The 340B Rebate Model

Cash Flow Analysis

3 Axis Advisors LLC

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1 EXECUTIVE SUMMARY

As the 340B program approaches its 30th anniversary, the program will likely remain in the political spotlight as the various drug pricing factions continue to debate the program's merits. Since the program's inception there have been debates over the importance of the program. Is the growth in the number of 340B sites, which has seen a 20-year compounded annual growth rate (CAGR) of 7.87%, a sign of the program's vital need? Or does such growth demonstrate that the U.S. healthcare system will always grow in the direction of opacity and pricing arbitrage?

The Kalderos 340B rebate model's goal is to add transparency to the program's pharmacy transactions in a manner that is sustainable for covered entities. The Kalderos program converts a prescription drug purchasing discount predicated on "buying low and selling high" to a retroactive rebate not unlike that seen in other programs such as the Medicaid Drug Rebate Program (MDRP) or other government subsidies. Furthermore, the conversion of the 340B purchasing discounts to a transparent retroactive rebate may better position the 340B program in an era that hopes to see broader U.S. health policy changes designed at increasing the affordability of drugs for all Americans, both with and without insurance.

3 Axis Advisors, LLC (3 Axis) was commissioned to study the potential cash flow impacts of the 340B rebate model proposed by Kalderos. Kalderos compensated 3 Axis to perform this analysis based upon our industry expertise; however, as with all work performed by 3 Axis, our payment was not dependent upon the outcome of the study.

Overall, 3 Axis finds the 340B rebate program proposed by Kalderos to be cash flow positive for a covered entity within the assumptions of our report.

Projected positive cash flow is resulting from two principal sources, namely:

I. the decrease in the time it takes for a covered entity to recognize the dollars generated from its relationships with 340B contract pharmacies,
II. the lower inventory carrying costs within the 340B rebate model, as covered entities are no longer purchasing extra inventory to deliver to the contract pharmacy and,
III. the potential for higher 340B revenues that results from a 340B rebate based upon Wholesale Acquisition Cost (WAC) versus the existing commercial reimbursement rates which are predicated upon a discount to Average Wholesale Price (AWP)

The sensitivity analysis conducted demonstrated a positive cash flow for a covered entity in all scenarios tested adding a reasonable degree of confidence to this conclusion.

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5 BASIS OF THE 340B REBATE CASH FLOW STUDY

5.1 LEGISLATIVE BACKGROUND

More than three decades ago, Congress passed the Omnibus Budget Reconciliation Act of 1990 (OBRA '90).[1] This act established the **Medicaid Drug Rebate Program (MDRP)**, the precursor to the **340B program**. The MDRP helped reduce Medicaid spending on prescription drugs. Spending on prescription drugs within Medicaid was escalating rapidly in the early 1990s as a result of advancements in drugs used to treat hypertension and cancer.[2] The MDRP enables states to receive discounts from drug manufacturers, via rebates after prescription drug purchases, equal to or greater than the best prices private insurers receive.[3] This is because in order for drug manufacturers to obtain Medicaid coverage for their drugs they must sign a rebate agreement with the Secretary of Health and Human Services (HHS) to provide MDRP rebates.[4]

Shortly after the passage of OBRA '90, Congress extended to select providers relief from high drug costs that was similar to what they had previously provided to state Medicaid payers via the MDRP. Drug manufacturers had responded to the MDRP's passage by limiting drug purchasing discounts to some providers that had historically received large discounts, including safety-net providers and the Department of Veterans Affairs (VA). These actions were undertaken by drug manufacturers, at least in part, to avoid eroding the prices they could charge to Medicaid. The loss of these discounts resulted in significant added drug purchasing costs for impacted providers.[5] Consequently, Congress decided to act to address the situation impacting these providers. With clear legislative intent "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services," Section 602 of the Veterans Health Care Act of 1992 amended Section 340B of the Public Health Service Act, increasing requirements on drug manufacturers in order for them to obtain drug coverage via federal pharmacy programs.[6] Specifically, it required pharmaceutical manufacturers to enter into an agreement, called a pharmaceutical pricing agreement (PPA), with the HHS Secretary in exchange for having their drugs covered by Medicaid and Medicare Part B. Under the PPA, the manufacturer agrees to provide front-end discounts equivalent to those of the MDRP on covered outpatient drugs purchased by specified providers, called "**covered entities**."[7] [8]

Because the 340B program is a discount on drug purchases, Congress effectively created a complex subsidy for 340B covered entities. Drug manufacturers are the first party responsible for subsidizing covered entities. Via the 340B program, covered entities are able to purchase drug inventory at a significant reduction in cost, beyond what they would otherwise negotiate in the typical commercial marketplace. After securing low-cost inventory, which itself frees up the business's carrying costs, covered entities rely upon the second source of their subsidy—privately insured individuals—to generate funding on these discounted drug purchases. This funding (i.e., profit between sale price and purchase price) enables covered entities to deliver care to the uninsured or underinsured. As stated within the Health Resources and Services Administration's (HRSA) Hemophilia Treatment Center Manual, "If the covered entities were not able to access resources freed up by the drug discounts when they apply for grants and

bill private health insurance, their programs would receive no assistance from the enactment of Section 340B and there would be no incentive for them to become covered entities."[9]

5.2 Overview of Providers Eligible to Participate in the 340B Program

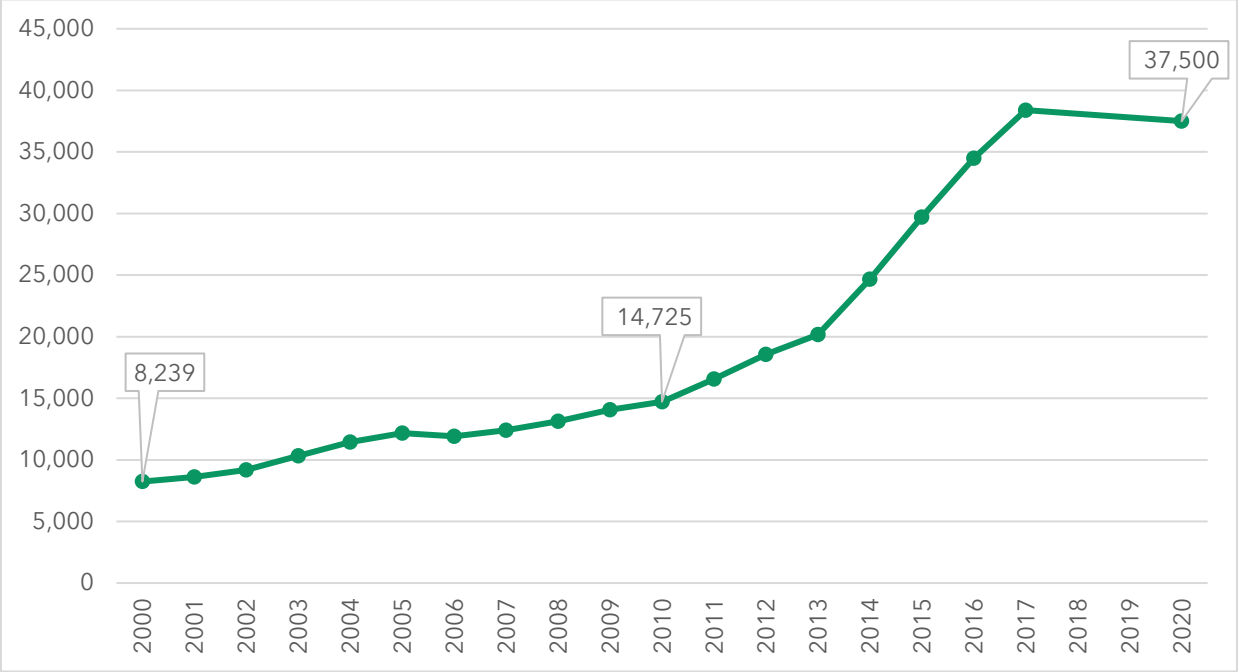
Since the passage of the 340B program, the number of providers eligible to acquire 340B drugs has increased, as has the number of pharmacies dispensing drugs purchased at a discount under the 340B program pricing. In 1996, the first **contract pharmacies** within the 340B program appeared via a sub-regulatory notice from **the Health Resources and Services Administration (HRSA)**, the government entity overseeing the 340B program.[10] [11] Contract pharmacies are an extension of the 340B covered entities beyond their physical location. The use of an individual contract pharmacy or multiple contract pharmacies is voluntary and based upon the covered entity's pharmacy service needs.[12] In 1998, the first expansion to the list of providers eligible to purchase 340B drugs occurred when family planning centers became eligible.[13] Perhaps the most significant expansion of the 340B program occurred in 2010 with the passage of the Affordable Care Act (a.k.a. "Obamacare"), which extended eligibility to many new provider types.[14] As of 2021, there are 16 specific covered entity types that may enroll within the 340B program, each with their own eligibility requirements for enrolling in the program. The specific eligible organizations are listed in **Table 5-1**.[15]

