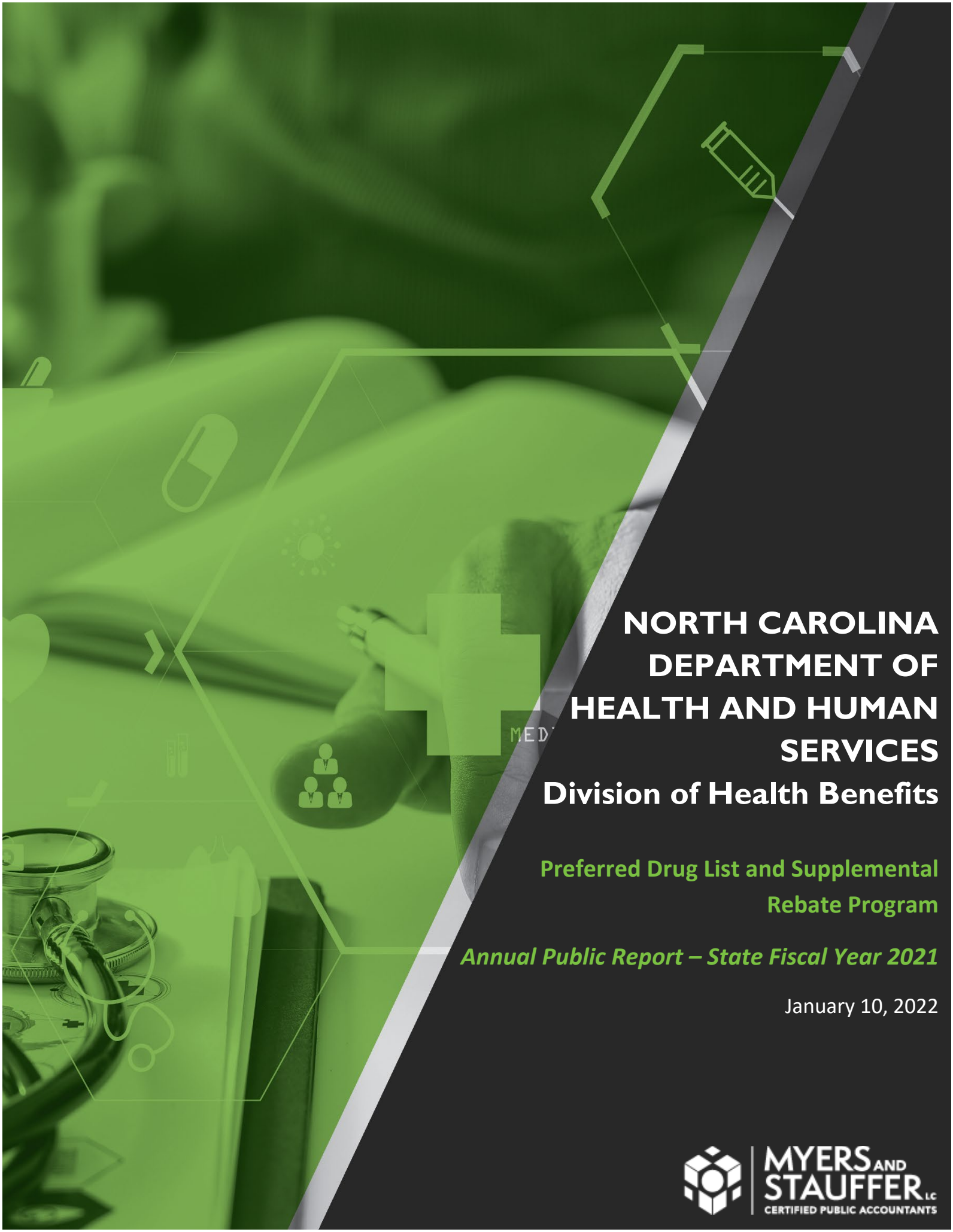

NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES

Division of Health Benefits

Preferred Drug List and Supplemental Rebate Program

Annual Public Report – State Fiscal Year 2021

January 10, 2022

MYERS AND STAUFFER LC
CERTIFIED PUBLIC ACCOUNTANTS

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Executive Summary

The North Carolina Department of Health and Human Services, Division of Health Benefits (Division or State), has engaged Myers and Stauffer LC (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) 2021 (July 1, 2020 through June 30, 2021). 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, in 2009 the Division was directed by the North Carolina General Assembly to develop and implement a PDL with supplemental rebates.

