IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA

ELI LILLY AND COMPANY, *Plaintiffs*, v. Alex M. AZAR II, in his official capacity as Secretary of the United States Department of Health; ROBERT P. CHARROW, in his official capacity as General Counsel of the U.S. Department of Health and Human Services; THOMAS J. ENGELS, in his official capacity as Administrator of the Health Resources and Services Administration; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; *and* HEALTH RESOURCES AND SERVICES ADMINISTRATION, *Defendants*.	Civil Action No. 1:21-cv-81-SEB-MJD

AARON VANDERVELDE'S UNOPPOSED MOTION FOR LEAVE TO FILE A BRIEF AS *AMICUS CURIAE* IN SUPPORT OF NEITHER PARTY

Aaron Vandervelde, by counsel, respectfully requests leave to file a brief as *amicus curiae* in support of neither party in the above-captioned matter. In support of his motion, Mr. Vandervelde states as follows:

1. Mr. Vandervelde is a Managing Director at Berkeley Research Group, LLC and a nationally recognized expert on the 340B program. He has testified in federal court and in arbitration on 340B contract pharmacy related matters and has conducted briefings for members of Congress and their staff on the 340B program broadly and contract pharmacy operations

specifically. He has authored numerous studies on the 340B program including how 340B pricing contributes to shifts in site of care, the participation of for-profit pharmacies in the 340B program, and factors contributing to growth in the 340B program.

2. Mr. Vandervelde has a substantial interest in this case. Among other things, he regularly consults with pharmaceutical manufacturers on different issues arising from utilization of 340B purchased drugs through contract pharmacies including duplicate Medicaid rebates, diversion of 340B purchased drugs to ineligible patients, and ineligible commercial and Medicare Part D rebates on 340B purchased drugs. His work has also included compliance consulting for 340B covered entities, audits of contract pharmacy operations for private equity firms, and primary research and data analysis for various trade organizations. With respect to his work for 340B covered entities, he has helped 340B covered entities access 340B pricing consistent with their compliance obligations under the program.

3. Mr. Vandervelde currently consults with pharmaceutical manufacturers on the various challenges that arise from 340B contract pharmacy operations. He has developed solutions that support some manufacturers' policies related to contract pharmacy utilization. He does not have a client relationship with Eli Lilly nor are the solutions that he provides to pharmaceutical manufacturers directly at issue in this case, but the ruling in this case may impact how his clients utilize the various solutions he has developed to address challenges that arise from contract pharmacy utilization in the 340B program. Mr. Vandervelde has no position on the legal issues in this case but seeks to provide background information to the Court on how contract pharmacy operations work and the compliance issues and downstream operational challenges that arise through contract pharmacy arrangements.

4. Mr. Vandervelde has contacted counsel for the Plaintiff and the Defendant regarding this motion. Counsel consent to the motion.

5. The proposed amicus brief that Mr. Vandervelde requests the Court consider is attached as Exhibit 1.

Dated: May 12, 2021

Respectfully submitted,

/s/ Dina M. Cox

Dina M. Cox, Indiana Bar No. 18590-49
J. Neal Bowling, Indiana Bar No. 19278-41
LEWIS WAGNER, LLP
501 Indiana Ave., Suite 200
Indianapolis, Indiana 46202
(317) 237-0500

CERTIFICATE OF SERVICE

I hereby certify that on May 12, 2021, I electronically filed the forgoing document. Service of this filing was made on all ECF-registered counsel by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

/s/ Dina M. Cox

Dina M. Cox, Indiana Bar No. 18590-49
J. Neal Bowling, Indiana Bar No. 19278-41
LEWIS WAGNER, LLP
501 Indiana Ave., Suite 200
Indianapolis, Indiana 46202
(317) 237-0500

EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
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BRIEF OF 340B EXPERT AARON VANDERVELDE AS AMICUS CURIAE IN SUPPORT OF NEITHER PARTY

Aaron Vandervelde
BERKELEY RESEARCH GROUP, LLC
1800 M Street, NW, Floor 2
Washington, DC 20036
T: (202) 480-2700
avandervelde@thinkbrg.com

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INTERESTS OF AMICUS CURIAE

Aaron Vandervelde is a Managing Director at Berkeley Research Group, LLC and a nationally recognized expert on the 340B program. He has testified in federal court and in arbitration on 340B contract pharmacy related matters and has conducted briefings for members of Congress and their staff on the 340B program broadly and contract pharmacy specifically. He has authored numerous studies on the 340B program including how 340B pricing contributes to shifts in site of care, the participation of for-profit pharmacies in the 340B program and factors contributing to growth in the 340B program. Among other things, he regularly consults with pharmaceutical manufacturers on different issues arising from utilization of 340B purchased drugs through contract pharmacies including duplicate Medicaid rebates, diversion of 340B purchased drugs to ineligible patients and ineligible commercial and Medicare Part D rebates on 340B purchased drugs. His work has also included compliance consulting for 340B covered entities, audits of contract pharmacy operations for private equity firms, and primary research and data analysis for various trade organizations. With respect to his work for 340B covered entities, he has helped 340B covered entities access 340B pricing consistent with their compliance obligations under the program.

He currently consults with pharmaceutical manufacturers on the various challenges that arise from 340B contract pharmacy operations. He has developed solutions that support some manufacturers' policies related to contract pharmacy utilization. He does not have a client relationship with Eli Lilly & Company nor are the solutions that he has developed at issue in this case. However, the ruling in this case may impact how his clients utilize the various solutions he has developed to address challenges that arise from contract pharmacy utilization in the 340B program. He has no position on the legal issues in this case and is solely providing background on 340B contract pharmacy operations and challenges that arise in their current form. The

information provided in this report reflects his personal understanding of the 340B program and does not necessarily reflect the views of his employer Berkeley Research Group, LLC.

INTRODUCTION

The 340B program was established in 1992 as part of the Public Health Services Act and grants certain eligible healthcare providers access to highly discounted prices on drugs dispensed or administered to eligible patients in an outpatient setting. Although a limited number of healthcare providers participated in the program initially, enrollment in the program has grown substantially over the last fifteen years and 40 percent of all hospitals and over 10,000 clinics and community health centers are registered as covered entities in the 340B program today. Between 2014 and 2019, total gross drug purchases through the 340B program grew by 350 percent – 10 times greater than growth in overall drug spending during the same period – making it the second largest federal drug purchasing program behind only Medicare Part D.

In 1996, Health Resources and Services Administration ("HRSA"), an agency of the U.S. Department of Health and Human Services, issued guidance outlining a process through which covered entities could contract with a single third-party pharmacy if the covered entity was unable to dispense 340B purchased drugs to its eligible patients through its own in-house pharmacy. This guidance improved access, for certain covered entities that did not operate a retail pharmacy, to 340B pricing on drugs dispensed to patients for self-administration at home. The contract pharmacy arrangements that covered entities established following the 1996 guidance typically involved a direct working relationship between the covered entities and the third-party pharmacies to establish patient eligibility. Inventories of 340B purchased drugs were closely managed by the covered entities and processes were established to ensure compliance with 340B program regulations.

In 2010, HRSA issued guidance that expanded the scope of contract pharmacy arrangements by notifying covered entities that they could establish an unlimited number of contract pharmacy arrangements. This ushered in an era of greatly expanded use of contract pharmacy arrangements supported by automated processes run by third party software vendors. These processes relied on a "replenishment model" where prescriptions were initially filled from a common inventory and later replenished with 340B purchased drugs. 340B eligibility was determined after the prescription was dispensed to the patient and paid for by a health insurance plan reducing the process to an accounting exercise supported by inventory replenishment. At the same time, HRSA relaxed its oversight of contract pharmacy arrangements as it shifted from comprehensive annual audits of all contract pharmacy arrangements to a recommendation that covered entities conduct self-audits of a small sample of claims. As HRSA initiated its 340B program audits in 2012 and began auditing contract pharmacy arrangements again, it became apparent that contract pharmacy arrangements were the single largest source of non-compliance in the 340B program.

When HRSA issued guidance regarding contract pharmacy arrangements in 1996, it sought to address a specific access issue that prevented certain covered entities from full participation in the 340B program. However, HRSA's 2010 guidance, which approved of unlimited contract pharmacy arrangements, and its limited oversight of these arrangements has created a number of challenges for a variety of 340B program stakeholders. In addition to the continued high rate of non-compliance with the 340B statute, a lack of transparency around contract pharmacy utilization creates challenges for patients, payers and pharmaceutical manufacturers. Outsized profit margins on 340B purchased drugs also create incentives for covered entities and their contract pharmacies to utilize more drugs and drugs with a higher list

price. These challenges have been amplified by significant growth in covered entity enrollment. In the absence of regulatory oversight, some pharmaceutical manufacturers and payers have taken independent actions to address these challenges.

DISCUSSION

I. The 340B Program has Grown Considerably Since Its Inception Which Amplifies the Impact of 340B Related Policies and Court Rulings.

A. The 340B Program Was Established in 1992 to Provide Discounted Drug Pricing to America's "Safety Net" Providers.

Congress established the 340B drug purchasing program in 1992 as part of the Public Health Services Act to "enable [covered entities] to stretch scarce Federal resources as far as possible" by providing access to discounted pricing on outpatient drugs.[1] Section 340B initially provided access to discounted drugs to certain healthcare providers that received federal grants ("Grantees") and approximately 100 non-profit disproportionate share hospitals that met certain eligibility requirements ("340B Hospitals"). These healthcare providers (referred to collectively as "covered entities") predominantly served uninsured or under-insured, low-income patients and constituted a "safety net" in America's healthcare system. The 340B program created a safe harbor for these safety net providers to purchase outpatient drugs at a discounted price without impacting the price at which pharmaceutical manufacturers sold their products in the Medicaid program.

[1] H.R. Rep. No. 102-384(II), at 12 (1992)

B. Participation in the 340B Program Has Increased Substantially over the Past Fifteen Years Due to a Variety of Factors

The 340B program was largely stable during the first ten years of its existence. By 2004 there were 6,760 Grantees and 168 340B Hospitals enrolled in the program.[2] A study commissioned by HRSA found that in 2004 340B Hospitals accounted for almost 50 percent of 340B purchases and estimated total drug purchases through the 340B program at $2.5 billion.[3]

The 340B program grew rapidly over the next fifteen years and by 2019, the most recent data available, total 340B purchases reached $30 billion.[4] 340B Hospital enrollment had grown to 2,439[5] - 40 percent of all US hospitals - and accounted for almost 90 percent of all 340B purchases.[6] Growth in 340B Hospital enrollment is attributable to at least three primary factors. First, Congress changed the formula for calculating the disproportionate share hospital ("DSH") percentage as part of the Medicare Modernization Act of 2003.[7] This change led to increased eligibility of 340B Hospitals and over 600 disproportionate share hospitals gained eligibility and enrolled in the 340B program between 2004 and 2009.[8] Second, in 2010 Congress created new eligibility pathways as part of the Patient Protection and Affordable Care Act ("Affordable Care Act") for critical access hospitals, sole community hospitals, rural referral centers and

[2] Based on analysis of 2004 HRSA 340B enrollment data

[3] Mathematica Policy Research, The PHS 340B Drug Pricing Program: Results of a Survey of Eligible Entities, at 44 (August 2004), *available at* https://www.mathematica.org/our-publications-and-findings/publications/the-phs-340b-drug-pricing-program-results-of-a-survey-of-eligible-entities

[4] Adam Fein, Drug Channels, *New HRSA Data: 340B Program Reached $29.9 Billion in 2019; Now Over 8% of Drug Sales* (June 2020), *available at* https://www.drugchannels.net/2020/06/new-hrsa-data-340b-program-reached-299.html

[5] Based on analysis of 2019 HRSA enrollment data

[6] The 340B Prime Vendor Program; Supporting All Stakeholders, Chris Hatwig, 340B Coalition 2014 Winter Conference, February 2014, **Attachment 1**

[7] Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. No. 108-173, Title IV, § 402 (2003)

[8] Based on analysis of 2009 HRSA enrollment data

freestanding cancer centers to enroll in the 340B program.[9] There are over 1,400 of these hospital types participating in the 340B program today.[10] Third, increased enrollment in the Medicaid program following changes to Medicaid eligibility criteria in the Affordable Care Act contributed to increased eligibility of non-profit disproportionate share hospitals, pediatric hospitals and sole community hospitals. This occurred because 340B eligibility for these hospital types includes a requirement that their DSH percentage exceeds a certain threshold. The DSH percentage is calculated in part based on the percentage of a hospital's inpatients that are enrolled in Medicaid.[11] As Medicaid enrollment increases, the Medicaid percentage of a hospital's inpatients also increases which leads to a higher DSH percentage. Since 2015, over 350 disproportionate share hospitals, pediatric hospitals and sole community hospitals gained eligibility and enrolled in the 340B program due to Medicaid expansion.[12]

C. The 340B Program is the Second Largest Government Drug Purchasing Program and Is Increasingly an Area of Focus for a Variety of Stakeholders

340B program growth, which exceeded 350 percent between 2014 and 2019,[13] has outpaced growth in pharmaceutical spend overall (35 percent)[14] and growth in spending for other

[9] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, Title VII, § 7101 (2010)

[10] Based on analysis of 2021 HRSA enrollment data

[11] 42 C.F.R. § 412.106

[12] Based on analysis of 2021 HRSA enrollment data and Medicare Provider Specific Files

[13] Adam Fein, Drug Channels, *New HRSA Data: 340B Program Reached $29.9 Billion in 2019; Now Over 8% of Drug Sales (June 2020)*, *available at* https://www.drugchannels.net/2020/06/new-hrsa-data-340b-program-reached-299.html.

[14] The IQVIA Institute, Medicine Use and Spending in the U.S., at 53 (April 2018) *available at* https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-use-and-spending-in-the-us-a-review-of-2017-and-outlook-to-2022.pdf? and The IQVIA Institute, Medicine Spending and Affordability in the United States, at 33 (August 2020) *available at* https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-use-and-spending-in-the-us-a-review-of-2017-and-outlook-to-2022.pdf?

government programs such as Medicaid (55 percent)[15] and Medicare (30 percent)[16]. By 2018, drug purchases through the 340B program accounted for 14 percent of all branded outpatient drug sales and was the second largest government drug purchasing program behind only Medicare Part D.[17] As the 340B program has grown, policy decisions and issues related to the 340B program have grown in importance to a variety of stakeholders and a broad range of stakeholders are increasingly focused on addressing the various challenges the 340B program presents. In addition to the recent policy positions that manufacturers have taken related to 340B contract pharmacy utilization, health plans and PBMs have instituted or sought to institute policies to reduce reimbursement on 340B purchased drugs[18,19], CMS has reduced Medicare Part B reimbursement on drugs purchased through the 340B program[20], states have introduced laws

[15] MACPAC, Medicaid Drug Spending Trends, Table 1 (February 2019) *available at* https://www.macpac.gov/wp-content/uploads/2019/02/Medicaid-Drug-Spending-Trends.pdf and MACPAC, Medicaid Drug Spending and Rebates For Drugs by Delivery System, Exhibit 28 (December 2020) *available at* https://www.macpac.gov/wp-content/uploads/2015/11/EXHIBIT-28.-Medicaid-Gross-Spending-and-Rebates-for-Drugs-by-Delivery-System-FY-2019-millions.pdf

[16] The Medicare Trustees, 2020 Medicare Trustees Report, at 10 (April 2020) *available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2015.pdf and The Medicare Trustees, 2015 Medicare Trustees Report, at 11 (July 2015) *available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2015.pdf*

[17] Aaron Vandervelde et al., *Revisiting the Pharmaceutical Supply Chain: 2013-2018* at 8 (Jan. 2020), *available at https://www.thinkbrg.com/insights/publications/revisiting-the-pharmaceutical-supply-chain-2013-2018/*

[18] Sara J. Dingwall et al., Re: Proposed Acquisition by Aetna of Humana – Impact on 340B Safety Net Providers and Their Patients, at 2 (Dec. 2016), *available at* https://www.rwc340b.org/wp-content/uploads/2017/03/Letter-to-DOJ-re.-Acquisition-of-Humana-by-Aetna-D0697847.pdf

[19] Susannah Luthi, Modern Healthcare, *CVS Caremark reverses course on planned pay cuts to 340B providers* (Feb. 2019), *available at* https://www.modernhealthcare.com/article/20190211/NEWS/190219992/cvs-caremark-reverses-course-on-planned-pay-cuts-to-340b-providers

[20] 85 Fed. Reg. 84,472 (2020), *available at https://www.govinfo.gov/content/pkg/FR-2020-12-28/pdf/2020-26815.pdf*

or regulations excluding Medicaid utilization from 340B pricing[21] and PBMs have instituted policies regarding the inclusion of 340B claims identifiers in prescription claims data[22,23].

II. Contract Pharmacy Arrangements Initially Addressed Access Issues but Evolved into a Mechanism to Increase 340B Program Income

A. Contract Pharmacy Arrangements were Introduced through Guidance in 1996 and Broadened in 2001 to Address Access Issues

In 1996, HRSA published guidelines for covered entities seeking to contract with a third-party pharmacy to dispense 340B purchased drugs.[24] HRSA sought to broaden access to 340B priced drugs for those covered entities that did not have the ability to dispense 340B purchased drugs directly to its patients because they did not maintain an in-house dispensing pharmacy. HRSA noted specifically "…only a very small number of the 11,500 covered entities used in-house pharmacies (approximately 500) ..." HRSA's guidance enabled 340B covered entities that did not have an in-house pharmacy capable of dispensing 340B purchased drugs to patients to contract with a single third-party pharmacy for that purpose. Despite HRSA's observation that very few covered entities operated in-house pharmacies, by the end of 2000 (4 years after the 1996 guidance was issued), only 47 covered entities had registered contract pharmacies.

In 2001, HRSA established Alternative Methods Demonstration Projects ("AMDPs"), which broadened the use of contract pharmacies for certain covered entities that applied to and were approved by HRSA. As noted in the 2007 Federal Register, "[t]he intent was to allow

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[21] GAO, *340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate*, at 16 (Jan. 2020), *available at* https://www.gao.gov/assets/710/706831.pdf

[22] The 340B Coalition, Re: New 340B Claim Identification Requirement, at 1 (March 2021), *available at* https://340breport.com/wp-content/uploads/2021/04/340B_Coalition_Letter_to_Express_Scripts_3_26_21.pdf

[23] Tom Mirga, 340B Report, *Providers Worried About Humana's 340B Claims ID and Data-Reporting Conditions* (March 2021), *available at* https://340breport.com/providers-worried-about-humanas-340b-claims-id-and-data-reporting-conditions/

[24] 61 Fed. Reg. 43,549 (1996), **Attachment 2**

community health centers and other 340B safety-net providers to develop new ways to improve access to 340B prescription drugs for their patients."[25] The AMDPs were managed closely by HRSA and all covered entities that pursued an AMDP were subject to annual independent audits to ensure compliance with prohibitions against duplicate discounts and diversion.[26] As of April 2006, 18 AMDPs were approved by HRSA of which 17 were operational at the time of the 2007 Federal Register notice.[27] By the end of 2009, there were a total of 2,031 contract pharmacy arrangements inclusive of both AMDP and non-AMDP registrations.[28]

B. In 2010, HRSA Issued Guidance Allowing Covered Entities to Contract with an Unlimited Number of Third-Party Pharmacies

Despite limited experience with just 18 AMDPs, HRSA issued proposed guidance in 2007 which approved of 340B covered entities contracting with an unlimited number of third-party pharmacies.[29] This guidance was finalized in 2010 and unlike the 1996 guidance, where HRSA outlined a clear access issue that would be addressed through contract pharmacy arrangements (i.e. "…only a very small number of the 11,500 covered entities used in-house pharmacies…"), HRSA offered no evidence of the existence of continued access issues that would be addressed by allowing an unlimited number of contract pharmacy arrangements. The effect of the expanded contract pharmacy guidance was that covered entities were able to increase profits generated from 340B purchased drugs by enabling additional prescriptions to be classified as 340B. It is unclear whether profiting from 340B purchased drugs is consistent with the original intent of the 340B program, but covered entities clearly recognized the opportunity

[25] 72 Fed. Reg 1,540 (2007), **Attachment 3**

[26] 72 Fed. Reg 1,540 (2007)

[27] 72 Fed. Reg 1,540 (2007)

[28] Based on analysis of 2009 HRSA enrollment data

[29] 75 Fed. Reg 10,277 (2010), **Attachment 4**

this new guidance presented and over the next ten years, over 100,000 contract pharmacy arrangements were registered with HRSA.

In finalizing the 2010 guidance, HRSA responded to commenters who expressed concern about the potential for diversion and duplicate discounts as a result of the new guidance by noting only that "HRSA believes that there are appropriate safeguards in place, based on the parameters of the program." At the same time HRSA's guidance significantly expanded the scope of contract pharmacy arrangements, it removed its mandatory independent audits and replaced them with a recommendation that covered entities conduct annual self-audits on a small sample of contract pharmacy prescriptions.[30] It is unknown whether all covered entities have employed these self-audits and what corrective actions have been taken based on the audit findings, but audits conducted by HRSA between 2012 and 2019 demonstrate that contract pharmacies have been and continue to be a primary source of duplicate discounts and diversion.[31]

III. Contract Pharmacy Operations Have Evolved from a Direct Working Relationships between Covered Entities and Their Contract Pharmacies to an Automated Process that Supports the Sophisticated Operations of Fortune 50 Companies

A. Contract Pharmacy Operations Were Initially Direct Working Relationships between Covered Entities and Their Contract Pharmacies

When HRSA published the 1996 contract pharmacy guidance, it provided program requirements that supported a direct working relationship between the covered entity and the contract pharmacy. HRSA required that a pharmacy could only dispense a 340B purchased drug if the prescription included "…a designation that the patient is an eligible patient".[32] This meant

[30] 75 Fed. Reg 10,274 (2010)

[31] Based on analysis of HRSA audit findings for 2012 through 2019

[32] 61 Fed. Reg. 43,549 (1996)

that the covered entity established patient eligibility prior to writing the prescription and included a designation of that eligibility on the prescription itself. When the contract pharmacy received the prescription, 340B status was clearly indicated and the pharmacy knew the prescription was to be filled with a 340B purchased drug prior to the drug being dispensed. In practice, most contract pharmacies maintained a separate physical inventory of 340B purchased drugs and dispensed drugs from that inventory when presented with a prescription that included the 340B designation. Although this process was manual and required maintaining a separate physical inventory, it was also simple and very effective at ensuring compliance with the prohibitions against diversion and duplicate discounts. A simple diagram of the process for dispensing 340B purchased drugs through a contract pharmacy is as follows:

HRSA further established that auditable records must be maintained to ensure that 340B purchased drugs were not dispensed to ineligible patients and to prevent duplicate Medicaid rebates. HRSA made clear that "[i]f the drug generates a Medicaid rebate or is diverted to an individual who is not a patient of the covered entity, the entity will be responsible for such activity." In light of these requirements, 340B covered entities worked directly with their contract pharmacies to ensure that 340B purchased drugs were dispensed to eligible patients and that duplicate discounts did not occur. The result of this highly collaborative approach was that

HRSA found no evidence of drug diversion in those contract pharmacy arrangements registered following the 1996 guidance or through the AMDPs.[33]

B. HRSA's 2010 Guidance Relaxed Requirements Related to 340B Eligibility Determination and Set the Stage for Automated Processes

In 2010, HRSA issued guidance that approved of covered entities contracting with an unlimited number of third-party pharmacies to dispense 340B purchased drugs. Much of the language that existed in the 1996 guidance was incorporated into the 2010 guidance including the requirement that the prescription include "…a designation that the patient is an eligible patient of the covered entity…" However, the process for determining 340B eligibility for prescriptions dispensed through a contract pharmacy evolved as covered entities rapidly expanded their utilization of contract pharmacies.

First, numerous software companies began offering solutions to covered entities for administering contract pharmacy arrangements. These third-party administrators ("TPAs") provided automated programs that combined medical claims data provided by the covered entities with prescription claims data provided by the contract pharmacy to identify prescriptions that were 340B eligible. These solutions replaced the direct working relationship between the covered entity and pharmacy with a highly scalable, highly automated process that enabled a single covered entity to contract with hundreds of different pharmacies and a single pharmacy to contract with hundreds of different covered entities. Establishing a broad network of contract pharmacies was appealing to covered entities because their patients chose to use any number of different pharmacies to fill their prescriptions. A broad network of contract pharmacies increased the likelihood that patients would choose to fill their prescriptions at a contract

[33] 72 Fed. Reg 1540 (2007)

pharmacy of the covered entity allowing for the prescription to be classified as 340B. As the volume of 340B prescriptions grew, contract pharmacies recognized the benefit of controlling the automated processes that determined 340B eligibility. Today the largest contract pharmacies all own and operate TPAs including Walgreens, CVS and Accredo.[34]

Second, HRSA acknowledged in a 2013 340B Program Notice that some covered entities utilized a "replenishment" model whereby non-340B purchased drugs were initially dispensed to a patient and then "replenish[ed] with 340B drugs once 340B patient eligibility is confirmed and can be documented through auditable records."[35] In addition to being inconsistent with the 2010 guidance which required that 340B eligibility be designated on the prescription, the replenishment model also represented a sizeable shift from how contract pharmacy arrangements were administered prior to the 2010 guidance in that identification of 340B eligible prescriptions took place after the prescription had already been filled. In the replenishment model, covered entities and contract pharmacies no longer worked together to establish 340B eligibility at the time of dispense. Instead, 340B eligibility determination was made days, weeks, months or, in some instances even a year or more after a prescription was filled and only then was a replenishment order at the 340B price placed on behalf of the covered entity. This effectively turned 340B eligibility determination and inventory management into an accounting exercise that allowed for a restatement of the acquisition price of the drug to the discounted 340B price and

[34] Blue and Co, *CVS Health has acquired 340B software provider, Wellpartner, Inc* (Jan. 2018), *available at* https://www.blueandco.com/cvs-health-has-acquired-340b-software-provider-wellpartner-inc/ and Verity Solutions, *Announcing Verity Solutions Acquisition by Express Scripts / Cigna* (October 2018), *available at* https://www.verity340b.com/verity-solutions-acquisition-by-express-scripts/ and https://www.walgreens.com/businesssolutions/payer/340BComplete.jsp

[35] Department of Health and Human Services, Statutory Prohibition on Group Purchasing Organization Participation, at 3 (Feb. 2013), *available at* https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/prohibitionongpoparticipation020713.pdf

creation of enhanced profitability of the prescription. This replenishment model became the predominant model in contract pharmacy arrangements and worked as follows:

IV. The Prevailing Replenishment Model Presents a Variety of Challenges for Stakeholders in the 340B Program

A. Diversion of 340B Purchased Drugs to Ineligible Patients is Commonplace in Contract Pharmacy Utilization

The evolution of contract pharmacy operations away from a collaborative approach between a covered entity and a single contract pharmacy to an automated process that identifies millions of prescriptions as 340B eligible each year created a variety of challenges for 340B stakeholders. First, it laid the groundwork for many covered entities' inability to follow program guidance and "[e]nsure against illegal diversion". Diversion, which occurs when a 340B purchased drug is dispensed to an ineligible patient, in contract pharmacy utilization can be attributed to two primary factors. First, a prescription claim does not include information on where a patient was seen at the time the prescription was written. It is unknown if the patient was seen at a 340B covered entity location or in a physician's private office. Second, a medical claim, which reflects the physician services billed to a health insurance plan and helps establish the patient eligibility, does not include information on whether the healthcare encounter resulted in a prescription being written nor a reference number to link a specific prescription with the

healthcare encounter. Lacking either of these critical pieces of information, TPAs devised algorithmic approaches to predict which prescriptions had a high likelihood of being 340B eligible. Furthermore, the TPAs enabled covered entities to configure the algorithms to be more inclusive or less inclusive. For example, a covered entity could configure the algorithm to designate a prescription as 340B eligible if the patient had a healthcare encounter at the covered entity on the same day, within the prior week, within the prior month or at any time in the prior year. Depending on how the algorithm was configured, a greater or lesser number of prescription drug claims would be identified as 340B eligible.

Since the 2010 contract pharmacy guidance, diversion has remained a challenge for covered entities. As the Government Accountability Office (GAO) observed in its 2018 report on contract pharmacy oversight, over two thirds of all findings of diversion in HRSA audits are attributable to contract pharmacy utilization.[36] 31 percent[37] of audited covered entities that used contract pharmacies between 2012 and 2019 (the last full year of audits) were found to have diverted 340B purchased drugs to ineligible patients through their contract pharmacies. Despite this high rate of non-compliance with the statutory prohibition against diversion, HRSA's corrective action plans simply required the covered entities to repay pharmaceutical manufacturers for the diverted drugs identified as part of the audit.[38] Covered entities were not subject to fines, barred from participation in the 340B program or required to conduct thorough audits of all contract pharmacy utilization to identify all instances of diversion.

[36] GAO, Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, at 44 (Table 7) (June 2018), *available at* https://www.gao.gov/assets/700/693080.pdf

[37] Based on analysis of HRSA audit findings for 2012 through 2019

[38] Based on analysis of HRSA audit findings for 2012 through 2019

B. Duplicate Medicaid Rebates for Managed Medicaid Claims Remain a Risk in Contract Pharmacy Operations

The 340B statute prohibits pharmaceutical manufacturers from paying a Medicaid rebate on a drug purchased at the 340B price. There is good reason for this – namely it is not uncommon for the Medicaid rebate to exceed the 340B price. When duplicate Medicaid rebates occur, a pharmaceutical manufacturer's net revenue on the prescription can become negative. Despite this statutory prohibition and the obvious financial harm to pharmaceutical manufacturers resulting from duplicate Medicaid rebates, HRSA has yet to issue guidance outlining how covered entities are to prevent duplicate discounts on managed Medicaid utilization and does not currently audit covered entities for duplicate discounts in managed Medicaid utilization.[39]

With no enforcement mechanism in place, HRSA is relying on 340B covered entities and their TPAs to properly identify and exclude managed Medicaid prescriptions from 340B. This presents real challenges for covered entities with contract pharmacy utilization. The prevailing replenishment model identifies 340B eligibility <u>after the prescription has been dispensed to the patient and reimbursed by the payer</u>. As a result, there is no 340B indicator on the prescription that a state Medicaid agency can utilize to identify that the prescription is not eligible for a rebate. Lacking this identifier, the state Medicaid agency will include the prescription in its rebate invoice and the pharmaceutical manufacturer will pay a duplicate discount.

In order to ensure a duplicate discount does not occur, a covered entity must properly identify and exclude the claim as non-340B eligible. This is challenging for several reasons. First, there is no indicator on a prescription that identifies the patient as a managed Medicaid

[39] GAO, Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, at 2 (June 2018), *available at* https://www.gao.gov/assets/700/693080.pdf

beneficiary. Instead, covered entities and TPAs must rely on financial information on the prescription claim regarding what payer reimbursed the claim. Second, this financial information does not always uniquely identify a payer as managed Medicaid. Managed Medicaid plans are run by private health insurance companies that receive payments from a state Medicaid program and often offer a combination of managed Medicaid and commercial health plans. In many instances a payer's financial information relates to both their commercial and managed Medicaid beneficiaries which makes it almost impossible to distinguish between the two. Third, unlike Medicare, a beneficiary's enrollment status in Medicaid can change on a monthly basis at any point throughout the year. A patient may be covered by a managed Medicaid plan in one month, a commercial plan in the next month and can be uninsured in the following month. As a result, a prescription for that beneficiary could be 340B eligible in one month and non-340B eligible in the following month.

Due to these factors, the risk for duplicate Medicaid rebates on managed Medicaid utilization is very high. Unfortunately, HRSA does not audit for duplicate discounts in the managed Medicaid population and it is unknown how commonly they occur. HRSA does audit for duplicate discounts for those prescriptions reimbursed directly by a state Medicaid program and despite regulatory guidance on how covered entities are to ensure against this statutory prohibition, duplicate discounts were identified in over 25 percent of audits conducted by HRSA between 2012 and 2019.[40]

[40] Based on analysis of HRSA audit results.

C. Lack of Transparency Creates Challenges for Payers to Offset Increases in the Net Cost of 340B Prescriptions

The 340B program is often viewed as a program with limited stakeholders – covered entities, pharmaceutical manufacturers and, more recently, contract pharmacies. However, as the 340B program has grown larger and more complex, the impact of the program on other stakeholders is coming into focus. Payers, which include health plans, pharmacy benefit managers and state and federal agencies are also impacted by the 340B program. Pharmaceutical manufacturers are prohibited from paying a Medicaid rebate on a drug purchased at the 340B price.[41] When a 340B purchased drug is dispensed to a Medicaid beneficiary, the state Medicaid agency is not allowed to collect a rebate from the pharmaceutical manufacturer on that prescription. Similarly, rebate agreements between pharmaceutical manufacturers and commercial and Medicare Part D plans exempt drugs obtained through federal programs from rebate eligibility. This includes drugs purchased through the 340B program and, as a result, commercial and Medicare Part D plans are not allowed to collect rebates on prescriptions filled with 340B purchased drugs. Paradoxically, the net cost to the payer of a prescription increases when that prescription is determined to be 340B eligible. In response to this increase in net cost, payers have sought to reduce reimbursement on 340B purchased drugs.

Reducing reimbursement on 340B purchased drugs dispensed through a contract pharmacy using a replenishment model is particularly challenging for a payer because the 340B status of the prescription is not known at the time of dispense. Furthermore, when a TPA does make a 340B eligibility determination after the drug has been dispensed and reimbursed, there is no feedback loop to the payer to notify it of the 340B designation. This lack of transparency

[41] 42 U.S.C. § 256b (Section 340B)

benefits the covered entity and contract pharmacy because it makes it more difficult for payers to reduce reimbursement on 340B purchased drugs. Many payers have sought to compel covered entities and their contract pharmacies to provide this information but, to date, these efforts have proven unsuccessful.[42]

D. Outsized Profit Margins in Contract Pharmacy Utilization Creates Incentives for Program Abuse

When Congress created the 340B program, it allowed covered entities access to a statutory price similar to the net Medicaid price. Due to a combination of the statutory pricing formula and market dynamics in competitive therapeutic categories, the 340B price for a drug is often much lower than the list price and in certain instances can drop to a single penny. A 2021 Congressional Budget Office study found that the net Medicaid price (which is the basis for the 340B price) on a market basket of 176 top-selling brand outpatient drugs was the lowest of any government purchasing program by a significant amount.[43] Mr. Vandervelde's own research has estimated covered entity margins on 340B brand drugs dispensed through contract pharmacies exceed 70 percent[44] which is twenty times greater than the average retail pharmacy margin for brand drugs.[45]

The potential for outsized margins available on 340B purchased drugs creates incentives for covered entities to favor higher cost brand drugs with the potential for larger margins. A

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[42] The 340B Coalition, Re: New 340B Claim Identification Requirement, at 1 (March 2021), *available at* https://340breport.com/wp-content/uploads/2021/04/340B_Coalition_Letter_to_Express_Scripts_3_26_21.pdf.

[43] Congressional Budget Office, A Comparison of Brand-Name Drug Prices Among Selected Federal Programs, at 2 (Feb. 2021), *available at* https://www.cbo.gov/system/files/2021-02/56978-Drug-Prices.pdf.

[44] Aaron Vandervelde et al., *For-Profit Pharmacy Participation in the 340B Program*, at 4 (Oct. 2020), *available at* https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf.

[45] Neeraj Sood et al., USC Schaeffer, *The Flow of Money Through the Pharmaceutical Distribution System*, at 5 (June 2017) *available at* https://healthpolicy.usc.edu/wp-content/uploads/2017/06/USC_Flow-of-MoneyWhitePaper_Final_Spreads.pdf

GAO study in 2015 found that "beneficiaries at 340B DSH hospitals were either prescribed more drugs or more expensive drugs than beneficiaries at the other hospitals in GAO's analysis."[46] The potential for outsized margins on 340B purchased drugs has also attracted some of the largest for-profit entities in the US. Walgreens and CVS operate large networks of contract pharmacy arrangements (36,309 and 32,336 respectively)[47] that span the country. Their operations are vertically integrated with TPAs such that the pharmacy controls the process of identifying the 340B eligible prescriptions, purchasing the replenishment inventory, dispensing the drug and collecting reimbursement on the prescription. These health conglomerates have captured a large share of the 340B margins and are generating hundreds of millions of dollars in 340B profits each year.[48]

CONCLUSION

HRSA's expansion of the contract pharmacy program in 2010 to allow an unlimited number of contract pharmacies has created numerous challenges for a variety of stakeholders. The highly automated processes that have been developed to facilitate the expansion of the program have led to high rates of diversion and duplicate discounts. The lack of transparency in contract pharmacy operations has led to increased prescription drug costs to payers while generating enormous profits for contract pharmacies. Despite years of HRSA audits that demonstrated high rates of duplicate discounts and diversion in contract pharmacy utilization, covered entities experienced little to no consequences for their failure to comply with the 340B

[46] GAO, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals, at 2 (June 2015), *available at* https://www.gao.gov/assets/gao-15-442.pdf.

[47] Based on analysis of 2021 HRSA contract pharmacy enrollment

[48] Eric Percher et al., Nephron Research, *The 340B Program Reaches a Tipping Point:Sizing Profit Flows & Potential Disruption*, at 7 (December 2020), **Attachment 5**

statute. As a result, 340B stakeholders, including pharmaceutical manufacturers and payers, are taking action to address the challenges inherent to 340B utilization through contract pharmacies.

Dated: May 12, 2021

Respectfully submitted,

/s/ Dina M. Cox

Dina M. Cox, Indiana Bar No. 18590-49
J. Neal Bowling, Indiana Bar No. 19278-41
LEWIS WAGNER, LLP
501 Indiana Ave., Suite 200
Indianapolis, Indiana 46202
(317) 237-0500

CERTIFICATE OF SERVICE

I hereby certify that on May 12, 2021, I electronically filed the forgoing document. Service of this filing was made on all ECF-registered counsel by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

/s/ Dina M. Cox

Dina M. Cox, Indiana Bar No. 18590-49
J. Neal Bowling, Indiana Bar No. 19278-41
LEWIS WAGNER, LLP
501 Indiana Ave., Suite 200
Indianapolis, Indiana 46202
(317) 237-0500

ATTACHMENT 1

Apexus®

The 340B Prime Vendor Program; Supporting All 340B Stakeholders

Christopher Hatwig, *President*, Apexus

340B Intent

Apexus

To permit covered entities “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”

H.R. Rep. No. 102-384(II), at 12 (1992)

Top Three C-Suite Myths

1. “This program can run itself—or at least the pharmacy director can just manage it.”
2. “Proposals from contract pharmacies or 3rd party vendors must be in our best interest if the bottom line looks good.”
3. “The team can probably pull together the data for a 340B audit without much effort.”

