

# REPORT FROM THE NEW YORK STATE SENATE

## COMMITTEE ON INVESTIGATIONS AND GOVERNMENT OPERATIONS

CHAIR  
SENATOR JAMES SKOUFIS



## Final Investigative Report: Pharmacy Benefit Managers in New York

MAY 31, 2019

*This report was produced in coordination with the*

COMMITTEE ON HEALTH

CHAIR

Senator Gustavo Rivera

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## I. Executive Summary

Today, America’s healthcare system is characterized by escalating pharmaceutical list prices, increasing out of pocket costs for consumers, and restricted access for patients. The healthcare market has become increasingly intricate, with a myriad of different stakeholders dictating the price of admission. A major player that has strained the contemporary healthcare system are Pharmacy Benefit Managers or “PBMs”. Initially created to control drug costs and manage prescription claims, PBMs have grown and consolidated so that only a handful of near-monopolies with limited accountability dominate the drug market, giving them immense power to affect the price of pharmaceuticals being paid by consumers and the State.

On January 9, 2019, Senator James Skoufis, Chair of the Senate Committee on Investigations & Government Operations, in coordination with Senator Gustavo Rivera, Chair of the Senate Committee on Health, opened an investigation into the practices of Pharmacy Benefit Managers in New York. The purpose of the investigation was to better understand the impact PBM practices have on New York State residents as well as delineate any legislative or regulatory recommendations for further action. The primary target of the inquiry was to assess the role of PBMs on rising prescription drug prices and declining patient’s access. This report serves as a culmination of the investigatory findings and final recommendations.

To sufficiently evaluate the role of PBMs in rising prescription drug costs in New York State, the Committee<sup>1</sup> sent multiple information and document requests to the three largest national

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<sup>1</sup> Reference to the “Committee” within this report refers to the actions and opinions of a majority of Investigation and Government Operations Committee members.

PBMs, CVS Caremark, Express Scripts Inc., and OptumRx.<sup>2</sup> In these requests, the Committee sought information and documents relating to industry practices and standard operating procedures in order to evaluate what impact PBMs are having on prescription costs. The investigative team held numerous meetings and discussions with representatives from the three PBMs regarding the requests, investigatory scope, and potential voluntary actions by the PBMs to adjust industry practices to better serve consumers.

Furthermore, the investigative team received information and documents from the New York State Department of Health and the New York State Department of Civil Service to evaluate the oversight—or lack thereof—of PBMs in New York State.<sup>3</sup> Regrettably, the Committee determined that both Departments have deficient oversight capabilities, leaving in question their ability to adequately regulate the practices of PBMs.<sup>4</sup>

In an effort to conduct an objective investigation, the investigative team participated in discussions with a myriad of interested stakeholders, including: independent and community pharmacists, drug manufacturer trade groups, the Pharmaceutical Research and Manufacturers of America (PhRMA), representatives from the Pharmacists Society of the State of New York (PSSNY), lobbyists on behalf of the PBMs, and representatives from the PBMs themselves. In order to understand the issues facing independent and community pharmacies throughout New York, the team conducted multiple site visits to pharmacies and attended PSSNY's annual convention.

PBMs play an important but contentious role in the healthcare industry. Acting as intermediaries between insurers, plan sponsors, drug manufacturers, pharmacies, and other

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<sup>2</sup> See *infra* IV.A.-IV.C.

<sup>3</sup> See *infra* VI.A.

<sup>4</sup> *Id.*

members of the healthcare industry, PBMs are primarily responsible for processing drug claims for plan members, managing formularies, determining reimbursement rates for pharmacies, and negotiating prescription drug prices with pharmaceutical manufacturers.<sup>5</sup> Nationwide, PBMs are now responsible for managing the pharmacy benefits for more than 266 million Americans with health insurance.<sup>6</sup>

At their inception, PBMs were created to address the substantial upsurge in prescription drug claims across the country. More recently, however, PBMs are under heightened scrutiny for anticompetitive business practices that are adversely affecting health plan sponsors, patients, and pharmacies. Rising prescription drug prices, complaints of increasing interference with patients' access to medications, and decreasing pharmacy reimbursement rates that pharmacies consider unsustainable bring the practices of PBMs into question.

Initially, numerous PBMs provided pharmacy benefit services for health plans across the United States. Today, however, three PBMs—CVS Caremark, Express Scripts Inc., and OptumRx—collectively control approximately 80 to 85 percent of the market.<sup>7</sup> As consolidation of PBMs has increased, concerns about the influence and secrecy of their practices, have too, intensified.<sup>8</sup> The Committee believes the consolidation and vertical integration of PBMs has contributed to skyrocketing list prices and declining patient access.

It is the opinion of the Committee that PBMs often employ controversial utilization and management tools to generate revenue for themselves in a way that is detrimental to health plan sponsors, patients, and pharmacies.<sup>9</sup> Such practices include maximum allowable cost lists, direct

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<sup>5</sup> See *infra* II.

<sup>6</sup> See *infra* II.

<sup>7</sup> See *infra* II.

<sup>8</sup> See *infra* II.

<sup>9</sup> See *infra* III.

and indirect remuneration fees, rebates, formularies, and most controversially, spread pricing. The Committee also found evidence that PBMs are undermining patient choice by forcing consumers to use their preferred distributors, which are predominantly their own retail and mail order operations.<sup>10</sup>

One of the key mechanisms by which PBMs generate revenue is through spread pricing. Most commonly practiced on generic prescription drugs, the spread pricing model involves charging plan sponsors one price for a prescription drug than what pharmacies are reimbursed for dispensing that drug.<sup>11</sup> The difference in the amount billed to the plan sponsor and the amount reimbursed is the “spread,” which—if a positive margin exists—the PBM reaps as additional profit.

Recently, PBMs have been exposed for using the spread pricing model to profit off state Medicaid programs.<sup>12</sup> In Ohio, PBMs have been accused by the Ohio Attorney General of overcharging Ohio State Medicaid managed care by \$224.8 million in spread fees from April 1, 2017 to March 31, 2018.<sup>13</sup> Similarly, in Kentucky, PBMs pocketed \$123.5 million in 2018 from the state’s Medicaid managed care program. In Michigan, the Medicaid managed care program was overcharged by an estimated \$64 million for prescription drug claims over a two-year period.<sup>14</sup>

In a 2019 report produced by the Pharmacists Society of the State of New York, it is estimated that New York Medicaid managed care organizations were overcharged by *at least* \$300 million due to spread pricing of generic prescription claims.<sup>15</sup> The Enacted Fiscal Year 2019-2020 budget banned the use of spread pricing in the State’s Medicaid Program.

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<sup>10</sup> *See infra* III.

<sup>11</sup> *See infra* V.A.-V.C.

<sup>12</sup> *Id.*

<sup>13</sup> *Id.*

<sup>14</sup> *Id.*

<sup>15</sup> *See infra* V.

The Committee is concerned that a lack of transparency, oversight, and accountability of PBMs has created an environment in which PBMs are able to engage in anticompetitive practices at the detriment of consumers and pharmacists across New York State.<sup>16</sup> As prescription drug costs continue to rise, reimbursement rates are declining, forcing many rural and independent pharmacies to permanently close their doors.

While the measures included in the 2019-2020 budget are beneficial, they must only be the beginning. Prompt action is necessary to address rising prescription costs and declining patient access. Legislation regulating questionable practices by PBMs is imperative. Specifically, the Committee urges the Legislature to take action by (1) regulating the practices of spread pricing in *all* pharmacy benefit contracts, (2) increasing the transparency of MAC appeals, (3) requiring the licensing and registration of PBMs operating in New York to enhance accountability and oversight, (4) prohibiting PBMs from mandating that patients use specialty and mail order pharmacies, (5) providing for the adequate and transparent reimbursements for pharmacies and (6) require PBMs to pass-through all discounts or rebates received from drug manufacturers to its Medicaid managed care clients. Most importantly, this Committee urges the New York State Comptroller to perform a full audit of New York's Medicaid managed care programs to understand the full effect PBMs—and spread pricing—has had on New York's consumers. A comprehensive audit of state Medicaid managed care dollars is urgently necessary.

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<sup>16</sup> *See infra* VIII.



## II. Overview of Pharmacy Benefit Managers

Throughout the United States, healthcare providers—also referred to as plan sponsors—predominantly contract with PBMs for the plan design and administration of prescription drug benefits. PBMs contract with pharmacies or pharmacy contracting agents, referred to as Pharmacy Services Administration Organizations (PSAOs), on behalf of a health plan, state agency, insurer, managed care organization, or other third party payor to provide pharmacy benefit services.<sup>17</sup> Plan sponsors that utilize PBMs for their healthcare plans include commercial health plans, self-insured employers, state government employee plans, Medicare Part D plans, and many more. Acting as intermediaries between insurers and other members of the healthcare system, PBMs are primarily responsible for negotiating prescription drug prices with pharmaceutical manufacturers, processing drug claims, managing formularies, and negotiating reimbursement rates. *Figure 1*, on the following page, illustrates a typical flow of products, services and funds between the primary parties in the healthcare system.

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<sup>17</sup> N.Y. PUB. HEALTH LAW § 280-a(1)(a) (2019).

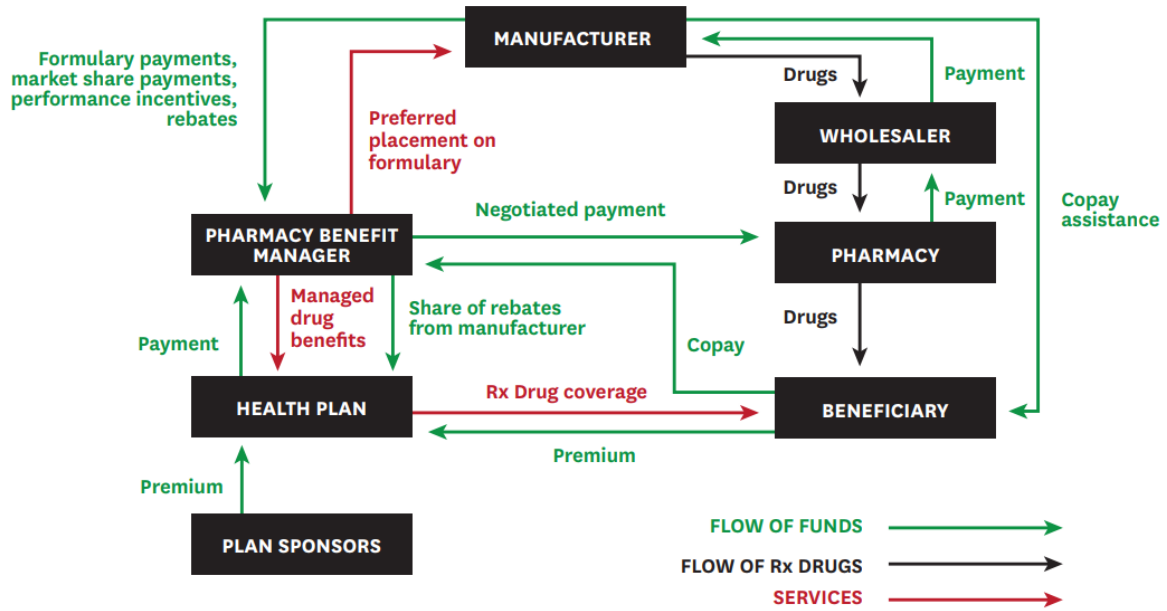


Figure 1<sup>18</sup>

PBMs were established in the 1960s to address the unprecedented increase in prescription drug claims that were overwhelming insurance companies, by serving as fiscal intermediaries adjudicating the claims.<sup>19</sup> Contemporary PBMs arose in the early 2000s, with the passage of the Medicare Modernization Act in 2003.<sup>20</sup>

With the Medicare Modernization Act, the function of PBMs in America's healthcare system dramatically changed. As Medicare expanded to include prescription drug payments through its Part D program, the role of PBMs expanded to implementing Part D by identifying patients, reducing the administrative burden on plan sponsors, and formulating drug prices with

<sup>18</sup> Sood, et al., *The Flow of Money Through the Pharmaceutical Distribution System*, USC SCHAEFFER CENTER FOR HEALTH POLICY & ECONOMICS 2 (2017).

<sup>19</sup> Judi Buckalew, *Pharmacy Benefit Managers Play Significant Role in Pricing*, AMERICAN ACADEMY OF ORTHOPEDIC SURGEONS NOW (Oct. 2017).

<sup>20</sup> Jessica Wapner, *Understanding the Hidden Villain of Big Pharma: Pharmacy Benefit Managers*, NEWSWEEK (Mar. 17, 2017).

manufacturers by negotiating discounts and rebates.<sup>21</sup> Initially, numerous PBMs were operating within the American healthcare system, but due to consolidation and amalgamation, three PBMs—CVS Caremark, Express Scripts, Inc. and OptumRx—collectively control an estimated 80 to 85 percent of the market, covering approximately 266 million Americans.<sup>22</sup>

At their onset, PBMs were established to reduce drug prices and increase patient access. More recently, however, PBMs are under significant scrutiny for anti-competitive business practices that are adversely affecting patients and independent pharmacists, including allegedly driving up drug prices and interfering with patients' access to medications.<sup>23</sup>

PBMs largely determine which pharmacies will be included in a pharmacy benefit plan's network and how much pharmacies will be paid for dispensing prescriptions.<sup>24</sup> PBMs also determine which medications will be covered by the plan—commonly referred to as a formulary—and drug manufacturers often pay “rebates” to PBMs in order to get their drugs—and exclude competitor's drugs—onto those formularies.<sup>25</sup>

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<sup>21</sup> *Id.*

<sup>22</sup> Buckalew, *supra* note 19. *See also* Frier Levitt, LLC, PBM DIR FEES COSTING MEDICARE AND BENEFICIARIES: INVESTIGATIVE WHITE PAPER ON BACKGROUND, COST IMPACT, AND LEGAL ISSUES 1 (Jan. 2017) [hereinafter Frier Levitt].

<sup>23</sup> Wapner, *supra* note 20.

<sup>24</sup> Per investigative teams' discussions and interviews with pharmacists operating in New York State.

<sup>25</sup> *Id.*

### III. Role of Pharmacy Benefit Managers in Rising Costs of Prescription Drugs

The Committee finds that PBMs utilize procedures and policies to generate revenue that are often detrimental to plan sponsors and pharmacies. PBMs primarily profit from (1) their own mail order pharmacies; (2) providing services such as drug utilization review, rebate administration, and data mining, and (3) negotiating with health plans, pharmaceutical manufacturers, and retail pharmacies.<sup>26</sup> PBMs use practices, such as maximum allowable cost lists, spread pricing, and direct and indirect remuneration fees to generate profit, which leads to higher prices for clients and consumers. Moreover, PBMs use practices that can undermine patient choice by forcing consumers to use their preferred distributors, which are often their own retail and mail order operations.<sup>27</sup>

#### III.A. Maximum Allowable Cost

A “maximum allowable cost” or “MAC” is a proprietary benchmark price set by PBMs for therapeutically equivalent multiple source generic drugs.<sup>28</sup> It designates the upper limit a plan will pay for generic drugs and brand name drugs that have generic versions available.<sup>29</sup> PBMs have free reign to determine which products, and at what prices, are included on their MAC lists; there

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<sup>26</sup> Allison Garrett & Robert Garis, *Leveling the Playing Field in the Pharmacy Benefit Management Industry*, 42 VAL. U. L. REV. 33, 36-37 (2007).

<sup>27</sup> David Balto, *Tackling High Drug Costs: Administration Works to Rein in Middlemen, Morning Consult* (June 6, 2018).

<sup>28</sup> N.Y. PUB. HEALTH LAW § 280-a(1)(b) (2019).

