MYERS AND 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 2019

December 19, 2019

DEDICATED TO GOVERNMENT HEALTH PROGRAMS

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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) 2019 (July 1, 2018 through June 30, 2019). 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 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 authorizations, 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 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, 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 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 2019 based upon PDL designation after exclusion of claims, as noted on page 19. The 113 therapeutic drug categories included in the PDL program represented 76 percent of total spend and 83 percent of total claims during the study period. As illustrated below, spend for preferred drugs represented 58 percent of total spend and 77 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.

Chart 1: SFY 2019 Spend Breakdown by PDL Designation

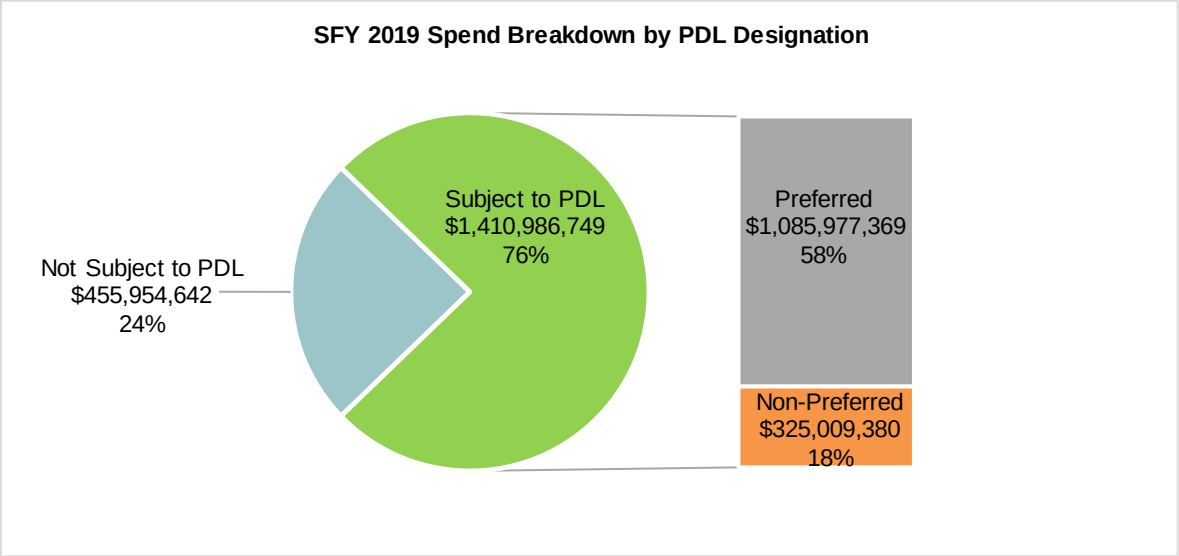
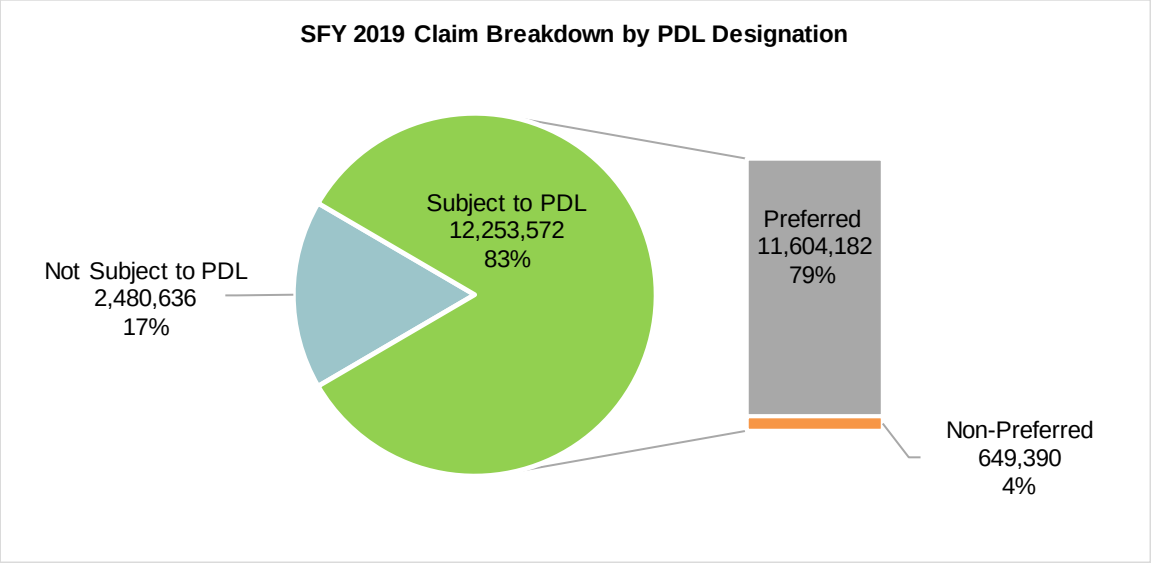