Prime Vendor Program History

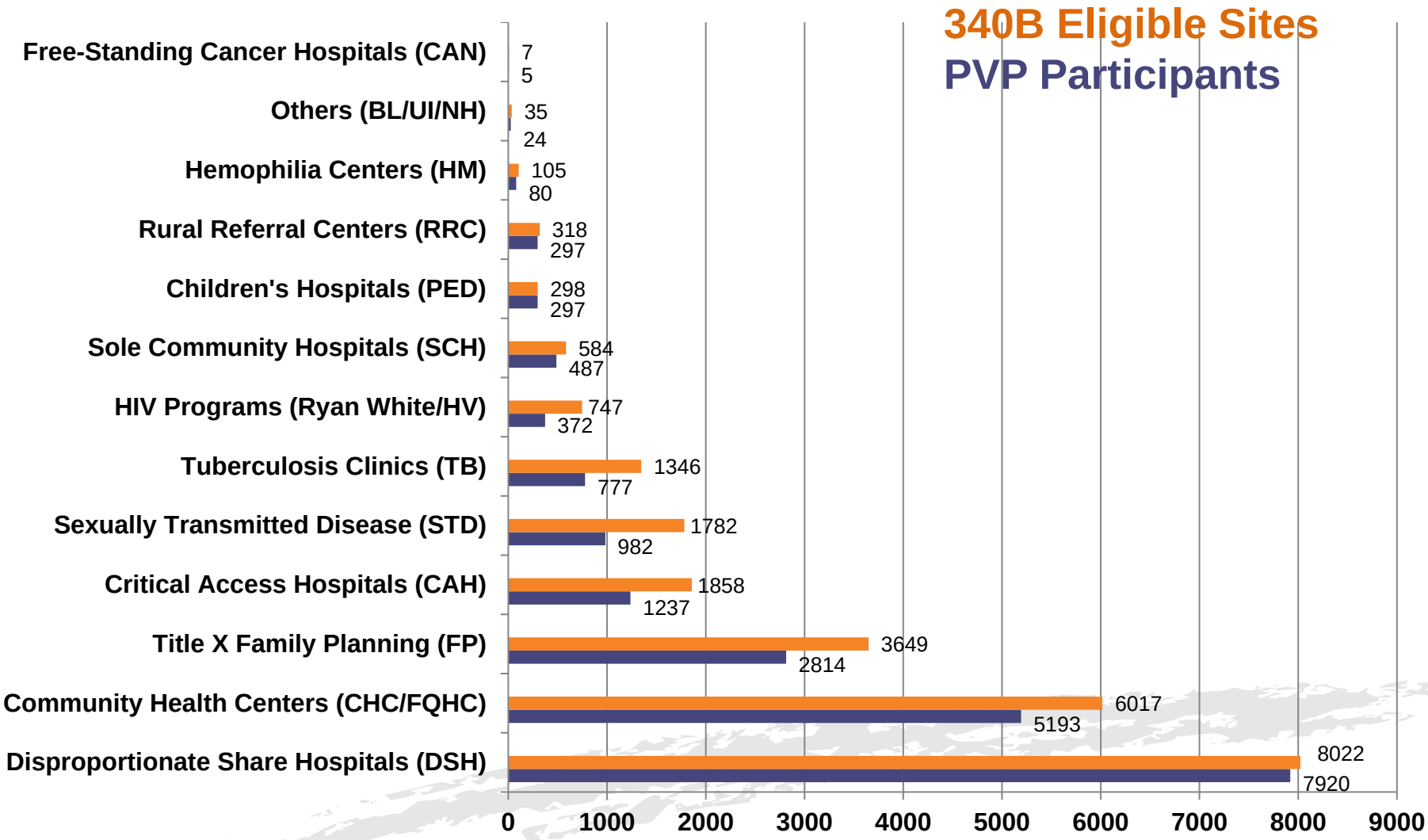
- Statutory requirement
- Competitively bid contract
- 1999 first Prime Vendor contract awarded
- Apexus awarded Health Resources and Services Administration (HRSA) agreement in 2004 & 2009

Prime Vendor Program

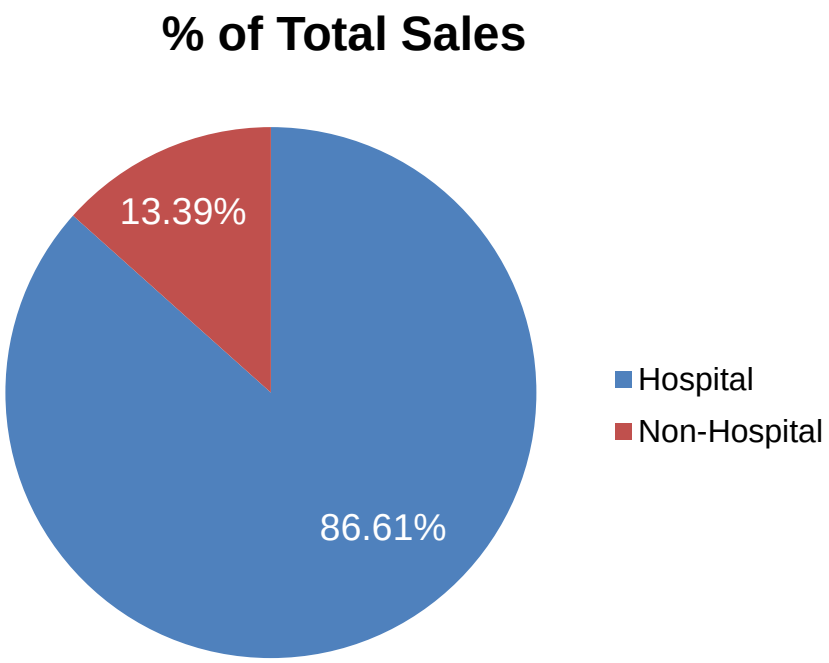
- Entity benefits
  - No cost to participate
  - Exclusive access to:
    - Sub-340B and sub-WAC pricing on pharmaceuticals
    - Discounts on value added products, services, and supplies
    - Apexus Generics Program
  - Pricing transparency
  - Spend optimization reports and tools
  - 340B University
  - ApexusAnswers Call Center

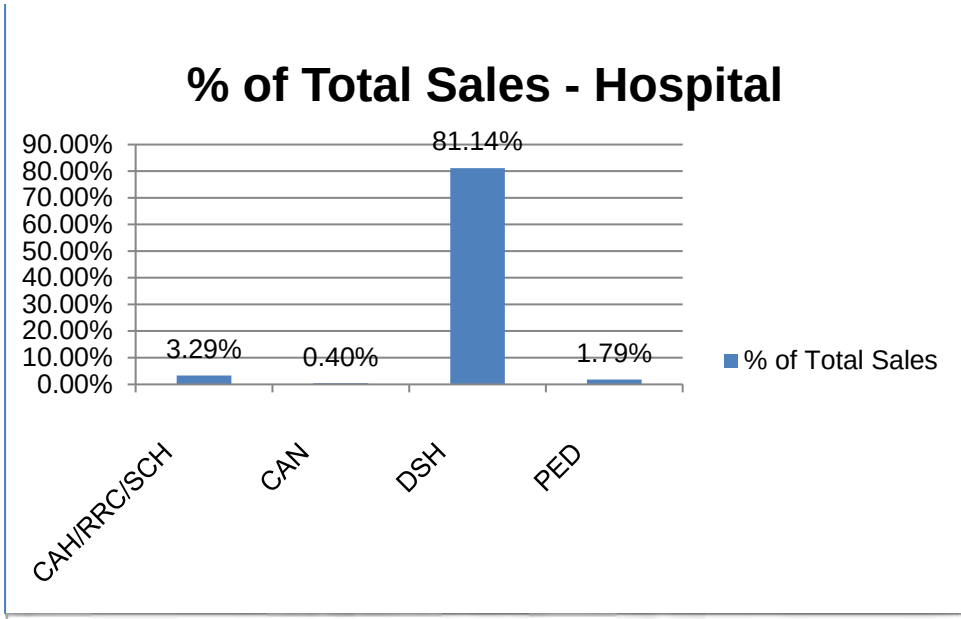
PVP Enrollment: 20,485 (83%)
HRSA Total: 24,768 (March 1, 2014)

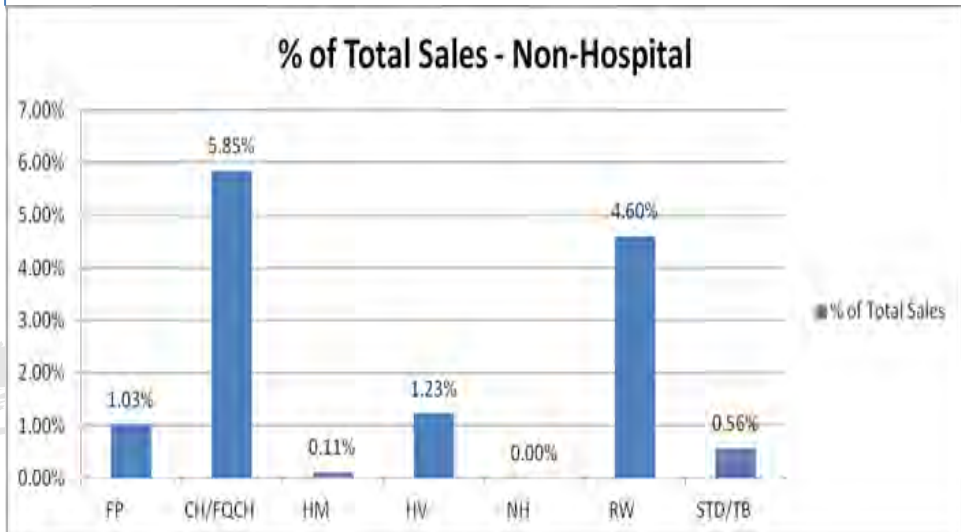
Apexus



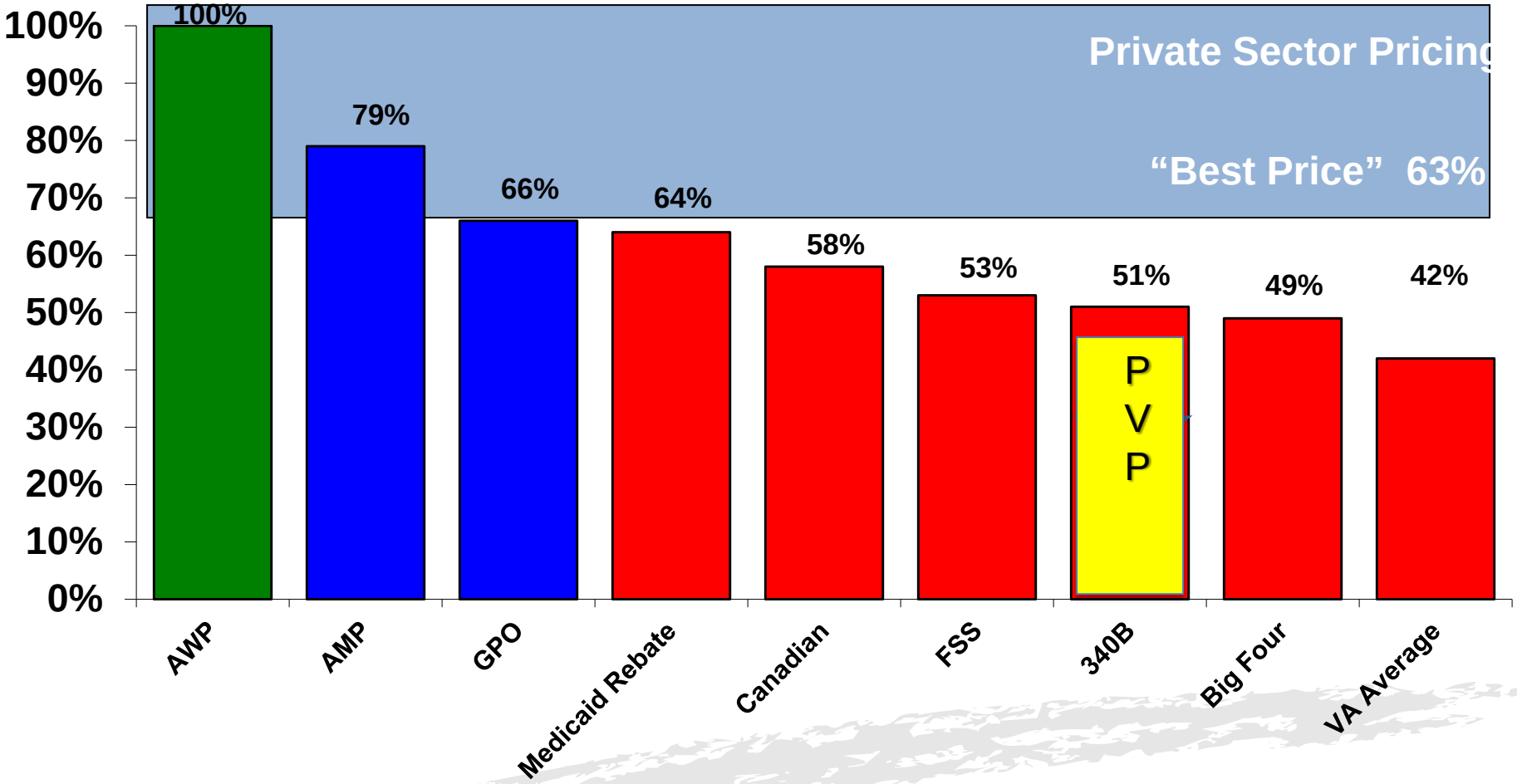
Breakout of 340B Sales by Entity







Relative Pricing



Adapted from a slide by Safety Net Hospitals for Pharmaceutical Access
Source: Data derived from Prices for Brand-Name Drugs Under Selected Federal Programs, Congressional Budget Office (June 2005)

Apexus Focus

Apexus

TEAMWORK

Contract Services

TRUTH

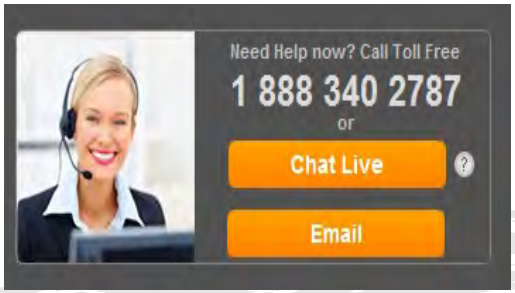
Apexus Answers Call Center

TEACHING

340B University & 340B OnDemand

340B™ Prime Vendor PROGRAM

Managed by Apexus



340B UNIVERSITY
1992
APEXUS

Apexus

TEAMWORK:

CONTRACT SERVICES

Apexus Responsive to HRSA Policy

- As HRSA issues policy clarifications, Apexus must be flexible to offer solutions to enable entities to comply
- Examples
  - Refund Service
  - GPO Prohibition

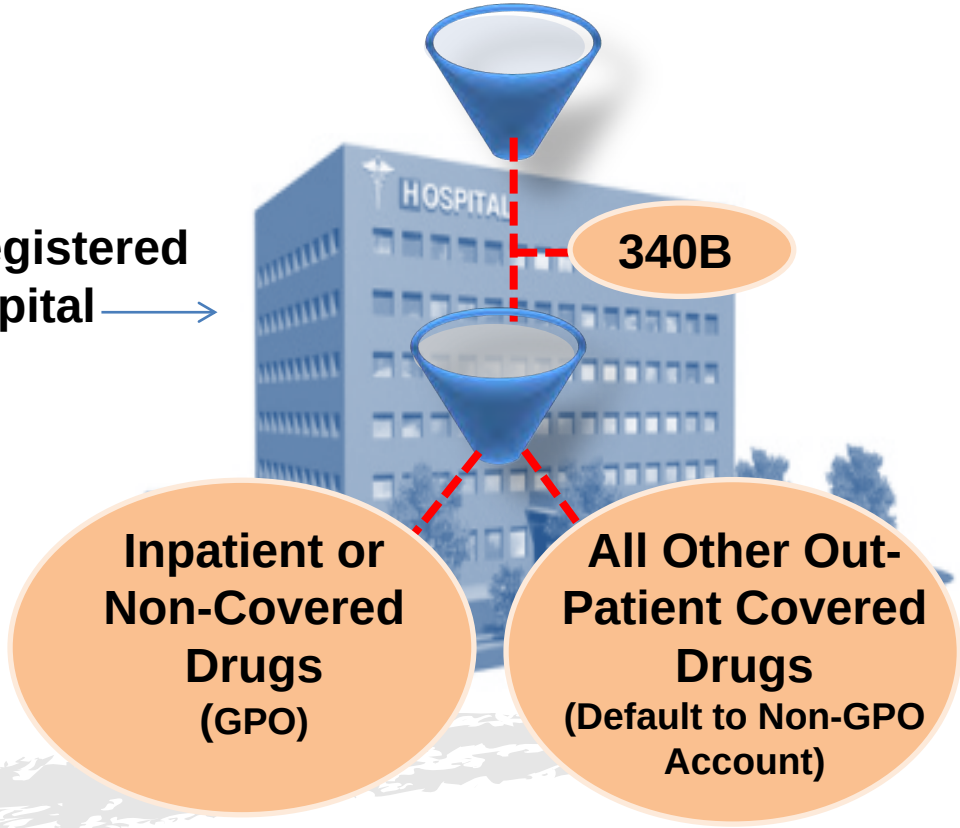
GPO Prohibition Clarification
– Purchase Flow for Some Hospitals

Apexus

- Non-compliant State

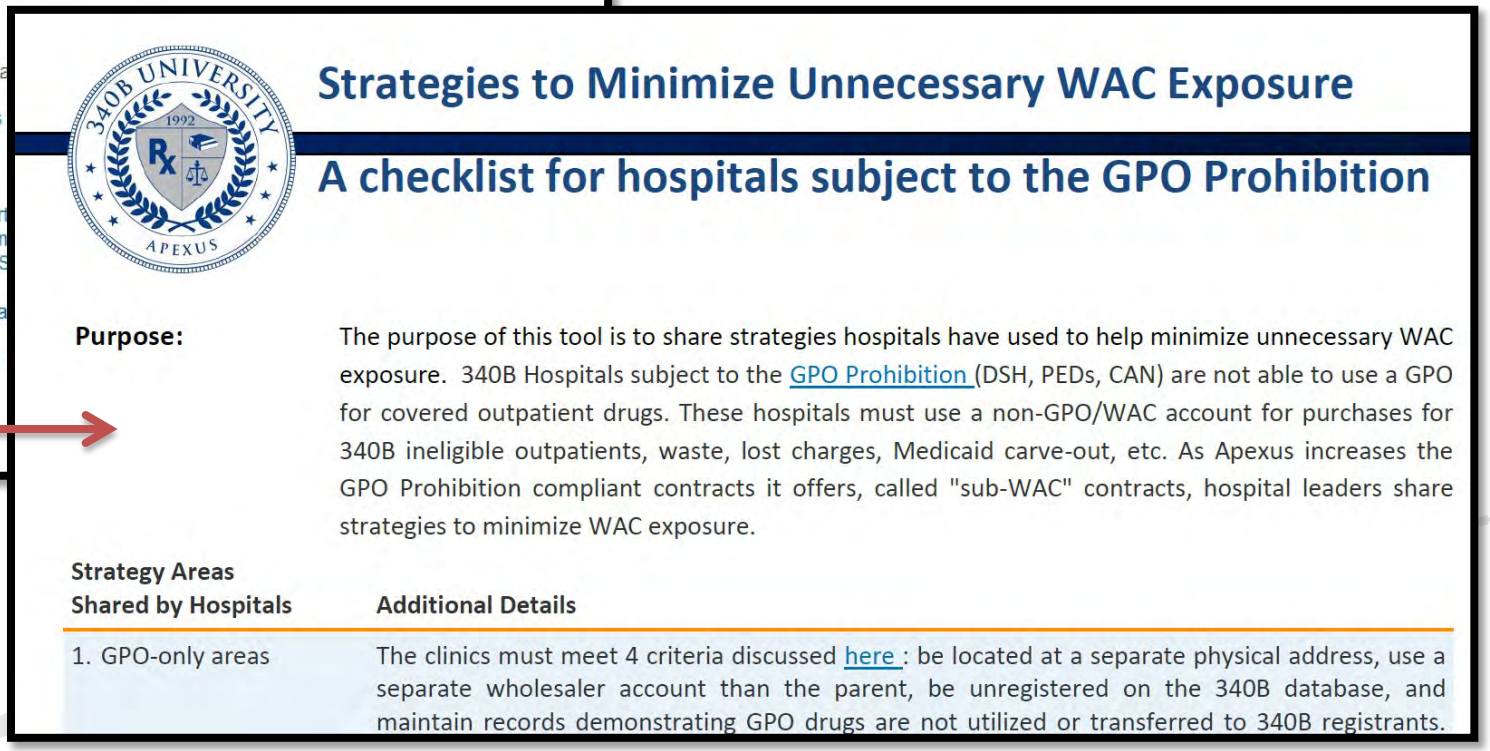
340B Registered Hospital

- Compliant State



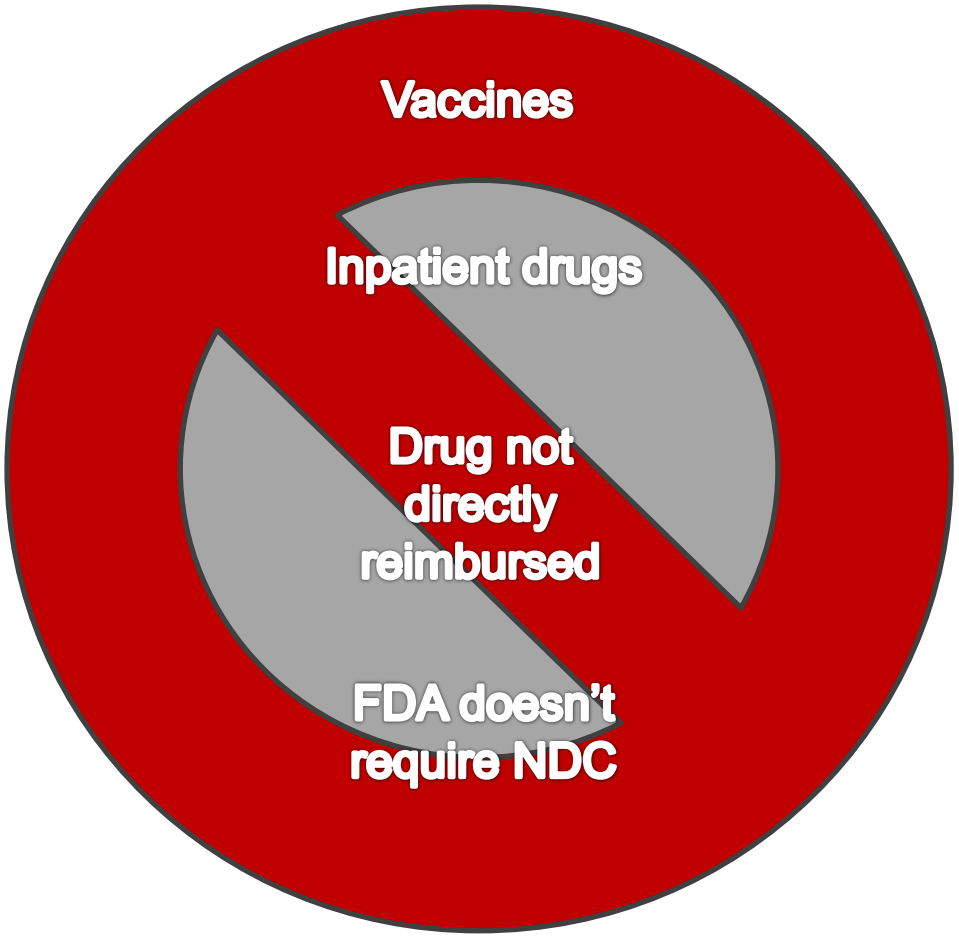
Minimizing WAC Exposure Tool

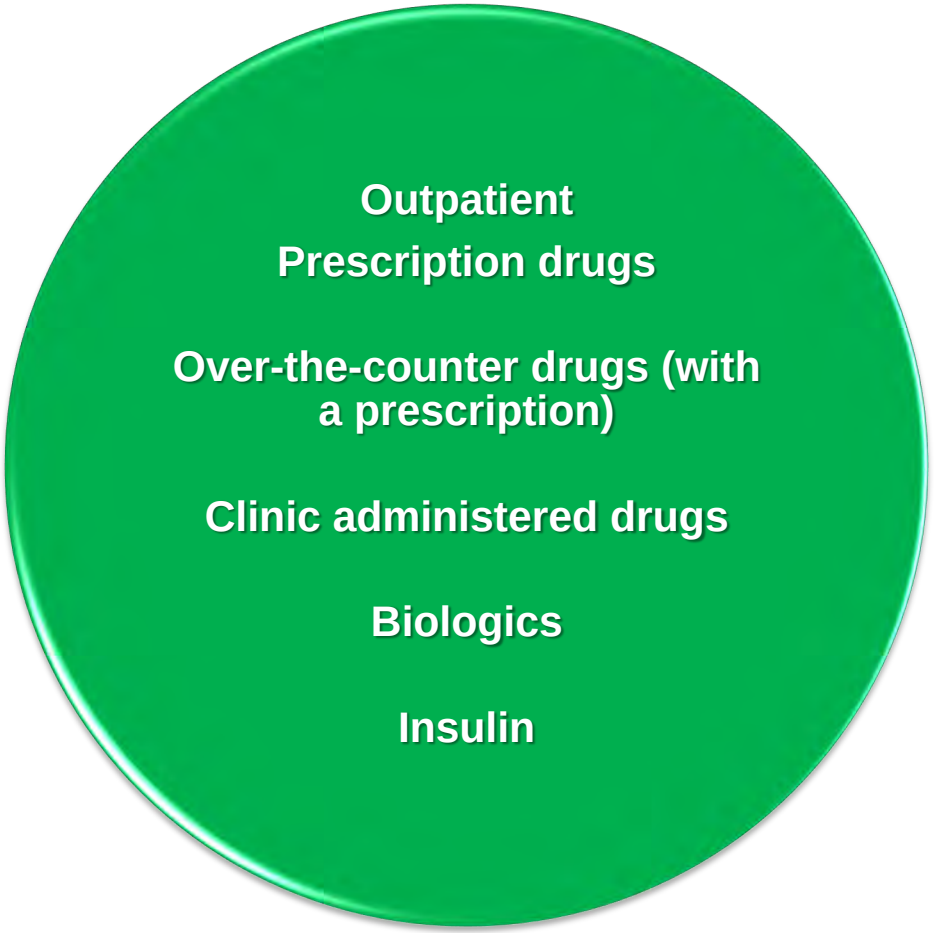
Apexus



340B Covered Outpatient Drugs

Apexus





http://www.ssa.gov/OP_Home/ssact/title19/1927.htm

Strategy #1: Covered Outpatient Drug

Q: Can a hospital subject to the GPO Prohibition use a GPO for drugs that are part of/incident to another service and payment is not made as direct reimbursement of the drug ("bundled drugs")?

A: If the entity interprets the definition of covered outpatient drug referenced in the 340B Statute (Social Security Act 1927 (k)) and decides that bundled drugs do not meet this definition, a GPO may be used for drugs that are not covered outpatient drugs. The decision the entity makes should be defensible, consistently applied in all areas of the entity, documented in policy/procedures, and auditable.

Strategy #2: GPO "Only" Clinics

Apexus

In certain off-site outpatient hospital facilities that meet **all** of the following criteria:

1. Are located at a different physical address than the parent;
2. Are not registered on the OPA 340B database as participating in the 340B Program;
3. Purchase drugs through a separate pharmacy wholesaler account than the 340B participating parent; and
4. The hospital maintains records demonstrating that any covered outpatient drugs purchased through the GPO at these sites are not utilized or otherwise transferred to the parent hospital or any outpatient facilities registered on the OPA 340B database.

Apexus

TRUTH:

APEXUS ANSWERS CALL CENTER

Look Familiar?

Apexus Answers

- National 340B source of truth, communicates HRSA policy
- Staff in constant communication with HRSA to ensure messaging is consistent
- FAQs available here: https://www.340bpvp.com/resource-center/faqs/
- Average monthly interactions ~2,000
- Tiered levels of response: can handle from basic to complex

Apexus

TEACHING:

340B UNIVERSITY

Learn. Share. Prepare.

Apexus

- National experts share leading practices at this one or two day live educational program
- Aligned with HRSA policy, compliance-focused
- Only HRSA-endorsed compliance training
- CE for pharmacists and technicians offered
- Interactive, opportunities to network, leave with tools to equip your entity
- 10+ Sessions in 2014
- E-based learning coming in Summer 2014 (including C-suite modules)

Free and Trusted 340B Tools

- Strategies to Minimize WAC Exposure
- Sample 340B Standard Operating Procedures
- Self-Reporting Non-Compliance
- Self-Audit Tool

FY 2012 Audits and 340B U Attendance and Sanction/Finding Rate

(In Entities with Sanctions/Findings)

Apexus

	340B U attendance prior to audit	No 340B U attendance prior to audit
Sanction Rate	0%	100%
Finding Rate	3%	97%

340B Contract Pharmacy - Overview

Apexus

- HRSA guidance permits entities to partner with outside pharmacies to provide eligible patients with 340B medications
  - Identification via shared patient and provider data
  - Inventory via "Bill To - Ship To" wholesale arrangements
- Entity-Contract Pharmacy relationship types :
  - Direct Contracting with Pharmacy
  - Contracting through 340B vendor with Pharmacy

340B Contract Pharmacy Process

Apexus

1. Contract Pharmacy dispenses drug (non-340B inventory) to 340B entity's eligible patient
2. When a full package size of the Rx is reached, the pharmacy or vendor orders a 340B drug to replace it
3. Replacement 340B drugs are "billed to" the entity and "shipped to" the contract pharmacy
4. Entity pays contract pharmacy for its services

What is a 340B Vendor?

Apexus

A company providing 340B contract pharmacy program implementation and management services

- Not a HRSA requirement
- Minimizes impact on retail pharmacy workflow
- Collects data from retail pharmacy at the switch
- Provides the interface to identify eligible claims (matches entity data and pharmacy data)
- Manages inventory replenishment
- Establishes contracts with pharmacies
- Provides reports and transparency for auditing

Contract Negotiation, Summary

- Entity pays flat fee per claim
- Stop-loss function (prevents 3rd party transmission if loss to entity)
- Entity does not pay fees on claim reversals (net paid claims)
- Entity pays lowest of U&C, MAC, and 340B
- Entity has access to ALL data (including prescriptions presented vs. filled with 340B)
- High complexity data management systems
  - HL7 interface

- Entity pays fees based on % of revenue or drug cost
- Entity does not keep 3rd party reimbursement
- Vendor recruits patients to its mail order pharmacy
- Early cancellation fees
- Entity not permitted to select wholesaler
- Entity may end up purchasing partial bottles at high rates due to non-replenishment
- Entity not permitted to contract with other 340b vendors

Split Billing of Contract Pharmacy Vendors - Buyer Beware

Apexus

- Not two vendors are the same
  - Rules applied can vary
  - Various levels of sophistication and and experience
  - What if HRSA reported vendors associated with all covered entity audit findings?
- Responsibility for 340B program compliance cannot be delegated to a 3rd party. Read the fine print of the agreements.
- Some Vendors do not feel it is their obligation to support 340B compliance (and offer non-compliant alternatives)
- Apexus is developing new tools to assist covered entities evaluate and select vendors

Entities Take Action

Apexus

340B Compliance Self-Assessment: Vendors

A Tool to Help 340B Entity Leaders Assess Contract Pharmacy Vendors

Purpose: The purpose of this tool is to enable 340B participating entity leaders to quickly assess the basic level of 340B program integrity contract pharmacy vendors will help entity achieve, in select areas.

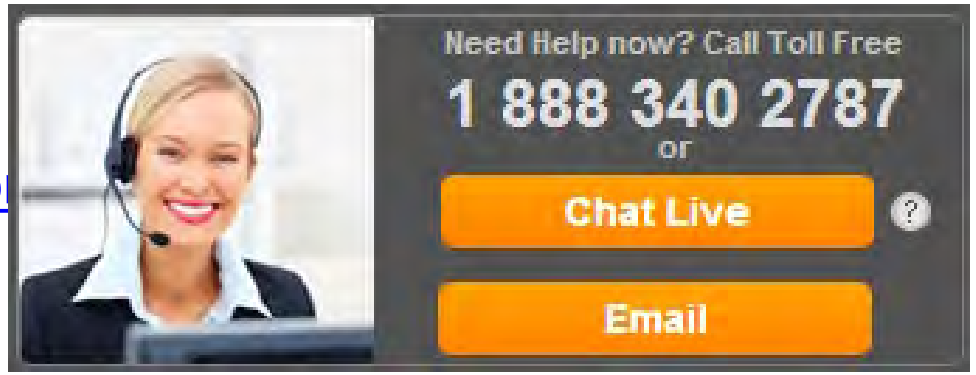
Contract Pharmacy OIG Report

- *Contract Pharmacy Arrangements in the 340B Program (OEI-05-13-00431)* released Feb. 5, 2014
  - Contract pharmacy arrangements create complications in preventing diversion and duplicate discounts, and covered entities addressed the complications in different ways.
  - **Some covered entities in the study offer the 340B discount to uninsured patients at the contract pharmacy and others do not.**
  - Most covered entities in the study do not conduct all of the HRSA-recommended oversight activities.

Contact Information

Apexus Answers:

M-F 8:00-5:00 PM CT
Email: ApexusAnswers@340bpvp.com
Website: www.340BPVP.com



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Questions?

Apexus

ATTACHMENT 2

businesses and organizations receiving grants from HHS; *Total Number of Respondents:* 25; *Frequency of Response:* monthly; *Average Burden per Response:* 15 minutes; *Estimated Annual Burden:* 75 hours.

The PMS–272, Federal Cash Transactions Report, is used to monitor Federal cash advances to grantees and obtain Federal cash disbursement data. It serves in place of the SF–272. *Respondents:* State and local governments, profit and nonprofit businesses and institutions receiving grants from HHS; *Total Number of Respondents:* 11,050; *Frequency of Response:* Quarterly; *Average Burden per Response:* 4 hours; *Estimated Annual Burden:* 176,800 hours.

Total Burden: 176,875 hours.

Send comments to Douglas F. Mortl, PSC Reports Clearance Officer, Room 17A08, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: August 19, 1996.

Lynnda M. Regan,

Director, Program Support Center.

[FR Doc. 96–21530 Filed 8–22–96; 8:45 am]

BILLING CODE 4160–17–M

Health Resources and Services Administration

RIN 0905–ZA96

Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Final notice.

SUMMARY: Section 602 of Public Law 102–585, the ''Veterans Health Care Act of 1992'' (the ''Act''), enacted section 340B of the Public Health Service Act (''PHS Act''), ''Limitation on Prices of Drugs Purchased by Covered Entities.'' Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible (covered) entities must sign a pharmaceutical pricing agreement with the Secretary of Health and Human Services (HHS) in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula.

The purpose of this notice is to inform interested parties of final guidelines regarding contract pharmacy services.

FOR FURTHER INFORMATION CONTACT: Annette Byrne, R. Ph., M.S., Director, Drug Pricing Program, Bureau of Primary Health Care, Health Resources and Services Administration, 4350 East West Highway, 10th Floor, Bethesda, MD 20814, Phone (301) 594–4353, FAX (301) 594–4982.

EFFECTIVE DATE: August 23, 1996.

SUPPLEMENTARY INFORMATION:

(A) Background

Proposed guidelines for contract pharmacy services were announced in the **Federal Register** at 60 FR 55586 on November 1, 1995. A comment period of 30 days was established to allow interested parties to submit comments. The Health Resources and Services Administration, Bureau of Primary Health Care, acting through the Office of Drug Pricing (ODP), received eleven letters including comments concerning the scope of the 340B Program, contractor certification, contractor and entity penalties for drug diversion, creation of an agency relationship between the entity and the contractor, entity responsibilities including price establishment, reimbursement, inventory control, and the like.

Although some manufacturers expressed concerns regarding the potential for drug diversion, the Department has received no evidence of diversion that has required an official Departmental investigation. This includes the various drug distribution systems, among them those using contract pharmacy services. However, in response to manufacturers' concerns, the Department intends to study the use of contracted pharmacy services for accessing 340B drugs to determine if there is evidence of drug diversion. In particular, the Department will examine closely documented complaints, including the results of manufacturers' audits, will use other analyses as deemed appropriate, and will consider whether additional safeguards are necessary.

We received some very positive comments in support of the mechanism. These comments discussed the many covered entities which do not operate their own licensed pharmacies; therefore, the guidelines encourage these entities to participate in the program. Because these covered entities provide medical care for many individuals and families with incomes well below 200% of the Federal poverty level and subsidize prescription drugs for many of their patients, it was essential for them to access 340B pricing. Covered entities could then use savings realized from participation in the program to help subsidize prescriptions for their lower income patients, increase the number of patients whom they can subsidize and expand services and formularies. One commenter described the guidelines as straightforward, clear and consistent with section 340B. Another commenter stated that the ''use of contract pharmacies by covered entities is fundamental to the success of the VHCA [Veterans Health Care Act] drug pricing program.'' The commenter supported the guidelines and urged the Department to expedite their completion, as the importance of the contract pharmacy option to their members could not be overstated.

The following section presents a summary of all major comments, grouped by subject, and a response to each comment. All comments were considered in developing this final notice, with changes made to increase clarity and readability. In addition, to provide further technical assistance and guidance to covered entities interested in using this mechanism, examples of report contents, a suggested system to ensure an adequate drug tracking system, and a method to ensure patient eligibility are included. Various commenters, and in particular drug manufacturers, suggested the need for detailed systems. The National Association of Community Health Centers suggested some of the specific examples.

(B) Comments and Responses

(1) General

Comment: The use of contract pharmacy services is inconsistent with section 340B of the PHS Act and results in an unauthorized expansion of the program.

Response: Section 340B, which established the Drug Pricing Program, requires manufacturers to sell to covered entities at or below a ceiling price determined by a statutory formula. The statute is silent as to permissible drug distribution systems. There is no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself. It is clear that Congress envisioned that various types of drug delivery systems would be used to meet the needs of the very diversified group of 340B covered entities.

It has been the Department's position that if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price. If the entity directs the drug shipment to its contract pharmacy, we see no basis on which to conclude that section 340B precludes this type of transaction or otherwise

exempts the manufacturer from statutory compliance. However, the entity must comply, under any distribution mechanism, with the statutory prohibition on drug diversion.

During the early period of program implementation, it became apparent that only a very small number of the 11,500 covered entities used in-house pharmacies (approximately 500), although additional entities participated by buying drugs for their physician dispensing activities. In addition, many of the larger groups of covered entities, including community and migrant health centers, hemophilia clinics and most of the Ryan White HIV service programs (e.g., State AIDS Drug Assistance Programs) depend upon outside pharmacy services. Yet, because the delivery of pharmacy services is central to the mission of (and a legal mandate in some instances for) these providers, they rely on outside pharmacies to fill the need. It would defeat the purpose of the 340B program if these covered entities could not use their affiliated pharmacies in order to participate in the 340B program. Otherwise, they would be faced with the untenable dilemma of having either to expend precious resources to develop their own in-house pharmacies (which for many would be impossible) or forego participation in the program altogether. Neither option is within the interest of the covered entities, the patients they serve, or is consistent with the intent of the law.

As early as 1993, several covered entity groups and a home care company came forward to assist the Department in developing a workable mechanism to use outside pharmacies under arrangements which would decrease the drug diversion potential. The result was the November 1 proposed notice, which articulates a voluntary model agreement. Currently, contract pharmacies are used by a number of large organizations, such as the American Red Cross, several community health centers, and the New York Blood Consortium.

It must be understood that the use of contract services is *only* providing those covered entities (which would otherwise be unable to participate in the program) a process for accessing 340B pricing. The mechanism does not in any way extend this pricing to entities which do not meet program eligibility. However, it has permitted more eligible entities to participate in the program with a reasonable assurance that the potential for drug diversion is eliminated.

Comment: The guidelines were proposed without a comprehensive notice and comment period.

Response: During the early months following enactment, it became clear that there were many gaps in the legislation and some form of program structure was necessary to move the program forward. There were approximately 11,500 eligible entities, 500 participating manufacturers, numerous wholesalers and many Federal programs affected by this legislation and all seeking guidance. It was incumbent upon the Department to implement this difficult Congressional mandate in an expeditious manner.

Interpretive rules and statements of policy were developed to provide necessary program guidance. The Department has published these guidelines in the **Federal Register**, used a Federal clearance process (including the Office of Management and Budget's clearance) and provided a public comment period to obtain both Federal as well as public input into guideline development. The Department considered all comments in developing these final guidelines.

The guidelines explain how the Department intends to administer the 340B, further explain the statutory language by clarifying the meaning given by the Department to particular words or phrases, and do not exceed the purpose of 340B or conflict with any of its provisions. We believe that these guidelines create no new law and create no new rights or duties; therefore, they are not subject to the Administrative Procedure Act's requirement of notice and comment. Nevertheless, the Department chose to solicit and respond to public comment.

Comment: As a matter of State law, entities possess the right to hire retail pharmacies to act as their agents in providing pharmaceutical care to their patients. As a general rule, a person or entity privileged to perform an act may appoint an agent to perform the act unless contrary to public policy or an agreement requiring personal performance. Restatement of Agency 2d § 17 (1995). Hence, even in the absence of Federal guidelines, covered entities have the right to contract with retail pharmacies for the purpose of dispensing 340B drugs. By issuing guidelines in this area, ODP is not seeking to create a new right but rather is simply recognizing an existing right that covered entities enjoy under State law.

Response: We agree. However, entities, under any distribution system, must comply with the statutory prohibition against diversion of 340B drugs to individuals who are not patients of the covered entities. Further, the dispensing of drugs, purchased with a 340B discount, must not result in the generation of a Medicaid rebate.

Comment: Participation in the contract pharmacy mechanism by hemophilia treatment centers funded under the Maternal and Child Health Block Grant Program would contravene the central goals of that program and could result in grant termination or non-renewal.

Response: Block grant funds are designed for formula allocation to the States to meet specific defined needs in the legislation. Congress recognized that the Maternal and Child Health Bureau (MCHB) had other needs that should be met more flexibly; therefore, fifteen percent of the appropriation is a discretionary set-aside. These funds are not subject to the specific parameters of block grant funds but instead are used to fulfill other goals within the MCHB mission. This includes the provision of services (including pharmaceuticals) to individuals with hemophilia disorders and their families. Therefore, the purchase of pharmaceuticals by hemophilia centers does not contravene grant principles.

Comment: The contract pharmacy mechanism contravenes Federal and State laws and regulations (e.g., Prescription Drug Marketing Act and the Anti-kickback Statute).

Response: We found no indication that the guidelines contravene Federal or State law. Regarding allegations that the guidelines contravene the Prescription Drug Marketing Act (PDMA), it is clear that the guidelines fall squarely within the PDMA resale exception that allows the dispensing of a prescription drug purchased by a health care entity when dispensing is pursuant to a prescription. See 21 U.S.C. 353(c)(3)(B)(v). Under the guidelines, the contract pharmacy would dispense 340B drugs to patients of the covered entity pursuant to a prescription. The contract pharmacy would act as an agent of the covered entity, in that it would not resell a prescription drug but rather distribute the drug on behalf of the covered entity. This situation is akin to a covered entity having its own pharmacy. Moreover, the guidelines include controls intended to prevent diversion and provide for accountability of drug stocks. For these reasons, the guidelines are consistent with both the letter and the spirit of the PDMA.

We believe it necessary to ensure that covered entities contracting with pharmacies to dispense 340B drugs are aware of the requirements of the Federal anti-kickback statute and the way in

which such requirements could apply to their arrangements with contracting pharmacies. To this end, we inserted into the guidelines a discussion of the statute's requirements and its potential application in this type of contracting situation.

In addition, provision (e) of the guidelines provides that the ''contractor and the covered entity will adhere to all Federal, State, and local laws and requirements.'' As a general matter, we found it impossible to discuss each State's laws and regulations regarding drug purchase, distribution, and dispensing in relation to the many different types of entities and their individual needs. We believe it appropriate that the guidelines include a provision that requires each entity and contractor to be responsible for ensuring that their particular contracting arrangements and operations conform to the requirements of all applicable laws and regulations.

Comment: The ODP should develop a uniform contractual agreement and distribute this agreement to covered entities for use without modification.

Response: The guidelines propose a model format only. The Department has included in the guidelines provisions necessary to ensure that covered entities and contract pharmacies understand and agree not to violate 340B provisions. Because of the wide diversity of covered entities (including hemophilia clinics, large hospitals, migrant health clinics, family planning service programs and State AIDS drug assistance programs), it would be impossible to include provisions responsive to the needs of all entities.

Comment: ODP should keep a list of all acceptable contract pharmacies.

Response: Any pharmacy licensed by a State Board of Pharmacy is acceptable.

Comment: Some State laws require that manufacturers ensure that a buyer is licensed to purchase pharmaceuticals. Covered entities that do not have pharmacy operations would not be licensed, and thus, in some States, manufacturers could not receive from the covered entity the assurance required by State law.

