195,093	Actual 3Q2016 (reflecting CMS federal rebates amounts under rebate rules established by ACA.)
4Q16	Q217	\$402,387	\$193,142	Estimated 4Q2016 Projections may be impacted by list of factors below.
1Q17	Q317	\$342,029	\$173,828	Estimated 1Q2017. Projections may be impacted by list of factors below.
2Q17	Q417	\$444,638	\$159,602	Estimated 2Q2017. Projections may be impacted by list of factors below.
Totals		\$1,608,207	\$721,665	

Actual savings may be different from projections due to various factors. The percent of Federal share of the newly eligible expansion 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. 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 the 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 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.

Effective June 2, 2016, pursuant to Act 33 of the 2016 Regular Session of the Louisiana Legislature, any new drug introduced into the market in one of the therapeutic classes reviewed by the P&T Committee may be prior authorized until the next P&T meeting. Previously new drugs (both brand and generic) processed without prior authorization before being reviewed by the P&T Committee. New drugs can gain market share quickly before the P&T Committee has an opportunity to review the data on the new drug so this change is a huge stride in achieving additional 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 12 months or, essentially, the life of the prescription. 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.

Currently, DHH does not have the authority to make brand and generic changes until approved by the P&T Committee. Having the flexibility to make a flip from brand to generic or vice versa can contribute positively towards savings. Magellan monitors brand and generic opportunities on a monthly basis for other States.

With the push to move ever more lives to MCOs, the savings will continue to trend downward for the FFS Pharmacy Program. The State of Louisiana should consider a uniform PDL approach or, alternatively, a uniform PDL for specific classes where supplemental rebates are high so that the State can collect the supplemental rebates on those drugs dispensed for the FFS and MCO population. Further research should be conducted to analyze this approach. With appropriate PDL management, relevant savings can still be realized.

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 more cost-effective alternatives.

The LDHH PDL program continues to be successful. Savings for FY2016 were almost \$1.8 million. For the first quarter of SFY2017, the savings are \$ \$614,246 with the estimated year-end savings of \$2.3 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.