CONGRESS MUST ACT TO BRING NEEDED REFORMS TO THE 340B DRUG PRICING PROGRAM

MAJORITY STAFF REPORT

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Senate Committee on
Health Education Labor & Pensions
Senator Bill Cassidy, M.D., Chair

CONGRESS MUST ACT TO BRING NEEDED REFORMS TO THE 340B DRUG PRICING PROGRAM

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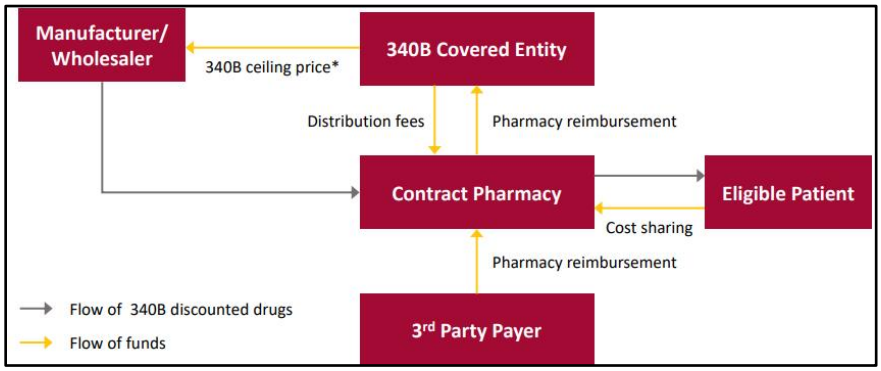
I. The 340B Drug Pricing Program

A. Background

Created by Congress in 1992, the 340B Drug Pricing Program (340B Program) is a federal program that requires drug manufacturers participating in the Medicaid Drug Rebate Program to provide outpatient drugs at significantly reduced prices for certain health care facilities or programs, known as "covered entities."[1] Covered entities under the 340B Program include federal grantees, such as federally qualified health centers (FQHCs) and Ryan White HIV/AIDS Program grantees, and certain hospitals, such as children's hospitals, critical access hospitals, and disproportionate share hospitals.[2] As of February 2025, there were more than 60,000 covered entities participating in the 340B Program, representing an increase of more than 600 percent since 2000.[3]

To participate in the 340B Program, covered entities must meet certain requirements including prohibiting the diversion of 340B drugs to ineligible patients and preventing duplicate discounts.[4] By participating, covered entities benefit in two ways: realizing 340B *savings* as well as generating 340B *revenue*. Participating covered entities realize 340B *savings* by purchasing discounted 340B drugs from drug manufacturers. Covered entities also generate 340B *revenue* when the patient's health insurance reimbursement or their out-of-pocket cost paid exceeds the 340B price the covered entity paid for the drugs.[5] Together, the 340B revenue and savings are colloquially referred to as the "340B benefit." A visual of the flow of funds and drugs is below:[6]



[1] *340B Drug Pricing Program*, HEALTH RES. & SERVS. ADMIN., https://www.hrsa.gov/opa (last updated Apr. 2025).
[2] 42 U.S.C. §§ 256b(a)(4)(A)–(K). The eligible covered entities in the 340B Program include: federally qualified health centers (health center program award recipients, health center program look-alikes, Native Hawaiian health centers, and tribal and urban Indian health centers), Ryan White HIV/AIDS Program grantees, certain hospitals (children's hospitals, critical access hospitals, disproportionate share hospitals, free standing cancer hospitals, rural referral centers, and sole community hospitals), and specialized clinics (black lung clinics, comprehensive hemophilia diagnostic treatment centers, Title X family planning clinics, sexually transmitted disease clinics, and tuberculosis clinics). *340B Eligibility*, HEALTH RES. & SERVS. ADMIN, https://www.hrsa.gov/opa/eligibility-and-registration (last updated June 2024).
[3] *Covered Entities*, HEALTH RES. & SERVS. ADMIN., https://340bopais.hrsa.gov/CoveredEntitySearch/000004667.
[4] *Program Requirements*, HEALTH RES. & SERVS. ADMIN, https://www.hrsa.gov/opa/program-requirements (last updated June 2024).
[5] *340B Drug Discount Program: Information about Hospitals That Received an Eligibility Exception as a Result of COVID-19*, U.S. GOV'T ACCOUNTABILITY OFF. (May 11, 2023), https://www.gao.gov/assets/gao-23-106095.pdf.
[6] Karen Mulligan, *The 340B Drug Pricing Program: Background, Ongoing Challenges, and Recent Developments*, USC SCHAEFFER (Oct. 2021), https://schaeffer.usc.edu/wp-content/uploads/2024/10/USC_Schaeffer_340BDrug PricingProgram_WhitePaper.pdf.