Table 5-1: 340B Covered Entity Types

Category	Eligible Organizations
Health Centers	• Federally Qualified Health Centers (FQHCs) • FQHC Look-Alikes • Native Hawaiian Health Centers • Tribal/Urban Indian Health Centers
Ryan White HIV/AIDS Program Grantees	• Ryan White HIV/AIDS Program Grantees
Hospitals	• Children's Hospitals • Critical Access Hospitals • Disproportionate Share Hospitals • Freestanding Cancer Hospitals • Rural Referral Centers • Sole Community Hospitals
Specialized Clinics	• Black Lung Clinics • Comprehensive Hemophilia Diagnostic Treatment Centers • Title X Family Planning Clinics • Sexually Transmitted Disease Clinics • Tuberculosis Clinics

With more providers eligible for the 340B program, the number of sites participating in the program has increased dramatically. Over the past 20 years, the number of participants has grown from just over 8,000 in 2000 to an estimated 37,500 in 2020 (see **Figure 5-1** on the next page). It is further estimated that 340B drug sales constitute approximately 8.3% of net drug sales by drug manufacturers in the U.S., making the 340B program nearly as large as the MDRP.[16] [17]

Figure 5-1: Growth of 340B Sites, 1998-2020 [18] [19] [20] [21] [22]



5.3 Current Challenges Within the 340B Program

It should come as no surprise that a program the size and scope of 340B has sparked some level of controversy throughout its existence. These concerns include, but are not limited to, the following:

Drug manufacturers contend, via lobbying organizations like Pharmaceutical Research and Manufacturers of America (PhRMA), that the definition of patients eligible to participate in the 340B program is overly broad, that reform is needed regarding eligibility standards for providers and their contract pharmacies, and that increased government oversight is needed.[23] These concerns, and perhaps others, have led some drug manufactures to unilaterally reduce participation in the 340B program by refusing to provide 340B discounts to covered entities that order the drugs themselves but then have the drug physically delivered to patients through contract pharmacies.[24]

Covered entities, via organizations such as the American Hospital Association (AHA), oppose efforts that would shrink the size and scope of the 340B program. This includes objections to contractual terms that would pay a different rate due to its participation in the 340B program. Furthermore, AHA advocates for increasing certain aspects of the 340B program, such extending 340B purchasing discounts on orphan drugs to covered entities currently excluded from making such purchases or allowing investor-owned hospitals to participate in the program as covered entities.[25]

The federal government, via the Government Accountability Office (GAO), has conducted several audits of the 340B program and raised concerns regarding oversight, transparency, and compliance of program rules by all program participants (i.e., drug manufacturers, covered entities, and contract pharmacies).[26]

5.4 Basis of Our Study

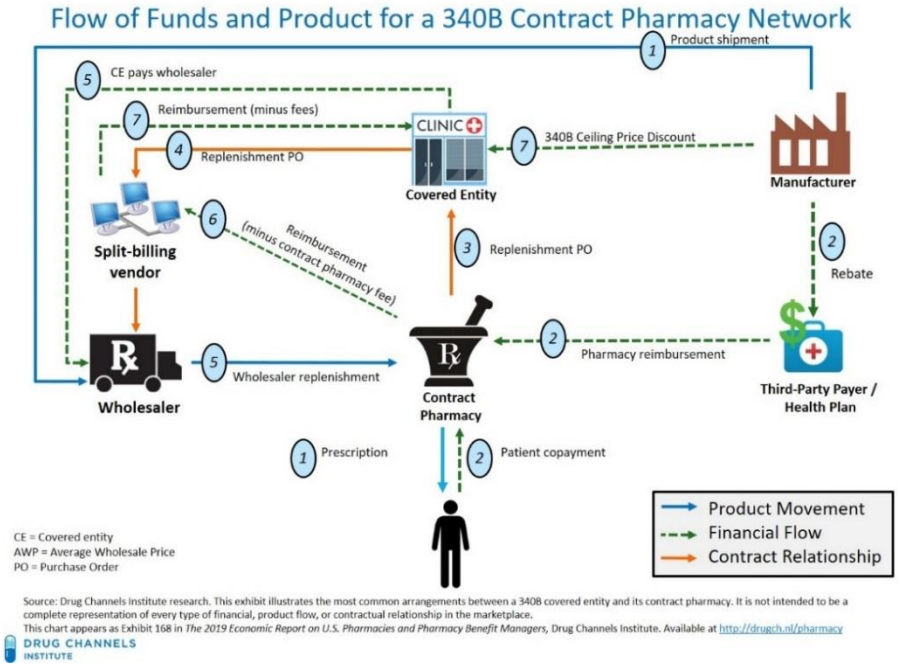
Against the backdrop of the current 340B dysfunction and concerns from nearly all program participants, Kalderos commissioned 3 Axis to analyze the cash flow implications of reengineering the program's current operations.

Currently, the principal challenge related to 340B program management is tied to inventory, particularly among contract pharmacies. Two common inventory models dominate how a covered entity, or its contract pharmacy, manages its 340B inventory: a separate physical inventory of retail and 340B drugs, or a virtual inventory model. The latter inventory management model is the more prevalent and is often referred to as the **replenishment model**.[27]

Within the replenishment model a software system, or **Third-Party Administrator (TPA)**, determines which of the drugs are eligible to be purchased at 340B pricing and replenished. Note that there is no physical separation of 340B and non-340B drugs in the replenishment model, which is a departure from older models where separate inventory management was required. Individual prescriptions are primarily determined eligible for 340B retrospectively after the patient has already obtained the medication, particularly in the virtual inventory model. To a lesser extent, purchases can be determined to be 340B eligible at the point of sale, but these are generally limited cases. Because 340B determination is made retrospectively in the replenishment model, eligible 340B purchases will accumulate, and an order will be placed to replenish the pharmacy's dispensed inventory once the drug, based on its **National Drug Code (NDC)**, has eligible totals equal to or greater than a full package size in the accumulator. This creates its own set of inventory challenges within the existing replenishment model when a particular purchase never reaches the accumulator total and requires **true ups** be performed between the dispensing pharmacy and covered entity. If a contract pharmacy cannot dispense enough of a specific NDC within a negotiated time frame (usually 90 days) then the TPA removes the dispensed quantity from the inventory management system and instead of the covered entity replenishing the drug at 340B costs, they reimburse the pharmacy for the negotiated full cost of the drug.

Once the 340B purchased drugs are received by the pharmacy they become part of the regular non-340B drug inventory. When a pharmacist fills prescriptions, any of the available products (whether purchased via 340B or not) can be dispensed to any patient who needs them.[28] See **Figure 5-2** (on the next page) for a visual representation of the inventory management via a replenishment model at a contract pharmacy:

Figure 5-2: 340B Contract Pharmacy Management, Drug Channels, 2019[29]



Because inventory is not segregated and identification of 340B eligibility is predominantly determined retroactively, compliance problems may arise for 340B program participants. The most common challenge encountered relates to prohibition of **duplicate discounts**, whether by federal law or private contract. Drug manufacturers are not required to offer a drug at the 340B discount rate to a covered entity (or their contractor) and pay a rebate to a payor (i.e., health insurer) for the same drug—it must be one or the other. Federal law prevents state Medicaid programs from seeking rebates on 340B claims, and rebate agreements between drug manufacturers and pharmacy benefit managers (PBMs) prevent such duplicate discounts via private contracts. However, the challenge of properly identifying 340B claims limits the enforceability of duplicate discount prohibitions. Further complicating the issue is the growing practice of price discrimination whereby 340B covered entities may receive reduced compensation for claims dispensed under the 340B program because the provider (or contractor) participates in the program. Such practices threaten the core integrity of the 340B program, as the steep discounts provided by drug makers could be consumed by intermediaries (i.e., PBMs) rather than the funds being used by covered entities as a means to provide care to uninsured or underinsured individuals.