<sup>29</sup> *The Need for Legislation Regarding “Maximum Allowable Cost” (MAC) Reimbursement*, NATIONAL COMMUNITY PHARMACISTS ASSOCIATION.

is no industry standard setting the criteria for determining which drugs are included on a MAC list or the methodology of how PBMs establish the ultimate rate.<sup>30</sup>

Further, the pricing lists maintained by PBMs are not required to cover a pharmacy's operating costs, and can change without notice.<sup>31</sup> Generally, MAC list rates are reviewed and updated at least every seven calendar days.

Plan sponsors and pharmacies are usually not privy to the MAC determination process; in some instances, pharmacists reported that they are compelled to blindly agree to contracts without knowing the details of what is being agreed to.<sup>32</sup> Contracted network pharmacies report being uninformed as to how reimbursements—how much they will ultimately be paid—are calculated.<sup>33</sup> Most plan sponsors report being unaware of how much revenue the PBM retains when the plan sponsors pay for pharmaceuticals or pharmacy services because PBMs are not obligated to share reimbursement information with their clients.<sup>34</sup>

Most states, including New York, have statutory requirements that mandate a reimbursement appeal process for pharmacies. Appeals, however, are almost always denied because a PBM has the unilateral ability to set the rates without any oversight from state agencies.<sup>35</sup>

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<sup>30</sup> *Id.*

<sup>31</sup> Per investigative teams' discussions and interviews with pharmacists operating in New York State.

<sup>32</sup> *Id.*

<sup>33</sup> *Id.*

<sup>34</sup> *Id.*

<sup>35</sup> Douglas Hoey, *Allowable Cost Reimbursements Under Federal Healthcare Need Transparency*, THE HILL (Mar. 24, 2017).

### III.B. Spread Pricing Model

PBMs also generate significant revenue from “spread pricing.” Most commonly practiced on generic drug prescriptions, spread pricing involves charging plan sponsors more for a prescription drug than what PBMs actually reimburse pharmacists for dispensing the drug.<sup>36</sup> The difference in the amount billed to a plan sponsor and the amount reimbursed to the pharmacy is where a PBM is able to generate additional revenue. In 2018, Bloomberg examined the prices of best-selling generic prescription drugs used by Medicaid, concluding that state insurance plans, including New York, were paying millions of dollars in fees to PBMs via spread pricing tactics.<sup>37</sup> For example, in 2017, a 30-day supply of Aripiprazole cost \$163 to New York Medicaid but only cost New York pharmacies \$21 to dispense. The \$142 difference between the cost to the New York Medicaid and the cost to the pharmacy is the spread.<sup>38</sup> *Figure 2*, on the following page, depicts this. While this analysis does not distinguish how the remaining \$142 is divided between the pharmacies and the PBMs, independent pharmacists interviewed by Bloomberg say the money is largely not going to them.<sup>39</sup>

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<sup>36</sup> Robert Langreth et al., *The Secret Drug Pricing System Middlemen Use to Rake in Millions*, BLOOMBERG (Sept. 11, 2018) [hereinafter *The Secret Drug Pricing System Middlemen Use to Rake in Millions*].

<sup>37</sup> *Id.*

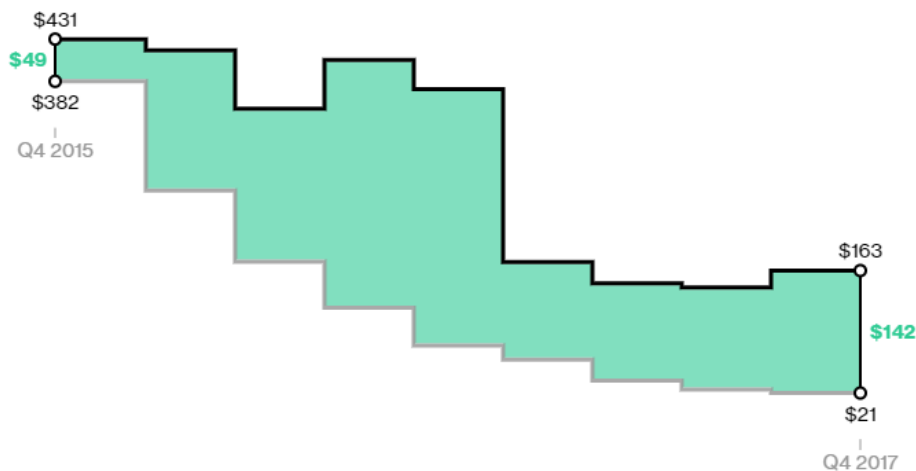
<sup>38</sup> *Id.*

<sup>39</sup> *Id.*

### Aripiprazole 5 mg (generic Abilify) in New York

Disease: Schizophrenia and depression

Cost to pharmacy    Cost to state Medicaid program    Combined pharmacy and PBM spread and fees



Note: Drug prices reflect a 30-day supply; numbers may not add precisely due to rounding

Figure 2<sup>40</sup>

PBMs also offer a pass-through model for pricing in contracts, which require a PBM to charge a managed care plan the exact amount the PBM pays for prescriptions and dispensing fees.<sup>41</sup> In lieu of paying the spread to PBMs under the traditional model, plans under the pass-through structure pay the PBM administrative fees for providing pharmaceutical services.

<sup>40</sup> *Id.*

<sup>41</sup> Thomas Beaton, *OH Medicaid Adopts Pass-Through Model for Managed Care Drugs*, HEALTH PAYER INTELLIGENCE (Aug. 15, 2018).

### III.C. Direct and Indirect Remuneration Fees

PBMs also use “direct and indirect remuneration” fees (“DIR”) to supplement their revenue. The Centers for Medicare and Medicaid Services (“CMS”) initially created DIR fees upon the enactment of Medicare Part D in order to track rebates and other price adjustments made to PBMs.<sup>42</sup> CMS contracts with various plan sponsors to administer Medicare Part D; these plan sponsors in turn contract with PBMs to manage the pharmaceutical drug benefit of Medicare Part D.<sup>43</sup>

PBMs are responsible for negotiating rebates from drug manufacturers as well as establishing price adjustments that ultimately lower the overall drug costs for Medicare Part D plans.<sup>44</sup> DIR fees were designed as a way for CMS to track the annual amount of the rebates and price adjustments for the purpose of accurately determining reimbursement on the lowest price.<sup>45</sup> However, over time the purpose of DIR fees has considerably transformed. Today, DIR fees have morphed into a “catch all” term used by PBMs to boost their profit.<sup>46</sup> Examples of a DIR fee include “costs for pharmacies to participate in a Part D preferred network, price reconciliations based on contractual rates, and compliance fees for contract-based performance metrics.”<sup>47</sup> Essentially, DIR fees are payments or payment adjustments made to PBMs after the point-of-sale that alter the cost of Part D covered drugs.

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<sup>42</sup> Michael Gabay, *Direct and Indirect Remuneration Fees: The Controversy Continues*, 52(11) HOSP. PHARM., 740, (Dec. 2017).

<sup>43</sup> *Id.*

<sup>44</sup> *Id.*

<sup>45</sup> *Id.*

<sup>46</sup> *Id.*

<sup>47</sup> *Id.*



While DIR fees are not applicable to New York Medicaid managed care, uncertainty in fees have significant impacts on pharmacies.<sup>48</sup> Community and specialty pharmacies argue DIR fees are essentially a means for PBMs to contractually “claw back” millions of dollars from pharmacies on medications that are already dispensed.<sup>49</sup> Typically, these fees are charged to pharmacies months after the initial point-of-sale, and a lack of transparency in contract language hinders pharmacies from accurately estimating how much will eventually be owed to the PBM.<sup>50</sup>

### III.D. Rebates, Discounts and Price Concessions from Drug Manufacturers

On behalf of their clients, PBMs negotiate rebates with drug manufacturers through the use of formularies and utilization management tools.<sup>51</sup> Manufacturers set the list price for their prescription drugs, and the PBMs negotiate price concessions for drugs dispensed to the beneficiaries of its plan sponsor clients, in exchange for having their prescription medications placed on a formulary. The Centers for Medicare and Medicaid Services (CMS) reported that PBMs have been able to negotiate large rebates from drug manufacturers, which has contributed to lower net costs.<sup>52</sup> A 2018 study, funded by the Pharmaceutical Care Management Association (PCMA),—the national association of PBMs—claimed that rebates in the Medicare Part D drug

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<sup>48</sup> Per investigative teams’ discussions and interviews with pharmacists operating in New York State.

<sup>49</sup> *Id.*

<sup>50</sup> *Id.*

<sup>51</sup> Elizabeth Seeley and Aaron S. Kesselheim, *Pharmacy Benefit Managers: Practices, Controversies, and What Lies Ahead*, THE COMMONWEALTH FUND, (Mar. 26, 2019).

<sup>52</sup> *Id.*

plan saved beneficiaries \$34.9 billion in premiums between 2014 and 2018.<sup>53</sup> In some cases, however, PBMs' use of rebates has contributed to high pharmaceutical prices.<sup>54</sup>

PBMs negotiate with drug manufacturers to achieve the lowest net cost by securing manufacturer discounts. Rebates are paid to PBMs after the point of sale, and can make up 40 percent or more of the drug's list price.<sup>55</sup> PBMs are not required to disclose information about rebates with their clients, so while PBMs claim they pass much of the discount back to customers, how much they choose to keep for themselves is generally concealed.

PBMs are partially reimbursed on the rebates they are able to negotiate with drug manufacturers, which are calculated as a percentage of a drug's list price.<sup>56</sup> Critics contend this system gives PBMs an incentive to prioritize high-price prescription drugs over drugs that are more cost-effective.<sup>57</sup> The incentive-based scheme is cited as an explanation for why tiering or other utilization management strategies were used to favor brand name drugs over less expensive drugs—such as generics—that are therapeutically similar.<sup>58</sup> Consumers that have high-deductible health plans may suffer from these prices.<sup>59</sup>

In effect, drug manufacturers are paying PBMs to increase the manufacturer's market shares. For example, two drug manufacturers may have similar but competing brand name drugs designed to treat asthma. Manufacturers are able to offer financial incentives to PBMs, in the form of rebates

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<sup>53</sup> RANDALL FITZPATRICK & CHRIS CARLSON, PREMIUM IMPACT OF REMOVING MANUFACTURER REBATES FROM THE MEDICARE PART D PROGRAM, OLIVER WYMAN 1, 2 (July 6, 2018). *See also* Michael Ollove, *Drug-Price Debate Targets Pharmacy Benefit Managers*, THE PEW CHARITABLE TRUSTS (Feb. 12, 2019).

<sup>54</sup> Seely & Kesselheim, *supra* note 51.

<sup>55</sup> *Id.*

<sup>56</sup> *Id.*

<sup>57</sup> *Id.*

<sup>58</sup> *Id.*

<sup>59</sup> *Id.*

or discounts, for achieving sales targets.<sup>60</sup> Moreover, PBMs may also receive rebates and discounts for placing a manufacturer’s drug—and excluding its competition—on a formulary.<sup>61</sup>

### III.E. Formularies

A formulary is a list of prescription drugs covered by a health plan’s pharmacy benefit design. It dictates which drugs a health plan predetermines will be covered, and at what level, for reimbursement under the terms of its pharmacy benefit plan. Formularies distinguish between preferred or discouraged prescription drugs by dividing products into different “tiers,” designating different levels of patient out of pocket costs.<sup>62</sup> A formulary may cover both generic and brand name prescription drugs.

Formulary selection involves an assessment of both the clinical and financial elements of a prescription medication.<sup>63</sup> Typically, PBMs employ Pharmacy and Therapeutics (“P&T”) committees to assess and recommend formulary placement for individual drugs.<sup>64</sup> These committees are typically comprised of clinicians, pharmacists, medical professionals, legal experts, and administrators.<sup>65</sup> Formularies generally have two to five “tiers.” For example, a five-tier formulary includes generic, preferred brand, non-preferred brand, preferred specialty drugs and non-preferred specialty drug tiers.<sup>66</sup> In addition to including therapeutic substitutions, a plan’s

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<sup>60</sup> Garrett & Garis, *supra* note 26, at 44.

<sup>61</sup> *Id.*

<sup>62</sup> Cole Werble, *Health Policy Brief: Formularies*, HEALTH AFFAIRS 1 (Sept. 14, 2017) [hereinafter *Health Policy Brief: Formularies*].

<sup>63</sup> *Id.*

<sup>64</sup> *Id.*

<sup>65</sup> *Id.*

<sup>66</sup> *Id.*

formulary may require a patient to accept a generic substitution for the chemical equivalent of the brand name drug.<sup>67</sup>

Pharmacy benefit plans may also use “open” or “closed” formularies. In an “open” formulary, the plan sponsor pays a portion of the cost for all drugs, whereas in a “closed” formulary, the plan sponsor does not cover any non-formulary drugs unless approved through a process.

Tier placement determines the amount a patient pays out of pocket for a prescription medication at the point of sale.<sup>68</sup> These costs are typically represented as coinsurance or copays.<sup>69</sup> Coinsurance is a percentage of the full cost of a drug; copays are a fixed amount per prescription.<sup>70</sup> Under this approach, the structure of the plan provides for lower out of pocket copays when preferred drugs are used.<sup>71</sup> In a three-tiered formulary copay structure, for example, a patient may have to pay \$10 for generic prescriptions, \$15 for preferred brand name prescriptions, and \$30 for nonpreferred brand name prescriptions.<sup>72</sup>

Prescription drugs that are on a plan’s formulary often have lower copayment amounts, thereby providing incentives to plan beneficiaries to obtain prescriptions included on the formulary, or even on a lower tier, to reduce or eliminate their out of pocket costs.<sup>73</sup> Thus, PBMs can steer patients towards one prescription drug over another by making their out-of-pocket costs less

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<sup>67</sup> Per investigative teams’ discussions and interviews with pharmacists operating in New York State. *See also* Garrett & Garis, *supra* note 26, at 43.

<sup>68</sup> *Health Policy Brief: Formularies*, *supra* note 62.

<sup>69</sup> *Id.*

<sup>70</sup> *Id.*

<sup>71</sup> Garrett & Garis, *supra* note 26, at 43.

<sup>72</sup> Robert I. Garis et al., *Examining the Value of Pharmacy Benefit Management Companies*, 61 AM. J. HEALTH-SYS. PHARMACISTS, 81, 82 (2004).

<sup>73</sup> FEDERAL TRADE COMMISSION, PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL-ORDER PHARMACIES 1, 6 (Aug. 2005) [hereinafter FEDERAL TRADE COMMISSION].

expensive.<sup>74</sup> Therefore, the placement of prescription drugs on a formulary can increase profits for the drug's manufacturer.<sup>75</sup>

PBMs negotiate with drug manufacturers to provide preferred formulary placement for the manufacturers' products, in exchange for discounts, rebates, and incentives.<sup>76</sup> This scheme has led to contentions that PBM-negotiated manufacturer rebates cause PBMs to be more interested in maximizing their rebates—which they receive a monetary portion of—than in minimizing a payer's prescription drug costs.<sup>77</sup>

Further, a recent study of Medicare Part D formularies found that PBMs might be creating formularies that “encourage the use of more expensive branded drugs by assigning them fewer utilization controls compared to generic equivalents.”<sup>78</sup>

Compliance with a plan's formulary is crucial for a PBM because it demonstrates the ability of a PBM to guide beneficiaries to obtain drugs on the formulary.<sup>79</sup> High compliance is important because it enables a PBM to show drug manufacturers that it “can induce use of formulary products and increase their market shares.”<sup>80</sup> PBMs utilize various strategies to ensure formulary compliance, including generic substitution, therapeutic interchange, step-therapy and prior authorization protocols.<sup>81</sup>

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<sup>74</sup> Michael Ollove, *supra* note 53.

<sup>75</sup> FEDERAL TRADE COMMISSION, *supra* note 73, at 6.