Response: Provision (e) provides that the covered entity will adhere to all Federal, State and local laws and requirements. Accordingly, if State X requires an entity to be licensed to purchase drugs and a covered entity subject to the laws of State X does not have a pharmacy license, it may not be able to purchase drugs. However, if State X permits a covered entity to use contract pharmacy services to purchase drugs on its behalf, the entity could presumably use this mechanism. To the extent the guidelines may be inconsistent with a State's distributor licensing requirements, this same reasoning would apply.

Comment: Covered entities may bill insurers for 340B drugs at the usual price, resulting in the savings not being passed on to the patients.

Response: Section 340B does not limit the pricing behavior of covered entities. It is our understanding that covered entities have a variety of drug pricing approaches. While some may pass all or a significant part of the discount to their patients, others may set the price slightly higher than the actual acquisition cost plus a reasonable dispensing fee, using the savings to reach more eligible patients and provide more comprehensive services. The Department intends to examine the section 340B drug pricing activities of covered entities to determine the various approaches used and the rationale for these approaches. However, until it completes its examination of this issue, the Department notes that a modest section 340B price markup, with saving realized from the discounts used by covered entities only for purposes of the federal program (including certain disproportionate share hospitals) which provides its section 340B eligibility does not appear to be inconsistent with the drug pricing program.

Comment: There should be a limitation to only those covered entities that do not have the capability under State pharmacy law to purchase and dispense prescription drugs.

Response: The guidelines have been revised to read that the ''mechanism is designed to facilitate program participation for those eligible covered entities that do not have access to an appropriate 'in-house' pharmacy services.'' However, this is not a bar to the use of the mechanism by any covered entity.

Comment: A covered entity should use only one form of participation, and if it purchases in its own right for some patients, it should not use a contractor for others.

Response: Some covered entities may receive nominal pricing directly from a manufacturer (e.g., family planning) for specific drugs, may obtain certain drugs through promotional discounts, or have a manufacturer-specific indigent free drug program which could necessitate the procurement of other pharmaceuticals from a retail pharmacy. The statute does not limit the covered entities' access to these avenues of drug purchasing.

Comment: The Department should establish criteria that a contractor and a covered entity must meet in order to be in compliance with section 340B provisions and receive 340B pricing.

Response: The contracted pharmacy mechanism does establish these criteria in that it includes provisions for purchasing only by the entity and not contractor, identifies customary and adequate records that can provide an audit trail, preclusion of the filling of Medicaid prescriptions (thus preventing duplicate discounting), and three provisions related to the potential for drug diversion (agreement not to divert with specified penalties, customary drug tracking systems, and an agreement to permit manufacturer and HHS audits).

Comment: The reference to ''facility'' in provision (b) should be changed to ''entity'' for clarification.

Response: The guidelines were revised accordingly.

Comment: The Department should review all contracts between covered entities and pharmacies or develop a procedure for certifying that each contract pharmacy arrangement meets the mechanism criteria.

Response: The Department has added a provision to the guidelines which suggests that covered entities utilizing contract pharmacy services submit to the ODP a certification that they have signed and have in effect an agreement with the pharmacy contractor containing provisions (a) through (k) as outlined in the guidelines. For the convenience of participating drug manufacturers, the names of covered entities which submit a certification, or have submitted an alternate mechanism to reduce the potential for drug diversion which has been approved by ODP, will be placed on the program electronic bulletin board (EDRS) for public access.

Comment: Covered entities should be permitted to contract with more than one site and contractor. Although we understand that the limitation of one contractor (with multiple sites) was intended to address drug diversion concerns, covered entities will have the incentive of directing their patients to the contract pharmacy site participating in the program, even though there may be several nonparticipating sites of contractors that would be more convenient for the patients.

Response: Covered entities are unlikely to select a contract pharmacy that is not convenient for their patients. See also the discussion of patient choice, below.

Comment: PHS is moving from a direct purchase discount program to an indirect charge-back contracting system.

Response: All 340B drugs will be sold to covered entities; therefore, there are no additional charge backs involved.

(2) Patient Choice

Comment: Provision (c) provides that the patient may obtain the prescription from the pharmacy provider of his or her choice. Pharmacy providers cannot provide prescriptions, as only a physician can write a prescription. The guidelines should permit the patient to obtain the prescription from the covered entity physician and then be able to fill that prescription at the pharmacy of his or her choice. Further, the covered entity physician should inform each patient that he or she has the freedom to choose any pharmacy to fill the prescription.

Response: The use of the word ''prescription'' may be somewhat confusing. We have revised this provision to read ''may obtain the prescription from the covered entity and then obtain the drug(s) from the pharmacy provider of his or her choice.'' In addition, a provision is added to address the responsibility of the covered entity physician to inform the patient of his or her freedom of choice.

Comment: Wording should be added to provision (c) to make it clear that when a patient obtains a drug from a retail pharmacy other than the entity's contract pharmacy, the manufacturer does not have to offer this drug at 340B pricing.

Response: The guidelines were revised accordingly.

(3) Bill to/Ship to

Comment: The type of ''bill to, ship to'' arrangement proposed in the notice is not a ''purchase'' by the covered entity.

Response: Please note provision (a) of the notice which states ''the covered entity will purchase the drug.'' The contract pharmacy does not purchase the drug. Title to the drugs passes to the covered entity.

Comment: A ''ship to, bill to'' arrangement may not be lawful in many States (e.g., state distributor licensing requirements).

Response: The Department obtained information from both the American Pharmaceutical Association and the National Association of Boards of Pharmacy which suggests that no State would consider this type of activity unlawful.

Comment: If the ''ship to, bill to'' procedure is implemented through wholesalers, there are no procedures in place that can enable a manufacturer to conduct an adequate audit.

Response: The guidelines provide that the covered entity will verify, using the contractor's (readily retrievable) customary business records, that a tracking system exists which will ensure that drugs purchased under the Act are not diverted to individuals who are not patients of the covered entity. These records will be maintained for the period of time required by the State law and regulations. The guidelines provide that the contractor will provide the covered entity with reports consistent with normal business practices as well as maintain records separate from it's own operation. In addition, the contractor will agree to be subject to audits by both the manufacturers and the Department. In light of these provisions, audits will be possible, regardless of whether drugs are shipped by manufacturers or wholesalers.

Comment: A ''ship to, bill to'' procedure could interfere with marketing arrangements that an individual manufacturer may have established as part of its usual business practices.

Response: Because the manufacturer is still selling to the covered entities, we can see no interference with marketing arrangements. The manufacturer will be using its usual business practices. Only the delivery of the drug will be altered.

Comment: The covered entity (not its contractor) will place all orders for drugs based upon its projections of the needs of its patients.

Response: Because the covered entity will have no knowledge of the inventory levels of the pharmacy, it would be unrealistic to include a provision that the covered entity will order 340B drugs.

Comment: The covered entity, consistent with customary business practices in wholesale purchases, should make timely payment of invoices for drugs shipped to the contractor pursuant to the entity's order.

Response: We have included this concept in the guidelines, Section 1 of Appendix.

(4) Penalties

Comment: The penalty for the contract pharmacy which violates the agreement not to resell or transfer a drug purchased at 340B pricing is inadequate. Knowing violators should be fined beyond their unjust profit and criminal and fraud penalties should be imposed.

Response: The Department has no statutory authority to assess additional penalties beyond the authority provided in section 340B. However, to the extent the Department is aware that improper action by an entity or a contract pharmacy may be a violation of law, we will refer such cases to appropriate authorities.

(5) Potential Drug Diversion

Comment: PHS should conduct an annual audit of each contract pharmacy to ensure compliance with all Departmental rules and regulations.

Response: Subject to the availability of funds, the Department intends to conduct a study of the contract pharmacy mechanism. Depending upon the results of this analysis and the availability of funds, further study may result. Annual audits of each contract pharmacy situation would be burdensome and are not feasible.

Comment: Contract pharmacies will be motivated to identify patients other than those of the covered entity whose drug usage can afford the contractor a profit opportunity. The covered entity should be responsible to the manufacturer for any diversion by the contractor of 340B drugs to individuals who are not patients of the covered entity.

Response: The guidelines contains provision (h), in which both parties agree to not ''resell or transfer a drug purchased at section 340B prices to an individual who is not a patient of the covered entity.'' In addition, this provision provides that if diversion has occurred, the contractor will pay the amount of the discount in question so that the covered entity can reimburse the manufacturer, as required by section 340B(a)(5)(D).

Comment: The mechanism should include provisions for ensuring that the agreement will, in fact, be enforced.

Response: The Department does have the authority to remove a covered entity from the eligibility list if it (or its contract pharmacy) is found to have diverted 340B drugs to individuals who are not patients of the entity. To this end, the Department has developed a mechanism to receive and investigate complaints concerning drug diversion. This mechanism was published in the **Federal Register** for notice and comment on June 10, 1994 (59 FR 30021). In addition, the Department, at various public meetings concerning the implementation of 340B, has requested documentation of any covered entity drug diversion. To date, the Department has received no indication of drug diversion in relation to drugs purchased at 340B discount pricing that has required an official Departmental investigation.

Comment: The manufacturer appears to bear the sole risk arising from abuses of the program and has no recourse if such abuse occurs. The manufacturer

has limited ability to verify an arrangement between the covered entity and the contract pharmacy. Under the statute, the manufacturer's only remedy is to demand an audit; however, the lack of final audit guidelines has effectively prevented manufacturers from undertaking this type of activity. PHS should make arrangements for injunctive relief to prevent damages from ongoing violations of the statute, or provisions for terminating the participation of covered entities or their contractors.

Response: The manufacturer has sufficient remedies available to detect and eliminate abuse of the program. First, the manufacturer may audit the entity. Although the audit guidelines were not published in final form, we consider the proposed guidelines, published in the **Federal Register**, a sufficient statement of Department guidelines to allow manufacturers to proceed with an entity audit. Second, the Department has developed a dispute resolution process to provide parties with an informal mechanism to bring before the Department allegations of behavior that is in violation of 340B. Third, the contract pharmacy guidelines provide that if the covered entity or its contractor is found to have violated the 340B prohibition against drug diversion (and duplicate discounting), the covered entity could be removed from the list of covered entities and could no longer access 340B pricing.

Comment: The covered entity should establish a process for a quarterly reconciliation of its prescribing records with the contractor's inventory and dispensing records to provide for early detection of diversion and remediation of irregularities.

Response: We have included a provision that covered entity will establish a process for a quarterly random (sample) comparison of its prescribing records with the contractor's dispensing records to detect potential irregularities.

Comment: The covered entity should establish prior authorization protocol, assuring that the individual's status as a patient of the entity is confirmed by the entity in advance of product dispensing.

Response: The contractor should have some type of assurance that the patient to whom the contractor is dispensing the 340B drug is a patient of a covered entity participating in the 340B Program. To that end, we have added a provision to the guidelines stating that the covered entity and the contractor will develop a system to verify patient eligibility (e.g., eligible patient list or a validated prescription). Additionally, we have included a suggested contract provision which states, ''(pharmacy) will dispense covered drugs only in the following circumstances: (1) Upon presentation of a prescription bearing the (covered entity's) name, the eligible patient's name, a designation that the patient is an eligible patient, and the signature of a legally qualified health care provider affiliated with the (covered entity); or (2) receipt of a prescription ordered by telephone on behalf of an eligible patient by a legally qualified health care provider affiliated with the (covered entity) who states that the prescription is for an eligible patient. The (covered entity) should provide a list to the (pharmacy) of all such qualified health care providers and will update the list of providers to reflect any changes, which is consistent with customary business practice.''

Comment: The contract agreement should restrict pharmacy services to only those patients who receive their medical care from the covered entity.

Response: Provision (g) of the guidelines provides that the contractor will not resell or transfer a 340B drug to an individual who is not a patient of the entity. The Department issued proposed guidelines to define the word ''patient'' in a **Federal Register** notice on August 3, 1995. See 60 FR 39762. Provision (2) of the definition provides that an individual is a patient of a covered entity if, among other requirements, the ''individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that the responsibility for the care provided remains with the covered entity.'' Currently, the Department is analyzing the comments received in response to that notice and is developing final guidelines.

It must be noted that the covered entity is responsible for any diversion of its drugs to ineligible individuals; therefore, it must make every effort to thoroughly scrutinize the contractor's dispensing records, to determine if the 340B drugs were dispensed to only eligible recipients. If a manufacturer believes that a covered entity contractor is diverting 340B drugs to ineligible recipients, the manufacturer should immediately contact the Department with this information and submit all supporting documentation so that a thorough investigation can be initiated.

Comment: PHS should oversee contractors' compliance with the contracts regarding the 340B prohibition against drug diversion and duplicate discounting.

Response: Because the covered entity purchases the drug, retaining title, and directs shipment to its contractor, it retains responsibility for the drug. If the drug generates a Medicaid rebate or is diverted to an individual who is not a patient of the covered entity, the entity will be responsible for such activity. The Department and a participating manufacturer have the authority to audit the records of the covered entity and the contractor that directly relate to that manufacturer's drugs and to the 340B prohibitions against drug diversion and duplicate discounting. See proposed Audit Guidelines, 59 FR 30021, June 10, 1994. Further, the Department has proposed a dispute resolution process in which a manufacturer may bring a claim against an entity for drug diversion or duplicate discounting. See Dispute Resolution, 59 FR 30023. If the entity (or its contractor) is found to have violated such prohibitions, the entity is required by 340B(a)(5)(D) to pay the manufacturer the amount of the discount in dispute, and, pursuant to 340B(a)(4), the Department may determine that the entity is no longer a ''covered entity'' eligible to access 340B pricing.

We have added several suggested contract provisions that are consistent with normal business practices to the guidelines (Appendix) to provide further technical assistance in this area. One provision concerning potential discrepancies in ordering and shipping states, ''the pharmacy will compare all shipments received to the orders and inform the covered entity of any discrepancy within five (5) business days of receipt.'' Concerning an appropriate tracking system to prevent drug diversion, another provision states, ''prior to the pharmacy providing pharmacy services pursuant to this agreement, the (covered entity) will have the opportunity, upon reasonable notice and during business hours, to examine the tracking system and may require (the pharmacy) to make any modifications to such system as the (covered entity) may, in its sole discretion, require. Such a system may include sample quarterly comparisons of eligible patient prescriptions to the dispensing records and a six (6) month comparison of 340B drug purchasing and dispensing records. The (pharmacy) will permit the (covered entity) or its duly authorized representatives to have reasonable access to (pharmacy's) facilities and records during the term of this agreement in order to make periodic checks regarding the efficacy of such tracking systems. (Pharmacy) agrees to

make any and all adjustments to the tracking system which (covered entity) advises are reasonably necessary to prevent diversion of covered drugs to individuals who are not patients of the (covered entity).''

Comment: There should be a process for excluding from the 340B Program those contractors that are in violation of the statute and the guidelines should explicitly note that the pharmacy contractor will be subject to additional civil or criminal penalties if violation of the guideline involves a violation of State or Federal law.

Response: Covered entities which are found to have violated the prohibitions of section 340B(a)(5) can be excluded from the 340B Program, after an appropriate opportunity to be heard. See Dispute Resolution Guidelines in 59 FR 30023, June 10, 1994. However, if the program finds that the pharmacy contractor has violated these statutory prohibitions, it cannot bar this pharmacy from dispensing 340B drugs for a covered entity. Nevertheless, the program intends to alert any entity which submits a certification with this particular pharmacy listed as the contractor as to this pharmacy's past activities. If the covered entity insists upon using this pharmacy, the Department will carefully scrutinize its activities. An additional provision was added to address the potential for civil or criminal penalties if the contractor violates Federal or State law.

Comment: The agreement should appoint the pharmacy contractor to be the agent of the covered entity and discuss the duties to be performed by the agent on behalf of the covered entity and the agent's rights.

Response: We believe that the relationship between the covered entity and the contract pharmacy is one of agency. However, the form of the relationship will be dictated by the terms of the contract; therefore, it is not essential to characterize the relationship as meeting or not meeting the standards which would serve under applicable law to establish an agency relationship. The contract terms address the relative duties of the parties in relation to section 340B and diversion and duplicate discount concerns that have been raised by the commenters. Accordingly, we have concluded that it is unnecessary to label the relationship between the covered entity and the contract pharmacy.

Comment: The contract pharmacy is fully accountable for maintaining the security of the PHS inventory.

Response: There is no requirement for a separate (physical) inventory for drugs purchased at a 340B discount, because a separate data system will be used to verify appropriate dispensing.

Comment: Contract pharmacies are most likely Medicaid pharmacy providers, while the covered entity likely is not. Because State Medicaid programs are unlikely to issue pharmacy numbers to anyone other than licensed pharmacies, covered entities that are not licensed pharmacies will not be able to bill Medicaid for prescriptions dispensed by the contract pharmacies. This task will be completed by the contract pharmacy. The mechanism excludes Medicaid drugs; therefore, the contract pharmacy must have two Medicaid numbers (i.e., 340B exclusion package and one to bill Medicaid for its regular customers). However, PHS has not required the contract pharmacy to do so. Moreover, neither the pharmacy nor the State has any incentive to ''make arrangements'' to carry out the statute, since both may gain from inadequate enforcement.

Response: The mechanism requires the parties to comply with the prohibition on filling Medicaid prescriptions with drugs purchased at 340B pricing. Neither the covered entity nor the contract pharmacy will bill Medicaid for 340B drug reimbursement; therefore, there will be no need for two Medicaid numbers. The 340B drugs will not generate Medicaid rebates.

Comment: As the owner of the drug, the covered entity should be responsible for establishing the price for each drug sold to a patient of the entity (effectively preventing the contractor from charging whatever price it chooses) and assuming full responsibility for such prices under the terms of the PHS grant and any applicable consumer protection laws.

Response: Even though it is clearly stated in the guidelines that the covered entity must purchase the drug (not the contractor), which would give to the covered entity title to and responsibility for the drug, we have added the following clarifying language to provision (a): ''* * * will purchase the drug and will assume full responsibility for establishing its price, pursuant to terms of a PHS grant (if applicable) and any applicable consumer protection laws.''

(6) Records

Comment: The contractor should assure that all pertinent reimbursement accounts and dispensing records maintained by the contractor for the covered entity are separate from the contractor's own operations and are accessible to the covered entity, PHS, and the manufacturers in the event of an audit. The contractor should provide these records to the manufacturer upon request.

Response: We have added the concept of separate records to provision (j) to assure the availability of these records in the case of an audit by the manufacturer. However, a manufacturer has statutory authority to access these entity records by performing an audit; therefore, to require the entity to submit records upon demand would be unduly burdensome.

Comment: ODP should establish standards for reporting that will ensure consistency of the information and approve whatever ''record-keeping'' system is used.

Response: Any reasonable system which will provide an adequate audit trail will be acceptable. However, reporting should be consistent with State pharmacy laws and other reporting mechanisms. As stated earlier in this section, sample contract provisions are suggested which describe such records and reports (e.g., prescription files, velocity reports, and records of ordering and receipt).

Comment: Reporting requirements should include some record or report that assures that only patients of the covered entity were served.

Response: Provision (f) provides that the contractor will provide the covered entity with reports as deemed appropriate using normal and customary business records.

Comment: The agreement should require that the pharmacy contractor maintain separate inventories and separate records for patients of the PHS entity contracting for pharmacy services.

Response: The guidelines have been changed to include a provision for separate dispensing records for patients of the covered entity. However, the requirement for a separate inventory of 340B drugs is unnecessary, because the covered entity is required to monitor dispensing and inventory records. In addition, these records are also subject to Department and manufacturer audits. A separate inventory is a wasteful concept with respect to time, space and money. Further, it provides little if any additional security, as a separate inventory only speaks to what is currently on the shelf and not what should be on the shelf. On the other hand, dispensing and other records will accurately indicate use of 340B drugs.

Comment: The covered entity is responsible for making arrangements to seek reimbursement from third parties for 340B drugs used in treating patients of the entity. If the covered entity receives a PHS grant, it would lose its

grant eligibility for failing to make appropriate arrangements.

Response: Since the entity purchases the drugs, it has the option of seeking reimbursement from third parties itself or contracting for this service. However, to the extent that a covered entity (or its contract pharmacy acting on its behalf) fails to comply with grant conditions, the entity may be subject to grant penalties.

Comment: To the extent that the covered entity makes arrangements for the pharmacy contractor to submit claims for third party reimbursement, the covered entity should assume full responsibility under State consumer protection laws, insurance, fraud, and State and Federal health care laws with respect to any false claims charges or allegations of consumer or insurance fraud.

Response: The ODP is not authorized to enforce or interpret such laws. If we become aware of possible violations of such laws, we will refer these cases to appropriate authorities.

(C) Contract Pharmacy Services Revised Final Mechanism

Covered entities that wish to utilize contract pharmacy services to dispense section 340B outpatient drugs are encouraged to sign and have in effect a contract pharmacy service agreement between the covered entity and the pharmacy. This mechanism is designed to facilitate program participation for those eligible covered entities that do not have access to appropriate ''in-house'' pharmacy services. *See* Appendix for suggested contract provisions.

(1) The following is a suggested model agreement format:

(a) The covered entity will purchase the drug and assume responsibility for establishing its price, pursuant to the terms of a PHS grant (if applicable) and any applicable consumer protection laws.

A ''ship to, bill to'' procedure may be used in which the covered entity purchases the drug, the manufacturer bills the entity for the drug that it purchased, but ships the drug directly to the contract pharmacy. *See* section 1 of Appendix.

(b) The contractor will provide all pharmacy services (e.g., dispensing, record keeping, drug utilization review, formulary maintenance, patient profile, counseling). Each covered entity which purchases its covered outpatient drugs has the option of individually contracting for pharmacy services with the pharmacy of its choice. The limitation of one pharmacy contractor per entity does not preclude the selection of a pharmacy contractor with multiple pharmacy sites, as long as only one site is used for the contracted services. [The ODP will be evaluating the feasibility of permitting these covered entities to contract with more than one site and contractor.]

(c) The covered entity health care provider will inform the patient of his or her freedom to choose a pharmacy provider. If the patient does not elect to use the contracted service, the patient may obtain the prescription from the covered entity and then obtain the drug(s) from the pharmacy provider of his or her choice.

When a patient obtains a drug from a retail pharmacy other than the entity contract pharmacy, the manufacturer is not required to offer this drug at 340B pricing.

(d) The contractor may provide the covered entity services, other than pharmacy, at the option of the covered entity (e.g., home care, reimbursement services). Regardless of the services provided by the contractor, access to 340B pricing will always be restricted to only patients of the covered entity.

(e) The contractor and the covered entity will adhere to all Federal, State, and local laws and requirements. Additionally, all PHS grantees will adhere to all rules and regulations established by the grant funding office.

Both the covered entity and the contract pharmacy are aware of the potential for civil or criminal penalties if the covered entity and/or the contract pharmacy violate Federal or State law. [The Department reserves the right to take such action as may be appropriate if it determines that such a violation has occurred.]

(f) The contractor will provide the covered entity with reports consistent with customary business practices (e.g., quarterly billing statements, status reports of collections and receiving and dispensing records). See Section 2 of Appendix.

(g) The contractor, with the assistance of the covered entity, will establish and maintain a tracking system suitable to prevent diversion of section 340B discounted drugs to individuals who are not patients of the covered entity. Customary business records may be used for this purpose. The covered entity will establish a process for a periodic random (sample) comparison of its prescribing records with the contractor's dispensing records to detect potential irregularities. See Section 3 of Appendix.

(h) The covered entity and the contract pharmacy will develop a system to verify patient eligibility. [The Department's draft guidance defining covered entity ''patient'' is set forth in an August 3, l995, **Federal Register** notice. See 60 FR 39762.]

Both parties agree that they will not resell or transfer a drug purchased at section 340B pricing to an individual who is not a patient of the covered entity. See section 340B(a)(5)(B). The covered entity understands that it can be removed from the list of covered entities because of its participation in drug diversion, a 340B(a)(5) prohibition, and no longer be eligible for 340B pricing. See Section 4 of Appendix.

(i) Both parties will not use drugs purchased under section 340B to dispense Medicaid prescriptions, unless the contract pharmacy and the State Medicaid agency have established an arrangement to prevent duplicate discounting.

(j) Both parties understand that they are subject to audits (by the Department and participating manufacturers) of records that directly pertain to the entity's compliance with the drug resale or transfer prohibition and the prohibition against duplicate Medicaid rebates and 340B discounts. See section 340B(a)(5).

The contractor will assure that all pertinent reimbursement accounts and dispensing records, maintained by the contractor, will be separate from the contractor's own operations and will be accessible to the covered entity, the Department, and the manufacturer in the case of a manufacturer audit.

(k) Upon request, a copy of this contract pharmacy service agreement will be provided to a participating manufacturer which sells covered outpatient drugs to the covered entity. All confidential propriety information may be deleted from the document.

(2) Certification

Under section 340B, we believe that if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price. If the entity directs the drug shipment to its contract pharmacy, we see no basis on which to conclude that section 340B precludes this type of transaction or otherwise exempts the manufacturer from statutory compliance. However, the entity must comply, under any distribution mechanism, with the statutory prohibition on drug diversion and duplicating discounting.

To provide ODP and manufacturers with assurance that the covered entity has acted in a manner which limits the potential for drug diversion, the covered entity is encouraged to submit to ODP a certification that it has signed and has in effect an agreement with the contract pharmacy containing the aforementioned provisions. However, ODP will review any alternative mechanism which is designed to reduce the potential for drug diversion. The names of those covered entities which submit a certification, or an alternate mechanism approved by ODP, will be placed on the EDRS for the convenience of participating drug manufacturers.

(3) Anti-kickback Statute

Contractors and covered entities must be aware of the potential for civil or criminal penalties if the contractor violates Federal or State law. In negotiating and executing a contracted pharmacy service agreement pursuant to these guidelines, contractors and covered entities should be aware of and take into consideration the provisions of the Medicare and Medicaid anti-kickback statute, 42 U.S.C. 1320a–7b(b). This statute makes it a felony for a person or entity to knowingly and willfully offer, pay, solicit, or receive

remuneration with the intent to induce, or in return for the referral of, Medicare or a State health care program business. State health care programs are Medicaid, the Maternal and Child Health Block Grant program, and the Social Services Block Grant program. Apart from the criminal penalties, a person or entity is also subject to exclusion from participation in the Medicare and State health care programs for a knowing and willful violation of the statute pursuant to 42 U.S.C. 1320a–7(b)(7).

The anti-kickback statute is very broad. Prohibited conduct covers not only remuneration intended to induce referrals of patients, but also includes remuneration intended to induce the purchasing, leasing, ordering, or arranging for any good, facility, service, or item paid for by Medicare or a State health care program. The statute specifically identifies kickbacks, bribes, and rebates as illegal remuneration, but also covers the transferring of anything of value in any form or manner whatsoever. This illegal remuneration may be furnished directly or indirectly, overtly or covertly, in cash or in kind and covers situations where there is no direct payment at all, but merely a discount or other reduction in price or the offering of a free good(s).

Arrangements between contractors and covered entities that could violate the anti-kickback statute would include any situation where the covered entity agrees to refer patients to the contractor in return for the contractor agreeing to undertake or furnish certain activities or services to the covered entity at no charge or at a reduced or below cost charge. These activities or services would include the provision of contracted pharmacy services, home care services, money or grants for staff or service support, or medical equipment or supplies, and the remodeling of the covered entity's premises. For example, if a contractor agreed to furnish covered outpatient drugs in return for the covered entity referring its Medicaid patients to the contractor to have their prescriptions filled, the arrangement would violate the anti-kickback statute. Similarly, if the contractor agreed to provide billing services for the covered entity at no charge in return for the covered entity referring its patients to the contractor for home or durable medical equipment, the statute would be violated.

Pursuant to the authority in 42 U.S.C. 1320a–7b(b)(3), the Secretary of HHS has published regulations setting forth certain exceptions to the anti-kickback statute, commonly referred to as ''safe harbors.'' These regulations are codified at 42 CFR 1001.952. Each of the safe harbors sets forth various requirements which may be met in order for a person or entity to be immune from prosecution or exclusion.

(D) Appendix—Suggested Contract Provisions

(1) ''The covered entity will order covered drugs directly from the manufacturer, from a designated sales representative, or a drug wholesaler and arrange to be billed directly for such drugs. The covered entity will arrange for shipment of such drugs directly to the pharmacy. The pharmacy will compare all shipments received to the orders and inform the covered entity of any discrepancy within five (5) business days of receipt. The covered entity will make timely payments for such drugs delivered to the (pharmacy) pursuant to the entity's order.''

(2) ''The covered entity will verify, using the contractor's (readily retrievable) customary business records, that a tracking system exists which will ensure that drugs purchased under the Act are not diverted to individuals who are not patients of the covered entity. Such records can include: prescription files, velocity reports, and records of ordering and receipt. These records will be maintained for the period of time required by State law and regulations.''

(3) ''Prior to the pharmacy providing pharmacy services pursuant to this agreement, the covered entity will have the opportunity, upon reasonable notice and during business hours, to examine the tracking system. For example, such a tracking system may include quarterly sample comparisons of eligible patient prescriptions to the dispensing records and a six (6) month comparison of 340B drug purchasing and dispensing records as is routinely done in other reconciliation procedures. The pharmacy will permit the covered entity or its duly authorized representatives to have reasonable access to pharmacy's facilities and records during the term of this agreement in order to make periodic checks regarding the efficacy of such tracking systems. The pharmacy agrees to make any and all adjustments to the tracking system which covered entity advises are reasonably necessary to prevent diversion of covered drugs to individuals who are not patients of the covered entity.''

(4) ''The pharmacy will dispense covered drugs only in the following circumstances: (a) Upon presentation of a prescription bearing the covered entity's name, the eligible patient's name, a designation that the patient is an eligible patient, and the signature of a legally qualified health care provider affiliated with the covered entity; or (b) receipt of a prescription ordered by telephone on behalf of an eligible patient by a legally qualified health care provider affiliated with the covered entity who states that the prescription is for an eligible patient. The covered entity will furnish a list to the pharmacy of all such qualified health care providers and will update the list of providers to reflect any changes. If a contract pharmacy is found to have violated the drug diversion prohibition, the pharmacy will pay the entity the amount of the discount in question so that the entity can reimburse the manufacturer.''

Dated: August 14, 1996.

Thomas G. Morford,

Acting Administrator, Health Resources and Services Administration.

[FR Doc. 96–21485 Filed 8–22–96; 8:45 am]

BILLING CODE 4160–15–P

National Institutes of Health

National Heart, Lung, and Blood Institute; Proposed Collection; Comment Request the Framingham Study

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on the proposed data collection projects, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

PROPOSED COLLECTION: Title: The Framingham Study. Type of Information Collection Request: Extension of a currently approved collection (OMB No. 0925–0216). Need and Use of Information Collection: This project involves physical examination and testing of the surviving members of the original Framingham Study cohort and the surviving members of the offspring cohort. Investigators will contact doctors, hospitals, and nursing homes to ascertain participants' cardiovascular events occurring outside the study clinic. Information gathered will be used to further describe the risk factors, occurrence rates, and consequences of cardiovascular disease in middle aged and older men and women. Frequency of Response: The cohort participants respond every two years; the offspring participants respond every four years. Affected Public: Individuals or households; Businesses or other for profit; Small businesses or

ATTACHMENT 3

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
106.100	5	10	50	4,000	200,000
107.50(c)(3)	3	10	30	3,000	90,000
Total					290,000

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

In compiling these estimates, FDA consulted its records of the number of infant formula submissions received in the past. The figures for hours per response are based on estimates from experienced persons in the agency and in industry.

Dated: January 8, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–331 Filed 1–11–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: Section 340B of the Public Health Service Act implements a drug pricing program in which manufacturers who sell covered outpatient drugs to covered entities must agree to charge a price that will not exceed an amount determined under a statutory formula. The purpose of this notice is to inform interested parties of proposed guidelines regarding contract pharmacy services that will allow covered entities to utilize contract pharmacy services arrangements previously limited to the Alternative Methods Demonstration Project program.

DATES: The public is invited to comment on the proposed guidelines by March 13, 2007. After consideration of the submitted comments, the Health Resources and Services Administration (HRSA) will issue the final guidelines.

ADDRESSES: Address all comments to Mr. Bradford R. Lang, Public Health Analyst, Office of Pharmacy Affairs (OPA), Health Resources and Services Administration (HRSA), 5600 Fishers Lane, Parklawn Building, Room 10C–03, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mr. Jimmy Mitchell, Director, OPA, HRSA, 5600 Fishers Lane, Parklawn Building, Room 10C–03, Rockville, MD 20857, or by telephone through the Pharmacy Services Support Center at 1–800–628–6297.

SUPPLEMENTARY INFORMATION:

A. Background

Section 602 of Public Law 102–585, the Veterans Health Care Act of 1992, enacted section 340B of the Public Health Service Act, Limitation on Prices of Drugs Purchased by Covered Entities. Previous guidelines pertaining to contract pharmacy services for the 340B drug pricing program (61 FR 43549, Aug. 23, 1996) stated that a covered entity could contract with only one pharmacy to provide all pharmacy services for any particular site of the covered entity. Furthermore, if the contract pharmacy had multiple locations, the covered entity site had to choose one, and only one, contract pharmacy location for provision of these services.

In 2001, HRSA established Alternative Methods Demonstration Projects (AMDPs) which allowed covered entities that applied and were approved by HRSA to pursue alternatives to contracting with a single pharmacy. These alternative models included the following: (1) The use of multiple contract pharmacy service sites, (2) the utilization of a contract pharmacy to supplement in-house pharmacy services, and/or (3) the development of a network of 340B covered entities. The intent was to allow community health centers and other 340B safety-net providers to develop new ways to improve access to 340B prescription drugs for their patients. From the time of the program's inception until the end of April 2006, a total of 18 AMDPs were approved. Of those, 11 utilize a multiple contract pharmacies model, four establish a network of 340B covered entities, one is a combination of the network model and the multiple contract pharmacies model, one utilizes a contract pharmacy to supplement an in-house pharmacy, and one utilizes multiple contract pharmacies to supplement an in-house pharmacy. All but one of the projects is currently ongoing. A condition of AMDP approval is the requirement that the approved demonstration project be audited annually by an independent, outside auditor for drug diversion and duplicative discounts under Medicaid. The results of the audits are required to be reported to the Office of Pharmacy Affairs (OPA). To date, there has been no evidence of drug diversion or duplicate manufacturer's discounts on 340B drugs in the AMDP program.

HRSA, acting through OPA, is proposing new guidelines that would allow covered entities to utilize multiple contract pharmacy service sites and the utilization of a contract pharmacy to supplement in-house pharmacy services that were previously limited to approved AMDPs. This proposed change is due to the success of the AMDPs, and the urging of safety net providers who wish to utilize alternatives to the single entity site/single pharmacy location contractor model to provide broader access to 340B discounted drugs to eligible patient populations. Other than permitting these specified models, HRSA is not proposing other substantive changes to the contract pharmacy guidelines. The AMDP process will continue for those covered entities wishing to develop 340B networks of covered entities. OPA will continue to review the utilization of network demonstration projects and consider adapting the rules to include them in the future. Of particular importance is the continued requirement that appropriate procedures be in place to prevent diversion of 340B drugs or a duplicative 340B drug discount and a Medicaid rebate on the same drug, which are prohibited under the statute.

These proposed guidelines replace all sections of previous 340B Program guidance documents addressing non-network contract pharmacy services, including, but not limited to, the ''Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services,'' 61 FR

43549 and any individual correspondence issued by HRSA on the subject. Demonstration projects previously approved under the multiple contract pharmacy model, the supplement to in-house pharmacy model, or a combination of the two models when this Federal guidance goes into effect, would be governed by this guidance and would no longer be subject to expiration of AMDPs, interim reporting or annual audits currently mandatory for all demonstration projects (this guidance only applies to audits required under the AMDP and leaves unchanged audit requirements under any other authority or program). While annual audits will no longer be required to be provided to OPA annually, covered entities are required to maintain fully auditable records and OPA expects covered entities to include appropriate sampling of multiple contract pharmacy arrangements in the course of routine annual audits. Demonstration projects previously approved to utilize the network model would continue to be subject to all program requirements and conditions set up under the AMDP. Any covered entity wishing to utilize a network model would still be required to seek approval under the AMDP and may not do so without formal approval.

B. Contract Pharmacy Services Mechanism

(1) Basic Requirements for Utilization of Contract Pharmacy Arrangements

Covered entities that wish to utilize contract pharmacy services to dispense section 340B outpatient drugs must have a written contract in place between themselves and a pharmacy. This mechanism is designed to facilitate program participation for those covered entities that do not have access to available or appropriate ''in-house'' pharmacy services, those covered entities who have access to ''in-house'' pharmacy services but who wish to supplement these ''in-house'' services, and covered entities that wish to utilize multiple contract pharmacies to increase patient access to 340B drugs. The covered entity has the responsibility to: ensure against illegal diversion and duplicate discounts, maintain readily auditable records, and meet all other 340B Drug Pricing Program requirements. OPA has provided a model agreement format below as guidance for the type of contractual provisions expected in such agreements as well as suggested contract provisions in the Appendix. All covered entities utilizing a contract pharmacy must comply with the certification requirements described in (4) below.

(2) Potential Alternatives to Single Location, Single Pharmacy Model

In addition to contracting with a single pharmacy for each clinical site, covered entities may pursue more complex arrangements that include multiple pharmacies only if: (a) There is a written agreement and procedures meeting the basic requirements outlined in (1) above between the covered entity and each pharmacy; (b) the operation continues to meet all 340B Drug Pricing Program requirements and does not create unlawful diversion or duplicate discounts; and (c) the arrangements are one of the two following models individually or in combination: (i) The use of multiple contract pharmacy service sites, and/or (ii) the utilization of a contract pharmacy (ies) to supplement in-house pharmacy services. The use of multiple contract pharmacy service sites refers to any arrangement wherein a covered entity site seeks to provide drugs at 340B discounted prices for its patients at more than one pharmacy location. Supplementing in-house pharmacy services with a contract pharmacy refers to any arrangement wherein a covered entity site seeks to purchase drugs at 340B discounted prices for its patients at both an in-house pharmacy and at least one additional contract pharmacy location.

(3) Model Agreement Provisions

The following are suggested provisions for a model agreement:

(a) The covered entity will purchase the drug, maintain title to the drug and assume responsibility for establishing its price, pursuant to the terms of a HHS grant (if applicable) and any applicable state and local laws and consumer protection laws.

A ''ship to, bill to'' procedure is used in which the covered entity purchases the drug; the manufacturer/wholesaler must bill the covered entity for the drug that it purchased, but ships the drug directly to the contract pharmacy (Section 1 of Appendix.) In cases where a covered entity has more than one site, it may choose between having each site billed individually or designating a single covered entity billing address for all 340B drug purchases.

(b) The contract pharmacy will provide comprehensive pharmacy services (e.g., dispensing, recordkeeping, drug utilization review, formulary maintenance, patient profile, patient counseling, and medication therapy management services). Each covered entity which purchases its covered outpatient drugs has the option of individually contracting for pharmacy services with a pharmacy(ies) of its choice.

(c) The covered entity health care provider will inform the patient of his or her freedom to choose a pharmacy provider. If the patient does not elect to use the contracted service, the patient may obtain the prescription from the covered entity and then obtain the drug(s) from the pharmacy provider of his or her choice.

When a patient obtains a drug from a retail pharmacy other than a covered entity's contract pharmacy, the manufacturer is not required to offer this drug at the 340B price.

(d) The contract pharmacy may provide other services to the covered entity at the option of the covered entity (e.g., home care, delivery, reimbursement services). Regardless of the services provided by the contract pharmacy, access to 340B pricing will always be restricted to only patients of the covered entity.

(e) The contract pharmacy and the covered entity will adhere to all Federal, State, and local laws and requirements. Additionally, all HHS grantees, disproportionate share hospitals and FQHC Look-Alikes will adhere to all rules and regulations that apply to them as grantees or otherwise eligible entities.

Both the covered entity and the contract pharmacy are aware of the potential for civil or criminal penalties if the covered entity and/or the contract pharmacy violate Federal or State law. [The Department reserves the right to take such action as may be appropriate if it determines that such a violation has occurred.]

(f) The contract pharmacy will provide the covered entity with reports consistent with customary business practices (e.g., quarterly billing statements, status reports of collections and receiving and dispensing records). *See* Section 2 of Appendix.

(g) The contract pharmacy, with the assistance of the covered entity, will establish and maintain a tracking system suitable to prevent diversion of section 340B drugs to individuals who are not patients of the covered entity. Customary business records may be used for this purpose. The covered entity will establish a process for a periodic comparison of its prescribing records with the contract pharmacy's dispensing records to detect potential irregularities. *See* Section 3 of Appendix.

(h) The covered entity and the contract pharmacy will develop a system to verify patient eligibility, as defined by HRSA guidelines.

Both parties agree that they will not resell or transfer a drug purchased at section 340B prices to an individual who is not a patient of the covered entity. *See* 42 U.S.C. 256a(a)(5)(B). The covered entity understands that it can be removed from the list of covered entities because of its participation in drug diversion and no longer be eligible for 340B pricing. *See* Section 4 of Appendix.

(i) Neither party will use drugs purchased under section 340B to dispense Medicaid prescriptions, unless the covered entity, the contract pharmacy and the State Medicaid agency have established an arrangement to prevent duplicate discounts. Any such arrangement shall be reported to the Office of Pharmacy Affairs by the covered entity.

(j) Both parties understand that they are subject to audits (by the Department and participating manufacturers) of records that directly pertain to the entity's compliance with the drug resale or transfer prohibition and the prohibition against duplicate discounts. *See* 42 U.S.C § 256a(a)(5).

The contract pharmacy will assure that all pertinent reimbursement accounts and dispensing records, maintained by the pharmacy, will be accessible separately from the pharmacy's own operations and will be made available to the covered entity, the Department, and the manufacturer in the case of an audit.

