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### 1.0 Overview

The Louisiana Department of Health (LDH) preferred drug list (PDL) program has been in operation since 2002 by Provider Synergies, LLC. Provider Synergies is an affiliate of Magellan Medicaid Administration, Inc., a Magellan Rx Management company ("Magellan").

Louisiana is entering its 21<sup>st</sup> 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 TOP\$ in 2005. The six states now participating in TOP\$ are Louisiana, Maryland, Idaho, Wisconsin, Nebraska, Washington, and Connecticut.

This review summarizes the results of the PDL program for fiscal year 2022-2023 (FY2023) and the first quarter of fiscal year 2023-2024 (FY2024). This report includes managed care organization (MCO) data.

# 2.0 Major Developments

In March 2010, President Barack 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 on October 1, 2013.

In 2012, ACA impacted Louisiana through 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 elected to employ MCOs for the coordination of benefits. States cannot collect supplemental rebates for MCO utilization if the MCOs are allowed 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 its reimbursement methodology, which created a more aggressive pricing model for payments to pharmacies. In October 2014, LDH changed pharmacy reimbursement to actual acquisition cost (AAC) plus a \$10.41 professional dispensing fee plus a \$0.10 provider fee, to comply with the CMS-approved state plan. This has enabled the state to take advantage of inexpensive generics and the opportunity for significant switch savings. Switch savings are associated with moving pharmacy utilization to less expensive products with similar clinical effectiveness. With this methodology in place, the state will re-evaluate all PDL classes for appropriate preferred products and the November 2012 TOP\$ review incorporated the new methodology to make projections under the new reimbursement model.

In SFY2015, the state underwent a significant decrease in the FFS population. This movement of lives to MCOs severely impacted the FFS pharmacy program savings/spending numbers.



During SFY2017 through SFY2018, the FFS population continued to remain stable post-MCO shifting.

On May 1, 2019, the state implemented a single PDL to address the significant Medicaid population that moved to MCOs. This implementation standardized the PDL across all the MCOs and the FFS program, simplifying the process for providers to prescribe medications to all Medicaid beneficiaries. Through a single PDL program, the state can collect supplemental rebates for contracted medications dispensed to all Medicaid members, rather than to FFS beneficiaries only. Additionally, a single PDL drove increased savings for the state by encouraging a market shift from nonpreferred medications to preferred, less costly alternatives.

Also in May 2019, the reimbursement methodology for FFS changed to the national average drug acquisition cost (NADAC) instead of AAC, plus a \$10.99 professional dispensing fee, plus a \$0.10 provider fee. During the 2017 Regular Session, the Louisiana Legislature passed a law requiring MCOs to pay local pharmacies the FFS rate.

On July 15, 2019, the state executed its hepatitis C subscription model to help eradicate this disease in Louisiana while using a cost-effective initiative. The state entered into a five-year Supplemental Rebate Agreement with Asegua that caps gross annual expenditure for one contracted hepatitis C medication (velpatasvir/sofosbuvir). Once this cap is met, the net cost for this drug to the state becomes zero for the rest of the state fiscal year. This model allows unlimited access to hepatitis C treatment for Medicaid MCO and FFS beneficiaries, as well as incarcerated individuals in the state.

# 2.1 Analysis

There was an increase in savings in SFY2023 over the previous year. This is mainly attributed to the rise in FDA approvals of high-cost specialty drugs and to the increase in prescription volume that is partly due to the surge in Medicaid enrollment.

# 3.0 Savings Methodology

Louisiana derives savings from the PDL in two ways: (1) supplemental rebates and (2) market shift savings. The quarterly PDL Supplemental Rebate and Market Shift Report sent to LDH lists both types of savings.

1. **Supplemental Rebates = Supplemental Rebate Per Unit x Number of Units Dispensed**Supplemental rebate per unit is calculated by 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 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 offers a GNUP of \$0.60 per unit, its federal rebate is \$0.25 and the wholesale acquisition cost (WAC) of the product is \$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 member on a nonpreferred product changes therapy to a preferred medication that is less expensive with similar clinical effectiveness. 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 LDH lower than the cost of competing therapies.

We calculate market shift savings for each drug class by first finding the savings for each individual drug name within the class, and then adding those savings together to get a total for the entire class. Total savings is the sum of market shift savings and supplemental rebate savings.

# 4.0 Review of Major Therapeutic Classes

Supplemental rebates along with shifting of market share to less expensive alternatives contributed to the savings from the PDL program for FY2023.

The following is a summary of the major therapeutic classes that generated the most savings for the PDL program.



# 4.1 The Top Five Classes

### 4.1.1 Group One: Cytokine and CAM Antagonists

Cytokine and CAM antagonists are used for the treatment of a wide array of inflammatory and autoimmune disorders such as rheumatoid arthritis, plaque psoriasis, psoriatic arthritis, Crohn's disease, and ankylosing spondylitis.

**SAVINGS**: For FY2023, the supplemental plus market shift savings totaled almost \$95.1 million, solely due to supplemental rebates.

