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STAUFFER** LC
CERTIFIED PUBLIC ACCOUNTANTS

NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES DIVISION OF HEALTH BENEFITS

PREFERRED DRUG LIST AND SUPPLEMENTAL REBATE PROGRAM
ANNUAL PUBLIC REPORT – STATE FISCAL YEAR 2017

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Executive Summary

The North Carolina Department of Health and Human Services, Division of Health Benefits (Division), has engaged Myers and Stauffer to provide an annual public report related to the Division's Preferred Drug List (PDL) and Supplemental Rebate Program as required by their Medicaid state plan. This annual report reflects the fiscal impact of the program, as well as the program impact on related services other than pharmacy for state fiscal year (SFY) 2017 (July 1, 2016 through June 30, 2017). Within this report, Myers and Stauffer evaluated the following:

- *Estimated cost savings associated with the PDL program.*
- *Estimated cost savings associated with the State's participation in the National Medicaid Pooling Initiative (NMPI) supplemental rebate program.*
- *Whether the PDL program impacted beneficiaries' access to PDL program medications.*
- *Whether the PDL program resulted in changes in expenditures and/or utilization of medical services (such as emergency department visits, inpatient hospital admissions, physician office visits, outpatient visits) and laboratory services.*

Background

Beginning in March 2002, the Division implemented a prior authorization (PA) process for certain prescription drugs. The selected drugs were chosen by a panel of clinical and academic physicians and pharmacists based on their cost and high potential for overuse in an effort to encourage and promote clinically appropriate use. In order to improve quality of care and reduce costs, the Community Care of North Carolina (CCNC) Clinical Directors developed and published the Prescription Advantage List (PAL) in November 2002. The PAL was a voluntary list intended as a guide to prescribe more cost-effective medications when clinically appropriate. Based on the success of the PAL, the Division implemented an updated PAL in November 2003. Because savings realized by enhancing the utilization management of the PAL were insufficient, the Division was directed to establish and implement a PDL with supplemental rebates by the North Carolina General Assembly in 2009.

As a result of Session Law 2009-451, Sections 10.66(a)-(d), the Division established a PDL and joined the NMPI supplemental rebate purchasing pool in March 2010. The NMPI is a multi-state Medicaid pharmaceutical purchasing pool administered by Magellan Medicaid Administration, Inc. The intent of multi-state purchasing pool programs is to allow participating state Medicaid programs to combine their covered lives and increase their negotiating power to obtain greater supplemental rebates and lower net drug costs.

Based upon Session Law 2014-100, Sections 12H.9(a)-(c), the Division was required to make adjustments to the PDL to maximize supplemental rebates for mental health drugs. This legislation also gave authority to the Division to impose prior authorization, utilization review criteria and other restrictions for mental health drugs. Effective June 2015, the Division implemented PDL updates regarding oral antipsychotic medications. These updates included showing preferred and non-preferred oral antipsychotics on the PDL, as well as requiring trial and



failure of one preferred antipsychotic without a prior authorization to obtain a non-preferred medication. Additionally, the Division reinstated their Off Label Antipsychotic Safety Monitoring in Beneficiaries through Age 17 (A+KIDS) and Off Label Antipsychotic Safety (ASAP-adults) programs. These programs require prior authorization for any preferred or non-preferred antipsychotic medication for children 17 years of age and younger or off label use for adults 18 years of age and older.

The Division initially established 88 PDL therapeutic drug categories, including preferred and non-preferred medications. Drugs on the PDL are indicated as “preferred” or “non-preferred” based on therapeutic effectiveness, safety and clinical outcomes. Generally, “preferred” drugs do not require prior authorization unless there are other clinical coverage criteria requirements or quantity limits. “Non-preferred” drugs are available through prior authorization. For therapeutic drug categories that do not appear on the PDL, prescribers can prescribe drugs in these classes as appropriate unless clinical coverage criteria requiring prior authorization exist. *Chart 1* below and *Chart 2* on the following page illustrate spend and claim breakdowns for SFY 2017 based upon PDL designation after exclusion of claims as noted on page 20. The 105 therapeutic drug categories included in the PDL program represented 77 percent of total spend and 83 percent of total claims during the study period. As illustrated below, spend for preferred drugs represented 63 percent of total spend and 82 percent of spend for medications subject to the PDL. Additionally, preferred drug claims represented 79 percent of total claims and 95 percent of claims subject to the PDL.

Chart 1: SFY 2017 Spend Breakdown by PDL Designation

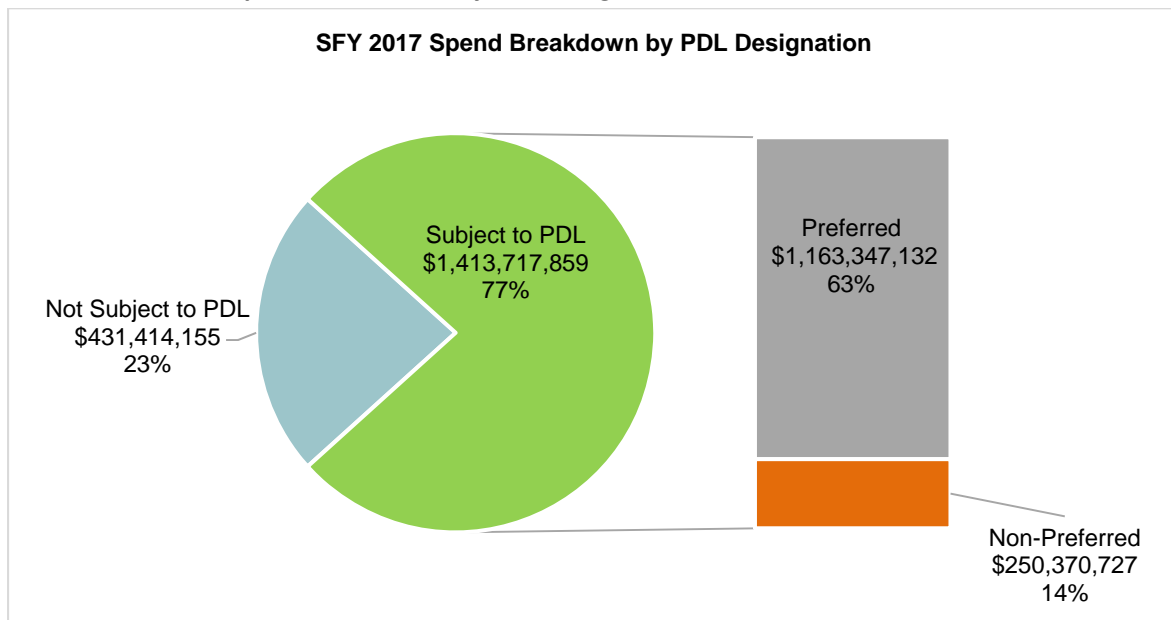
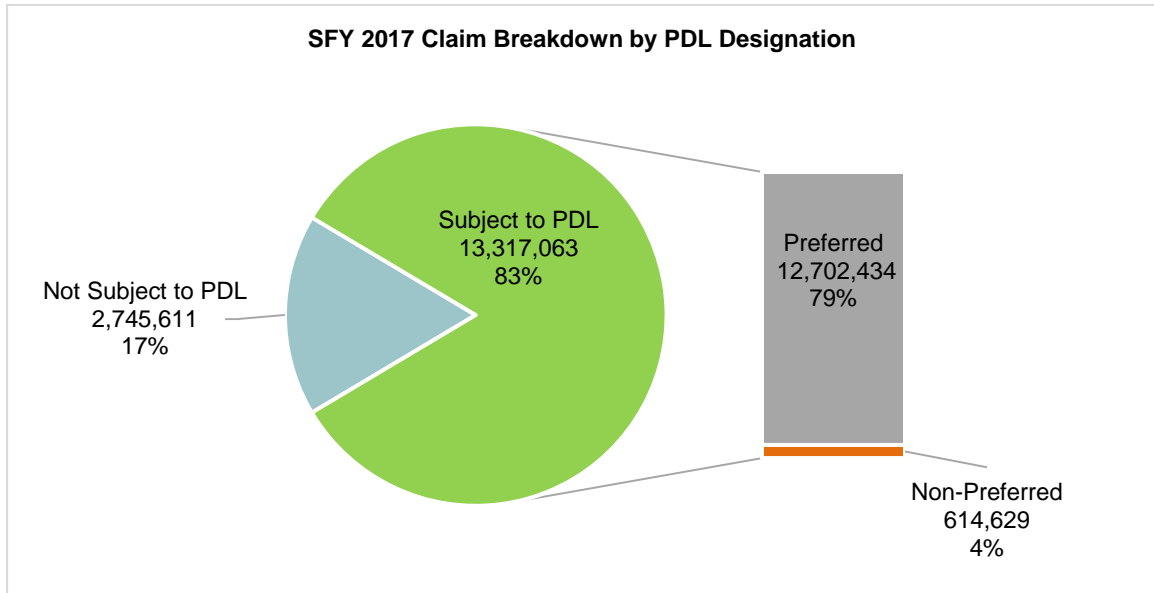