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 on 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 PAs, utilization review criteria and other restrictions on 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 PA 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 PA for any preferred or non-preferred anti-psychotic 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, clinical outcomes, and their net cost after federal and supplemental drug rebates. Supplemental drug rebates are collected in addition to the statutorily required rebates collected under the Medicaid Drug Rebate Program (MDRP) and are negotiated with manufacturers. Supplemental rebates are offered by manufacturers through a competitive bidding process as an incentive to be selected as part of the Division's PDL. Drugs that are preferred on the PDL typically do not require a PA, which results in increased utilization and market share over their non-preferred counterparts within a therapeutic drug class. It is important to note that supplemental rebate offers from manufacturers do not guarantee preferred placement on the PDL. Net cost associated with the supplemental rebates is a secondary consideration for preferred placement on the PDL after evaluation of therapeutic effectiveness, safety, and clinical outcomes. Non-preferred drugs are available through PA. 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 PA exist.

Figure 1 and *Figure 2* on the following page illustrate spend and claim breakdowns for SFY 2021 based on PDL designation after exclusion of claims, as noted on page 20. The 118 therapeutic drug categories included in the PDL program represented 74 percent of total spend and 83 percent of total claims during the study period. As illustrated below, preferred drugs represented 56 percent of total spend and 76 percent of spend for drugs subject to the PDL. Additionally, preferred drug claims represented 79 percent of total claims and 95 percent of claims subject to the PDL.