Chart 2: SFY 2019 Claim Breakdown by PDL Designation



It is worth noting that specialty drugs represent 77 percent of spend not subject to the PDL. Drugs used to treat HIV and hemophilia represent over one-third (37 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 2019, there were 113 therapeutic drug categories included on the PDL. PDL changes were made to a total of 85 therapeutic drug categories in October 2018, December 2018 and January 2019. Because changes were minimal and only nine therapeutic drug categories had greater than five percent of claims shift based upon 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 2019, 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 $187.4 million with a state share of $60.6 million. *Table 1* below illustrates the net PDL, clinical PA and supplemental rebate program savings by program component.

Table 1: SFY 2019 Savings by Program Component

Program Component	Total Savings	State Share
PDL Savings	$58,771,432.88	$19,235,889.98
Supplemental Rebate Collections	$98,018,259.80	$32,081,376.43
Market Shift Savings	$1,255,663.76	$410,978.75
Clinical PA Savings	$33,316,306.10	$10,904,426.99
Total Program Savings	**$191,361,662.54**	**$62,632,672.15**
Program Administrative Costs	$4,009,054.80	$2,004,527.40
Net Program Savings	**$187,352,607.74**	**$60,628,144.75**

After allocation of the program administrative costs, approximately $157.4 million, with a state share of $51.4 million, of the total net savings can be attributed to the Division's PDL and supplemental rebate programs. In addition, approximately $30.0 million, with a state share of $9.2 million, can be attributed to the clinical PA program.

The top 10 therapeutic drug categories contributed to 67 percent of the total savings associated with the PDL, clinical PA and supplemental rebate programs ($128.7 million with a state share of $42.1 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
Stimulants and related agents	$32.0	$10.5	17%
Cytokine and CAM antagonists	$21.0	$6.9	11%
Hepatitis C agents	$20.1	$6.6	10%
Antipsychotics	$17.8	$5.8	9%
Opiate dependence treatments	$10.5	$3.4	6%
Growth hormone	$7.7	$2.5	4%
Glucocorticoids, inhaled	$5.4	$1.8	3%
Bronchodilators, beta agonist	$5.1	$1.7	3%
Anticonvulsants	$4.7	$1.5	2%
Antiparasitics, topical	$4.4	$1.4	2%
Top 10 Total Savings	**$128.7**	**$42.1**	**67%**
Remaining Category Savings	**$62.7**	**$20.5**	**33%**
Total Program Savings	**$191.4**	**$62.6**	**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 10.9 percent of unique continuously eligible beneficiaries (120,325 out of 1,099,026) 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 1.4 percent increase when compared to SFY 2018 (9.5%). 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 3.5 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 (0.3 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 2019.