The 340B statute does not specify how covered entities must use 340B revenue and whether it should directly benefit patients. When the 340B Program was created, Congress intended for covered entities to use this revenue "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[7] However, concerns persist about whether the 340B Program truly benefits low-income and uninsured patients, with some studies suggesting that the 340B benefit does not translate into increased charity care or lower costs for vulnerable populations.

In a 2018 survey, the Government Accountability Office (GAO) found that three-fifths of covered entities provided discounts directly to uninsured patients at some or all of their contract pharmacies.[8] Notably, GAO found that 67 percent of federal grantee covered entities provided discounts to patients at some or all of their contract pharmacies compared to 43 percent of hospital covered entities.[9] A 2014 analysis from the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) found that 27 percent of the covered entities do not offer the discounted 340B price to uninsured patients at any of their contract pharmacies, while 60 percent offered the discounted 340B price in at least one of their contract pharmacies.[10] Similar to GAO's findings, HHS OIG found that federal grantee covered entities more commonly provided the 340B discount to uninsured patients than hospital covered entities.[11]

In 2023, covered entities purchased approximately $66.3 billion in covered outpatient drugs at the discounted 340B price, with the top 10 drugs purchased representing about one-third of total 340B spending.[12] The Health Resources and Services Administration (HRSA), which administers and oversees the 340B Program, does not report the wholesale acquisition cost (WAC) of 340B drugs purchased, but IQVIA reports that covered entities purchased $124.1 billion (at WAC pricing) in covered outpatient drugs in 2023.[13] This pricing data illustrates that the average 340B discount for all covered outpatient drugs was about 53.4 percent in 2023. IQVIA also notes, "[t]he growth of the program accelerated in 2023, with year-over-year 340B sales increasing 16.5%, up from 12% growth in 2022 . . . [attributed to] the increasing number of new specialty drugs that have been launched, many of which are prescribed or administered by physicians working in hospitals."[14]

Since its inception in 1992, the 340B Program has grown significantly. However, this growth accelerated beginning in 2010 when new covered entity types were added following the passage

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[7] H.R. Rep. No. 102-384(II), at 12 (1992).
[8] *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GOV'T ACCOUNTABILITY OFF. 30–31 (June 2018), https://www.gao.gov/assets/d18480.pdf. Of these 30 covered entities that provided discounts, 23 reported providing patients the 340B discount at all of their contract pharmacies and seven reported providing patients the 340B discount at some of their contract pharmacies. The remaining 25 covered entities reported that they did not provide patients the 340B discount at any of their contract pharmacies. *Id*.
[9] *Id.*
[10] Memorandum from Stuart Wright, Deputy Inspector Gen. for Evaluation & Inspections, U.S. Dep't of Health & Hum. Servs. Off. of Inspector Gen., to Mary K. Wakefield, Adm'r, Health Res. & Servs. Admin. (Feb. 4, 2014), https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf.
[11] *Id*.
[12] *340B Covered Entity Purchases*, HEALTH RES. & SERVS. ADMIN., https://www.hrsa.gov/opa/updates/2023-340b-covered-entity-purchases (last updated Oct. 2024).
[13] Rory Martin & Harish Karne, *The 340B Drug Discount Program Grew to $124B in 2023*, IQVIA 2 (2024), https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2024/iqvia-update-on-size-of-340b-program-report-2024.pdf.
[14] *Id.*

