

United States Senate

COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS

WASHINGTON, DC 20510-6300

WARREN GUNNELS, MAJORITY STAFF DIRECTOR
AMANDA LINCOLN, REPUBLICAN STAFF DIRECTOR

www.help.senate.gov

January 17, 2024

VIA ELECTRONIC TRANSMISSION

Karen S. Lynch
President & Chief Executive Officer
CVS Health
One CVS Dr.
Woonsocket, RI 02895

Dear Ms. Lynch:

I write to request information regarding your company's participation in the 340B Drug Discount Program (340B Program). The 340B Program was designed to allow covered entities, like certain hospitals, clinics, and community health centers, to "obtain lower prices on the drugs that they provide for their patients," and enables these entities to stretch scarce federal resources as far as possible.¹ By participating in the 340B Program, covered entities are expected to pass on these savings to America's most vulnerable patients, by either offering discounted drugs or by providing charity care to patients. However, federal law imposes few restrictions with respect to how these savings are used.

Contract pharmacies provide prescription drugs to patients of covered entities participating in the 340B Program.² Initially, the Health Services Resources Administration (HRSA) restricted covered entities to enter into agreements with only one contract pharmacy.³ However, in 2010, HRSA issued new guidance that allowed covered entities to enter into agreements with an unlimited number of contract pharmacies.⁴ As a result, the number of contract pharmacies participating in the 340B Program has skyrocketed. To illustrate, between 2009 and 2022, the number of retail pharmacies participating in the 340B Program, not including mail order and specialty pharmacies, grew exponentially from 789 to 25,775—an approximately 3,166 percent increase in less than 15 years.⁵

¹ H.R. Rept. No. 102-384(II), at 12 (1992). As a condition of participation in the 340B Program, drug manufacturers are required to charge no more than the "ceiling price" on certain outpatient prescription drugs purchased by the covered entities. 42 U.S.C. § 256b(a)(1), (4).

² U.S. DEP'T OF HEALTH AND HUMAN SERVS., OEI-05-13-00431, CONTRACT PHARMACY ARRANGEMENTS IN THE 340B PROGRAM (2014). Contract pharmacies include retail, mail-order, and specialty pharmacies.

³ 61 FR 43,551 (1996).

⁴ 75 FR 10,272 (2010).

⁵ Sayeh Nikpay, et al., *Trends in 340B Drug Pricing Program Contract Growth Among Retail Pharmacies From 2009 to 2022*, JAMA HEALTH FORUM (Aug. 4, 2023), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10403775/>.

Due to the complexity of the 340B Program, covered entities often use third-party administrators (TPAs), like CVS' Wellpartner (Wellpartner), to determine eligibility and process 340B-eligible claims. Wellpartner, a subsidiary of CVS Health, markets its services as "End-to-End 340B Program Management" and as a covered entity's "strategic partner to optimize [their 340B program]"⁶ According to Wellpartner, these services include ensuring program compliance, maximizing claims capture, and driving program value.⁷

The 340B Program does not impose any restrictions or limitations on the fees a covered entity may pay their contract pharmacy or TPA.⁸ According to the Government Accountability Office (GAO), contracts between a covered entity and a contract pharmacy typically include language requiring the covered entity to pay a flat fee, plus a percentage of revenue generated for each 340B prescription to the contract pharmacy.⁹ Between 2014 and 2016, these fees, according to GAO, ranged from \$6 to \$15 dollars per prescription. These favorable reimbursement terms allow the contract pharmacy and/or the TPA to realize large profit margins.

CVS Health is the largest contract pharmacy participant in the 340B Program.¹⁰ The company also happens to operate the largest pharmacy benefit manager (PBM) by market share, and is vertically integrated with health insurer, Aetna.¹¹ Out of the more than 194,000 contractual relationships between contract pharmacies and covered entities, an estimated 63,400 are with a CVS Health-affiliated pharmacy.¹²

CVS Health's oversized role in the 340B Program allows it to realize significant profits. Indeed, CVS Health's most recent 2023 financial report warns that "[a] reduction in the number of covered entities participating in contract pharmacy arrangements . . . a reduction in the use of the company's administrative services by Covered Entities, or a reduction in drug manufacturers' participation in the program could materially and adversely impact the Company."¹³

As one of the largest pharmacy participants in the 340B Program, and to better understand how CVS generates revenue from it, please respond to the following questions on a question-by-question basis, no later than February 6, 2024. I request that all documents be unredacted, produced in electronic form, and Bates stamped. Unless otherwise stated, the below questions seek information or documentation from 2019 to the date of this letter.