(k) Upon written request to the covered entity, a copy of this contract pharmacy service agreement will be provided to a participating manufacturer which sells covered outpatient drugs to the covered entity. All confidential or proprietary information may be deleted from the document.

(4) Certification

Under section 340B, if a covered entity using contract pharmacy services requests to purchase a covered outpatient drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at a price not to exceed the statutory 340B discount price. If the entity directs the drug shipment to its contract pharmacy(ies), we see no basis on which to conclude that section 340B precludes this type of transaction or otherwise exempts the manufacturer from statutory compliance. However, the entity must comply, under any distribution mechanism, with the statutory prohibition on drug diversion and duplicate discounting.

To provide OPA and manufacturers with assurance that the covered entity has acted in a manner which limits the potential for drug diversion, the covered entity is required to submit to OPA a certification that it has signed and has in effect an agreement with the contract pharmacy(ies) containing the aforementioned provisions (see 3 above). However, if a covered entity wishes to utilize an agreement with provisions different from those listed above that it believes meets 340B requirements; OPA will review the proposed agreement provisions for sufficiency. The names of those covered entities which submit a certification, or an alternate mechanism approved by OPA, will be listed on the OPA Web site for the convenience of participating drug manufacturers and wholesaler distributors.

In addition, any covered entity that has opted to utilize any pharmacy arrangement described in (2) must specify which arrangement or combination of arrangements it is utilizing, the names and 340B identification numbers of all covered entities participating, and the names of any pharmacies participating.

(5) Anti-Kickback Statute

Contract pharmacies and covered entities should be aware of the potential for civil or criminal penalties if the contract pharmacy violates Federal or State law. In negotiating and executing a contract pharmacy service agreement pursuant to these guidelines, contract pharmacies and covered entities should be aware of and take into consideration the provisions of the Medicare and Medicaid anti-kickback statute, 42 U.S.C. 1320a–7b(b). This statute makes it a felony for a person or entity to knowingly and willfully offer, pay, solicit, or receive remuneration with the intent to induce, or in return for the referral of, Medicare or a State health care program business. State health care programs are Medicaid, the Maternal and Child Health Block Grant program, and the Social Services Block Grant program. Apart from the criminal penalties, a person or entity is also subject to exclusion from participation in the Medicare and State health care programs for a knowing and willful violation of the statute pursuant to 42 U.S.C. 1320a–7(b)(7).

The anti-kickback statute is very broad. Prohibited conduct covers not only remuneration intended to induce referrals of patients, but also includes remuneration intended to induce the purchasing, leasing, ordering, or arranging for any good, facility, service, or item paid for by Medicare or a State health care program. The statute specifically identifies kickbacks, bribes, and rebates as illegal remuneration, but also covers the transferring of anything of value in any form or manner whatsoever. This illegal remuneration may be furnished directly or indirectly, overtly or covertly, in cash or in kind and covers situations where there is no direct payment at all, but merely a discount or other reduction in price or the offering of a free good(s).

Arrangements between contract pharmacies and covered entities that could violate the anti-kickback statute would include any situation where the covered entity agrees to refer patients to the contract pharmacy in return for the contract pharmacy or an entity owned or controlled by the contract pharmacy agreeing to undertake or furnish certain activities or services to the covered entity at no charge or at a reduced or below cost charge. These activities or services would include the provision of contract pharmacy services, home care services, money or grants for staff or service support, or medical equipment or supplies, or the remodeling of the covered entity's premises. For example, if a contract pharmacy agreed to furnish covered outpatient drugs in return for the covered entity referring its Medicaid patients to the contract pharmacy to have their prescriptions filled, the arrangement would violate the anti-kickback statute. Similarly, if the contract pharmacy agreed to provide billing services for the covered entity at no charge in return for the covered entity referring its patients to the contract pharmacy for home or durable medical equipment, the statute would be violated.

Pursuant to the authority in 42 U.S.C. 1320a–7b(b)(3), the Secretary of HHS has published regulations setting forth certain exceptions to the anti-kickback statute, commonly referred to as ''safe harbors.'' These regulations are codified at 42 CFR 1001.952. Each of the safe harbors sets forth various requirements which must be met in order for a person or entity to be immune from prosecution or exclusion under the safe harbors.

C. Appendix—Suggested Contract Provisions

(1) ''The covered entity owns covered drugs and arranges to be billed directly for such drugs. The pharmacy will compare all shipments received to the orders and inform the covered entity of any discrepancy within five (5) business days of receipt. The covered entity will make timely payments for such drugs delivered to the (pharmacy).''

(2) ''The covered entity will verify, using the contract pharmacy's (readily retrievable) customary business records, that a tracking system exists which will

ensure that drugs purchased under the 340B Drug Pricing Program are not diverted to individuals who are not patients of the covered entity. Such records can include: prescription files, velocity reports, and records of ordering and receipt. These records will be maintained for the period of time required by State law and regulations.''

(3) ''Prior to the contract pharmacy providing pharmacy services pursuant to this agreement, the covered entity will have the opportunity, upon reasonable notice and during business hours, to examine the tracking system. For example, such a tracking system may include quarterly sample comparisons of eligible patient prescriptions to the dispensing records and a six (6) month comparison of 340B drug purchasing and dispensing records as is routinely done in other reconciliation procedures. The contract pharmacy will permit the covered entity or its duly authorized representatives to have reasonable access to contract pharmacy's facilities and records during the term of this agreement in order to make periodic checks regarding the efficacy of such tracking systems. The contract pharmacy agrees to make any and all adjustments to the tracking system which the covered entity advises are reasonably necessary to prevent diversion of covered drugs to individuals who are not patients of the covered entity.''

(4) ''The pharmacy will dispense covered drugs only in the following circumstances: (a) Upon presentation of a prescription bearing the covered entity's name, the eligible patient's name, a designation that the patient is an eligible patient of the covered entity, and the signature of a legally qualified health care provider affiliated with the covered entity; or (b) receipt of a prescription ordered by telephone or other means of electronic transmission that is permitted by State or local law on behalf of an eligible patient by a legally qualified health care provider affiliated with the covered entity who states that the prescription is for an eligible patient. The covered entity will furnish a list to the pharmacy of all such qualified health care providers and will update the list of providers to reflect any changes. If a contract pharmacy is found to have violated the drug diversion prohibition, the contract pharmacy will pay the covered entity the amount of the discount in question so that the covered entity can reimburse the manufacturer.''

Dated: December 22, 2006.

Elizabeth M. Duke,

Administrator.

[FR Doc. E7–334 Filed 1–11–07; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Definition of ''Patient''

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: Section 602 of Public Law 102–585, the ''Veterans Health Care Act of 1992,'' enacted Section 340B of the Public Health Service (PHS) Act ''Limitation on Prices of Drugs Purchased by Covered Entities.'' Section 340B provides that in order to obtain Medicaid reimbursement for its covered outpatient drugs, a manufacturer must sign a pharmaceutical pricing agreement with the Secretary of Health and Human Services in which the manufacturer agrees to charge a price to covered entities for outpatient drugs that will not exceed an amount determined under a statutory formula. Section 340B is administered as the ''340B Drug Pricing Program'' and is commonly referred to as ''the 340B Program.''

Section 340B states that it is illegal for covered entities to sell medications purchased under the 340B Program to persons who are not considered ''patients'' of the covered entity. The purpose of this notice is to inform interested parties of proposed clarifications to the definition of ''patient'' for whom the covered entity can purchase discounted pharmaceuticals under the 340B Program. This clarification is necessary to protect the integrity of the 340B Program and to assist covered entities and other participants in their compliance efforts.

DATES: The public is invited to submit comments on the proposed guidelines by March 13, 2007. After consideration of the comments submitted, the Secretary will issue final guidelines.

ADDRESSES: Address all comments to Mr. Bradford R. Lang, Public Health Analyst, Office of Pharmacy Affairs (OPA), Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), 5600 Fishers Lane, Parklawn Building, Room 10C–03, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mr. Jimmy Mitchell, Director, OPA, HSB, HRSA, 5600 Fishers Lane, Parklawn Building, Room 10C–03, Rockville, MD 20857, or by telephone through the Pharmacy Services Support Center at 1–800–628–6297.

SUPPLEMENTARY INFORMATION:

Introduction

Section 340B(a)(4) of the PHS Act and section 1927(a) of the Social Security Act list the various types of organizations eligible to participate in and purchase discounted drugs under the 340B Program. Eligibility for participation in the 340B Program is strictly limited to the specific categories of entities specified in these statutes.

Section 340B(a)(5)(B) of the PHS Act prohibits entities from selling (or otherwise transferring) drugs purchased under the 340B Program to anyone who is not a patient of the covered entity. Responsibility for ensuring compliance with this provision rests with the covered entity. Congress did not define the term ''patient'' in Section 340B, and initial HRSA guidelines implementing the 340B Program directed covered entities to ''develop and institute adequate safeguards to prevent the transfer of discounted outpatient drugs to individuals who are not eligible for the discount'' in order to prevent diversion. To accomplish this, entities were encouraged to utilize a separate purchasing account and separate dispensing records (See 59 FR 25110).

As covered entities, manufacturers, and others began to implement the 340B Program, it became apparent that additional clarification of the patient definition was needed and on October 24, 1996, HRSA issued additional guidelines regarding the definition of a covered entity ''patient'' (61 FR 55156). These guidelines stated that the following definition of patient would apply for the purposes of the 340B Program:

An individual is a ''patient'' of a covered entity (with the exception of State-operated or funded AIDS drug purchasing assistance programs) only if:

1. *The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and*

2. *The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity; and*

3. *The individual receives a health care service or range of services from the covered entity which is consistent with the service or*

ATTACHMENT 4

republished in its entirety; and amended on September 28, 2009 to provide targeted liability protections for pandemic countermeasures to enhance distribution and to add provisions consistent with other declarations and republished in its entirety. This Declaration incorporates all amendments prior to the date of its publication in the **Federal Register**. Any future amendment to this Declaration will be published in the **Federal Register**, pursuant to section 319F–2(b)(4) of the Act.

X. Definitions

For the purpose of this Declaration, including any claim for loss brought in accordance with section 319F–3 of the PHS Act against any covered persons defined in the Act or this Declaration, the following definitions will be used:

Administration of a Covered Countermeasure: As used in section 319F–3(a)(2)(B) of the Act includes, but is not limited to, public and private delivery, distribution, and dispensing activities relating to physical administration of the countermeasures to recipients, management and operation of delivery systems, and management and operation of distribution and dispensing locations.

Authority Having Jurisdiction: Means the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (*e.g.,* city, county, Tribal, State, or Federal boundary lines) or functional (*e.g.,* law enforcement, public health) range or sphere of authority.

Covered Persons: As defined at section 319F–3(i)(2) of the Act, include the United States, manufacturers, distributors, program planners, and qualified persons. The terms "manufacturer," "distributor," "program planner," and "qualified person" are further defined at sections 319F–3(i)(3), (4), (6), and (8) of the Act.

Declaration of Emergency: A declaration by any authorized local, regional, State, or Federal official of an emergency specific to events that indicate an immediate need to administer and use pandemic countermeasures, with the exception of a Federal declaration in support of an emergency use authorization under section 564 of the FDCA unless such declaration specifies otherwise.

Pandemic influenza A viruses and those with pandemic potential: Animal and/or human influenza A viruses, except those included in seasonal influenza vaccines and/or covered under the National Vaccine Injury Compensation Program, that are circulating in wild birds and/or domestic animals, that cause, or have significant potential to cause, sporadic or ongoing human infections, or historically have caused pandemics in humans, or have mutated to cause pandemics in humans, and for which the majority of the population is immunologically naïve.

Pandemic Phase: The following stages, as defined in the National Strategy for Pandemic Influenza: Implementation Plan (Homeland Security Council, May 2006): (4) First Human Case in North America; and (5) Spread Throughout United States.

Pre-pandemic Phase: The following stages, as defined in the National Strategy for Pandemic Influenza: Implementation Plan (Homeland Security Council, May 2006): (0) New Domestic Animal Outbreak in At-Risk Country; (1) Suspected Human Outbreak Overseas; (2) Confirmed Human Outbreak Overseas; and (3) Widespread Human Outbreaks in Multiple Locations Overseas.

Dated: February 26, 2010.

Kathleen Sebelius,

Secretary.

APPENDIX

I. List of U.S. Government Contracts—Covered H5N1, H2, H6, H7, H9, and 2009–H1N1 Vaccine Contracts

1. HHSN266200400031C
2. HHSN266200400032C
3. HHSN266200300039C
4. HHSN266200400045C
5. HHSN266200205459C
6. HHSN266200205460C
7. HHSN266200205461C
8. HHSN266200205462C
9. HHSN266200205463C
10. HHSN266200205464C
11. HHSN266200205465C
12. HHSN266199905357C
13. HHSN266200300068C
14. HHSN266200005413C
15. HHSO100200600021C (formerly 200200409981)
16. HHSO100200500004C
17. HHSO100200500005I
18. HHSO100200700026I
19. HHSO100200700027I
20. HHSO100200700028I
21. HHSO100200600010C
22. HHSO100200600011C
23. HHSO100200600012C
24. HHSO100200600013C
25. HHSO100200600014C
26. HHSO100200600022C (formerly 200200511758)
27. HHSO100200600023C (formerly 200200410431)
28. CRADA No. AI–0155 NIAID/MedImmune
29. HHSO100200700029C
30. HHSO100200700030C
31. HHSO100200700031C
32. All present, completed and future Government H5N1, H2, H6, H7, H9, and 2009–H1N1 vaccine contracts not otherwise listed.

[FR Doc. 2010–4644 Filed 3–4–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Final notice.

SUMMARY: Section 602 of Public Law 102–585, the "Veterans Health Care Act of 1992" enacted Section 340B of the Public Health Service Act (PHS). Section 340B implements a drug pricing program by which manufacturers who sell covered outpatient drugs to particular covered entities listed in the statute must agree to charge a price that will not exceed the amount determined under a statutory formula. The purpose of this Final Notice is to inform interested parties of final guidelines regarding the utilization of multiple contract pharmacies and suggested contract pharmacy provisions, which had been previously limited to the Alternative Methods Demonstration Project program.

FOR FURTHER INFORMATION CONTACT: Mr. Jimmy Mitchell, Director, Office of Pharmacy Affairs (OPA), Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), 5600 Fishers Lane, Parklawn Building, Room 10C–03, Rockville, Maryland 20857 or by telephone through the Pharmacy Services Support Center at 1–800–628–6297.

DATES: *Effective Date:* April 5, 2010.

SUPPLEMENTARY INFORMATION:

A. Background

Proposed guidelines for contract pharmacy services were announced in the **Federal Register** at 72 FR 1540 on January 12, 2007. A comment period of 60 days was established to allow interested parties to submit comments. HRSA, HSB, acting through the OPA, received 32 comments concerning the proposal.

In 1996, HRSA issued guidelines that permitted covered entities participating in the 340B Drug Pricing Program to contract with a pharmacy to provide services to the covered entity's patients (61 FR 43549, August 23, 1996). Those guidelines permitted a covered entity to use a single point for pharmacy services, either an in-house pharmacy or an

individual contract pharmacy. Since 2001, covered entities that have wanted to use other types of arrangements, or to blend the method of providing services (*e.g.* contract pharmacy to supplement an in-house pharmacy) have needed to apply to the OPA for an Alternative Methods Demonstration Project (AMDP) and secure approval in order to proceed.

It is important for all covered entities to keep in mind that use of a contract pharmacy arrangement (single, multiple or AMDP) does not lessen a covered entity's duty to ensure that the 340B program is being administered in compliance with the statute and HRSA guidelines. The covered entity has, and continues to bear, full responsibility and accountability for compliance with all requirements to prevent diversion of covered drugs to individuals other than patients of the covered entity, and to prevent situations in which a drug is subject to both the 340B discount and a Medicaid Rebate claim. Covered entities will be permitted to use multiple pharmacy arrangements as long as they comply with guidance developed to help ensure against diversion and duplicate discounts and the policies set forth regarding patient definition. Auditable records must be maintained to demonstrate compliance with those requirements. Such records must be maintained for as long as required by Federal, State and local law. Additionally, compliance with 340B requirements and guidelines does not excuse individual providers, covered entities, pharmacies, wholesale distributors or manufacturers from adherence to all other local, State or Federal requirements.

Covered entities should also be mindful that use of a contract pharmacy is voluntary. Covered entities are not required to use multiple contract pharmacies or any contract pharmacy at all. Each covered entity should conduct its own business review and patient assessment to determine what level of pharmacy services is needed, and the appropriate delivery mechanism for those services.

We received many comments in support of the proposal. Many of these came from covered entities that participate in 340B and highlighted how their delivery of patient care would be enhanced with a multiple contract pharmacy option. According to these comments, some patients currently face transportation barriers or other obstacles that limit their ability to fill their prescriptions. It would be a significant benefit to patients to allow the use of more easily accessible, multiple contract pharmacy arrangements by covered entities. This would permit covered entities to more effectively utilize the 340B program and create wider patient access by having more inclusive arrangements in their communities which would benefit covered entities, pharmacies and patients served.

Comments raised a number of issues: Audits; protecting against diversion; network models; limits on the number or location of contract pharmacies; and the need for model agreement provisions and certification procedures. Also addressed was the potential impact on manufacturers, pharmacies, covered entities and patients. Additional comments challenged the sufficiency of the data used to justify the changes, and questioned whether the proposed notice was in compliance with the Administrative Procedure Act.

The following section presents a summary of all major comments, grouped by subject, and a response to each grouping. All comments were considered in developing this Final Notice, and changes were made accordingly. Other changes were made to improve clarity and readability.

B. Comments and Responses

(1) Administrative Procedure Act (APA) Compliance

Comment: The proposed revisions represent a substantive rulemaking under the APA because they constitute new obligations and burdens on manufacturers. They also create new rights for covered entities under the law.

Response: HRSA disagrees. This guidance neither imposes additional burdens upon manufacturers, nor creates any new rights for covered entities under the law. HRSA has used interpretive guidance and statements of policy to provide guidance since the inception of the program and to create a working framework for its administration. Contract pharmacy service guidelines have been considered by HRSA to be "interpretative rules and statements of policy" exempt from notice and comment rulemaking under the APA. Nonetheless, HRSA has published these guidelines in the **Federal Register** and provided a public comment period to obtain input into guideline development. The present guidelines used this same process. HRSA has considered all comments, both Federal and public, in developing the Final Guidelines.

Comment: Eleven demonstration projects out of a total of 12,000 covered entities do not give HRSA enough data to expand the scope of the contract pharmacy model. An additional demonstration project, with not less than 100 sites, should be the next step to further evaluate risks and benefits of the expanded model.

Response: At the time of publication of the proposed guidance there had been 18 demonstration projects. HRSA realizes that only a small percentage of covered entities have gone through the AMDP process. HRSA is working with the data that exists, which was overwhelmingly supportive of the guidelines. Although there have been a limited number of AMDPs approved, some of the approved projects included a large number of health care sites and contract pharmacies. The number of participating health care sites exceeded 50 and the number of contract pharmacy sites was over 170. The results of the AMDP are not the only basis for issuing this guidance. The circumstances surrounding pharmacy practice and the resources available to track transactions have changed substantially over the past decade. The AMDP provides concrete examples of the ability of covered entities to utilize multiple contract pharmacies without sacrificing program integrity. Upon review of the evidence and current circumstances, HRSA does not find sufficient basis to continue limiting contract pharmacies to a single site. The restriction has imposed its own costs by restricting the flexibility of covered entities in meeting the needs of their patients. Furthermore, pharmacy and inventory management processes are available that make utilization of more than one pharmacy readily feasible for many covered entities without increasing the risk of diversion. The use of multiple contract pharmacies is not appropriate for all covered entities; however, we do not find a blanket restriction on all covered entities to be justified.

(2) Audits

Many commenters presented varying perspectives on the topic of audits. Multiple comments from drug manufacturers argued that manufacturers should be given the ability to audit covered entities that use multiple pharmacy contracting services due to the heightened risk of drug diversion and duplicate discounts. Other comments focused on HRSA audit requirements, arguing that they should be identical to the current standards required for the AMDP. Finally, some comments supported not having an audit requirement, arguing that audits would be burdensome and costly for the covered entities.

Comment: The audit requirements from the AMDP process should be applied to multiple contract pharmacies. There is no evidence of diversion and duplicate discounts

because of the audit requirements. Their elimination may lead to increased diversion and duplicate discounts. Some commenters recommended retaining the audit requirements for at least a few years until a track record of compliance with multiple contract pharmacies can be created. Audits should include a full compliance review of all mandatory contract terms/requirements including implementation of tracking system, patient status verification, and providing information about other pharmacy options.

Response: Although HRSA does not believe that precisely the same procedures are appropriate as utilized under the AMDP, HRSA agrees that independent audits can play an important role in ensuring program integrity. The guidelines have been revised to state that the covered entity must have sufficient information to meet its obligation of ensuring ongoing compliance and the recognition of any problem. Furthermore, the guidelines have been revised to indicate that it is the expectation of HRSA that covered entities will fulfill their ongoing obligation by the utilization of independent audits. However, HRSA leaves it up to covered entities to determine how to meet their compliance responsibilities. The guidelines intentionally do not specify the precise method, personnel or items for ensuring sufficient information is obtained by the covered entity. As long as covered entities comply with their obligations under the guidelines, HRSA prefers to leave the method of compliance to the judgment of the covered entities.

To the extent that any internal compliance activity or audit performed by a covered entity indicates that there has been a violation of 340B program requirements, it is HRSA's expectation that such finding be disclosed to HRSA along with the covered entity's plan to address the violation.

Comment: A copy of the audits conducted by covered entities should be submitted to OPA. The results of such audit should be made available to manufacturers.

Response: HRSA does not feel there is a need for the automatic submission of audits conducted by covered entities. HRSA believes that there are already appropriate safeguards in place. Covered entities are required to maintain auditable records sufficient to demonstrate continued compliance with 340B requirements; and, to the extent that a situation warrants, HRSA will request copies of any internal compliance documents of covered entities.

Comment: Covered entities should be required to conduct audits of their contract pharmacies and be required to terminate the contract with pharmacies found to be in violation.

Response: As noted earlier, HRSA agrees that audits can play an important role in ensuring integrity, and that covered entities are required to have sufficient information to ensure against diversion and duplicate discounts. The extent to which an audit of the contract pharmacy or other arrangement is necessary to satisfy that obligation will depend upon the individual circumstances. Covered entities have the responsibility to have agreements with contract pharmacies and procedures in place sufficient to enable the covered entity to meet its obligations under the law, including the prohibition on diversion and duplicate discounts. While an audit capability and various grounds for termination are terms that could be included in such contracts, there is no requirement in the guidelines for such terms. However, covered entities are reminded that they retain ultimate responsibility for compliance with the 340B program. Covered entities may be well-served by ensuring that compliance terms are included in their pharmacy contracts. To the extent that covered entities uncover these problems, the appropriate response is to report those problems to HRSA and ensure that they are properly addressed.

Comment: Manufacturers should be permitted to audit covered entities that use multiple contract pharmacy services. No reasonable cause should be required, due to heightened risk of diversion.

Response: We do not agree that utilization of more than one contract pharmacy creates automatic cause to suspect diversion. The issue as to whether additional audits by an outside manufacturer are permitted is addressed in the guidance published in the **Federal Register** on that issue (61 FR 65406, December 12, 1996). To the extent a manufacturer believes there is a reasonable basis to conclude that a covered entity is in breach of program requirements, it may audit a covered entity consistent with these guidelines. Additionally, HRSA has developed a dispute resolution process to provide parties with an informal mechanism to bring before the Department allegations of behavior that are in violation of 340B. For further guidance on the audit and dispute resolution process *see* 61 FR 65406 (December 12, 1996). As indicated in this guidance, covered entities and contract pharmacies must retain auditable records of 340B covered drug transactions sufficient to demonstrate compliance with the requirements to ensure against diversion to non-patients and against duplicate discounts.

Comment: It would be burdensome for covered entities to provide reports and data for audits. It is unclear who would be required to construct the actual components of the audit, what would be included, and who would pay for it.

Response: HRSA would like to remind all 340B stakeholders that it is an option for covered entities to voluntarily enter into contract pharmacy arrangements. Each covered entity is encouraged to conduct its own analysis of the costs and benefits of implementing or expanding their pharmacy services. It is the responsibility of the covered entity to ensure against diversion and duplicate discounts. Covered entities may determine how to best meet that responsibility: By performing a separate audit, including spot audits as part of pre-existing auditing responsibilities, or via other mechanisms. HRSA believes that including these issues as part of an independent audit is the best but not necessarily the only approach to meet covered entities' ongoing responsibility to know that their covered outpatient drugs are being appropriately ordered and distributed to their patients.

(3) Diversion

Comment: The proposed guidelines do not adequately describe safeguards that will combat drug diversion and duplicate discounts. There should be more severe penalties for violations, especially duplicate discounts. Reimbursement of any inappropriate discounts is insufficient and will not deter bad behavior. A covered entity should be excluded from 340B if it continues to use a pharmacy found to be in violation of the program.

Response: HRSA believes that there are appropriate safeguards in place, based on the parameters of the program. HRSA has the ability to exclude covered entities that abuse the program. HRSA has no statutory authority to assess additional penalties beyond the authority provided in section 340B. However, to the extent HRSA is aware that an action by a covered entity or contract pharmacy may be a violation of the law, such cases are referred to appropriate authorities.

Comment: The proposed guidance appears to limit the need to segregate records for easy accessibility by auditors rather than for purposes related to ensuring there is no diversion. Is this intended, or is segregation, virtual or

otherwise, still expected to be used by the contract pharmacy as a method of showing that diversion has not occurred?

Response: All covered entities are required to have auditable records sufficient to fully demonstrate compliance with all 340B requirements. Any covered entity that chooses to utilize a contract pharmacy must ensure that any such contract fully addresses that requirement and has the responsibility to ensure that the contract is actually performed and administered in compliance with those requirements. Inventory and record segregation is one of many methods that can be used to ensure compliance with the program guidelines. HRSA does not intend to limit the methods covered entities may use in order to remain in compliance with the guidelines. As noted previously, covered entities and contract pharmacies must retain auditable records of 340B covered drug transactions sufficient to demonstrate compliance with the requirements to ensure against diversion to non-patients as well as duplicate discounts.

Comment: Covered entities should be required to maintain and provide to HRSA and manufacturers written policies and procedures for preventing diversion and duplicate discounts in their contract pharmacy services.

Response: The ultimate responsibility for compliance with all aspects of the 340B program lies with each covered entity. The contract arrangements between covered entities and outside pharmacies will have various terms and procedures, which are acceptable as long as there are no violations of the program. It is expected that all covered entities will have written policies and procedures for preventing diversion and duplicate discounts as part of their obligations to prevent diversion and duplicate discounts. They are also required to maintain auditable records. HRSA will not automatically require covered entities to submit such policies and procedures for HRSA review.

(4) Contract Pharmacy Services Mechanism—Potential Alternatives to Single Location/Single Pharmacy Model

Comment: HRSA should permit separate covered entity sites to enter into one comprehensive agreement between the sites and a single contract pharmacy, instead of requiring a separate agreement for each site. Additionally, HRSA should permit a covered entity to enter into one comprehensive agreement with a chain pharmacy binding on multiple locations of the chain, instead of requiring a separate agreement for each contract pharmacy site.

Response: Each covered entity retains its own responsibility for compliance with the program. With respect to a covered entity with multiple sites, HRSA agrees that a single covered entity may contract for sites that are integral parts of the covered entity and for which it has legal control of so long as all of the requirements are met in the contract. This approach maintains and recognizes the central responsibility of the covered entity. In the case of agreements with "chain pharmacies," there appears to be potential for loss of accountability without a clearly established relationship between the actual pharmacy site and the covered entity. Covered entities are not precluded from entering into agreements with chain pharmacies, however, each participating pharmacy location must be listed on the contract and comply with the requirements.

Comment: One comment suggested that HRSA should clarify the definition of "multiple." The commenter interprets "multiple" to mean that an FQHC could contract with more than one pharmacy, including more than one site of a chain pharmacy, more than one independent pharmacy, or a combination of chain sites and independent pharmacies. Additionally, the commenter interprets "multiple" to mean that a covered entity with an in-house pharmacy could use any acceptable contract pharmacy arrangement to supplement the in-house pharmacy. The commenter encourages OPA to adopt this interpretation in the final guidance.

Response: HRSA agrees with the comment about the meaning of "multiple" and believes that the Final Notice is clear with respect to this meaning.

Comment: Does a covered entity that currently has an agreement with only one contract pharmacy need to revise its agreement with that pharmacy if the entity subsequently enters into agreements with additional pharmacies?

Response: The covered entity may need to revise its existing contract, depending on the terms that it contains. There is no requirement in the guidelines to revise contracts, as long as they meet the criteria outlined. All entities are encouraged to seek competent counsel to assess their needs.

Comment: The proposed guidelines do not provide cautionary language about possible negative results of implementing a multiple contract pharmacy model. Some small pharmacies that currently contract with covered entities may be hurt by implementation of the guidance due to reduced business. More guidance and decision analysis tools should be provided to guide the process of deciding whether to implement.

Response: HRSA notes that participation in any multiple contract pharmacy models is completely voluntary. All stakeholders are encouraged to conduct a full business analysis to determine whether to implement a multiple contract pharmacy model before moving forward. HRSA also provides free technical assistance for covered entities, including assistance with business analysis, to help navigate these issues. Ultimately, the decisions and responsibility for those decisions lies with the covered entity.

(5) Network Models

Comment: Multiple commenters proposed that network arrangements (*i.e.* arrangements involving a network of more than one covered entity) should be permitted under the guidelines without prior approval from HRSA. They argued that network arrangements would decrease the burden on covered entities and contract pharmacies by simplifying the contracting process and maintaining multiple inventory records. They also made the point that networks would also encourage parties to participate in 340B and therefore, expand access to eligible patients.

Response: HRSA understands the comments that a network model might potentially ease the administrative burden for participants in some cases. However, due to ongoing concerns about maintaining the integrity of the program with such complex arrangements, at this time, we decline to include network models in the guidelines without the added scrutiny of the AMDP process. HRSA will reassess the appropriateness of the utilization of networks outside the AMDP process as sufficient experience with them is gained in the future.

Comment: Some comments urged HRSA not to permit networks of multiple covered entities outside the framework of the AMDP process and requested confirmation that under the new guidance the development of a network of 340B covered entities will remain subject to the entire process now applicable to the AMDPs.

Response: HRSA agrees that covered entity networks should remain under the AMDP process, as indicated in the response to the prior comment.

Comment: "All covered entities participating" language is unclear. Does it mean a covered entity with multiple sites, a network model, or a DSH would need to name each covered entity that

has an agreement with a pharmacy under contract with the covered entity? If so, that would be burdensome on the entity, which would need to research and identify other covered entities that may contract with a particular pharmacy. What is the justification for requiring a covered entity to specify the names and 340B ID numbers of other participating covered entities?

Response: If a covered entity wants to use any alternative to a single location/single pharmacy model, it must submit its name and 340B identification number, and the names of all participating pharmacies to HRSA. Network models will still need to go through the AMDP process. The commenter is correct that the "all covered entities participating" language is unclear, because such arrangements only apply to a single covered entity. The language has been changed in response to this comment.

Comment: The guidelines should limit the numbers and geographical locations (not over State lines) for contract pharmacy relationships. Perhaps contract pharmacies should only be added one at a time. Monitoring various sites by the covered entity may be extremely difficult unless safeguards are in place.

Response: HRSA understands the commenter's concerns, but at this point, HRSA declines to limit the number of arrangements, as long as each arrangement meets our guidelines. Each covered entity retains the obligation to ensure its program remains compliant with the guidelines. HRSA does not intend to prescribe the methods covered entities use to run their programs or to ensure compliance at this time. Each covered entity and contract pharmacy is responsible for ensuring that its particular contracting arrangements and operations conform to the requirements of all applicable Federal, State and local laws and regulations.

(6) Model Agreement Provisions/Covered Entity Compliance Elements

In the final guidelines the phrase "Model Agreement Provisions" has been changed to "Covered Entity Compliance Elements" to better reflect the purpose of the elements and to distinguish them from model contract provisions.

Comment: Covered entities with multiple contract pharmacy arrangements should have written contracts with each pharmacy, including procedures to ensure against drug diversion and duplicate discounts, to maintain records available for audit, and to meet all other 340B requirements. Covered entities should submit these contracts and procedures to HRSA.

Response: HRSA agrees in part, which is why the guidelines do require a covered entity to have a contract that specifies all participating pharmacy locations. Such contracts must include adequate terms to ensure compliance with all aspects of the 340B program as listed in the Covered Entity Compliance Elements. However, at this time, HRSA does not have the need, or the resources to collect and review each contract. The covered entity bears responsibility for compliance with the program and will be held accountable in the event of non-compliance.

Comment: HRSA should create a single list of model contract terms, add suggested language on duplicate discount prohibition, and require covered entities to certify that their contracts use these terms or apply to HRSA for approval to use alternative terms.

Response: The Appendix of the guidelines does include a list of suggested contract provisions. HRSA has included provisions necessary to ensure that covered entities and contract pharmacies understand and agree not to violate 340B provisions. Because of the wide diversity of covered entities, it would be impossible to include provisions that would respond to the needs of all covered entities.

Comment: Manufacturers should be allowed to request copies of the contracts between the covered entities and contract pharmacies.

Response: Manufacturers are certainly permitted to request copies of such contracts, however, HRSA declines to mandate that covered entities must provide copies of contracts upon any request. In the event a manufacturer demonstrates a reasonable need for the copy of a contract and its request for a copy of the contract has been denied, the manufacturer may ask OPA to obtain a copy. The suggested Covered Entity Compliance Elements include providing a copy of the contract pharmacy service agreement upon the request of the Office of Pharmacy Affairs.

Comment: The Appendix provisions impose additional requirements not discussed in Section (3) of the proposed guidance and the suggested provisions in Section (3) do not appear in the Appendix. The Appendix does not mention the 340B prohibition on duplicate discounts.

Response: The Suggested Contract Provisions, found in the Appendix of the Guidelines, are not meant to be comprehensive, exhaustive, or required. They offer a model format and sample provisions, but are not intended to be used as the complete terms of the contract.

Comment: Covered entities should not be permitted to use alternative mechanisms other than the model agreement provisions. The use of alternatives would increase OPA's oversight responsibilities, which may lead to different standards or the potential for abuse. A commenter also cited GAO/OIG reports on lack of oversight of the program to support his/her assertion that the model provisions should be required.

Response: The Covered Entity Compliance Elements are not intended to be required contract provisions. All covered entities must certify that all of the elements have been addressed; however, HRSA gives the covered entities the discretion to negotiate contract provisions suitable to their individual circumstances and jurisdictions. The various complexities of covered entities and the pharmacies with whom they will contract led HRSA to permit flexibility between the parties in designing their contract terms. HRSA does not intend to review contracts. As under the previous guidelines, the covered entity is ultimately responsible for assuring full compliance with 340B.

HRSA disagrees with the comment that recent reports by the GAO and the OIG would support the creation of a standard uniform contract. HRSA has worked diligently to implement the recommendations of both the GAO and the OIG, and HRSA does not believe that dictating to covered entities specific contract language that must be used in all contracts regardless of individual circumstances would assist in those efforts at this time.

(7) Miscellaneous Comments

Comment: Anti-kickback provisions may prohibit pharmacies from offering Medication Therapy Management and Pharmacy by Mail activities that would be beneficial to 340B and patients.

Response: Covered entities are not exempt from anti-kickback provisions. Section 340B does not authorize HRSA to grant any exceptions whether beneficial or not. It is recommended that covered entities get competent professional legal advice when appropriate.

Comment: In section B(3)(c), the proposal states that the manufacturer is not required to offer the 340B drug price if the patient declines to use the contract pharmacy. If however, the manufacturer does extend the 340B price in this case, please clarify whether this extension sets a new best price for the drug.

Response: The 340B drug pricing program does not restrict the prices that manufacturers voluntarily choose to offer to patients outside the parameters of the program. Whether such actions serve to set a new best price for a drug is beyond the scope of this guidance. We encourage anyone with specific best price questions to consult with the Centers for Medicare & Medicaid Services.

Comment: To prevent drug diversion, an additional contract requirement should be added that the contract pharmacy may not fill or refill a prescription using 340B medications until the covered entity confirms that the individual is a patient of the entity at the time the prescription is filled. There should also be an independent, annual audit to review the covered entity's policies and procedures for patient verification.

Response: The program guidelines for 340B make it clear that only individuals who are patients of the covered entity are eligible for drugs purchased under the program. Like all other program requirements, responsibility for compliance lies with the covered entity, which must structure agreements and systems appropriately to ensure that diversion does not occur. Technical assistance may be available for help with implementation and compliance for the 340B program, and maximizing the value of comprehensive pharmacy services for their patients. However, HRSA has chosen not to require time-of-services verification as suggested in the comment.

Comment: Pharmacy records from contract pharmacies should be made available to covered entities to ensure patient safety and continuity of care.

Response: HRSA agrees that this might be beneficial for patient care and encourages the parties to include such terms in their contract agreements. However, this is a decision which will be left to the contracting parties. In any case, the covered entity must have sufficient records or direct access to records for the covered entity to meet its responsibility to ensure compliance and to provide a complete audit trail to verify that there is no diversion or duplicate discounts.

Comment: HRSA should include in its final guidance and suggested contract provisions, language to reinforce that all savings from the 340B program should remain with the covered entity. Without written guidance, all savings will not be returned to the covered entity.

Response: HRSA agrees that the intent of the 340B program was to permit the covered entities to stretch scarce Federal resources, and that the benefit of the program was intended to accrue to the covered entities. However, the covered entity is free to negotiate how it chooses to use any such funds as it sees fit. For example, the covered entity is free to choose to use those dollars to pay contract pharmacies for their services or for extra services such as delivery.

C. Contract Pharmacy Services Mechanism

These final guidelines replace all previous 340B Program guidance documents addressing non-network contract pharmacy services, including, but not limited to, the "Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services," (61 FR 43549) and any individual correspondence issued by HRSA on the subject.

(1) Basic Compliance Issues in Utilization of Pharmacy Services Contracts

A covered entity that wishes to utilize contract pharmacy services to dispense section 340B outpatient drugs must have a written contract in place between itself and a specified pharmacy. A single covered entity that has more than one 340B eligible site at which it provides health care may have individual contracts for each such site or include multiple sites within a single pharmacy services contract. This mechanism is designed to facilitate program participation for those covered entities that do not have access to available or appropriate "in-house" pharmacy services, those covered entities that have access to "in-house" pharmacy services but wish to supplement these services; and covered entities that wish to utilize multiple contract pharmacies to increase patient access to 340B drugs. The covered entity has the responsibility to: Ensure against illegal diversion and duplicate discounts; maintain readily auditable records; and meet all other 340B Drug Pricing Program requirements (*See: http://www.hrsa.gov/opa/introduction.htm*). HRSA has provided essential covered entity compliance elements below as guidance for the type of contractual provisions expected in such agreements. Suggested contract provisions are also in the Appendix. All covered entities utilizing a contract pharmacy must comply with the certification requirements described in (5) below.

(2) Potential Alternatives to Single Location/Single Pharmacy Model

In addition to contracting with a single pharmacy for each clinical site, covered entities may pursue more complex arrangements that include multiple pharmacies only if: (a) There is a written agreement and procedures that meet the requirements outlined above in (1) between the covered entity and each pharmacy; (b) the written agreement includes, and fully addresses, all of the essential elements outlined in (3) and (4) below and a full listing of all pharmacy locations that may be utilized under that agreement; (c) the operation under the contract continues to meet all 340B Drug Pricing Program requirements and does not create diversion of covered drugs or duplicate discounts; (d) the arrangements are one of the two following models either individually or in combination: (i) The use of multiple contract pharmacy service sites, and/or (ii) the utilization of a contract pharmacy(ies) to supplement in-house pharmacy services (the use of multiple contract pharmacy service sites refers to any arrangement wherein a covered entity site seeks to provide drugs at 340B discounted prices for its patients at more than one pharmacy location). Supplementing in-house pharmacy services with a contract pharmacy refers to any arrangement wherein a covered entity site purchases drugs at 340B discounted prices for its patients at both an in-house pharmacy and at least one additional contract pharmacy location; and (e) the arrangement involves a single identifiable 340B covered entity and does not include a network, or other similar arrangement, of more than one covered entity unless specifically authorized in writing by HRSA through an AMDP or by other official written authorization.

(3) Essential Covered Entity Compliance Elements

The following are essential elements to address in contract pharmacy arrangements: (a) The covered entity will purchase the drug, maintain title to the drug and assume responsibility for establishing its price, pursuant to the terms of an HHS grant (if applicable) and any applicable Federal, State and local laws.

A "ship to, bill to" procedure is used in which the covered entity purchases the drug; the manufacturer/wholesaler must bill the covered entity for the drug that it purchased, but ships the drug directly to the contract pharmacy. *See* Section 1 of Appendix. In cases where a covered entity has more than one site, it may choose between having each site billed individually or designating a single covered entity billing address for all 340B drug purchases.

(b) The agreement will specify the responsibility of the parties to provide comprehensive pharmacy services (*e.g.,*

dispensing, recordkeeping, drug utilization review, formulary maintenance, patient profile, patient counseling, and medication therapy management services and other clinical pharmacy services). Each covered entity has the option of individually contracting for pharmacy services with a pharmacy (ies) of its choice. Covered entities are not limited to providing comprehensive pharmacy services to any particular location and may choose to provide them at multiple locations and/or "in-house."

(c) The covered entity will inform the patient of his or her freedom to choose a pharmacy provider. If the patient does not elect to use the contracted service, the patient may obtain the prescription from the covered entity and then obtain the drug(s) from the pharmacy provider of his or her choice.

When a patient obtains a drug from a pharmacy other than a covered entity's contract pharmacy or the covered entity's in-house pharmacy, the manufacturer is not required to offer this drug at the 340B price.