of the Patient Protection and Affordable Care Act and HRSA guidance allowing covered entities to engage with an unlimited number of contract pharmacies, a significant expansion from the previous allowance of one contract pharmacy per covered entity.[15] According to an analysis conducted by the Drug Channels Institute, in 2023 "more than 33,000 pharmacy locations—more than half of the entire U.S. pharmacy industry—act[ed] as contract pharmacies . . . in the 340B Program," up from fewer than 1,300 pharmacy locations in 2010.[16] Of these, five large pharmacy chains—CVS Health (Aetna), Walgreens, Express Scripts (Cigna), OptumRx (UnitedHealth Group), and Walmart—accounted for 75 percent of all 340B contract pharmacy relationships with covered entities.[17] This growth in the use of contract pharmacies has amplified the complexity of 340B Program oversight, particularly regarding patient eligibility, drug diversion, and duplicate discounts.

HHS OIG and GAO have identified longstanding, fundamental vulnerabilities with the 340B Program that impede effective program oversight and operations. These issues include limited oversight and lack of accountability, as well as concerns regarding covered entities' use of contract pharmacies. For example, according to HHS OIG, "[t]he operations of contract pharmacies are often quite complex, and this complexity has important consequences—variation in [patient] eligibility determinations across different 340B providers and inconsistencies in whether uninsured patients benefit directly from the 340B [P]rogram."[18] GAO also found weaknesses with HRSA's oversight, including that HRSA's Office of Pharmacy Affairs only audits 200 covered entities per year, which may hinder HRSA's ability to effectively oversee the rapidly growing federal program[19] given that there are now over 60,000 covered entities participating.[20]

HRSA also has limited rulemaking authority in the 340B Program and its ability to enforce its guidance has led to lawsuits between drug manufacturers and the federal government. For example, since the summer of 2020, over 20 drug manufacturers, including Eli Lilly, Amgen, and Johnson & Johnson, have enacted policies restricting covered entities from dispensing some or all of the manufacturers' 340B drugs at more than one contract pharmacy despite HRSA's 2010 guidance allowing covered entities to utilize an unlimited number of contract pharmacies.[21] In response, HRSA issued warning letters to six of the manufacturers, threatening fines if they did not rescind their contract pharmacy restrictions. At least three drug manufacturers then filed lawsuits against HRSA, arguing that it lacks the statutory authority to reject the manufacturers' changes to their policies restricting covered entities' ability to use an unlimited number of contract

[15] Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10272, 10277 (Mar. 5, 2010).
[16] *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.
[17] *Id.*
[18] *Hearing on Examining HRSA's Oversight of the 340B Drug Pricing Program Before the Subcomm. on Oversight & Investigations of the H. Comm. on Energy & Com.*, 115th Cong. 5 (2017) (testimony of Erin Bliss, Assistant Inspector Gen. for Evaluation & Inspections, U.S. Dep't of Health & Hum. Servs. Off. of Inspector Gen.), https://oig.hhs.gov/documents/testimony/50/20170718_-_Bliss_Testimony.pdf.
[19] *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GOV'T ACCOUNTABILITY OFF. (June 2018), https://www.gao.gov/assets/d18480.pdf.
[20] *Covered Entities*, HEALTH RES. & SERVS. ADMIN., https://340bopais.hrsa.gov/CoveredEntitySearch/000004667.
[21] *See* Hannah-Alise Rogers, *Litigation Continues Over Use of Contract Pharmacies in 340B Drug Discount Program*, CONG. RSCH. SERV. (May 23, 2024), https://crsreports.congress.gov/product/pdf/LSB/LSB11163.

pharmacies to dispense 340B drugs.[22] In another group of cases, five hospital covered entities each filed lawsuits against HRSA alleging that HRSA failed to comply with its own guidelines for approving an audit request from drug manufacturers under the 340B Program.[23] Furthermore, four drug manufacturers each filed lawsuits alleging that HRSA lacks the authority to restrict how drug manufacturers distribute 340B discounts, arguing that they should be able to provide 340B discounts in the form of rebates that take effect after the sale as opposed to at the point of sale.[24]