5.4.1 340B Rebate Model

To address these concerns, Kalderos has developed a 340B rebate model which does not require a covered entity to "buy low, sell high." Instead, it proposes to convert the 340B subsidy into a cash rebate from the drug manufacturer, with increased transparency into contract pharmacy operations. The functionality of the model, adapted from materials presented by Kalderos to 3 Axis, is described in the following steps over the next two pages:

Step 1:

Contract pharmacy dispenses drug to the patient from existing inventory and collects the patient's copayment and payer reimbursement.

Step 1

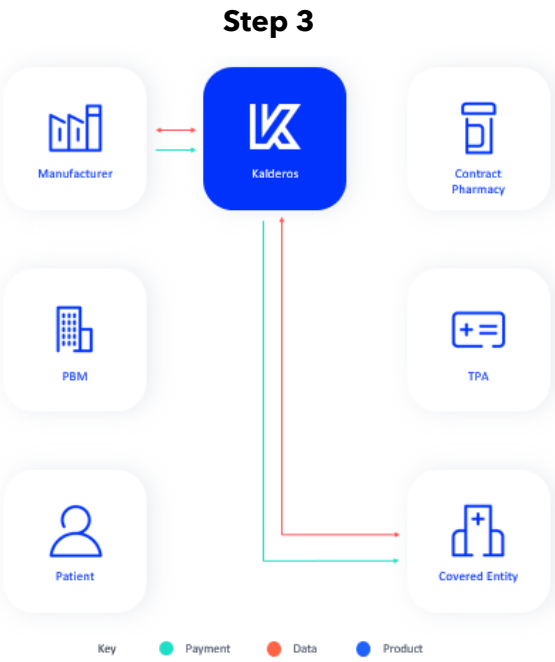
Step 2:

Contract pharmacy works with TPA and covered entity to verify patient is eligible to receive a drug acquired under the 340B program.

Step 2

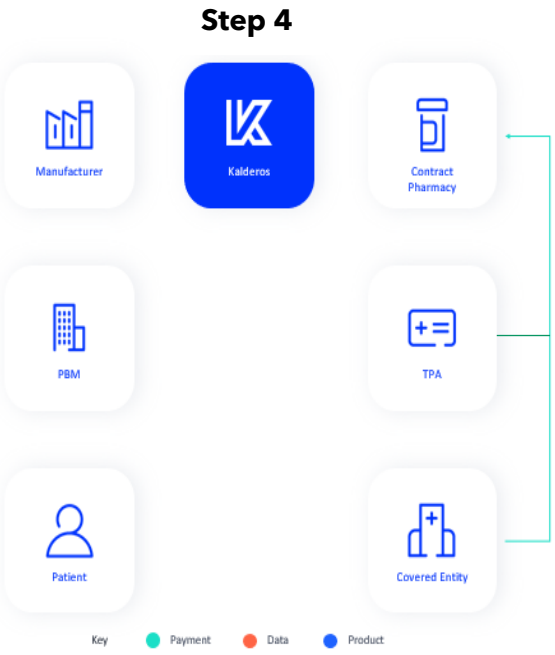
Step 3:

Covered entity submits a request for a 340B rebate via the rebate intermediary (Kalderos) on eligible claims. Payment to the covered entity occurs 15 days post submission of eligible claims.



Step 4:

Covered entity pays fees to contract pharmacy and TPA.



Step 5: The PBM submits a request for a rebate to a drug manufacturer. The manufacturer compares the claim data provided by the PBM, finds the match to the contract pharmacy claim, and denies the PBM a rebate. Terms and conditions limiting the use of claim data by drug manufacturers to rebate validation purposes only reduces risk of PBMs obtaining and using 340B rebate claim data to reduce covered entity and/or contract pharmacy reimbursements.

This report will analyze the cash flow implications to a covered entity if switching from the existing replenishment model for contract pharmacies to the 340B rebate model.

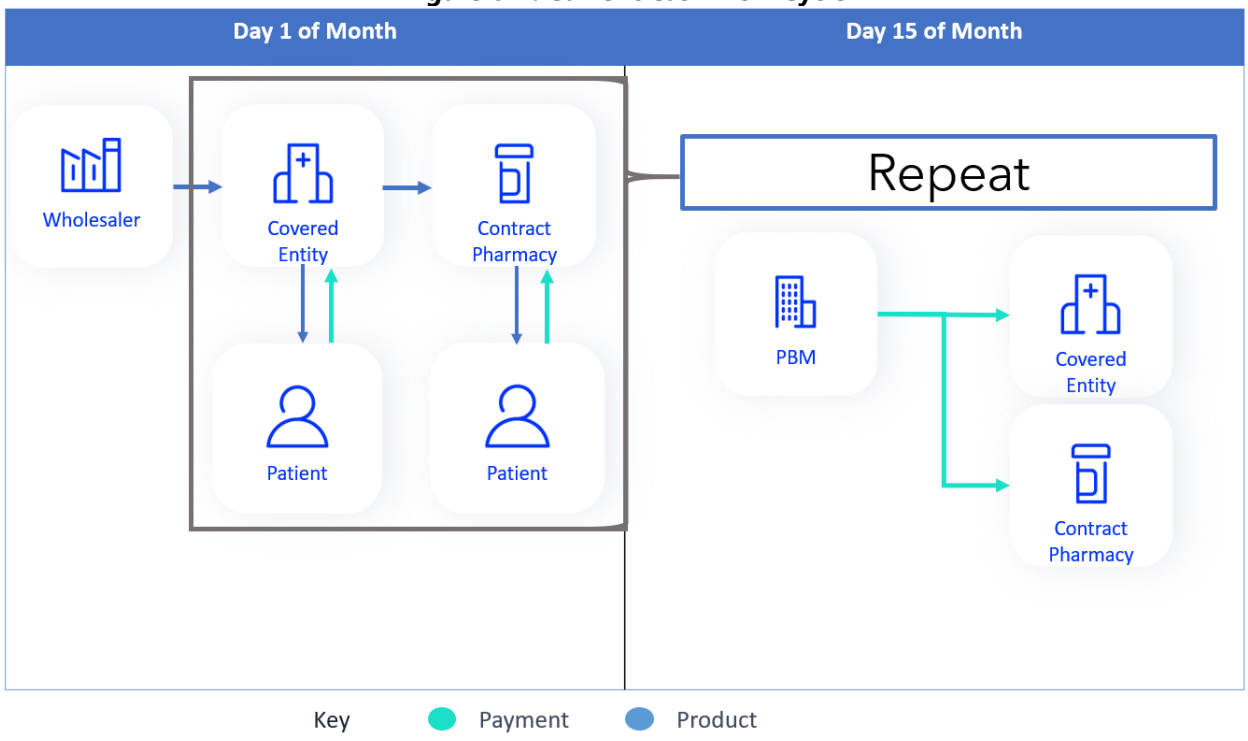
6 ANALYSIS

To understand the cash flow implications of the Kalderos 340B rebate model, 3 Axis designed two scenarios to facilitate our analysis. The first identifies the current cash flow implications of 340B contract pharmacies on covered entities within the replenishment model. The second identifies the changes that occur with the switch to managing contract pharmacies via a 340B rebate program (see **Section 5.4.1** for details of the 340B rebate program).

6.1 DESIGN

To effectively review the potential cash flow impact to covered entities, 3 Axis first explored how cash flows in the current system. To do this, 3 Axis developed the following cash flow scenario (**Figure 6-1**) based on sample 340B purchasing data over one quarter from a 340B covered entity (see **Section 8** for details regarding data sources and methodology).

Figure 6-1: Current Cash Flow Cycle



Under our model, 3 Axis assumes that all inventory the covered entity needs to dispense for all prescription drug claims for the month is received from the wholesaler on Day 1 each month. Inventory is delivered to the covered entity and the contract pharmacy on the first day based upon the assumption of pharmacy sales by covered entity versus contract pharmacy (see **Section 8** for all assumptions). 3 Axis then assume that half of all claims that will be dispensed in the month are dispensed on the first day of the month (again, by both the covered entity and contract pharmacy). Claims are distributed among the payer types (cash, commercial, and Medicaid) based upon the assumption regarding payer type distribution. The covered entity and the contract pharmacy receive the full revenue for cash-paying customers on Day 1, respectively. On Day 15, the covered entity and contract pharmacy dispense the remaining

half of their inventory for the month. Again, these claims are dispensed across the payer types per the payer type assumption (including cash-paying customers). In addition, the covered entity and the contract pharmacy receive their reimbursement from insurers (e.g., commercial PBMs) on the basis of a net 15 payment term for the prescriptions dispensed on Day 1. At the 30-day mark (or the start of the next month), the contract pharmacy will return revenue to the covered entity per the assumed contract terms.