(d) The contract pharmacy may provide other services to the covered entity or its patients at the option of the covered entity (*e.g.,* home care, delivery, reimbursement services). Regardless of the services provided by the contract pharmacy, access to 340B pricing will always be restricted to patients of the covered entity.

(e) The contract pharmacy and the covered entity will adhere to all Federal, State, and local laws and requirements.

Both the covered entity and the contract pharmacy are aware of the potential for civil or criminal penalties if either violates Federal or State law. [The Department reserves the right to take such action as may be appropriate if it determines that such a violation has occurred.]

(f) The contract pharmacy will provide the covered entity with reports consistent with customary business practices (*e.g.,* quarterly billing statements, status reports of collections and receiving and dispensing records). *See* Section 2 of Appendix.

(g) The contract pharmacy, with the assistance of the covered entity, will establish and maintain a tracking system suitable to prevent diversion of section 340B drugs to individuals who are not patients of the covered entity. Customary business records may be used for this purpose. The covered entity will establish a process for periodic comparison of its prescribing records with the contract pharmacy's dispensing records to detect potential irregularities. *See* Section 3 of Appendix.

(h) The covered entity and the contract pharmacy will develop a system to verify patient eligibility, as defined by HRSA guidelines. The system should be subject to modification in the event of change in such guidelines.

Both parties agree that they will not resell or transfer a drug purchased at section 340B prices to an individual who is not a patient of the covered entity. See 42 U.S.C. 256b(a)(5)(B). The covered entity understands that it may be removed from the list of covered entities because of its participation in drug diversion and no longer be eligible for 340B pricing. *See* Section 4 of Appendix.

(i) Neither party will use drugs purchased under section 340B to dispense Medicaid prescriptions, unless the covered entity, the contract pharmacy and the State Medicaid agency have established an arrangement to prevent duplicate discounts. Any such arrangement shall be reported to the OPA, HRSA, by the covered entity.

(j) The covered entity and contract pharmacy will identify the necessary information for the covered entity to meet its ongoing responsibility of ensuring that the elements listed herein are being complied with and establish mechanisms to ensure availability of that information for periodic independent audits performed by the covered entity.

(k) Both parties understand that they are subject to audits by outside parties (by the Department and participating manufacturers) of records that directly pertain to the entity's compliance with the drug resale or transfer prohibition and the prohibition against duplicate discounts. *See* 42 U.S.C. 256b(a)(5)(c).

The contract pharmacy will assure that all pertinent reimbursement accounts and dispensing records, maintained by the pharmacy, will be accessible separately from the pharmacy's own operations and will be made available to the covered entity, HRSA, and the manufacturer in the case of an audit. Such auditable records will be maintained for a period of time that complies with all applicable Federal, State and local requirements.

(l) Upon written request to the covered entity, a copy of the contract pharmacy service agreement will be provided to the Office of Pharmacy Affairs.

(4) Ongoing Responsibility of Covered Entity To Ensure Compliance

Covered entities are responsible for ensuring that the system of distribution chosen fully meets statutory obligations of ensuring against diversion to non-patients or creating a situation that results in a State Medicaid Program seeking a rebate on a discounted drug. The covered entity remains responsible at all times for the disposition of covered outpatient drugs it purchases through a contract pharmacy. Annual audits performed by an independent, outside auditor with experience auditing pharmacies are expected, although the exact method of ensuring compliance is left up to the covered entity. The covered entity must have sufficient information to ensure it is meeting that responsibility. Independent audits are particularly valuable where the covered entity utilizes multiple pharmacy options. They should follow standard business practices for audits, including audit trails provided by the entity to the auditor, and use of standard reports. The precise methodology utilized to ensure compliance and obtain the necessary information is up to the covered entity given its particular circumstances and, for example, might include spot audits where the system in place permits. Drug diversion and duplicate discounts are a significant concern of HRSA and all efforts to avoid these problems should be well documented. In the event a covered entity determines that drug diversion or duplicate discounts have occurred or that it is otherwise unable to comply with its responsibility to reasonably ensure compliance, then it must take immediate remedial action to assure compliance and notify the OPA about such compliance problems and actions taken to remedy those problems.

(5) Certification

Under section 340B, if a covered entity using contract pharmacy services requests to purchase a covered outpatient drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at a price not to exceed the statutory 340B discount price. If the covered entity directs the drug shipment to its contract pharmacy or pharmacies, the covered entity must comply, under any distribution mechanism, with the statutory prohibition on drug diversion and duplicate discounting.

To provide HRSA and manufacturers with assurance that the covered entity has acted in a manner which limits the potential for drug diversion, covered entities should submit to OPA a certification that it has signed and has in effect an agreement with the contract pharmacy or pharmacies that satisfies both (3) and (4) above (*i.e.* that the contract(s) fully address the issues listed in (3) and that the covered entity has a

plan to meet its ongoing responsibilities to ensure compliance). The names of those covered entities which submit a certification, or an alternate mechanism approved by OPA, will be listed on the OPA Web site for the convenience of participating drug manufacturers and wholesaler distributors.

In addition, any covered entity that has opted to utilize any pharmacy arrangement described in (2) must specify which arrangement or combination of arrangements it is utilizing and the names of any pharmacies participating when registering. Covered entities seeking to materially change this arrangement that entail changes in the covered entity database should notify OPA of any such proposed changes and be aware that some changes may require advanced notice to manufacturers and wholesalers as part of quarterly updates to the database.

In order to ensure accuracy, integrity and transparency, the OPA may conduct a recertification process periodically (most likely annually) where covered entities affirmatively certify as to their ongoing compliance with 340B requirements. It is currently expected that the annual process would include certification by a duly authorized official: (1) That all information listed on the database for that covered entity is complete, accurate, and correct; (2) that the covered entity met the 340B eligibility requirements throughout the prior year and continues to do so; (3) that any contract pharmacy arrangement was actually performed in accordance with specified requirements including, but not limited to, that the covered entity obtained sufficient information from the contractor to ensure compliance with applicable policy and legal requirements; and (4) the methodology utilized to ensure compliance (*e.g.* through independent audit or other mechanism).

(6) Anti-Kickback Statute

Contract pharmacies and covered entities should be aware of the potential for civil or criminal penalties if the contract pharmacy violates Federal or State law. In negotiating and executing a contract pharmacy service agreement pursuant to these guidelines, contract pharmacies and covered entities should be aware of and take into consideration the provisions of the Medicare and Medicaid anti-kickback statute, 42 U.S.C. 1320a–7b(b).

D. Appendix—Suggested Contract Provisions

The following suggested contract provisions are included for illustrative purposes and are not intended to be comprehensive, exhaustive or required. They offer sample provisions for

consideration, but are not intended to be used as the complete terms of the contract. Given the variances among many jurisdictions and among the numerous types of covered entities, HRSA has decided at this time not to include a complete model contract in this notice.

(1) "The covered entity owns covered drugs and arranges to be billed directly for such drugs. The pharmacy will compare all shipments received to the orders and inform the covered entity of any discrepancy within five (5) business days of receipt. The covered entity will make timely payments for such drugs delivered to the pharmacy."

(2) "The covered entity will verify, using the contract pharmacy's (readily retrievable) customary business records, that a tracking system exists which will ensure that drugs purchased under the 340B Drug Pricing Program are not diverted to individuals who are not patients of the covered entity. Such records can include: Prescription files, velocity reports, and records of ordering and receipt. These records will be maintained for the period of time required by State law and regulations."

(3) "Prior to the contract pharmacy providing pharmacy services pursuant to this agreement, the covered entity will have the opportunity, upon reasonable notice and during business hours, to examine the tracking system. For example, such a tracking system may include quarterly sample comparisons of eligible patient prescriptions to the dispensing records and a six (6) month comparison of 340B drug purchasing and dispensing records as is routinely done in other reconciliation procedures. The contract pharmacy will permit the covered entity or its duly authorized representatives to have reasonable access to contract pharmacy's facilities and records during the term of this agreement in order to make periodic checks regarding the efficacy of such tracking systems. The contract pharmacy agrees to make any and all adjustments to the tracking system which the covered entity advises are reasonably necessary to prevent diversion of covered drugs to individuals who are not patients of the covered entity."

(4) "The pharmacy will dispense covered drugs only in the following circumstances: (a) Upon presentation of a prescription bearing the covered entity's name, the eligible patient's name, a designation that the patient is an eligible patient of the covered entity, and the signature of a legally qualified health care provider affiliated with the covered entity; or (b) receipt of a prescription ordered by telephone or other means of electronic transmission that is permitted by State or local law on behalf of an eligible patient by a legally qualified health care provider affiliated with the covered entity who states that the prescription is for an eligible patient. The covered entity will furnish a list to the pharmacy of all such qualified health care prescribers and will update the list of prescribers to reflect any changes. If a contract pharmacy is found to have violated the drug diversion prohibition, the contract pharmacy will pay the covered entity the amount of the discount in question so that the covered entity can reimburse the manufacturer."

Dated: March 2, 2010.

Mary K. Wakefield,

Administrator.

[FR Doc. 2010–4755 Filed 3–4–10; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–3070 and CMS–416]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of*

ATTACHMENT 5

nephron

DECEMBER 7, 2020

Pharma Supply Chain & HCIT

Eric Percher
646-876-0115
eric@nephronresearch.com

Dolph Warburton, CFA
646-876-0118
dolph@nephronresearch.com

Simon Mach
646-876-0117
simon@nephronresearch.com

Pharma Supply Chain & HCIT

The 340B Program Reaches a Tipping Point: Sizing Profit Flows & Potential Disruption

The 340B Drug Discount Program is at a tipping point. After a decade of advocating unsuccessfully for regulatory and legislative change, pharmaceutical manufacturers have begun to take matters into their own hands. The financial impact of recent manufacturer actions challenging 340B regulatory authority on Walgreens, CVS Health and, to a lesser extent, Cigna, are underappreciated as is the likelihood of escalation as we enter 2021.

New manufacturer 340B discount policies could impact 35%-40% of high margin contract pharmacy expenditures (totaling $29.3bn at WAC) in 2021. Lilly, AstraZeneca, Merck, Sanofi, Novartis and Novo together account for 29% of U.S. brand pharma expenditures but run closer to 35%-40% of 340B contract pharmacy sales.

Competitive dynamics may be close to pushing 340B past the tipping point. Novo Nordisk's notice limiting discounts for contract pharmacies Jan. 1st may have been necessitated by policies implemented in the fall by Lilly and Sanofi. **As similar trends play out across therapies, manufacturers could be forced to adopt similar 340B policies in rapid succession.**

Contract pharmacy 340B gross profit losses may exceed 340B op profits retained. Pharmacy operators are quick to note the vast majority of 340B discounts are passed to covered entities and a significant portion of discount gross profit retained is utilized to subsidize pharmacy network rates. **Our primary concern is that mfr. actions could disrupt the flow of discounts in 2021 but subsidized WBA and CVS network rates could prove difficult to ratchet up.**

Walgreens' exposure is far beyond all other operators at $1,037mn. If all 340B discounts captured by Walgreens were to remain with the company, we estimate the 340B profit pool at $1,037mn in 2020, or 22% of retail and spec brand gross profit. **Mfr. policy changes to date could represent a ($166mn) headwind in 2021, equating to 3% of brand gross profit and 3% of EPS**. **Expansion in early 2021 could expose 11% of gross profit and EPS on an annual basis, playing a *leading role* in our downgrade of WBA shares to Sell form Hold.**

CVS is positioned for rapid 340B expansion 2020 to 2021. We size CVS 340B discount retention across specialty and retail at $797mn in 2020. **Mfr. policy changes could represent a ($140mn) headwind in CY21, equating to 3% of brand gross profit but only 1% of EPS**. **Expansion in early 2021 could expose 9% of brand gross profit and 4% of EPS, one of several factors leading to our one notch downgrade of CVS shares to Hold from Buy.**

Cigna/Evernorth and United/OptumRx 340B impact is limited by diversification. After rapid 340B specialty pharmacy relationship expansion and TPA optimization by Cigna/Evernorth 2018 to 2020, **we see a material potential impact to the Evernorth PBM from Mfr. action but only a 1% impact to CI EPS based on current policy changes** and 3% if we see expansion in Jan. **Diversification is even more apparent at United Health, where the impact is well below 1%.**

Please see important disclosures at the end of this report.

TABLE OF CONTENTS

Introduction

The Key Question: How much money is moving through the 340B program and what portion of discounts are retained by pharmacies?

The goal of this report is to shed light on a question that we have observed obsesses pharma and pharmaceutical supply chain executives but receives little attention from pharmaceutical supply chain investors: *How much money is moving through the 340B drug discount program and what portion of the discounts provided by pharmaceutical manufacturers are retained by retail and specialty contract pharmacy operators vs passed on to 340B hospitals and clinics?*

Within this report we size the 340B program, project the share of discounts flowing through the seven largest retail and specialty pharmacy operators, examine the quantity of discounts retained by pharmacies vs passed on to payors and quantify the risk to Walgreens Boots Alliance, CVS Health, Walmart, Cigna, UnitedHealth, and other supply chain participants should recent pharma manufacturer 340B discount policy changes reduce 340B contract pharmacy profit pools in 2021.

Before we dig in deep, let us review key 340B program concepts and participants, including the role of contract pharmacies operated by the largest retail chains and integrated PBMs-Payors.

- **The 340B Program:** The 340B program was established in 1992, to ensure that manufacturers could provide Medicaid level discounts for outpatient drugs to safety-net hospitals and clinics serving poor patients that did not qualify for Medicaid. Hospitals and clinics purchase drugs from wholesalers at the 340B discount price but are reimbursed at contracted rates for Medicaid, Medicare Part D and Commercial with substantial margins earned in Part D and Commercial.

- **Covered Entities and Contract Pharmacies:** Initially hospitals and clinics that qualified as '340B covered entities' only received discounts when drugs were administered by community outpatient pharmacies operated by the hospital or clinic. In 1996, the Health Resource & Services Administration (HRSA), the regulatory agency that administers the 340B program, issued guidance allowing covered entities that did not operate a pharmacy to establish a single relationship with a 'contract pharmacy' in their community, typically an independent pharmacy.

- **Contract Pharmacy Expansion:** HRSA guidance issued in 2010 dramatically expanded the role of contract pharmacies, enabling all hospital and clinic covered entities to establish an unlimited number of relationships with an unlimited number of contract pharmacies. This guidance ushered in a period of rapid expansion in 340B program participation by retail pharmacy chains **Walgreens, CVS Health** and **Walmart** (now 57% of contract pharmacies) and beginning in 2015, specialty pharmacies run by **Cigna (Evernorth), CVS, Walgreens, United Health (OptumRx)** and **Walmart** (specialty is now 20% of total 340B contract entity relationships, up from 1% in 2014).

- **340B Discount Proliferation.** Expansion in the number of hospitals and clinics seeking to qualify as 340B entities and in the number of integrated pharmacy and Third-Party Administrators (TPAs) identifying and serving 340B eligible claims served to dramatically increase the size of the program from $9bn of government spending with manufacturers providing $4.5bn of 340B discounts in 2014 to a Nephron projection of $36bn of government spending with manufacturers providing $45bn of 340 discounts in 2020. **We project that $12.9bn of those discounts will flow through contract pharmacies in 2020 of which $3.3bn will be retained by contract pharmacies ($2.8bn by the five largest integrated players, Walgreens, CVS, Walmart, Cigna and United).**

- **Manufacturers Begin to Push Back:** After a decade of advocating unsuccessfully for regulatory and legislative change, pharmaceutical manufacturers have begun to take matters into their own hands. New manufacturer 340B discount policies introduced this fall could impact 35%-40% of 340B contract pharmacy sales by our projections. We expect many additional manufacturers are poised to introduce similar policies in January 2021.

Executive Summary: 340B At a Tipping Point

Manufacturers have begun to take action to directly counter duplicate 340B discounts and contract pharmacy growth

On Oct. 9th, 2019, the Trump administration issued an Executive Order that effectively prohibited federal agencies from issuing binding rules through guidance documents: the memorandums, bulletins and letters that help industry comply with complex regulation but which are not legally binding. **Given that much of the 340B program is defined by sub-regulatory guidance, not statute, this Executive Order called into question the ability for the Health Resources and Services Administration (HRSA) to enforce elements of the 340B program, setting the stage for manufacturer challenges that have so far gone largely unchallenged by covered entities.**

Over the last six-months, seven manufacturers have introduced policies intended to reduce duplicate discounts and reverse 340B contract pharmacy growth with a focus on broad 340B retail networks and specialty pharmacies operated by WBA, CVS, WMT, CI and to a lesser extent UNH. We summarize the six most significant new policies in Fig. 1. For a detailed timeline of manufacturer actions and exploration of the nuances of each approach see Appendix I on page 42.

Fig. 1: Manufacturer 340B actions began to impact contract pharmacies on Sept 1st 2020, are likely to expand Jan 2021

Manufacturer	Covered Entity (CE) Policy and Scope	Contract Pharmacy (CP) Policy	Implicit Goal	Effective Date	2019 Brand Market Share
Lilly	• **Limit access to 340B discounts** – initially focused on Cialis, later expanded to Lilly's entire portfolio	• **No longer provide 340B discounts** to CP • Exception for Insulin if discount is passed to patient	• Limit 340B transactions/CP activity • Limit duplicate claims	• **Sept 1st**, 2020	• **6%**
AstraZeneca	• **Limit access to 340B discounts** - entire portfolio	• **No longer provide 340B discounts** to contract pharmacy	• Limit 340B transactions/CP activity • Limit duplicate claims	• **Oct 1st**, 2020	• **3%**
Merck	• Require covered entity to 'voluntarily' supply 340B claims data to **340B ESP**	• No access to discounts **unless** claims data is submitted	• Identify and reduce duplicate claims	• **Aug. 14th**, 2020	• **6%**
Sanofi	• Require covered entity to 'voluntarily' supply 340B claims data to **340B ESP**	• No access to discounts **unless** claims data is submitted	• Identify and reduce duplicate claims	• **Oct 1st**, 2020	• **4%**
Novartis	• Require covered entity to 'voluntarily' supply 340B claims data to **340B ESP**	• **No longer provide 340B discounts** to CE when CP is more than **40 miles away**	• Maintain access for clinics and hospitals within community • Limit 340B CP transactions with a focus on specialty and national chains	• Set for Oct 1st, delayed until new guidance provided **Oct 30th**, 2020	• **4%**
Novo Nordisk	• **Limit access to 340B discounts** – Novo's policy could indicate Lilly and Sanofi's actions are having the desired effect	• **No longer provide 340B discounts** to CP for CE hospitals but allow CP for 340B 'grantees'	• Limit 340B transactions/CP activity • Maintain access for 340B 'grantees'	• **Jan. 1st**, 2021	• **6%**

Source: Nephron Research, Company Disclosures, 2019 Brand Share from IQVIA SMART-US Edition

Manufacturer actions to date could impact 35%-40% of 340B contract pharmacy sales. The impact on insulin competitive dynamics is already visible.

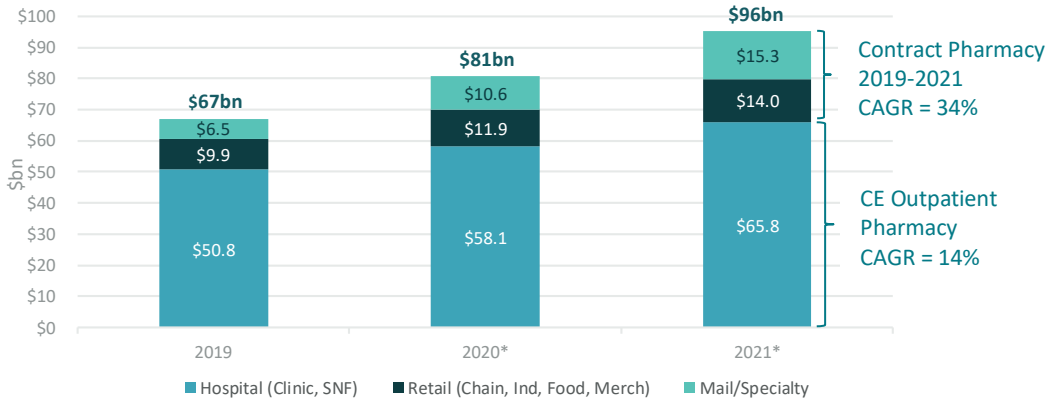
Publicly disclosed changes in manufacturer 340B discount policies over the last six-months could impact 35%-40% of 340B contract pharmacy sales and we expect many additional manufacturers are poised to introduce similar policies. Lilly, AstraZeneca, Merck, Sanofi, Novartis and Novo together account for 29% of U.S. brand pharma expenditures but run closer to 35%-40% of 340B contract pharmacy sales with even higher share in the retail channel at **Lilly, Novartis, Novo** and to a

lesser extent, **Merck**. The impact of Lilly's early moves may already be apparent in the insulin market where Novo Nordisk's published a notice December 1st limiting discounts for contract pharmacies as of Jan. 1st. This move may have been necessitated by policies implemented in the fall by Lilly and Sanofi. **As similar trends play out across therapies, manufacturers could be forced to adopt similar 340B policies in rapid succession.** While actions to date have been retail pharmacy centric, the three manufacturers that we expect will have the greatest impact on specialty contract pharmacy are **Gilead, Pfizer and JNJ**.

We project the dollarized value of 340B expenditures at $81bn in 2020, of which $22.5bn, or 28%, will flow through retail and specialty contract pharmacies

To identify the potential impact of changes in 340B policies on contract pharmacy operators, PBMs and Payors, we first must identify the value of 340B expenditures and discounts flowing through retail and specialty contract pharmacies. As seen in Fig 2, we size the gross dollarized value of 340B expenditures at $81bn in 2020 (i.e.: gross value of 340B pharmaceuticals at WAC price, which is well above the net value of 340B program expenditures at the 340B discounted price), of which retail contract pharmacies are projected to account for $11.9bn, or 15%, and specialty contract pharmacies are projected to account for $10.6bn, or 13%.

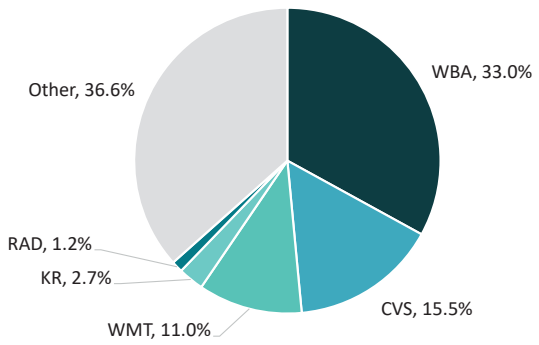
Fig. 2: 340B Gross Expenditures (Dollarized@WAC) by Channel; 2019-2021 CAGR=19%



Sources: Estimate for 2019 IQVIA Market Access Center of Excellence; Projections 2020-2021 Nephron Research.
Note: Contract Pharmacy calculation at right = Retail + Mail/Specialty

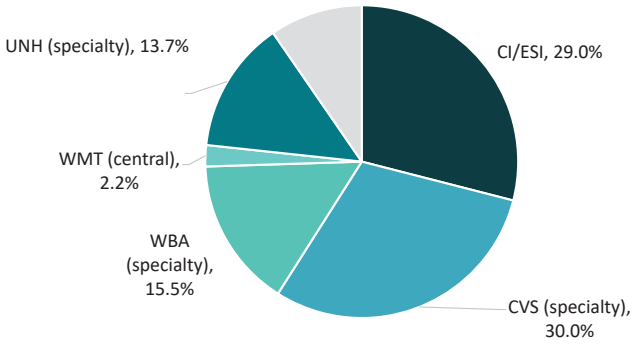
We then apply our estimates for each contract pharmacy operator's specialty and retail 340B market share against our market sizing to arrive at an estimate of the value of 340B expenditures and discounts that are passing through each of the largest contract pharmacy operators.

Fig. 3: Retail Contract Pharmacy Share



Source: Nephron Research 340B Market Model Projection

Fig. 4: Specialty Contract Pharmacy Share

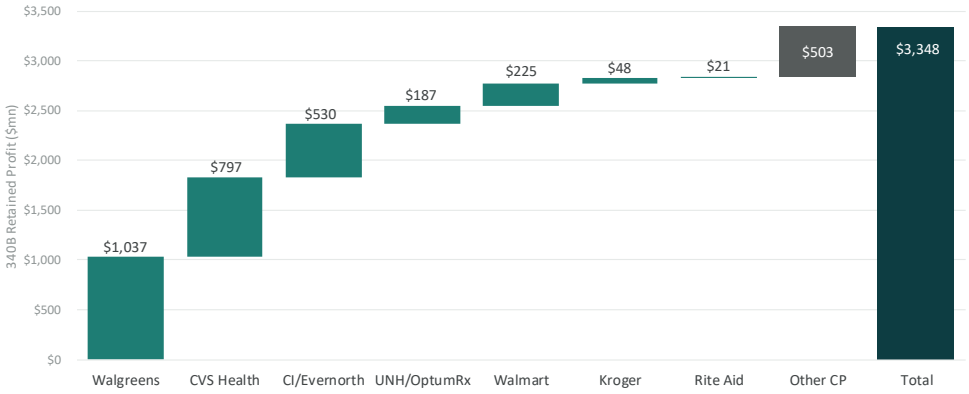


Source: Nephron Research 340B Market Model Projection

We size the contract pharmacy 340B discount profit pool at $3.4bn, 26% of discounts passing through contract pharmacies and 7% of total 340B discounts

Finally, we apply projections of spread and fixed fees against retail and specialty market share to arrive at contract pharmacy specific estimates of discounts retained. **The estimates (laid out in Fig 5 below) equate to the gross profit attributable to combined 340B retail and specialty operations if we assume that all 340B discounts and fees remain with the contract pharmacy operator (i.e.: putting to the side the extent to which discounts have been utilized to fund lower pharmacy network rates).**

Fig. 5: 2020 Contract Pharmacy 340B Gross Profit Pool (assuming 340B profits remain with the contract pharmacy – they do not)



Source: Nephron Research

The scale of 340B discounts captured by contract pharmacy operators is massive relative to measures of non 340B pharmacy brand and specialty profitability - both on a margin percentage and as a share of absolute gross profits – though we note that not all 340B discounts retained by contract pharmacies are ultimately recognized as gross profit.

- If all 340B discounts captured by the contract pharmacy were to remain within the contract pharmacy, we estimate the 2020 340B profit pool would total **$1,037mn at Walgreens and $797mn at CVS Health, accounting for 22% and 25% of Walgreens and CVS retail and specialty brand gross profit, respectively, prior to investment in lower retail network rates**.
- Moving from the integrated PBM/Payor operation of CVS to Cigna/Evernorth and United/OptumRx, we compare the estimated discount profit pool of $530mn at Evernorth and $187mn at OptumRx to our projections for brand profit generated by specialty and mail operations. **We estimate that after significant growth 2019 to 2020, 340B could account for 21% and 14% of Evernorth and OptumRx specialty and mail fulfillment brand gross profit prior to investment in lower specialty network rates**.

While the profit pool represents 26% of discounts, only a portion of this amount is retained as contract pharmacy gross profit

When examining 340B discount flows, it is important to keep in mind first that the vast majority of discounts flow to covered entities and second that the 340B discount pool that is retained by the contract pharmacy have been utilized to counter (or perhaps enable) the pursuit of volume via aggressive narrow network contracts with the largest payors/PBMs at ever lower reimbursement rates.

- While the level of 340B gross profit investment in lower rates is impossible to determine from the outside, we put the annual reimbursement pressure on WBA's estimated 2020 U.S. pharmacy gross profit of $19.1bn (inclusive of specialty) and CVS's estimated 2020 retail pharmacy gross profit of $18.8bn (excluding specialty) at $450mn-$900mn, only $250-$450mn of which is offset by organic growth.

- We believe that specialty contract pharmacy operators have also utilized 340B program discounts to lower specialty network rates in an effort to accrue incremental share (particularly from independents who have more limited access to 340B profit pools) and expand manufacturer data related specialty profit pools and admin fees.

Our primary concern is that mfr. actions could disrupt the flow of discounts in 2021 but subsidized network rates for WBA and CVS could prove difficult to ratchet up

However, while contract pharmacy operators have been quick to note that they are not retaining hundreds of millions of profit from the 340B program, the fact that funds have been contracted away to payors and PBMs to drive volume or offset reimbursement pressure, does not mean pharmacy operators are off the hook if the program is disrupted by manufacturer or regulatory action. **Should manufacturer policies constraining contract pharmacy access to 340B discount prices prove durable in early 2021, pharmacies could be caught in the middle as they lose a significant source of funding and have limited leverage to ratchet narrow network rates higher (with Part D contracts negotiated annually and commercial contracts typically negotiated on a three year cycle). As such, 340B earnings exposure could run closer to the gross profit pool levels we identified above than to the much lower levels of profits that we believe are being recognized as earnings after the pool has been drained to fund payor contracts.**

In Fig 6 we size the potential annual impact on the four largest integrated contract pharmacy operators. We segment between a *base* case reflecting actions taken to date by 7 manufacturers (15% reduction to retail 340B discounts, 10% to specialty) and an *expand* case reflecting rapid adoption of similar policies by additional manufacturers in early 2021 (50% reduction to retail, 40% reduction to specialty).

Fig. 6: 2021 Contract Pharmacy Operator Impact Analysis: Base vs Expand Case

	WBA (Retail+Spec)	CVS (Retail + Spec)	Cigna (Evernorth)	UNH (OptumRx)
340B Gross Profit (Discount Retained)	$1,215	$1,170	$763	$295
Share of Retail & Spec Brand Gross Profit	*25%*	*21%*	*30%*	*20%*
Share of Total Company EPS	*24%*	*9%*	*10%*	*1%*
Brand GP Impact at ***Base*** Case	$166	$140	$76	$30
Share of Retail & Spec Brand Gross Profit	*3%*	*3%*	*3%*	*2%*
Brand GP Impact at ***Expand*** Case	$576	$513	$305	$118
Share of Retail & Spec Brand Gross Profit	*12%*	*9%*	*12%*	*8%*
EPS Impact at ***Base*** Case	$0.16	$0.08	$0.16	$0.02
Share of EPS	*3%*	*1%*	*1%*	*0%*
EPS Impact at ***Expand*** Case	$0.55	$0.29	$0.66	$0.10
Share of EPS	*11%*	*4%*	*4%*	*1%*

Source: Nephron Research

Walgreens Boots Alliance:

WBA: 340B exposure plays a key role in our downgrade of WBA shares to Sell from Hold

Walgreens exposure is far beyond all other operators at $1,037mn. If all 340B discounts captured by Walgreens were to remain with the company, we estimate the 340B profit pool at $1,037mn in 2020, or 22% of retail and spec brand gross profit. **Mfr. policy changes to date could represent a ($166mn) headwind in 2021, equating to 3% of brand gross profit and 3% of EPS. Broad expansion in early 2021 could expose ($576mn), or 11%, of gross profit and 11% of total company EPS on an annual basis – a much greater potential EPS impact than any of its more diversified peers.**

- **Our WBA rating downgrade to Sell, from Buy, is predicated on five risk factors, of which the 340B contract pharmacy profit pools exposure is most concerning.** Walgreens has by far the greatest exposure within the supply chain to changes to the 340B program, in part owing to the company's long history providing contract pharmacy, TPA and technology services and in part

owing to the limited diversity of the overall operation relative to integrated PBM-Payor peers. It also doesn't help that COVID will depress U.S. and U.K. earnings contributions in 2020 and 2021.

CVS Health:

CVS: 340B exposure is one of several factors that lead us to downgrade CVS Health shares to Hold from Buy

CVS's is positioned for rapid 340B expansion 2020 to 2021. We size CVS 340B discount retention across specialty and retail at $797mn in 2020. Rapid expansion of 340B pharmacies and specialty relationships could drive as much as 40%+ growth in 2021 to $1,170 or 21% of brand gross profit. **Mfr. policy changes could represent a ($140mn) headwind in CY21, equating to 3% of brand gross profit but only 1% of EPS. Broad expansion in 2021 could expose ($513mn), or 9%, of brand gross profit and 4% of total company EPS.**

- If Walgreens has the *deepest* exposure to 340B via retail, then CVS has the *broadest* exposure with significant profit centers across both the Pharmacy Services segments (specialty contract pharmacy and TPA) and Retail Segment (contract pharmacy operations). Moreover, CVS has continued to rapidly expand the number of specialty contract pharmacy relationships with covered entities and retail contract pharmacy locations in 2019 and through the first ten-months of October.
- While our downgrade today of CVS shares to Hold from Buy balances our positive outlook for the Health Benefits business with multiple concerns related to four pressures facing the Retail and Pharmacy Services businesses, the outcome of our analysis of 340B contract pharmacy profit pools served to catalyze the move to a Hold rating.

Cigna/Evernorth:

CI: Significant impact for Evernorth, limited impact for Cigna

After rapid 340B specialty pharmacy relationship expansion and TPA optimization by Cigna/Evernorth 2018 to Oct 2020, **we see a material potential impact to the Evernorth PBM organization from our *base* case (10% reduction to spec pharmacy 340B discounts) but given the diversity of the total enterprise the impact is far more limited than at WBA or CVS.** Under the base case, 2021 340B discounts retained decline by ($76mn) resulting in a similar reduction in Evernorth gross profit. This would equate to a 1% headwind to CI EPS. Under the expansion scenario the headwind to projected growth increases to ($229mn) or a 3% headwind to EPS.

UnitedHealth/OptumRx:

UNH: Loss of a growth driver for OptumRx, minimal impact to UnitedHealth Group

As OptumRx's specialty expansion and 340B optimization efforts appear to have only accelerated in 2019 and 2020, the impact to OptumRx is limited and the diversification of UNH results in a very modest earnings impact for the total company. What is more interesting is the extent to which expanded 340B profitability is helping to support OptumRx's guidance for EBIT per Rx expansion from $2.94 in 2020 to $3.01 to $3.05 in 2021 on revenue growth guidance that was substantially lower than our 6%-7% revenue growth outlook at 2%-3%.

MARKET LEVEL ANALYSIS: SIZING 340B DISCOUNTS & CHANNEL SHARE

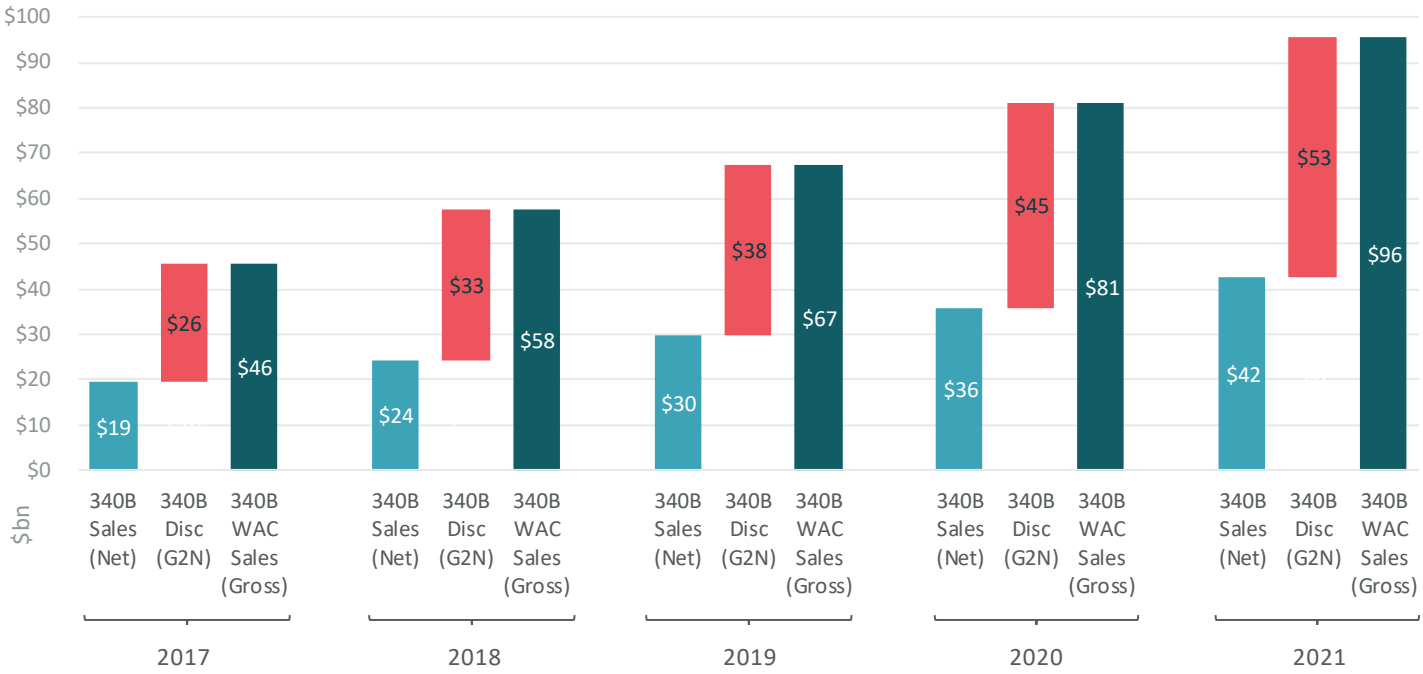
Market Level Analysis – Sizing 340B Discounts & Channel Share

We project the dollarized 'gross' price value of drugs flowing through the 340B program at $81bn in 2020, or 12.5% of total U.S. pharmaceutical expenditures

We begin our analysis of 340B profit pools by examining the size and growth of the 340B program at both ***gross pharmaceutical value*** (WAC dollarized value of manufacturer 340B sales before discounts) and ***net pharmaceutical value*** (the price to covered entities after 340B discounts). We then segment the market between the value of 340B product flowing through the hospital and clinic channel (via outpatient pharmacies run by covered entities) and the value of product flowing through the retail and specialty/mail pharmacy channels (via contract pharmacy relationships with covered entities).

- **Gross pharmaceutical value is key to projecting the profit earned by contract pharmacies which is often calculated based on the gross (WAC) price, not the net price after 340B discounts.** Building off historical IQVIA estimates, we project 2020 dollarized expenditures at $81bn. This equates to 12.5% of our estimate for total U.S. pharmaceutical expenditures in 2020.
- **The delta between gross and net 340B value, referred to throughout this report as gross-to-net (or G2N) is key to determining the value of 340B discounts flowing through contract pharmacies that are passed on to covered entities versus retained by the pharmacy.** Building off historical estimates from IQVIA and the Drug Channels Institute, we project 2020 340B discount/G2N value based on dollarized (WAC) gross sales at $45bn.

Fig. 7: We project the value of 340B discounts will total $45bn in 2020, up from $26bn in 2017



Sources for 340B Program Expenditure (Net): 2017-2019 HRSA 340B program budget requests (reflecting Apexus provided value), 2020 projection is attributable to Drug Channels Institute (building off of the budget estimate), for 2021 we build off the Drug Channels estimate to arrive at a Nephron Research estimate. This number is likely understated by ~2% as it does not capture Aids Drug Assistance Program (ADAP) 340B Rebates such as those processed through Kalderos.

Sources for Dollarized WAC 340B Expenditure (Gross): Est. 2017-2019 IQVIA Market Access Center of Excellence 340B Report, 2020; Projections 2020-2021 Nephron Research. Note that this is dollarized G2N at invoice prices whereas actual invoice as reported by IQVIA (and estimated in our G2N Market Model) reflect 340B discounts in the invoice price (i.e.: measures of G2N typically do not reflect the full dollarized value of 340B discounts as shown above).

Note that our market analysis attempts to bridge and build on several unique data sources and analyses, including data sets from CMS, HHS/HRSA, IQVIA and Drug Channels as well as 340B whitepapers from IQVIA and Berkley Research Group. We have attempted to identify all inputs and

note where our perspective and assumptions differ materially (particularly with respect to where 340B discounts are retained within the supply chain and among covered entities).

Sizing the 340B Program by Channel (Outpatient Pharmacy vs Retail & Mail)

Contract pharmacies' share of 340B expenditures are on track to expand from 24% in 2019 to 31% in 2021 – we identify three primary drivers

Having sized the value of gross 340B expenditures and net 340B sales after discounts for the market, we now estimate gross and net by channel, segmenting between **outpatient pharmacies** operated by covered entity hospitals and clinics, **retail community contract pharmacies** and **specialty (inclusive of mail) contract pharmacies**. We use as our stepping off point an IQVIA analysis of 2019 dollarized WAC sales based on point of service data, which found that 75% of 340B value flows through the hospital channel vs 15% via the retail pharmacy channel and 10% via the specialty/mail channel[1].

Our estimates for retail and specialty 340B growth (which assume no impact from recent manufacturer actions), indicate that combined retail and specialty share of gross 340B spend will increase from 24% in 2019 to 28% in 2020 and 31% in 2021. Higher growth among contract pharmacies relative to covered entity outpatient pharmacies 2019-2021 is driven by a combination of:

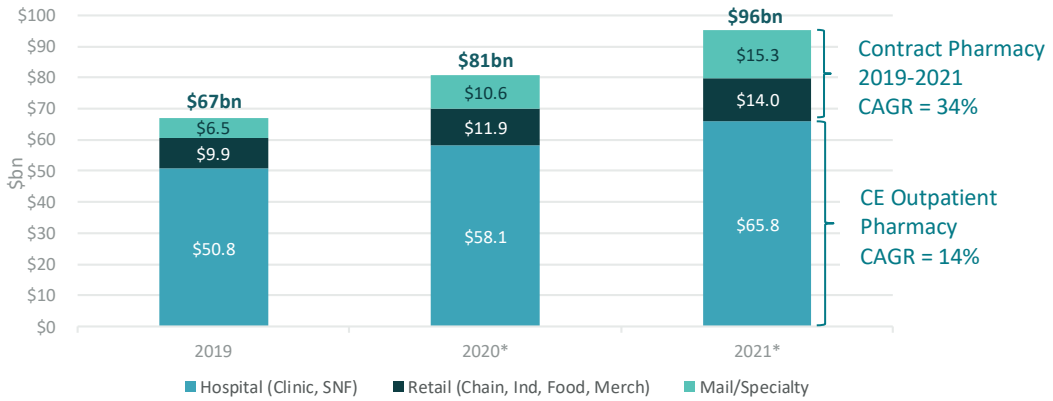
1) **Expanding retail pharmacy participation** among the largest chains to a point where effectively all Walgreens and CVS Health pharmacies will be 340B contract pharmacies by the end of 2021.