Figure 1: SFY 2021 Spend Breakdown by PDL Designation

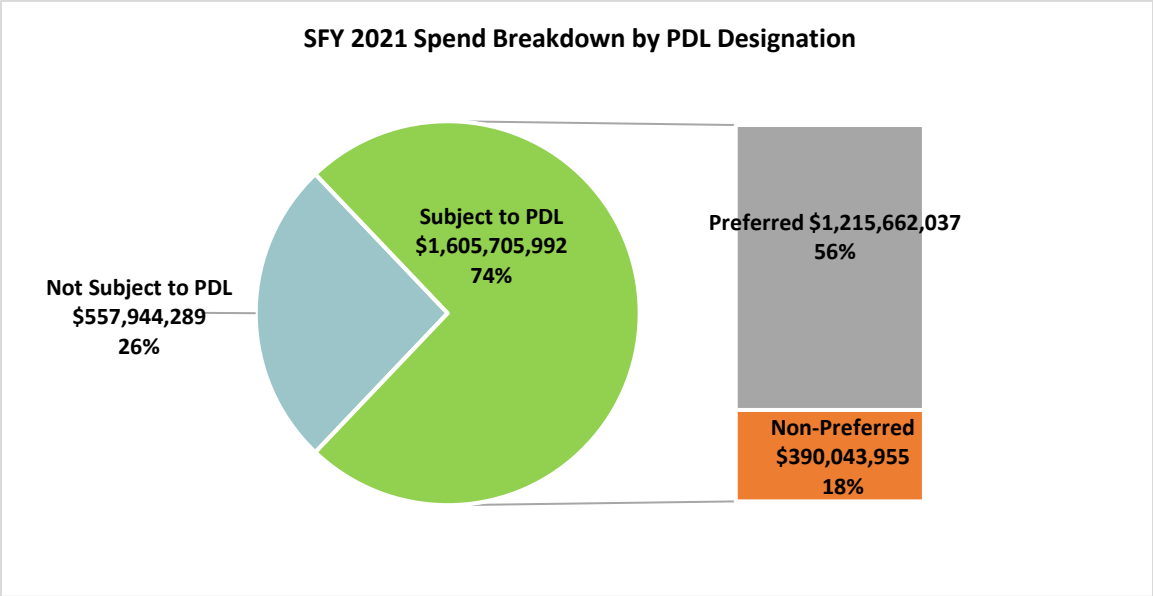
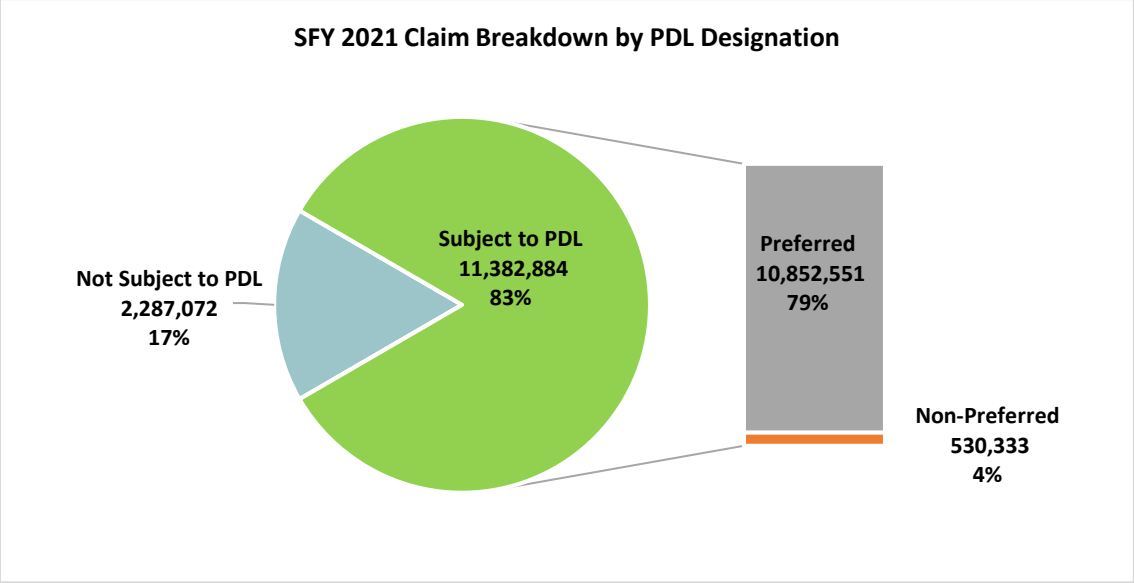


Figure 2: SFY 2021 Claim Breakdown by PDL Designation



It is worth noting that specialty drugs represent nearly 84 percent of spend not subject to the PDL. Drugs used to treat human immunodeficiency virus (HIV) and hemophilia represent one-third (33 percent) of this specialty drug spend. Although a universally accepted definition of specialty drug has not been determined, these drugs typically treat complex, chronic, rare, and difficult to manage conditions. Often, they are only available through a limited distribution system due to their

requirement for special handling (i.e., cold chain management), as well as the need to provide ongoing monitoring for efficacy, safety, and an overall positive clinical response.

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 have been made to it each year. Prescribers' awareness of the program increases as the program ages, and their increased familiarity with the products included on the PDL can impact prescribing habits. During SFY 2021, there were 118 therapeutic drug categories included on the PDL. PDL changes were made to a total of 75 therapeutic drug categories in September 2020 and June 2021. Because changes were minimal and only 10 therapeutic drug categories had greater than five percent of claims shift based on PDL changes, 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 2021, Myers and Stauffer estimated the total net savings associated with the program components, as defined on page 9. After accounting for program administrative costs of $5.7 million, the net savings associated with the PDL, clinical PA, and supplemental rebate programs were $275.2 million with a state share of $71.6 million. *Table 1* below illustrates the net PDL, clinical PA, and supplemental rebate program savings by program component.