PDL Program Impact on Medical and Laboratory Services

For most 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. Myers and Stauffer examined graphically the one therapeutic drug category with the largest study group size where beneficiaries had switched from non-preferred to preferred medications during the study period and evaluated the differences between the therapy change and no therapy change groups using a two-tail *t*-test. No statistically significant differences in the average monthly number of physician office and outpatient visits or the associated costs were observed. In conclusion, it is unclear if the minor changes in medication therapy were due to the PDL, market access issues 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 2019. 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

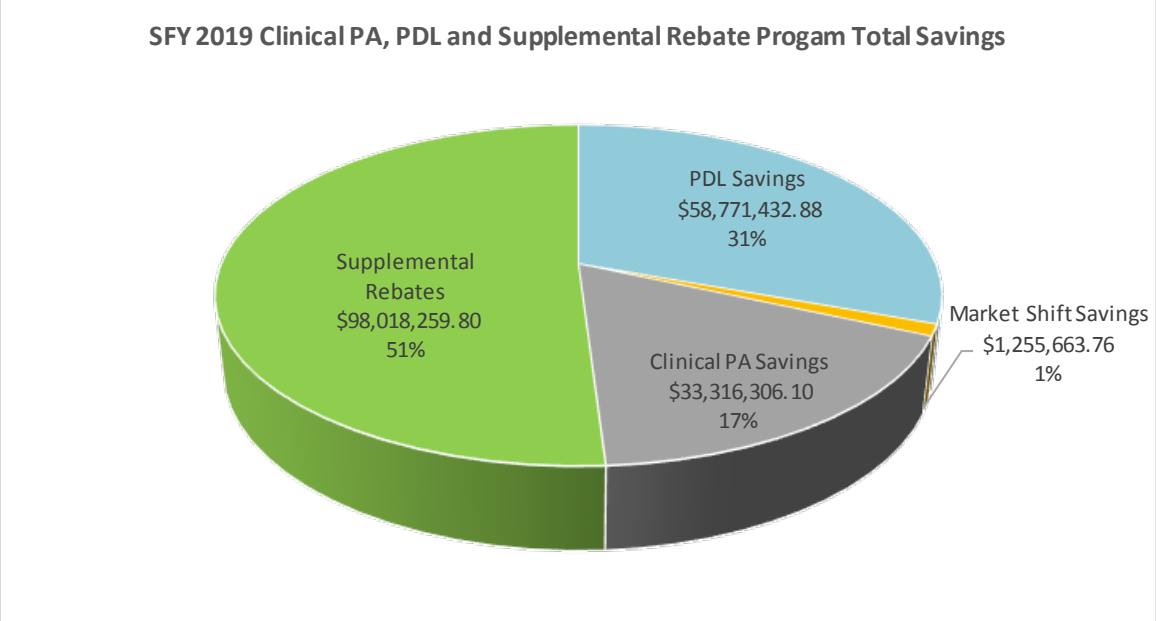
Myers and Stauffer estimated that the total net savings associated with the PDL, clinical PA and supplemental rebate programs were $187.4 million with a state share of $60.6 million. Of the total net savings, approximately $157.4 million, with a state share of $51.4 million, can be attributed to the Division's PDL and supplemental rebate programs and $30.0 million, with a state share of $9.2 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	$58,771,432.88	N/A	$39,535,542.90	$19,235,889.98
Supplemental Rebate Collections	$98,018,259.80	N/A	$65,936,883.37	$32,081,376.43
PDL and Supplemental Rebate Administrative Costs	$651,134.64	N/A	$325,567.32	$325,567.32
Market Shift Savings	$1,255,663.76	N/A	$844,685.01	$410,978.75
Net PDL and Supplemental Rebate Savings	**$157,394,221.80**	**84%**	**$105,991,543.96**	**$51,402,677.84**
Clinical PA Savings	$33,316,306.10	N/A	$22,411,879.11	$10,904,426.99
Clinical PA Administrative Costs	$3,357,920.16	N/A	$1,678,960.08	$1,678,960.08
Net Clinical PA Savings	**$29,958,385.94**	**16%**	**$20,732,919.03**	**$9,225,466.91**
Total Net PDL and Clinical PA Savings	**$187,352,607.74**	**100%**	**$126,724,462.99**	**$60,628,144.75**