Chart 2: SFY 2017 Claim Breakdown by PDL Designation



The Division's PDL program has been in operation since 2010 and, consequently, the program and savings associated with it have remained relatively stable. Because the program is mature and stable, relatively few changes are made to the program each year. Prescribers' awareness of the program increases as the program ages which can impact prescribing habits. During SFY 2017, there were 105 therapeutic drug categories included on the PDL. PDL changes were made to a total of 83 therapeutic drug categories in October 2016, November 2016, January 2017 and May 2017. The changes were minimal and only 14 therapeutic drug categories had greater than five percent of claims shift based upon PDL changes. Due to this, the risk of impacting beneficiaries' access to PDL medications and utilization and/or expenditures on medical and laboratory services was low. It is important to note that during this analysis, Myers and Stauffer can only determine association and not causality.



Summary of Results

Estimated Program Savings

For SFY 2017, Myers and Stauffer estimated the total net savings associated with the program components, as defined on page 7. The savings associated with the PDL, clinical PA and supplemental rebate programs were \$219.9 million with a state share of \$72.7 million. *Table 1* below illustrates the net PDL, clinical PA and supplemental rebate program savings by program component.

Table 1: SFY 2017 Savings by Program Component

Program Component	Total Savings	State Share
PDL Savings	\$89,851,302.34	\$29,902,513.42
Supplemental Rebate Collections	\$86,849,050.79	\$28,903,364.10
Market Shift Savings	\$393,641.55	\$131,003.91
Clinical PA Savings	\$45,851,682.11	\$15,259,439.81
Program Administrative Costs	\$3,044,962.72	\$1,522,481.36
Total Net PDL and Clinical PA Savings	\$219,900,714.07	\$72,673,839.88

After allocation of the program administrative costs, approximately \$176.6 million, with a state share of \$58.7 million, of the total net savings can be attributed to the Division's PDL and supplemental rebate programs and \$43.3 million, with a state share of \$14.0 million, can be attributed to the clinical PA program.

The top 10 therapeutic drug categories contributed to 66 percent of the total savings associated with the PDL, clinical PA and supplemental rebate programs (\$148.1 million with a state share of \$49.3 million). *Table 2* highlights the top 10 therapeutic drug categories associated with the greatest overall program savings during the study period.

Table 2: Top 10 Therapeutic Drug Categories – Overall Program Savings

Therapeutic Drug Category	Total Savings (in millions)	State Share (in millions)	% of Total Savings
Hepatitis C agents	\$33.1	\$11.0	15%
Stimulants and related agents	\$31.7	\$10.6	14%
Antipsychotics	\$29.2	\$9.7	13%
Cytokine and CAM antagonists	\$11.1	\$3.7	5%
Hypoglycemics, metformins	\$10.8	\$3.6	5%
Opiate dependence treatments	\$7.6	\$2.5	3%
Growth hormone	\$7.3	\$2.4	3%
Acne agents, topical	\$6.8	\$2.3	3%
NSAIDS	\$6.2	\$2.1	3%
Proton pump inhibitors	\$4.3	\$1.4	2%
Top 10 Total Savings	\$148.1	\$49.3	66%
Remaining Category Savings	\$74.8	\$24.9	34%
Total Program Savings	\$222.9	\$74.2	100%



Beneficiary Access to PDL Program Medications

Myers and Stauffer evaluated the impact of the PDL on beneficiaries' access to PDL program medications. The results of this analysis demonstrated that, similar to SFY 2016, 7.9 percent of unique continuously eligible beneficiaries (91,266 out of 1,162,503) experienced a denied non-preferred point-of-sale pharmacy claim related to a pharmacy point-of-sale PDL edit and did not receive a subsequent paid claim within the same therapeutic drug category. For all therapeutic drug categories, 2.5 percent of beneficiaries with a denied non-preferred claim did not receive a paid claim within the same therapeutic drug category. This percentage is also comparable to past years. Additionally, there was a small number (0.4 percent) of beneficiaries who reverted back to a non-preferred medication after switching to a preferred medication due to the PDL program changes in SFY 2017.

PDL Program Impact on Medical and Laboratory Services

Myers and Stauffer examined the PDL impact on medical and laboratory services. For most of the therapeutic drug categories that had PDL changes during the study period, the sample sizes were too small to perform a statically valid analysis; therefore, no statistically conclusive results could be drawn. Myers and Stauffer examined graphically the one therapeutic drug category with the largest study group sample size where beneficiaries had switched from non-preferred to preferred medications during the study period. In conclusion, it is unclear if the minor changes in medication therapy were due to the PDL or clinical prescriber intervention and, therefore, resulting changes in expenditures and/or utilization of medical and laboratory services should not be relied upon to evaluate the PDL impact.