Table 1: SFY 2021 Savings by Program Component

Program Component	Total Savings	State Share
PDL Savings	$92,485,096.24	$24,499,301.99
Supplemental Rebate Collections	$153,806,345.25	$40,743,300.86
Market Shift Savings	$1,120,519.53	$296,825.62
Clinical PA Savings	$33,456,662.56	$8,862,669.91
Total Program Savings	**$280,868,623.58**	**$74,402,098.39**
Program Administrative Costs	$5,651,125.54	$2,825,562.77
Net Program Savings	**$275,217,498.04**	**$71,576,535.62**

Approximately $247.4 million, with a state share of $65.5 million of the total gross savings can be attributed to the Division's PDL (including market shift) and supplemental rebate programs. In addition, approximately $33.5 million, with a state share of $8.9 million, can be attributed to the clinical PA program. Of the total program administrative costs of $5.7 million, approximately $1.4 million can be attributed to the PDL and supplemental rebate programs and $4.3 million can be attributed to the clinical PA program. Upon allocation of these administrative cost, the PDL (including market shift) and supplemental rebate programs represent approximately $246.0 million, with a state share of $64.9

million, in total net savings. Additionally, approximately $29.2 million, with a state share of $6.7 million, of the total net savings can be attributed to the clinical PA program.

Compared to SFY 2020, there was an increase in total net program savings by approximately $43.8 million. This increase can likely be attributed to the supplemental rebate collections. In response to the COVID-19 pandemic, the Division implemented a five percent increase in the professional dispensing fees with an effective date of March 1, 2020. This policy change required claims with dates of service beginning in March of SFY 2020 to be reprocessed. Fee-for-service (FFS) rebates are based on paid date and not date of service; therefore, these reprocessed claims would have associated supplemental rebates included in the SFY 2021 report, even though they were accounted for previously in the SFY 2020 report.

The top 10 therapeutic drug categories contributed to 75 percent of the total savings associated with the PDL, clinical PA, and supplemental rebate programs ($209.9 million with a state share of $55.6 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
Cytokine and CAM antagonists	$89.5	$23.7	32%
Antipsychotics	$24.3	$6.4	9%
Stimulants and related agents	$22.5	$6.0	8%
Glucocorticoids, inhaled	$17.3	$4.6	6%
Hepatitis C agents	$13.5	$3.6	5%
Opiate dependence treatments	$13.5	$3.6	5%
Growth hormone	$11.7	$3.1	4%
Movement disorders	$6.6	$1.7	2%
Hypoglycemics, incretin mimetics/enhancers	$5.5	$1.5	2%
Immunomodulators, atopic dermatitis	$5.4	$1.4	2%
Top 10 Total Savings	**$209.9**	**$55.6**	**75%**
Remaining Category Savings	**$71.0**	**$18.8**	**25%**
Total Program Savings	**$280.9**	**$74.4**	**100%**

**Rounding may result in slight total savings discrepancies.*

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 12.2 percent of unique, continuously eligible beneficiaries (115,716 out of 951,102) 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. This is a 0.4 percent increase when compared to SFY 2020 (11.8 percent). However, beneficiaries may have PDL denials in multiple therapeutic drug categories and

when these beneficiaries are allowed to be counted in each applicable therapeutic drug category, only 4.0 percent of beneficiaries with a denied non-preferred claim did not receive a paid claim within the same therapeutic drug category. This percentage is the same as SFY 2020. Additionally, there was a small number (0.36 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 2021.

PDL Program Impact on Medical and Laboratory Services

For all of the therapeutic drug categories that had PDL changes during the study period, the population sizes were too small to perform a statically valid analysis to examine the PDL impact on medical and laboratory services; therefore, no statistically significant conclusions could be drawn.