<sup>76</sup> Per investigative teams' discussions and interviews with pharmacists, PBM representatives, and drug manufactures.

<sup>77</sup> Robert I. Garis et al., *Examining the Value of Pharmacy Benefit Management Companies*, 61 AM. J. HEALTH-SYS. PHARMACISTS, 81, 82 (2004).

<sup>78</sup> Letter from U.S. Sen. Charles E. Grassley, Chairman, Senate Finance Committee and U.S. Sen. Ron Wyden, Ranking Member, Senate Finance Committee to Timothy C. Wentworth, President, Express Scripts and Cigna Services (Apr. 2, 2019), (citing Mariana P. Socal, Ge Bari & Gerald F. Anderson, *Favorable Formulary Placement of Branded Drugs in Medicare Prescription Drug Plans When Generics Are Available*, Research Letter, JAMA Internal Med. (Mar. 18, 2019)).

<sup>79</sup> FEDERAL TRADE COMMISSION, *supra* note 73, at 6.

<sup>80</sup> *Id.* at 7.

<sup>81</sup> *Id.* at 12.

Generic substitution is the dispensing of a bioequivalent generic drug that contains the same active ingredients, and is chemically identical in terms of strength, concentration, dosage, and route of administration, to its brand-name drug.<sup>82</sup> It generally occurs without prior physician authorization when a beneficiary presents a prescription for a brand name drug and the pharmacy dispenses it with a generic version of the product.<sup>83</sup> Unless a state legally requires generic substitution, where applicable, or a physician orders a prescription to be dispensed as written (“DAW”), PBMs and pharmacists may have the discretion to substitute a generic drug for a brand name drug without prior approval.<sup>84</sup>

Similarly, therapeutic interchange is the substitution of one drug for another in the same therapeutic class.<sup>85</sup> However, in therapeutic interchanges, the drug is substituted for a therapeutically equivalent, but chemically distinct, drug product.<sup>86</sup> The substitution can be brand drug to brand drug or an interchange of a generic version of a therapeutically similar brand drug for the prescribed brand drug.<sup>87</sup> For example, in the latter scenario, generic Prozac is dispensed in lieu of prescription Zoloft.<sup>88</sup>

PBMs have utilized step-therapy and prior authorization tools to lower prescription drug costs and boost formulary compliance.<sup>89</sup> In step-therapy programs, plans will pay for certain expensive drugs only if a physician first prescribes at least one less expensive prescription or over-the-counter drug first.<sup>90</sup> Prior authorization requires that a physician or patient receive prior approval from the

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<sup>82</sup> *Id.*

<sup>83</sup> *Id.*

<sup>84</sup> *Id.* at 13.

<sup>85</sup> *Id.*

<sup>86</sup> *Id.*

<sup>87</sup> *Id.*

<sup>88</sup> *Id.*

<sup>89</sup> *Id.*

<sup>90</sup> *Id.*

PBM before certain non-preferred drugs are reimbursed by insurance.<sup>91</sup> Typically, prior authorization requires a clinical justification for the use of prescription drugs that are prone to misuse or are more expensive.<sup>92</sup>

Prior authorization also enables PBMs to influence patients' choices by requiring them to get special permission from their health plan to use certain drugs or by requiring patients to try a less expensive drug before being authorized to use the medicine initially prescribed by their physician.<sup>93</sup>

### III.F. Ownership of Retail and Mail Order Pharmacies

Many PBMs also profit by owning and operating their own retail and mail order pharmacies. A PBM is “vertically integrated” if it owns a pharmacy, whether it is retail or mail order.<sup>94</sup> A vertically integrated PBM may have a greater ability to control which prescription drugs are dispensed under the benefit plans it administers than a non-vertically integrated PBM.<sup>95</sup> PBMs mail order pharmacies typically fill and ship prescriptions that require a 90-day supply.<sup>96</sup> CVS Health, Express Scripts Inc., and OptumRx own and operate mail order pharmacy services.<sup>97</sup>

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<sup>91</sup> *Id.* at 13-14.

<sup>92</sup> *Id.* at 14.

<sup>93</sup> Michael Ollove, *supra* note 53.

<sup>94</sup> FEDERAL TRADE COMMISSION, *supra* note 73.

<sup>95</sup> *Id.*

<sup>96</sup> *Pharmacy Benefit Managers: Mail Order Services 101*, NATIONAL COMMUNITY PHARMACISTS ASSOCIATION.

<sup>97</sup> *See infra* IV.A-C.

Vertical integration can have the ability to lower prescription drug costs by reducing transaction costs and avoiding double markups.<sup>98</sup> However, when a PBM administers the pharmacy benefits for a client *and* sells prescription drugs to a client’s beneficiary (member) via the PBM’s owned mail order pharmacy, the strong possibility of a conflict of interest arises.<sup>99</sup> In such a scenarios, PBMs have an opportunity to manipulate drug dispensing at their mail order pharmacies to enhance their own profits at the expense of plans and its members.<sup>100</sup>

#### IV. Investigatory Process and Report Findings

To examine the role of PBMs in rising prescription drug costs in New York State, the Committee sent multiple information and document requests to the three largest national PBMs, CVS Caremark, Express Scripts Inc., and OptumRx. In these requests, the Committee sought information and documents relating to industry practices and standard operating procedures in order to evaluate what impact PBM’s are having on prescription costs. Furthermore, the Committee held numerous meetings and discussions with representatives from the three PBMs regarding the requests, investigatory scope, and potential voluntary actions by the PBMs to adjust industry practices to better serve consumers.

The Committee specifically sought information and documentation relating to policies and standard operating procedures utilized by PBMs to determine MAC (Maximum Allowable Cost)

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<sup>98</sup> FEDERAL TRADE COMMISSION, *supra* note 73. Double markups, or “double marginalization” occurs when two independent, vertically related firms each have some ability to charge about the marginal cost. *Id.*

<sup>99</sup> *Id.*

<sup>100</sup> Per investigative teams’ discussions and interviews with pharmacists operating in New York State. *See also* FEDERAL TRADE COMMISSION, *supra* note 73.



lists, drug coverage and formularies, administrative fees, spread pricing, reimbursement rates, and MAC appeals.

#### IV.A. CVS Caremark

CVS Caremark is a subsidiary of CVS Health Corporation (“CVS Health”), which has more than 9,900 retail locations, 1,100 walk-in medical clinics, serves 92 million pharmaceutical benefit plan members, and provides specialty pharmacy services to consumers.<sup>101</sup> CVS Health is currently ranked seventh on the Fortune 500 list, with over \$184 billion in annual revenue.<sup>102</sup> For the three-month period ending March 31, 2019, CVS Health reported a revenue of approximately \$33.6 million for its pharmacy services.<sup>103</sup> CVS Health and its subsidiaries provide pharmaceutical benefits and clinical services to consumers. Of the 9,900 CVS pharmacy locations nationwide, 564 are pharmacies and retail stores located in New York.<sup>104</sup>

On November 28, 2018, CVS acquired Aetna, the nation’s third-largest health insurance company and fourth-largest individual prescription drug plan insurer, for \$69 billion.<sup>105</sup> Aetna managed over two million prescription drug plan members and earned a revenue of approximately

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<sup>101</sup> CVS Health Corp., Annual Report (Form 10-K) (Feb. 28, 2019).

<sup>102</sup> FORTUNE 500.

<sup>103</sup> CVS Health Corp., Quarterly Report 13 (Form 10-Q) (May 1, 2019).

<sup>104</sup> *The Impact of CVS Health New York*, CVS HEALTH.

<sup>105</sup> Bruce Jaspen, *CVS-Aetna Deal Closes With Vow to Change ‘Consumer Health Experience’*, FORBES (Nov. 28, 2018). *See also* Press Release, United States Department of Justice, Justice Department Requires CVS and Aetna to Divest Aetna’s Medicare Individual Part D Prescription Drug Plan Business to Proceed with Merger (Oct. 10, 2018) (on file with author).

\$60 billion in 2017.<sup>106</sup> The Department of Justice granted conditional approval of the merger of CVS and Aetna as long as Aetna divested its private Medicare Part D prescription drug plans.<sup>107</sup> Despite federal agency approval, the merger currently faces an antitrust challenge in the United States District Court in the District of Columbia.<sup>108</sup> The Court is reviewing the merger to determine whether the deal violates the Antitrust Procedure and Penalties Act, or the Tunney Act, a claim asserted by many medical associations and consumer protection agencies.<sup>109</sup>

CVS Caremark maintains a national pharmacy benefit network of more than 68,000 retail pharmacies, consisting of 41,000 chain pharmacies and 27,000 independent pharmacies.<sup>110</sup> According to CVS Caremark's January 30, 2019, response to the Committee's information request, CVS Caremark contracts with 5,023 pharmacies for the provision of pharmacy benefit services in New York State.

CVS Caremark negotiates reimbursement rates with contracted pharmacies on behalf of its clients; contracts are negotiated at the pharmacy, pharmacy chain, or pharmacy service organization ("PSAO") level.<sup>111</sup> Reimbursement is set by using the industry standard lesser-of logic. Typically, reimbursement is the lesser-of (1) the "usual and customary" price, (2) submitted ingredient cost plus a dispensing fee, (3) the contractual rate, or (4) MAC price.<sup>112</sup> Some contracts negotiated by CVS Caremark only use the lesser-of (1) the "usual and customary" price or (2) the

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<sup>106</sup> Press Release, United States Department of Justice, Justice Department Requires CVS and Aetna to Divest Aetna's Medicare Individual Part D Prescription Drug Plan Business to Proceed with Merger (Oct. 10, 2018) (on file with author).

<sup>107</sup> *Id.*

<sup>108</sup> Emily Baumgaertner, *Judge Seeks Monitoring of CVS and Aetna During Antitrust Review*, THE NEW YORK TIMES (Dec. 18, 2018).

<sup>109</sup> Kevin Curran, *A Review of the Regulatory Hurdles Remaining for the CVS Aetna Acquisition*, REAL MONEY (May 1, 2019).

<sup>110</sup> CVS Health Corp., Annual Report (Form 10-K) (Feb. 28, 2019).

<sup>111</sup> Response from CVS Caremark to the New York State Senate Committee on Investigations and Government Operations (Mar. 1, 2019).

<sup>112</sup> *Id.*

contract rate or the MAC for generics on a MAC list.<sup>113</sup> For brand drugs, CVS Caremark typically sets the reimbursement rate as a percentage discount from AWP (Average Wholesale Price) plus a dispensing fee.<sup>114</sup>

Independent pharmacies account for about 40 percent of CVS Caremark’s network of more than 68,000 pharmacies across the United States.<sup>115</sup> In determining its reimbursement rates, CVS Caremark claims that independent pharmacies are reimbursed at a higher rate than larger regional and national chains.<sup>116</sup> Specifically, CVS Caremark asserts that “[i]ndependently-owned pharmacies [...] receive a fair and competitive reimbursement rate, that is generally higher than the rate for national chain pharmacies in [its] network (including CVS Pharmacy).”<sup>117</sup>

As stated previously MAC prices specify the allowable reimbursement a PBM will allocate to a pharmacy for dispensing a generic drug. CVS Caremark sets its MAC list and rates by reviewing marketplace dynamics, product availability, and different pricing sources, including but not limited to, Medi-span, wholesalers, MAC lists published by CMS, and retail pharmacies.<sup>118</sup> CVS Caremark’s MAC pricing often changes on a weekly basis, or more often, on a daily basis, if needed.<sup>119</sup>

CVS Caremark uses MAC lists to provide pricing by individual generic drug, and may express generic drug reimbursement as a discount from AWP plus a dispensing fee or MAC plus

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<sup>113</sup> *Id.*

<sup>114</sup> *Id.*

<sup>115</sup> *Independent Pharmacies Play an Integral Role in Helping CVS Caremark Members Access Medications*, CVS HEALTH.

<sup>116</sup> *Id.*

<sup>117</sup> *Our Maximum Allowable Cost (MAC) Pricing is a Commonly Used Tool to Manage Drug Costs*, CVS HEALTH.

<sup>118</sup> *Id.*

<sup>119</sup> Response from CVS Caremark to the New York State Senate Committee on Investigations and Government Operations (Mar. 1, 2019).

a dispensing fee.<sup>120</sup> Not all prescription drugs are subject to CVS Caremark’s MAC pricing; some contracts have a Generic Effective Rate (GER), which is an average discount from AWP, and is calculated on a periodic basis.<sup>121</sup>

As required by Public Health Law § 280-a, PBMs in New York are required to set forth a MAC appeals process for pharmacies.<sup>122</sup> From 2014 to 2018, the number of MAC appeal claims for pharmacies participating in CVS Caremark’s networks increased from 5,646 claims to 340,611 claims, or by 5932.78 percent.<sup>123</sup> However, the number of appeals approved only increased by 1093.57 percent. Pharmacies who have their MAC appeals denied are told “[p]rice remains based on CVS Health’s review of current market price range.”<sup>124</sup>

<b>YEAR</b>	<b>CLAIM</b>	<b>APPROVED</b>	<b>DENIED</b>	<b>PERCENT APPROVED</b>	<b>PERCENT DENIED</b>
<b>2014</b>	5,646	1,337	4,309	23.7%	76.3%
<b>2015</b>	23,465	2,293	21,172	9.8%	90.2%
<b>2016</b>	43,787	2,606	41,181	6.0%	94.0%
<b>2017</b>	139,580	1,751	137,829	1.3%	98.7%
<b>2018</b>	340,611	15,958	324,653	4.7%	95.3%

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<sup>120</sup> *Id.*

<sup>121</sup> *Id.*

<sup>122</sup> *See infra* VI.A.

<sup>123</sup> Response from CVS Caremark to the New York State Senate Committee on Investigations and Government Operations (Mar. 1, 2019).

<sup>124</sup> *Id.*

CVS Caremark creates a “formulary” that a client can adopt as part of its plan design or opt to design its own. In determining the prescription drugs on its formularies, CVS Caremark utilizes an independent panel of doctors, pharmacists and other medical experts to review and approve the selection of drugs that meet the Company’s standards of safety and inclusion on one of the Company’s template formularies.<sup>125</sup> While not required to do so, many of CVS Caremark’s clients choose to adopt a template formulary as part of their plan design.<sup>126</sup>

In contracts that utilize the traditional spread pricing model, CVS Caremark separately negotiates rates with its clients for the provision of pharmacy benefit services and reimbursement rates with pharmacies to dispense drugs to patients.<sup>127</sup> In lieu of administrative fees, CVS Caremark earns the “spread” between the price charged to its clients and the reimbursement paid to pharmacies.<sup>128</sup> CVS Caremark asserts the spread is used to cover its expenses for various services, including clinical and customer support, programs to improve medication adherence, and management of drug formulary and rebates. CVS Caremark claims that clients who choose the spread pricing model receive greater price certainty on the costs of drugs, while it bears the financial risk that it will not be able to negotiate prices below the levels contract with the client.

CVS Caremark also offers clients the pass-through model, in which the PBM negotiates reimbursement rates with the pharmacies and clients pay those negotiated reimbursement rates. In lieu of the spread paid to CVS Caremark, pass-through clients pay the PBM administrative fees for providing pharmacy services. In the pass-through model, the administrative fees that PBMs receive from clients are not tied to performance in negotiating lower drug prices.<sup>129</sup>

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<sup>125</sup> CVS Health Corp., Annual Report (Form 10-K) (Feb. 28, 2019).

<sup>126</sup> Response from CVS Caremark to the New York State Senate Committee on Investigations and Government Operations (Mar. 1, 2019).