To control for potential confounding variables, 3 Axis designed this model to assume near perfect management of pharmacy inventory by the covered entity and its contract pharmacy or pharmacies. While it is likely impossible for a pharmacy to cycle through its inventory this way, this assumption was made to control for drug mix variability. There should be no underlying change to the business operation of the covered entity or contract pharmacy(ies) with the switch to a 340B rebate model, and the normal course of pharmacy business should remain unchanged. By simplifying drug-dispensing activities to align with payment terms from commercial and Medicaid sources, we are better able to examine the cash flow implications of the 340B rebate model Kalderos proposes within the current prevailing market.

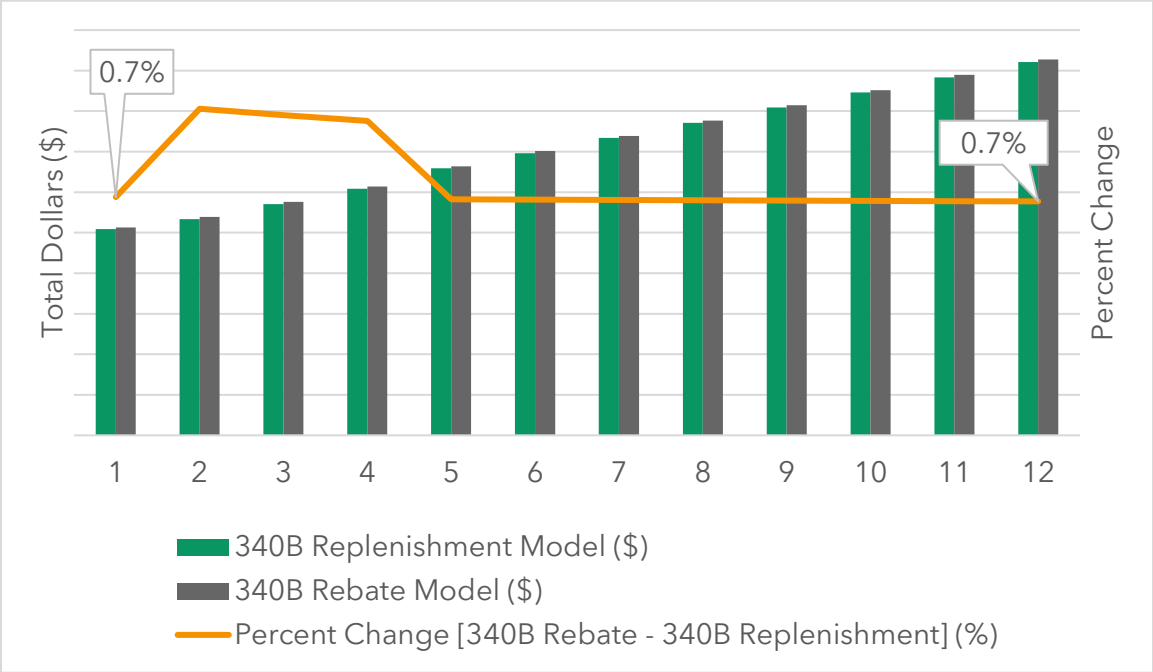
After establishing the current model and cash flow, 3 Axis modified our existing model in the following ways to represent the Kalderos 340B rebate model as outlined in **Section 5.4.1**:

- Total covered entity 340B inventory purchases are reduced by the assumption of the amount of pharmacy volume with the contract pharmacy.
    - Within the rebate model, the contract pharmacy uses its own inventory to dispense claims which are later identified as 340B eligible and rebated. Consequently, no 340B purchases by the covered entity for delivery to the contract pharmacy are made in the 340B rebate model. This reduces 340B inventory and so is appropriately captured in our model. Additionally, this should address current issues related to true ups costs for covered entities.
- The covered entity no longer receives revenue from the contract pharmacy weeks after the 340B-eligible claim is dispensed. Rather, the covered entity submits the 340B-eligible claims from the contract pharmacy dispensing activities directly to the drug manufacturer to obtain a rebate.
    - Contract pharmacies retain all revenue on the claim from the primary payor, potentially reducing the risk for payment discrimination due to participation in the 340B rebate program.
    - Contract pharmacies do not remit any money back to the covered entity in the 340B model as they do under the current replenishment model.
- On all 340B eligible claims (both from the covered entity and the contract pharmacy), the covered entity submits a rebate request to the drug manufacturer, due to be paid in 15 days.
    - In our model, 3 Axis assumed this is net 23 days post claim adjudication to allow for TPA activities of claim identification as 340B eligible to take place.
- The covered entity submits payment to the contract pharmacy and related stakeholders (i.e., TPAs) per their contractual terms.

6.2 FINDINGS

Based upon our comparison model, 3 Axis finds the switch to a 340B rebate model to have positive cash flow implications to a covered entity under our base assumptions, as can be seen in **Figure 6-2**:

Figure 6-2: Cash Flow Implications on Covered Entity of 340B Rebate Model



As can be seen in **Figure 6-2**, the covered entity is experiencing positive cash flow with the rebate model (**grey bars**) relative to the existing replenishment model (**green bars**). The difference, in terms of positive cash flow, is expressed as a percent improvement over the replenishment model (orange line) and demonstrates a significant improvement over 1 year.

The following key differences between the replenishment model and 340B rebate model may explain the observation of positive cash flow for the covered entity seen in **Figure 6-2**:

- The covered entity recognizes 340B revenues from claims dispensed at contract pharmacies faster in the rebate model then the replenishment model. Specifically, rebates from the drug manufacturer are due 15 days post rebate submission whereas in the existing replenishment model contract pharmacies submit revenues to the covered entity 30 to 90 days post adjudication (see **Section 8** for assumptions of our model).
- The covered entity is recognizing lower inventory carrying costs within the 340B rebate model, as they are no longer purchasing extra inventory to deliver to the contract pharmacy. Under the 340B rebate model, the contract pharmacy uses its own inventory and keeps its own reimbursement for pharmacy claims.
- The potential to secure higher 340B revenue due to the differences between existing replenishment-based payments for drugs and the proposed rate for 340B rebates. PBMs generally pay for drugs based on a discount to the drug's AWP, which may be a lower reimbursement than a rebate payment at WAC (the basis of the Kalderos 340B

rebate). This is similar to contract pharmacy reimbursements based upon a reference-based pricing arrangement. Specifically:

- The aggregate payment on drugs (brand or generics) is below the WAC price based upon our study assumptions. As a result, the difference between the WAC price and the 340B acquisition price will result in more revenue than the difference between the PBM-based reimbursement at the assumed AWP discount and the 340B acquisition price (the basis of the current revenue within 340B).[i]

6.3 SENSITIVITY ANALYSIS

To test the results in **Section 6.2**, 3 Axis conducted a sensitivity analysis to examine the impact to a covered entity's cash flow based upon changes to the key assumptions of our model. Specifically, the sensitivity analysis conducted assessed the impact on a covered entity's cash flow with changes to the percent of 340B claim volume distributed between the covered entity and the contract pharmacy as well as the AWP brand discount. Because 340B revenue is principally generated off of brand name medications, brand reimbursement is a key determinant of current 340B cash flow. Similarly, within the existing replenishment model, contract pharmacies are a key source of revenue, as well as costs due to associated fees to covered entities, and so were identified as the other key variable for the sensitivity analysis. The results of this analysis are summarized in the **Table 6-1.**

Table 6-1: Sensitivity Analysis: AWP Discount and Contract Pharmacy Volume, % Improvement

1-Year Cash Flow Differential		AWP Brand Discount				
		10%	15%	17.42%	20%	25%
Contract Pharmacy 340B Volume	10%	0.2%	0.5%	0.7%	0.9%	1.4%
	20%	0.4%	1.1%	1.4%	1.9%	2.8%
	30%	0.6%	1.6%	2.2%	2.9%	4.4%
	40%	0.8%	2.3%	3.1%	4.0%	6.0%
	50%	1.0%	2.9%	4.0%	5.2%	7.8%

In **Table 6-1** the data is presented as a percent change based upon the base assumption of the replenishment model after 1 year, akin to the orange line in **Figure 6-2**. Our base assumptions are (1) a brand AWP discount equivalent to 17.42% and (2) 340B contract pharmacy volume being 10% (**shaded cell above**). As can be seen in this table, all instances where different assumptions are made regarding AWP discounts and 340B contract volumes result in positive cash flow to the covered entity. In general, alterations of our base assumptions result in cash flow that, while still positive, is not as positive as initially modeled when the AWP-based brand discount is a lower percentage (i.e., further from the WAC equivalent). The model is more favorable, in terms of cash flow improvement, when the 340B volume at contract pharmacies increases.