PDL and PA Program Savings

Myers and Stauffer calculated the estimated savings across all therapeutic drug categories associated with the PDL program effective in SFY 2017. The estimated savings calculations account for:

- *PDL savings, which are the savings, net of federal rebates, associated with denied point-of-sale outpatient pharmacy claims for non-preferred PDL medications. The PDL savings include the offset in savings due to alternate drug therapies dispensed within the market basket.*
- *Supplemental rebates collected from manufacturers as reported by the Division's supplemental rebate vendor.*
- *Market shift savings, which are the savings, net of federal rebates, associated with beneficiaries switching from a non-preferred medication to a preferred medication without a point-of-sale outpatient pharmacy claim denial.*
- *Clinical PA savings, which are the savings, net of federal rebates, associated with denied point-of-sale outpatient pharmacy claims for clinical edit codes. These savings are independent of the supplemental rebate program. This program requires PA for certain medications to ensure that clinically appropriate criteria are followed.*
 - *If the denied claim contained both clinical PA and PDL edit codes, the savings were accounted for in the clinical PA savings and not the PDL savings.*
- *Administrative costs associated with the program.*

Estimated Net Savings

Myers and Stauffer estimated that the total net savings associated with the PDL, clinical PA and supplemental rebate programs were \$219.9 million with a state share of \$72.7 million. Of the total net savings, approximately \$176.6 million, with a state share of \$58.7 million, can be attributed to the Division's PDL and supplemental rebate programs and \$43.3 million, with a state share of \$14.0 million, can be attributed to the clinical PA program.

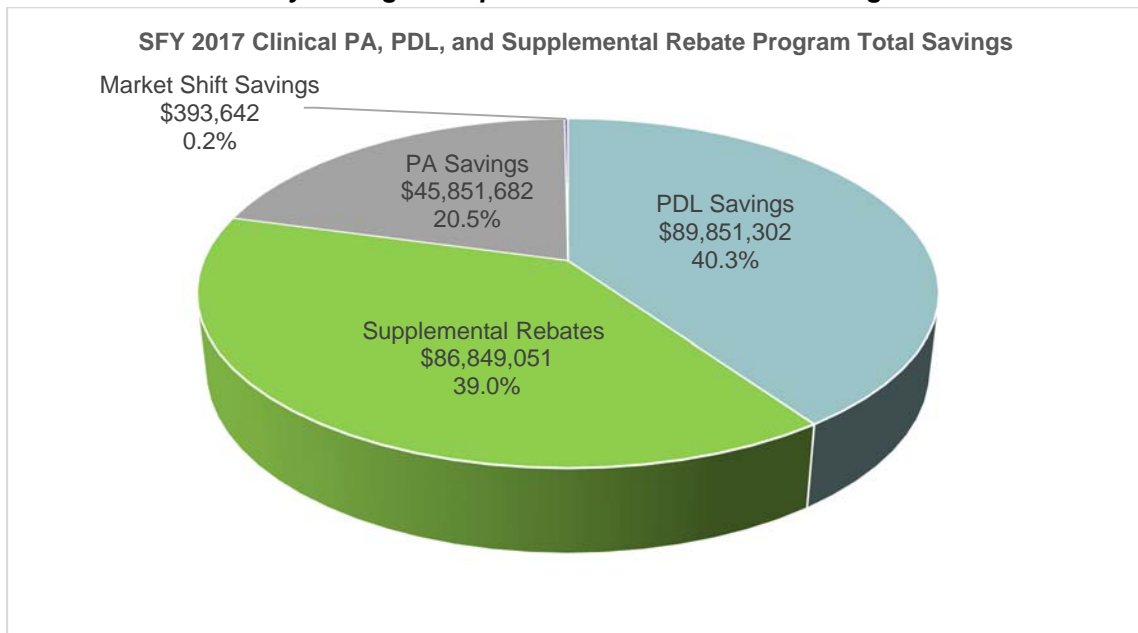
Table 3 and Chart 3 on the following page illustrate the breakdown of savings, including both state and federal allocations.



Table 3: Clinical PA, PDL and Supplemental Rebate Program Savings

Program Component	Total	% of Total	Federal Share	State Share
PDL Savings	\$89,851,302.34	N/A	\$59,948,788.92	\$29,902,513.42
Supplemental Rebate Collections	\$86,849,050.79	N/A	\$57,945,686.69	\$28,903,364.10
PDL and Supplemental Rebate Administrative Costs	\$521,742.50	N/A	\$260,871.25	\$260,871.25
Market Shift Savings	\$393,641.55	N/A	\$262,637.64	\$131,003.91
Net PDL and Supplemental Rebate Savings	\$176,572,252.18	80%	\$117,896,242.00	\$58,676,010.18
Clinical PA Savings	\$45,851,682.11	N/A	\$30,592,242.30	\$15,259,439.81
Clinical PA Administrative Costs	\$2,523,220.22	N/A	\$1,261,610.11	\$1,261,610.11
Net Clinical PA Savings	\$43,328,461.89	20%	\$29,330,632.19	\$13,997,829.70
Total Net PDL and Clinical PA Savings	\$219,900,714.07	100%	\$147,226,874.19	\$72,673,839.88

Chart 3: Distribution by Savings Component – SFY 2017 Total Savings



Preferred Drug List Savings

For SFY 2017, Myers and Stauffer estimated a total savings of \$89.9 million, net of federal rebates, associated with the PDL as described above. The state share of the savings would be approximately \$29.9 million, before accounting for administrative costs. *Table 4* on the following page highlights the top 10 therapeutic drug categories with the largest PDL associated savings during the study period.



Table 4: Top 10 Therapeutic Drug Categories – PDL Program Savings

Therapeutic Drug Category	Total Savings (in millions)	State Share (in millions)	% of Total Savings
Hypoglycemics, metformins	\$10.7	\$3.6	12%
Stimulants and related agents	\$8.7	\$2.9	10%
Acne agents, topical	\$6.8	\$2.3	8%
Cytokines and CAM antagonists	\$6.4	\$2.1	7%
Antipsychotics	\$5.3	\$1.8	6%
Hepatitis C agents	\$4.9	\$1.6	5%
NSAIDs	\$4.2	\$1.4	5%
Proton pump inhibitors	\$4.0	\$1.3	4%
Intranasal rhinitis agents	\$3.2	\$1.1	4%
Bronchodilators, beta agonist	\$3.0	\$1.0	3%
Top 10 Total Savings	\$57.2	\$19.1	64%
Remaining Category Savings	\$32.7	\$10.8	36%
Total PDL Savings	\$89.9	\$29.9	100%

The top 10 therapeutic drug categories comprised 64 percent of the overall savings associated with the PDL program (\$57.2 million with a state share of \$19.1 million) while the top five therapeutic drug categories accounted for 43 percent of the PDL program savings (\$37.9 million with a state share of \$12.7 million).

Supplemental Rebate Collections

In SFY 2017, the total of supplemental rebates collected from pharmaceutical manufacturers was approximately \$86.8 million with a state share of \$28.9 million. Rebates collected for the top 10 therapeutic drug categories were \$74.0 million and represented 85 percent of total supplemental rebates collected. The top 10 therapeutic drug categories with the largest supplemental rebate associated savings during the study period included:

- *Stimulants and related agents*
- *Antipsychotics*
- *Growth hormone*
- *Hepatitis C agents*
- *Cytokine and CAM antagonists*
- *Opiate dependence treatments*
- *Anticoagulants*
- *Progestational agents*
- *Antiparasitics, topical*
- *Ophthalmics for allergic conjunctivitis*



Market Shift Savings

For SFY 2017, Myers and Stauffer estimated the market shift savings based on the number of days between the paid non-preferred claim and the paid preferred claim (7 days, 30 days and 60 days). To be included in this savings analysis, beneficiaries must have had a paid outpatient pharmacy claim for a non-preferred medication and a subsequent paid claim for a preferred medication within the same therapeutic drug category without a point-of-sale denial between the two claims. Because claims for seizure medications for beneficiaries with a seizure diagnosis are not subject to the PDL and prior authorization criteria, market shift savings were not calculated for these claims. *Table 5* illustrates the market shift savings using variable days between paid claims for the top 10 therapeutic drug categories.