B. Chairman Cassidy's Investigation into the 340B Program

In September 2023, now-Chairman Bill Cassidy of the U.S. Senate Committee on Health, Education, Labor, and Pensions (HELP) initiated an investigation into the 340B Program.[25] The investigation's goal was to determine how covered entities spend 340B revenue in the wake of multiple reports of certain 340B covered entities announcing record-setting profits with no transparency surrounding if and how much of their 340B revenue directly benefits patients.[26]

The investigation sought information from eight participants in the 340B Program in order to gain a comprehensive understanding of where the dollars generated by this program flow and how such revenue benefits patients. The information gathering included letters requesting information and data from hospital covered entities, Bon Secours Mercy Health and Cleveland Clinic;[27] FQHC covered entities, Sun River Health and Yakima Valley Farm Workers Clinic;[28] contract

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[22] *See Eli Lilly & Co. v. U.S. Dep't of Health & Hum. Servs.*, No. 1:21-cv-00081, 2021 U.S. Dist. LEXIS 209257 (S.D. Ind. Oct. 29, 2021); *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696 (3d Cir. 2023); *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452 (D.C. Cir. 2024). In all three cases, federal courts ruled in favor of the drug manufacturers, saying that their contract pharmacy restrictions did not violate the 340B statute and that HRSA could not enforce its alternative reading of the statute against them. *See id.*

[23] *See* Complaint, *Univ. of Washington Med. Ctr. v. Becerra*, No. 1:24-cv-2998 (D.D.C. Oct. 22, 2024); Complaint, *Oregon Health & Sci. Univ. v. Johnson*, No. 1:24-cv-02184 (D.D.C. July 24, 2024); Complaint, *MaineGeneral Med. Ctr. v. Johnson*, No. 1:24-cv-02187 (D.D.C. July 24, 2024); Complaint, *Child.'s Nat'l Med. Ctr. v. Johnson*, No. 1:24-cv-02563 (D.D.C. Sept. 6, 2024); Complaint, *Univ. of Rochester v. Johnson*, No. 1:24-cv-02268 (D.D.C. Oct. 1, 2024).

[24] *See* Complaint, *Johnson & Johnson Health Care Sys. Inc. v. Becerra*, No. 1:24-cv-3188 (D.D.C. Nov. 12, 2024); Complaint, *Eli Lilly & Co. v. Becerra*, No. 1:24-cv-3220 (D.D.C. Nov. 14, 2024); Complaint, *Bristol Myers Squibb Co. v. Johnson*, No. 1:24-cv-3337 (D.D.C. Nov. 26, 2024); Complaint, *Sanofi-Aventis U.S. LLC v. U.S. Dept. of Health & Hum. Servs.*, No. 1:24-cv-03496 (D.D.C. Dec. 16, 2024).

[25] *See* Press Release, S. Comm. on Health, Educ., Lab., & Pensions, Ranking Member Cassidy Opens Investigation into Hospital Revenue Generated by 340B Drug Program (Sept. 28, 2023), https://www.help.senate.gov/ranking/newsroom/press/ranking-member-cassidy-opens-investigation-into-hospital-revenue-generated-by-340b-drug-program.

[26] *E.g.* Katie Thomas & Jessica Silver-Greenberg, *Profits Over Patients: How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits*, N.Y. TIMES (Sept. 27, 2022), https://www.nytimes.com/2022/09/24/health/bon-secours-mercy-health-profit-poor-neighborhood.html; Anna Wilde Mathews et al., *Many Hospitals Get Big Drug Discounts. That Doesn't Mean Markdowns for Patients.*, WALL ST. J. (Dec. 20, 2022), https://www.wsj.com/articles/340b-drug-discounts-hospitals-low-income-federal-program-11671553899.