2) **More aggressive 340B contract pharmacy optimization** among TPAs and data providers, enabled in part by consolidation and integration of these services by the largest contract pharmacy operators.

3) **The culmination of specialty pharmacy expansion and penetration** efforts that began in 2016 and have proliferated 2018-2020.

As seen in **Fig 8**, we project **gross 340B expenditures flowing through retail and specialty contract pharmacies will expand at a 34% CAGR 2019-2021, equating to $12.9bn in absolute growth** ($8.8bn in spec pharmacy and $4.1bn in retail) as compared to **gross 340B expenditures flowing through hospital outpatient pharmacy expanding at a 14% CAGR, $15.1bn in absolute growth**.

Fig. 8: 340B WAC Dollarized Sales (Gross) by Channel; 2019-2021 CAGR = 19%



Sources: Estimate for 2019 IQVIA Market Access Center of Excellence; Projections 2020-2021 Nephron Research.
Note: Contract Pharmacy calculation at right = Retail + Mail/Specialty

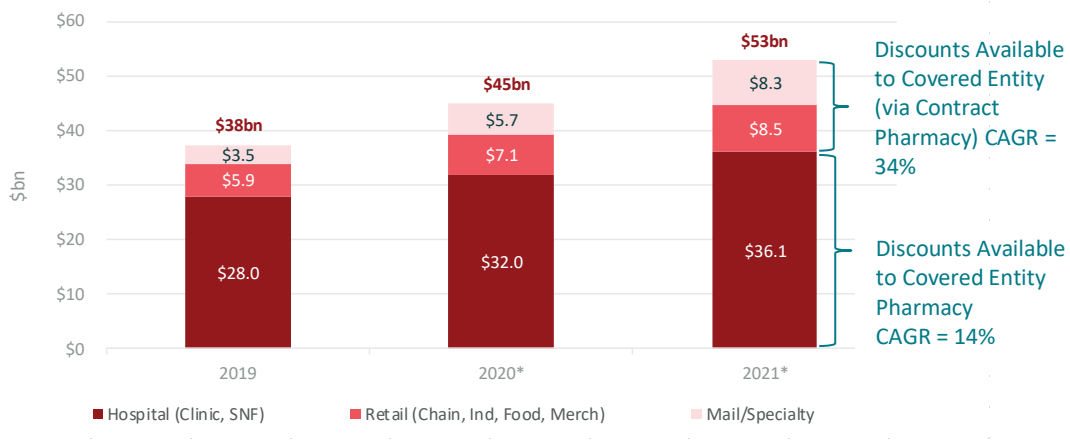
[1] The 340B Drug Discount Program: Complexity, Challenges and Change, IQVIA Market Access Center of Excellence, August 2020

We project the value of 340B discounts flowing through contract pharmacies at $12.9bn in 2020, as compared to $32.0bn flowing through covered entities' captive outpatient pharmacies

The delta between gross expenditures at WAC price and net expenditures after discounts (Fig 7 and 8, above) provide us with a measure of the 340B discount pool flowing primarily to covered entities and secondarily to contract pharmacies (with additional fee retention by the Third-Party Administrators [TPAs] and the 340B claim and split-billing technology vendors that support the 340B program). **As seen in Fig 9, we project that in 2020 340B discounts/G2N will total $32.0bn for covered entities (outpatient pharmacies) and $12.9bn for contract pharmacies (inclusive of both retail and specialty/mail channels).**

- Note that this represents the value of 340B discounts flowing through both covered entity pharmacy and contract pharmacies, only a portion of which will be retained by contract pharmacies. The share retained by contract pharmacies vs. passed on to covered entities is the focus of our profit analysis.

Fig. 9: The value of 340B discounts/G2N flowing through contract pharmacies is expanding at a much faster rate than at covered entity outpatient pharmacies



Source: Nephron Research Projections

Sizing the 340B Program by Contract Pharmacy Operator – RETAIL SHARE

We now turn from the value of the 340B program to the value of discounts flowing through each of the major 340B contract pharmacy operators

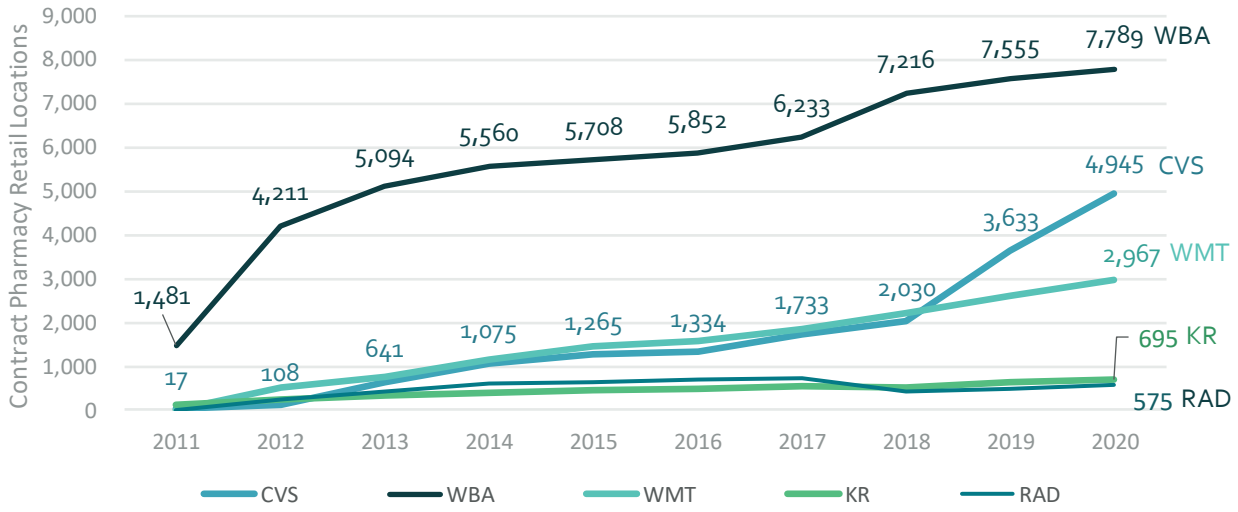
Having sized the value of gross 340B expenditures and 340B discounts flowing through hospital outpatient vs retail and specialty contract pharmacies, we now turn to the value flowing through each of the major 340B contract pharmacy operators. **Walgreens was early to recognize the contract pharmacy opportunity that arose following 2010 HRSA guidance.** As seen in **Fig. 10**, Walgreens expanded from 190 retail contract pharmacies in 2010 to 4,211 in 2012 and continued to expand its share of 340B contract pharmacies until 2018, when **CVS Health** began to drastically increase the number of CVS retail pharmacies participating in the program[2].

- Hospital outpatient pharmacies run by covered entity hospitals and clinics are by definition not included in our count of contract pharmacies. However, on-site hospital pharmacies run by pharmacy chains and specialty focused community pharmacies are included in our retail count.
- This distinction is most important when considering Walgreens and CVS Health share. **Walgreen's** operates 200 pharmacies located within hospitals and 300 specialty-focused

[2] Nephron analysis of Health Resource & Services Administration (HRSA) Office of Pharmacy Affairs Information System (OPASIS) covered entity relationship and contract pharmacy program participation data 2011-20220. This data set is supplemented with IQVIA and Drug Channels Institute retail pharmacy market share data and Nephron Projections for specialty pharmacy sales and share in 2020 and 2021.

community pharmacies which lead to 340B program share above what is indicated by pharmacy count. **CVS Health** also operates a more limited number of such pharmacies which boost share.

Fig. 10: Walgreens was early to recognize the 340B contract pharmacy opportunity, CVS expanded rapidly in 2019 and 2020



Source: Nephron Research analysis of HRSA OPASIS data 2011-2020

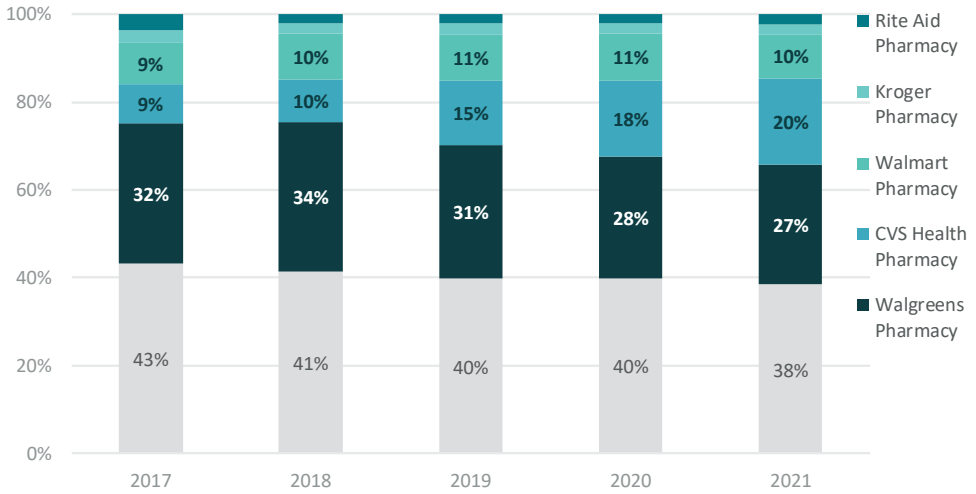
Note: Jan-20 Data represents the net of all contracts begun or terminated on or before 10/23/2020, all prior years are as of January 1st of that year

WBA retail pharmacies accounted for 28% of all 340B contract pharmacies in 2020 as compared to 18% at CVS and 11% at Walmart

As seen in **Fig 11,** HRSA data indicates **Walgreens'** share of retail contract pharmacies stood at 28% of all contract pharmacy participants in the 340B program in 2020 as compared to 18% at **CVS** and 11% at **Walmart**. **Kroger** and **Rite Aid** each possess 2% share.

As we look out to the end of 2021, we expect that as many as 9,000 of WBA's ~9,200 retail pharmacies will participate in the 340B program as contract pharmacies and CVS could expand participation to 6,500 of its ~9,900 retail pharmacies. **As such, we expect CVS share will expand to 20% in 2021 while WBA share will decline modestly to 27% and Walmart will decline slightly to 10%**.

Fig. 11: 340B pharmacy share of total RETAIL 340B contract pharmacies



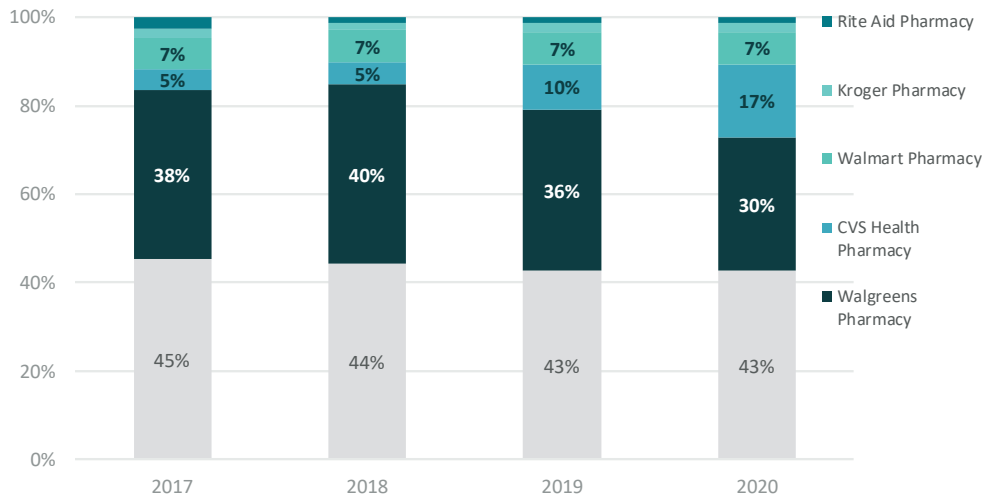
Source: Nephron Research analysis of HRSA OPASIS data 2011-2019. Nephron Research projection for 2021.

WBA retail pharmacies accounted for 36% of all 340B covered entity retail relationships in 2020 as compared to 10% at CVS and 7% at Walmart

We now move from pharmacy operator's share of retail 340B contract pharmacies to their share of total relationships between retail contract pharmacies and 340B covered entities. It is important to keep in mind that while *hospital* covered entities drive the majority of 340B value, with revenue easily 10-20x that of *clinic* covered entities, much of the growth in 340B retail relationships in recent years has come via expanding contract pharmacy engagement with clinics and other qualified entities.

- Among the largest 340B pharmacy operators, **CVS Pharmacy** and **Kroger Pharmacy** have increased their share of hospital covered entity relationships in excess of total relationship growth, accruing incremental share over the last three years. **Walgreens, Walmart and Rite Aid** have maintained relative share in line with market growth.
- A large portion of the 125% increase in retail contract pharmacy relationships 2017 to 2020 are attributable to further penetration of Federally Qualified Health Centers (FQHC) and other non-hospital 340B contract entities. **CVS has been the biggest share gainer here as well, expanding FQHC relationships 300% between 2017 and 2019, absorbing a majority of market growth.**

Fig. 12: 340B pharmacy share of total RETAIL 340B covered entity relationships

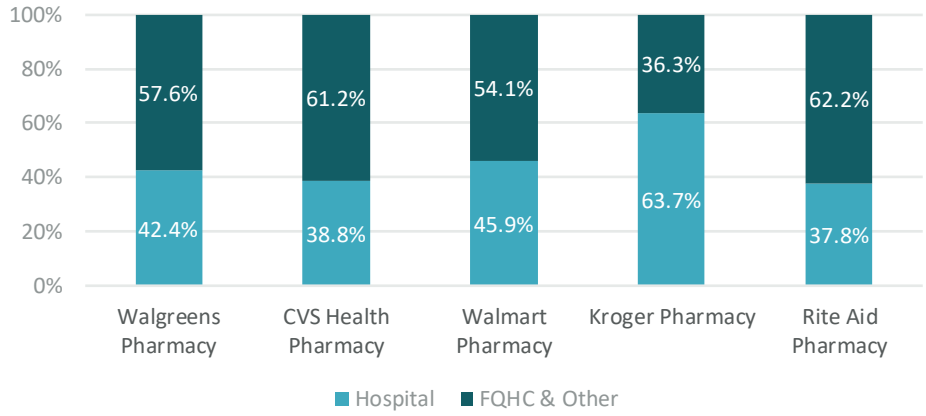


Source: Nephron Research analysis of HRSA OPASIS data 2011-2019. Nephron Research projection for 2021

Given the substantial delta between hospital and clinic purchasing levels, the ratio of hospital to FQHC relationships is important in determining what weight should be given to each retail pharmacy chain's share of covered entity relationships. **Data from early 2020 in Fig. 13 shows that FQHC's and other non-Hospital qualified entities will account for 54%-62% of relationships at Walgreens, CVS Health, Rite Aid and Walmart but only 36% of Kroger.** This may suggest that Kroger has been more focused on hospital relationships, and perhaps less aggressive in expanding 340B, than have Walgreens, CVS and Walmart.

Kroger indexes more toward hospitals whereas WBA and CVS have made expansion with clinics a major focus in recent years

Fig. 13: After two years of rapid expansion, CVS hospital/FQHC mix now mimics WBA



Source: Nephron Research analysis of HRSA OPASIS data

Figure 14 and 15 provide HRSA Office of Pharmacy Affairs Information System pharmacy and relationship data for each year 2010-2020. Exceptional growth years (in excess of 30%) are denoted in red.

CVS has clearly been working to close the gap with WBA in 2019 and 2020 with respect to both pharmacies and covered entity relationships. Walmart and Kroger have also been expanding relationships rapidly.

Fig. 14: 340B Participating RETAIL Pharmacies

Participating Pharmacies	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
CVS (retail)	15	17	108	641	1,075	1,265	1,334	1,733	2,030	3,633	4,945
y/y%		13%	535%	494%	68%	18%	5%	30%	17%	79%	36%
WBA (retail)	190	1,481	4,211	5,094	5,560	5,708	5,852	6,233	7,216	7,555	7,789
y/y%		679%	184%	21%	9%	3%	3%	7%	16%	5%	3%
WMT (retail)	1	1	503	749	1,138	1,446	1,569	1,849	2,219	2,609	2,967
y/y%				49%	52%	27%	9%	18%	20%	18%	14%
KR (retail)	36	111	239	329	379	454	499	556	512	650	695
y/y%		208%	115%	38%	15%	20%	10%	11%	-8%	27%	7%
RAD (retail)	4	4	237	432	592	645	695	724	426	476	575
y/y%				82%	37%	9%	8%	4%	-41%	12%	21%

Source: Nephron Research analysis of HRSA OPAIS

Fig. 15: 340B RETAIL Pharmacy Relationships

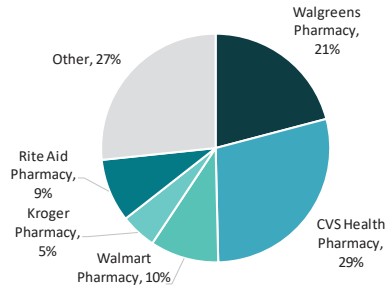
Pharmacy Relationships	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
CVS (retail)	33	35	126	666	1,227	1,507	1,726	2,224	2,761	7,106	16,092
y/y%		6%	260%	429%	84%	23%	15%	29%	24%	157%	126%
WBA (retail)	2,895	4,372	11,232	12,852	14,513	14,101	15,188	17,817	22,337	25,249	29,036
y/y%		51%	157%	14%	13%	-3%	8%	17%	25%	13%	15%
WMT (retail)	1	1	1,059	1,395	2,019	2,872	2,835	3,343	4,080	5,099	7,003
y/y%				32%	45%	42%	-1%	18%	22%	25%	37%
KR (retail)	49	204	379	483	513	631	754	934	850	1,420	2,042
y/y%		316%	86%	27%	6%	23%	19%	24%	-9%	67%	44%
RAD (retail)	5	5	1,803	2,130	1,034	1,059	1,184	1,265	759	928	1,199
y/y%				18%	-51%	2%	12%	7%	-40%	22%	29%

Source: Nephron Research analysis of HRSA OPAIS

Contract Pharmacy Share Estimates - Retail

The retail 340B share projections that drive our company specific models take four primary factors into account: 1) pharmacy operator **share of all retail pharmacy sales, 2)** pharmacy operator **share of 340B contract pharmacy locations, 3)** pharmacy operator **share of 340B relationships** (which largely mirror the number of pharmacies, unlike we will see in the specialty/mail channel) and **4) hospital vs. clinic covered entity relationship mix**.

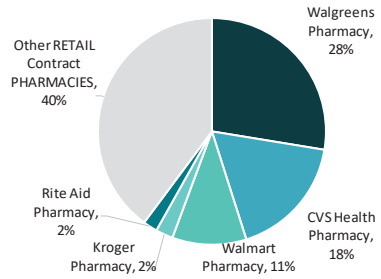
Fig.16: Retail Pharmacy Share (Sales)



Source: Nephron Research analysis of company disclosures and Drug Channels Est.

Note: Total retail pharmacy sales (not 340B sales)

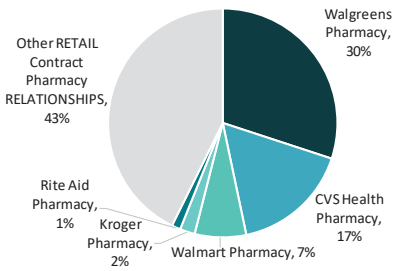
Fig.17: Retail Share (Pharmacies)



Source: Nephron Research analysis of HRSA OPAIS

Note: Share of the total number of 340B retail pharmacies

Fig.18: Retail Share (Relationships)



Source: Nephron Research analysis of HRSA OPAIS

Note: Share of the total number of 340B retail pharmacy relationships

Walgreens Pharmacy – Retail Share

Walgreens captured 21% share of total retail pharmacy sales in 2020 but has a much greater share of 340B expenditures as WBA retail pharmacies account for 28% of all 340B pharmacies and 30% of retail pharmacy 340B relationships (note that this is retail only and does not include specialty, infusion, or WBA TPA relationships). **For the purposes of our 340B profit model we project WBA's share of 340B program RETAIL contract pharmacy expenditures total 33.0% in 2020, well above the next closest player CVS at 16.5%.**

Fig. 19: WBA 340B RETAIL Share Projection

Walgreens Pharmacy	2018	2019	2020*	2021*
340B Market Share Inputs				
Share of Contract Pharmacies (HRSA)	34.1%	30.5%	27.6%	27.3%
Share of RETAIL CP Relationships (HRSA)	40.4%	36.4%	30.0%	
Share of RETAIL Pharmacy Sales (IQVIA/DC)	21.7%	21.3%	20.9%	
Hospital/Clinic Ratio (Hosp as % of Total)	*42.8%*	*42.6%*	*42.4%*	
340B RETAIL Market Share Projection				
NEPHRON LOW CASE		30.4%	27.5%	27.9%
NEPHRON BASE CASE		**36.5%**	**33.0%**	**31.0%**
NEPHRON HIGH CASE		39.0%	35.5%	33.0%

Source: Nephron Research

- We expect that WBA's share of retail 340B expenditures further exceeds its store and relationships share owing to **1)** the company's **longstanding focus** on 340B contract pharmacy expansion, **2)** early investment in **340B program management technology solutions** for covered entities and **3) integration of 340B third party administration services** to identify 340B eligible patients well outside the immediate community and when filling centralized specialty and mail claims.

- Note that beyond improving penetration/compliance, 340B technology and TPA solutions for split billing, analytics and compliance management generate incremental per transaction service fees as reflected in our estimates of **WBA (*Walgreens 340B Complete*)**, **CVS (*Wellpartner*)** and **Cigna (*Verity Solutions*)** transaction fees in our model. **McKesson** is also a significant player in this space with **Macro Helix**. Other significant operators include SunRx (owned by MedImpact), and Texas based CaptureRx.

- Given the maturity of WBA's 340B operations and our view that elevated retail program growth is primarily attributable to expansion at CVS (with a positive but lesser impact from WMT, KR and RAD), we project that **WBA will grow at 11% in 2021, below the market rate of 18%, leading to a decline in WBA's retail 340B share from 33.0% in 2020 to 31.0% in 2021.**

CVS Health Pharmacy – Retail Share

CVS retail pharmacy sales share stood at 30% in 2020 and would likely be higher if specialty sales at retail were not accounted for in the Pharmacy Services (PBM) segment. However, CVS has historically held 340B share well below its pharmacy sales market share and only began to close the gap with WBA in 2018. As of early 2020, CVS accounted for 18% of all 340B pharmacies and 17% of 340B retail pharmacy relationships (again excluding specialty, infusion, and TPA relationships). **Our 340B profit model assumes CVS' share of 340B program retail pharmacy expenditures total 16.7% in 2020 or just 56% of CVS retail market share.**

- **After several years of relatively modest 340B contract pharmacy expansion 2011-2017, CVS appeared to get more aggressive in 2018 after acquiring 340B program administrator Wellpartner.** The company expanded the number of retail contract pharmacies from 2,030 in 2018 to 3,633 in 2019 and 4,945 in 2020, expanding pharmacy share from 9.6% to 17.5%.

- The expansion effort is also seen in growth in covered entity relationships where Wellpartner has enabled CVS to expand from 2,761 relationships in 2018 to 16,092 in 2020, a 6.2x increase on a 2.4x increase in contract pharmacies. Similar to WBA, we expect captive ownership of Wellpartner has helped expand CVS's share of 340B expenditures in excess of its share of pharmacies and relationships. **We project that CVS's share of retail 340B expenditures will grow from 15.5% in 2020 to 18.0% in 2021.**

Fig. 20: CVS 340B RETAIL Share Projection

CVS Health Pharmacy	2018	2019	2020*	2021*
340B Market Share Inputs				
Share of Contract Pharmacies (HRSA)	9.6%	14.7%	17.5%	19.7%
Share of RETAIL CP Relationships (HRSA)	5.0%	10.2%	16.7%	
Share of RETAIL Pharmacy Sales (IQVIA/DC)	30.3%	30.2%	28.7%	
Hospital/Clinic Ratio	*65.0%*	*50.4%*	*38.8%*	
340B RETAIL Market Share Projection				
NEPHRON LOW CASE		9.0%	12.5%	15.0%
NEPHRON BASE CASE		**12.0%**	**15.5%**	**18.0%**
NEPHRON HIGH CASE		14.6%	17.5%	20.2%

Source: Nephron Research

Walmart Pharmacy – Retail Share

Walmart appears to capture its fair share of 340B revenue relative to total pharmacy sales share of 10%. Walmart has a slightly greater share of contract pharmacies at 11% but indexes slightly lower than its fair share of relationships at 7%.

- **We expect that WMT will grow at 16% in 2021, below the 18% retail market growth rate, leading to a modest decline in share from 11.0% to 10.8%.**

Fig. 21: Walmart 340B RETAIL Share Projection

Walmart Pharmacy	2018	2019	2020*	2021*
340B Market Share Inputs				
Share of Contract Pharmacies (HRSA)	10.5%	10.5%	10.5%	10.0%
Share of RETAIL CP Relationships (HRSA)	7.4%	7.3%	7.2%	
Share of RETAIL Pharmacy Sales (IQVIA/DC)	10.2%	10.2%	9.7%	
Hospital/Clinic Ratio	*51.0%*	*49.6%*	*45.9%*	
340B RETAIL Market Share Projection				
NEPHRON LOW CASE		7.3%	7.2%	7.2%
NEPHRON BASE CASE		**11.1%**	**11.0%**	**10.8%**
NEPHRON HIGH CASE		12.5%	12.5%	12.3%

Source: Nephron Research

Kroger Pharmacy – Retail Share

Kroger possesses 5% share of the retail pharmacy market but accounts for only 2% of retail contract pharmacies and covered entity relationships. We attribute this to a greater focus on aggregating clinics at WBA, CVS and to a lesser extent WMT. However, given Kroger's greater mix of hospitals over clinics, we project the company is able to maintain 340B share just above its share of contract pharmacies at 2.7% in 2020.

- **We assume Kroger grows 9% in 2021, below the industry growth rate of 18% leading to a decline in share from 2.7% to 2.5%.**

Fig. 22: Kroger 340B RETAIL Share Projection

Kroger Pharmacy	2018	2019	2020*	2021*
340B Market Share Inputs				
Share of Contract Pharmacies (HRSA)	2.4%	2.6%	2.5%	2.3%
Share of RETAIL CP Relationships (HRSA)	1.5%	2.0%	2.1%	
Share of RETAIL Pharmacy Sales (IQVIA/DC)	5.4%	5.3%	5.1%	
Hospital/Clinic Ratio	*54.7%*	*62.5%*	*63.7%*	
340B RETAIL Market Share Projection				
NEPHRON LOW CASE		2.0%	2.1%	1.9%
NEPHRON BASE CASE		**2.8%**	**2.7%**	**2.5%**
NEPHRON HIGH CASE		3.1%	3.0%	2.8%

Source: Nephron Research

Rite Aid Pharmacy – Retail Share

Since selling 1,932 stores to Walgreens in 2018 (including ~300 340B contract pharmacies), Rite Aid has under-indexed in 340B with just 2% share of retail contract pharmacies and covered entity relationships despite 9% share of retail pharmacy sales. New management has stated an increased focus on 340B programs, and the company expanded the number of contract pharmacies from 476 in 2019 to 575 in 2020, a 21% increase, though still far behind WBA and CVS.

- **We project Rite Aid grows above the market at 30% in 2021, leading to an increase in share from 1.2% in 2020 to 1.3% in 2021.**

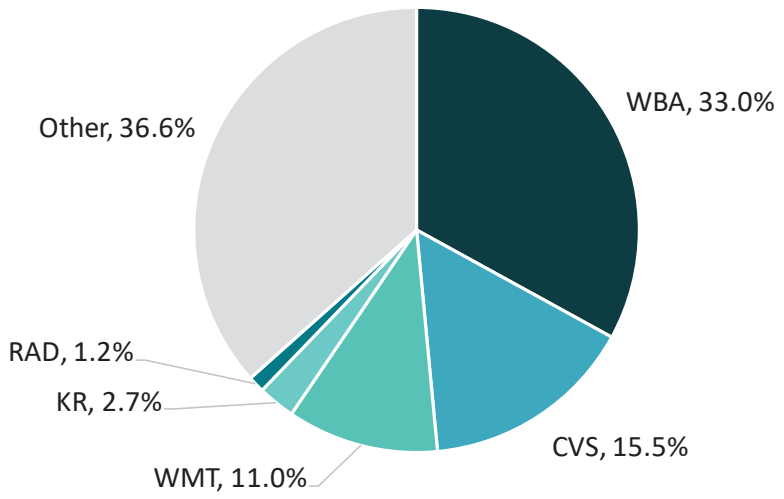
Fig. 23: Rite Aid 340B RETAIL Share Projection

Rite Aid Pharmacy	2018	2019	2020*	2021*
340B Market Share Inputs				
Share of Contract Pharmacies (HRSA)	2.0%	1.9%	2.0%	2.3%
Share of RETAIL CP Relationships (HRSA)	1.4%	1.3%	1.2%	
Share of RETAIL Pharmacy Sales (IQVIA/DC)	9.4%	9.4%	8.9%	
Hospital/Clinic Ratio	*49.3%*	*42.8%*	*37.8%*	
340B RETAIL Market Share Projection				
NEPHRON LOW CASE		1.0%	1.0%	1.0%
NEPHRON BASE CASE		**1.3%**	**1.2%**	**1.3%**
NEPHRON HIGH CASE		1.9%	2.0%	2.3%

Source: Nephron Research

Figures 24 summarizes the key retail market share assumptions that drive our 340B revenue and profit models in the following section.

Fig. 24: Nephron BASE case 340B RETAIL Share 2020



Source: Nephron Research

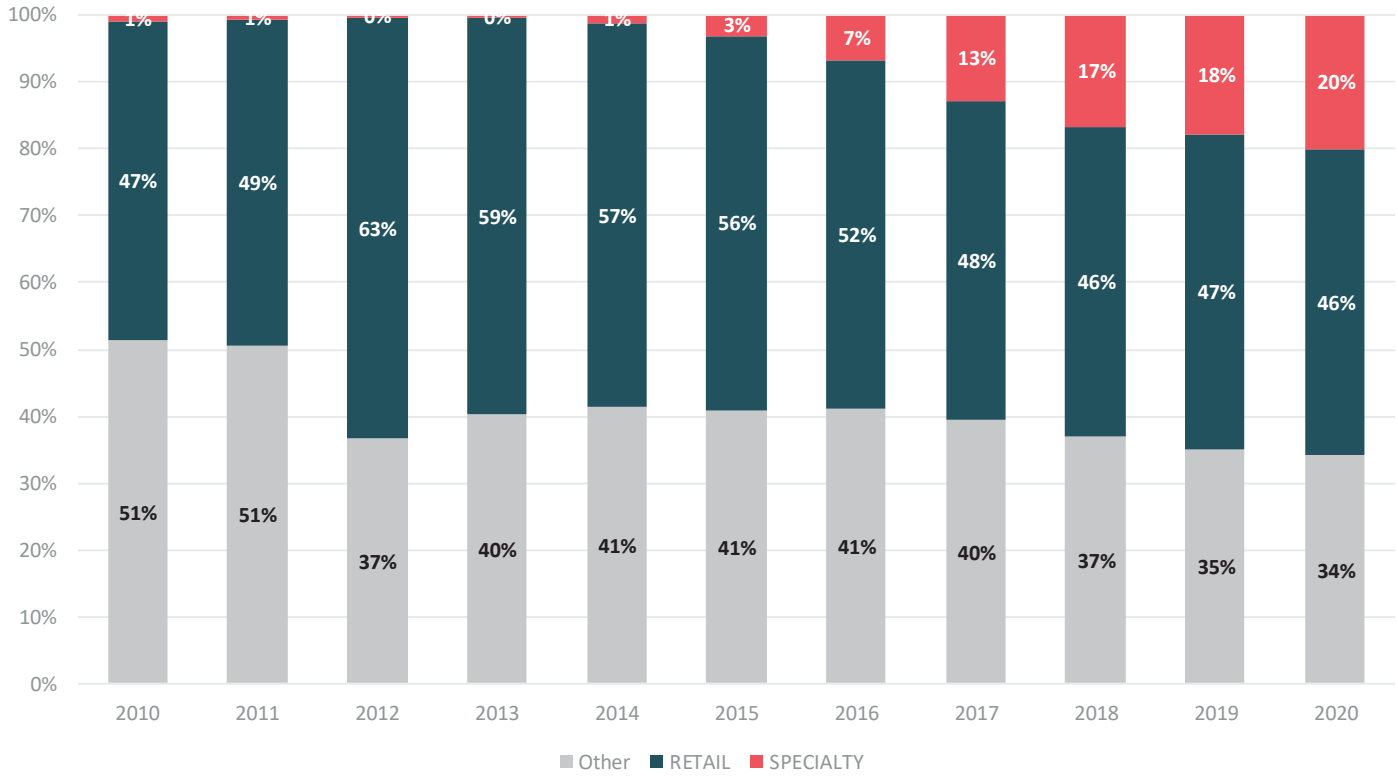
Sizing the 340B Program by Contract Pharmacy Operator – SPECIALTY SHARE

Mail/Specialty Contract Pharmacy participation expanded rapidly 2015-2020

Having established projections for retail contract pharmacy operators, we now turn to the Mail/Specialty contract pharmacy market, which has experienced rapid expansion 2015-2020 (Note: we will refer to the Mail/Specialty channel primarily as 'Specialty' as specialty products account for the vast majority of 340B Mail/Specialty channel sales).

Given that specialty pharmacies may serve dozens or even hundreds of covered entities from just a few centralized pharmacy locations, we focus our analysis of specialty share on covered entity relationship count not pharmacy count. As seen in Fig 25, the number of covered entity relationships with what we term 'specialty pharmacies' (including mail, excluding infusion) was less than 1% of all 340B relationships prior to 2014 but expanded to 7% in 2016 and 20% in 2020.

Fig. 25: Specialty Pharmacy 340B contract entity relationships expanded from 1% of all relationships in 2014 to 20% in 2020

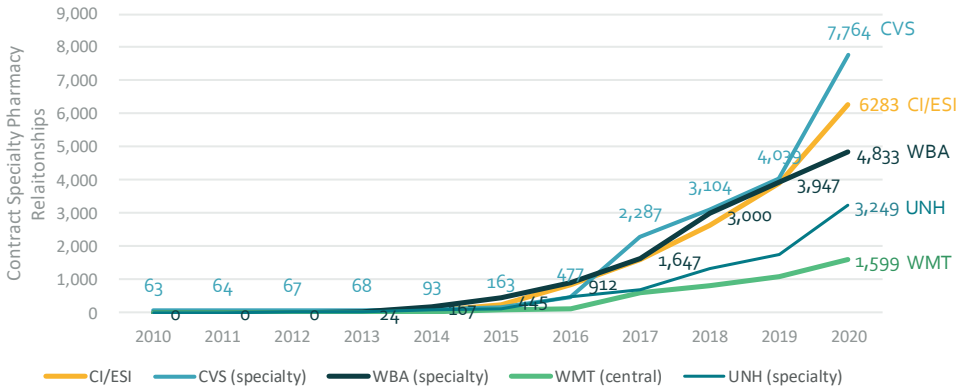


Source: Nephron Research

Acquisitions appear to have catalyzed specialty pharmacy relationships expansion

The number of relationships increased from 423 in 2014 to 7,183 in 2017 to 24,475 in 2020 with expansion driven by the centralized specialty operations of **CIGNA post ESI/Accredo acquisition** in 2018 (2017-2020 CAGR of 58%) and **CVS Specialty post Wellpartner acquisition** in 2017 (CAGR of 50%) as well as more recent contributions from **UNH/OptumSpecialty** following the Avella and Diplomat acquisitions (though we expect the increase has more to do with an internal focus on growing 340B share at Optum than the legacy relationships of Avella and Diplomat).

Fig. 26: CVS Specialty, Cigna/ESI (now Evernorth) and Walgreens/AllianceRx have led the charge, now followed by UNH/OptumSpecialty Pharmacy



Source: Nephron Research analysis of HRSA OPASIS data 2011-2020

We project specialty contract pharmacy will drive $8.8bn in 340B program growth 2019-2021, well above retail contract pharmacy growth of $4.1bn

Figure 27 provides HRSA OPAIS relationship data for each year 2010-2020. Exceptional growth years (in excess of 30%) are again denoted in red. Given Walgreen's focus on 340B within the retail sphere, it comes as no surprise that the company was early to develop relationships in the specialty sphere. However, Walgreen's specialty pharmacy operations, which are operated as part of a JV with Prime Therapeutics, lag those of CVS and Cigna in terms of both scale and sophistication (leading to Prime's recent decision to align with Cigna/Evernorth). **What is clear from the figure below, is the extent to which both CVS and Cigna/ESI began to expand specialty pharmacy contract entity relationships in 2016 and 2017, working in tandem with inhouse TPAs to capture 340B eligible scripts across broad national networks.** UNH/Optum Specialty Pharmacy, was a more limited participant in the market 2010-2018, but began to close the gap as we progressed through 2019 and entered 2020.

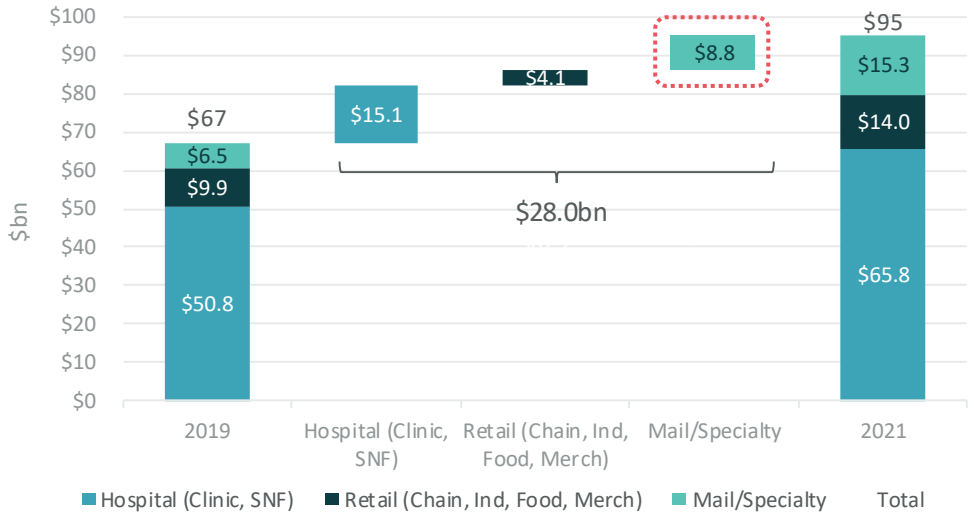
Fig. 27: 340B Specialty Pharmacy Relationships

Specialty Relationships	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
CI/Evernorth	0	0	1	5	64	253	845	1,597	2,648	3,907	6,283
y/y%						295%	234%	89%	66%	48%	61%
CVS (specialty)	9	8	11	12	30	93	387	2,196	3,059	4,002	7,734
y/y%		-11%	38%	9%	150%	210%	316%	467%	39%	31%	93%
WBA (specialty)	0	0	0	24	167	445	912	1,647	3,000	3,947	4,833
y/y%					596%	166%	105%	81%	82%	32%	22%
WMT (central)	0	0	0	0	22	98	124	604	814	1,089	1,599
y/y%						345%	27%	387%	35%	34%	47%
UNH (specialty)	1	2	16	38	73	129	471	680	1,338	1,755	3,249
y/y%				138%	92%	77%	265%	44%	97%	31%	85%

Source: Nephron Research analysis of HRSA OPAIS

It is important to put specialty contract pharmacy growth in perspective relative to retail contract pharmacy growth. Earlier in this report, we projected gross dollarized 340B expenditures at WAC flowing through both retail and specialty contract pharmacies will expand at a 34% CAGR 2019-2021, equating to $12.9bn in absolute growth over this time frame (see Fig. 8 on Pg. 11). This compared to the covered entity run hospital outpatient pharmacy CAGR of 14%, equating to $15.1bn in absolute growth, or a total of $28bn across both covered entity and contract pharmacy. **As seen in Fig. 28, specialty contract pharmacy expenditure growth of $8.8bn accounts for 68% of total contract pharmacy growth and 31% of total 340B expenditure growth 2019-2021.**

Fig. 28: We project 340B dollarized WAC expenditures will grow by $28bn 2019-2021

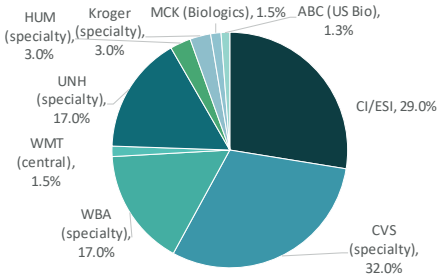


Source: Nephron Research

Contract Pharmacy Share Estimates - Specialty

The specialty pharmacy 340B share projections that drive our company specific models take four primary factors into account: 1) pharmacy operator **share of all specialty pharmacy sales, 2)** specialty pharmacy **share of 340B relationships** (which are a far better indicator than pharmacy locations given the centralized nature of specialty pharmacy) and **3) infusion relationships** (recognizing specialty home infusion accounts for a $6bn market by our estimates whereas the Nephron Specialty Market Model sizes the specialty pharmacy marketplace at $131bn in 2020).