⁶ *Wellpartner, End-to-End 340B Program Management*, WELLPARTNER, <https://www.wellpartner.com/solutions/> (last visited Nov. 29, 2023).

⁷ *Id.*

⁸ GOV'T. ACCOUNTABILITY OFF., GAO-18-480, DRUG DISCOUNT PROGRAM, FEDERAL OVERSIGHT OF COMPLIANCE AT 340B CONTRACT PHARMACIES NEEDS IMPROVEMENT (June 2018).

⁹ *Id.* at 25.

¹⁰ Adam Fein, *EXCLUSIVE: For 2023, Five For-Profit Retailers and PBMs Dominate an Evolving 340B Contract Pharmacy Market*, DRUG CHANNELS (July 11, 2023), <https://www.drugchannels.net/2023/07/exclusive-for-2023-five-for-profit.html>.

¹¹ *How Aetna and CVS Health are delivering a new model of integrated care*, AETNA, <https://www.aetna.com/health-guide/integrated-health-care.html> (last viewed Dec. 12, 2023).

¹² *Id.* This figure includes retail, mail order, specialty, and infusion pharmacies. However, the vast majority of contractual relationships are with retail pharmacies.

¹³ *CVS Health, Form 10-K*, SEC, <https://d18m0p25nwr6d.cloudfront.net/CIK-0000064803/e4b97418-e95e-4391-b2d9-8c604c4950ac.pdf> (last viewed Dec. 12, 2023).

1. Regarding your company's participation in the 340B Program:
 - a. Please describe the types of services Wellpartner provides to covered entities participating in the 340B Program.
 - b. Are covered entities required to use Wellpartner as their designated TPA?
 - c. Describe the firewalls that exist between: (a) CVS Caremark and Wellpartner; and (b) CVS Caremark and Aetna.
 - d. How does Wellpartner identify prescriptions as 340B-eligible vs. noneligible? What level of information is shared? Please describe the mechanisms in place to ensure confidentiality.
 - e. Does CVS Caremark and/or Wellpartner offer savings from the 340B Program to your health plan clients? If so, please explain.
 - f. Does CVS Caremark and/or Wellpartner assist covered entities in sharing 340B discounts with patients? If so, please explain.
2. Regarding your business relationships with covered entities:
 - a. Please describe how revenue is generated from the 340B Program for your company. How does CVS Health account for this revenue in its annual financial statements submitted to the U.S. Securities and Exchange Commission? Is it accounted for as part of CVS Health's Pharmacy Services Segment, its Retail/Long-Term Care Pharmacy Segment, or both? If both, please explain.
 - b. Please describe the types of revenue that your company receives from covered entities, including but not limited to, fees, discounts, services, business offerings, or other remuneration, including those offered by wholly-owned or partially-owned subsidiaries or affiliates. Please explain how these fees are structured.
 - c. Please provide a list of all covered entities that contract with Wellpartner to provide 340B pharmacy services.
 - d. For each covered entity that your company contracts with, please provide CVS Health and Wellpartner's annual gross and net revenues generated from the 340B Program.
 - e. Please produce unredacted copies of all TPA and contract pharmacy agreements between CVS Health and covered entities.
 - f. Please also produce unredacted copies of all TPA and contract pharmacy agreements entered into with Yakima Valley Farm Workers Clinic, Sun River Valley, Cleveland Clinic, and Bon Secours Mercy Health, if applicable.

3. Regarding your contract pharmacies:

- a. Please provide the number of contract pharmacy arrangements between CVS Health-affiliated pharmacies and covered entities. Please list the name, location, and distance from the covered entity for each affiliated pharmacy. What percentage of these covered entities are located in either urbanized areas (UA) or urban clusters (UC)?¹⁴
- b. Please provide the number of CVS Health-affiliated pharmacies who, as of November 1, 2023, were able to dispense 340B-eligible prescriptions, including those pharmacies who might not have a direct contractual relationship with a covered entity.

Sincerely,

Bill Cassidy, M.D.

Bill Cassidy, M.D.

Ranking Member

U.S. Senate Committee on Health,

Education, Labor, and Pensions

¹⁴ 87 FR 16,706 (2022).