[27] Letter from Sen. Bill Cassidy, Ranking Member, S. Comm. on Health, Educ., Lab., & Pensions, to John M. Starcher, Jr., Chief Exec. Officer, Bon Secours Mercy Health (Sept. 28, 2023), https://www.help.senate.gov/imo/media/doc/bon_secours_340b_letter.pdf; Letter from Sen. Bill Cassidy, Ranking Member, S. Comm. on Health, Educ., Lab., & Pensions, to Tomislav Mihaljevic, Chief Exec. Officer, Cleveland Clinic (Sept. 28, 2023), https://www.help.senate.gov/imo/media/doc/cleveland_clinic_340b_letter.pdf.

[28] Letter from Sen. Bill Cassidy, Ranking Member, S. Comm. on Health, Educ., Lab., & Pensions, to Anne Kauffman Nolon, Chief Exec. Officer, Sun River Health (Nov. 16, 2023), https://www.help.senate.gov/imo/media/doc/sun_river_health_letter.pdf; Letter from Sen. Bill Cassidy, Ranking Member, S. Comm. on Health, Educ., Lab.,

pharmacies, CVS Health and Walgreens;[29] and drug manufacturers, Eli Lilly and Amgen.[30] In addition, drug manufacturer Johnson & Johnson voluntarily submitted data and information.[31]

While this investigation is limited in scope given the tens of thousands of covered entities and the vast number of contract pharmacies and drug manufacturers currently participating in the 340B Program, the following findings reveal insights into how 340B revenue flows among the largest 340B participants, and how they use this revenue on behalf of patients.

II. Findings

A. Hospital Covered Entities

On September 28, 2023, Chairman Cassidy sent letters to Bon Secours Mercy Health (BSMH) and Cleveland Clinic regarding the hospitals' use of the 340B Program and how patients realized the 340B revenue and savings generated either by receiving discounted drugs or other related services. These hospitals were selected for this investigation as a result of media reports alleging abuse of the 340B Program, such as hospitals cutting services to underserved populations and expanding into affluent areas to increase reimbursement rates and subsequent revenue under the 340B Program.[32] The investigation focused on BSMH's Richmond Community Hospital (RCH) and Cleveland Clinic's flagship hospital.

1. BSMH and Cleveland Clinic generated hundreds of millions of dollars in savings and revenue from the 340B Program.

Based on written responses and the accompanying documents produced pursuant to Chairman Cassidy's investigation, BSMH and Cleveland Clinic each generated hundreds of millions of dollars in 340B savings and revenue from the 340B Program between 2018 and 2023. Both RCH and Cleveland Clinic calculated their 340B savings by subtracting the drugs' actual purchase price (the 340B price or a sub-340B price) from the group purchasing organization (GPO) price that

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& Pensions, to Christy Trotter, Chief Exec. Officer, Yakima Valley Farm Workers Clinic (Nov. 16, 2023), https://www.help.senate.gov/imo/media/doc/yakima_workers_clinic_letter.pdf.

[29] Letter from Sen. Bill Cassidy, Ranking Member, S. Comm. on Health, Educ., Lab., & Pensions, to Karen S. Lynch, President & Chief Exec. Officer, CVS Health (Jan. 17, 2024), https://www.help.senate.gov/imo/media/doc/340b_cvs_letter.pdf; Letter from Sen. Bill Cassidy, Ranking Member, S. Comm. on Health, Educ., Lab., & Pensions, to Tim Wentworth, Chief Exec. Officer, Walgreens Boots All. (Jan. 17, 2024), https://www.help.senate.gov/imo/media/doc/340b_walgreens_letter.pdf.

[30] Letter from Sen. Bill Cassidy, Ranking Member, S. Comm. on Health, Educ., Lab., & Pensions, to David A. Ricks, Chair & Chief Exec. Officer, Eli Lilly & Co. (Sept. 23, 2024), https://www.help.senate.gov/imo/media/doc/2024-09-23_letter_from_bc_to_eli_lilly_re_340b_programpdf.pdf; Letter from Sen. Bill Cassidy, Ranking Member, S. Comm. on Health, Educ., Lab., & Pensions, to Robert A. Bradway, Chairman & Chief Exec. Officer, Amgen Inc. (Sept. 23, 2024), https://www.help.senate.gov/imo/media/doc/2024-09-23_letter_from_bc_to_amgen_re_340b_programpdf.pdf.