Chart 3: Distribution by Savings Component – SFY 2019 Total Savings



Preferred Drug List Savings

For SFY 2019, Myers and Stauffer estimated a total savings of $58.8 million net of federal rebates associated with the PDL, as described above. The state share of the savings is approximately $19.2 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
Stimulants and related agents	$6.7	$2.2	11%
Bronchodilators, beta agonist	$5.0	$1.6	9%
Opiate dependence treatments	$3.1	$1.0	5%
Acne agents, topical	$3.1	$1.0	5%
Hypoglycemics, incretin mimetics/enhancers	$2.4	$0.8	4%
Hypoglycemics, insulin and related agents	$2.4	$0.8	4%
Movement disorders	$2.3	$0.7	4%
Epinephrine, self-injected	$2.0	$0.6	3%
Cytokine and CAM antagonists	$1.7	$0.6	3%
Antihyperuricemics	$1.7	$0.6	3%
Top 10 Total Savings	**$30.4**	**$9.9**	**52%**
Remaining Category Savings	**$28.4**	**$9.3**	**48%**
Total PDL Savings	**$58.8**	**$19.2**	**100%**

As shown in *Table 4* above, the top 10 therapeutic drug categories comprised 52 percent of the overall savings associated with the PDL program ($30.4 million with a state share of $9.9 million). A further breakdown of savings revealed that the top five therapeutic drug categories accounted for 35 percent of the PDL program savings ($20.3 million with a state share of $6.6 million).

Supplemental Rebate Collections

In SFY 2019, the total of supplemental rebates collected from pharmaceutical manufacturers was approximately $98.0 million with a state share of $32.1 million. Rebates collected for the top 10 therapeutic drug categories totaled $87.0 million and represented 89 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:

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

Market Shift Savings

For SFY 2019, 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 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
Broken down by Number of Days between Paid Claims

Days Between Paid Claims	Number of Beneficiaries	Total Savings	State Share
7	2,550	$409,272	$133,955
30	4,892	$843,513	$276,082
60	5,997	$1,015,692	$332,436

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
Stimulants and related agents	2,299	$313,580	$102,635
Antiemetic/antivertigo agents	786	$176,261	$57,690
PAH agents, oral and inhaled	15	$172,540	$56,472
Immunomodulators, atopic dermatitis	79	$91,537	$29,960
Proton pump inhibitors	590	$63,075	$20,645
COPD agents	559	$52,618	$17,222
Glucocorticoids, inhaled	900	$49,487	$16,197
Phosphate binders	65	$32,953	$10,785
Antibiotics, inhaled	28	$32,735	$10,714
Skeletal muscle relaxants	676	$30,906	$10,115
Top 10 Total Savings		**$1,015,692**	**$332,436**
Remaining Category Savings		**$239,972**	**$78,543**
Total Market Shift Savings		**$1,255,664**	**$410,979**

Clinical PA Savings

For SFY 2019, Myers and Stauffer estimated a total of $33.3 million net of federal rebates associated with the clinical PA program, as described previously on page 8. The state share of the savings is approximately $10.9 million, before accounting for administrative costs. *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	$11.0	$3.6	33%
Antipsychotics	$5.5	$1.8	17%
Ingrezza	$3.1	$1.0	9%
Glucocorticoids, inhaled	$2.5	$0.8	8%
Anticonvulsants	$2.4	$0.8	7%
Cytokine and cam antagonists	$2.3	$0.7	7%
Analgesics, narcotics long	$0.7	$0.2	2%
PAH agents, oral and inhaled	$0.6	$0.2	2%
Xolair	$0.5	$0.2	1%
Orkambi	$0.5	$0.2	1%
Top 10 Total Savings	**$29.1**	**$9.5**	**87%**
Remaining Category Savings	**$4.2**	**$1.4**	**13%**
Total Clinical PA Savings	**$33.3**	**$10.9**	**100%**

As shown in *Table 7* above, the top 10 therapeutic drug categories comprised 87 percent of the overall savings associated with the clinical PA program ($29.1 million with a state share of $9.5 million). A further breakdown of savings revealed that the top five therapeutic drug categories accounted for 74 percent of the clinical PA program savings ($24.5 million with a state share of $8.0 million).

