SUPREME COURT OF NEW YORK COUNTY OF NEW YORK		
THE PEOPLE OF THE STATE OF NEW YORK,	X :	
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by and through LETITIA JAMES, Attorney General of the State of New York,	:	Index No.
Plaintiff,	:	Summons
V.	:	Date Index No. Purchased:
CVS HEALTH CORP.,	:	July 28, 2022
	•	
Defendant.	:	
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# TO THE ABOVE NAMED DEFENDANTS

You are hereby summoned to answer the complaint in this action and to serve a copy of your answer, or, if the complaint is not served with this summons, to serve a notice of appearance, on the Plaintiffs attorney within 20 days after the service of this summons, exclusive of the day of service (or within 30 days after the service is complete if this summons is not personally delivered to you within the State of New York); and in case of your failure to appear or answer, judgment will be taken against you by default for the relief demanded in the complaint.

The basis of venue pursuant to CPLR § 503(a) is that Plaintiff is located and resides in New York County, with its address at 28 Liberty Street, New York, New York 10005.

Dated: New York, New York July 28, 2022

> LETITIA JAMES Attorney General of the State of New York Attorney for Plaintiff

By: (

Jeremy Kasha Assistant Attorney General, Antitrust Bureau 28 Liberty Street New York, New York 10005 Tel. (212) 416-8277

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THE PEOPLE OF THE STATE OF NEW YORK,	
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Plaintiff,	COMPLAINT
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	<u>A</u>

The People of the State of New York (the "People"), by their attorney, LETITIA JAMES, Attorney General of the State of New York (the "NYAG"), bring this action for injunctive relief, equitable monetary relief, and civil penalties, under N.Y. Gen. Bus. L. § 340 et seq. and N.Y. Exec. Law § 63(12), against CVS Health Corporation ("Defendant" or "CVS"). This action is brought to enjoin and remediate CVS's ongoing anticompetitive scheme by which it forces New York safety net hospitals and other health care providers ("Covered Entities") in the federal 340B Drug Pricing Program ("340B Program") to also purchase administrative services from its recently-acquired subsidiary, Wellpartner LLC ("Wellpartner"), as a condition for allowing Covered Entities to contract with CVS retail and specialty pharmacies to process 340B-eligible prescriptions filled by patients at CVS pharmacies. The purpose of this action is to prevent CVS from continuing this unlawful anticompetitive per se illegal tying scheme, and to equitably remediate past harm.

Plaintiff, the People of the State of New York, by LETITIA JAMES, Attorney General of the State of New York, alleges:

#### **INTRODUCTION**

1. CVS owns and operates the largest chain of retail pharmacies in the United States, including numerous pharmacies in New York, through its wholly-owned subsidiary, CVS Pharmacy, Inc. It also owns and operates the largest specialty pharmacy in the United States through another wholly-owned subsidiary, CVS Specialty, Inc. A third wholly-owned CVS subsidiary, Wellpartner, is a 340B third-party administrator ("TPA") that provides technology solutions to hospitals and other healthcare providers participating in the 340B Program. Since its acquisition of Wellpartner, CVS has told hospitals and other providers participating in the 340B Program ("Covered Entities") that if they want to realize 340B Savings from patient prescriptions filled at CVS pharmacies and CVS specialty pharmacies, they have to use Wellpartner as their TPA. They cannot choose another TPA. This constitutes an illegal tie prohibited by the Donnelly Act.

2. By requiring Covered Entities to use its wholly-owned TPA, CVS effectively forces Covered Entities to either forgo substantial savings from the 340B program (i.e., not collect any savings at all for patients who fill their 340B eligible prescriptions at a CVS pharmacy) or forgo utilization of another TPA that might offer better pricing, quality, or service to the Covered Entity, or with which it already has a business relationship. Some Covered Entities incur or have incurred substantial costs to transition and train personnel for Wellpartner services that were otherwise unwanted, and some Covered Entities bite the bullet and pay for two different 340B TPA providers – i.e., the one that they really want, and then also the one that is forced on them (Wellpartner) by the tying arrangement.

3. This suppression of competition in the TPA market: (1) harms safety-net hospitals by depriving them of the benefits of choice in a fully competitive TPA market, including competition based on price, quality, and service; and (2) serves to artificially enhance the market power of CVS's TPA,

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reducing its incentive to compete and innovate while allowing CVS as a parent corporation to capture larger shares of the 340B Savings than it otherwise would in a more competitive environment. Ultimately, that means more 340B Savings diverted to CVS and less 340B Savings for Covered Entities to use for improving and expanding care at safety net facilities.<sup>1</sup> This anticompetitive tie harms the communities served by these institutions and undermines the goals of the 340B program.

4. Congress created the federal 340B Program to improve the financial condition of safety net healthcare providers.<sup>2</sup> The 340B Program "requires participating drug manufacturers to provide significant rebates [to Covered Entities] ... as a condition of having their outpatient drugs covered by Medicaid."<sup>3</sup> The 340B Program allows Covered Entities to purchase pharmaceuticals from manufacturers at a discount and to dispense the discounted medicines to patients with eligible prescriptions. The Covered Entities then direct the savings realized in these purchases to expanding and enhancing patient care.

5. Safety net health care providers in New York obtain substantial savings from the 340B

Program, which may be critical to the viability of these Covered Entities, and, in turn, critical to the health of the surrounding community.<sup>4</sup> Many of these institutions provide treatment to underserved areas or populations, and include hospitals, community-based health centers, emergency departments,

<sup>&</sup>lt;sup>1</sup> Safety net health care providers have long faced financial challenges because they provide high levels of uncompensated care. Typically, a large share of their patients are governmentally insured by Medicare or Medicaid or are uninsured, while a relatively small share of their patients are commercially insured. Commercial insurance plans generally provide higher reimbursement rates to health care providers than do government insurance plans, offsetting the costs of providing uncompensated care. Because safety net providers are reimbursed at commercial rates for only a small proportion of the care they provide, they frequently cannot offset the costs of uncompensated care that they offer to indigent patients. The 340B Program exists to support the financial condition of safety net healthcare providers. See https://www medpac.gov/wpcontent/uploads/import data/scrape files/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf

<sup>&</sup>lt;sup>2</sup> See https://www.medpac.gov/wp-content/uploads/import\_data/scrape\_files/docs/default-source/reports/may-2015-report-tothe-congress-overview-of-the-340b-drug-pricing-program.pdf

<sup>&</sup>lt;sup>3</sup> https://www.ncsl.org/research/health/340b-drug-pricing-program-and-states.aspx

<sup>&</sup>lt;sup>4</sup> *Id*.

academic medical centers, and free clinics in New York.

6. In order to maximize the benefits of the 340B Program, each Covered Entity will typically contract with a network of pharmacies (each a "Contract Pharmacy") that are frequented by the Covered Entity's patient population. By contracting with a pharmacy, such as CVS, the Covered Entity can receive 340B Program rebates on prescriptions filled at that pharmacy. The Contract Pharmacy typically obtains an additional fee from the Covered Entity for agreeing to the relationship.

7. Covered Entities (not Contract Pharmacies) are responsible for complying with the rules of the 340B Program, and must ensure that scripts are eligible, savings are properly tracked and calculated, and inventories are replenished. To meet these responsibilities, Covered Entities typically retain a TPA. Prior to CVS's acquisition of Wellpartner, CVS retail and specialty pharmacies, like most other Contract Pharmacies, worked with many different TPAs retained by Covered Entities.

8. Under the 340B Program rules, hospitals and other Covered Entities are strictly prohibited from "steering" patients to a particular pharmacy (including to a Contract Pharmacy). And, patients typically have no visibility into whether a pharmacy is a Contract Pharmacy (allowing the Covered Entity to potentially obtain 340B Savings from a given script), nor do patients receive any financial incentive to select a particular pharmacy. As a result, regardless of a Covered Entity's network of Contract Pharmacies, patients continue to fill scripts at their preferred pharmacy-usually the pharmacy most convenient to where they live or work.