<sup>127</sup> *Id.*

<sup>128</sup> *Id.*

<sup>129</sup> *Id.*

CVS Caremark maintains contractual relationships with generic and brand name drug manufacturers that provide for purchase discounts or rebates on drugs dispensed by pharmacies in their network and by their specialty and mail order pharmacies.<sup>130</sup> In 2018, CVS Caremark retained two percent of its rebates from drug manufacturers, which is three percent of its annual earnings per share of about \$300 million.<sup>131</sup> In December of 2018, CVS Health announced its new “guaranteed net cost” model for pricing.<sup>132</sup> The model guarantees the client’s average spend per prescription, after any discounts, across each channel of distribution.<sup>133</sup> Under the new pricing model, CVS Caremark will pass through 100 percent of rebates to all government health programs, commercial insurer and employer clients.<sup>134</sup> Plan sponsors will then have the option to choose whether and how to pass any rebates to their members.<sup>135</sup>

CVS Health also owns and operates mail order dispensing pharmacies and specialty mail order pharmacies. Its specialty mail order pharmacies deliver advanced medications to individuals with chronic or genetic diseases and disorders.<sup>136</sup> CVS Health’s mail service dispensing pharmacies also sell prescription drugs directly to consumers.<sup>137</sup> For the three month period ending on March 31, 2019, CVS Health received approximately \$11.84 million in revenue from its mail order dispensing and specialty mail order services.<sup>138</sup>

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<sup>130</sup> *Id.*

<sup>131</sup> Bruce Japsen, *Amid Drug Price Scrutiny, CVS Says Its PBM Retains Just 2% of Rebates*, FORBES (Aug. 8, 2018).

<sup>132</sup> Press Release, CVS Health, *CVS Health Introduces New Approach to Pricing of Pharmacy Benefit Management Services* (Dec. 5, 2018).

<sup>133</sup> *Id.*

<sup>134</sup> *Id.* See also Bruce Japsen, *CVS to Return 100% of Drug Rebates Under New PBM Price Model*, FORBES (Dec. 5, 2018).

<sup>135</sup> Deena Beasley, *CVS Offers ‘Guaranteed Net Cost’ for Pharmacy Benefit Clients*, REUTERS (Dec. 5, 2018).

<sup>136</sup> CVS Health Corp., Annual Report 3 (Form 10-K) (Feb. 28, 2019).

<sup>137</sup> CVS Health Corp., Quarterly Report 10 (Form 10-Q) (May 1, 2019).

<sup>138</sup> *Id.* at 13.

## IV.B. Express Scripts, Inc.

Express Scripts is a subsidiary of Cigna Corporation, an international health services corporation with an adjusted revenue of \$48 billion in 2018.<sup>139</sup> On December 20, 2018, Cigna acquired Express Scripts, the nation's largest PBM, for \$67 billion.<sup>140</sup> Express Scripts offers specialized pharmacy care, home delivery pharmacy services, retail network pharmacy benefits, drug formulary management and specialty pharmacy services to its clients and plan members.<sup>141</sup> Approximately 90 percent of all prescriptions filled by Express Scripts are generic medications.<sup>142</sup>

Express Scripts currently manages drug benefits for more than 80 million Americans, including those enrolled in union-sponsored plans, state employee health plans, and public purchasers.<sup>143</sup> Over 67,000 retail pharmacies across the United States participate in one or more of Express Scripts' contracted pharmacy benefit networks.<sup>144</sup> In 2017, Express Scripts adjudicated over 877 million claims through those pharmacies.<sup>145</sup> Per Express Scripts' February 27, 2019, response to the Committee's information request, it contracts with approximately 5,000 pharmacies for the provision of pharmacy benefit services in New York State.

There is no fee for pharmacies to participate in Express Scripts' networks. However, before a pharmacy can participate in their network, they must go through a credentialing process, for which

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<sup>139</sup> 2018 Annual Report, CIGNA (Mar. 2019).

<sup>140</sup> Joe Cooper, *Cigna Closes \$67B Express Scripts Purchase*, HARTFORD BUSINESS (Dec. 20, 2018). See also Cigna Corp., Annual Report (10-k) (Feb. 28, 2019).

<sup>141</sup> 2018 Annual Report, CIGNA (Mar. 2019).

<sup>142</sup> *Drug Pricing in America: A Prescription for Change, Part III: Before the S. Committee on Finance*, 116th Cong. 7 (2019) (testimony of Steve Miller, M.D., Executive Vice President and Chief Clinical Officer, Cigna Corp.).

<sup>143</sup> Response from Eric W. Sitarchuk on behalf of Express Scripts Inc., to the New York State Senate Investigations and Government Operations Committee (Feb. 27, 2019).

<sup>144</sup> *Id.*

<sup>145</sup> *Id.*

Express Scripts charges a credentialing fee.<sup>146</sup> For every transaction a network pharmacy transmits to Express Scripts, it charges a service fee in accordance with its agreements.<sup>147</sup> The amount of the fee is negotiated by pharmacies, and varies pharmacy to pharmacy.

Express Scripts reimburses pharmacies for dispensing drugs to its clients in accordance with their network provider agreements. Reimbursement is the lesser of the following: “average wholesale price (AWP) of the product ingredient cost, less the contracted discount, plus the applicable contracted dispensing fee [...]; the pharmacy’s submitted ingredient cost plus applicable contracted dispensing fee; the pharmacy’s usual and customary retail price (U&C); MAC [...] plus the applicable contracted dispensing fee.”<sup>148</sup> Brand drug reimbursement is generally a percentage discount off an industry benchmark. Generic drug reimbursement is frequently determined by MAC, or a discount off of AWP.

Express Scripts uses multiple sources in evaluating MAC pricing, including at least one nationally recognized pricing service and pricing from at least one drug wholesale or manufacturer.<sup>149</sup> MAC price lists are reviewed at least every seven days.<sup>150</sup> It updates prescription drugs on the MAC list based on market conditions and product availability.

As required by Public Health Law § 280-a, Express Scripts permits network pharmacies to appeal reimbursements determined by MAC prices. MAC appeals are limited to 30 days following the initial claim or payment. Appeals within the scope of § 280-a are investigated and responded to within seven calendar days. According to its response, between 2014 and 2018, approximately

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<sup>146</sup> Response from Eric W. Sitarchuk on behalf of Express Scripts Inc., to the New York State Senate Investigations and Government Operations Committee (Feb. 27, 2019).

<sup>147</sup> *Id.*

<sup>148</sup> *Id.*

<sup>149</sup> *Id.*

<sup>150</sup> *Id.*



0.02% of claims in New York were appealed.<sup>151</sup> Although the Committee requested it, Express Scripts did not provide specific appeals data.

Express Scripts uses three distinct committees—the Therapeutic Assessment Committee, the Pharmacy and Therapeutics Committee, and the Value Assessment Committee—to determine which prescription medications are to be included on a formulary. The first two committees use only clinical considerations in determining approved medications, but the Value Assessment Committee utilizes both clinical and financial considerations.<sup>152</sup> While Express Scripts may create the formulary, a client is responsible for adopting, or choosing a formulary for its pharmacy benefits program. Clients also have the option to create their own formularies. Express Scripts clients may choose “open” or “closed” formularies.

In its response, Express Scripts informed the Committee that it does not have a policy or procedure with respect to price spreading for prescription drugs.<sup>153</sup> However, clients whose members fill prescriptions at pharmacies within its networks pay Express Scripts for those filled prescriptions; if the rate paid by a client exceeds the reimbursement rate contracted with the pharmacy, Express Scripts retains the positive margin—also commonly referred to in the industry as the spread.<sup>154</sup> Express Scripts also utilizes the pass-through model for contracts, in which the client pays the ingredient cost and dispensing fee paid by Express Scripts to the pharmacy for a particular claim.

Express Scripts, like other PBMs, negotiates rebates for prescription drugs dispensed to beneficiaries of its plan sponsor clients. Express Scripts claims that it returns on average 90

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<sup>151</sup> Response from Eric W. Sitarchuk on behalf of Express Scripts Inc., to the New York State Senate Investigations and Government Operations Committee (Feb. 27, 2019).

<sup>152</sup> *Id.*

<sup>153</sup> *Id.*

<sup>154</sup> *Id.*

percent of the rebates it negotiates with drug manufacturers to its clients.<sup>155</sup> According to a financial disclosure to the United States Securities and Exchange Commission, Express Scripts retains approximately \$400 million in rebates per year.<sup>156</sup>

In November of 2018, Express Scripts announced a new formulary that will favor lower-cost generics rather than expensive, brand name versions.<sup>157</sup> In an effort to normalize rebates in the marketplace, the new “National Preferred Flex Formulary,” was designed to encourage drug manufacturers to move away from paying rebates after a prescription is filled.<sup>158</sup> Express Scripts’ chief medical officer, Steve Miller, stated the new formulary may appeal to plan sponsors “seeking to reduce out-of-pocket costs and reliance on brand rebates.”<sup>159</sup> This allows clients to choose between formularies that include drugs with a high list price—and high rebate—or their new list with lower drug prices, but with little or no rebate.<sup>160</sup> However, others in the pharmaceutical industry remain hopeful that it will cause a pharmaceutical company to lower their brand name drug prices.<sup>161</sup>

Cigna, through Express Scripts, operates four automated mail order dispensing pharmacies and seven specialty home delivery pharmacies throughout the United States.<sup>162</sup> In its annual report to the Securities Exchange Commission, Cigna claims that through its mail order (home delivery) services, it was able to reach “a higher level of generic substitutions, therapeutic interventions and

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<sup>155</sup> *Lets Talk About Rebates*, EXPRESS SCRIPTS (May 15, 2018)..

<sup>156</sup> *Cigna Reiterates Support for Proposed Merger with Express Scripts*, CIGNA (Aug. 2018).

<sup>157</sup> Deena Beasley, *Express Scripts Offers New Formulary for Lower List-Price Drugs*, REUTERS (Nov. 13, 2018).

<sup>158</sup> *Id.*

<sup>159</sup> *Id.*

<sup>160</sup> Paulina Firozi, *The Health 202: Express Scripts Takes on Rebates in Plan it Says Will Lower Drug Prices*, THE WASHINGTON POST (Nov. 19, 2018).

<sup>161</sup> *Id.*

<sup>162</sup> Cigna Corp., Annual Report 9 (Form 10-K) (Feb. 28, 2019).

better adherence than is achieved through retail pharmacy networks.”<sup>163</sup> However, Cigna also stated that its home delivery generic fill rate is lower than the network generic fill rate because fewer generic substitutions are available among medications treating chronic conditions, which are commonly dispensed from home delivery pharmacies.<sup>164</sup> Its specialty pharmacy services predominantly treat complex diseases that generally require frequent dosing adjustments, intensive clinical monitoring and specific administration requirements.<sup>165</sup> For the three month period ending on March 31, 2019, Cigna had approximately \$11.78 million in revenue for its home delivery and specialty services.<sup>166</sup>

#### IV.C. OptumRx

OptumRx is a company within Optum, a subsidiary of UnitedHealth Group. In 2018, Optum and UnitedHealth Group earned a revenue of over \$101.3 billion and \$226 billion, respectively.<sup>167</sup> OptumRx provides pharmacy care services to over 65 million people in the United States through its network of more than 67,000 retail pharmacies, home delivery services, specialty and compounding pharmacies, and home infusion services.<sup>168</sup> OptumRx provides pharmacy care services to 250,000 patients each day.<sup>169</sup> In 2018, OptumRx managed \$91 billion in pharmaceutical

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<sup>163</sup> *Id.* at 10.

<sup>164</sup> *Id.*

<sup>165</sup> *Id.* at 58.

<sup>166</sup> Cigna Corp., Quarterly Report 42 (Form 10-Q) (May 2, 2019).

<sup>167</sup> *News Release* UNITEDHEALTH GROUP (Jan. 15, 2019).

<sup>168</sup> UnitedHealth Group Inc., Annual Report (Form 10-K) 7 (Feb. 12, 2019).

<sup>169</sup> *Drug Pricing in America: A Prescription for Change, Part III: Before the S. Committee on Finance*, 116th Cong. 1 (2019) (testimony of John. M. Prince, Chief Executive Officer, OptumRx).

spending, and fulfilled 1,343 million adjusted scripts.<sup>170</sup> OptumRx had a reported revenue of \$69 billion in 2018, a growth of 9.1 percent, or \$5.8 billion, compared with 2017.<sup>171</sup> OptumRx currently contracts with 4,998 pharmacies in New York, including more than 2,500 independent pharmacies.<sup>172</sup>

In its response to the Committee, OptumRx stated it reimburses pharmacies based on “competitive rates that balance the need to fairly compensate pharmacies with providing a cost-effective benefit for [its] plan customers and their members.” Reimbursement is generally set at the lesser of (1) provider’s customary charge, less any patient expenses; or (2) the fee schedule amount, less any patient expenses.<sup>173</sup>

Network pharmacies are assessed a credentialing fee and a per transaction administration fee.<sup>174</sup> For chain pharmacies and pharmacies that participate in PSAOs, the credentialing fee is waived. OptumRx retains both the administrative and credentialing fees, per contractual client agreements.<sup>175</sup>

OptumRx determines MAC pricing based on a review of (i) pricing information from a nationally recognized pricing service; (ii) at least one national drug wholesaler and/or manufacturer; and (iii) publicly available results of CMS’ survey of retail prices (NADAC).<sup>176</sup> OptumRx reviews MAC prices at least every seven days, and updates its lists as needed.<sup>177</sup>

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<sup>170</sup> UnitedHealth Group Inc., Annual Report (Form 10-K) 7, 29 (Feb. 12, 2019).

<sup>171</sup> *News Release* UNITEDHEALTH GROUP (Jan. 15, 2019).

<sup>172</sup> Response from Natalie A. Pons, General Counsel, OptumRx to the New York State Senate Investigations and Government Operations Committee (Mar. 11, 2019).

<sup>173</sup> *OptumHealth Care Solutions, LLC Provider Operations Manual*, OPTUM 16 (Mar. 2019).

<sup>174</sup> Response from Natalie A. Pons, General Counsel, OptumRx to the New York State Senate Investigations and Government Operations Committee (Mar. 11, 2019).

<sup>175</sup> *Id.*

<sup>176</sup> *Id.*

<sup>177</sup> *Id.*

Since March of 2016, OptumRx has received approximately 673,688 MAC appeals from pharmacies participating in its networks; approximately 69,230 appeals, or 10.2 percent received a rate change, but 604,459 appeals were denied, or 89.8 percent.<sup>178</sup> In 2017 and 2018, OptumRx received 155,328 and 363,834 MAC appeal claims, respectively.<sup>179</sup> The total number of MAC appeal claims skyrocketed approximately 42.7% in 2018 from 2017.<sup>180</sup> Of the approximate 155,328 appeals, OptumRx reviewed in 2017, it granted 6,799, or 4.4% rate changes, but denied 148,529, or 95.6 percent.<sup>181</sup> In 2018, OptumRx approved a rate change in 53,885, or 14.8 percent of its claims, denying a total of 309,949, or 85.2 percent.<sup>182</sup>

Like most PBMs, clients of OptumRx retain the authority to design and administer their own plan, including the contents of the plan's formulary. OptumRx also offers standard formularies that are derived from clinical input driven by an independent Pharmacy & Therapeutic Committee (P&T).<sup>183</sup> OptumRx's P&T Committee is comprised of independent practicing physicians and pharmacists who use clinical and financial data to evaluate which drugs should be included on a formulary.<sup>184</sup> Clients may choose to formulate their own or adopt one of the standard formularies for their plan design.<sup>185</sup>

OptumRx offers clients the option to choose between different pricing models for its pharmacy benefit services, including the spread pricing model and the pass-through model. The impact spread pricing has on rising drug costs is also impacting beneficiaries whose plan sponsors contract

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<sup>178</sup> Response from Natalie A. Pons, General Counsel, OptumRx to the New York State Senate Investigations and Government Operations Committee (Mar. 11, 2019).