Preferred Drug List and Prior Authorization Program Savings

Myers and Stauffer calculated the estimated savings across all therapeutic drug categories associated with the PDL program effective in SFY 2021. 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 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.*

The numbers provided in the top 10 PDL and PA savings tables are presented in millions and rounding may result in slight total savings discrepancies.

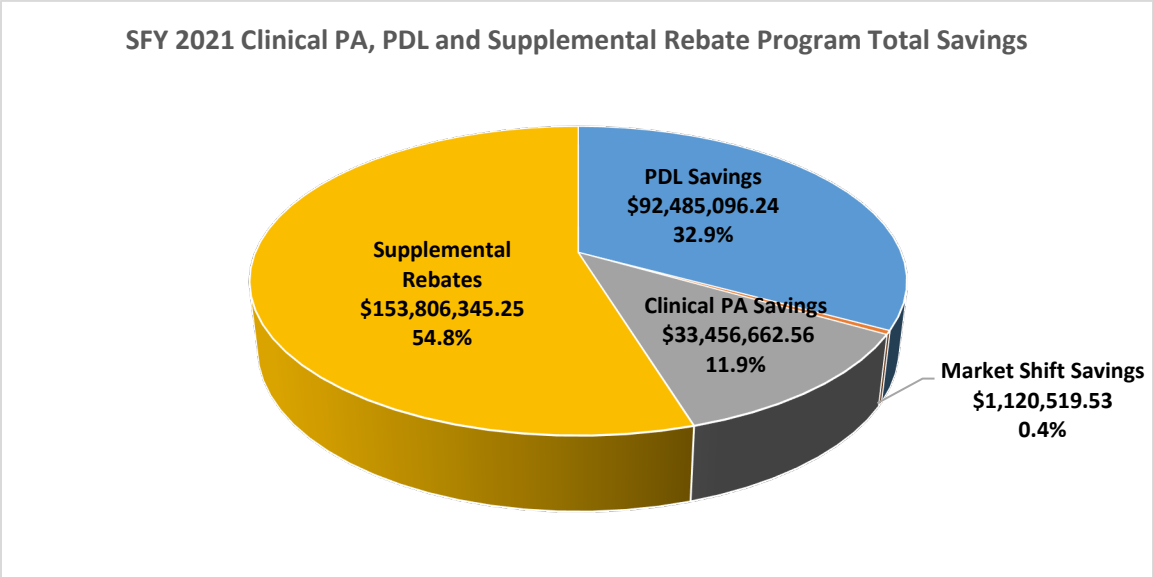
Estimated Net Savings

Myers and Stauffer estimated that the total net savings associated with the PDL, clinical PA, and supplemental rebate programs were $275.2 million with a state share of $71.6 million. Of the total net savings, approximately $246.0 million, with a state share of $64.9 million, can be attributed to the Division's PDL and supplemental rebate programs, and $29.2 million, with a state share of $6.7 million, can be attributed to the clinical PA program. *Table 3* and *Figure 3* illustrate the breakdown of savings, including 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	$92,485,096.24	N/A	$67,985,794.25	$24,499,301.99
Supplemental Rebate Collections	$153,806,345.25	N/A	$113,063,044.39	$40,743,300.86
PDL and Supplemental Rebate Administrative Costs	$1,376,510.88	N/A	$688,255.44	$688,255.44
Market Shift Savings	$1,120,519.53	N/A	$823,693.90	$296,825.62
Net PDL and Supplemental Rebate Savings	**$246,035,450.14**	**89%**	**$181,184,277.10**	**$64,851,173.03**
Clinical PA Savings	$33,456,662.56	N/A	$24,593,992.65	$8,862,669.91
Clinical PA Administrative Costs	$4,274,614.66	N/A	$2,137,307.33	$2,137,307.33
Net Clinical PA Savings	**$29,182,047.90**	**11%**	**$22,456,685.32**	**$6,725,362.58**
Total Net PDL and Clinical PA Savings	**$275,217,498.04**	**100%**	**$203,640,962.42**	**$71,576,535.62**