Table 5: Top 10 Therapeutic Drug Categories – Market Shift Savings by Days Between Paid Claims

Days Between Paid Claims	Number of Beneficiaries	Total Savings	State Share
7	912	\$72,107	\$23,997
30	2,654	\$214,536	\$71,398
60	3,788	\$325,133	\$108,204

Table 6 highlights the top 10 therapeutic drug categories with the largest market shift savings during the study period within 60 days between paid non-preferred and paid preferred claims.

Table 6: Top 10 Therapeutic Drug Categories – Market Shift Savings

Therapeutic Drug Category	Number of Beneficiaries	Total Savings	State Share
Hypoglycemics, metformins	116	\$84,277.12	\$28,047.42
Antipsychotics	296	\$57,817.82	\$19,241.77
Anticonvulsants	263	\$47,376.40	\$15,766.87
Antidepressants, SSRIs	553	\$31,982.03	\$10,643.62
Skeletal muscle relaxants	211	\$25,624.76	\$8,527.92
Glucocorticoids, oral	211	\$22,392.48	\$7,452.22
Neuropathic pain	1,667	\$16,658.03	\$5,543.79
Antihistamines, minimally sedating	326	\$14,557.59	\$4,844.77
COPD agents	95	\$13,691.32	\$4,556.47
Analgesics, narcotics long	50	\$10,755.58	\$3,579.46
Top 10 Total Savings	3,788	\$325,133.13	\$108,204.31
Remaining Category Savings	2,367	\$68,508.42	\$22,799.60
Total Market Shift Savings	6,115	\$393,641.55	\$131,003.91

Clinical PA Savings

For SFY 2017, Myers and Stauffer estimated a total of \$45.9 million net of federal rebates associated with the clinical PA program as described previously on page 7. The state share of the savings was approximately \$15.3 million. *Table 7* on the following page highlights the top 10 therapeutic drug categories with the largest clinical PA associated savings during the study period.



Table 7: Top 10 Therapeutic Drug Categories – Clinical PA Savings

Therapeutic Drug Category	Total Savings (in millions)	State Share (in millions)	% of Total Savings
Hepatitis C agents	\$21.6	\$7.2	47%
Antipsychotics	\$8.7	\$2.9	19%
Glucocorticoids, inhaled	\$2.8	\$0.9	6%
Opiate dependence treatments	\$2.1	\$0.7	5%
Anticonvulsants	\$2.0	\$0.7	4%
Neuropathic pain	\$1.4	\$0.5	3%
Botox – Non-PDL	\$1.1	\$0.4	2%
Orkambi – Non-PDL	\$0.6	\$0.2	1%
Bronchodilators, beta agonist	\$0.5	\$0.2	1%
Hypoglycemics, incretin mimetics/enhancers	\$0.5	\$0.2	1%
Top 10 Total Savings	\$41.3	\$13.9	89%
Remaining Category Savings	\$4.6	\$1.4	11%
Total Clinical PA Savings	\$45.9	\$15.3	100%

The top 10 therapeutic drug categories comprised 89 percent of the overall savings associated with the clinical PA program (\$41.3 million with a state share of \$13.9 million) while the top five therapeutic drug categories accounted for 81 percent of the clinical PA program savings (\$37.2 million with a state share of \$12.4 million).

Administrative Costs

The Division works collaboratively with its fiscal agent, GDIT, to manage the PDL, clinical PA and supplemental rebate programs. For SFY 2017, the Division paid GDIT a fixed monthly rate of \$52,174.25 beginning in September 2016 to operate the PDL and supplemental rebate programs. The cost of the PA program varies month over month based upon the number of PAs reviewed. The rate per PA is variable and decreases with higher PA review volume. *Table 8* illustrates the administrative costs by program.

Table 8: Administrative Cost by Program

Program	SFY 2017 Cost	State Share
PDL and Supplement Rebate Program	\$521,742.50	\$260,871.25
Clinical PA Program	\$2,523,220.22	\$1,261,610.11
Total	\$3,044,962.72	\$1,522,481.36

It would be assumed that administrative costs related to operation of the PDL, clinical PA and supplemental rebate programs would be categorized as administrative expenses subject to a FMAP of 50 percent.



Beneficiary Access to PDL Program Medications

A potential concern with implementation and administration of a PDL program is that beneficiaries may be negatively impacted due to delays in initiation of drug therapy or “restricting access” to certain non-preferred medications. Upon a point-of-sale denial of a non-preferred medication, the pharmacist must contact the prescriber for a resolution. The prescriber may 1) authorize the pharmacist to dispense a preferred medication, 2) submit a PA request to GDIT or 3) determine the medication is not medically necessary. Prescribers may submit PA requests via fax, phone or through the secure NCTracks provider portal. If the pharmacist cannot contact the prescriber and bring a resolution to the denied claim rather quickly, the beneficiary may leave the pharmacy without the prescribed medication. When a beneficiary leaves the pharmacy without the prescribed medication, they may eventually receive the medication after a delay, or they may choose not to follow-up and either discontinue or never begin therapy. To reduce the occurrence of beneficiaries leaving without any medication, the Division encourages pharmacy providers to use the 72-hour emergency supply allowed for medications requiring prior authorization. Use of this emergency supply ensures access to medically necessary medications.

All delays associated with non-preferred medications cannot be attributed directly to the PDL program. Delays in therapy can occur for a number of reasons. The beneficiary could have requested an early refill, the physician may have chosen to discontinue therapy and not pursue a prior authorization for the medication or the beneficiary’s Medicaid eligibility may have ended. Furthermore, delays within this analysis, identified as time between paid claims, does not necessarily indicate delays in therapy. Beneficiaries could have received samples or an emergency fill to cover the delay between paid claims. For purposes of this analysis, identified delays are quantified whereas it would be inappropriate to associate any causality to delay in therapy.

Myers and Stauffer evaluated the impact the PDL program had on beneficiaries’ access to PDL program medications. To monitor this impact the following were evaluated:

- *The number of beneficiaries who experienced a denied non-preferred point-of-sale claim at the pharmacy and the subsequent outcome from that denied claim. The outcomes included a paid non-preferred claim, a paid preferred claim or no subsequent paid claim within the same therapeutic drug category.*
- *The percentage of beneficiaries who had a paid non-preferred claim with a subsequent paid preferred claim and reverted back to a non-preferred medication within the same therapeutic drug category.*
- *Prior Authorizations.*



Beneficiaries with a Denied Non-Preferred Claim

Myers and Stauffer evaluated the number of continuously eligible beneficiaries who experienced a denied non-preferred point-of-sale claim at the pharmacy and the subsequent outcome from that denied claim. The beneficiaries were divided into three groups based on the outcome after the initial denied non-preferred claim within the same therapeutic drug category. The outcome groups consisted of a subsequent paid preferred claim, a subsequent paid non-preferred claim and no subsequent paid claim. *Table 9* illustrates the total count of beneficiaries and associated percent of total within each group for all therapeutic drug categories.