9. A Covered Entity typically seeks to enter into a Contract Pharmacy relationship with a particular pharmacy based on the volume of the Covered Entity's patients' prescriptions filled at that pharmacy. Since a Covered Entity cannot alter its patients' choice of pharmacy, each Contract Pharmacy has substantial leverage to extract a percentage of the 340B Program benefits that a Covered Entity can

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obtain. A Contract Pharmacy that provides substantial 340B Savings for a Covered Entity, such as CVS, cannot be replaced - the Covered Entity cannot simply switch its business, i.e., its patients' prescriptions, to another Contract Pharmacy.

340B Contract Pharmacies receive a financial benefit from serving as Contract 10. Pharmacies. This benefit typically is in the form of a prescription dispensing fee. However, because extracting a large percentage of 340B Program benefits—intended to support safety net hospitals through its dispensing fees could attract regulatory attention, a large Contract Pharmacy such as CVS has a strong incentive to avoid doing so.

11. For years prior to the 2017 acquisition of Wellpartner, Covered Entities were free to choose which TPA they wished to use to engage with CVS Contract Pharmacies. There are various TPAs that have historically provided services to Covered Entities in New York, under their respective contracting and pricing arrangements. Covered Entities could choose among competing TPA service providers, based on price, quality, and service.

12. However, following its 2017 acquisition of Wellpartner, CVS launched an unlawful scheme to force Covered Entities that contracted with CVS for retail or specialty contract pharmacy services to also use Wellpartner as a TPA. This scheme illegally tied Wellpartner TPA services, which had previously been one of many TPA products available in the market (the "TPA Services Market") to CVS's Contract Pharmacy services ("CVS Contract Pharmacy Market"). Specifically, CVS announced that use of Wellpartner would be "exclusive," meaning that CVS would not allow a competitor to Wellpartner to provide TPA Services for CVS Contract Pharmacies.

Covered Entities had to use Wellpartner, or their 340B benefit would go up in smoke for 13. patients that go to CVS. Since Covered Entities cannot, by law, steer their patients to a particular

pharmacy<sup>5</sup>, and since patients themselves are not generally involved or even aware of the 340B program, CVS has monopoly power as to contract pharmacy services for 340B prescriptions filled at CVS pharmacies. Under these circumstances, there is no interchangeable product. No other pharmacy offering contract pharmacy services to a Covered Entity can competitively constrain CVS, because Covered Entities cannot direct patients to another pharmacy in the event of a price increase or quality decrease. This is an unavoidable consequence of the market structure and rules of the 340B program – not the Covered Entities' preferences or choices.

Safety net health care providers are the consumers of these services. They are harmed by 14. this scheme because it diverts 340B Savings associated with prescriptions that patients fill at CVS pharmacies – savings intended for Covered Entities like themselves – to the pockets of CVS. Given how prevalent CVS pharmacies are in New York, Covered Entities could lose substantial funds needed for their work as safety net health care providers – unless they also agree to contract Wellpartner for TPA Services, whether they want Wellpartner or not. The diversion of these funds into CVS's coffers comes at the expense of the intended beneficiaries of the 340B Program - the Covered Entities - which could otherwise use such funds to improve or expand their quality of care, or for salaries of nurses and other essential staff.

15. In addition, Defendants' tying arrangement causes even broader harm to competition because the scheme financially pressures Covered Entities to use Wellpartner for all their 340B Program administration needs - not just CVS - lest they have to host, pay for and integrate multiple TPA platforms.

CVS's actions undermine the aim of the 340B Program and hurt the financial condition of 16.

<sup>5</sup> This prohibition on steering is sometimes referred to as the "Anti-Steering Rule."

safety net healthcare providers. With its illegal tie, CVS has harmed the competitive process and has caused substantial harm to the market for the provision of TPA Services in New York, foreclosing the ability of other TPA providers to compete on the merits.

New York patients are the ultimate victims of CVS's scheme. When CVS siphons off 17. 340B Program money from the very hospitals and health care providers for which the Program is intended, it deprives safety net hospitals and health care providers of funds that could be used to improve quality and access to health care for the neediest New Yorkers-including New Yorkers without health insurance or an ability to pay for health care.

# JURISDICTION AND PARTIES

18. Plaintiff, the People of the State of New York, through the Attorney General, brings this action in its sovereign capacity and pursuant to the Donnelly Act, N.Y. Gen. Bus. Law §§ 340-342-c and New York's Executive Law § 63(12). New York sues to obtain injunctive relief, redress of injury to the State, its general economy, and its citizens, and seeks equitable monetary relief, including disgorgement and/or restitution, as well as costs, and civil penalties, for CVS's unlawful conduct.

19. This Court has subject matter jurisdiction over the claims asserted in this action pursuant to Article 6, Section 7 of the New York State Constitution, Section 342 of the New York General Business Law, and Section 63 of the New York Executive Law.

20. Defendant CVS directly transacted business and/or contracted to supply goods and services to purchasers within the State of New York. The causes of action alleged in this Complaint arise from such acts. Accordingly, this Court has personal jurisdiction over CVS under N.Y. CPLR § 302(a)(1).

Venue is proper in New York County pursuant to N.Y. CPLR § 503 because Plaintiff 21.

resides in New York County.

22. Plaintiff Letitia James is the Attorney General of the State of New York and brings this action on behalf of the People of the State of New York to protect the State of New York and its residents from Defendant's exclusionary and exploitative, anticompetitive business practices.

23. Defendant CVS is incorporated under the laws of Rhode Island, with its principal place of business at One CVS Drive, Woonsocket, Rhode Island, 02895.

### FACTUAL BACKGROUND

24. The 340B Program was established by the Veterans Health Care Act of 1992 to help eligible health care providers "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."<sup>6</sup> It is codified in and named for section 340B of the Public Health Service Act, 42 U.S.C. § 256b.<sup>7</sup> The 340B Program is budget-neutral for the federal government but provides substantial benefit to participating hospitals and health care providers, by requiring participating drug manufacturers to sell prescription pharmaceuticals to Covered Entities at a low price.

#### **340B** Covered Entities A.

### **Background**

The 340B Program allows Covered Entities to "obtain lower prices on the drugs that they 25. provide to their patients."8 Under the 340B Program, the U.S. Health Resources and Services Administration ("HRSA") calculates a 340B maximum price ("340B Price") for each covered outpatient drug, which typically is substantially less than the wholesale or retail price of the drug. Covered Entities

<sup>&</sup>lt;sup>6</sup> H.R. Rept. No. 102-384(II), at 12 (1992). <sup>7</sup> H.R. Rep. No. 102-34(II), at 11 (1992) (Conf. Rep.). <sup>8</sup> Id. at 7.

may then purchase covered drugs from the drug's manufacturer at the 340B Price. Most drug manufacturers offer 340B discounts to Covered Entities because the federal government requires them to offer such discounts to have their drugs covered by Medicaid.<sup>9</sup>

26. Drugs purchased at the 340B Price by a Covered Entity can be dispensed to fill eligible 340B prescriptions at the Covered Entity's in-house pharmacy (e.g., an in-clinic or in-hospital pharmacy) or, more frequently, at an outside retail pharmacy (such as a Walgreens, a CVS, or an independent community pharmacy) that has contracted with the Covered Entity to dispense eligible prescriptions (a Contract Pharmacy).

27. Generally, an eligible 340B prescription is dispensed at an in-house or Contract Pharmacy at the contract price that the pharmacy and drug manufacturer have negotiated with third-party payors. In other words, the pharmacy processes the prescription as a prescription paid by the patient's commercial or government (e.g., Medicare) insurance. The Covered Entity then retains the difference between the 340B Price and the insurance reimbursement, minus any fees paid to TPAs or Contract Pharmacies. This surplus is sometimes referred to as the Covered Entity's "340B Savings."

28. The insured patient who presents a 340B-eligible prescription at a pharmacy is unaware of whether the prescription will be filled as a 340B prescription. The patient receives no direct benefit and suffers no direct detriment if the prescription is processed as a 340B prescription.

29. The Covered Entity realizes 340B Savings from its patients' 340B-eligible prescriptions only if those prescriptions are dispensed at an in-house or Contract Pharmacy. If the patient fills a 340Beligible prescription at pharmacy unaffiliated with or not under contract with the Covered Entity, the Covered Entity receives no benefit.