Figure 3: Distribution by Savings Component – SFY 2021 Total Savings



Preferred Drug List Savings

For SFY 2021, Myers and Stauffer estimated a total savings of $92.5 million net of federal rebates associated with the PDL, as described above. The state share of the savings is approximately $24.5 million before accounting for administrative costs. *Table 4* 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
Glucocorticoids, inhaled	$14.7	$3.9	16%
Stimulants and related agents	$12.5	$3.3	13%
Hypoglycemics, incretin mimetics/enhancers	$5.4	$1.4	6%
Cytokine and CAM antagonists	$4.9	$1.3	5%
Immunomodulators, atopic dermatitis	$4.4	$1.2	5%
Opiate dependence treatments	$3.5	$0.9	4%
Acne agents, topical	$3.5	$0.9	4%
Proton pump inhibitors	$3.3	$0.9	4%
Antimigraine agents, other	$3.1	$0.8	3%
Multiple sclerosis agents	$3.0	$0.8	3%
Top 10 Total Savings	**$58.2**	**$15.4**	**63%**
Remaining Category Savings	**$34.3**	**$9.1**	**37%**
Total PDL Savings	**$92.5**	**$24.5**	**100%**

**Rounding may result in slight total savings discrepancies.*

As shown in *Table 4* above, the top 10 therapeutic drug categories comprised 63 percent of the overall savings associated with the PDL program ($58.2 million with a state share of $15.4 million). A further breakdown of savings revealed the top five therapeutic drug categories accounted for 45 percent of the PDL program savings ($41.8 million with a state share of $11.1 million).

Supplemental Rebate Collections

In SFY 2021, the total of supplemental rebates collected from pharmaceutical manufacturers were approximately $153.8 million with a state share of $40.7 million. Rebates collected for the top 10 therapeutic drug categories totaled $144.0 million and represented 94 percent of total supplemental rebates collected. The top 10 therapeutic drug categories with the largest supplemental rebate associated savings during the study period included the following:

- *Cytokine and CAM antagonists.*
- *Anti-psychotics.*
- *Growth hormone.*
- *Opiate dependence treatments.*
- *Stimulants and related agents.*
- *Hepatitis C agents.*
- *Progestational agents.*
- *Glucocorticoids, inhaled.*

- *Ophthalmics for allergic conjunctivitis.*
- *Movement disorders.*

Market Shift Savings

For SFY 2021, 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 or PA 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
(Broken down by Number of Days between Paid Claims)

Days Between Paid Claims	Number of Beneficiaries	Total Savings	State Share
7	1,481	$369,726	$97,941
30	3,711	$884,107	$234,200
60	4,524	$1,026,360	$271,883

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
Immunomodulators, atopic dermatitis	166	$345,377	$91,490
Stimulants and related agents	1,495	$279,657	$74,081
PAH agents, oral and inhaled	13	$135,834	$35,982
Antiemetic/antivertigo agents	352	$61,538	$16,301
Hypoglycemics, incretin mimetics/enhancers	155	$47,150	$12,490
Proton pump inhibitors	416	$41,889	$11,096
Anticonvulsants	121	$34,910	$9,248
GI motility, chronic	141	$31,512	$8,347
Glucocorticoids, inhaled	299	$26,848	$7,112
NSAIDs	1,366	$21,645	$5,734
Top 10 Total Savings		**$1,026,360**	**$271,883**
Remaining Category Savings		**$94,160**	**$24,943**
Total Market Shift Savings		**$1,120,520**	**$296,826**