Table 9: Impact and Outcome of Beneficiaries Experiencing a Denied Non-Preferred Claim

Outcome	Total Beneficiaries	Impacted Beneficiaries	% of Total
Paid Preferred	1,162,503	178,404	15.3%
Paid Non-Preferred		42,095	3.6%
No Subsequent Claim		91,266	7.9%
Total		311,765	26.8%

Of the 105 therapeutic drug categories, changes were implemented in 83 categories during the study period. Overall, 7.9 percent (91,266) of unique continuously eligible beneficiaries (1,162,503) had a denied non-preferred claim with no subsequent paid claim within the same therapeutic drug category.

The top 10 therapeutic drug categories by beneficiary count who had a denied claim with no subsequent paid claim within the therapeutic class are presented in *Table 10*. Beneficiaries in *Table 10* could be counted more than once in the total if they are on medications in multiple therapeutic drug categories.

Table 10: Top 10 Therapeutic Drug Categories by Beneficiary Count Who Had a Denied Claim and No Subsequent Paid Claim Within the Therapeutic Drug Category

Ordered by Beneficiaries with No Subsequent Paid Claim Descending

Therapeutic Drug Category	Total Beneficiaries	Beneficiaries with No Subsequent Paid Claim	% of Total
NSAIDs	234,686	14,713	6.3%
Neuropathic pain	71,242	6,973	9.8%
Bronchodilators, beta agonist	221,215	4,835	2.2%
Acne agents, topical	35,924	4,796	13.4%
Intranasal rhinitis agents	146,013	3,676	2.5%
Glucocorticoids, inhaled	85,189	3,515	4.1%
Skeletal muscle relaxants	83,272	3,401	4.1%
Proton pump inhibitors	97,022	3,320	3.4%
Otic antibiotics	39,589	2,819	7.1%
Lipotropics, other	8,334	2,526	30.3%
Total for Top 10	1,022,486	50,574	4.9%
Total for All	4,234,555	104,512	2.5%



Table 11 below highlights the top 10 therapeutic drug categories by percent of beneficiaries who had a denied non-preferred claim and did not have a subsequent paid claim within the therapeutic drug category.

Table 11: Top 10 Therapeutic Drug Categories by Percent of Total Who Had a Denied Claim and No Subsequent Paid Claim Within the Therapeutic Drug Category

Ordered by % of Total Descending

Therapeutic Drug Category	Total Beneficiaries	Beneficiaries With No Subsequent Paid Claim	% of Total
Otic anti-infective & anesthetics	456	172	37.7%
Lipotropics, other	8,334	2,526	30.3%
Antivirals, topical	2,579	669	25.9%
Nasal preparations, antibiotics	538	132	24.5%
Antipsoriatics, oral	50	11	22.0%
Phosphate binders	1,337	282	21.1%
Hepatitis B agents	92	18	19.6%
Immunomodulators, topical	2,702	467	17.3%
Ulcerative colitis agents	1,248	210	16.8%
Angiotensin modulator combinations	2,507	419	16.7%

Beneficiaries Reverting to Non-Preferred Medication

Myers and Stauffer evaluated the count of continuously eligible beneficiaries who had a non-preferred medication then switched to a preferred medication and subsequently reverted back to a non-preferred medication. This was determined based upon paid point-of-sale claims at the pharmacy. A beneficiary must have received a paid non-preferred, then a paid preferred, then paid non-preferred, respectively, within the same therapeutic drug category.

Overall, approximately 14,000 out of nearly 3.6 million (0.4 percent) continuously eligible beneficiaries reverted back to a non-preferred medication after receiving a preferred medication.

Prior Authorizations

A total of 137,081 prior authorization requests were reported by GDIT for SFY 2017. The count of approvals and denials for these PA requests was not available for inclusion in this report and cannot be obtained from the data sets received by Myers and Stauffer.



PDL Program Impact on Medical and Laboratory Services

To comply with the Medicaid state plan, the Division is required to evaluate if the PDL program has an impact on related services, such as hospitalizations. Myers and Stauffer conducted an analysis to determine if there were any changes in the utilization and/or expenditures of beneficiaries' medical or laboratory services as a result of the PDL program. The following services were included in the analysis:

- *Emergency Department Visits*
- *Inpatient Hospital Visits*
- *Physician Office and Outpatient Visits*
- *Laboratory Services*

In order to evaluate the PDL program impact on medical and laboratory services, Myers and Stauffer assigned beneficiaries into a study group (therapy change) or a control group (no therapy change). The study group contained beneficiaries who experienced a change in drug therapy within a PDL drug category and the control group beneficiaries did not experience a change in drug therapy within the PDL drug category. Beneficiaries must have been continuously eligible and on continuous therapy within the PDL drug category to be assigned to one of the two groups.

Myers and Stauffer used the following criteria to evaluate which therapeutic drug categories to include in this analysis:

- *Therapeutic drug categories comprised of maintenance medications used for the treatment of chronic disease states.*
- *Therapeutic drug categories that had PDL changes during the study period which could result in a therapy change.*

The therapeutic drug categories identified with the above criteria did not contain an adequate number of beneficiaries to perform a statistically valid analysis. Since it is difficult to determine if the therapy change was due to the PDL or a provider clinical intervention, it would be difficult to substantiate any conclusions regarding the impact of the PDL on medical and laboratory utilization and expenditures with this approach. In an attempt to isolate beneficiaries who experienced a therapy change due to the PDL, the study group was restricted to those beneficiaries who had a denied non-preferred claim before the therapy change. For SFY 2017, only one therapeutic drug category, antipsychotics, contained a large enough sample size to be included for analysis. *Charts 4 through 11* on the following pages illustrate the monthly average utilization and expenditures for medical and laboratory services for the therapy change and no therapy change groups. It is worth noting that because the sample size is so small for the therapy change group, 79 beneficiaries, the variability is higher than that compared to the no therapy change group which has a much larger sample size (15,550 beneficiaries).



There are many programmatic and clinical considerations that must be made when evaluating the PDL program effect on the antipsychotic category. First, while the antipsychotics therapeutic drug category is subject to the PDL, trial and failure of only one preferred product is required before a non-preferred product can be obtained without prior authorization. This allows alternative therapies to be more easily prescribed and accessed. Secondly, it is important to note that there is a large amount of clinical variability when determining the best course of therapy for psychiatric patients. Medication therapy regimens may have to be changed frequently until the optimal patient specific regimen is determined. Lastly, there was a higher proportion of medical claims that were coded with a place of service code of “intermediate care facility/individuals with intellectual disabilities” in the study group versus the control group. This type of facility provides health related care and services above the level of custodial care, but does not provide the level of care or treatment available in a hospital. Therefore, these claims are not included in the inpatient visit category and this may contribute to the lower number of inpatient visits for the study group. Due to the small sample size and the considerations above, caution should be taken when evaluating and drawing conclusions from the graphs on the following pages.