<sup>&</sup>lt;sup>9</sup> See https://www.medpac.gov/wp-content/uploads/import\_data/scrape\_files/docs/default-source/reports/may-2015-report-tothe-congress-overview-of-the-340b-drug-pricing-program.pdf

30. Under the terms of the 340B Program, Covered Entities are not permitted, and have never been permitted, to direct or steer patients to any particular pharmacy.

31. As of July 2021, more than 4,440 Covered Entities serving low-income patients across New York were enrolled in the 340B Program.<sup>10</sup> Covered Entities rely on 340B Savings to fund patient care services to underserved and vulnerable populations. Savings from the 340B Program are essential to the hospitals and other providers that participate in the 340B Program if they are to maintain and expand healthcare access for disadvantaged communities.

#### Covered Entities' Compliance with the 340B Program's Requirements and Other Laws

32. HRSA verifies that a health care provider meets the statutory requirements to become a 340B Program Covered Entity. The 340B Program statutorily defines the types of health care providers eligible to participate, which include Federally Qualified Health Centers ("FQHCs"), critical access hospitals, Ryan White HIV/AIDS Program grantees, rural referral centers, sole community hospitals, black lung clinics, community health centers, family planning clinics, and tuberculosis clinics.<sup>11</sup>

Covered Entities bear sole legal responsibility for compliance with the complex 33. regulatory requirements that bind Covered Entities participating in the 340B Program. 340B Program requirements include meeting preliminary enrollment criteria, annual re-registration in the 340B Program,<sup>12</sup> avoidance of duplicate discounts related to Medicaid programs, and not steering patients to fill 340B eligible prescriptions at particular pharmacies.<sup>13</sup> All Covered Entity records pertaining to 340B Program participation are subject to audit by HRSA.

34. 340B Program Covered Entities must also ensure that the drugs purchased by

<sup>&</sup>lt;sup>10</sup> https://340bopais hrsa.gov/coveredentitysearch. As of July 29, 2021, 4,441 Covered Entities operate in New York.

<sup>&</sup>lt;sup>11</sup> 42 U.S.C. § 256b; 42 U.S.C. § 256b(a)(4); 42 U.S.C. § 256(b)(4).

<sup>&</sup>lt;sup>12</sup> 42 U.S.C. § 256(b)(5)(D).

<sup>&</sup>lt;sup>13</sup> See 42 U.S.C. § 256(b)(5).

Covered Entities at the discounted rate are not diverted to patients filling ineligible prescriptions.<sup>14</sup> HRSA requires that the patient filling an eligible prescription must: (i) have an established relationship with the Covered Entity such that the entity maintains that individual's healthcare records, (ii) receive health care services from a provider who is employed by or affiliated with that Covered Entity, and (iii) receive healthcare services in line with those for which the Covered Entity was granted funding or FQHC status.<sup>15</sup>

35. 340B Covered Entities are also responsible for ensuring that 340B Program prescriptions are strictly segregated from prescriptions filled through Medicaid programs. Covered Entities must ensure that Medicaid drug rebates are not charged to drug manufacturers for drugs dispensed pursuant to the 340B Program.<sup>16</sup> Such "duplicate discounts" can occur if the manufacturer first provides a direct discount on the price of a drug purchased by a Covered Entity through the 340B program and then provides a duplicate discount by paying out a required rebate if that same drug is used to fill a Medicaid patient's prescription.<sup>17</sup> The 340B program requires Covered Entities to establish a mechanism to segregate Medicaid prescriptions from 340B prescriptions, ensuring that a prescription is not processed both as a Medicaid prescription (triggering a Medicaid drug rebate) and a 340B prescription (which is filled using drug stock purchased by the Covered Entity at the discounted 340B price).<sup>18</sup> A Covered Entity may be liable for damages to the drug manufacturer if the Covered Entity erroneously obtains duplicate discounts on a drug.<sup>19</sup>

<sup>&</sup>lt;sup>14</sup> 42 U.S.C. § 256(b)(5)(B); see H.R. Rep. No. 102-384(II), at 16.

<sup>&</sup>lt;sup>15</sup> Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55157 (1996). Disproportionate share hospitals may issue 340B drugs to patients who do not meet the third requirement. <sup>16</sup> 42 U.S.C. § 256(b)(5)(A); see H.R. Rep. No. 102-384(II), at 16.

<sup>&</sup>lt;sup>17</sup> H.R. Rep. No. 102-384(II), at 16.

<sup>&</sup>lt;sup>18</sup> 42 U.S.C. § 256(b)(5)(A)(ii).

<sup>&</sup>lt;sup>19</sup> 42 U.S.C. § 256(b)(5)(D); 75 Fed. Reg. 10272, 10277.

36. The rules governing the 340B program place full responsibility for compliance on the Covered Entity. Failure to comply with 340B Program requirements may also give rise to monetary liability to pharmaceutical manufacturers if there were duplicate discounts, as described above. More drastically, failure to comply with 340B Program requirements can result in the Covered Entity's removal from the 340B Program.<sup>20</sup> Covered Entities therefore make every effort possible to comply with 340B program rules.

Contract Pharmacies who partner with Covered Entities to dispense 340B Program 37. prescriptions bear no legal liability for failure to comply with the regulatory requirements of the 340B Program.

As stated above, the 340B program additionally prohibits Covered Entities from directing 38. or "steering" patients to fill 340B-eligible prescriptions at any particular pharmacy. Indeed, after issuing a prescription, HRSA guidance states that the prescriber "will inform the patient of [their] freedom to choose a pharmacy provider."<sup>21</sup>

39. 340B Covered Entities, including many New York hospital systems, understand the requirements of the 340B Program to prohibit their staff from telling a patient with a 340B eligible prescriptions that the patient should go to a specific pharmacy. One large health system explained that they did not direct patients with 340B eligible prescriptions to particular pharmacies due to the longstanding rule that it is always the patient's consent and the patient's choice, so they never direct patients to specific pharmacies. Another hospital explained that when a patient with a 340B eligible

<sup>&</sup>lt;sup>20</sup> 42 U.S.C. § 1320a-7(b)(1)(A) (Federal Anti-Kickback Statute);

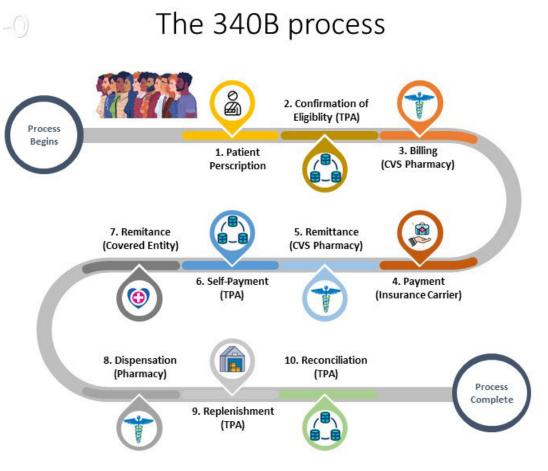
<sup>&</sup>lt;sup>21</sup> Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10272, 10278. The entire statement reads: "The Covered Entity will inform the patient of his or her freedom to choose a pharmacy provider. If the patient does not elect to use the contracted 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."

prescription gives them a pharmacy to call the prescription into, they call the prescription into the requested pharmacy, regardless of whether that pharmacy is one of the hospital's Contract Pharmacies.

40. TPAs, including Wellpartner, read HRSA's patient choice provision the same way. The Wellpartner Contract Pharmacy Services, 340B Contract Pharmacy Policy and Procedure with Internal Audit Recommendations compels its employees to "[r]eview all communications and promotional materials for the 340B program to ensure that all patients have a right to choose their pharmacy and no steerage to Contract Pharmacies is occurring."

41. In addition to the regulatory requirements of the 340B Program, Covered Entities are prohibited from steering patients to specific pharmacies pursuant to the provisions of other state and federal laws. Covered Entities whose physicians or other staff members steer patients to specific pharmacies might violate the regulatory requirements of the 340B Program, state and federal antikickback statutes, and state laws concerning health provider licensing.