Clinical Prior Authorization Savings

For SFY 2021, Myers and Stauffer estimated a total of $33.5 million net of federal rebates associated with the clinical PA program, as described previously on page 9. The state share of the savings is approximately $8.9 million before accounting for administrative costs. *Table 7* 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
Antipsychotics	$7.8	$2.1	23%
Hepatitis C agents	$5.6	$1.5	17%
Cytokine and CAM antagonists	$4.3	$1.1	13%
Movement disorders	$3.7	$1.0	11%
Anticonvulsants	$1.9	$0.5	6%
Xolair	$1.4	$0.4	4%
Transmitters and sensors	$0.8	$0.2	3%
Angiotensin Modulators	$0.8	$0.2	3%
Immunomodulators, atopic dermatitis	$0.7	$0.2	2%
Glucocorticoids, inhaled	$0.7	$0.2	2%
Top 10 Total Savings	**$27.8**	**$7.4**	**83%**
Remaining Category Savings	**$5.7**	**$1.5**	**17%**
Total Clinical PA Savings	**$33.5**	**$8.9**	**100%**

**Rounding may result in slight total savings discrepancies.*

As shown in *Table 7* above, the top 10 therapeutic drug categories comprised 83 percent of the overall savings associated with the clinical PA program ($27.8 million with a state share of $7.4 million). A further breakdown of savings revealed the top five therapeutic drug categories accounted for 70 percent of the clinical PA program savings ($23.4 million with a state share of $6.2 million).

Administrative Costs

The Division works collaboratively with its fiscal agent, General Dynamics Information Technology (GDIT), to manage the PDL, clinical PA, and supplemental rebate programs. The Division paid GDIT a fixed monthly rate of $114,709.24 to operate the PDL and supplemental rebate programs for SFY 2021. The cost of the PA program varies month over month based on 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 Costs, Broken Down by Program

Program	SFY 2021 Cost	State Share
PDL and Supplement Rebate Program	$1,376,510.88	$688,255.44
Clinical PA Program	$4,274,614.66	$2,137,307.33
Total	**$5,651,125.54**	**$2,825,562.77**

It is 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 federal medical assistance percentage (FMAP) of 50 percent.

Beneficiary Access to Preferred Drug List 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 quickly bring a resolution to the denied claim, 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 PA. 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 PA 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 emergency fills to cover the delay between paid claims. Although identified delays are quantified for purposes of this analysis, 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.*
- *PAs.*

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	951,102	145,295	15.3%
Paid Non-Preferred		35,476	3.7%
No Subsequent Claim		115,716	12.2%
Total		296,487	31.2%

Overall, 12.2 percent (115,716) of unique continuously eligible beneficiaries (951,102) had a denied non-preferred claim with no subsequent paid claim within the same therapeutic drug category for all PDL applicable therapeutic drug categories. Of the 118 therapeutic drug categories, changes were implemented in 75 categories during the study period.

Table 10 and *Table 11* include counts for beneficiaries who had a denied claim with no subsequent paid claim within the therapeutic class and are presented for the top 10 therapeutic drug categories. Total counts are not unique due to the possibility that beneficiaries were counted more than once if they were on medications in multiple therapeutic drug categories. *Table 10* provides the top 10 therapeutic drug categories ordered by beneficiary count, whereas, *Table 11* provides the top 10 therapeutic drug categories ordered by percent of total.

Of the top 10 therapeutic drug categories listed in *Table 10*, all categories, except diabetes meters and antihistamines, minimally sedating, had a PDL change during the study period. Of the top 10 therapeutic drug categories listed in *Table 11,* five categories had no PDL changes during the study period: acne agents, topical; antihyperuricemics, IV; antivirals, topical; diabetes meters; otic anti-infectives; and anesthetics and otics, anti-inflammatory. Diabetes meters, continuous and lipotropics: next generation were new categories in SFY 2021. It is important to note that preferred meters are provided free to North Carolina Medicaid beneficiaries through a manufacturer program from Roche Diagnostics Corporation. Billing information can be found on the North Carolina Division of Health Benefits Medicaid and Health Choice PDL online. The percentages provided in *Table 10* and *Table 11* indicates that 99.9 percent of beneficiaries not receiving a subsequent paid claim does not mean that a beneficiary did not

receive a meter. These numbers indicate that the pharmacy billed the claim to Medicaid and did not initially submit the diabetes meter claim with the appropriate billing information for the manufacturer free meter program.