<sup>179</sup> *Id.*

<sup>180</sup> *Id.*

<sup>181</sup> *Id.*

<sup>182</sup> *Id.*

<sup>183</sup> *OptumRx National Pharmacy and Therapeutics Committee*, OPTUMRX (2018).

<sup>184</sup> *Id.*

<sup>185</sup> Response from Natalie A. Pons, General Counsel, OptumRx to the New York State Senate Investigations and Government Operations Committee (Mar. 11, 2019).

with OptumRx and UnitedHealth for pharmacy benefit services. For example, a patient's copay for three-month supply of generic Crestor cost \$83.94 to fill at a local Walgreens using UnitedHealth insurance, whereas the same generic medication only cost \$45.89 for a three-month supply from Blink Health, a pharmacy services startup.<sup>186</sup>

Similar to other PBMs, OptumRx negotiates discounts and rebates from drug manufacturers. OptumRx asserts its clients receive approximately 98 percent of the value of rebates and discounts negotiated from drug manufacturers.<sup>187</sup> OptumRx stated that, in an attempt to mitigate the impact of list price increases, it also negotiates price protection guarantees in its agreements with drug manufacturers, which requires manufacturers to pay penalties in the form of additional discounts when they increase a drug's list price beyond an established threshold. Further, in 2018, OptumRx implemented a point-of-sale discount for fully insured group customers; through this program, consumers receive the discount benefit at the pharmacy counter.<sup>188</sup> In March of 2019, OptumRx announced it will extend the discount benefit to all new employer-sponsored plans beginning in January of 2020.<sup>189</sup>

OptumRx also provides home delivery and specialty pharmacy services to its clients' members.<sup>190</sup> As of December of 2018, OptumRx operated four home delivery pharmacies and 70 specialty and infusion pharmacies throughout the United States.<sup>191</sup> Its specialty and infusion

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<sup>186</sup> Charles Ornstein and Katie Thomas, *Prescription Drugs May Cost More With Insurance Than Without It*, THE NEW YORK TIMES (Dec. 9, 2017).

<sup>187</sup> *Drug Pricing in America: A Prescription for Change, Part III: Before the S. Committee on Finance*, 116th Cong. 3 (2019) (testimony of John. M. Prince, Chief Executive Officer, OptumRx).

<sup>188</sup> *Id.*

<sup>189</sup> *Id.*

<sup>190</sup> UnitedHealth Group Inc., Annual Report (Form 10-K) 7 (Feb. 12, 2019).

<sup>191</sup> *Id.*

pharmacy services include the delivery of advanced medications for chronic or genetic diseases and disorders.<sup>192</sup> In 2018, OptumRx managed \$40 billion in specialty pharmaceutical spending.<sup>193</sup>

However, Ohio State Attorney General Dave Yost found that between 2015 and 2018 OptumRx failed to pass on discounts to Ohio's Bureau of Workers' Compensation, totaling \$15.8 million in pharmacy overcharges.<sup>194</sup> Attorney General Yost asserted that OptumRx failed to manage its clients MAC list to achieve promised discounts and wrongfully increased prices charged to the client.<sup>195</sup> This past March, Attorney General Yost filed a lawsuit against OptumRx seeking at least \$15 million in compensatory damages and \$15 million in punitive damages.<sup>196</sup> The suit alleges that OptumRx breached its contract with the Ohio Bureau of Workers' Compensation by failing to provide a guaranteed discount on generic drug pricing, misusing information for commercial purposes, and through use of fraudulent misrepresentations in the course of its efforts to secure the contract.<sup>197</sup>

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<sup>192</sup> *Id.*

<sup>193</sup> *Id.*

<sup>194</sup> Letter from Dave Yost, Ohio Attorney General, to Ellen Nelson, OptumRx Administrative Services, LLC (Feb. 11, 2019).

<sup>195</sup> *Id.*

<sup>196</sup> Nate Raymond, *Ohio Accuses UnitedHealth's OptumRx of Drug Overcharges in Lawsuit*, REUTERS (Mar. 18, 2019).

<sup>197</sup> Complaint, *Ohio Bureau of Workers' Compensation et al. v. OptumRx Administrative Services LLC*, No. 19CVS002263 (Ohio Com.Pl. filed Mar. 15, 2019).

## V. Spread Pricing as a Revenue Scheme for Pharmacy Benefit Managers

### V.A. Spread Pricing Model Overview

As previously mentioned, one of the key mechanisms by which PBMs generate revenue is through spread pricing. In a generic drug transaction, the buyer—a plan sponsor—has a contract with a PBM that specifies that the managed care organization will pay a discount to the average wholesale price (AWP) for a prescription medication claim.<sup>198</sup> The seller—a pharmacy—has a contract with a PBM that specifies that it will receive MAC plus a fee for dispensing the same prescription medication claim.<sup>199</sup> In the generic drug transaction, there are now two prices for the same prescription medication on either side of the transaction.<sup>200</sup> If there is a difference in the two prices, the gap constitutes the “spread.”

The rates for AWP and MAC are not products of a competitive market place. Rather, the AWP of a generic prescription drug is set by the drug manufacturer, which has an incentive to keep the drug cost artificially high, while the discount to the AWP for a transaction is set by the PBM.<sup>201</sup> MAC, as mentioned above, is a proprietary benchmark solely determined by the PBM.<sup>202</sup> Since AWP and MAC are not set by a prevailing market rate, PBMs have tremendous latitude to control and set the spread.<sup>203</sup>

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<sup>198</sup> 3 AXIS ADVISORS, ANALYSIS OF PBM SPREAD PRICING IN NEW YORK MEDICAID MANAGED CARE 8 (Jan. 17, 2019) [hereinafter 3 AXIS ADVISORS].

<sup>199</sup> Per investigative teams’ discussions and interviews with pharmacists operating in New York State.

<sup>200</sup> *Id.*

<sup>201</sup> 3 AXIS ADVISORS, *supra* note 198, at 8.

<sup>202</sup> *Id.*

<sup>203</sup> *Id.*



## V.B. Spread Pricing in State Medicaid Managed Care Programs

Throughout the United States, reports have shown PBMs using spread pricing to profit off state Medicaid programs. A recent report conducted by the Ohio State Auditor found that Ohio Medicaid managed care paid PBMs \$224.8 million due to the spread alone from April 1, 2017 to March 31, 2018.<sup>204</sup> The \$224.8 million in spread retained represents 8.9 percent of the total \$2.5 billion Ohio paid to each of the five Medicaid managed care plans.<sup>205</sup> PBMs retained \$208.4 million dollars (31.4 percent) of \$662.7 million spent on generic drugs, \$9.8 million (0.8 percent) of \$1.25 billion spent on brand name drugs, and \$6.6 million dollars (1.1 percent) of \$617.7 million spent on specialty drugs.<sup>206</sup> The audit determined the overall average spread was \$5.71 per prescription, however for generic drugs—which comprises more than 86 percent of all prescriptions—the spread was higher, at \$6.14 per prescription.<sup>207</sup> Of the five Medicaid managed care plans in Ohio, OptumRx contracts with one, and CVS Caremark contracts with the remaining four.<sup>208</sup> Of the approximate \$225 million paid in spread, CVS retained approximately \$196 million and OptumRx approximately retained \$29 million.<sup>209</sup>

In response to the Auditor’s findings, the Ohio Department of Medicaid sent letters to the state’s five managed care plans, directing them to terminate contracts with PBMs that use the

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<sup>204</sup> DAVE YOST, AUDITOR OF STATE OF OHIO, OHIO’S MEDICAID MANAGED CARE PHARMACY SERVICES 2 (Aug. 16, 2018).

<sup>205</sup> *Id.* at 24.

<sup>206</sup> *Id.* at 2.

<sup>207</sup> *Id.*

<sup>208</sup> *Id.* at 8.

<sup>209</sup> *Id.* at 2.

spread pricing model and negotiate new contracts utilizing the pass-through pricing model before January 1, 2019.<sup>210</sup>

In Kentucky, a report produced by the Kentucky Cabinet for Health and Family Services determined that in 2018, PBMs pocketed \$123.5 million from the state's Medicaid managed care organizations.<sup>211</sup> The spread per prescription averaged \$8.70 in 2018, a 43.3 percent increase from 2017, which averaged \$6.07 per prescription.<sup>212</sup> Of the five managed care organizations that contract with Kentucky's Department of Medicaid Services, four contract with CVS Caremark and one contracts with Express Scripts, for their pharmacy benefit services.<sup>213</sup>

In Indiana, Bloomberg determined that the State's four privately run Medicaid plans averaged more than \$13 per prescription in 2017, significantly more than any other State managed care plan reviewed.<sup>214</sup> Further, in 2017, Indiana's private Medicaid plans spent more than \$800 for a 30 day supply of Entecavir, a hepatitis B pill that cost pharmacies less than \$140 to purchase.<sup>215</sup> Indiana's Medicaid plans spent more than \$100 per prescription for generic versions of Nexium, a heartburn drug, which cost less than \$25 to purchase in late 2017.<sup>216</sup> Importantly, pharmacists in Indiana state they are receiving only a small amount of the prescription drug markup.<sup>217</sup>

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<sup>210</sup> Kaitlin Schroeder, *UPDATE: Pharmacy Middlemen Could Lose Billions in Ohio Medicaid Contracts*, DAYTON DAILY NEWS (Aug. 14, 2018). See also Catherine Candisky & Lucas Sullivan, *Ohio Ends Deals With Pharmacy Middlemen That Costs Million*, THE COLUMBUS DISPATCH (Aug. 14, 2018).

<sup>211</sup> MEDICAID PHARMACY PRICING OPENING THE BLACK BOX, KENTUCKY CABINET FOR HEALTH AND FAMILY SERVICES 5 (Feb. 19, 2019).

<sup>212</sup> Robert Langreth, *Drug Middlemen Took \$123.5 Million in Hidden Fees, State Claims*, BLOOMBERG (Feb. 21, 2019).

<sup>213</sup> MEDICAID PHARMACY PRICING OPENING THE BLACK BOX, KENTUCKY CABINET FOR HEALTH AND FAMILY SERVICES 3 (Feb. 19, 2019).

<sup>214</sup> *The Secret Drug Pricing System Middlemen Use to Rake in Millions*, *supra* note 36.

<sup>215</sup> *Id.*

<sup>216</sup> *Id.*

<sup>217</sup> *Id.*

Wapello County in Iowa now purchases its prescription drugs for its jails directly from a pharmacy after discovering that it was paying CVS Caremark more than \$4,500 a month, while CVS Caremark was only reimbursing the pharmacy approximately \$1,500.<sup>218</sup>

In Michigan, a report conducted by the Michigan Pharmacists Association concluded that over a two-year period, state Medicaid managed care was overcharged by at least \$64 million for prescription drug claims.<sup>219</sup> Furthermore, the report found that in the two-year period, the spread margin on oral solid generic prescription drugs increase from two percent of the managed care program's costs to more than 34 percent.<sup>220</sup> In early 2018, Michigan pharmacies were being reimbursed only five percent of the average \$10.64 costs involving in purchasing and dispensing prescription drugs.<sup>221</sup>

## V.C. Spread Pricing in New York State Medicaid Managed Care

In a recently commissioned report by the Pharmacists Society of the State of New York (PSSNY)<sup>222</sup> it is estimated that in 2017, New York Medicaid managed care spent nearly \$1.3

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<sup>218</sup> *Id.*

<sup>219</sup> Press Release, Michigan Pharmacists Association, New Report Highlights Role of Pharmacy Benefit Managers in Manipulating Drug Costs for Michigan Patients, Pharmacists and Taxpayers (Apr. 29, 2019).

<sup>220</sup> 3 Axis Advisors, Analysis of PBM Spread Pricing in Michigan Medicaid Managed Care 1 (Apr. 2019).

<sup>221</sup> Larry Wagenknecht, *Opinion: Transparency Drives Down Drug Costs*, THE DETROIT NEWS (May 22, 2019).

<sup>222</sup> *The study was based on connecting generic drug spending data reported by New York Medicaid managed care as part of CMS' State Utilization Database with pharmacy reimbursement data collected from a geographically diverse sample of 11 community pharmacies. The report also obtained reimbursement information on the NDC level and CMS' NADAC database. All three databases were used to study the difference between state cost, pharmacy reimbursements, and pharmacy cost on both an aggregated basis for all generic drugs, and an individual basis for selected generic drugs over the study time period. The study relied only on community pharmacy reimbursement data; Publishers did not have access to chain pharmacy reimbursement information.*

billion on generic drugs, which is more than any other state managed care program in the United States.<sup>223</sup>

To estimate the nature and extent of spread pricing in New York Medicaid managed care, the report analyzed nearly 170,000 generic oral solid prescriptions dispensed between January 1, 2016 and March 31, 2018.<sup>224</sup> The report publishers compared pharmacy unit revenue to publicly available datasets from the Centers for Medicare & Medicaid Services (CMS) that measure state drug costs, or State Utilization Data, and pharmacy acquisition cost, or National Average Drug Acquisition Costs (NADAC).

For generic solids included in its analysis, the report found that while the PBMs were increasing New York State's relative generic drug prices, they were simultaneously reducing pharmacy margins, resulting in a substantial increase in spread.<sup>225</sup>

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<sup>223</sup> 3 AXIS ADVISORS, *supra* note 198. \$6.7 billion combined for generic and brand name drugs. The study was commissioned and funded by the Pharmacists Society of the State of New York (PSSNY) for the purpose of evaluating the nature and extent of spread pricing within the New York Medicaid managed care program. *Id.*

<sup>224</sup> *Id.* Generic oral solids include, but are not limited to, tablets and capsules.

<sup>225</sup> *Id.* at 13.