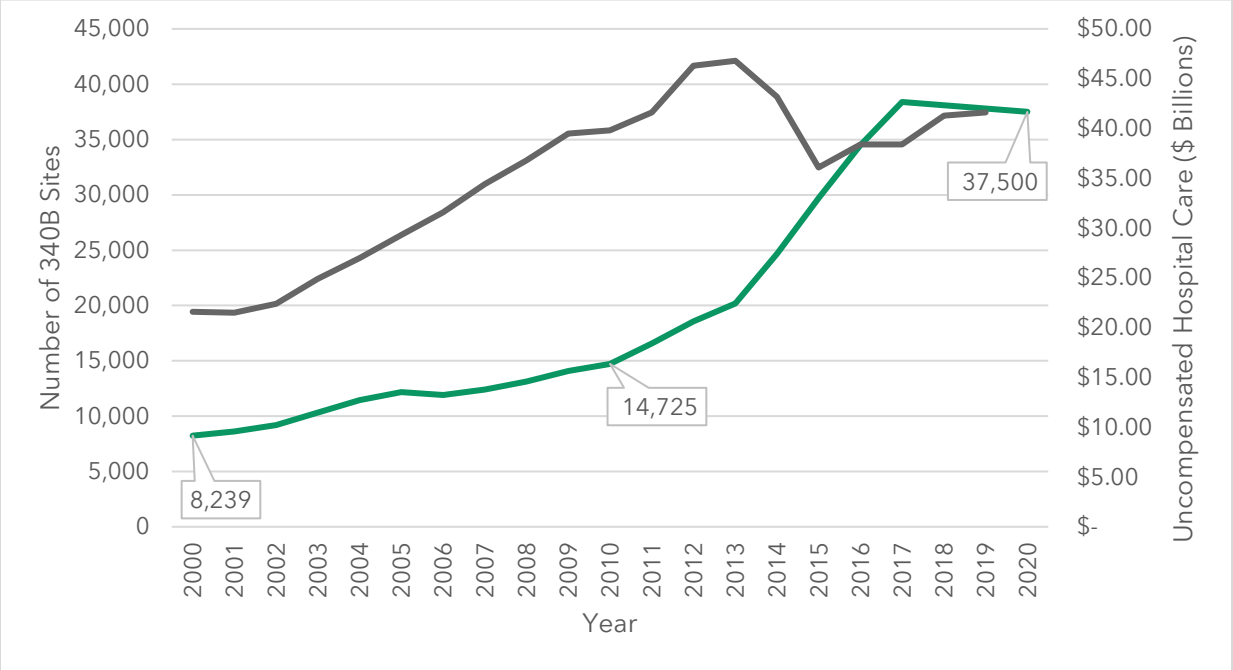
[i] Specific to our study, the aggregate brand discount is a 17.42% discount to AWP. This is equivalent to a brand WAC discount of 6%. Consequently, there is more revenue available from a rebate to 100% WAC than from the existing AWP-based discount.

7 Discussion

In order to secure coverage of their medications, manufacturers participating in Medicaid and Medicare agree to provide outpatient drugs to covered entities at significantly reduced prices, below the price at which other providers would be able to acquire prescription drugs. Persons with health insurance enable covered entities to generate resources (profit) off 340B purchases based upon the difference between commercial insurance reimbursement rates and the 340B acquisition price. While this function is no different than any other transaction, where profit is the difference between sales price and acquisition price, covered entities within the 340B program are uniquely positioned to acquire their products at a discount unlike that seen in any other industry. Taken together, manufacturers and people with insurance provide a subsidy to covered entities that enables them to stretch scarce resources as far as possible, with the goal of reaching more eligible patients and offering more comprehensive services.

The 340B program has grown over time through regulatory action, such as the Affordable Care Act which enabled new organizations to participate in the program, as well as through expansion of the reach of existing covered entities, such as covered entities developing relationships with contract pharmacies. During the past 20 years, the number of healthcare sites participating in the program has grown from just over 8,000 locations to more than 37,000 locations (or a 7.87% CAGR). During this same time frame, critics of the 340B program have questioned whether it is achieving its stated goal, namely "stretching scarce federal resources as far as possible." This is because, during the time frame of 340B provider growth, the amount of uncompensated care provided by hospitals has grown by only a 3.51% CAGR, according to AHA data.[30]

Figure 7-1: Comparison of 340B Covered Entity Growth to Uncompensated Hospital Care [31] [32] [33] [34] [35] [36]



This paper's analysis does not seek to address whether the 340B program is providing net benefits to the U.S. healthcare system. Rather, the goal is to examine the impact of a 340B rebate model to the cash flow of a covered entity. The 340B rebate program proposed by Kalderos adds transparency and simplicity to the 340B claim transaction that, in our view, is sorely lacking today.

Overall, 3 Axis finds the 340B rebate program proposed by Kalderos to be cash flow positive from the perspective of a covered entity within the assumptions of our report. Positive cash flow likely results from several sources:

I. the decrease in the time it takes for a covered entity to recognize the dollars generated from its relationships with 340B contract pharmacies (30 to 90 days currently to an average of 24 days in the rebate model),
II. lower inventory carrying costs due to the 340B program purchases not extending to contract pharmacies and being limited to just the covered entity and,
III. the higher payment that results from a 340B rebate based upon Wholesale Acquisition Cost (WAC) versus the existing commercial reimbursement rates which are predicated upon a discount to Average Wholesale Price (AWP).

The conducted sensitivity analysis resulted in a positive cash flow for the covered entity in all tested scenarios, adding a reasonable degree of confidence to the conclusion of our analysis.

The analysis is predicated on many variables with the potential to confound this analysis. These variables include the drug mix between a covered entity and its contract pharmacy, the inventory management systems within a pharmacy, and the contractual terms related to purchasing and dispensing prescription medications (see **Section 8**). While the study design attempted to control for these variables, it is possible that not all confounding variables were identified or accounted for. It is not practical to opine on the impact these potentially unknown variables may have on our analysis. Therefore, the analysis is most appropriately considered within its base assumptions.

While not evaluated, contract pharmacies may experience changes in their cash flow as a result of the 340B rebate model. Such changes could have downstream effects, including the contract pharmacy's ability or inability to provide 340B benefits to cash-paying patients. The potential negative cash flow impact to contract pharmacies may be lessened by reductions in other 340B related expenses they incur, such as inventory management, as they no longer receive 340B purchased goods and therefore are not managing 340B inventory. Nonetheless, a negative cash flow impact, should one exist, to the contract pharmacy may affect pharmacy business operations, which could potentially impact the services they are able to offer covered entities. Additional research is needed to understand the impact of the 340B rebate model on contract pharmacies.

8 METHODOLOGY

8.1 DATA SOURCES

All analytics performed in this study were based on the following raw data sources:

1. Medi-Span PriceRx by Wolters Kluwer Clinical Drug Information, Inc.
2. 340B covered entity purchase data
3. 340B contract pharmacy contract
4. Large Pharmacy Service Administration Organization (PSAO) pharmacy claims data

Details regarding the data sources and their transformations used as part of our analysis are provided below.

8.1.1 Medi-Span PriceRx by Wolters Kluwer Clinical Drug Information, Inc.

Medi-Span PriceRx, an online pricing and drug information portal, offers one of the most extensive histories of drug manufacturer pricing, with NDC-level drug pricing dating back to the 1980s.

PriceRx was the source of the raw AWP and WAC data that we used to map purchases to their aggregate AWP and WAC value.

PriceRx also contains clinical information, enabling identification of drug products by a hierarchical therapeutic classification system. This classification helps standardize drug lists and is the basis for all therapeutic category investigations. It was used to identify brand versus generic status, prescription drug status, and therapeutic drug classes, among other clinical information.