42. The diagram on the following page summarizes the 340B process.



- Doctor prescribes medication to 340B-eligible patient and sends prescription to pharmacy of patient's choice. 1.
- If patient selects Contract Pharmacy, Covered Entity's TPA confirms 340B eligibility. 2.
- 3. Contract Pharmacy bills Insurance Carrier for appropriate covered amounts
- Insurance Carrier remits payment of appropriate covered amounts to Contract Pharmacy 4.
- 5. Contract Pharmacy remits Insurance Carrier proceeds to Covered Entity. TPA pays dispensing fee to Pharmacy from those proceeds.
- 6. TPA pays its own fee out of Insurance Carrier proceeds.
- 7. TPA remits balance of Insurance Carrier proceeds to Covered Entity.
- 8. Pharmacy dispenses medication to Patient On behalf of Covered Entity, TPA analyzes drug dispensation patterns and quantities and periodically replenishes stock at contract pharmacies.
- 9. TPA manages replenishment process for Covered Entity by ordering drugs at 340B prices, paying Wholesaler for drugs, and ensuring that replenishment stock is directed to correct pharmacy.
- 10. TPA periodically reconciles all steps of process and performs audit function for Covered Entity compliance.

# **B. 340B Contract Pharmacies**

# Background

43. Covered Entities can dispense drugs purchased at the 340B Price at the Covered Entity's in-house pharmacy if it has one. 340B Covered Entities may also elect to dispense 340B drugs to patients through Contract Pharmacy services, whereby the Covered Entity signs a written contract with a pharmacy to provide pharmacy services to the Covered Entity's 340B patients. These contract arrangements typically provide that the Covered Entity pay the Contract Pharmacy a per-prescription dispensing fee for filling 340B prescriptions.

44. Since 2010, HRSA has allowed Covered Entities to contract with multiple outside pharmacies to fill 340B prescriptions. The number of pharmacies that contract with Covered Entities under the auspices of the 340B Program grew 4,228% from 2010 to 2020.<sup>22</sup> 75% of those Contract Pharmacy relationships are with large for-profit retail chains, such as CVS.<sup>23</sup>

45. Most patients fill their eligible prescriptions at Contract Pharmacies, rather than at the Covered Entity's in-house pharmacy.

46. Because Covered Entities lose the 340B Savings associated with any script not filled at an in-house or contracted pharmacy, most Covered Entities choose to work with outside Contract Pharmacies to maximize the 340B Savings captured by the Covered Entity.

When selecting pharmacies with which to contract, many Covered Entities attempt to 47. contract with the pharmacies that fill the highest volume of the Covered Entity's 340B prescriptions. Most prescriptions issued today are e-prescriptions, where the prescription is electronically transmitted

<sup>&</sup>lt;sup>22</sup> https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B\_2020.pdf <sup>23</sup> https://340breform.org/wp-content/uploads/2021/04/AIR340B\_340B-Contract-Pharmacies.pdf at 3.

from the healthcare provider's office to the pharmacy. E-prescribing technology allows Covered Entities to identify the pharmacies to which their healthcare providers send prescriptions. The Covered Entity thereby knows which pharmacies are likely to fill the highest volume of their 340B prescriptions and seeks to contract with those pharmacies so that the Covered Entity can capture 340B Savings associated with its 340B Program prescriptions.

48. CVS is one of two major national retail pharmacy chains. CVS has a significant presence across New York, and prescriptions filled at CVS pharmacies generate significant 340B Savings for many Covered Entities. Many New York Covered Entities' 340B-eligible patients are existing customers of CVS and choose to have all of their prescriptions - including 340B-eligible prescriptions electronically sent to CVS. For many New York Covered Entities, a potential loss of the CVS 340Beligible patients would be substantial. They must either contract with CVS or lose even more by foregoing those benefits altogether (since, as discussed above, in Paragraphs 13, 30, 33, 38, 40, and 41, they cannot steer patients).

49. With this raw power in the market, CVS has been able to force Covered Entities to use its subsidiary's TPA services if they want to take advantage of the 340B Savings - regardless of price or quality, and regardless of other options that would otherwise be available in a competitive TPA Services Market. Specifically, as discussed, below, CVS's market power enables CVS to force Covered Entities to use Wellpartner TPA services; this tie ultimately siphons off 340B funds meant to benefit hospitals and other Covered Entities, or rural and poor communities in New York.

50. Specialty pharmacies – which fill prescriptions for many high-cost treatments, some of which also require special handling – dispense a large and increasing proportion of prescriptions in the

United States. Specialty prescriptions made up nearly 40% of outpatient prescription revenues in 2021.<sup>24</sup> CVS is the largest specialty pharmacy in the U.S., accounting for 27% of pharmacy prescription revenues from specialty drugs in 2020.<sup>25</sup> Use of specialty pharmacy prescriptions has increased in recent years.

51. The Anti-Steering Rule applies to Covered Entities in the specialty pharmacy context as well, as the Rule prevents Covered Entities from directing patients to use a particular specialty pharmacy. Because they cannot steer their patients to alternative specialty pharmacies, New York Covered Entities that have a significant share of patients who use CVS Specialty as their specialty pharmacy regard CVS Specialty as a necessary Contract Pharmacy in the specialty pharmacy space.

#### **CVS's Enhanced Market Power by Virtue Of Owning A Pharmacy Benefit Manager**

52. CVS's market power in retail and specialty pharmacy is enhanced by its corporate affiliation with CVS Caremark, which is one of only three major Pharmacy Benefit Managers ("PBMs"). As described, this relationship effectively allows CVS Caremark to "steer" patients (including non-340B patients) to CVS pharmacies over other competing pharmacies. Although this kind of "steering" does not violate the 340B Program's Anti-Steering Rule, it gives CVS even more leverage as their pharmacies continue to expand by virtue of their PBM.

53. PBMs are entities that coordinate prescription drug programs on behalf of health insurance plans. This coordination includes negotiating drug prices and rebates from pharmaceutical manufacturers and establishing benefit structures for health insurance plan sponsors (for example, copay and other price and fee structures for policyholders). Three major PBMs in the United States-CVS Caremark, Express Scripts, and OptumRx—together make up 90% of the PBM market. CVS Caremark,

<sup>24</sup> https://drugchannelsinstitute.com/files/2022-PharmacyPBM-DCI-Overview.pdf

<sup>25</sup> https://www.drugchannels.net/2021/05/dcis-top-15-specialty-pharmacies-of.html

owned by CVS Health, has about a  $30\%^{26}$  share of the PBM market.

54. PBMs, in consultation with health insurance plan sponsors, determine whether there are "in network" pharmacies for particular health insurance plans, and whether those "in network" pharmacies will offer enhanced benefits (e.g., lower co-pays, the ability to fill 90-day instead of 30-day prescriptions) for patients relative to the benefits offered at "out-of-network" pharmacies.

55. For patients whose health plans use the CVS Caremark PBM, CVS Caremark (together with the health insurance plan sponsor) can effectively steer patients to CVS retail and specialty pharmacies by offering enhanced benefits if the patient fills their prescription at a CVS pharmacy instead of competitor pharmacies. For example, a patient may pay a lower co-pay on prescriptions filled at CVS pharmacies or may be able to fill a prescription for a 90-day supply of medication (rather than the conventional 30-day supply).

56. CVS Caremark's efforts to steer have proved effective: in 2014, CVS specialty pharmacies dispensed nearly 60% of CVS Caremark-covered prescriptions for specialty drugs, and CVS retail pharmacies dispensed nearly 40% of all CVS Caremark-covered non-specialty prescriptions.

57. In New York, many health plans use CVS Caremark as their PBM, and CVS Caremark sometimes steers patients insured by those plans to fill prescriptions at CVS pharmacies. For example, some health plans offered by Capital Region insurer MVP Health, which uses Caremark as its PBM, designate CVS as the preferred or exclusive pharmacy for patients. Likewise, over 200 Blue Cross/Blue Shield of Western New York plans use CVS Caremark as the plan PBM and make CVS Specialty the exclusive specialty pharmacy for patients. Additionally, Aetna, the health insurance company owned by CVS Health, uses CVS Caremark as its PBM, and designates CVS Specialty pharmacies as preferred

<sup>26</sup> https://www.beckershospitalreview.com/pharmacy/pbms-ranked-by-market-share-cvs-caremark-is-no-1.html

pharmacies for patients insured by Aetna. Finally, many major Medicare Part D plans use CVS Caremark as a PBM and make CVS retail or specialty pharmacies preferred pharmacies.