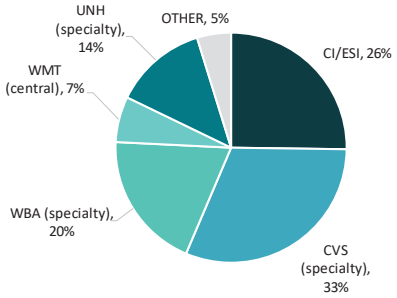
Fig.29:Specialty Pharmacy Share(Sales)



Source: Nephron Research sales projections

Note: Total specialty pharmacy sales (not 340B sales)

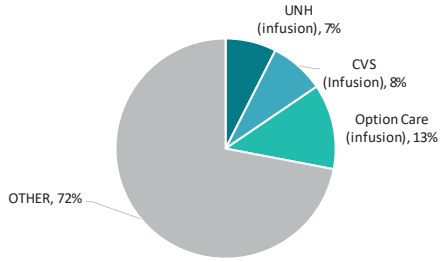
Fig. 30: Spec Pharmacy (Relationships)



Source: Nephron Research analysis of HRSA OPAIS

Note: Share of the total number of 340B specialty pharmacy relationships

Fig. 31: Infusion (Relationships)



Source: Nephron Research analysis of HRSA OPAIS

Note: Share of infusion relationships. WBA infusion now independently operated by OptionCare.

Cigna/Evernorth (ESI/Accredo) – Specialty Share

Cigna/ESI's Accredo (recently rebranded under the Evernorth banner) specialty pharmacy sales share stood at 29% in 2020. This is above Evernorth's share of specialty pharmacy covered entity relationships at 26%. **Our 340B profit model assumes CI/Evernorth's share of 340B program specialty pharmacy expenditures totals 29.0% in 2020.**

- **CI/Evernorth covered entity relationships expanded to 6,283 in 2020, up 61% from 3,907 in 2019, continuing several years of ~45-65% growth.**

- **We project that Evernorth's share of specialty pharmacy 340B expenditures will remain steady at 29% 2020 to 2021.**

Fig. 32: Cigna 340B SPECIALTY Share Projection

CI/Evernorth (Accredo)	2018	2019	2020*	2021*
340B SP Market Share Inputs				
Share of SPECIALTY CP Relationships (HRSA)	23.1%	26.5%	26.5%	
Share of SP Sales (Nephron Est)			29.0%	
Share of INFUSION CP Relationships (HRSA)	NA	NA	NA	
340B SPECIALTY Market Share Projection				
NEPHRON LOW CASE		26.5%	26.5%	26.5%
NEPHRON BASE CASE		**29.0%**	**29.0%**	**29.0%**
NEPHRON HIGH CASE		32.0%	32.0%	32.0%

Source: Nephron Research

CVS Health Pharmacy – Specialty Share

CVS specialty pharmacy sales share stood at 32% in 2020, inclusive of specialty sales at retail captured in the Pharmaceutical Services segment. This is in-line with CVS's share of specialty pharmacy covered entity relationships at 33%. We estimate that CVS possesses 15%-20% share of the much smaller specialty home infusion market. **Our 340B profit model assumes CVS' share of 340B program specialty pharmacy expenditures total 30.0% in 2020.**

- **CVS covered entity relationships expanded to 7,764 in 2020, up 92% from 4,039 in 2019 after several years of ~30% growth.**
- **We project that CVS's share of specialty pharmacy 340B expenditures will grow from 30% in 2020 to 32% in 2021 as the company leverages recent contract additions and expands compliance.**

Fig. 33: CVS 340B SPECIALTY Share Projection

CVS (Specialty Pharmacy)	2018	2019	2020*	2021*
340B SP Market Share Inputs				
Share of SPECIALTY CP Relationships (HRSA)	27.0%	27.4%	32.7%	
Share of SP Sales (Nephron Est)			32.0%	
Share of INFUSION CP Relationships (HRSA)	8.2%	8.1%	8.0%	
340B SPECIALTY Market Share Projection				
NEPHRON LOW CASE		25.0%	25.6%	27.6%
NEPHRON BASE CASE		**27.4%**	**30.0%**	**32.0%**
NEPHRON HIGH CASE		30.0%	32.0%	34.0%

Source: Nephron Research

Walgreens Pharmacy (AllianceRx Walgreens Prime) – Specialty Share

Walgreen's specialty pharmacy share is for now joined with Prime Therapeutics in the AllianceRx Walgreens Prime JV. We project that AllianceRx specialty pharmacy sales share stood at 17% in 2020 but in contrast to the retail operation where WBA is the 340B leader, we project WBA's specialty 340 share under-indexes relative to total market share at 15.5%. **Our 340B profit model assumes Walgreen's 340B specialty business grows below market levels, leading WBA share to decline from 15.5% in 2020 to 15.0% in 2021 not accounting for the fact that 3 of Prime Therapeutics' 23 plans will move from the JV to Cigna/Evernorth.**

- Our estimate of 17% market share is inclusive of $4-5bn of Prime Therapeutics member centralized specialty sales, $5.5bn of FEP government specialty sales and $11bn associated with Walgreens specialty pharmacy. **We project that WBA's specialty operation could lose 80% of $4-$5bn in Prime Therapeutics specialty spend to CI/Evernorth in 2022.** It is unclear to what extent 340B discounts associated with Prime are benefitting Walgreens. We note that payments to Prime via WBA's *non-controlling interest* line suggest a modest contribution from 340B, however we expect that Prime's goal would be to have any 340B benefits flow to members via lower rates, not via the NCI line and of course this does not tell us if WBA is benefitting via its TPA.

- We further note that our estimates for AllianceRx's may overstate market share to the extent that our specialty estimates include volumes captured in our retail estimates (i.e. flowing through WBA's community specialty pharmacy locations). As such, **we discount WBA's market share in our 340B model at 15.5% as compared to specialty sales share of 17% and relationship share of 20%.**

Fig. 34: WBA 340B SPECIALTY Share Projection

WBA (AllianceRx WBA Prime)	2018	2019	2020*	2021*
340B SP Market Share Inputs				
Share of SPECIALTY CP Relationships (HRSA)	26.1%	26.8%	20.4%	
Share of SP Sales (Nephron Est)			17.0%	
Share of INFUSION CP Relationships (HRSA)	11.8%	11.8%	12.5%	
340B SPECIALTY Market Share Projection				
NEPHRON LOW CASE		18.0%	15.0%	15.0%
NEPHRON BASE CASE		**17.0%**	**15.5%**	**15.0%**
NEPHRON HIGH CASE		22.0%	20.0%	20.0%

Source: Nephron Research

Walmart Specialty Pharmacy – Specialty Share

Walmart specialty pharmacy sales share stood at only 1.5% of the total market in 2020 but specialty pharmacy share of relationships stood at 7%, suggesting WMT has leveraged its retail 340B participation to capture a greater share of 340B specialty volume, with participation limited by WMT's ability to access limited distribution products.

- **Our 340B profit model assumes WBA's share of 340B program specialty pharmacy expenditures totals 2.2% in 2020, or roughly double its specialty market share.**

Fig. 35: WMT 340B SPECIALTY Share Projection

WMT (Central Specialty)	2018	2019	2020*	2021*
340B SP Market Share Inputs				
Share of SPECIALTY CP Relationships (HRSA)	7.1%	7.4%	6.7%	
Share of SP Sales (Nephron Est)			1.1%	
Share of INFUSION CP Relationships (HRSA)	NA	NA	NA	
340B SPECIALTY Market Share Projection				
NEPHRON LOW CASE		1.3%	1.1%	1.0%
NEPHRON BASE CASE		**2.9%**	**2.2%**	**1.7%**
NEPHRON HIGH CASE		5.5%	5.0%	4.5%

Source: Nephron Research

UNH/Optum Specialty Pharmacy – Specialty Share

Optum Specialty Pharmacy sales share stood at 17% in 2020, inclusive of the Diplomat pharmacy acquisition. Optum Specialty Pharmacy has historically under-indexed relative to its market share accounting for only 11.9% of specialty relationships in 2019, expanding to 13.7% in 2020. Optum has taken a more cautious approach to 340B program optimization than have Cigna and CVS. We are not aware of a captive TPA or 340B technology and services offering at UNH/Optum.

- Optum did not appear focused on 340B following the Catamaran/BriovaRx acquisition in 2015. With increased investment in specialty beginning with the Avella and Genoa acquisitions in 2018 and culminating with the Diplomat acquisition in late 2019, we expect 340B became a strategic priority in 2020.
- Share of specialty pharmacy 340B relationships increased from 1,755 in 2019 to 3,249 in 2020. We expect that the vast majority of this expansion is attributable to increased internal focus (i.e. not the acquisitions) and the organization is now attempting to close the 340B specialty gap with Cigna and CVS.
- **With recent acquisitions and increased focus on specialty, we expect Optum could expand from 13.7% share in 2020 to 15% share in 2021.**

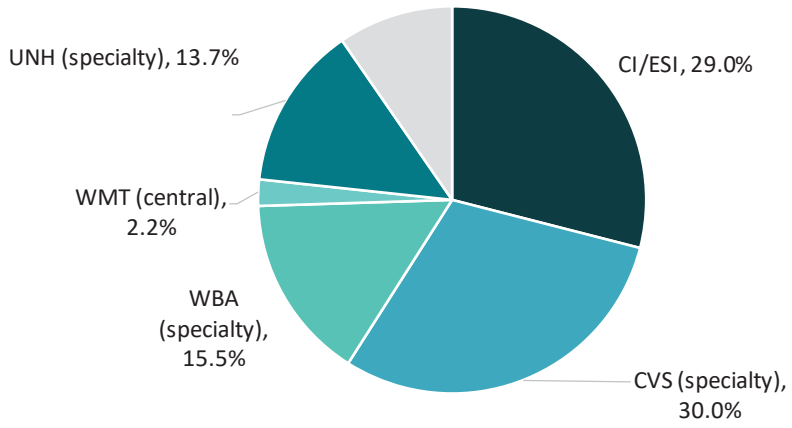
Fig. 36: UNH 340B SPECIALTY Share Projection

UNH (Optum Specialty Pharmacy)	2018	2019	2020*	2021*
340B SP Market Share Inputs				
Share of SPECIALTY CP Relationships (HRSA)	11.7%	11.9%	13.7%	
Share of SP Sales (Nephron Est)			17.0%	
Share of INFUSION CP Relationships (HRSA)	NA	0.1%	7.5%	
340B SPECIALTY Market Share Projection				
NEPHRON LOW CASE		9.0%	10.3%	11.5%
NEPHRON BASE CASE		**11.9%**	**13.7%**	**15.0%**
NEPHRON HIGH CASE		15.5%	17.0%	19.0%

Source: Nephron Research

Figures 37 summarizes the key specialty market share assumptions that drive our 340B revenue and profit models in the following section.

Fig. 37: Nephron BASE case 340B SPECIALTY Share 2020



Source: Nephron Research

CONTRACT PHARMACY LEVEL ANALYSIS: SIZING 340B DISCOUNTS & GROSS PROFIT RETENTION

Contract Pharmacy Discount/Gross Profit Retention Analysis

We now turn from 340B market share to 340B profit share, identifying the level of 340B discounts retained by contract pharmacies vs passed to covered entities

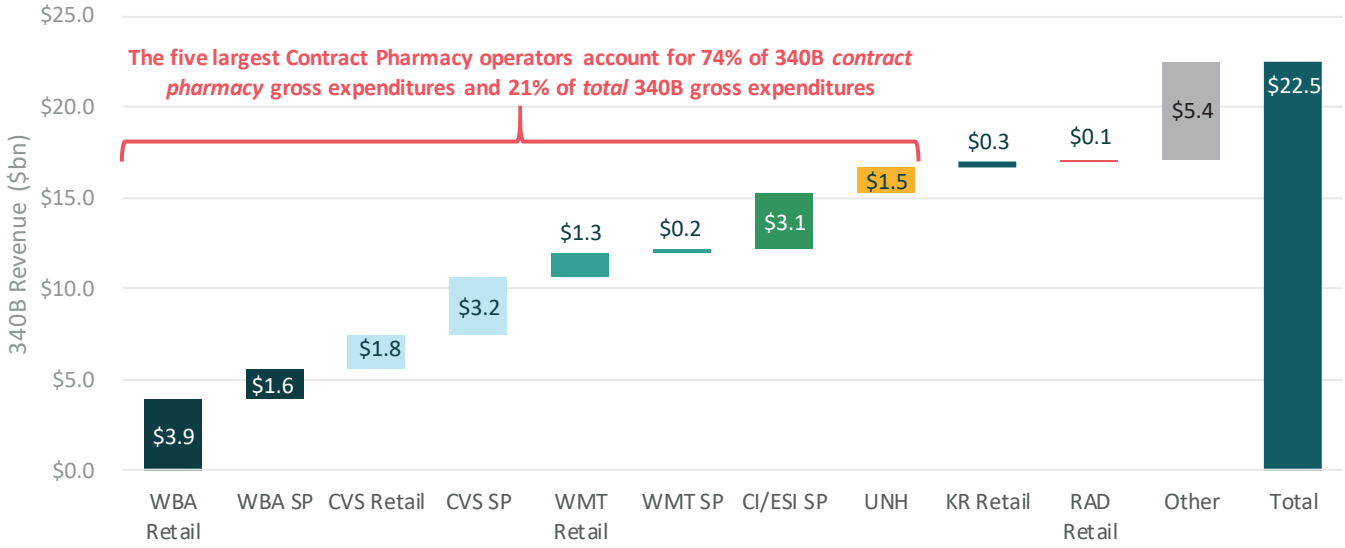
In return for their services, contract pharmacies may earn per transaction fees and/or receive a percentage spread based on gross WAC or net 340B discounted prices. As such, our calculations of contract pharmacy profitability, or the portion of 340B discounts retained by contract pharmacies, are based on **1)** applying varying levels of **spread based fees** to our projections for each pharmacy operator's **gross 340B pharmaceutical value** for retail and specialty, and **2)** applying varying levels of **per transaction fees** on our projections for each pharmacy operator's **total number of 340B transactions**.

❶ First, we estimate **gross 340B pharmaceutical value flowing through each of the major contract pharmacy operators,** segmenting between retail and specialty pharmacy, as seen in Fig. 38.

340B contract pharmacy share has been consolidated among five contract pharmacy operators

- Expenditures at gross (dollarized WAC) flowing through the three integrated PBMs – **CVS Retail & Specialty**, **Cigna/Evernorth** and **UNH/Optum Specialty Pharmacy** – total $9.6bn in 2020, equating to 42% of contract pharmacy 340B expenditures and 12% of total 340B spending.
- Adding **Walgreens** and **Walmart** to the mix, the five largest 340B contract pharmacy operators account for $16.7bn of gross expenditures, equating to 74% of contract pharmacy 340B expenditures and 21% of total 340B spending.

Fig. 38: Contract Pharmacy Operator 2020 WAC Dollarized 340B Expenditures: $22.5bn across all contract pharmacies



Source: Nephron Research 340B Market Model

❷ Second, we estimate the **number of 340B transactions** (scripts) at each of the 340B contract pharmacy operators, segmenting between retail and specialty pharmacy operations.

❸ Third, we determine the **portion of 340B sales that are high vs low vs zero spread** and **high vs low vs zero fee**.

Fig. 39: Segmenting between high/low/zero spread vs fixed fee contracts, we estimate CPs retain 12-34% of 340B discounts

Source: Nephron Research

Note: We have treated 340B admin, billing and technology fees as part of retained discounts when captured by TPAs owned by integrated contract pharmacies.

For those interested in the detail we provide a basic overview of our spread and fee assumptions. For those that would like to skip to the punch line, see Figures 40-42 on the following pages.

- **Retail Contract Pharmacy Spread & Fees:** Based on our review of publicly available 340B contract pharmacy contracts and government reports on the 340B program, we arrive at four simplified tiers for combinations of spread and fee (they are simplified but not simple).
  - **Retail Spread:** Our spread tier assumptions run from 0% for high fixed-fee contracts to 20% spread of WAC price for 'high spread' contracts. The percentage of retail sales receiving 'high spread only' ranges 10-15%. The percentage receiving fixed fee only accounts for 10%-15% among the big five but closer to 50% across the 'other' CPs, primarily regional chains and independent pharmacies. The vast majority of contracts are assumed to fall into the two tiers retaining both spread and fixed fees. **Why is spread so high relative to brand pharmaceutical gross margins of ~3%?** The large retail pharmacy networks operated by Walgreens, CVS and Walmart are uniquely positioned to identify 340B eligible transactions with WBA and CVS benefitting from captive TPA operations.
  - **Retail Fee:** Retail fixed fees are projected from $0 to $28. We note that our model projects WBA averages fees in the $15 range and CVS average fees in the $14 range per Rx inclusive of transaction fees attributable to captive 340B program administration and technology offerings (with WBA the most significant beneficiary of these fees followed by CVS). Our per script fees for Walmart, Kroger and Rite Aid are substantially lower averaging in the $9 range.
- **Specialty Contract Pharmacy Spread & Fees:**
  - **Specialty Spread:** Our specialty pharmacy tier assumptions run from 0% for high fixed-fee contracts to 22% spread for a relatively small number of 'high spread' contracts. The percentage of sales receiving 'high spread only' ranges from 10-25% while the portion receiving a combination of spread and fixed fee ranges from 45%-80% (over two tiers). Fixed fee only accounts for 10%-30%. **Why is spread so high relative to specialty pharmacy gross margins of 4%-6%?** Integrated PBM specialty pharmacies are uniquely positioned to survey and identify 340B eligible transactions flowing through their centralized

pharmacies (transactions that are less likely to be identified by other TPAs), even when these pharmacies are hundreds or thousands of miles from a covered entity.

- **Specialty Fee:** Specialty fixed fees are projected from $0 to $25 with incremental $8-$10 per transaction fees attributable to 340B program administration and technology offerings (with WBA again the most significant beneficiary of these fees, though Cigna and CVS also earn incremental fees for such services).

- **TPA Fees.** Third Party Administrators and 340B claim and billing technology vendors, many of which are now integrated within the largest contract pharmacy operators, may earn significant fees in return for identifying 340B eligible transactions and providing the technology necessary to split the billing, payment and inventory fulfillment processes.
  - **Captive 340B Administrators.** With integration it has become harder to segment between the economic value of 'pharmacy dispensing fees' for *administering* the script and 'TPA fees' for *identification and administration* of the script. As noted above, our retail and specialty fees are set higher at those entities that have captive TPA operations. Specifically, **Walgreens' 340B Complete** (inclusive of substantial technology and billing capabilities), **CVS' Wellpartner** and **Cigna/Evernorth's Verity Solutions.**
  - **Independent TPA & 340B Tech Vendors:** Other significant players in the 340B admin and billing market include **McKesson's Macro Helix**, and **CaptureRx** followed by **RxStrategies, 340B Basics, Omnicell** and **Medimpact's SUNRx**. We expect **Optum** will build or buy similar capabilities if recent manufacturer actions do not prove durable as the organization continues to shift specialty drug spend from the medical to pharmacy benefit. **Note that fees paid to split-billing vendors by covered entities are not included in our estimates for discount retention unless they are embedded within the contract pharmacy** (i.e.: in the case of WBA 340B complete).

- **Pharmaceutical Wholesaler's Role.** Also not included in our measures of retained discounts are any fees collected by pharmaceutical wholesalers Amerisource, Cardinal and McKesson. The distributor initially buys the product from the manufacturer at WAC and later sells the product to the covered entity at the 340B discount price, submitting a '340B chargeback' to the manufacturer for the difference and collecting an associated distribution fee. **We do not believe the distribution fee is significantly higher than average brand margin but there is a working capital benefit from the ship to/bill to relationship (e.g.: the distributor receives the chargeback at day ten but does not pay the manufacturer for the product until day 30). While we do not believe the P&L impact is material, the sheer volume of chargebacks in the system as 340B discounts approach $53bn gives us pause.**

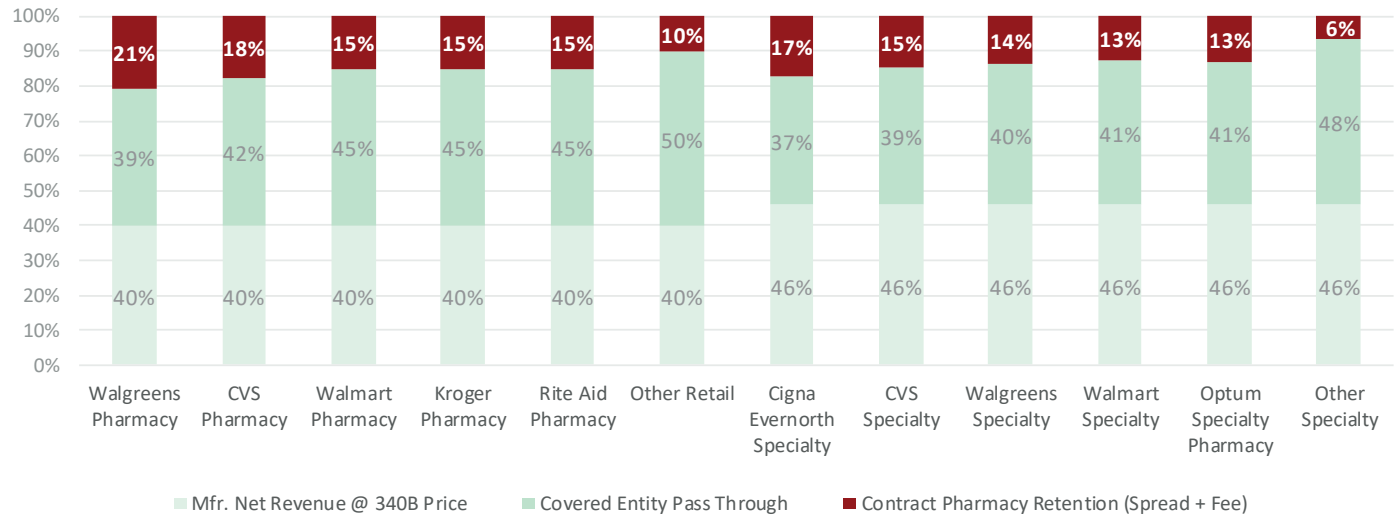
The largest contract pharmacies retain 13%-21% of gross expenditures as gross profit, well above average brand and specialty margins

❹ Fourth, we arrive at a measure of the portion of 340B gross expenditures (dollarized at WAC) **retained by contract pharmacies** vs **passed to covered entities** vs **booked as net revenue by manufacturers (Fig. 40)**. Our analysis finds that **the largest retail contract pharmacy operators retain between 15% and 21% of expenditures** while **the largest specialty contract pharmacies retain between 13% and 17%**. We find that independent pharmacies earn far less at 10%, though even here the gross profit contribution is well above average retail pharmacy brand gross profit margins of ~3%.

It is important to note that this is a market level analysis and represents an average value across the entire 340B portfolio based on average discounts of 54% in specialty and 60% in retail pharmacy. Our product specific analyses find significant variance at the therapeutic level, with the CPI penalty driving

'penny priced' examples with much higher contract pharmacy and covered entity retention of WAC prices.

Fig. 40: Discount retention among the largest retail chains averages 15%-21% of WAC vs specialty pharmacies at 13%-17%

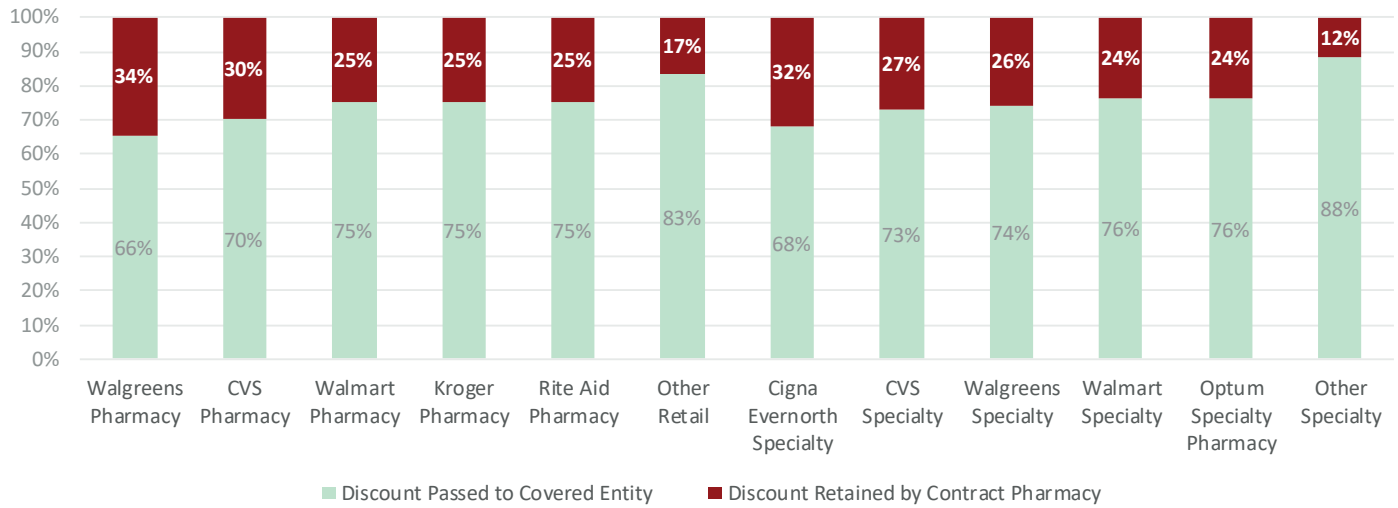


Source: Nephron Research 340B Market Model

The largest contract pharmacies are retaining 24%-34% of 340B discounts

Moving from retention of gross expenditures to retention of the discounts that contract pharmacies are capturing on behalf of covered entities, we find that fees of 13%-21% of gross equate to retention of 24%-34% of 340B discounts flowing through the contract pharmacy.

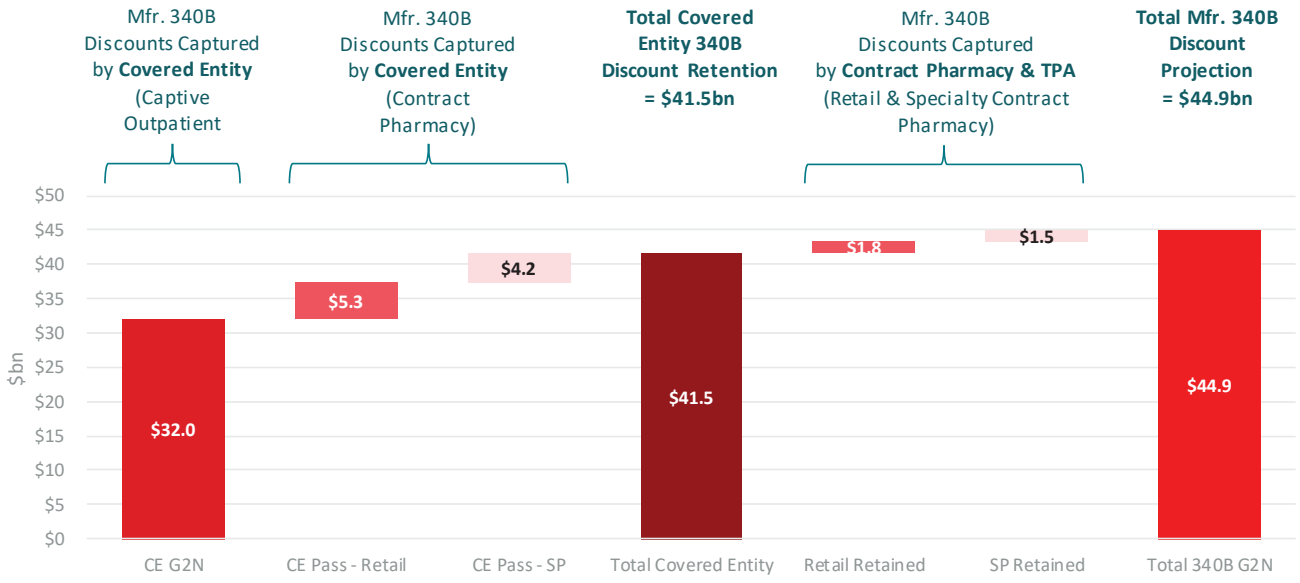
Fig. 41: Contract Pharmacy Fees averaging 13%-21% of WAC Prices, equate to retention of 24%-34% of 340B discounts



Source: Nephron Research 340B Market Model

A reference point on contract pharmacies. While contract pharmacies are a key source of 340B program growth, 71% of 340B sales continues to flow through outpatient pharmacies operated by covered entities. As seen in Fig. 42, Contract pharmacies will retain a relatively large portion of 340B discounts passing through their hands ($3.3bn on $12.9bn of discounts), but account for only 7% of total discounts ($3.3bn on $44.9bn).

Fig. 42: Nephron 2020 Projections: Contract Pharmacies & TPAs will retain $3.3bn in 340B Manufacturer Discounts (Covered Entities will Retain $41.5bn)

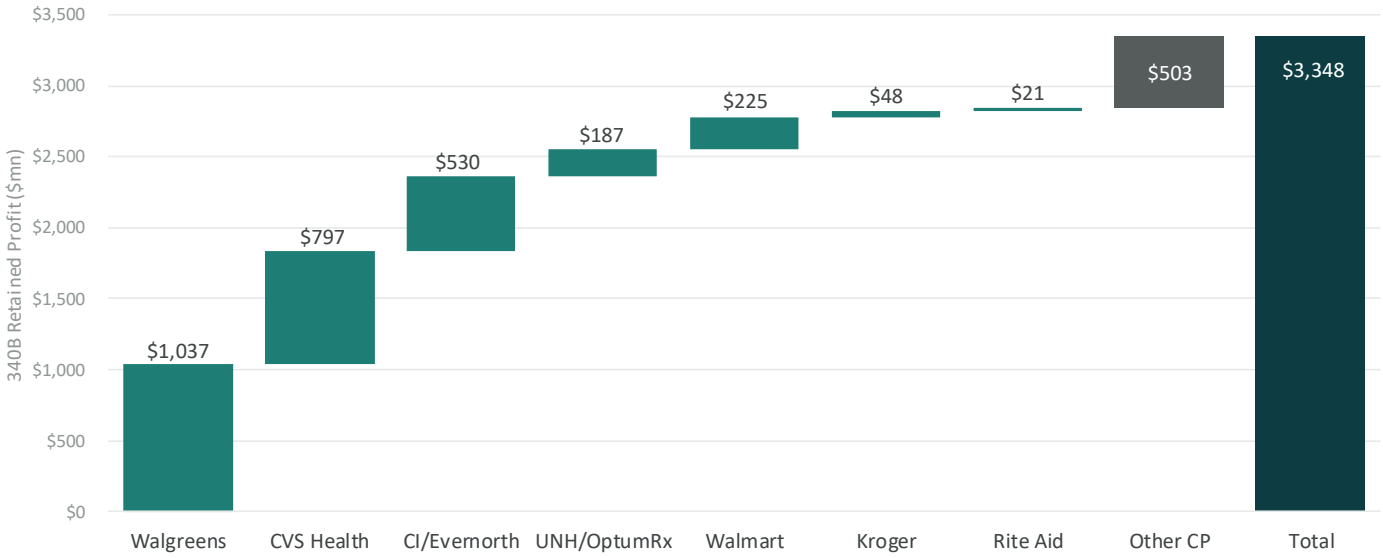


Source: Nephron Research 340B Market Model Projections

We arrive at a measure of contract pharmacy operator 340B gross profit across retail and specialty operations

❺ Finally, we apply projections of spread and fixed fees to retail and specialty market share to arrive at contract pharmacy specific estimates of discounts retained. **These estimates equate to the gross profit attributable to combined 340B retail and specialty operations if we assume that all 340B discounts and fees remain with the contract pharmacy operator (i.e.: putting to the side for now the extent to which discounts have been utilized to fund lower pharmacy network rates).**

Fig. 43: Contract Pharmacy 340B Gross Profit Pool (Assuming 340B profits were to remain at the contract pharmacy)



Source: Nephron Research

- The scale of 340B discounts retained by contract pharmacy operators is massive relative to measures of non 340B pharmacy brand and specialty profitability - both on a margin percentage and as a share of absolute profits. For example, **if all 340B discounts captured by the contract pharmacy were to remain within the contract pharmacy, we estimate the 2020 340B profit pool would total $1,037mn at WBA and $797mn at CVS, accounting for 22% and 25% of WBA and CVS retail and specialty brand gross profit, respectively**.

Fig. 44: Walgreens Alliance Boots 340B Profit Pool

Walgreens	2019	2020*	2021*
340B Gross Sales (Dollarized @ WAC)	$4,716	$5,568	$6,641
340B Gross Profit (Discount Retained)	$899	$1,037	$1,215
Discount Retained as % of Gross	*19.1%*	*18.6%*	*18.3%*
Impact if Profit Remains w/Pharmacy			
Share of Retail & Spec Brand Gross Profit	*19.5%*	*22.2%*	*25.1%*
Share of Total Company EPS	*13.9%*	*21.3%*	*23.9%*

Source: Nephron Research, assumes growth absent impact from mfr. actions
Note: WBA ongoing annual EPS impact may be overstated in 2020 and 2021 given COVID pressure on both U.S. and total company gross profit and EPS.

Fig. 45: CVS Health 340B Profit Pool

CVS Health	2019	2020*	2021*
340B Gross Sales (Dollarized @ WAC)	$2,962	$5,026	$7,415
340B Gross Profit (Discount Retained)	$473	$797	$1,170
Discount Retained as % of Gross	*16.0%*	*15.9%*	*15.8%*
Impact if Profit Remains w/Pharmacy			
Share of Retail & Spec Brand Gross Profit	*9.5%*	*15.0%*	*21.0%*
Share of Total Company EPS	*3.8%*	*6.1%*	*8.7%*

Source: Nephron Research, assumes growth absent impact from mfr. actions
Note: Retail & Specialty Brand GP estimate does not include PBM profit pools (i.e.: includes retail & spec brand profit but not rebate & admin fee profit)

- **A point of triangulation:** Walgreens disclosed to us in the fall that 340B volume had grown from 1% to 2% of script volume (projected at 1.165bn in 2020). Given that brand scripts account for 10% of total scripts, this suggests 340B could be 20% of brand volume (i.e. 2% on 10%), implying that our profit attribution is only 1.1x-1.3x volume share.
- **A point of refutation:** To be fair, Walgreens also disclosed to us in the fall that 340B profits were not measured in 'billions' and provided commentary that led us to a value in the hundreds of millions. It was this disclosure that catalyzed the analysis you are now reading. An analysis that sizes the 340B discounts retained by Walgreens at greater than $1bn but recognizes that WBA does not capture that full value at the EPS line (more on this below).

- For Cigna/Evernorth and United/OptumRx, we compare 340B specialty contract pharmacy discount retention gross profit to our projections for PBM brand *fulfillment* gross profit (i.e. including specialty and mail, excluding rebates, admin fees and spread). We find that **after significant growth 2019 to 2020, 340B could account for 21% and 14% of 2020 Evernorth and OptumRx brand gross profit derived from specialty and mail**, respectively.

Fig. 46: Cigna/Evernorth 340B Profit Pool

Cigna/Evernorth	2019	2020*	2021*
340B Gross Sales (Dollarized @ WAC)	$1,876	$3,077	$4,431
340B Gross Profit (Discount Retained)	$323	$530	$763
Discount Retained as % of Gross	*17.2%*	*17.2%*	*17.2%*
Impact if Profit Remains w/Pharmacy			
Share of Evernorth Brand Gross Profit	*11.7%*	*20.6%*	*30.1%*
Share of Total Company EPS	*4.9%*	*7.8%*	*10.1%*

Source: Nephron Research, assumes growth absent impact from mfr. Actions
Note: Evernorth Brand GP estimate does not include PBM profit pools (i.e.: includes spec and mail brand profit but not rebate & admin fee profit)

Fig. 47: UNH/OptumRx 340B Profit Pool

UNH/OptumRx	2019	2020*	2021*
340B Gross Sales (Dollarized @ WAC)	$770	$1,454	$2,292
340B Gross Profit (Discount Retained)	$99	$187	$295
Discount Retained as % of Gross	*12.9%*	*12.9%*	*12.9%*
Impact if Profit Remains w/Pharmacy			
Share of OptumRx Brand Gross Profit	*10.5%*	*14.2%*	*20.1%*
Share of Total Company EPS	*0.6%*	*0.9%*	*1.4%*

Source: Nephron Research, assumes growth absent impact from mfr. Actions
Note: OptumRx Brand GP estimate does not include PBM profit pools (i.e.: includes spec and mail brand profit but not rebate & admin fee profit)

Discounts Retained vs. Discounts Recognized as Gross Profit

Tracing the path of manufacturer discounts to pharmacy, PBM and payor/employer

Returning to the question of 340B discounts retained vs 340B discounts ultimately recognized as profit or earnings, we do not believe that WBA is capturing $1,037mn of 340B discounts as gross profit or that CVS is retaining $797mn. Rather we expect that the growth in 340B gross profit at WBA and CVS has helped to counter (or enable) the pursuit of volume via aggressive narrow network contracts with the largest payors/PBMs at ever lower reimbursement rates. **While the level of 340B gross profit investment in lower rates is impossible to determine from the outside, it is fair to note that the annual reimbursement pressure on WBA's estimated 2020 U.S. pharmacy gross profit of $19.1bn (inclusive of specialty) and CVS's estimated 2020 retail pharmacy gross profit of $18.8bn (excluding specialty) is measured in the hundreds of millions.** We estimate annual reimbursement pressures at $450mn-$900mn in recent years (WBA was likely higher last year due to multiple commercial renewals). While volume growth continues to provide a natural offset of $250mn-$450mn, historically significant generic conversion benefits have declined over the last two years, yet reimbursement pressure appears to have remained consistent, a not insignificant portion of which we view to be self-inflicted, or perhaps mutually inflicted, via narrow network discount competition.

- **It follows that growth in the 340B program via contract pharmacy, has led to 340B 'cost sharing' with payors and PBMs.** This is true both with respect to the 340B discounts retained by the contract pharmacy that are shared with payors via lower network rates and the impact of 'duplicate discounts' where the commercial or Part D payor obtains a manufacturer rebate for a script that also received a manufacturer 340B discount. **It also follows, that unwinding of 340B contract pharmacy as a profit center could hold significant implications for not just contract pharmacy operators but also for payors, employers and PBMs.**

Industry Impact: Retail, Specialty, PBM, Payor/Employer & Distributor

Industry implications for Contract Pharmacies, PBMs, Payors and Distributors are far reaching

We consider the potential impact to each industry segment in this section before sizing the potential 2021 financial impact to the largest contract pharmacy operators in the following section.

Retail Pharmacy Impact:

Although contract pharmacy operators have been quick to note that they are not retaining hundreds of millions of profit from the 340B program, **the fact that funds have been contracted away to payors and PBMs to drive volume or offset reimbursement pressure, does not mean the pharmacy is off the hook if the program is disrupted by manufacturer or regulatory action.**

- **Should manufacturer policies constraining contract pharmacy access to 340B discount prices prove durable in early 2021, pharmacies could be caught in the middle as they lose a significant source of funding and have limited leverage to ratchet narrow network rates higher** (with Part D contracts negotiated annually and commercial contracts typically negotiated on a three-year cycle). **As such, 340B earnings exposure could run closer to the profit pool levels we identified above than to the much lower levels of profits that we believe are being recognized as earnings after the pool has been drained to fund payor contracts.**

Specialty Pharmacy Impact:

We believe that specialty contract pharmacy operators have also utilized the program to lower specialty network rates in an effort to accrue incremental share (particularly from independents who have more limited access to 340B profit pools) and expand manufacturer data related specialty profit pools and admin fees.

- While network competition among the largest players likely limited retention of 340B profits 2015-2018, **we expect that specialty pharmacies have retained a greater portion of 340B gross profits than have retail pharmacies as growth went hyperbolic in 2019 and 2020** as reflected in expectations for increasing PBM EBITDA/Rx in 2020.
- Looking at the therapeutic and channel mix of the seven manufacturers that have announced action to date, we note that there is greater concentration in the retail channel than in the mail/specialty channel (impact to 20% of 340B spend vs 35% for retail). However, **many of the manufacturer 340B actions announced over the last six-months appear specifically designed to reverse rapid specialty pharmacy 340B growth**, putting this increasingly important driver of EBITDA/Rx at risk.

PBM, Payor and Employer Impact:

Integration of specialty pharmacies and TPAs within PBMs that have now been integrated within payors with large commercial and Part D books leads to several complex 340B cross currents for PBMs and payors as well as for employers.

- Beyond the loss of fulfillment profits stemming from specialty contract pharmacy operations noted above, **PBMs and their customers could lose the benefit of 340B cost sharing via network rates if manufacturer action depletes the pool of 340B discounts that pharmacies have utilized to subsidize ever lower network rates.** (Could this be the crisis that leads the national pharmacies to take a more rational approach to network reimbursement pressure? If it is, it's going to get worse before it gets better.) However, even significant manufacturer action in 2021 is unlikely to show up in reimbursement rates until 2022 or 2023 (2021 Part D bids make clear PBMs did not become less aggressive for fear of manufacturer action on 340B).
- **Perhaps more concerning for payors and employers, if manufacturer actions to identify and restrict duplicate discounts are successful, rebates could be impacted by a significant sum.** Duplicate discounts occur when a manufacturer has provided a 340B discount to the covered entity and then unwittingly pays a second rebate to a state Medicaid (FFS or managed), Part D or commercial payor, a duplicate rebate or discount that should be ineligible. **Contracts between manufacturers and payors typically include language that prevent manufacturers from paying a duplicate discount/rebate in commercial and Part D (such claims are barred by statute in Medicaid)** but historically contract pharmacies and TPAs have not shared claims data required to identify such claims and the manufacturer typically only has 30 days to identify and challenge duplicate claims. *(For more on this topic see Appendix I which outlines manufacturer actions and 340B participant responses)*.
    - **Adoption of solutions that identify or even prevent duplicate rebates from being paid could significantly reduce commercial and Part D rebates.** We have found no reliable source sizing duplicate discounts in commercial and Part D. **Our best estimate based on available data is that duplicates could total $10-$17bn in 2020 or 12%-21% of commercial and Medicare rebates** *(a wide range reflecting that data on such rebates is limited).*

- **It is interesting to think through what the payor response to a reduction in 12%-21% of commercial and Medicare rebate could look like.** We expect payors would respond by pricing for what could be a significant negative impact on pharmaceutical trend with employers forced to absorb a portion of the impact and the potential for premiums and consumer out-of-pocket cost to increase. At present we do not believe even the most sophisticated employers have these 340B dynamics on their radar.
- **To the extent manufacturer actions lead not to identification of duplicates but to a decline in contract pharmacy volumes, we expect the impact on rebates will be minimal.** Actions to constrain contract pharmacies may reduce duplicate rebates/discounts by reducing 340B discount payments. If this is the case, rebates will continue to be collected, resulting in a lesser impact on payors and employers but still significant impact on specialty pharmacy operations.