Antipsychotics

Chart 4: Average Number of Emergency Department Visits

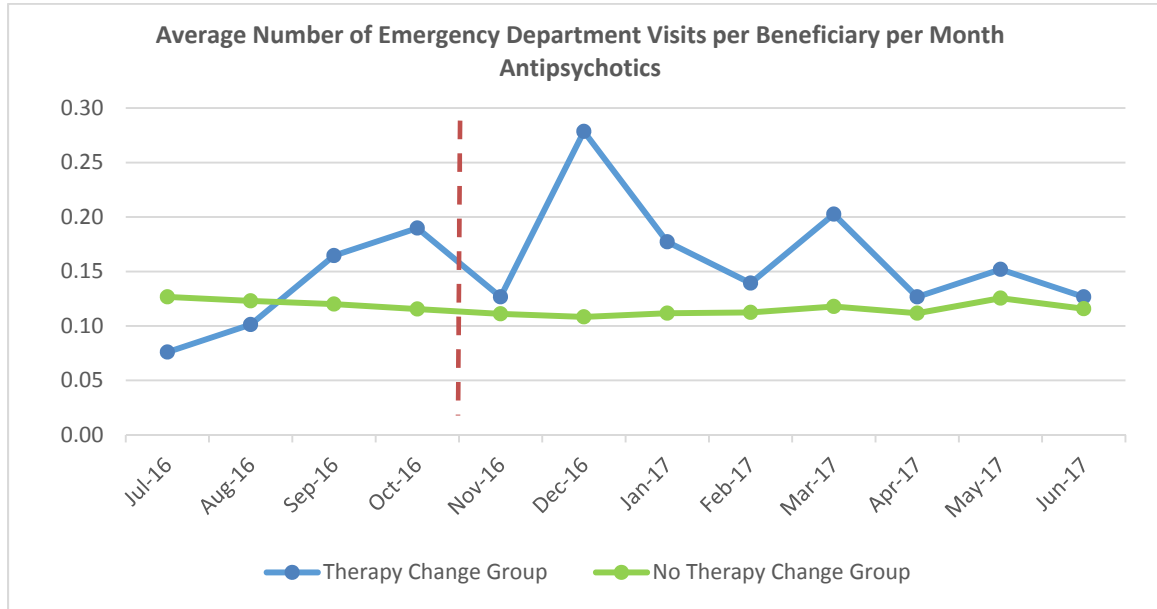


Chart 5: Average Amount Paid for Emergency Department Visits

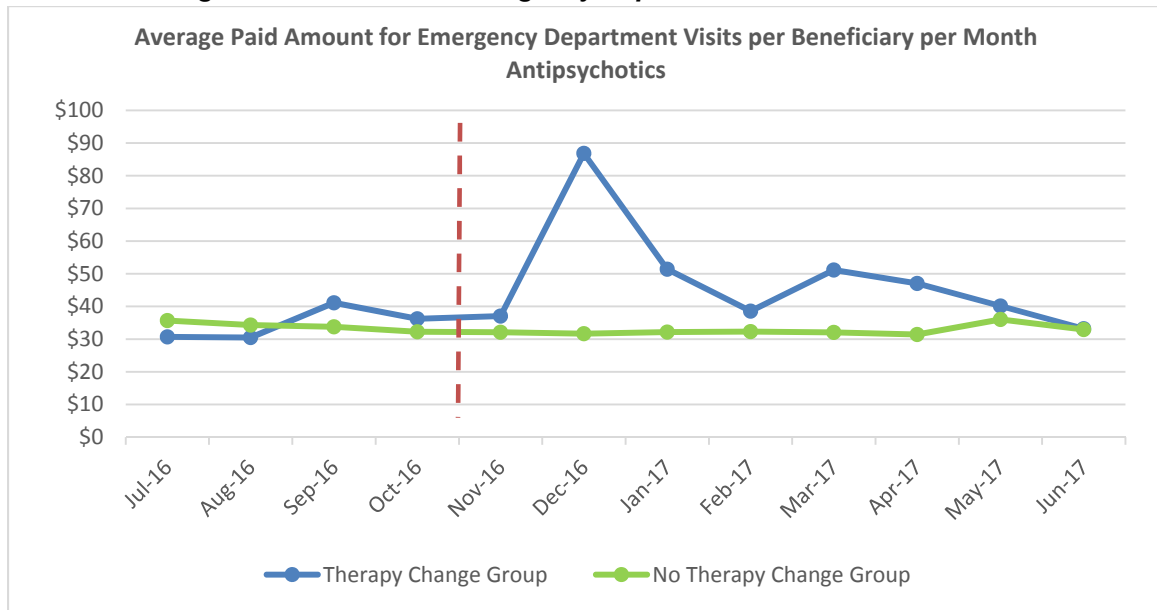




Chart 6: Average Number of Inpatient Admissions

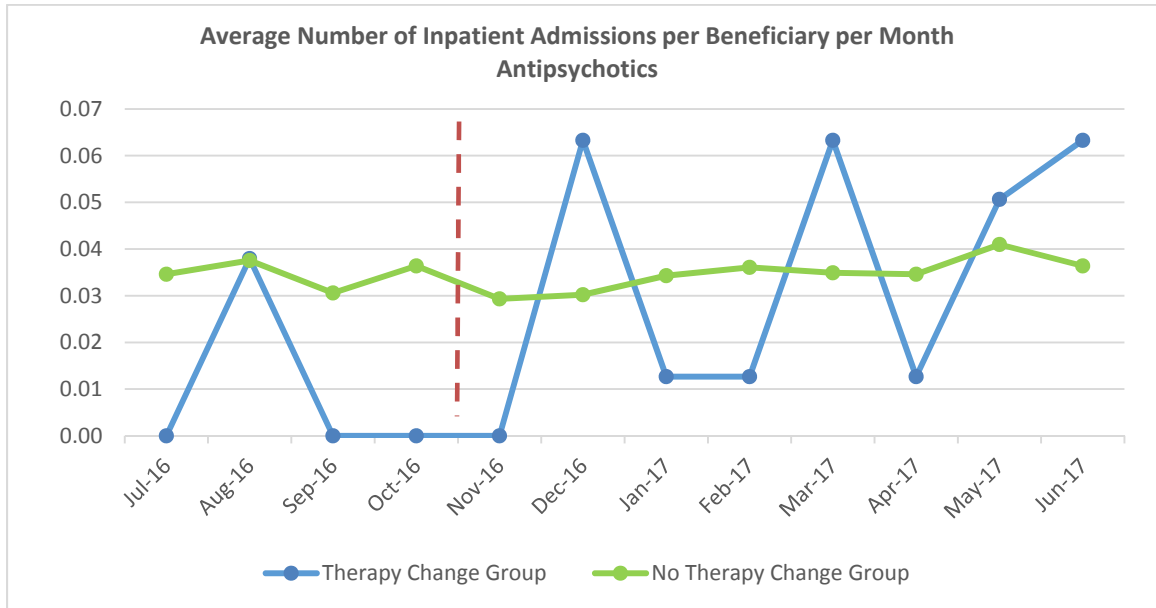


Chart 7: Average Amount Paid for Inpatient Admissions

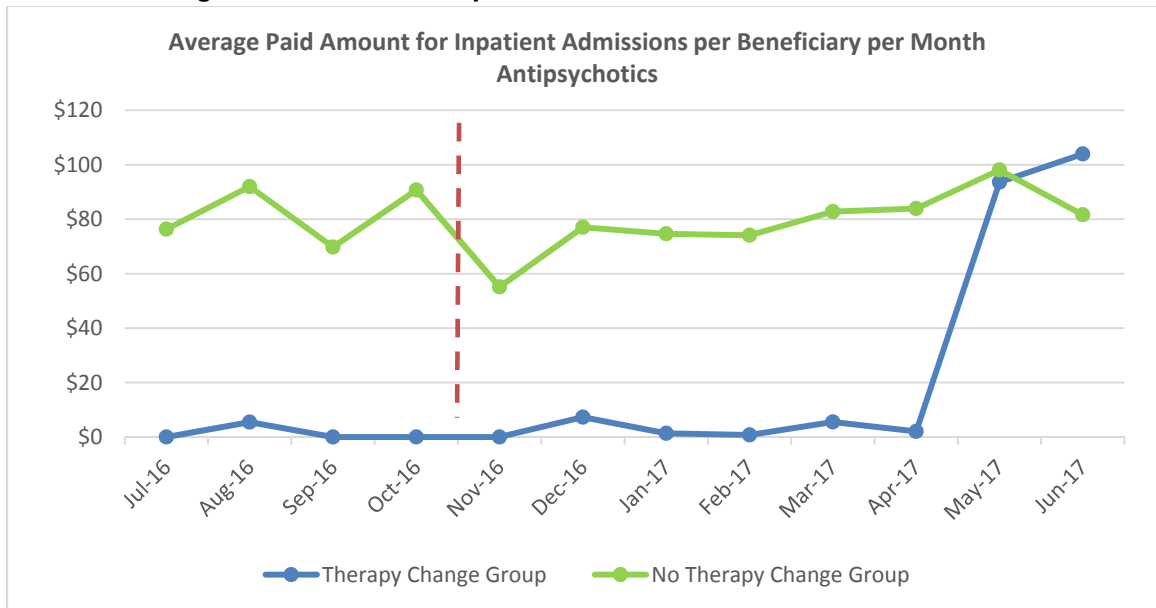




Chart 8: Average Number of Physician Office/Outpatient Visits

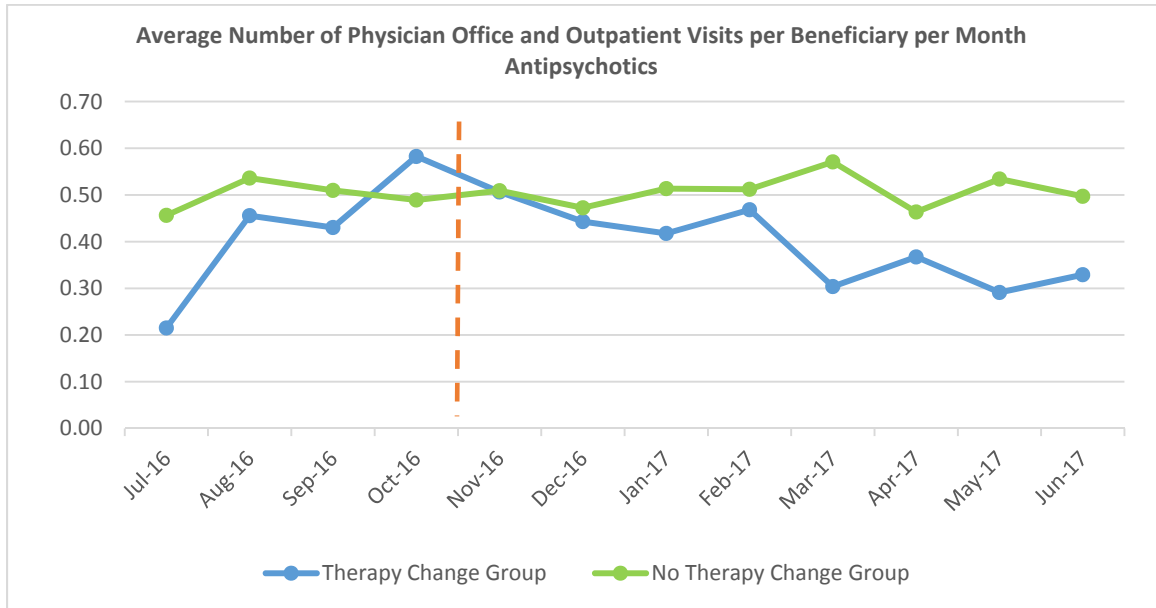


Chart 9: Average Amount Paid for Physician Office/Outpatient Visits

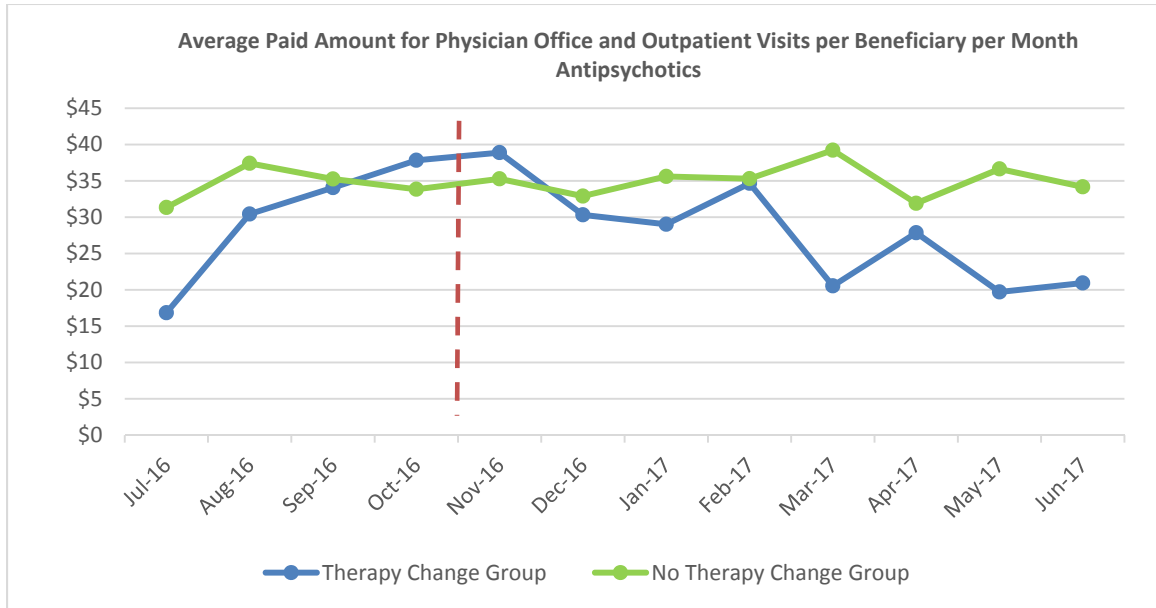




Chart 10: Average Number of Laboratory Services

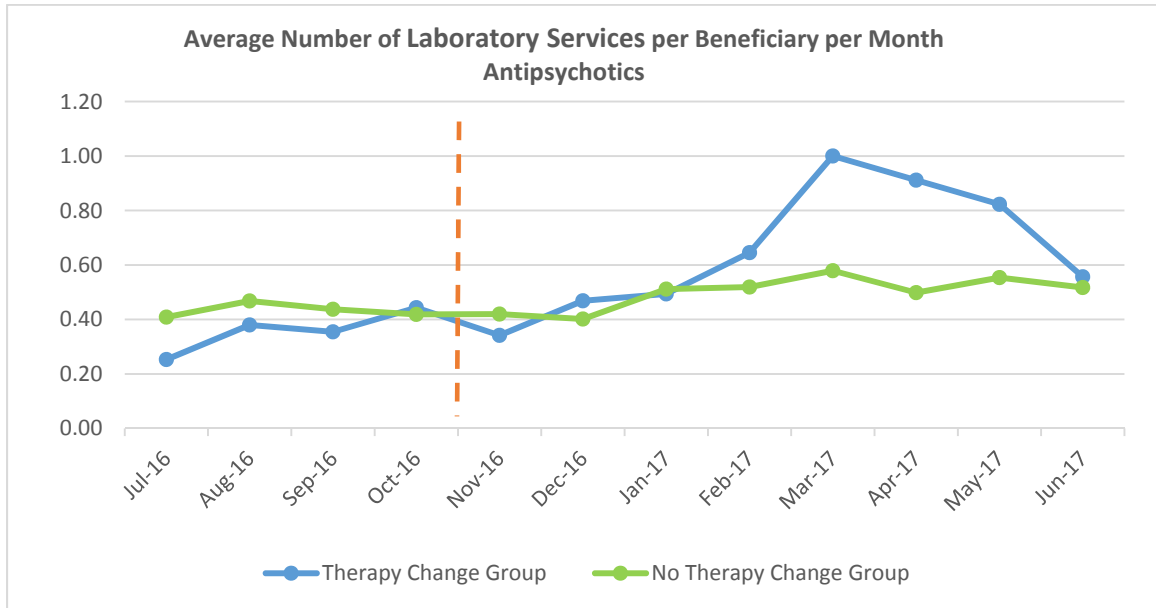
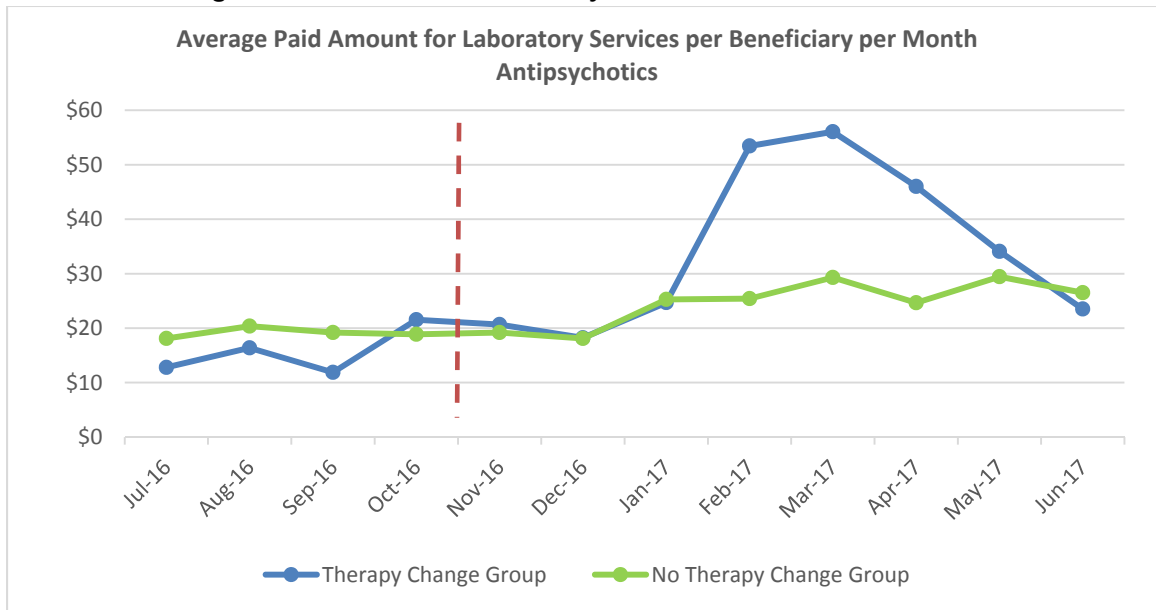


Chart 11: Average Amount Paid for Laboratory Services





Assumptions, Exclusions and Limitations of Analysis

- *This analysis was based on outpatient pharmacy claims data with dates of service from July 1, 2016 through June 30, 2017 available at the time of the analysis.*
- *Although rebates are collected for third party liability (TPL) claims, Myers and Stauffer excluded these claims because the Division is not the primary payer of these claims and the PDL and PA edits are bypassed during claims processing.*
- *340B claims and Title XXI Children's Health Insurance Program (CHIP) claims were excluded from the analysis because these claims are not eligible for rebates.*