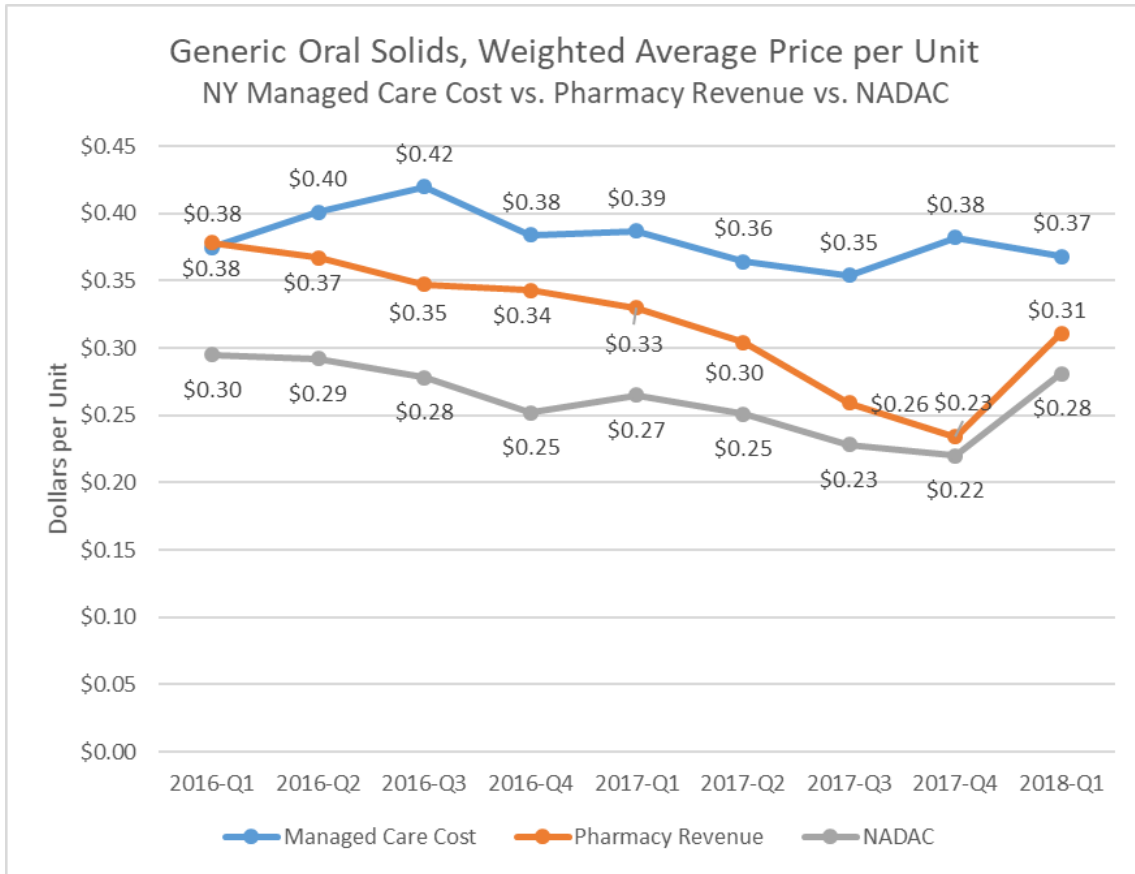


Figure 3<sup>226</sup>

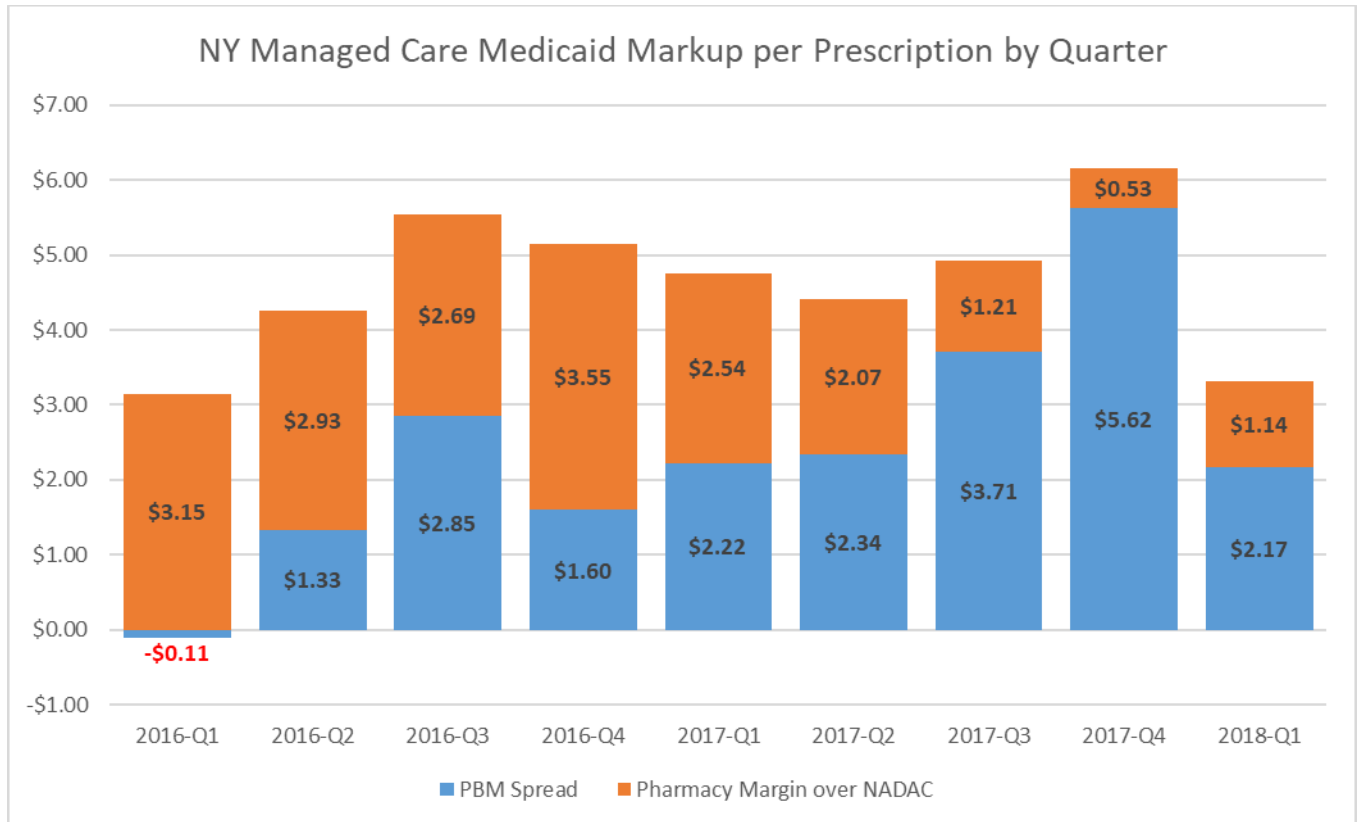
As illustrated above in *figure 3*, in Quarter 1 (Q1) of 2016, New York Medicaid managed care paid an average of \$0.375 per unit of generic drugs in the dataset, while pharmacies, on average, received \$0.378 per unit, virtually the same amount, resulting in no spread for that quarter.<sup>227</sup> In Q4 of 2017, the State’s cost per unit rose to \$0.382, however, the pharmacy revenue per unit was cut 38% to \$0.234 per unit. While it may appear to be insignificant per unit, the decrease in pharmacy reimbursement for Q4 2017 resulted in an 83% reduction when compared

<sup>226</sup> 3 AXIS ADVISORS, *supra* note 198 at 15.

<sup>227</sup> *Id.*

to Q1 in 2016.<sup>228</sup> Furthermore, in Q4 for 2017, the average PBM spread, *or profit*, was \$0.148 per unit, or \$5.62 per prescription.<sup>229</sup>

The chart below, *figure 4*, presents a different view of same results for the PBM spread on generic oral solids data.



*Figure 4*<sup>230</sup>

The height of the stacked bars in *figure 4* increased from just over \$3.00 per prescription in Q1 2016 to more than \$6.00 in Q4 2017, showing that PBMs doubled the “markup” charged to

<sup>228</sup> 3 AXIS ADVISORS, *supra* note 198.

<sup>229</sup> *Id.*

<sup>230</sup> *Id.* 13. *NY Managed Care Medical Markup Per Prescription – All Generic Oral Solids.*

New York State for its Medicaid managed pharmacy benefits.<sup>231</sup> Furthermore, *figure 4* demonstrates that while PBMs were increasing New York State's relative generic drug prices, they were simultaneously reducing pharmacy margin (orange), resulting in a substantial increase in the spread (blue), or their profit.<sup>232</sup> The PBMs did not contest the findings of the PSSNY report when the Committee gave them the opportunity to do so.

#### V.D. Case Study: Aripiprazole 5 mg Tablet

The report commissioned by PSSNY also included a spread pricing case study of generic Abilify, Aripiprazole. Abilify, and its generic Aripiprazole, are antipsychotic drugs commonly prescribed to treat schizophrenia, bipolar disorder, and Tourette syndrome.<sup>233</sup>

In 2012, a decade after receiving approval from the U.S. Food and Drug Administration, Abilify was generating over \$2.5 billion per year worldwide.<sup>234</sup> In 2014, New York Medicaid spent over \$206 million on all strengths of brand name Abilify.<sup>235</sup> Of the total \$206 million, New York spent \$46 million, before rebates, to purchase 1.78 million Abilify 5mg tablets, for an average cost of \$25.85 per tablet, which at the time was nearly identical to the wholesale average cost (WAC), of \$25.88 per tablet.<sup>236</sup> In April 2015, after Abilify's patent expired, four different manufacturers

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<sup>231</sup> 3 AXIS ADVISORS, *supra* note 198.

<sup>232</sup> *Id.*

<sup>233</sup> *Id.* at 9.

<sup>234</sup> *Id.*

<sup>235</sup> *Id.*

<sup>236</sup> *Id.*

brought its generic, Aripiprazole, to market.<sup>237</sup> In December of 2018, twelve different manufacturers produced Aripiprazole, driving down the acquisition cost to \$0.33 per tablet.<sup>238</sup>

However, market-based acquisition costs are not factored into a transaction for generic prescriptions because PBMs are allowed to set and capture pricing spreads through their contractual agreements with clients.<sup>239</sup> Despite the steep decline in the actual cost of Aripiprazole 5mg, its average wholesale price (AWP) has remained constant around \$32.50 per tablet. Therefore, the AWP for Aripiprazole 5mg is a staggering 98 times greater than its market-based acquisition cost.<sup>240</sup>

Using CMS's utilization data, *figure 5*, on the following page, shows the relationship between what New York managed care actually paid for Aripiprazole 5mg, and its acquisition cost, as determined by NADAC, for the period 2016 through 2018. For example, in Q1 of 2016, New York managed care paid an average of \$14.01 per Aripiprazole 5mg tablet, while a pharmacy's typical acquisition cost was only \$7.03 per tablet.<sup>241</sup> Importantly, the chart depicts that the price New York managed care pays for Aripiprazole 5mg appears to be arbitrary; the price does not change concurrently with changes in acquisition costs, but instead appears to "reset" in Q1 of 2017. Despite the price reductions beginning in Q1 2017, New York still paid \$3.74 per tablet in Q1 of 2018, which is more than 7.5 times Aripiprazole 5mg's acquisition cost.<sup>242</sup>

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<sup>237</sup> 3 AXIS ADVISORS, *supra* note 198 at 9.

<sup>238</sup> *Id.* The market-based acquisition cost is measured by NADAC.

<sup>239</sup> *Id.*

<sup>240</sup> *Id.*

<sup>241</sup> *Id.*

<sup>242</sup> *Id.*



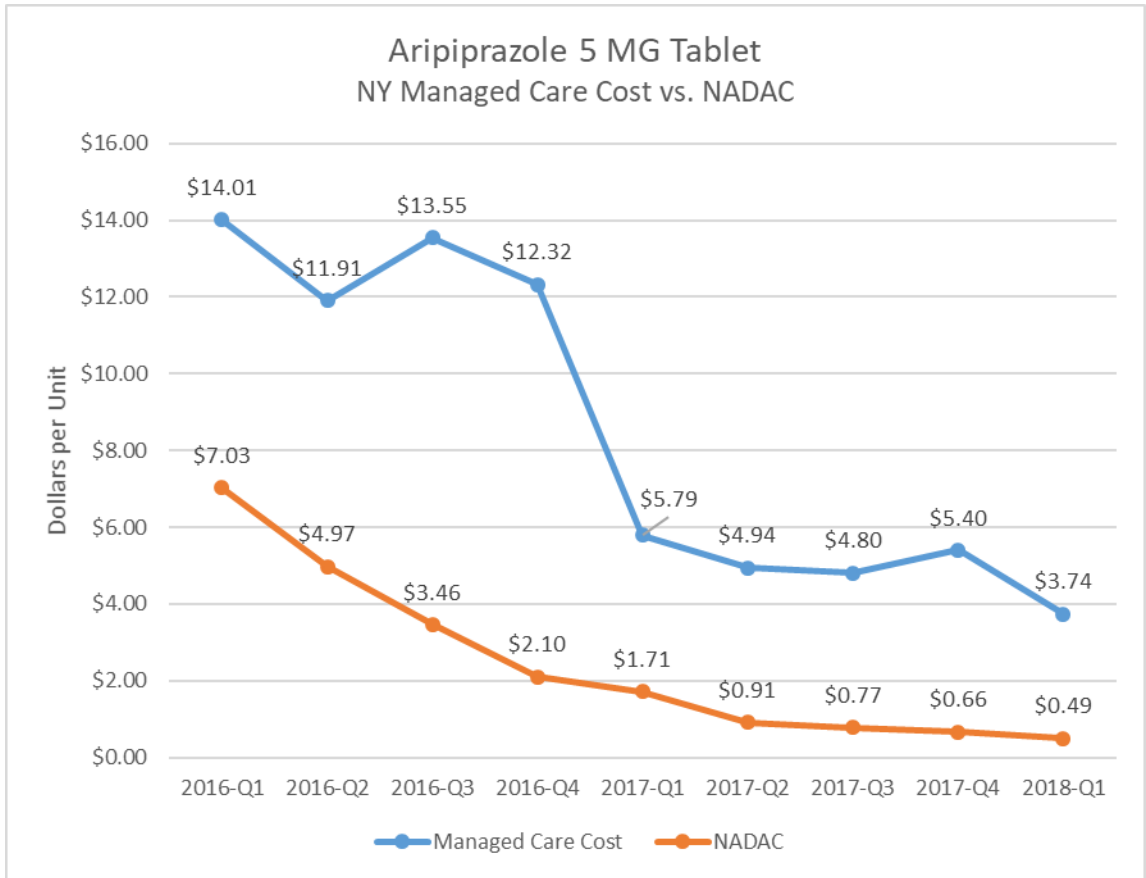


Figure 5<sup>243</sup>

While the chart demonstrates that New York managed care was overpaying for Aripiprazole 5mg, it does not depict how the spread was being distributed—whether PBMs were paying pharmacies above-market charges for Aripiprazole or if the PBMs were keeping the spread as profit. To determine where the spread was going, the report collected a sample of average pharmacy revenue for Aripiprazole 5mg between 2016 and 2018.

<sup>243</sup> 3 AXIS ADVISORS, *supra* note 198 at 10.

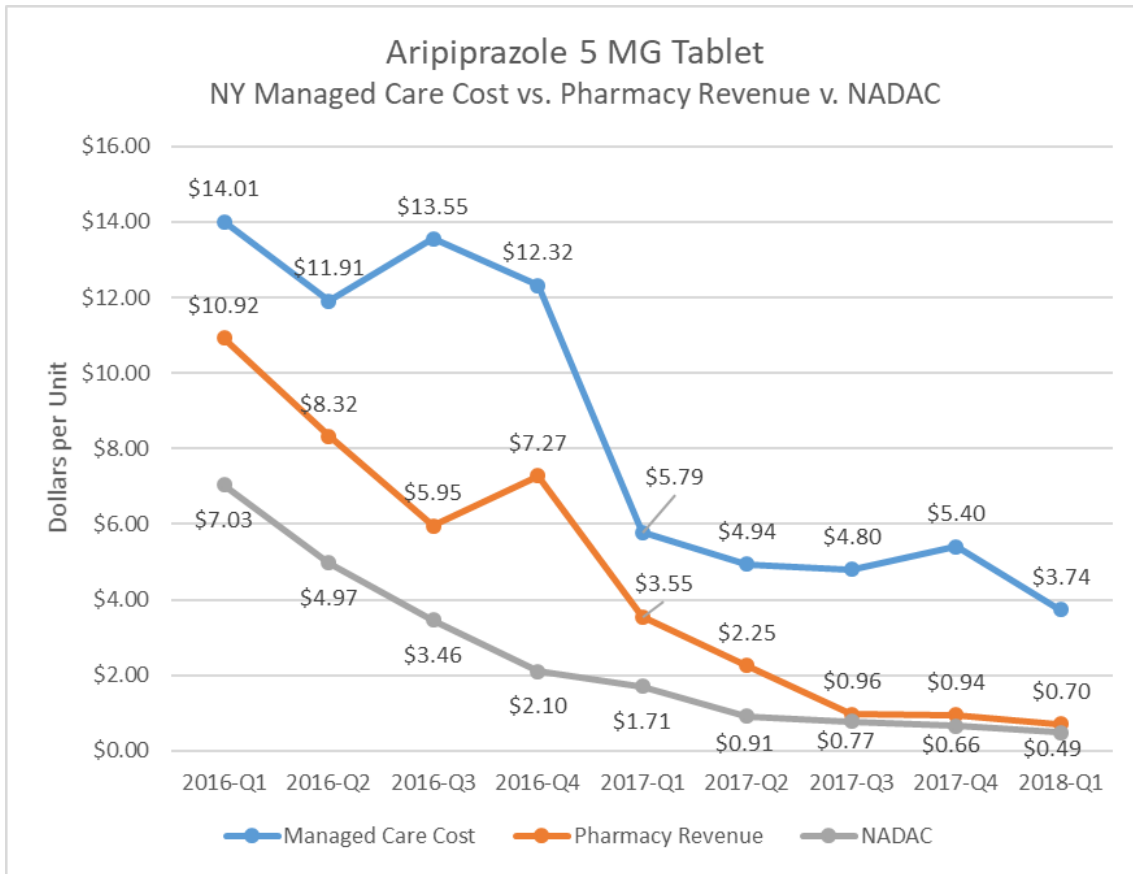


Figure 6<sup>244</sup>

As shown in *figure 6* above, in Q1 of 2016, sampled pharmacies received an average of \$10.92 per tablet, resulting in a gross margin of \$3.89 per tablet.<sup>245</sup> Based on the cost reported to New York, the managed care PBMs priced Aripiprazole 5mg at \$14.01 per tablet. After taking out the \$10.92 per tablet reimbursement to the pharmacy, the spread on Aripiprazole for that quarter was \$3.09 per tablet.<sup>246</sup>

<sup>244</sup> 3 AXIS ADVISORS, *supra* note 198 at 10.