8.1.2 340B Covered Entity Purchase Data

Kalderos supplied 3 Axis with one quarter's worth of sample 340B purchasing data from an FQHC from Q1 2018. The format of the data is shown in **Table 8-1**.

Table 8-1: 340B Covered Entity Purchase Data Format

Field	Description
NDC/UPC	NDC or Universal Product Code (UPC), an identifier for the drug purchased
Item Description	The product name
Generic Description	The generic description for the product
Ord Qty	The amount of NDC purchased
Fill	The number of units of NDC delivered
Return	The number of units of NDC returned
Net	The cumulative amount between delivered and returned products
UOM	Unit of measure
Unit Price	Price per unit for the NDC
Ext. Price	The total price for the net quantity of the NDC purchased

8.1.3 340B Contract Pharmacy Contract

Kalderos supplied 3 Axis with a contract for a 340B contract pharmacy between a covered entity and community retail pharmacy. The contractual terms informed the basis of the assumptions for 340B contract pharmacy payment terms.

8.1.4 Large PSAO Pharmacy Claims Data

3 Axis relied upon claims data from a large PSAO to inform assumptions throughout this report as discussed in **Section 8.2**.

8.2 Assumptions

8.2.1 PBM Reimbursement Terms

There is very little information within the public domain regarding PBM-specific reimbursement terms for pharmacy expenditures. However, 3 Axis has experience reviewing dozens of contracts of various types (i.e., pharmacies, benefit brokers, insurers, etc.) across the country. Most commercial pharmacy network reimbursements are set as the lower of (1) usual and customary, (2) Maximum Allowable Cost (MAC), or (3) a discount to AWP. Recently, PBMs have shifted the overwhelming majority of their contracts into annual guarantees, called effective rates, which ensures that claims are trued up to a set discount to AWP at the end of the year.[37] As a result, the AWP discount becomes the most important aspect of pharmacy reimbursement and was the basis of our reimbursement assumptions for this analysis. Our assumptions related to reimbursement for this analysis are listed in **Table 8-2**.

Table 8-2: PBM Commercial Reimbursement Assumptions

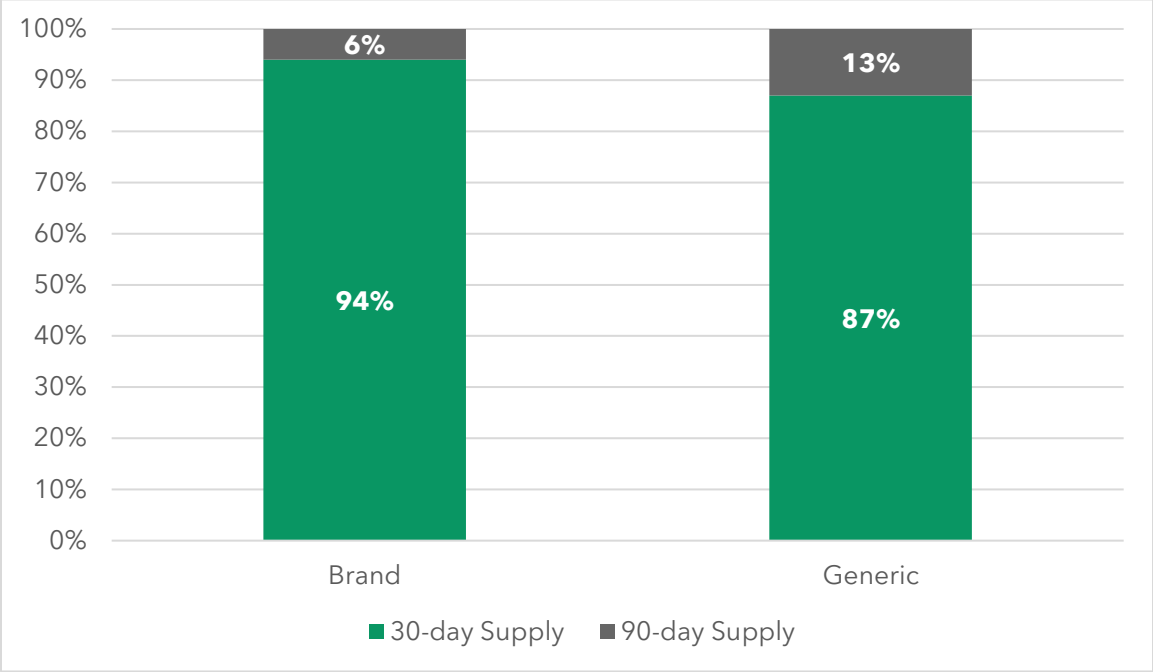
Description	Reimbursement Term
Brand 30-day supply reimbursement	AWP – 17%
Brand 90-day supply reimbursement	AWP – 24%
Generic 30-day supply reimbursement	AWP – 87%
Generic 90-day supply reimbursement	AWP – 97%
Dispensing fee	$0.50
Payment date	15 days post

Because reimbursement terms are specific to days' supply, we needed to generate assumptions regarding the disruption of prescription drug fills by days' supply. To inform an appropriate assumption in this analysis, we relied upon retail pharmacy claims transaction data from over 1,000 community retail pharmacies from 2019. We evaluated drugs based upon a brand or generic status according to the following definitions:

- Brands were any drugs with a Food and Drug Administration (FDA) license type of New Drug Application (NDA) or Biologic License Application (BLA), and whose Medi-Span Brand Name Code (BNC) was T or B.
- Generics were all other drugs.

A prescription was categorized as a 90-day supply if the claim transacted at 85 days or more (NCPDP Field# 4Ø5-D5). All others were categorized as a 30-day supply. The distribution of claims by brand, generic status, and day supply is shown in **Figure 8-1.**

Figure 8-1: Distribution of Days' Supply Among Brand and Generic Claims, Large PSAO

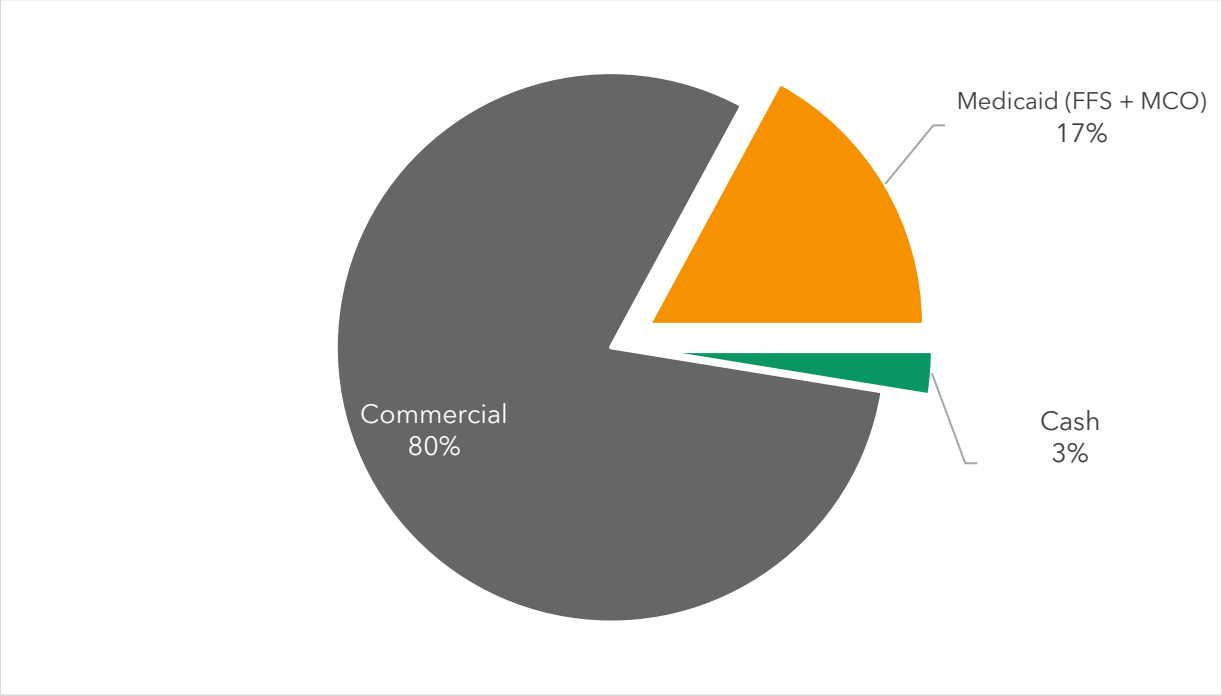


The distribution of these claims was used to weight the aggregate brand and generic AWP guarantees to aggregate brand and generic payment terms. For our analysis, we assumed a brand AWP payment term of AWP – 17.42%; generic was AWP – 87.78%.

