IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S., LLC, *Plaintiffs*, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al,* *Defendants*.	Civil Action No. 3:21-cv-634

PROPOSED BRIEF OF 340B EXPERT AARON VANDERVELDE AS AMICUS CURIAE IN SUPPORT OF NEITHER PARTY

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My name is Aaron Vandervelde and I am a Managing Director at Berkeley Research Group, LLC and a nationally recognized expert on the 340B program. I have testified in federal court and in arbitration on 340B contract pharmacy related matters and have conducted briefings for members of Congress and their staff on the 340B program broadly and contract pharmacy specifically. I have 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, I regularly consult 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. My 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 my work for 340B covered entities, I have helped 340B covered entities access 340B pricing consistent with their compliance obligations under the program.

I currently consult with pharmaceutical manufacturers on the various challenges that arise from 340B contract pharmacy operations. I have developed solutions, including the 340B ESP™ platform, that support some manufacturers' policies related to covered entities' contract pharmacy utilization. The 340B ESP™ platform allows 340B covered entities to submit de-identified claims data for prescriptions dispensed through contract pharmacies that are identified by 340B covered entities as eligible for 340B pricing. 340B claims data submitted to the 340B ESP™ platform are linked with rebate utilization data maintained by pharmaceutical manufacturers to identify all instances of ineligible Medicaid, Medicare Part D and commercial

rebates. The platform provides pharmaceutical manufacturers and 340B covered entities with a simple to use technology that promotes compliance within the 340B program. The 340B ESP™ platform is free to covered entities and users register on the platform using a standard web browser such as Google Chrome or Microsoft Edge. Once registered, a user can de-identify and submit the required 340B claims data (which represents a small subset of the data submitted to payers by the dispensing contract pharmacy) utilizing a Health Insurance Portability and Accountability Act compliant process that is available through the 340B ESP™ platform. Depending on the complexity of a covered entity's contract pharmacy network, this process takes approximately 5 to 15 minutes and covered entities complete this process twice each month.

Sanofi, the plaintiff in this litigation, currently licenses for a fee and utilizes the 340B ESP™ platform to support its policy requiring certain 340B covered entities to submit claims data for 340B purchased drugs dispensed through contract pharmacies. The ruling in this case may impact how my clients, including Sanofi, utilize the various solutions I have developed to address challenges that arise from contract pharmacy utilization in the 340B program. I have no position on the legal issues in this case and am solely providing background on 340B contract pharmacy operations and challenges that arise in their current form. The information provided in this report reflect my personal understanding of the 340B program and do not necessarily reflect the views of my 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. 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.

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

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

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

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 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

[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

[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

[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

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 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

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[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?

[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*

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 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

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[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*

[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)

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 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]

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

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

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

[28] Based on analysis of 2009 HRSA enrollment data

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 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

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

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

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 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 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:

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

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

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.

[33] 72 Fed. Reg 1540 (2007)

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 relationships 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. As the volume of 340B eligible 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

[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

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 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 direct working relationship 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

[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

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.

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 after the prescription has been dispensed to the patient and reimbursed by the payer. 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

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

[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

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 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]

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

[40] Based on analysis of HRSA audit results.

[41] 42 U.S.C. § 256b (Section 340B)

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 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] My 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]

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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

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 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,

[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)

covered entities experienced little to no consequences for their failure to comply with the 340B 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

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CERTIFICATE OF SERVICE

I hereby certify that on May 13, 2021, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system.

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Dated: May 13, 2021