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
Acne agents, topical	38,428	13,318	34.7%
NSAIDs	184,222	10,614	5.8%
Diabetes meters*	10,582	10,576	99.9%
Glucocorticoids, inhaled	64,221	8,707	13.6%
Antihistamines, minimally sedating	229,005	7,964	3.5%
Neuropathic pain	75,441	7,020	9.3%
Stimulants and related agents	101,631	5,374	5.3%
Otic antibiotics	30,442	3,977	13.1%
Ophthalmics for allergic conjunctivitis	18,141	3,908	21.5%
Immunomodulators, atopic dermatitis	10,377	2,847	27.4%
Total for Top 10	**762,490**	**74,305**	**9.7%**
Total for All	**3,439,621**	**137,350**	**4.0%**

**Diabetes meters are provided free through a manufacturer program from Roche Diagnostics and should not be billed to Medicaid. Billing information can be found on the North Carolina DHB Medicaid and Health Choice PDL.*

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
Antihyperuricemics, IV	1	1	100.0%
Diabetes meters*	10,582	10,576	99.9%
Lipotropics: Next generation	24	12	50.0%
Otics, anti-inflammatory	502	237	47.2%
Antivirals, topical	1,511	662	43.8%
Antipsoriatics, topical	547	219	40.0%
Otic anti-infectives & anesthetics	474	170	35.9%
Acne agents, topical	38,428	13,318	34.7%
H. Pylori treatment	415	117	28.2%
Diabetes meters, continuous	2,747	766	27.9%

**Diabetes meters are provided free through a manufacturer program from Roche Diagnostics and should not be billed to Medicaid. Billing information can be found on the North Carolina DHB Medicaid and Health Choice PDL.*

Beneficiaries Reverting to Non-Preferred Medication

Myers and Stauffer evaluated the counts 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 on 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, for SFY 2021, approximately 7,814 out of nearly 2.8 million (0.3 percent) continuously eligible beneficiaries reverted back to a non-preferred medication after receiving a preferred medication.

Prior Authorizations

A total of 207,423 PA requests were reported by GDIT for SFY 2021. 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.

Preferred Drug List 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 considered 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 included beneficiaries who experienced a change in drug therapy within a PDL drug category, and the control group included beneficiaries who 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.*

It can be difficult to determine if a therapy change is due to the PDL or to a clinical intervention by the provider; therefore, it is difficult to substantiate any conclusions regarding the impact of the PDL on medical and laboratory utilization and expenditures. 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 2021, no therapeutic drug category had a large enough sample size within the study group to perform a statically valid analysis to examine the PDL impact on medical and laboratory services; therefore, no statistically significant conclusions could be drawn.

Assumptions, Exclusions, and Limitations of Analysis

- *This analysis was based on outpatient pharmacy claims and medical claims data with dates of service from July 1, 2020 through June 30, 2021 available at the time of the analysis.*
- *Although rebates are collected for third-party liability 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 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 National Drug Code (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.*
- *Claims identified as outliers and determined to have been submitted with an unreasonable number of units were excluded from the analysis.*
- *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 & Medicaid Services URA unit and the National Council for Prescription Drug Programs (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 FMAP of 73.51 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 a FMAP of 50 percent.*
- *The estimated state share of savings did not account for the Affordable Care Act 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.*
- *For this analysis, Myers and Stauffer relied on data and other sources of information as described in this report. Myers and Stauffer relied on 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.*
- *Due to the reprocessing of claims in response to COVID-related program changes, the aggregated supplemental rebate amounts provided to Myers and Stauffer contained rebates that would have been accounted for in the SFY 2020 report. This is due to the claim's paid date being utilized to invoice rebates for FFS claims. These claims had a date of service in SFY 2020 but a paid date in SFY 2021 after reprocessing. The amount of supplemental rebates associated with these claims was not available at the timing of this report.*