[31] *Response Letter to Senator Cassidy's Office, J&J Data*, JOHNSON & JOHNSON (Dec. 19, 2024) (on file with Committee).

[32] *E.g.* Katie Thomas & Jessica Silver-Greenberg, *Profits Over Patients: How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits*, N.Y. TIMES (Sept. 27, 2022), https://www.nytimes.com/2022/09/24/health/bon-secours-mercy-health-profit-poor-neighborhood.html; Anna Wilde Mathews et al., *Many Hospitals Get Big Drug Discounts. That Doesn't Mean Markdowns for Patients.*, WALL ST. J. (Dec. 20, 2022), https://www.wsj.com/articles/340b-drug-discounts-hospitals-low-income-federal-program-11671553899.

would have been available at the time if they were not subject to the GPO prohibition by participating in the 340B Program.[33] In other words, this calculation yields a lower 340B savings amount than if savings were calculated based on the drugs' higher WAC price.

The hospitals utilized both "in-house" wholly-owned and entity-owned pharmacies, as well as third-party contract pharmacies to dispense 340B drugs and generate 340B revenue. A wholly-owned pharmacy is owned by the covered entity or its health system, but the pharmacy must be registered with HRSA as a contract pharmacy and must have a written contract with the covered entity to be able to dispense 340B drugs. An entity-owned pharmacy is both owned by, and a legal part of, the covered entity, and the pharmacy address is listed with HRSA as an additional shipping address for the covered entity (if the address differs from the parent site)—it is not registered separately as a contract pharmacy. Because an entity-owned pharmacy is a legal part of the covered entity and not a contract pharmacy, it can avoid the manufacturer restrictions on contract pharmacy use. A third-party contract pharmacy (i.e., CVS and Walgreens) is a for-profit pharmacy that maintains a contract with covered entities to dispense medications to eligible patients of the covered entity on their behalf. Third-party contract pharmacies must be registered with HRSA as a contract pharmacy and can have relationships with thousands of covered entities.

RCH's total 340B benefit (340B savings and revenue) from September 2018 through September 2023 was $276.5 million.[34] RCH realized $232.1 million in savings through physician-administered 340B drug purchases during this time period, with all of its savings coming from its provider-based outpatient infusion centers as opposed to the parent hospital itself.[35] In addition to these savings, RCH also generated $44.4 million in revenue from self-administered 340B drugs dispensed through its wholly-owned pharmacies and third-party contract pharmacies during this time period.[36] Of this pharmacy revenue, 84 percent came from BSMH's wholly-owned retail, specialty, and home delivery pharmacies.[37] The remaining 16 percent was generated through third-party contract pharmacies, with the vast majority of those claims going through Accredo Specialty Pharmacy.[38]

Cleveland Clinic's total 340B benefit from April 2020 through June 2023 was $933.7 million.[39] Cleveland Clinic realized $395.4 million in savings through physician-administered 340B drug purchases during this time period, with 56 percent of these savings coming from its entity-owned pharmacies serving its flagship hospital and 44 percent of these savings coming from its entity-owned and wholly-owned pharmacies at its child sites.[40] In addition to these savings, Cleveland Clinic also generated $538.4 million in revenue from self-administered 340B drugs dispensed