58. Covered Entities are aware of CVS Health's ability to steer 340B-eligible patients to CVS retail and specialty pharmacies by establishing insurance plan pharmacy benefit design through its CVS Caremark PBM. One health system noted that CVS, as a PBM, dictates where the health system's patients go. Thus, although Covered Entities cannot effectively steer patients to a particular pharmacy due to 340B Program prohibitions, CVS Health is able to use its CVS Caremark PBM to steer patients to use its pharmacies. This creates the perverse result that Covered Entities — the intended beneficiaries of the 340B Program — cannot steer patients to maximize the Covered Entities' 340B Savings, but CVS, through its CVS Caremark PBM, can steer patients to particular pharmacies through benefit design. This reinforces CVS' market power.

# C. 340B Third Party Administrators

59. In order to ensure compliance with the 340B Program requirements and to assist with implementation of the 340B program, Covered Entities contract with TPAs. TPAs provide billing software and compliance tools to administer the Covered Entities' participation in the 340B Program. TPAs are typically for-profit businesses and charge Covered Entities a fee for TPA Services.

60. TPAs also manage Covered Entity relationships with Contract Pharmacies. They determine and confirm the 340B eligibility of prescriptions and maintain records of dispensed drugs. They track and replenish inventory at Contract Pharmacies. They calculate the Covered Entity's 340B Savings and coordinate the transfer of those funds from the Contract Pharmacy to the Covered Entity. They also assist the Covered Entity in selecting pharmacies with which to contract,

and sometimes assist in the negotiation of contracts with a Covered Entity's Contract Pharmacies.

61. Covered Entities have no close substitute for the specialized 340B workflow software and other technologies provided by TPAs. Because these technologies are specially optimized to reconcile data streams from multiple parties to ensure compliance with 340B Program rules and regulations, software and technologies that are not designed for the 340B context cannot, in practice, be adapted to the 340B context. Due to the complexity of 340B Program administration, Covered Entities generally purchase these services rather than attempting to self-provide them through their internal information technology departments.

62. Again, 340B Covered Entities bear all the legal risk of non-compliance with the complex requirements of the 340B Program. Although Covered Entities cannot and do not physically oversee the dispensing of their 340B-purchased drugs at Contract Pharmacy locations, the Covered Entities remain solely legally liable for any penalties (monetary or otherwise) if any 340B Program rule or regulation is broken when a drug is dispensed by a Contract Pharmacy. Because the Covered Entity bears all 340B Program legal compliance risk,<sup>27</sup> Covered Entities typically take great care in selecting a TPA.

63. TPA technology works by capturing and monitoring data concerning 340B-eligible prescriptions from both the Covered Entity and its Contract Pharmacies. Covered Entities have a substantial interest in being able to select a TPA to ensure that the TPA with which they partner employs strong compliance mechanisms and oversight procedures that Covered Entities trust and want to use.

64. The Covered Entities' interest in carefully choosing a TPA is further magnified by the

<sup>27</sup> 42 U.S.C. § 256(b)(5)(D); 75 Fed. Reg. 10272, 10277

fact that, for Covered Entities that work with Contract Pharmacies, the majority of 340B-eligible prescriptions are typically filled at Contract Pharmacies. The bulk of the Covered Entity's legal compliance risk is thus associated with Contract Pharmacy prescription dispensing. TPAs, which assesses data from Contract Pharmacies, are therefore managing the bulk of the Covered Entity's legal compliance risk.

65. When selecting a TPA, Covered Entities take into consideration factors such as quality, price, audit performance, and references from other Covered Entities. This process only works well in a competitive marketplace.

66. For example, prior to CVS' illegal tying scheme, one New York hospital system used a competitive "request for proposals" process to select a TPA. In one instance, after evaluating approximately five different proposals on metrics such as experience, service quality, audit performance, references from similar hospitals, and price, that hospital system chose to work with a TPA other than Wellpartner. Through this process, the hospital system ranked Wellpartner among the middle-to-lower end of bids because of its relatively high cost and because it was not widely used by other very large health systems.

Beyond the baseline costs, Covered Entities also have an interest in carefully choosing 67. their TPA because they prefer for a single TPA to manage the data streams from their different Contract Pharmacies. Although it is technologically possible to work with multiple TPAs to manage this data, it is not efficient to do so – both because of duplicate costs and because using a single TPA streamlines and makes uniform the flow of information that Covered Entities receive from multiple Contract Pharmacies. Covered Entities using multiple TPAs may not know which TPA is performing a

particular function, making it difficult for them to ensure that they are fully complying with 340B program requirements. Partnering with a single TPA across multiple Contract Pharmacies allows Covered Entities to further manage their compliance risks while minimizing their administrative costs.

68. Prior to its 2017 acquisition by CVS, Wellpartner worked with a variety of Contract Pharmacies on behalf of its TPA clients, including with CVS retail and specialty pharmacies.

69. Prior to its 2017 acquisition of Wellpartner, CVS retail and specialty pharmacies were available to contract with Covered Entities that had relationships with a number of TPAs, including MacroHelix, PSG, RxStrategies, Sentry, Verity Health, and Wellpartner. During this time period, CVS did not condition access to its retail and specialty pharmacies on the Covered Entity's use of any particular TPA.

70. In 2014, CVS engaged another TPA - Sentry - to work with CVS Health to develop a "backbone" product for CVS. This product was intended to provide CVS retail and specialty pharmacies with a single point of integration for the 340B Program, streamlining pharmacy chain operations, inventory management, and financial reimbursements across all CVS retail and specialty pharmacy relationships with Covered Entities.

71. As a matter of internal CVS policy, CVS generally refused to contract with more than one Covered Entity per CVS retail location prior to its 2017 acquisition of Wellpartner. This internal policy was implemented to facilitate inventory management at CVS retail locations. No 340B Program rule or regulation requires that Contract Pharmacies only work with a single Covered Entity, and many other Contract Pharmacies work with multiple Covered Entities.

72. The Sentry backbone product was intended to ease inventory management and other

Contract Pharmacy administrative functions to make it easier for CVS retail locations to contract with more than one Covered Entity, and thereby to expand CVS's Contract Pharmacy role in the 340B space. The planned backbone product would have been interoperable with a number of TPAs.

73. In addition to its work on the "backbone" that would ease inventory management concerns and help CVS to contract with multiple Covered Entities at each retail pharmacy, CVS had other expansion objectives related to the 340B Program. In one internal strategy document, CVS recognized that 340B sales were "estimate[d]...at \$16.2 billion" in 2016. On the specialty pharmacy side, CVS intended to "[e]xpand CVS Specialty 340B footprint by contracting 90% of Covered Entities by end of 2018." To capture additional 340B business at its pharmacies, CVS planned to "restructure [its] approach to client enrollment and pricing model" to encourage Covered Entities to use CVS Contract Pharmacies in order to "continue to grow CVS retail relationships." CVS planned to expand its activity related to the 340B Program even absent an acquisition of Wellpartner.

#### **CVS ACQUISITION OF WELLPARTNER LLC & THE ANTICOMPETITIVE TIE**

Prior to its acquisition of Wellpartner, Covered Entities contracting with CVS retail or 74. specialty pharmacies could partner with the TPA of their choice. And, as discussed above, CVS was on its way to implementing a new model that would add profitable business and serve more Covered Entities - without restricting competition. But then, CVS changed direction towards an anticompetitive alternative: Instead of deploying the Sentry backbone that was already in development, and that would have allowed multiple TPAs to interoperate with CVS Contract Pharmacies, CVS instead acquired Wellpartner and implemented a brazenly anticompetitive tying scheme. CVS did this to squeeze 340B Savings out of safety net hospitals and other Covered Entities in New York, beyond what it was already

charging in official fees.