Administrative Costs

The Division works collaboratively with its fiscal agent, GDIT, to manage the PDL, clinical PA and supplemental rebate programs. Beginning in July 2018, the Division paid GDIT a fixed monthly rate of $54,261.22 to operate the PDL and supplemental rebate programs for SFY 2019. 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 Costs, Broken down by Program

Program	SFY 2019 Cost	State Share
PDL and Supplement Rebate Program	$651,134.64	$325,567.32
Clinical PA Program	$3,357,920.16	$1,678,960.08
Total	**$4,009,054.80**	**$2,004,527.40**

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 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 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 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 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.*
- *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	1,099,026	232,930	21.2%
Paid Non-Preferred		43,712	4.0%
No Subsequent Claim		120,325	10.9%
Total		396,967	36.1%

Overall, 10.9 percent (120,325) of unique continuously eligible beneficiaries (1,099,026) 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 113 therapeutic drug categories, changes were implemented in 85 categories during the study period.

In *Table 10* below, counts for beneficiaries who had a denied claim with no subsequent paid claim within the therapeutic class 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. Of the top 10 therapeutic drug categories listed in *Table 10*, all categories had a PDL change during the study period.

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
Antihistamines, minimally sedating	275,860	16,550	6.0%
NSAIDs	210,275	12,418	5.9%
Glucocorticoids, inhaled	74,934	9,293	12.4%
Bronchodilators, beta agonist	204,433	9,019	4.4%
Acne agents, topical	35,496	8,887	25.0%
Neuropathic pain	68,783	6,723	9.8%
Ophthalmics for allergic conjunctivitis	30,945	5,107	16.5%
Antivirals, oral	119,567	4,331	3.6%
Epinephrine, self-injected	21,778	4,270	19.6%
Stimulants and related agents	108,297	3,852	3.6%
Total for Top 10	**1,150,368**	**80,450**	**7.0%**
Total for All	**3,919,778**	**138,581**	**3.5%**

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 for all PDL applicable therapeutic drug categories. Of the top 10 therapeutic drug categories listed in *Table 11,* two categories had no PDL changes during the study period: *H. Pylori* treatment and Otic anti-infectives & anesthetics.

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%
Movement disorders	316	156	49.4%
Otics, anti-inflammatory	225	109	48.4%
***H. Pylori* treatment**	472	203	43.0%
Otic anti-infectives & anesthetics	509	201	39.5%
Antipsoriatics, topical	547	215	39.3%
Antivirals, topical	2,136	697	32.6%
Antibiotics, inhaled	419	117	27.9%
Antihyperuricemics	5,237	1,333	25.5%
Bile salts	830	209	25.2%

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 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, for SFY 2019, approximately 9,500 out of nearly 3.3 million (0.3 percent) continuously eligible beneficiaries reverted back to a non-preferred medication after receiving a preferred medication.

Prior Authorizations

A total of 195,150 prior authorization requests were reported by GDIT for SFY 2019. 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 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 2019, only one therapeutic drug category contained a large enough number of beneficiaries with a therapy change (n=147) to be included for analysis: Stimulants and related agents. It is unlikely for attention deficit disorder to be the primary diagnosis for an emergency department visit or hospitalization or to lead to increased utilization of laboratory services. To evaluate this assumption, the admitting diagnoses for all hospitalizations for the entire population (study group and control group) were assessed. Of the 24,853 beneficiaries included in this population, there was only one hospitalization with an admitting diagnosis of attention deficit disorder. Because the majority of the medications within the Stimulants and related agents therapeutic drug category

are Schedule II (CII) controlled substances requiring a new prescription with every fill or therapy change, it is common for beneficiaries to have monthly physician office and outpatient clinic visits. Due to the factors previously mentioned, only the physician office and outpatient visits were evaluated. *Charts 4* through *7* on the following pages illustrate the monthly average utilization and expenditures for physician office and outpatient visits for the study group (therapy change) and the control group (no therapy change).