<sup>245</sup> *Id.*

<sup>246</sup> *Id.*

Two years later, in Q1 of 2018, the PBM's spread is nearly identical at \$3.04 per tablet, but the sampled pharmacies average reimbursement was reduced 98% to \$0.21 per tablet.<sup>247</sup> While the trend from Q1 2016 to Q1 2018 shows that New York has recognized savings on Aripiprazole, the analysis shows that there more potential savings to be had. Further, it appears that any savings the State had realized was financed primarily through reduction in the sampled pharmacy's reimbursement, which is negotiated and controlled by the PBMs.<sup>248</sup>

## VI. Oversight of Pharmacy Benefit Managers in New York State

Official oversight of PBMs operating within New York State is minimal. Currently, PBMs in New York are treated as Independent Practice Associations (IPAs).<sup>249</sup> Unlike pharmacies, wholesalers, drug manufacturers, and health plans, PBMs are not licensed by New York State.<sup>250</sup> While a PBM's organizational documents are filed with, reviewed and approved by the Department of Health, and where appropriate, the Department of Financial Services, they are not regulated entities.<sup>251</sup> The New York State 2019-2020 Budget, however, includes several provisions that increase transparency and reform the practices of PBMs operating in New York.

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<sup>247</sup> 3 AXIS ADVISORS, *supra* note 198 at 10.

<sup>248</sup> *Id.*

<sup>249</sup> Nili S. Yolin, *New York (Again) Seeks to Regulate Pharmacy Benefit Managers*, NATIONAL LAW REVIEW (Mar. 15, 2019).

<sup>250</sup> *Id.*

<sup>251</sup> *Id.*

## VI.A. State Regulation and Oversight

To determine the extent of oversight of PBMs operating in New York State, the Committee issued information and document requests to the New York State Department of Health and the New York State Department of Civil Service. In these requests, the Committee sought information relating to the authority and oversight, or lack thereof, over PBMs who contract with pharmacies and plan sponsors in New York.

The Public Health Law of New York State does not specify a regulatory role for the New York State Department of Health in overseeing PBMs. In its response, the New York State Department of Health stated it does not regulate, license, or register PBMs operating within New York State.<sup>252</sup>

The Department of Health is responsible for reviewing and approving management contracts submitted by managed care plans that delegate management functions to PBMs in order to ensure such PBMs are complying with regulatory and statute requirements.<sup>253</sup>

PBMs are not under an obligation to provide the Department of Health with internal policies, procedures, or standard operating procedures regarding its practices within New York State.<sup>254</sup> In limited circumstances, such as when a PBM is undergoing the utilization review process to become a registered Utilization Review Agent, policy or procedure manuals may be requested to show that a PBM is in compliance with the requirements set forth in Public Health Law Article 49 or 42 CFR

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<sup>252</sup> Response from Diana Vance, Assistant Counsel, New York State Department of Health to the New York State Senate Committee on Investigations and Government Operations (Mar. 1, 2019).

<sup>253</sup> *Id.*

<sup>254</sup> *Id.*

§ 438.<sup>255</sup> The Department of Health does not exercise any additional authority or oversight over PBMs.<sup>256</sup>

Public Health Law § 280-a sets forth requirements that a PBM must adhere to when contracting with pharmacies or PSAOs. Public Health Law § 280-a requires PBMs to include specific provisions establishing a reasonable process to appeal, investigate and resolve disputes regarding multi-source generic drug pricing.<sup>257</sup> Further, Public Health Law § 280-a also prohibits PBMs from including “gag clauses” in contracts. Specifically, § 280-a prohibits PBMs from: (1) prohibiting or penalizing a pharmacist or pharmacy for disclosing to an individual purchasing a prescription medication information regarding the cost of the medication or the availability of any therapeutically equivalent alternative medications; and (2) charging or collecting from an individual a copayment that exceeds the total charges submitted by the pharmacy.<sup>258</sup>

The Department of Health stated in its response that because Public Health Law § 280-a governs contracts between PBMs and pharmacies, the statute is essentially self-enforcing. The Department of Health noted that although the Commissioner of Health retains general authority to enforce New York State’s Public Health Law, § 280-a merely requires PBMs to follow a specific process, as outlined in contractual requirements.<sup>259</sup> The Department further stated that it has not received any evidence that PBMs have failed to follow the processes outlined in Public Health Law § 280-a.<sup>260</sup>

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<sup>255</sup> *Id.*

<sup>256</sup> *Id.*

<sup>257</sup> *Id.* See also N.Y. PUB. HEALTH LAW § 280-a (2019).

<sup>258</sup> Response from Diana Vance, Assistant Counsel, New York State Department of Health to the New York State Senate Committee on Investigations and Government Operations (Mar. 15, 2019). See also N.Y. PUB. HEALTH LAW § 280-a (2019). If an individual pays a copayment, the pharmacy is entitled to retain the adjudicated costs. N.Y. PUB. HEALTH LAW § 280-a (4) (2019).

<sup>259</sup> Response from Diana Vance, Assistant Counsel, New York State Department of Health to the New York State Senate Committee on Investigations and Government Operations (Mar. 15, 2019).

<sup>260</sup> *Id.*

The Department of Health did state, however, that it has received complaints from pharmacies regarding unsatisfactory appeals of their MAC reimbursements for specific drugs.<sup>261</sup> When the Department of Health receives such complaints, it contacts the PBM.<sup>262</sup> In some instances, PBMs were responsive to such inquiries, and adjusted the MAC reimbursements in favor of the pharmacies; in most inquiries, however, PBMs stated to the Department of Health that the MAC prices were valid, and made no adjustments.<sup>263</sup>

The Department of Health reiterated in its final response to the Committee that it continues to support initiatives that would establish more accountability and transparency from PBMs.<sup>264</sup>

According to the New York State Department of Civil Service's response to the Committee, they do not have any authority or oversight over PBMs operating within New York State.<sup>265</sup>

## VI.B. 2019-2020 Budget

The 2019-2020 New York State Budget includes significant strides towards reforming the practices of PBMs by eliminating spread pricing for Medicaid managed care in New York as well as increasing transparency in the services they provide.

The Budget requires that Medicaid managed care providers that contract with PBMs for pharmacy benefit services base their contractual agreements on a pass-through pricing model,

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<sup>261</sup> *Id.*

<sup>262</sup> *Id.*

<sup>263</sup> *Id.*

<sup>264</sup> *Id.*

<sup>265</sup> Response from J. Marc Hannibal, Acting Counsel, New York State Department of Civil Service to the New York State Senate Committee on Investigations and Government Operations (Mar. 1, 2019).

rather than on a spread pricing model.<sup>266</sup> In addition to the elimination of spread pricing, the 2019-2020 Budget precisely delineates what a PBM can charge New York State managed care organizations. Specifically, the Budget: (1) limits payment to a PBM for pharmacy benefit services to “the actual ingredient costs, dispensing fees paid to pharmacies, and an administrative fee that covers the cost of providing the services,” (2) requires PBMs to identify and disclose to the Department of Health and the health care plan “all sources and amounts of income, payments and financial benefits...related to its provision of and administration of services[,]” (3) requires PBMs to identify all ingredient costs and dispensing fees paid to any pharmacy in connection with New York State managed care, and (4) requires PBMs to make their payment model for administrative fees available to the Department of Health and the health care plan.<sup>267</sup> Furthermore, the Budget requires that managed care providers also report to the Department of Health “all sources and amounts of income, payments, and financial benefits related to the provision of pharmacy benefits,” as well as any “administrative fees paid to cover the cost of providing” such pharmacy services.<sup>268</sup>

Under the 2019-2020 Budget, PBMs and managed care organizations are required to revise and resubmit their contracts to reflect the new restrictions in Section 4406-c of the Public Health Law and Section 346-j of the Social Services Law.<sup>269</sup>

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<sup>266</sup> S1507C, 2019-2020 Sess., (N.Y. 2019).

<sup>267</sup> *Id.*

<sup>268</sup> *Id.*

<sup>269</sup> *Id.*

## VII. Other Investigatory Findings

### VII.A. Buyout Letters and a Pattern of Impropriety

During its investigation, the Committee met and spoke with numerous independent pharmacists from across New York State. PSSNY, on behalf of its members, informed the Committee that beginning in 2017, CVS Caremark had significantly decreased its reimbursement rates for generic prescription medications for pharmacies across New York. Pharmacies with reduced rates were primarily community and independent pharmacies, many of which have expressed concerns that the reduced reimbursement rates have caused severe financial hardship, especially when reimbursement rates do not even cover the cost of dispensing the medication. PSSNY also shared with the Committee copies of buyout letters and emails that many of these pharmacies received from CVS Caremark only a few months after the reduction in reimbursements.

Shrinking reimbursement rates have resulted in dwindling profit margins, creating the difficult option to sell their pharmacy *directly* to CVS Caremark's parent corporation, CVS Health. While the Committee was unable to prove a direct purposeful relationship between CVS Caremark lowering its reimbursement rate and the buyout letters, there appears to be a pattern of impropriety on behalf of CVS Caremark. Importantly, the same pattern of impropriety seen in New York was also apparent in Arkansas.<sup>270</sup>

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<sup>270</sup> Andy Davis, Arkansas *Legislator: Got Governor's Rx Vow*, ARKANSAS DEMOCRAT GAZETTE (Feb. 22, 2018).



## VII.B. Good Faith Discussions with Pharmacy Benefit Managers

As part of the Committee's investigation, the investigative team engaged in regular, voluntary discussions with representatives from the three major PBMs as well as a drug manufacturing trade group. The purpose of these meetings was to discuss the role both groups have in rising prescription costs for New York consumers as well as potential, voluntary actions to help alleviate the burden. Increased transparency, a more efficient and equitable appeal processes for pharmacies, financial disclosures, and even potential monetary reimbursements to the State were discussed. Unfortunately, despite the positive tenor of these meetings, the PBMs abruptly and, without notice, pulled out of the discussions in the weeks leading up to the 2019-2020 Budget's adoption. Based on information the Committee subsequently received, it appears other government stakeholders interfered with the Committee's efforts upon discovering the conversations were taking place.

## VIII. Conclusion and Recommendations

It is the Committee's opinion that the lack of transparency and oversight of PBMs has created an environment in which PBMs are able to engage in self-dealing to the detriment of consumers across New York State. Throughout the investigation, the Committee identified several practices of PBMs that require further evaluation and demand enhanced transparency. Specifically, the Committee concludes that New York State must take immediate action to regulate the practices of spread pricing, MAC appeals, mail order operations, and reimbursements. Most significantly,

because of the unknown extent of spread pricing in New York Medicaid managed care, the Committee urges the New York State Comptroller to perform a full audit of all dollars paid to PBMs via spread pricing.

Thus, this Committee strongly urges the New York State Comptroller to conduct an audit and evaluation of PBM practices and urges the State Legislature to enact legislation that regulates PBMs and mandates transparency for all health plan sponsors in New York. Such legislation should: (1) regulate the practices of spread pricing in *all* pharmacy benefit contracts, (2) enhance the transparency of MAC appeals, (3) require the licensing and registration of PBMs to enhance accountability and oversight by instituting a fiduciary duty for their clients, (4) prohibit PBMs from mandating that patients use specialty and mail order pharmacies, (5) providing for the adequate and transparent reimbursements for pharmacies, and (6) require PBMs to pass-through all discounts or rebates received from drug manufacturers to its Medicaid managed care clients.

### VIII.A. Audit of New York Medicaid Managed Care Pharmacy Program

It is the opinion of the Committee that PBMs are significantly overcharging New York Medicaid managed care organizations for providing pharmacy benefit services through the use of spread pricing. As previously discussed, spread pricing is a pricing model PBMs use in their pharmacy benefit services contracts. The difference in the amount charged to a plan sponsor and the amount reimbursed to the pharmacy is the spread, or the PBM profit.

In an attempt to conduct an objective evaluation, the Committee sought prescription drug pricing information from the three PBMs discussed in this report, CVS Caremark, Express Scripts,

and OptumRx. The Committee gave the PBMs an opportunity to dispute the findings reported by Bloomberg and PSSNY, however, the PBMs declined to share specific prescription drug pricing data when requested. Thus, while the Committee cannot provide an exact estimate of how much PBMs profited off New York Medicaid through spread pricing, the Committee is confident that New York is gravely overpaying PBMs for prescription drug claims.

Recent studies and audits performed in other states are illuminative, and show how much other state Medicaid programs are paying PBMs solely in spread pricing fees. In Ohio, State Medicaid managed care was charged \$224.8 million *solely in spread pricing fees* to PBMs in less than one year.<sup>271</sup> In Kentucky, PBMs reaped \$123.5 million in profit from the State's Medicaid managed care organizations through spread pricing fees.<sup>272</sup> In Michigan, state Medicaid plans paid PBMs more than \$64 million in spread pricing fees from 2016 to 2018.<sup>273</sup> In 2016, PBMs nationwide received \$1.3 billion of the \$4.2 billion private Medicaid insurers spent on 90 of the most common generic drugs used by Medicaid managed care plans.<sup>274</sup>

Therefore, it is the opinion of the Committee that an audit of New York Medicaid managed care is crucial to determine the financial impact of spread pricing on New York taxpayers. It is crucial to conduct a full analysis of *all* prescription drug spending in New York Medicaid managed care. New York State has 19 Medicaid managed care plans. Of the 19 plans, CVS Caremark contracts with 9, Express Scripts contracts with 3, and OptumRx contracts with 2, for its pharmacy benefit services.

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<sup>271</sup> *See supra* V.B.

<sup>272</sup> *Id.*

<sup>273</sup> *Id.*

<sup>274</sup> *The Secret Drug Pricing System Middlemen Use to Rake in Millions*, *supra* note 36. The \$1.3 billion includes reimbursements to pharmacies for dispensing the prescription drugs.

While the 2019-2020 Budget eliminates spread pricing for Medicaid managed care organizations in the future, the total profits from spread pricing is unknown. Moreover, PBMs are still able to utilize the spread pricing model with other governmental and non-governmental health plan sponsors. Understanding the impact spread pricing has on Medicaid managed care is crucial to exposing the dubious practices of PBMs for all of those involved in New York's healthcare industry. While the Budget anticipates that eliminating spread pricing for Medicaid will save New York taxpayers more than \$43 million, according to the study conducted by PSSNY, New York was overcharged on Medicaid managed care prescriptions by nearly \$300 million.<sup>275</sup> Importantly, when discussing this claim with the producers of the report, the investigative team was informed the \$300 million in spread pricing fees was likely a conservative estimation given the data access limitations of the study.