### 4.1.2 Group Two: Opiate Dependence Treatments

Opiate dependence treatments are used to treat opiate addiction and overdose.

**SAVINGS**: The supplemental plus market shift savings for the opiate dependence treatments class totaled over \$13.1 million, primarily driven by supplemental rebates.

### **4.1.3 Group Three: Antipsychotics**

Antipsychotics are used to treat a wide variety of behavioral health disorders such as schizophrenia, bipolar disorder, and irritability associated with autism spectrum disorder.

**SAVINGS:** For FY2023, the supplemental plus market shift savings totaled over \$9 million in this class. Supplemental rebates account for all of the savings in this class.

### 4.1.4 Group Four: Growth Hormone

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

**SAVINGS:** For FY2023, the supplemental plus market shift savings totaled almost \$8.3 million in this class. The positive savings come from supplemental rebates and market share savings.

# 4.1.5 Group Five: Hypoglycemics, Incretin Mimetics/Enhancers

Hypoglycemics and incretin mimetics/enhancers are used to manage Type 2 diabetes mellitus.

**SAVINGS**: For FY2023, the supplemental plus market shift savings totaled almost \$7.4 million. The savings are due to supplemental rebates.



### 4.2 Number of Therapeutic Classes Reviewed

The number of PDL classes reviewed by LDH has significantly increased since the inception of the TOP\$ program, culminating with the review of 135 classes during the Louisiana FY2023 Pharmaceutical and Therapeutics Committee (P&T) Review 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 FY2023, the PDL Compliance average rate was 97.3% for FFS; that rate was 97.9% for MCOs.

# 4.4 Reported Savings FY2022 through FY2023

### 4.4.1 Factors Affecting the PDL Program

Below are major factors that have affected the PDL Program in the past several years: (1) U.S. healthcare reform, (2) a shift in population from FFS to MCOs, (3) the inception of the single PDL, and (4) the Hepatitis C Subscription Model.

#### 1. U.S. Healthcare Reform

As referred to in 2.0 Major Developments in FY2016, the ACA resulted 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 Federal Medical Assistance Percentage (FMAP) regulations. This act reduced state Medicaid supplemental rebate dollars initially for those drugs under contract starting January 1, 2010.

#### 2. Shift of Population from FFS to MCOs

The shift of lives from the FFS Pharmacy Program to the MCOs resulted in a loss of savings due to less utilization of medications with high federal and/or supplemental rebates. Supplemental rebates decreased 83% due to population loss to the MCOs between the last two quarters of FY2015.

#### 3. Inception of the Single PDL

Implemented in May 2019, the single PDL has driven significant cost savings for the state and improved provider convenience. Instead of looking up each MCO's formulary, prescribers can simply use one PDL to prescribe medications to all Medicaid beneficiaries. For members, a single PDL can simplify the process of choosing an MCO and can make switching between MCOs less difficult. From a financial standpoint, the single PDL execution offers a significant positive financial impact on rebates for the state.



### 4. The Hepatitis C Subscription Model

The hepatitis C subscription model was implemented on July 15, 2019, to eliminate hepatitis C in Louisiana while using a cost-effective approach. In the U.S., this infection kills more individuals than all other infectious diseases combined. Louisiana Medicaid signed a five-year contract with Asegua to pay a fixed amount each year in exchange for an unlimited hepatitis C regimen for that year to treat patients in its Medicaid program and correction facilities. LDH aims to treat at least 31,000 people by the end of 2024.

### 4.4.2 Savings Results

In FY2023, savings with the Louisiana single PDL program totaled almost \$143.7 million, an increase from nearly \$102.8 million in FY2022.

Table 1: Reported Savings by Quarter for FY2022

Savings Results FY 2022					
Calendar Quarter	LA Fiscal Quarter	Quarterly Reported Savings	Comments		
3Q21	Q122	\$ 26,673,072	Actual 3Q2021 (reflecting CMS federal rebate amounts under rebate rules established by ACA)		
4Q21	Q222	\$ 25,576,199	Actual 4Q2021 (reflecting CMS federal rebate amounts under rebate rules established by ACA.		
1Q22	Q322	\$ 22,555,312	Actual 1Q2022 (reflecting CMS federal rebate amounts under rebate rules established by ACA)		
2Q22	Q422	\$ 27,997,802	Actual 2Q2022 (reflecting CMS federal rebate amounts under rebate rules established by ACA)		
Total		\$ 102,802,385			



Table 2: Reported Savings by Quarter for FY2023

Savings Results FY 2023					
Calendar Quarter	LA Fiscal Quarter	Quarterly Reported Savings	Comments		
3Q22	Q123	\$ 34,901,935	Actual 3Q2022 (reflecting CMS federal rebate amounts under rebate rules established by ACA)		
4Q22	Q223	\$ 36,243,476	Actual 4Q2022 (reflecting CMS federal rebate amounts under rebate rules established by ACA.		
1Q23	Q323	\$ 37,359,025	Actual 1Q2023 (reflecting CMS federal rebate amounts under rebate rules established by ACA)		
2Q23	Q423	\$ 35,187,502	Actual 2Q2023 (reflecting CMS federal rebate amounts under rebate rules established by ACA)		
Total		\$ 143,691,938			

# 5.0 Estimated Savings for FY2024

The estimated savings for FY2024 are dependent on elements that continue to influence the PDL program.