A total of 24,706 beneficiaries met the criteria to be included in the control group. *Charts 4* and *5* represent a simple visualization of the outcomes for these two groups. To perform the statistical analysis, 147 beneficiaries out of the total control group population were randomly selected to ensure equal number of recipients in each group. Differences between the two groups in the average monthly number of physician office and outpatient visits as well as costs associated with those visits were assessed using a two-tail *t*-test. No significant differences were observed between the study group and control group with respect to the monthly average number of physician office and outpatient visits (*Chart 6*). The mean for the study group was 0.50 and for the control group was 0.50 (t=0.05; p=0.96). Additionally, the two groups did not differ significantly on monthly average cost associated with physician office and outpatient visits per beneficiary (*Chart 7*). The monthly average cost was $39.76 for the study group and $36.06 for the control group (t=1.11; p=0.28).

Considerations must be made when evaluating the effect of the PDL program on the Stimulants and related agents therapeutic drug category. First, it is important to note that beginning in SFY 2018, this therapeutic drug category experienced market access issues consisting of drug shortages for the preferred products Quillivant and Quillichew. During the shortage, Quillivant and Quillichew were moved to non-preferred status on the PDL and Concerta was moved to preferred status; all of these drugs are methylphenidate extended-release products. The market access issues were resolved during SFY 2019. Due to this resolution, Concerta was moved back to non-preferred status and Quillivant and Quillichew were moved back to preferred. Secondly, it is important to note that there is a large amount of clinical variability when determining the best course of therapy for the products within the Stimulants and related agents therapeutic drug category and medication regimens may have to be changed frequently to determine the optimal patient specific regimen.

Stimulants and Related Agents

Chart 4: Average Number of Physician Office/Outpatient Visits – Entire Population