- *Compound drug claims were excluded from the analysis because the header paid amount is split evenly across the line items and the paid amount per NDC cannot be accurately determined from the data. Compound drug claims represent a small number of claims; therefore, the impact on the results of this analysis would be minimal.*
- *Five denied claims were excluded from the savings calculation due to what appeared to be a billing error of an unreasonably high number of units.*
- *To estimate federal rebates, Myers and Stauffer utilized the federal unit rebate amount (URA) assigned to each NDC. In cases where the Centers for Medicare and Medicaid Services (CMS) URA unit and the NCPDP billing unit were not equal, a rebate unit conversion was applied. A comprehensive list of rebate unit conversions was not able to be provided to Myers and Stauffer; therefore, not all unit rebate conversions may have been identified. Myers and Stauffer reviewed rebate amounts for reasonableness and performed a manual conversion for those NDCs that were identified during the review.*
- *To estimate the federal and state shares, Myers and Stauffer calculated a weighted federal medical assistance percentage (FMAP) of 66.72 percent utilizing the two associated FMAPs for the study period. It was assumed that administrative costs related to operation of the PDL and PA Programs were likely categorized as administrative expenses subject to FMAP of 50 percent.*
- *The estimated state share of savings did not account for the Affordable Care Act (ACA) offset of rebates.*
- *For purposes of the PDL and PA savings estimates, Myers and Stauffer calculated savings throughout the study period as long as the beneficiary remained eligible. Medication therapy compliance was assumed for maintenance medications and may have resulted in an overestimate of savings, particularly for beneficiaries who did not receive a subsequent paid claim after the initial non-preferred denial.*
- *Market shift savings estimates did not account for beneficiaries receiving concurrent preferred and non-preferred medications within the same therapeutic drug category and may have resulted in a potential overestimation of savings.*



Analysis Assumptions, Exclusions and Limitations

North Carolina Division of Health Benefits
Preferred Drug List and Supplemental Rebate Program
Annual Public Report – SFY 2017
January 8, 2019

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- *For this analysis, Myers and Stauffer relied upon data, as well as other sources of information as described in this report. Myers and Stauffer relied upon this data without independent audit; however, the data was reviewed for reasonableness and consistency.*
 - *Due to the proprietary and confidential nature of federal and supplemental drug rebates, the savings estimates were provided in the aggregate to avoid any potential disclosure of this confidential financial information.*