75. Specifically, after acquiring Wellpartner in 2017, CVS Health announced that it would require all Covered Entities using CVS as a Contract Pharmacy to also use Wellpartner as their TPA for related 340B compliance services - or lose access to CVS retail and specialty pharmacies. Thus, CVS forced Covered Entities to use Wellpartner as a condition of using CVS Contract Pharmacies.

76. This illegal tie puts Covered Entities in the position of having to either (i) forgo 340B Savings for patients who choose to go to CVS; (ii) agree to use Wellpartner as their TPA for CVS and then pay additional fees to *another* TPA to work with other Contract Pharmacies, at higher regulatory risk; or (iii) effectively give into to CVS' market power and use Wellpartner as their TPA for all 340B TPA Services, with all Contract Pharmacies, while simultaneously surrendering the long term benefits of quality competition. These are dismal choices that add up to no choice at all.

# WELLPARTNER LLC

Wellpartner LLC ("Wellpartner") has been a wholly-owned subsidiary of CVS Health 77. since 2017, when CVS began its scheme.

78. Prior to its acquisition in 2017 by CVS Health, Wellpartner provided 340B TPA services to some Covered Entity clients and operated a small number of mail-order pharmacies. As of 2015, Wellpartner provided TPA services for approximately 100 Covered Entities.

79. Historically, Wellpartner's business model was to charge the Covered Entity a fee for each 340B prescription dispensed. Wellpartner charged the greater of (1) a small flat fee per prescription or (2) a percentage of the difference, or "spread," between the commercial reimbursement for the drug and the drug's 340B Price.

80. CVS Health acquired Wellpartner in November 2017. The illegal tie was part of the deal from the beginning. Specifically, in internal documents, Wellpartner touted the positive strategic and financial impact that would flow to CVS following the Wellpartner acquisition, noting that the acquisition would allow CVS to "[r]eturn [v]alue to [s]hareholders" by "[g]enerating approximately \$1.9 billion of incremental revenue with very high margins." Wellpartner envisioned that CVS would realize this revenue by requiring Covered Entities to contract with Wellpartner as a TPA in order to access CVS retail and specialty pharmacies.

It was part of the plan to notify Covered Entities, post-acquisition, that their contract 81. arrangement with CVS pharmacies would terminate within 90 days, and that, "should they continue to desire a Contract Pharmacy arrangement [the Covered Entity] will need to have it administered by Wellpartner." This compulsory use of Wellpartner as TPA would allow CVS to "retai[n]" 40% of the 340B Covered Entity's spread because CVS/Wellpartner would both "administer [the Covered Entity relationship] and dispense" the 340B pharmaceuticals to Covered Entity patient. Wellpartner expected this to generate an "[i]ncremental revenue opportunity" of \$568 million related to CVS retail pharmacy sales and \$1.37 billion related to CVS specialty pharmacy sales.

82. CVS had the same scheme in mind. Internally, CVS shared the view that the Wellpartner acquisition would allow for the generation of significant revenue. In an internal document analyzing the impact of the Wellpartner acquisition, CVS recognized that "340B Savings are more important to Covered Entities than ever," and that "[a]ccess to CVS Health retail and specialty pharmacies is critically important to Covered Entities." Since many Covered Entities need to contract with CVS because a significant amount of their patients choose to go CVS Pharmacies, CVS convinced itself that it was entitled to divert as much as possible of the 340B Benefits to itself. CVS felt entitled to "Top of

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the Market' pricing" for Wellpartner TPA services and sought to take a percentage "of the 340B spread" as the Wellpartner administrative fee for all 340B prescriptions. To ensure that CVS would realize substantial increased revenues as a result of the Wellpartner acquisition, it determined that "Wellpartner will evolve to the exclusive 340B TPA for all of CVS Health's retail and specialty pharmacies by December 31, 2018." Indeed, internal documents explain a plan to make Wellpartner the "only option" if Covered Entities want access to 340B Savings arising from transactions at CVS stores.

83. CVS was not blind to the impact that this would have on hospitals and other Covered Entities. A CVS senior vice president at the time testified that "[t]he hospital industry [is] a low margin business" and that hospitals do not have "big operating margins." He admitted that "the 340B savings are [...] important to them to kind of help them continue to execute on their mission." He also acknowledged that he had tried to "flag" that "there would be some providers or Covered Entities that might not be happy" about the tying scheme.

84. In December 2017, CVS began to notify Covered Entities across the nation (including Covered Entities in New York) that the Covered Entities no longer had a choice of TPA if they wished to continue using CVS pharmacies as 340B Contract Pharmacies. On December 18, 2017, CVS announced in writing to its Covered Entity customers that it had completed an acquisition of Wellpartner, and that Wellpartner would be "the exclusive 340B program administrator for all CVS Health retail and specialty pharmacies." CVS informed its customers that it would "transition all Covered Entities to Wellpartner by December 31, 2018."

85. Following the CVS announcement that it would require Covered Entities to use Wellpartner as a TPA in order to access CVS retail and specialty pharmacies, Wellpartner experienced a

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surge of business. Whereas Wellpartner only had 155 Covered Entity clients in 2017 (including in New York) before the scheme, by 2021, that figure had increased eightfold because of the anticompetitive tie.

86. The reason for the surge in Wellpartner's business is apparent: after the 2017 CVS announcement, a number of Covered Entities began using Wellpartner to preserve their access to 340B Savings for patients who happen to go to CVS. For example, at least two major New York City health systems began working with Wellpartner in addition to their pre-existing TPA after CVS implemented its tie. This is because many Covered Entities must have CVS retail and/or specialty pharmacies as Contract Pharmacies in order to realize sufficient savings from the 340B Program. For some health systems in New York State, 340B savings from prescriptions filled at CVS pharmacies constitute a quarter of the health system's overall 340B savings.

87. Some of the Covered Entities that began using Wellpartner TPA services after CVS implemented its anticompetitive plan had previously decided against working with Wellpartner during competitive RFP processes. For example, one Covered Entity that had previously decided against using Wellpartner noted that TPA services are not all alike, and that "the devil is in the details," such as the quality of the data, and the robustness of the initial setup. That Covered Entity also indicated that the transition to Wellpartner might add more than \$100,000 in otherwise avoidable costs. But, given the larger sums that would be lost if CVS refused to contract with them for not complying with the scheme, they had little choice. Another Covered Entity estimated that switching to Wellpartner for their five CVS specialty pharmacy locations would increase their costs by \$1.4 million.

88. Another Covered Entity that did not want to switch to Wellpartner lamented that, given how many of their patients are required to use CVS pharmacies under their health plans, they would

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stand to lose tens of millions of dollars of 340B Program benefit if they did not acquiesce.

89. And yet another Covered Entity expressed concern that using two TPAs would be costly, require integration, and would expose the hospital to regulatory risk because of the increased chance of errors. Among other things, the hospitals would have to train internal auditors on a second system, if they hypothetically chose to use two TPAs, notwithstanding the costs. That Covered Entity also noted that using two TPAs would increase the risk of a data breach involving sensitive patient data. Given the number of their patients who go to CVS pharmacies, they felt they had no choice in practice but to switch to Wellpartner.

90. Faced with the loss of 340B Savings from CVS retail and specialty pharmacies, these Covered Entities were in effect compelled to begin using Wellpartner. Some Covered Entity customers converted all of their TPA business to Wellpartner; others continued to work with their legacy TPA for all pharmacies other than CVS pharmacies, despite the additional cost associated with using two TPAs.

91. As previously noted, working with multiple TPAs is difficult for Covered Entities. Forcing Covered Entities to work with multiple TPAs (i.e., Wellpartner in addition to their previous TPA) places Covered Entities at higher risk of noncompliance with the requirements of the 340B program. Working with more than one TPA also increases a Covered Entity's internal information technology costs, as - among other things - they must have staff trained to interface with two different TPA technology platforms, must maintain computer infrastructure sufficient to handle data exchanges with two TPAs, and must have an in-house administrative team capable of managing two TPA relationships. The cost of having multiple TPAs is substantial for the Covered Entities.