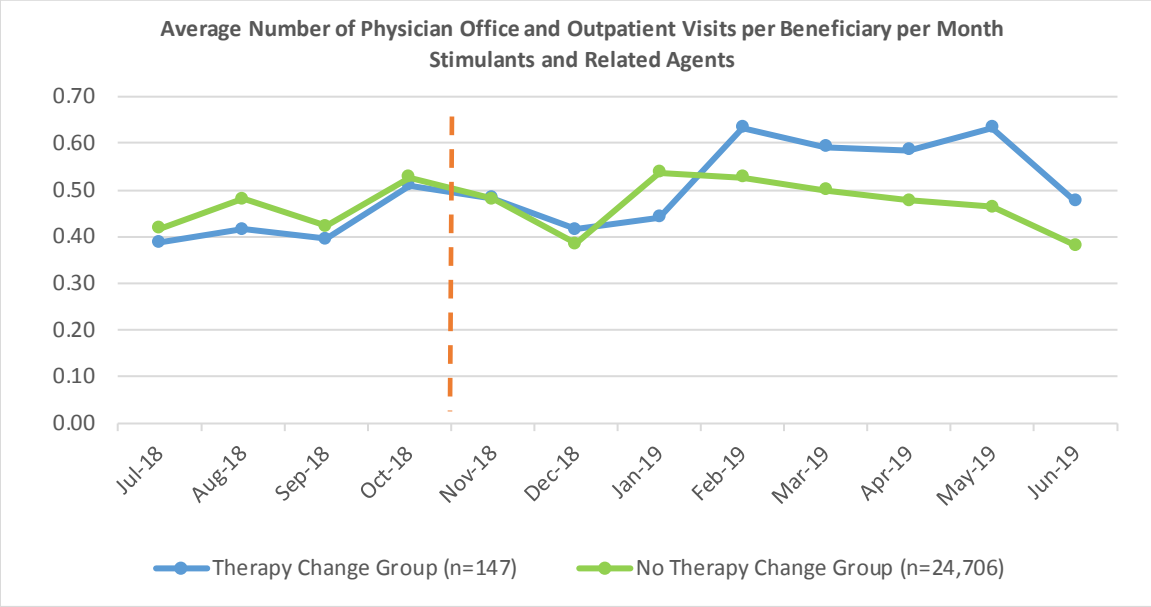


Chart 5: Average Amount Paid for Physician Office/Outpatient Visits – Entire Population