The Committee supports the Office of the State Comptroller's decision to audit the Department of Health to examine whether New York Medicaid managed care organizations are obtaining pharmacy services in an economical and transparent manner.<sup>276</sup> While the audit is still in its scoping phase, the Committee urges the Comptroller to evaluate *all* Medicaid managed care plans to accurately determine how much PBMs have been profiting off of New York taxpayers.

The Committee further urges the Office of the State Comptroller and the Department of Health to perform an analysis to identify the costs and benefits of mandating a pass-through model in Medicaid managed care contracts for its pharmacy services. This analysis could offer crucial conclusions for all those who contract with PBMs for their pharmacy benefit services, not just Medicaid managed care.

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<sup>275</sup> David Reich-Hale, *Change in Medicaid Drug Pricing Could Save Taxpayers \$43M, lawmakers say*, NEWSDAY (Apr. 2, 2019).

<sup>276</sup> Letter from Paul Alois, Audit Manager, to Commissioner Howard A. Zucker, Department of Health (Feb. 12, 2019) (on file with author).

Evaluating both the spread pricing and pass-through models in Medicaid managed care is imperative for New York’s healthcare industry. Those plan sponsors who contract with PBMs for pharmacy benefit services other than Medicaid—including unions, government purchases, and self-insured employers—may not have as much negotiating power as larger insurance companies and managed care organizations. Moreover, they often do not have the capability or resources to conduct evaluations to determine the best interests for their pharmacy benefit services. Therefore, evaluating the pricing models is crucial for those plan sponsors to understand the uncertainties that lie in contracting with PBMs for pharmacy benefit services. In the interim, the Department of Health should work with plan sponsors in New York to ensure that pricing models reflect reasonable costs associated with the services PBMs provide.

Lastly, the Committee strongly urges the Office of the State Comptroller or the Department of Health to conduct, or if needed engage an independent third party to conduct an analysis of the impact of moving Medicaid managed care pharmacy services to a fee-for-service model,<sup>277</sup> similar to the change West Virginia implemented in 2017, which saved the state \$30 million in fees in one year.<sup>278</sup>

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<sup>277</sup> S5923, introduced by Senator Rivera, would allow New York’s Preferred Drug Plan, which currently administers the drug benefit for fee-for-service Medicaid, to negotiate drug prices and administer the drug benefit for all New York Medicaid managed care recipients. This would effectively eliminate the need for PBMs in the Medicaid system, moving the entire Medicaid pharmacy benefit to a fee-for-service model. S5923, 2019-2020 Sen. (Ny. 2019). Due to unknown fiscal implications, the Committee recommends the impacts of transitioning to a fee-for-service scheme should be closely analyzed.

<sup>278</sup> Marty Schladen & Lucas Sullivan, *West Virginia a Possible Model For Cheaper Prescription Drug Prices*, COLUMBUS DISPATCH (Dec. 10, 2018).

## VIII.B. Increased Transparency in Prescription Drug Pricing

Currently, because PBMs are the sole common counterparty with health plans, pharmacies, and drug manufacturers, the economic transactions among the parties remain unknown to anyone other than the PBMs.<sup>279</sup> The lack of transparency allows for PBMs to engage in self-dealing practices, such as spread pricing, to the financial detriment of their clients. The status quo allows PBMs to hide what they pay for prescriptions from their own clients. It is the opinion of the Committee that the lack of transparency and lack of regulation of PBMs operating in New York must be addressed.

Plan sponsors, including Medicaid managed care organizations and private employers, that contract with PBMs should insist on provisions of pricing transparency, reporting, and audit rights in their pharmacy service contracts. Further, contracting parties should insist on a full disclosure of cash flows to and through the PBM that is administering the pharmacy benefit services of their health plan. Preserving the right to audit and inspect pricing is crucial to keeping PBMs accountable to their health plan clients. Additionally, PBMs should be required to disclose any and all price discounts or rebates they receive from drug manufacturers as well as any agreements made between the parties for those discounts. S2087, introduced by Senator Rivera, directly addresses these concerns. S2087 includes provisions requiring PBMs to account for any funds received by the PBM relating to its provision of pharmacy benefit services.<sup>280</sup> Moreover, S2087 allows for health plans to have access to all financial and utilization information from the PBM

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<sup>279</sup> Garrett & Garis, *supra* note 26, at 61.

<sup>280</sup> S2708, 2019-2020 Sen. (Ny. 2019).

relating to the services it provides for the health plan.<sup>281</sup> The Committee urges the Senate to pass S2087.

PBMs may claim that legislating increased transparency legislation will harm prescription drug prices by reducing the discounts that the PBMs are able to negotiate on behalf of health plans. However, economists generally agree that transparent pricing will ensure the survival of the best firms and will result in lower prices as the firms compete with each other for market share.<sup>282</sup>

S1705, introduced by Senator Sepulveda, provides for enhanced transparency of PBMs to the entities that contract with them. Also referred to as the “Pharmacy Benefit Manager Transparency Act,” S1705 requires a PBM under contract with a covered entity submit to the covered entity financial data related to its pharmacy benefit services. Specifically, the bill requires a PBM to submit for the previous year: (1) the wholesale acquisition cost for each drug on its formulary and the total number of prescriptions that were dispensed, (2) the amount of rebates, discounts, and prices concessions the PBM received for each drug on its formulary and the amount that were passed through to the covered entity, (3) the amount of any fee received from a manufacturer, (4) the nature, type, and amount of all other payments that the PBM received from a manufacturer in connection with the services it provides, and (5) the amount of any reimbursements the PBM pays to pharmacies as well as the negotiated price covered entities pay the PBM for each drug on its formulary.

S1705 currently remains in the Senate Insurance Committee. Given the many positive impacts of S1705, the Committee urges its passage.

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<sup>281</sup> *Id.*

<sup>282</sup> Garrett & Garis, *supra* note 26, at 61.

### VIII.C. Increased Transparency of Appeals in Public Health Law § 280-a

As discussed *infra*, Public Health Law § 280-a sets forth requirements that a PBM must follow in adjudicating maximum allowable cost or MAC appeals. Current law mandates that if a PBM determines an appeal to be valid, “the maximum allowable cost for the drug shall be adjusted for the appealing pharmacy as of the date of the original claim for payment.”<sup>283</sup> However, if an appeal is denied, § 280-a only mandates that a PBM identify “a therapeutically equivalent drug [...] that is available for purchase by pharmacies in this state from wholesalers [...] at a price which is equal to or less than the maximum allowable cost for that drug as determined by the pharmacy benefit manager.”<sup>284</sup> There is no requirement in law that a PBM provide any justification or explanation for its denial of a MAC appeal. While PBMs may internally decide to give such an explanation, most of these justifications are blanket responses that give little or no insight regarding their denial. It is the opinion of the Committee that § 280-a be amended to allow for a more transparent appeal processes for pharmacies. This is critical given the persistent decrease in reimbursement rates for pharmacies in recent years.

### VIII.D. Licensing and Registration of Pharmacy Benefit Managers

It is the opinion of the Committee that in order to hinder the anti-competitive practices of PBMs, it is crucial to license and register PBMs operating in New York State. S2087, introduced

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<sup>283</sup> N.Y. PUB. HEALTH LAW § 280-a (2019).

<sup>284</sup> *Id.*



by Senator Rivera and currently in the Senate Committee on Health, would license PBMs operating in New York State and specify their duties and obligations as service providers to their clients. S2087 will amend Public Health Law § 280 to provide that PBMs have a fiduciary relationship with, and a duty to their clients to “perform pharmacy benefit management with care, skill, prudence, diligence, and professionalism.” Further, it requires that all funds received by PBMs belong to the client other than any administrative fee or payment expressly delineated in the contract.

Importantly, S2087 requires that PBMs be licensed by the Department of Health, and gives the Commissioner of the Department of Health the authority to revoke, or refuse to issue or renew, a PBM’s license if, in their judgment, the PBM is not trustworthy or competent to act as a PBM in New York State. Again, the Committee strongly urges the Senate to pass S2087.

#### VIII.E. Regulation of Mail Order Pharmacies

As previously discussed, PBMs also own—and profit from—mail order pharmacies that operate as automated dispensing facilities. While some may appreciate the convenience of mail order prescriptions, the closed-environment of a PBM mail order pharmacy often does not deliver the value-added benefits of a traditional pharmacy. For many patients, especially those with complex medical conditions, the safe and secure delivery of prescriptions is crucial to their care. Those with specific treatment regimens can be disrupted if prescriptions are not promptly received. Importantly, access to local pharmacies for medications can be essential, especially for those that require the in-person counseling of a pharmacist. Furthermore, vertically integrated mail order

pharmacies can undermine patient choice by forcing patients to use their preferred distributors or drug manufacturers. It is the opinion of the Committee that the decision to receive pharmacy benefits from a retail pharmacy rather than a mail order pharmacy should be made between the patient and their prescriber.

A347, introduced by Assemblywoman Joyner, speaks directly to this crucial and personal decision-making process. A347 expands the Insurance Law of New York §§ 3216, 3321 and 4303 to ensure that a prescriber, considering all factors relevant to the patient, can determine when mail order is or is not appropriate.<sup>285</sup> Furthermore, A347 ensures cost security by requiring the retail pharmacy to agree to the same reimbursement amount before finalizing the prescribers' determination.<sup>286</sup>

S4463, introduced by Senator Breslin, is also crucial in limiting PBM's operations of mail order pharmacies, while enhancing patient's access to vital medications and care.<sup>287</sup> It is the opinion of the Committee that consumers should have the freedom to choose where and how to receive their covered medications. While legislation in 2012 attempted to guarantee this important choice, consumers in New York continue to be directed away from their local pharmacies, and are forced to receive their medications from out-of-state specialty pharmacies. Thus, ensuring patient choice in obtaining their covered medications is crucial.

Importantly, S4463 strengthens current Insurance Law to ensure that patients have the option to access every covered medication from a local network participating pharmacy or a specialty

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<sup>285</sup> A347, 2019-2020 Assemb. (Ny. 2019).

<sup>286</sup> *Id.*

<sup>287</sup> S4463, 2019-2020 Sen. (Ny. 2019).

pharmacy.<sup>288</sup> Furthermore, it prohibits a health plan from requiring a higher co-payment for a prescription dispensed by a network retail pharmacy than a specialty network pharmacy.<sup>289</sup>

The Assembly version of this bill, A3043, introduced by Assemblywoman Joyner, passed the Assembly on May 6, 2019.<sup>290</sup> The Committee urges the Senate to pass this bill.

### VIII.F. Adequate and Transparent Reimbursement

As prescription drug costs rise, consumers are paying more at the counter and pharmacies are being reimbursed at lower rates, with the majority of the spread being reaped as profit by PBMs. For pharmacies across the United States, reimbursements are dwindling, making it harder for pharmacies to turn a profit. While a pharmacy's revenue includes over-the-counter products, vitamins, cosmetics, groceries, and other merchandise, a typical independent pharmacy generates more than 90 percent of its revenues from prescriptions.<sup>291</sup>

Local, independent community pharmacies, especially those in rural areas, are steadily closing. In 2011, there were 23,106 independent pharmacies across the United States; by 2017, only 21,909 independent pharmacies remained.<sup>292</sup> Independent community pharmacies care for underserved populations; 75 percent of independent pharmacies are situated in communities with less than 50,000 people.<sup>293</sup> Approximately 1,800 rural independent pharmacies in the United States serve

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<sup>288</sup> *Id.*

<sup>289</sup> *Id.*

<sup>290</sup> A3043, 2019-2020 Assemb. (Ny. 2019).

<sup>291</sup> Adam J. Fein, Ph.D., *New Data: Pharmacy Owners' Profits Fall As Industry Competition Rises*, Drug Channels (Jan. 9, 2018).

<sup>292</sup> Karen Appold, *Independent Pharmacies: Not Dead Yet*, 163 DRUG TOPICS 1 (Jan. 12, 2019).

<sup>293</sup> Press Release, NCPA Releases 2018 Digest, NATIONAL COMMUNITY PHARMACIES ASSOCIATION (Oct. 8, 2018).

as the only pharmacy provider in their community.<sup>294</sup> For many patients especially in rural areas, independent community pharmacies are a critical—and often the only—source of medications and clinical services. In rural communities, pharmacies assist patients with numerous services such as medication counseling, blood pressure and glucose monitoring, immunizations, consultation, and over-the-counter medications.<sup>295</sup> Closures are leaving vulnerable populations with limited ability to obtain medication and other crucial health services. From 2003 to 2018, 1,238 independently owned rural pharmacies around the country closed their doors.<sup>296</sup> During that period, 302 rural communities lost all but one local pharmacy.<sup>297</sup>

Independent pharmacies are especially susceptible to closure because they are faced with particular financial challenges—including low reimbursements—because of their limited negotiating power and a greater reliance on prescription drug sales as a predominant source of revenue.<sup>298</sup> Below-cost reimbursements significantly contribute to declines in an independent pharmacy’s revenue. According to the Independent Pharmacy Association, independent pharmacies are often reimbursed less than what they paid for drugs.<sup>299</sup> For a Fentanyl Patch 100, CVS Caremark reimbursed its own CVS pharmacies \$400.65, while independent pharmacies were reimbursed \$75.74.<sup>300</sup> Similarly, for Amoxicillin, CVS pharmacies were reimbursed \$39.92, while

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<sup>294</sup> *Independent Pharmacy Today*, NATIONAL COMMUNITY PHARMACIES ASSOCIATION.

<sup>295</sup> Abiodun Salako, Fred Ullrich, & Keith J. Mueller, *Rural Policy Brief: Update: Independently Owned Pharmacy Closures in Rural America, 2003-2018*, RURAL POLICY RESEARCH INSTITUTE 1 (July 2018).

<sup>296</sup> *Id.*

<sup>297</sup> Paulina Firozi, *The Health 202: Here’s Why Rural Independent Pharmacies are Closing Their Doors*, THE WASHINGTON POST (Aug. 23, 2018).

<sup>298</sup> *Id.*

<sup>299</sup> *Id.*

<sup>300</sup> Linette Lopez, *What CVS is Doing to Mom-and-Pop Pharmacies in the US Will Make Your Blood Boil*, BUSINESS INSIDER (Mar. 30, 2019).

independent pharmacies were reimbursed only \$12.21.<sup>301</sup> In a study from Arkansas, many pharmacists stated they were not reimbursed enough to cover the cost of filling prescriptions.<sup>302</sup>

Therefore, it is the opinion of the Committee that legislation ensuring pharmacy reimbursements *at the very least* cover the cost to dispense is crucial to combat the anti-competitive practices of PBMs that are impacting independent community pharmacies across New York.

### VIII.G. Mandate All Reimbursements are Passed Back to Medicaid Clients

As discussed, PBMs negotiate with drug manufactures on behalf of their clients for rebates and discounts on prescription medications dispensed through their pharmacy benefit plans. Rebates are paid to PBMs after the point of sale, and can make up 40 percent or more of a prescription drug's list price.<sup>303</sup> While PBMs allege they pass much of the discount back to its clients, they often keep some of the savings as revenue.<sup>304</sup> Importantly, with the exception of new provisions for Medicaid under the 2019-2020 Budget, PBMs are not required to disclose rebate information to their clients.

While some PBMs plan to institute rebate pass-through “assurances” in the near future, such programs are not required by New York State law, and therefore are not guaranteed. The Committee recommends the introduction of legislation that requires all PBMs providing pharmacy benefit services to New York State Medicaid managed care organizations to pass back 100 percent of all rebates, discounts, and price concessions given to them by drug manufacturers.

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<sup>301</sup> *Id.*

<sup>302</sup> *Id.*

<sup>303</sup> *See supra* III.F.

<sup>304</sup> *Id.*