92. Further, the Wellpartner TPA fees were higher for some Covered Entities than the fees

charged by their legacy TPAs. Many competitor TPAs charge fees based on utilization (e.g., a "per click" fee for each 340B script processed by the TPA). CVS's Wellpartner fees for all but the least expensive prescriptions were instead typically based on a percentage of the "340B spread," or the difference between the Covered Entity's acquisition cost of the drug and the reimbursed amount. For Covered Entities who had been using a lower-cost TPA, the compulsory switch to Wellpartner for CVS transactions resulted in the transfer of a huge amount of 340B Savings from the Covered Entity to CVS due to Wellpartner's percentage-based fee model. Covered Entities have complained to CVS that Wellpartner's fees were "excessive."

93. Knowing that Covered Entities could not effectively steer patients to a particular pharmacy, and that Covered Entities were therefore beholden to CVS if they wanted to realize 340B Savings from prescriptions filled at CVS pharmacies, CVS mandated the use of Wellpartner TPA services for Covered Entities seeking to contract with CVS retail and specialty pharmacies. This arrangement allowed CVS to collect TPA fees as well as dispensing fees from the Covered Entities' 340B Savings.

94. This illegal tying scheme provided enhanced and ill-gotten revenues to CVS. By unlawfully forcing 340B Covered Entities to use Wellpartner TPA services for CVS pharmacy transactions, CVS increased its "cut" of the Covered Entities' 340B Savings. The scheme harmed competition by preventing TPAs other than Wellpartner from being able to compete with Wellpartner on a level playing field. This harmed the Covered Entities by depriving them of savings critical to carry out their public health missions. Moreover, it harmed the people of the State of New York by reducing the amount of 340B Savings that could be used by Covered Entities to expand access to care and offer vital health services to underserved communities.

# THE RELEVANT MARKETS: THE MARKET FOR CVS 340B CONTRACT PHARMACY SERVICES AND THE MARKET FOR 340B PROGRAM TPA SERVICES

95. The relevant markets at issue in this lawsuit are (1) the CVS Contract Pharmacy Market; and (2) the TPA Services Market.

# **The CVS Contract Pharmacy Market**

96. CVS's provision of Contract Pharmacy services to 340B Program Covered Entities (the "CVS Contract Pharmacy Market") is a relevant market. It is the "tying" market over which Defendants have market power.

97. The CVS Contract Pharmacy Market is a relevant market because of the peculiarities of the 340B Program. Specifically, as discussed below, the existence of the Anti-Steering Rule and the fact that patients themselves receive no benefit from and are generally unaware of the 340B program, together mean that patients go where they choose to go, and they do not respond to price pressures that affect Covered Entities. Changes in fees charged to Covered Entities cannot be passed on to patients to change their behavior, nor do the fees directly cause patients to go to different brand pharmacies. Since a Covered Entity cannot substitute one Contract Pharmacy in response to a price increase, each Contract Pharmacy, such as CVS, that provides substantial savings to a Covered Entity is its own relevant market.

98. A large number of New York State Covered Entities use CVS's retail and specialty pharmacies as 340B Contract Pharmacies and do not view other Contract Pharmacies as reasonably interchangeable with CVS. As discussed, Covered Entities can identify where their 340B-eligible prescriptions are sent but lack all ability to direct these prescriptions to a particular pharmacy because Covered Entities (and their prescribing physicians) are barred from steering prescriptions to any specific pharmacy by 340B Program regulations and federal and state anti-kickback laws. If a Covered Entity

does not contract with CVS as a Contract Pharmacy, it will not realize 340B Savings from any 340Beligible prescription that is filled at a CVS location. Thus, if Covered Entities want to realize 340B Savings from patient prescriptions that are filled at CVS pharmacies, the Covered Entities have no alternative but to engage with CVS as a Contract Pharmacy.

99. Because Covered Entities cannot steer their patients from CVS to another pharmacy, the cross-elasticity of demand for CVS 340B retail and specialty Contract Pharmacy services and any potential alternative Contract Pharmacy is at or near zero. No other pharmacy offering retail or specialty Contract Pharmacy services to Covered Entities can competitively constrain CVS, because Covered Entities have no ability to direct patient flows to any particular pharmacy. CVS thus has market power in fact monopoly power – in the CVS Contract Pharmacy market.

100. CVS's market power is apparent from the behavior of Covered Entities after CVS implemented its illegal tie: although they did not want to, many Covered Entities began using CVS 340B TPA services. One CVS official noted, after implementation of the tie, that "some provider groups...were not overjoyed with having to move" to Wellpartner. The fact that many Covered Entities switched to Wellpartner, despite their reservations, substantiates CVS's considerable power in the market for Contract Pharmacy services.

101. The geographic scope of the CVS Contract Pharmacy Market is the United States. CVS retail and specialty pharmacies nationwide can serve as Contract Pharmacies to Covered Entities located in New York State. For example, a Covered Entity anywhere in the State could contract with CVS Specialty and CVS retail stores nationwide. Courts routinely recognize that the healthcare market is represented by a two-stage model of competition and that determination of the geographic market must

take into account the commercial realities of the specific industry involved.

# The 340B TPA Services Market

102. The provision of 340B TPA Services to Covered Entities – including the identification of 340B-eligible prescriptions, the implementation of tracking software to prevent drug diversion and duplicate discounts, and the maintenance of an auditable record of 340B workflows and payments -is a relevant market (the "340B TPA Services Market"). It is the tied market, into which Defendants are expanding and demanding supra-competitive fees, using their leverage in the tying market.

103. The geographic scope of the 340B TPA Services Market is the United States. Firms in the 340B TPA Services Market, which include Wellpartner, Sentry, RxSolutions, MacroHelix, and others, compete for business across the country, and Covered Entities engage firms nationwide to provide 340B TPA services.

# **CVS ILLEGALLY TIED TPA SERVICES TO ITS CONTRACT PHARMACY SERVICES**

340B Program TPA Services and CVS 340B Contract Pharmacy services are separate 104. products in separate markets. Firms offering 340B TPA Services are distinct from the firms offering 340B Contract Pharmacy services, and Covered Entities have the ability to choose between TPA service providers – unless forced to do otherwise as they are now. Covered Entities do not usually seek to purchase these two products from the same firm. On the contrary, Covered Entities frequently prefer to have a 340B Program TPA services vendor that does not operate Contract Pharmacies, as they view independent 340B Program TPA services vendors as more likely to advocate effectively for Covered Entity clients in the Covered Entity's dealings with Contract Pharmacies.

105. Defendants have tied access to the CVS Contract Pharmacy Market to Covered Entities'

agreement to also hire their subsidiary Wellpartner in the independent 340B TPA Services Market.

106. By coercing Covered Entities to use CVS's 340B Program TPA services (the "tied" services) as a condition of obtaining access to the Contract Pharmacy services of CVS retail and specialty pharmacies (the "tying" services), CVS orchestrated and implemented a per se unlawful tying scheme. CVS' conduct is a naked restraint on trade that constitutes a per se illegal violation tying arrangement. The challenged arrangement also violates the "rule of reason" analytical framework deployed in antitrust jurisprudence.

107. CVS's tying regime harmed, and continues to harm, competition. This tie has foreclosed other providers of 340B Program TPA services from competing to provide 340B Program TPA services to Covered Entities using CVS retail and specialty Contract Pharmacies. Moreover, the tie has significant spillover effects: because Covered Entities do not like to work with multiple TPAs, and because TPAs other than Wellpartner cannot administer CVS Contract Pharmacy relationships, TPAs cannot compete for the entirety of a Covered Entity's Contract Pharmacy "book of business" if the Covered Entity engages CVS pharmacies as Contract Pharmacies. This fundamentally alters the playing field, harming the competitive process by giving Wellpartner an unfair competitive advantage.

A not insubstantial volume of commerce is affected by CVS's tie. Hundreds of Covered 108. Entities have abandoned their legacy TPA and have begun contracting with CVS for 340B Program TPA services as a result of the tie. CVS's tying of 340B Program TPA services to the Contract Pharmacy services of CVS retail and specialty pharmacies also harmed, and continues to harm, consumers. Consumers of the services – here, the hospitals and other Covered Entity healthcare providers – are harmed as they are forced to pay higher prices for a service that they do not want to purchase from

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Wellpartner. They also faced increased costs stemming from the mandated switch to Wellpartner, and in some cases had to expend additional funds to manage two 340B Program TPA services vendors. Downstream consumers – indigent New Yorkers who use the expanded services afforded by Covered Entities' 340B Savings - were also harmed, as, after the tie was implemented, Covered Entities were forced to remit a larger portion of their 340B Savings to CVS and its Wellpartner subsidiary than they would have absent the tie.