8.2.2 Payer Types and Percentage of Claims

We also used the pharmacy data available to us to determine the distribution of payments by payer type. We were specifically looking for the number of claims paid at cash, under Medicaid, and via commercial payers, as these are the important payor types via the 340B contractual terms. Our analysis found the distribution of payer types as a percentage of total paid claims shown in **Figure 8-2**.

Figure 8-2: Percentage of Claims by Payer Type



The results of our claims analysis appear in line with the work of other data researchers.[38] [39]

To determine payment from Medicaid FFS programs, we assumed that payment was at the National Average Drug Acquisition Cost (NADAC) equivalency metric to AWP [ii] plus the aggregate professional dispensing fee within the U.S. at $10.71.[40] [41]

8.2.3 PBM Payment Terms

There is very little information within the public domain regarding PBM-specific reimbursement terms for pharmacy expenditures. However, 3 Axis has experience reviewing dozens of contracts of various types (i.e., pharmacies, benefit brokers, insurers, etc.) across the country. This industry experience, informed by data available within the public domain, informed the basis for our assumptions regarding PBM contract terms for pharmacies.[42]

8.2.4 Wholesaler Payment Terms

Because we relied upon the supplied invoicing of prescription drug purchases between a covered entity and a wholesaler, the only assumption we had to make was with regard to the payment terms, which were set at net 30. We did not include, nor did our analysis require, assumptions regarding typical purchase discounts from wholesalers.

8.2.5 340B Contract Pharmacy Payment Terms

There is a lack of information within the public domain regarding contract terms between a covered entity within the 340B program and their network of contract pharmacies. However, 3 Axis has experience with the 340B contracting process, including negotiating contracts between a covered entity and a retail pharmacy within the past five years. In addition, Kalderos

[ii] Brand AWP mean discount of 20.5%, generic AWP mean discount of 79% as of December 2020

supplied 3 Axis with a contract to review which informed our base assumptions. Note that the provided information appeared in line with what 3 Axis was familiar with and found available within the public domain.[43]

8.2.6 340B Rebate

The 340B rebate is calculated as the WAC minus the 340B price.

8.2.7 Assumptions Matrix

Figure 8-3 provides a visual overview of the assumptions made in this report.

Figure 8-3: Assumption Matrix

PBM Reimbursement Terms		
This section enables the user to enter contract terms for commercial PBMs for brand and generic Medications.		
Default Entries are based upon terms of national PBM contracts		
30-day Supply	Brand Name	17.00%
	Generic	87.00%
90-day Supply	Brand Name	24.00%
	Generic	93.00%
Dispensing Fee	Brand Name	$ 0.50
	Generic	$ 0.50
Payment Due By Date		15 days post

Medicaid FFS Reimbursement Terms	
This section enables the user to enter Medicaid reimbursement terms	
Default entries are based upon national average	
Brand Name AWP to NADAC Equivalency	20.50%
Generic AWP to NADAC Equivalency	79.00%
Professional Dispensing Fee	$ 10.71
Payment Due by Date	15 days post

Wholesaler Payment Terms	
Invoice history from Covered Entity should be loaded onto the second tab (User Purchase Data)	
Payment Due by Date	15 days post

True Up Costs	
Historical Covered Entity Experience Related to True Up Costs with Traditional 340B Model	
Annual dollar amount	

Utilization Assumptions				
This section enables the user to enter drug and payer mix distribution values				
Default Entries are based upon large pharmacy group data				
Brand Name	30-day supply	94.00%	Calculated Weighted Avg AWP	17.42%
	90-day supply	6.00%		
Generic	30-day supply	87.00%	Calculated Weighted Avg AWP	87.78%
	90-day supply	13.00%		
Sources of Pharmacy Claim Payment (i.e. Payer Type)	Cash	3.00%		
	Medicaid FFS	3.00%		
	Medicaid MCO	17.00%		
	Commercial	77.00%		
340B Volume	Percent of Volume at Contract Pharmacy (ies)	10%		

340B Contract Pharmacy Reimbursement Terms		
This section enables the user to enter in the payment terms between the Covered Entity and their Contract Pharmacy		
Default entries are based upon terms of 340B Contract Pharmacy experience of Kalderos		
Cash Paying Patients (i.e., Self-Pay)	Administrative Fee	$ 0.50
	Dispensing Fee	$ 15.00
	Ingredient Cost	340B Acquisition Cost
Commercial Insurance (i.e., Private Pay)	Administrative Fee	$ 15.00
	Percentage Fee	16.00%
	Per Prescription Fee	$ -
	Specialty Fee	$ -
Payment Date		30 days post
340B Rebate Commercial Insurance (i.e., Private Pay)	Dispensing Fee	$ 15.00
	Administrative Fee (%)	16.00%
	Per Prescription Fee ($)	$ -
	Specialty Fee	$ -
Payment Date (days post transaction)		23

8.3 DATA TRANSFORMATIONS

To conduct our analysis, we needed to join the 340B covered entity purchase data with the Medi-Span data. Joining the data would give us the AWP and WAC pricing information along with the brand and generic definition we needed. We joined the data sets on the basis of NDC via the following Structured Query Language (SQL) transaction:

```
WITH CTE AS (
SELECT [NDC_UPC_HRI_Unformatted]
      ,[History_Price_Type]
      ,[History_Effective_Date]
      ,[History_End_Date]
      ,[History_Package_Price]
      ,[Size]
      ,[Qty]
      ,[History_Unit_Price]
      ,[History_Price_Change_Percent]
  FROM [MediSpan]
  where [History_Price_Type]='AWP'
)
,CTE2 AS (
SELECT [NDC_UPC_HRI_Unformatted]
      ,[History_Price_Type]
      ,[History_Effective_Date]
      ,[History_End_Date]
      ,[History_Package_Price]
      ,[Size]
      ,[Qty]
      ,[History_Unit_Price]
      ,[History_Price_Change_Percent]
  FROM [MediSpan]
  where [History_Price_Type]='WAC'
)
,CTE4 AS (
SELECT cte.NDC_UPC_HRI_Unformatted
,cte.History_Effective_Date
,cte.History_End_Date
,cte.size
,cte.Qty
,cte.History_Package_Price as AWP_PACK
,cte2.History_Package_Price as WAC_PACK
FROM CTE
left JOIN CTE2 on CTE.NDC_UPC_HRI_Unformatted=cte2.NDC_UPC_HRI_Unformatted and
cte.History_Effective_Date=cte2.History_Effective_Date and cte.History_End_Date=CTE2.History_End_Date
)
,cte3 AS(
SELECT [McK_Item]
      ,[NDC_UPC]
      ,[Item_Description]
      ,[Generic_Description]
      ,[Ord_Qty]
      ,[Fill]
      ,[Return]
      ,[Net]
      ,[UOM]
      ,[Unit_Price]
          ,Ext_Price
      ,'340B' as [Purchase Type]
          ,'2018-01-01' as [Date]
  FROM [Kalderos_Purchases] KP)

  SELECT CTE3.*
  ,CTE4.Size
  ,CTE4.Qty
  ,CTE4.AWP_PACK
```

```
  ,CTE4.WAC_PACK[iii]
  ,MDDB.CMS_Drug_Category_Code
  ,MDDB.Brand_Name_Code_BNC
  ,MDDB.Drug_Application_Type_FDA
  FROM cte3
  left JOIN CTE4 on CTE4.NDC_UPC_HRI_Unformatted=cte3.NDC_UPC and cte3.Date>=CTE4.History_Effective_Date
and cte3.Date<=CTE4.History_End_Date
  left join [MediSpan] MDDB on MDDB.ndc_upc_Hri_unformatted=cte3.NDC_UPC
```

Within the resulting database we performed the calculations shown in **Figure 8-5**.