# **5.1** Factors That Affected the PDL Program in FY2023

### **5.1.1 Growth of Specialty Drugs**

The number of specialty drug approvals continues to be astounding. Along with the growth of specialty drugs comes the hefty price of these products. State Medicaid programs struggle with utilization controls on these products for a variety of reasons that may include lack of competition, legislative protections, grandfathering, or pharmacy department policy.

### 5.1.2 COVID-19 Pandemic

The COVID-19 pandemic significantly impacted Louisiana's LDH PDL program. Due to shortages of preferred medications (like albuterol inhalers for breathing problems), LDH was forced to switch several expensive, non-preferred drugs to preferred status. This coincided with a surge in Medicaid enrollment as economic hardship caused by the pandemic pushed more people toward Medicaid eligibility. The Families First Coronavirus Response Act (FFCRA) further amplified this effect by requiring states to maintain continuous coverage for existing enrollees. Despite these enrollment changes, the pandemic also fostered increased prescription volume alongside cost savings for the program.



# 5.2 Projected Savings for FY2024

Savings estimates for FY2024 total over \$188.6 million.

Table 3: Projected Savings by Quarter for FY2024

Calendar Quarter	LA Fiscal Quarter	Estimated Savings	Comments
3Q23	Q124	\$34,841,976	Actual 3Q2023 (reflecting CMS federal rebate amounts under rebate rules established by ACA)
4Q23	Q224	\$45,497,334	Estimated 4Q2023. Projections may be impacted by the list of factors below
1Q24	Q324	\$51,082,702	Estimated 1Q2024. Projections may be impacted by the list of factors below
2Q24	Q424	\$57,254,518	Estimated 2Q2024. Projections may be impacted by the list of factors below
Totals		\$188,676,530	

Actual savings may be different from projections due to the following various factors:

- Medicaid expansion with eligibility.
- Drug utilization may change depending on the health of the newly eligible population.
- Large population changes because of the economy, hurricanes, or other disasters would have a potentially large effect on the population.
- The percentage of the federal share of the newly eligible population changes over several vears.
- New drugs will enter the market, causing unforeseen impact on drug utilization and unknown participation in the 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 a 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.
- If state MAC pricing is more aggressive over time, it will likely make generics lower cost than branded products in some classes.
- Limiting the number of branded products in a class would likely lower supplemental rebates in that class and potentially for the whole PDL program.
- Base Federal Rebates for generic drugs have increased from 11% to 13%.



- The Health Care Reform Act establishes a generic program within the FDA for biologic agents; the impact of this over the next 10 years is unknown.
- FMAP changes will impact the state's share of all rebates.

# 6.0 Features of the Louisiana Medicaid PDL that Impact Savings

Louisiana's PDL program has achieved numerous significant improvements over the past years. However, some limitations still exist that the state continues to work on.

# 6.1 Strengths

Louisiana participates in the multi-state purchasing pool and benefits from volume purchasing while maintaining 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 supplemental rebates.

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, Medicaid covered new drugs (both brand and generic) without prior authorization before the P&T Committee's review. New drugs are usually very expensive and can gain market share quickly before the P&T Committee has an opportunity to review them, so this change has been a huge stride in achieving additional savings.

The number of reviewed PDL classes for Louisiana Medicaid has increased to 135, an important achievement because usually, a positive correlation exists between the number of reviewed classes and savings accrual.

The switch to a single PDL in May 2019 is another major advancement. The state can collect supplemental rebates on contracted medications dispensed to all Medicaid beneficiaries, rather than to FFS members only. The state can gain additional savings through favorable market shifts. Both factors result in a massive surge in cost avoidance for the state.

### 6.2 Weaknesses

LDH does not achieve the full savings potential for the HIV/AIDS drug class because legislative regulations currently mandate all HIV/AIDS drugs to be available to members without prior authorization. Due to this restriction, many of these drugs do not qualify for supplemental rebate offers worth millions of dollars.

Preferred branded drugs continue to be intentionally limited on the single PDL due to pharmacy provider abrasion and increased MCO expenditures.



To improve convenience for providers, members, and MCOs, the PDL prioritizes certain highutilization drugs by MCOs, even if these drugs are more expensive for the state.

# 7.0 Summary

The Preferred Drug List generates cost savings in two ways. First, the state collects supplemental rebates from pharmaceutical manufacturers for their inclusion as a preferred product. Secondly, a prior authorization (PA) requirement on non-preferred products actively pushes claims towards more cost-effective alternatives by making it harder to get the expensive medications approved.

The LDH PDL program continues to be very successful. Savings for FY2023 were over \$143 million, mainly due to supplemental rebates. Savings have increased from FY2022 due to increased prescription volume and the continued growth of specialty drugs. Louisiana's estimated savings for FY 2024 are over \$188.6 million.