109. There is no valid procompetitive justification for CVS's implementation of its unlawful tie. CVS's internal rule (prior to the Wellpartner acquisition) was to limit its pharmacies to a Contract Pharmacy relationship with a single Covered Entity. It was not required by any federal or state law, rule, or regulation.

110. CVS pursued a program that was anticompetitive, rather than adopt a less restrictive alternative to address the administrative burden of contracting with multiple Covered Entities. Prior to the Wellpartner acquisition, CVS was developing a "backbone" model that would ease CVS's administrative burden when dealing with multiple Covered Entities. Rather than pursue that option, CVS decided to acquire Wellpartner and then implement an illegal tie in order to increase its revenues in the 340B space. Argument to the contrary is pretextual for a greedy – and so far, successful – attempt to make a killing at the expense of competition and vulnerable health care providers and their communities.

111. New York, its patients and consumers, and New York Covered Entities have suffered and continue to suffer harm as a result of CVS's anticompetitive conduct. This harm is of a type that the antitrust laws were intended to prevent.

112. To stop these ongoing harms and prevent recurrence, Plaintiff State of New York requests

that the Court order appropriate equitable relief, including an injunction against CVS's anticompetitive tie and possibly, an order that Wellpartner be divested. Plaintiff State of New York also seeks an award of civil penalties, and equitable monetary relief including disgorgement and/or restitution.

# COUNT 1

# Anticompetitive Contracts, Agreements, and/or Arrangements in Violation of New York's Donnelly Act, New York General Business Law § 340 et seq.

113. The People restate, re-allege, and incorporate by reference each of the allegations set forth in paragraphs 1 through 112 above as if fully set forth herein.

CVS's conduct violates the Donnelly Act, N.Y. Gen. Bus. L. 340 et seq., which prohibits, 114. inter alia, "[e]very contract, agreement, arrangement, or combination whereby [a] monopoly in the conduct of any business, trade or commerce or in the furnishing of any service in this state, is or may be established or maintained, or whereby [c]ompetition or the free exercise of any activity in the conduct of any business, trade or commerce or in the furnishing of any service in this state is or may be restrained... is hereby declared to be against public policy, illegal and void."

115. Through its contracts, agreements, arrangements and/or combinations, CVS has unlawfully tied access to Contract Pharmacy services at CVS retail and specialty pharmacies to use of CVS Wellpartner 340B TPA services.

116. CVS has sufficient economic power in the tying market, the CVS 340B Contract Pharmacy Market, because Covered Entities cannot divert 340B-eligible patient prescriptions to any other Contract Pharmacy. Engaging in Contract Pharmacy relationships with CVS pharmacies is the sole means by which Covered Entities can realize 340B Savings from their patient prescriptions that are

filled at CVS pharmacies.

117. CVS has coerced Covered Entities in New York to CVS Wellpartner 340B TPA Services as a condition to access the CVS 340B Contract Pharmacy Market, over which CVS has market power. This constitutes a per se unlawful tying arrangement. It is also a violation under the "rule of reason."

118. The tying product (CVS 340B Contract Pharmacies) and the tied product (CVS' Wellpartner in the 340B TPA Services Market) are distinct. CVS's unlawful tying arrangement ties two separate products that are in two separate markets, leveraging CVS's power over the tying product to foreclose competition in the tied product.

119. CVS's conduct has foreclosed, and continues to foreclose, competition in the 340B TPA Services Market, affecting a substantial volume of commerce in this market.

120. CVS has thus engaged in a per se illegal tying arrangement and the Court does not need to engage in a detailed assessment of the anticompetitive effects of CVS's conduct or any purported justifications.

121. In the alternative, even if arguendo CVS's conduct does not constitute a per se illegal tie, the arrangement violates the rule of reason and is illegal, as there are no procompetitive justifications for the tie. Moreover, Sentry's "backbone" solution that CVS rejected (see infra) would have constituted a less restrictive alternative to the tie. Therefore, even if there were a procompetitive justification, it is outweighed by the competitive harm.

New York consumers and businesses have been harmed by CVS's conduct in a manner 122. that the antitrust law was intended to prevent. This harm is ongoing and will continue until this Court issues an order enjoining CVS from enforcing its illegal tie against New York Covered Entities,

including equitable relief which could include an injunction and an order of divestiture.

123. To prevent these ongoing harms and any recurrence, the State of New York requests that that Court issue an order enjoining the defendants' anticompetitive conduct and ordering such other and further equitable relief as this Court may deem appropriate to restore competitive conditions and lost competition and to prevent future violations, including divestiture or reconstruction of illegally acquired businesses or business lines.

124. The State of New York request that the Court use its inherent equitable powers to order appropriate restitution and/or disgorgement to remedy the harms inflicted since the implementation of this scheme.

125. The State of New York also requests that the Court order civil penalties and an assessment under the Donnelly Act, pursuant to N.Y. Gen. Bus. Law §§ 342 and 342-a.

# COUNT 2

#### Illegality in Violation of New York Executive Law § 63(12)

126. The People restate, re-allege, and incorporate by reference each of the allegations set forth in paragraphs 1 through 125 above as if fully set forth herein.

127. Defendants' conduct violates § 63(12) of New York's Executive Law, in that Defendants engaged in repeated and/or persistent illegal acts – violations of Section 340 *et seq* of the Donnelly Act – in the carrying on, conducting, or transaction of business within the meaning and intent of Executive Law § 63(12).

128. The State of New York respectfully requests that the Court enjoin the defendants'

anticompetitive conduct and order such other and further equitable relief as this Court may deem appropriate to restore competitive conditions and lost competition and to prevent future violations, including divestiture or reconstruction of illegally acquired businesses or business lines.

129. The State of New York also respectfully requests that the Court order that Defendant disgorge its unjust gains and provide appropriate restitution.

WHEREFORE, New York General Business Law § 342 authorizes this Court to issue a permanent injunction for violations of New York's Donnelly Act; New York General Business Law § 341 authorizes this Court to award penalties for violations of the Donnelly Act; and New York Executive Law § 63(12) authorizes this Court to grant equitable relief based on the Defendants' repeated and/or persistent violation of the Donnelly Act, Plaintiff demands judgment against Defendant as follows:

Adjudging and decreeing that Defendants have violated the Donnelly Act, N.Y. a. General Business Law §§ 340 et seq.;

- Adjudging and decreeing that Defendants have violated N.Y. Exec. Law § 63(12); b.
- Enjoining the illegal conduct; c.
- d. Ordering Defendants to immediately inform all New York Covered Entities that

exclusive use of Wellpartner is no longer required;

Ordering the divestiture of Wellpartner, with conditions that the buyer not engage e. in similar conduct;

This is a copy of a pleading filed electronically pursuant to New York State court rules (22 NYCRR §202.5-b(d)(3)(i)) which, at the time of its printout from the court system's electronic website, had not yet been reviewed and approved by the County Clerk. Because court rules (22 NYCRR §202.5[d]) authorize the County Clerk to reject filings for various reasons, readers should be aware that documents bearing this legend may not have been accepted for filing by the County Clerk.

f. Awarding New York all equitable relief, including equitable monetary relief such

as disgorgement and restitution, as the Court finds necessary to redress and prevent recurrence of Defendants' violations of the Donnelly Act and Executive Law § 63(12);

Awarding maximum New York civil penalties, pursuant to N.Y. Gen. Bus. Law g.

§ 341 for each violation;

h. Awarding New York an additional allowance of twenty thousand dollars, pursuant

to N.Y. Gen. Bus. Law § 342;

- i. Awarding New York costs and fees associated with this action; and
- j. Granting such other and further relief as this Court deems just and proper.

Dated: New York, New York July 28, 2022

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By:

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