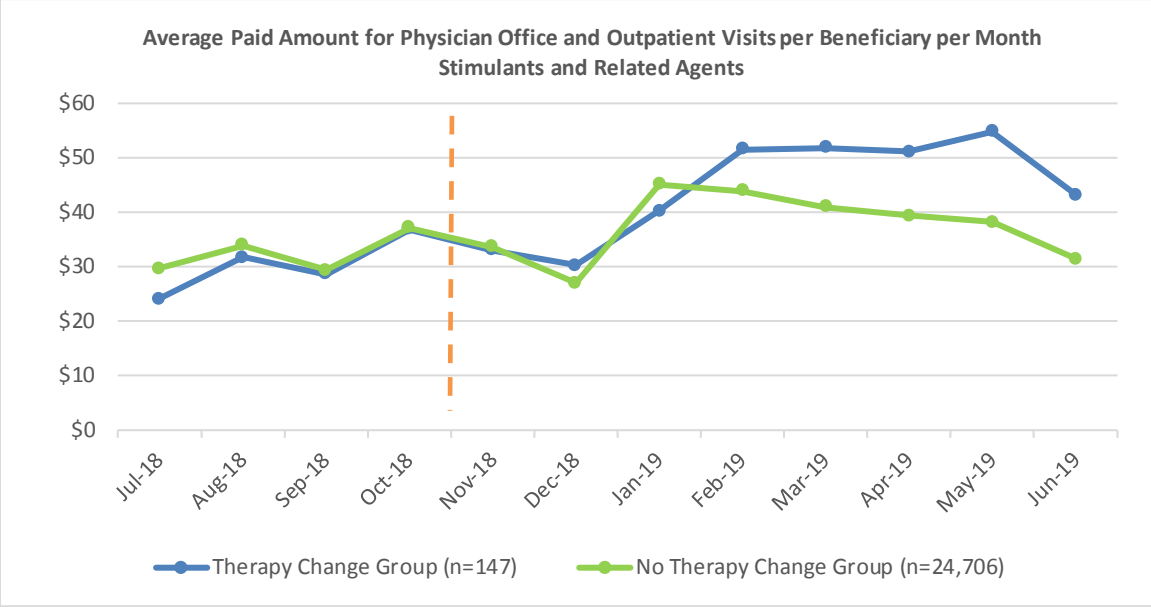


Chart 6: Average Number of Physician Office/Outpatient Visits – Random Selection

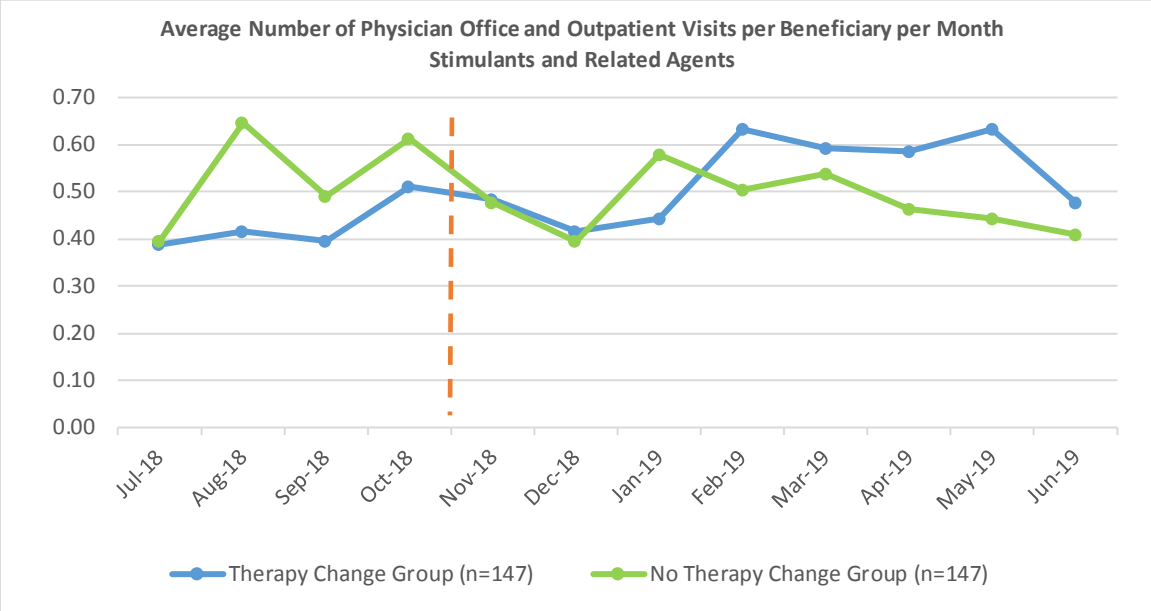
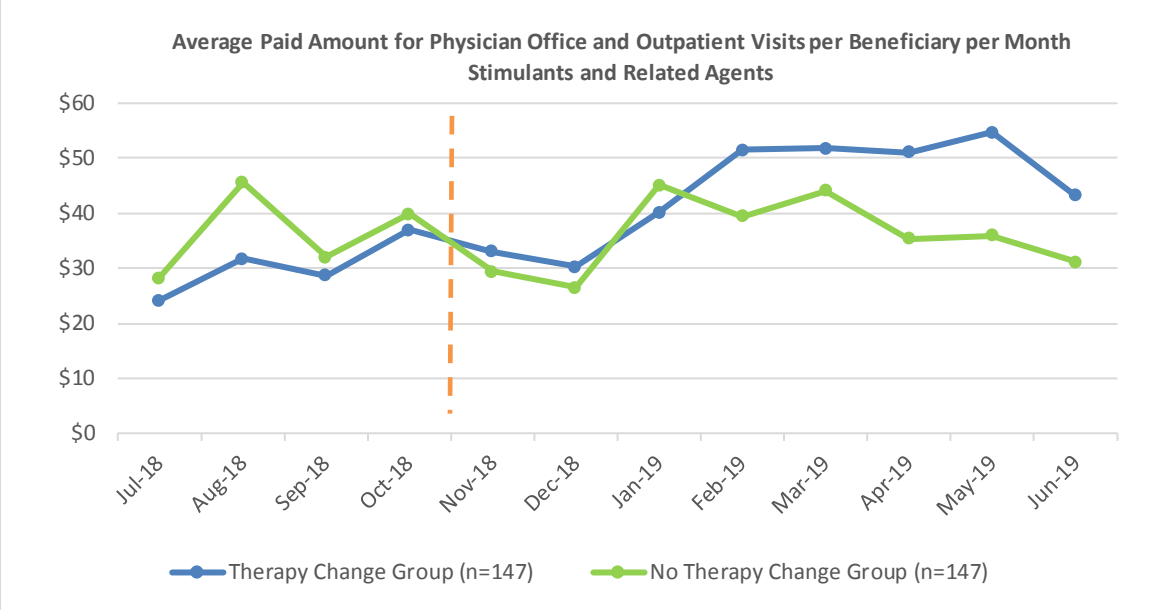


Chart 7: Average Amount Paid for Physician Office/Outpatient Visits – Random Selection



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, 2018 through June 30, 2019 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.*
- *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 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 67.27 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 (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.*

- *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.*