Figure 8-4: Calculations for Analysis Based upon 340B Purchase and Medi-Span Data

Calculation	Description
Qty per Rx	Calculates the average quantity per prescription as a whole number for the NDC based on pharmacy claim experience and clinical knowledge regarding usual dose
Total AWP	Calculates the total AWP value of the purchased NDC on an NDC basis by the total number of units
Total WAC	Calculates the total WAC value of the purchased NDC on an NDC basis by the total number of units
Total units	Calculates the total number of units of drug available based on the number of units of the NDC purchased
# of Rxs	Uses the Qty per Rx field to calculate the total number of prescriptions eligible to be filled based on the total units purchased within the period
15-day Rx cycle	Converts the number of prescriptions into an estimate of fills per 15-day cycle based on the inventory loaded representing one quarter's worth of data (therefore, six 15-day cycles)
Total AWP per Rx	Calculates the total AWP value per prescription by dividing the total AWP by the number of prescriptions
Total WAC per Rx	Calculates the total WAC value per prescription by dividing the total WAC by the number of prescriptions
Total 340B per Rx	Calculates the total 340B value per prescription by dividing the total purchase price by the number of prescriptions
Total 340B per Rx 15 day	Converts the Total 340B per Rx value into a 15-day cycle
Total AWP per Rx 15 day	Converts the Total AWP per Rx value into a 15-day cycle
Total WAC per Rx 15 day	Converts the Total WAC per Rx value into a 15-day cycle

[iii] There was one instance where a product did not have a WAC price updated alongside an AWP update. For this NDC, the assumption was that the WAC and AWP were the same.

8.4 LIMITATIONS

As with all research, our report is predicated on the accuracy of the data provided. Kalderos provided 3 Axis with the basis of covered entity purchases and the contractual terms related to covered entity purchases and relationships with contract pharmacies. The degree that such data differs from actual market conditions will have a notable impact on our report. Similarly, 3 Axis relied upon our industry knowledge to confirm the reasonableness of the provided data and develop assumptions as outlined in **Section 8.2**. To the degree that these assumptions differ from current market conditions, particularly post-pandemic, there may be a material impact to the analysis presented in this report.

In our study we assumed that the drug mix between the covered entity and the contract pharmacy was fixed. This means that all drugs purchased were equally distributed between the covered entity and contract pharmacy, and that drug distribution was also fixed over time. While the analysis was run for inventory cycles of one year, we assumed no changes to purchases we otherwise know will exist during the normal course of business (i.e., Tamiflu prescriptions being dispensed during flu season and not during the rest of the year). We do not believe the move to a 340B rebate model will alter a pharmacy's regular course of business, including drug mix change; therefore, this limitation was felt to be adequately controlled, as fixing drug mix over time enables the analysis to better examine the impact specific to the 340B rebate model on cash flow. Additionally, as it relates to drug mix, we would note that our model was predicated off of FQHC provided data. The degree to which the purchase history of the provided FQHC is not representative of all FQHCs or all covered entities may have a notable impact to our findings.

3 Axis assumed that prices were static throughout our study. While we have conducted outside research that AWP and WAC prices are largely fixed over a given year time frame, particularly for brand name drugs, there is a lack of research regarding the 340B price for drugs. We know that the 340B price is tied to the MDRP, which is calculated quarterly based upon **Average Manufacturer Price (AMP)** and **Consumer Price Index (CPI)**, and thus has a degree of variability to it. Our staff has observed this variability in our prior work within Medicaid programs. Furthermore, PBM-based reimbursement terms based upon these pricing benchmarks (i.e., AWP or WAC) are likely declining over time. Again, these limitations are felt to be appropriately controlled within the context of our study, as the proposed 340B rebate model will not impact the regular course of business of covered entities purchasing 340B drugs or the industry trends regarding reimbursement pressures of prescription drugs. From a cash flow standpoint, it may actually be more advantageous for covered entities to move 340B reimbursements away from more aggressive PBM-based reimbursements to a rebate due to the trend of decreasing PBM reimbursement, particularly differential reimbursement rates for participants within the 340B program. Further study would be needed to explore this topic and its impact.

3 Axis developed its model without tracking complete purchases of the contract pharmacy to whole units. Within the existing 340B replenishment model, new inventory is not shipped to the contract pharmacy until it meets the replenishment threshold. This can be particularly concerning to contract pharmacies that dispense obscure drugs in incomplete quantities (i.e., in amounts that do not equal a whole package size). We controlled for this variable by basing

prescription dispensation volume off the supplied 340B covered entity invoice. In doing so, we ensured that complete bottles were dispensed over at least one quarter and, therefore, should meet whatever replenishment terms exist. Again, this assumption was made because it better controls for potentially confounding variables that may exist within the business operations of covered entities or their contract pharmacies. The movement to a 340B rebate model should reduce these concerns, as the rebate will not be predicated on the full purchase of a bottle. As a result, our estimate for potential cash flow savings may be underestimated as a result of failing to account for the existing issues of replenishment based 340B programs.

Finally, 3 Axis assumes that all 340B rebate revenues will be paid timely. In actual operation it is unknown whether rebates by drug manufacturers will be paid timely and the degree to which rebate invoices will be disputed. The transparency offered to drug manufacturers related to contract pharmacy claims data should hopefully limit rebate disputes. However, should rebates be delayed or disputed to lower amounts there will be cash flow implications introduced via this new model that do not exist currently.

To address the outlined limitations, 3 Axis developed a model with customizable inputs that enable a more nuanced view of the 340B rebate impact to interested covered entities based on their 340B purchasing history, historic utilization trends, and existing contractual terms.

9 GLOSSARY OF KEY TERMS

- **340B Program**
  A US federal government program created as part of the Veterans Health Care Act of 1992 that requires drug manufacturers to provide outpatient drugs to eligible health care organizations (i.e., covered entities) at significantly reduced prices
- **Contract pharmacy**
  Pharmacies contracted with covered entities within the 340B to dispense drugs to 340B eligible patients on behalf of the covered entity
- **Covered Entity**
  Covered entities are healthcare organizations able to purchases drugs at a significant discount within the 340B program created as part of the Veterans Health Care Act of 1992
- **Duplicate discounts**
  A duplicate discount occurs when inventory acquired at a 340B discount is also submitted for a Medicaid drug rebate, causing the drug manufacturer to pay two discounts on the same drug
- **Health Resources and Services Administration (HRSA)**
  An agency of the U.S. Department of Health and Human Services for improving access to health care services for people who are uninsured, isolated or medically vulnerable
- **Medicaid Drug Rebate Program (MDRP)**
  A program that includes Centers for Medicare & Medicaid Services (CMS), state Medicaid agencies, and participating drug manufacturers that helps to offset the Federal and state costs of most outpatient prescription drugs dispensed to Medicaid patients via a prescription drug rebate
- **National Drug Code (NDC)**
  A unique, three-part segmented number published by the Food and Drug Administration (FDA) used to identify for drugs within the US Drug Supply chain
- **Replenishment model**
  An inventory model which tracks 340B eligible drugs that have been dispensed at a pharmacy. When a sufficient quantity of a given drug has been dispensed on behalf of the covered entity, the covered entity purchases that quantity of the drug at the discounted 340B price and has it delivered to the contract pharmacy.
- **Third-Party Administrator (TPA)**
  Companies that provide 340B and other related services to covered entities. These services include data analytics, compliance, and contract negotiations with contract pharmacies
- **True Ups**
  The process by which inventory remediation is undertaken to address issues where the inventory of a contract pharmacy cannot be replenished by the covered entity. This can be due to drug shortages, discontinuations or other situations where a dispensed product is deemed 340B eligible but the NDC cannot be reordered for the pharmacy.

10 About 3 Axis Advisors LLC

3 Axis Advisors LLC is an elite, highly specialized consultancy that partners with private and government sector organizations to solve complex, systemic problems and propel industry reform through data-driven advocacy. With a primary focus on identifying and analyzing U.S. drug supply chain inefficiencies and cost drivers, 3 Axis Advisors LLC offers unparalleled expertise in project design, data aggregation and analysis, government affairs, and media relations. 3 Axis Advisors LLC arms clients with independent data analysis needed to spur change and innovation within their respective industries. The cofounders of 3 Axis Advisors LLC were instrumental in exposing the drug pricing distortions and supply chain inefficiencies embedded in Ohio's Medicaid managed care program. They are also the cofounders of 46brooklyn Research, a nonprofit organization dedicated to improving the transparency and accessibility of drug pricing data for the American public. To learn more about 3 Axis Advisors LLC, visit www.3axisadvisors.com.

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