Distributor Impact:

Among the distributors, only McKesson operates a significant 340B technology and billing entity in Macro Helix, however we do not believe it is a material contributor to Pharmaceutical Segment profitability. **Our primary concern relative to 340B is the extent to which Amerisource, Cardinal and McKesson net working capital could be impacted by a reduction in the chargebacks required to facilitate discounts projected at $53bn in 2020.**

- Assuming discounts average 55%, chargebacks are paid in 15 days and payables are due on day 30, 340B chargebacks could provide $14.6bn of working capital to distributors in 2021, up from $12.5bn in 2020. **Or to put it another, if the 340B program is disrupted, 340B discount chargebacks could quickly move from a source of incremental working capital to a use of working capital** (recognizing contract pharmacies represent only 25% of total chargebacks).

COMPANY IMPACT ANALYSIS

340B At a Tipping Point: Company Impact Analysis

Manufacturer actions to date could impact 35%-40% of 340B contract pharmacy sales.

Manufacturer actions over the last six-months could impact 35%-40% of 340B contract pharmacy sales, we expect more will be forthcoming in early 2021. Merck, Lilly, Sanofi, AstraZeneca, Novartis and Novo account for 29% of U.S. brand pharmaceutical expenditures but likely account for 35%-40% of 340B contract pharmacy sales with greater impact on retail vs specialty given the 340B product mix of **Lilly, Novartis, Novo** and **Merck**. After initially refraining from taking action, Novo announced a new policy on Dec. 1st, three months after Lilly's policy changes became effective and two months after Sanofi, suggesting that their early moves on insulin are proving effective, necessitating a response from Novo. **We take this as a significant milestone and expect a similar trend could necessitate responses in additional therapeutic categories in early 2021 expanding the number of manufacturers implementing new 340B contract pharmacy policies.**

- Retail Impact Analysis: **Based on the seven manufacturer 340B discount policy changes outlined in Appendix I, we put the potential impact on the RETAIL contract pharmacy channel at 15% in Q1 (our 'base' case for company financial impact).** However, we expect that many of the top-20 manufacturers (accounting for 75% of both retail and specialty channels) are prepared to introduce new data collection and discount qualification strategies in early January, particularly if the Jan. 6th Georgia runoff determining control of the senate leads to divided government (and consequently, less likelihood of radical action on drug pricing). **As such, we expect the impact on the RETAIL 340B channel as we exit 1Q 2021 could be 50%** (our **'expansion' case** for company financial impact analysis).
- SPECIALTY IMPACT ANALYSIS: **The manufacturers that have taken the most aggressive action to date have a greater mix of retail than mail/specialty products, but it is clear that the policies have been designed to counter specialty contract pharmacy growth.** We put the potential impact on the SPECIALTY contract pharmacy channel at 10% in Q1 for our 'base' case financial impact. The three manufacturers that we expect would have the greatest impact on specialty contract pharmacy are Gilead, Pfizer and JNJ. We expect the impact on the SPECIALTY 340B channel as we exit 1Q2021 could easily be 40% (our 'expansion' case) and higher if we see action by all three of the manufacturers noted above.

Fig. 48: Contract Pharmacy Operators: 340B Policy Change 2021 Impact Analysis

	WBA (Retail+Spec)	CVS (Retail + Spec)	Cigna (Evernorth)	UNH (OptumRx)
340B Gross Profit (Discount Retained)	**$1,215**	**$1,170**	**$763**	**$295**
Share of Retail & Spec Brand Gross Profit	***25%***	***21%***	***30%***	***20%***
Share of Total Company EPS	***24%***	***9%***	***10%***	***1%***
Brand GP Impact at ***Base*** Case	$166	$140	$76	$30
Share of Retail & Spec Brand Gross Profit	*3%*	*3%*	*3%*	*2%*
Brand GP Impact at ***Expand*** Case	$576	$513	$305	$118
Share of Retail & Spec Brand Gross Profit	*12%*	*9%*	*12%*	*8%*
EPS Impact at ***Base*** Case	$0.16	$0.08	$0.16	$0.02
Share of EPS	*3%*	*1%*	*1%*	*0%*
EPS Impact at ***Expand*** Case	$0.55	$0.29	$0.66	$0.10
Share of EPS	*11%*	*4%*	*4%*	*1%*

Source: Nephron Research Projections

Walgreens Alliance Boots Impact Analysis

Walgreens has by far the greatest exposure to changes to the 340B program, in part owing to the company's long history providing contract pharmacy, TPA and technology services and in part owing to the limited diversity of the overall operation relative to integrated PBM-Payor peers. It also doesn't help that COVID will depress U.S. and U.K. earnings contribution in 2020 and 2021.

Our 340B model projects that absent manufacturer action 340B discount retention will account for 22% of retail and specialty brand gross profit in 2020, or $1,037mn, if zero is passed on to payors via network discounts. This number expands to 25.1%, or $1,215mn in 2021.

- **Impact of Current Activity:** Our base case impact analysis incorporating a 15% reduction in the $897mn of discounts attributable to retail contract pharmacy in 2021 in our model and 10% reduction to the $318mn of discounts attributable to specialty pharmacy **results in a 3%, or ($166mn), reduction in brand gross profit and 3.3%, or $0.16, reduction in WBA EPS.**
- **Impact of Expanded Activity:** If we see expansion of manufacturer activity in early 2021 to the point where 50% of retail and 40% of specialty contract pharmacy volume is impacted - an outcome that should be considered given recent activity - **our estimate of annual impact increases to 11% of brand gross profit and total company EPS.**
- **In tandem with publication of this report we are downgrading shares of WBA from Hold to Sell. For more detail see our company reports published today.**

Fig. 49: Sizing the impact of manufacturer actions on Walgreens

Walgreens	2021	% of Total
340B Gross Profit (Discount Retained)	$1,215	25%
Brand GP Impact at *Base* Case	**$166**	**3%**
Brand GP Impact at *Expand* Case	**$576**	**12%**
WBA EPS Impact at *Base* Case	**$0.16**	**3%**
WBA EPS Impact at *Expand* Case	**$0.55**	**11%**

Source: Nephron Research, $ in Millions

CVS Health Impact Analysis

If Walgreens has the *deepest* exposure to 340B via retail, then CVS has the *broadest* exposure with significant profit centers across both the PBM CVS Specialty Pharmacy and CVS Retail pharmacy operations. Moreover, CVS has continued to rapidly expand the number of specialty contract pharmacy relationships with covered entities and retail contract pharmacy locations in 2019 and through the first ten months of October.

Our 340B model projects that absent manufacturer action 340B discount retention will account for 26% of retail and mail/specialty brand gross profit in 2020, or $797mn, if not passed on to payors via network discounts. This number expands to 21.0%, or $1,170mn in 2021.

- **Impact of Current Activity:** Our base case impact analysis incorporating a 15% reduction in the $452mn of discounts attributable to retail contract pharmacy in 2021 in our model and 10% reduction to the $718mn of discounts attributable to specialty pharmacy **results in a 3%, or ($140mn), reduction in brand gross profit and 1%, or $0.08, reduction in CVS EPS.**

- **Impact of Expanded Activity:** If we see broad expansion of manufacturer activity in early 2021, **our estimate of annual impact to CVS increases to 9% of brand gross profit and 4% of total company EPS.**
- **In tandem with publication of this report we are downgrading shares of CVS from Buy to Hold. For more detail see our company reports published today.**

Fig. 50: Sizing the impact of manufacturer actions on CVS Retail and Spec Pharmacy

CVS Health	2021	% of Total
340B Gross Profit (Discount Retained)	$1,170	21%
Brand GP Impact at *Base* Case	**$140**	**3%**
Brand GP Impact at *Expand* Case	**$513**	**9%**
CVS EPS Impact at *Base* Case	**$0.08**	**1%**
CVS EPS Impact at *Expand* Case	**$0.29**	**4%**

Source: Nephron Research

Cigna/Evernorth Impact Analysis

After rapid 340B specialty pharmacy relationship expansion and TPA optimization by Cigna/Evernorth 2018 to Oct 2020, we see a material potential impact to the Evernorth PBM organization from our *base* case but to materially impact CI total company the *expand* case would have to come to fruition. Our base case assumes a 10% reduction in 340B specialty contract pharmacy volume, resulting from policies specifically targeting the specialty channel put forth by Lilly and Novo among others which results in a ($76mn) reduction in 340B discounts retained and potentially a similar impact to Evernorth gross profit. This would equate to a 1% headwind to CI EPS.

Again, we note that while announcements to date suggest such an impact is possible in 1Q2021, expansion in early January cold quickly lead us toward the *expand* case with particular focus on Gilead, Pfizer and JNJ. The expand case equates to a more material annual impact of ($229mn) or 9% of brand profit at Evernorth and a 3% headwind to EPS.

Fig. 51: Sizing the impact of manufacturer actions on Cigna/Evernorth

Cigna/Evernorth	2021	% of Total
340B Gross Profit (Discount Retained)	$763	30%
Brand GP Impact at *Base* Case	**$76**	**3%**
Brand GP Impact at *Expand* Case	**$305**	**12%**
CI EPS Impact at *Base* Case	**$0.16**	**1.0%**
CI EPS Impact at *Expand* Case	**$0.66**	**4%**

Source: Nephron Research, $ in millions

United/OptumRx Impact Analysis

As OptumRx's specialty expansion and 340B optimization efforts appear to have only accelerated in 2019 and 2020 we see a less significant impact to the OptumRx segment and the diversification of UHG results in a very modest earnings impact to the total company. What is more interesting is the extent to which expanded 340B profitability is helping to support OptumRx's guidance for EBIT per Rx expansion from $2.94 in 2020 to $3.01 to $3.05 in 2021 on revenue growth guidance that was substantially lower than our 6%-7% revenue growth outlook at 2%-3%.

Fig. 52: Sizing the impact of manufacturer actions on UNH/OptumRx

UNH/OptumRx	2021	% of Total
340B Gross Profit (Discount Retained)	$295	20%
Brand GP Impact at *Base* Case	**$30**	**2%**
Brand GP Impact at *Expand* Case	**$118**	**8%**
UNH EPS Impact at *Base* Case	**$0.02**	**0.1%**
UNH EPS Impact at *Expand* Case	**$0.10**	**0.5%**

Source: Nephron Research, $ in Millions

APPENDIX I

Appendix I: Detailed Examination of 340B Manufacturer Policy Changes

On Oct. 9th, 2019, the Trump administration issued Executive Order 13891 *Promoting the Rule of Law Through Improved Agency Guidance Documents* calling for open and fair regulatory processes. This order required that agencies treat guidance documents as non-binding in law and in practice, or to put it another way the EO prohibited federal agencies from issuing binding rules through guidance documents (the memorandums, bulletins and letters that help industry comply with complex regulations but which are not legally binding). **Given that much of the 340B program is defined by sub-regulatory guidance, not statute, this EO called into question the ability for HHS and HRSA to enforce elements of the 340B program, setting the stage for manufacturer challenges.** While it is possible that the Biden administration may reverse this executive order, it is our view that HRSA's authority has been weakened and will remain so absent specific 340B legislative or regulatory action.

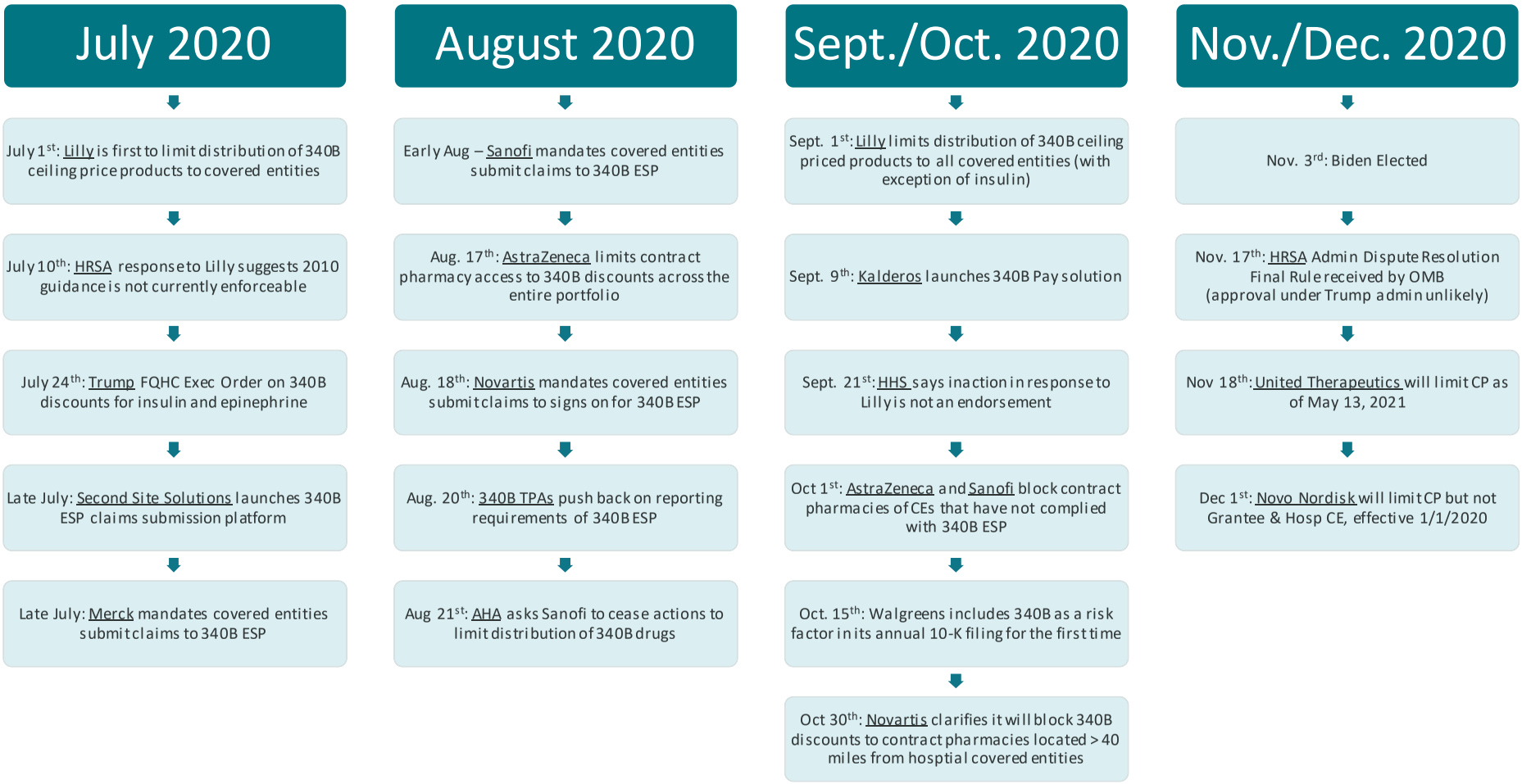
To date, seven manufacturers have taken significant actions impact 340B contract pharmacies. We summarize the six most significant announcements in Fig. 1 and then provide a detailed timeline of developments exploring the nuances of each approach.

Fig. 53: Manufacturer 340B actions began to impact contract pharmacies on Sept 1st 2020, are likely to expand Jan 2021

Manufacturer	Covered Entity (CE) Policy and Scope	Contract Pharmacy (CP) Policy	Implicit Goal	Effective Date
Lilly	• **Limit access to 340B discounts** – initially focused on Cialis, later expanded to Lilly's entire portfolio	• **No longer provide 340B discounts** to CP • Exception for Insulin if no mark up of dispensing fee	• Limit 340B transactions/CP activity • Limit duplicate claims	• Sept 1st, 2020
AstraZeneca	• **Limit access to 340B discounts** - entire portfolio	• **No longer provide 340B discounts** to contract pharmacy	• Limit 340B transactions/CP activity • Limit duplicate claims	• Oct 1st, 2020
Merck	• Require covered entity to 'voluntarily' supply 340B claims data to **340B ESP**	• No access to discounts **unless** claims data is submitted	• Identify and reduce duplicate claims	• Aug. 14th, 2020
Sanofi	• Require covered entity to 'voluntarily' supply 340B claims data to **340B ESP**	• No access to discounts **unless** claims data is submitted	• Identify and reduce duplicate claims	• Oct 1st, 2020
Novartis	• Require covered entity to 'voluntarily' supply 340B claims data to **340B ESP**	• **No longer provide 340B discounts** to CE when CP is more than **40 miles away**	• Maintain access for clinics and hospitals within community • Limit 340B CP transactions with a focus on specialty and national chains	• Set for Oct 1st, delayed until new guidance provided Oct 30th, 2020
Novo Nordisk	• **Limit access to 340B discounts** – Novo decision could indicate Lilly and Sanofi's actions are having the desired effect	• **No longer provide 340B discounts** to CP for CE hospitals but allow CP for 340B 'grantees'	• Limit 340B transactions/CP activity • Maintain access for 340B 'grantees'	• Jan. 1st, 2020

Source: Nephron Research, Company Documents

Fig. 54: Summary of Second Half 2020 340B Activity



Source: Nephron Research

JULY 2020:

July 1st: Lilly dips a toe in the water in early July before announcing more significant action September 1st. Effective July 1st, the company limited distribution of 340B ceiling price products to covered entities and their child sites only. The company is explicitly excluding covered entities' contract pharmacies including contract pharmacies owned or affiliated with covered entities. Covered entities that lack an in-house pharmacy were told to contact Lilly to get an exception that would allow them to designate a single contract pharmacy location.

- Lilly made clear that the action was taken in response to concerns regarding contract pharmacy compliance and with the goal of **limiting the number of 340B transactions** to those required by statute. It noted that there was no statutory obligation to provide 340B priced product to contract pharmacies. **This represented a direct challenge to the Health Resources & Services Administration's (HRSA) 2010 guidance that could hold significant implications for the 340B operations of pharmacy chains Walgreens and CVS Health, and to a lesser material extent Rite Aid, Walmart and Kroger. Potential disruption of contract pharmacy distribution would also negatively impact the specialty pharmacy operations of CVS and CI/ESI (Accredo) and to a lesser extent Optum (Optum Specialty/Diplomat) and the allianceRx joint venture between Walgreens and Prime Therapeutics.**

- A May 18th letter from Lilly to HHS that was disclosed in October made clear that the company had informed HRSA of its intention to discontinue contract pharmacy 340B discounts on May 18th and requested a response prior to the end of June**. Within the letter, Lilly stated that it does not believe 330B purchases for contract pharmacies are required and provided specific examples of conflicts within the 340B HRSA guidance with a focus on 1) HRSA authority, 2) diversion/transfer beyond 340B patients, and 3) duplicate discounts.**

- We were somewhat surprised to see Lilly take the first step given that there are several manufacturers with greater 340B exposure. However, Cialis provided an interesting test case as the formulations of Cialis chosen by Lilly were available from generic competitors making it difficult to argue that the restriction would cause irreparable harm (and we are talking erectile disfunction here). **Lilly certainly picked a thorny setting for HSRA to defend its sub-regulatory guidance on contract pharmacies.**

July 9th: 340B Report publishes a response from the **Health Resources & Services Administration (HRSA)** that oversees the 340B program noting that manufacturers who chose to not serve orders from contract pharmacies could limit 340B access. **The real headline was that while the 2010 guidance remained in effect HRSA had concluded ten years later that it was not legally enforceable under the program's current authority**.

- HRSA's response suggested that HHS and HSRA cannot compel Lilly to provide 340B discounted drugs to all contracted pharmacies as long as there is not a clear violation of the statute. **This statement by HSRA effectively opened the door for manufacturers to further test the requirements of the 340B program.**

- HRSA's position was not strengthened when the House Appropriations Committee turned down a request by HHS to provide it broad regulatory authority over the 340B program when passing an appropriations bill covering HRSA on July 13th.

July 24th: President Trump introduces four executive orders including one that would require Federally Qualified Health Centers (FQHCs) to provide 340B discounts for insulin and epinephrine to patients without insurance at cost + a 'nominal' admin fee, shifting any 340B profit pools that exist at the FQHC level to patients (we note that FQHC's are governed by strict requirements on patient service). While we noted at the time that this was a roundabout approach to lowering prices for

insulin and epi-pens and that FCHQ are highly regulated and mandated to provide affordable care, it is interesting to consider how such an order could expand alongside other potential disruptions to the 340B program.

- **We were surprised to see a 340B related reform targeting FQHCs.** The key question is to what extent this could act as a gateway to action impacting other 340B participants (i.e. from clinic to hospital) and other therapeutic classes. While the EO makes clear the Trump administrations' interest in reforming 340B and driving point of care rebates we expect continued challenges.

- **Awaiting a draft final rule.** Comments on the EO were due on Oct. 28th at which point 222 comment letters had been received. Of those available to readers, the majority were criticisms from health centers. It is unclear if HHS will finalize a draft rule and submit it to OMB this late in the game.

July: 340B ESP (part of the Berkeley Research Group family) **launches a new technology solution to address duplicate 340B claims under the 'Second Sight Solutions' name.** The focus of Second Sight Solutions is to help manufacturers identify duplicate 340B claims, i.e.: instances when the manufacturer has provided a 340B discount to the covered entity and then pays a secondary rebate to a state Medicaid (FFS or managed), Part D or commercial payors, a duplicate rebate or discount that should be ineligible. **Contracts between manufacturers and payors typically include language protecting manufacturers from paying a duplicate discount/rebate in commercial and Part D (such claims are barred by statute in Medicaid) but the manufacturer typically only has 30 days to identify and challenge duplicate claims.**

- **In 2018 and 2019, 30% of audits by HRSA found duplicate Medicaid rebates.** The value of duplicate rebates in Part D and commercial is not known. **Our best estimate for duplicate discounts is a rather wide range of $10-$17bn in 2020, equating to 12%-21% of commercial and Medicare rebates.**

- **Second Site/340B ESP provide a platform for covered entities to upload de-identified 340B claims data** (Rx Number, prescribed date, fill date, NDC, quantity, pharmacy ID, prescriber ID, wholesaler invoice number and 340B covered entity ID) from contract pharmacies. This data is then linked with Medicaid and commercial claims data captured by manufacturers to identify duplicate discounts.

- **The data can be provided to 340B ESP/Second Site by the covered entity or by the contract pharmacy (if authorized by the covered entity).** The company's website notes that it is working with several TPAs to establish data submission protocols though we note that several TPA's have made clear to covered entities that they oppose submission of claims and have raised questions about the protection of HIPAA and protected health information (PHI).

- **The Second Site solution embraced by Merck, Sanofi and Novartis differs significantly from the strategies being implemented by Lilly, AstraZeneca and Novo Nordisk.** Whereas the latter directly target the contract pharmacy model, the Second Site solution directly targets duplicate discounts first and foremost, though it is fair to observe that identification of duplicate discounts could lead to a reduction in rebates flowing to payors and result in contraction of the contract pharmacy channel (we are less concerned about the impact to payors and PBMs than to retail and mail/spec pharmacy operations that appear to earn elevated margins on 340B transactions).

- **To date, covered entities have pushed back aggressively against submission requirements but have refrained from direct legal action against manufacturers, suggesting an opening for**

more direct action to limit contract pharmacies. We expect the twenty largest manufacturers (accounting for 75% of 340B discounts) are watching the response to Merck, Sanofi, AstraZeneca and Lilly closely. We are interested to see if the 340B ESP model picks up support or if more manufacturers attempt to follow the more blunt examples of Lilly and AstraZeneca. **Ultimately, we expect that 340B ESP faces an uphill battle in getting covered entities and contract pharmacies to submit the data it is seeking. However, the fact that covered entities and contract pharmacies are not complying with what could be viewed as a 'middle ground' solution, may clear the way for manufacturers to take more direct action to limit contract pharmacy access to 340B discounts.**

- **Expansion of manufacturer duplicate discount audit programs could create a potential headwind for PBMs/Payors.** Whereas companies such as IQVIA, Kalderos and 340B ESP, have historically focused on reducing Medicaid duplicate payments, new offerings could have the effect of reducing duplicate rebates in Medicare Part D and commercial, where the reversal will also impact the payors pocket. **While all solutions are limited in scope, we heard positive feedback on IQVIA's offering for the commercial and Part D marketplace and are interested to see what develops of Kalderos.**

Late July: Merck begins asking covered entities to voluntarily supply 340B claims data to ***340B ESP*** which will use this data to reduce 340B duplicate rebates across not just FFS Medicaid but also Medicare Part D and commercial.

- The requirement went into effect August 14th though we note there has been push back by CVS and Optum over privacy and contractual concerns.
- Last we checked only a handful of Merck products were included in 340B ESP's NDC list

July 31st: The **U.S. Court of Appeals for the District of Columbia** overturns a ruling that CMS had exceeded its authority by reducing Part B drug reimbursement for 340B hospitals in 2018 and 2019 upholding a 28.5% cut to the hospital **Outpatient Prospective Payment System (OPPS)**.

- A few days after the decision CMS released the **2021 OPPS** rule which included a 6.2% incremental cut to average sale price for Medicare Part B payments for 340B drugs to ASP-28.7%.
- The American Hospital Association (AHA) sized the impact of the 2018 and 2019 cuts at $1.6bn and the 2021 cut is projected to reduce hospital reimbursement by an incremental $427mn.

AUGUST 2020:

Early August: Sanofi follows Merck's footsteps releasing a letter announcing that covered entities will be required to submit claims data via 340B ESP beginning Oct 1st. The letter notes that entities that do not provide claims data will no longer be eligible to receive Sanofi products via contract pharmacies.

AstraZeneca states intention to block contract pharmacy access to 340B discounts, effective Oct. 1st

August 17th: AstraZeneca raises the bar on Lilly's July endeavors by limiting contract pharmacy access to 340B discounts across its entire portfolio. **The company issued a letter to covered entities and wholesalers stating that effective Oct 1st 340B pricing would only be available through a single contract pharmacy unless covered entities operate their own on-site pharmacy.**

- The letter to wholesalers made clear that AstraZeneca would stop processing 340B chargebacks for contract pharmacies on Oct 1st. Similar to Lilly, the company noted that covered entities without a pharmacy could apply for a single contract pharmacy to work on their behalf.
- It will be interesting to see if Lilly and AstraZeneca will allow a centralized specialty pharmacy to be designated as the single contract pharmacy. This would appear to be at odds with the purpose of limiting distribution but we wonder to what extent manufacturers will feel the need to

ensure that access is not completely curtailed. **The key risk for contract pharmacies run by the largest retailers and specialty pharmacies run by the largest PBMs is that the number of 340B scripts could be dramatically reduced.**

August 18th: The 340B Report reports that **Novartis will join Merck and Sanofi** in requiring that covered entities submit claims to the 340B ESP portal to help identify duplicate discounts beginning Oct 1st.

August 19th: The National Association of Chain Drugstores (NACDS) publishes a letter to HHS Secretary Azar and HRSA administrator Engles stating concern that the actions of manufacturers would undermine the 340B program. The response makes clear that the combined actions to limit contract pharmacy access and reduce duplicate discounts have garnered the attention of the chain drugstores.

- **While investor focus to date has been on the retail operations of WBA and CVS, it is important to recognize the outsized role that a relatively small number of mail and specialty pharmacies operated by CVS, Cigna/ESI, Walgreens and OptumRx play in supporting the 340B system. A role that could be significantly impacted should manufacturers recent actions continue to spread.**

August 20th: Several TPAs pushed back against the reporting requirements recently introduced by Merck, Sanofi and Novartis. **CVS' Wellpartner** and **UHG/OptumRx's Optum Specialty & Diplomat Specialty** issued letters to covered entities indicating privacy and contractual concerns.

- These letters were clearly intended to dissuade covered entities and contract pharmacies from working with **340B ESP**. The focus on receiving indemnification from 340B ESP and privacy concerns could create a major hurdle.
- TPAs run by **CVS (Wellpartner)** and **Walgreens (Walgreens 340B Complete)** made clear at this time that they have begun to block Lilly NDCs from 340B formulary replenishment systems.

August 21st: The **AHA** publishes a letter to Sanofi asking it to cease actions to limit the distribution of 340B drugs to hospitals and health systems.

Lilly blocks contract pharmacy access to 340B discounts (save Insulin) on Sept 1st

September 1st: Lilly announced that effectively immediately it will limit distribution of all 340B ceiling priced products to covered entities and will no longer provide 340B discounts to contract pharmacies with exception of insulin.

- Furthermore, **discounts for insulin will only be provided if the contract pharmacy commits to not mark up the drug or charge a dispensing fee,** in line with the Executive Order for FQHCs outlined above.
- Two months ago we would have expected that HRSA would take action to show that Lilly was in violation of the 340B statute or even that CMS could rescind Lilly's participation in the Mcaid program.

SEPTEMBER 2020:

September 4th: The **National Association of Community Health Centers (NACHC)** releases a statement making clear the organization will take legal action against both manufacturers that are limiting distribution of 340B discounted drugs and requiting that health centers turn over data. **We expect this this will be the first of many legal actions but are more interested in what action HHS and congress may take.**

September 8th: Kalderos launches the ***340B Pay*** solution. We are interested to see if 340B ESP will become an industry standard or if Kalderos, a player long focused on Medicaid duplicate discounts will find a warm reception for its solution for Medicare Part D and commercial as the Kalderos

methodology side steps some of the key privacy issues in transitioning 340B discounts via a rebate structure similar to that used in AIDS Drug Assistance Programs.

- **The Kalderos model.** Whereas Second Sight's 340B ESP is collecting claims data and reconciling claims after the fact, Kalderos effectively takes on the treasury role of the manufacturer, providing a 'request app' to covered entities via which manufacturers can pay a rebate. There are several distinct advantages and disadvantages to this model.
  - **Benefit:** Kalderos has demonstrated its solution in the Medicaid market where the company has saved manufacturers $100mn to date. If the solution was applied to Medicaid broadly the company estimates savings to date would be $1bn.
  - **Benefit:** Sidestep privacy issues by taking on treasury role and requesting limited data.
  - **Benefit:** Not limiting contract pharmacies (could be debated).
  - **Benefit:** Covered entities appear to like this model as it enables them to communicate with the manufacturer directly without intermediaries.
  - **Negative:** Reinventing the bill to/ship to model – though if ever there was a model in need of reform, this would be it.
- **The IQVIA model.** As they attempt to more aggressively target duplicate discounts in Part D and commercial, we expect that manufacturers will examine both Kalderos and 340B ESP' offerings, as well as offerings from IQVIA and the strategies being employed by Lilly and AstraZeneca.
  - **We have heard positive commentary on the IQVIA duplicate discount offering.** IQVIA leverages multiple data sets (physician, point of servicer, and covered entity claims data) and analytics to identify potential duplicate discounts for manufacturers. IQVIA does this via analysis of unique data sets as opposed to 340B ESP's data repository (requiring authorization and submission by CEs) and Kalderos' model which inserts the company into the manufacturers treasury function.

September 21st: HHS says inaction relative to Lilly should not be construed as an endorsement. HHS general counsel sends a letter to LLY responding to the manufacturer's Sept 8th inquiry into possible sanctions related to the company's new 340B policies (announced Sept. 1st) that limit distribution to covered entities to only one contract pharmacy if the covered entity does not have an on-site pharmacy.

- While the HHS does not specifically address Lilly's sanctions inquiry, the HHS has told Lilly that **inaction on this issue should not be construed as an endorsement,** leaving Lilly open to the possibility of future penalties.

September 24th: 340B Report reports that Novartis is backing off the Oct 1st deadline for compliance with 340B claims reporting requirements established in August. We note that this was around the time of the HHS letter to Lilly and that the House Oversight and Reform Committee planned hearings that would include Thomas Kendris, U.S. Country President and Global Head of Litigation for Oct 1st (the focus was Gleevec, not 340B).

- It is possible that the company was reacting to the HHS letter or that it simply did not want to draw attention to this topic during the hearings.
- We expect Novartis will join Sanofi in implementing reporting requirements and limiting contract pharmacy access to 340B discounts in the near future.

OCTOBER 2020

AstraZeneca and Sanofi block contract pharmacy access to 340B discounts on Oct 1st

October 1st: AstraZeneca and **Sanofi** inform distributors of their intention to implement policies set out in August that will block contract pharmacies that have not complied with reporting requirements from utilizing NDCs associated with select products.

- While distributors continue to ship products to the pharmacies, discounts are no longer be extended.

October. 9th: House E&C leader **Walden** and **Senate HELP** Committee chair **Alexander** released a statement calling for input on how to improve the 340B program. The senators asked stakeholders to submit suggestions for how to improve on the program by Oct. 30th.

- It is worth noting that both Alexander and Walden are not standing for reelection and will retire in January – and it's a safe bet that legislation on 340B is unlikely to come during the lame duck session. We expect activity to limit manufacturer's actions is more likely to come via legal challenges.

- Nonetheless, the E&O received comments from both hospitals and manufacturers as well as other industry participants. If the E&O or HELP committee eventually take on 340B legislation, the range of outcomes is broad, though again we note that there are strong interests on both sides.

- **Potential election impact:** It is possible a Biden administration could rescind the Trump EA from Oct 2019 that prevents government agencies from taking action against private entities. But it is not clear where a Biden Admin will go on 340B.

- **Potential SCOTUS impact:** The supreme court decision on ACA could significantly impact the 340B program. The most obvious question is can 340B provisions remain if the law's individual mandate is found unconstitutional. Note that if ACA is thrown out, the guidance that opened the door to mass contract pharmacy networks could also disappear.

Oct. 15th: Walgreens includes 340B as a risk factor in a financial filing for the first time. Form 10-K for the fiscal year ending August 2021 published on Oct. 15th notes 340B as a risk factor under the heading of potential healthcare industry and regulatory changes that could adversely affect the business. While the risk factors noted by WBA are broad and inclusive, the decision to name 340B for the first time is notable.

- WBA specifically states that "*Changes in pharmaceutical manufacturers' **pricing or distribution policies and practices as well as applicable government regulations**, including, for example, in connection with the federal **340B drug pricing program**, could also significantly reduce our profitability.*"

October. 16th: The **American Hospital Association** sent a letter to HHS Secretary Azar asking that the agency and HRSA take action to require that Lilly, AstraZeneca and Sanofi make 340B ceiling prices available to contract pharmacies and engage the OIG to assess potential penalties.

- The AHA letter stated that the manufacturers' failure to sell their drugs to covered entities for delivery to patients through contract pharmacies at the 340B ceiling price violates the 340B statute.

October 21st: The **National Association of Community Health Centers** (NACHC) sued HHS Secretary Azar to 'Defend the 340B drug discount program'. The suit seeks to compel HHS to implement a dispute resolution process that would allow health centers to take action against manufacturers who have stopped shipping to health center's contract pharmacies (they continue to ship to health center operated pharmacies).

- While the ACA required HHS to establish a dispute resolution process in 2010 and HRSA published a proposed rule in 2016, the Trump admin withdrew this rule and stated it would not put such a rule forth until Congress provided HRSA with greater regulatory authority. As such, we do not see this going anywhere near-term.
- For those keeping track we now have lawsuits against HHS from Ryan White Clinics (Oct 9th) and NACHC (Oct 21st). The AHA and other groups representing covered entities are likely to follow suit.

Novartis clarified its position on Oct 30th, with a focus on curtailing specialty pharmacy and national chain discounts while maintaining local access

October 30th: After initially backing away from an Oct. 1st implementation deadline for compliance with 340B claims reporting requirements **Novartis** clarified its intention in the form of a 340B fact sheet. The company sought to strike a balance between supporting the program's intent and countering expansion by maintaining access for *clinics* and *community health center* covered entities while constraining *hospital* covered entity contract pharmacy participation to a 40-mile radius. **This move will drastically limit specialty contract pharmacies and could have a significant impact on the largest retail chains.** While the impact may not be as significant as that of Lilly and AstraZeneca or even Sanofi Merck and Sanofi, it would still represent a significant reduction in 340B discounts by a major player.

- **Maintaining access for clinics.** Ryan White clinics, community health centers and other federal grantee covered entities will continue to receive 340B discounts from Novartis. The company noted that the regulatory framework requires such entities to share 340B savings with vulnerable populations. **This is a less onerous position than has been adopted by some of the manufacturers challenging the program.**
- **Moderating access for hospitals.** Hospital contract pharmacy arrangements will be honored within 40-mile radius of the covered entity hospital. The company noted that this is consistent with federal policy regarding hospitals and off-site affiliates. **This is less controversial than the move to limit all hospital contract pharmacies or limit covered entities to a single pharmacy but is unlikely to mollify critics of manufacturer action.**
- **Directly targeting specialty pharmacy participation.** The fact sheet implies that Novartis will no longer provide 340B discounts to contract pharmacies in excess of 40 miles from a hospital covered entity. **This move will drastically limit specialty contract pharmacies and could have a significant impact on the largest retail chains.** We expect the policy was designed with recent growth in PBM-owned specialty pharmacies in mind. Consider that Cigna/ESI operates 34 specialty and mail pharmacies but accounts for 6,283 340B relationships (hospital and clinic), equating to 5% of all 340B relationships. Clearly the vast majority of hospital CE relationships will be beyond 40 miles from a specialty location.
    - By comparison, CVS Specialty operates 47 specialty and mail pharmacies and accounts for 6.4% of relationships, AllianceRx WBA/Prime operate 8 pharmacies and account for 4% of relationships and UNH/Optum operate 44 specialty and mail pharmacies and account for 2.7% of relationships.

November 18th: United Therapeutics, released a new 340B contract pharmacy policy effective Nov 20th, that will continue to accept 340B contract pharmacy orders if that pharmacy has purchased a United Therapeutics drug during the first 9-mos of the year, but will not accept contract pharmacy orders after May 13th, 2021 unless the covered entity agrees to provide claims data via a third-party platform.

- United Therapeutics did not indicate if the claims platform would be 340B ESP. More details will be provided in advance of May 13th.
- We were somewhat surprised to see the company take a lead role in 340B given that its product base does not screen as particularly 340B centric though it is possible that recent specialty pharmacy products are driving the decision.
- The fact that United Therapeutics, a smaller player without massive 340B exposure is taking action could indicate that we are likely to see a number of second wave fast followers announce and implement 340B policies as we enter 2021.

November 18th: Recent manufacturer 340B activity appears to have prompted **HRSA** to revisit the Administrative Dispute Resolution (ADR) process for the 340B program that was submitted as a proposed rule during the last months of the Obama administration in 016 and was withdrawn by the Trump administration in 2017. The OMB website indicates that a Final Rule was received on Nov 17th.

- We are doubtful that the administration will advance this rule given that regulatory authority under current guidance is murky at best and the Trump administration has facilitated a wholesale move away from regulation that is not locked in statute. **As the administration is full of surprises, a final rule is possible but we expect it would face challenges on several levels ranging from process to authority.**

Novo's decision to take action against contract pharmacies could indicate Lilly and Sanofi's efforts are proving successful

December 1st: Novo Nordisk released a notice that that **specifically targeted contract pharmacies,** declaring that **beginning January 1, 2021 the manufacturer will no longer facilitate 'bill-to/ship-to' distribution of 340B products at discounted prices.**

- Novo will limit discounts for contract pharmacies but will **continue to extend 340B discounts to all 'grantee' covered entities** such as Community Health Centers, and Ryan White HIV Clinics.
- Novo will **continue to provide 340B discount prices to covered entity on-site outpatient pharmacies**. Covered entities without in-house pharmacies will be allowed to designate a single contract pharmacy location.
- **It is interesting to consider to what extent Novo's decision was necessitated by moves of the other two large insulin manufacturers, Eli Lilly and Sanofi.** We take Novo's move as a sign that **actions to limit contract pharmacy discounts from Lilly on September 1st and Sanofi on October 1st are potentially resulting in 340B share shifts toward Novo products** though it is also possible that a portion of 340B insulin sales at retail are simply shifting out of the 340B program (an outcome that is more likely if discounts are not shared with patients) or to the hospital channel where 340B discounts are still available (an outcome that would require direction from the hospital). Regardless, Novo's decision to embrace a strategy specifically targeted at contract pharmacies starting Jan 1, 2020 is significant development.

December to January: Stay Tuned!

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EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA

ELI LILLY AND COMPANY, *Plaintiffs*, v. Alex M. AZAR II, in his official capacity as Secretary of the United States Department of Health; ROBERT P. CHARROW, in his official capacity as General Counsel of the U.S. Department of Health and Human Services; THOMAS J. ENGELS, in his official capacity as Administrator of the Health Resources and Services Administration; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; *and* HEALTH RESOURCES AND SERVICES ADMINISTRATION, *Defendants*.	Civil Action No. 1:21-cv-81-SEB-MJD

ORDER GRANTING AARON VANDERVELDE'S UNOPPOSED MOTION FOR LEAVE TO FILE A BRIEF AS *AMICUS CURIAE* IN SUPPORT OF NEITHER PARTY

Aaron Vandervelde, by counsel, has moved for leave to file a brief as *amicus curiae* in support of neither party in the above-captioned matter. No party opposes Mr. Vandervelde's motion.

Having considered the same, the Court orders that Mr. Vandervelde's motion is granted. His Brief as Amicus Curiae, with attachments, is accepted for filing and shall be deemed filed as of this date.

SO ORDERED THIS _____ day of May, 2021.

_____
Judge, United States District Court,
Southern District of Indiana

DISTRIBUTION:

All counsel of record.