[33] Letter from John M. Starcher, Jr. to Sen. Bill Cassidy, Ranking Member, S. Comm. on Health, Educ., Lab., & Pensions 17 (Nov. 1, 2023) (attached at App. 19) [hereinafter BSMH Nov. 1, 2023 Letter]; Letter from Cleveland Clinic to Sen. Bill Cassidy, Ranking Member, S. Comm. on Health, Educ., Lab., & Pensions 11 (Nov. 17, 2023) (attached at App. 47) [hereinafter Cleveland Clinic Nov. 17, 2023 Letter].
[34] BSMH Nov. 1, 2023 Letter, *supra* note 33; *id.* at exhibits 3, 4 (on file with Committee).
[35] *Id.* at 17 (attached at App. 19), exhibit 3 (on file with Committee). RCH itself actually experienced a $70,058 loss during this time period. *Id.* at exhibit 3 (on file with Committee).
[36] *Id.* at exhibit 4 (on file with Committee).
[37] *Id.*
[38] *Id.*
[39] Cleveland Clinic Nov. 17, 2023 Letter, *supra* note 33, at 12 (attached at App. 48); *id.* at attach. CCF_0001201 (on file with Committee).
[40] *Id.* at attach. CCF_0001201 (on file with Committee).

through its wholly-owned and entity-owned pharmacies, as well as through third-party contract pharmacies during this time period.[41] Of this pharmacy revenue, 52 percent was generated from its wholly-owned and entity-owned retail, specialty, and home delivery pharmacies.[42] The remaining 48 percent of revenue was generated through third-party contract pharmacies.[43]

For RCH, 10 therapeutic classes accounted for 92 percent of its 340B savings from physician-administered drugs, with antineoplastic agents (chemotherapy drugs) alone accounting for 46 percent of the total savings.[44] Regarding specific drugs, Krystexxa accounted for nine percent of RCH's total 340B revenue from physician-administered drugs, and Keytruda and Neulasta each accounted for eight percent.[45] Furthermore, 24 therapeutic classes accounted for 99 percent of its 340B revenue from self-administered drugs, with disease-modifying antirheumatic agents (drugs treating inflammatory diseases) accounting for 51 percent of the total savings and HCV protease inhibitors (Hepatitis C drugs) accounting for 24 percent of the total savings.[46] Regarding specific drugs, drugs with no Healthcare Common Procedure Coding System (HCPCS) code accounted for 58 percent of RCH's total 340B revenue from self-administered drugs, Humira accounted for 16 percent, Enbrel accounted for 11 percent, and Bevacizumab accounted for five percent.[47]

RCH 340B Savings by Top 10 Physician-Administered Drugs		
Drug	**340B Savings**	**Percentage of Total 340B Savings**
Krystexxa	$20,561,661	8.86%
Keytruda	$19,490,887	8.40%
Neulasta	$17,689,750	7.62%
Prolia and Xgeva	$8,682,902	3.74%
Remicade	$7,415,477	3.19%
Opdivo	$6,793,880	2.93%
Herceptin	$6,713,155	2.89%
Stelara	$5,903,879	2.54%
Entyvio	$5,825,456	2.51%
Perjeta	$5,699,873	2.46%

[41] *Id.*
[42] *Id.*
[43] *Id.*
[44] BSMH Nov. 1, 2023 Letter, *supra* note 33, at exhibit 3 (on file with Committee).
[45] *Id.*
[46] *Id.* at exhibit 4 (on file with Committee).
[47] *Id.*

RCH 340B Revenue by Top 10 Self-Administered Drugs		
Drug	**340B Revenue**	**Percentage of Total 340B Revenue**
Drugs with no HCPCS Code	$25,813,605	58.13%
Humira	$7,230,210	16.28%
Enbrel	$5,076,631	11.43%
Bevacizumab	$2,007,527	4.52%
Cabometyx	$986,295	2.22%
Orencia	$825,567	1.86%
Actemra	$608,785	1.37%
Cimzia	$562,905	1.27%
Simponi	$309,714	0.70%
Stelara	$173,589	0.39%

Cleveland Clinic did not provide a breakdown for which therapeutic classes were physician-administered versus self-administered. However, 17 therapeutic classes accounted for 85 percent of its total 340B benefit (340B savings and revenue).[48] Of these therapeutic classes, disease-modifying antirheumatic agents accounted for 21 percent of the 340B benefit, antineoplastic agents accounted for 19 percent, and immunomodulatory agents (immune system stimulant or suppression drugs) accounted for 11 percent.[49] Regarding specific drugs, drugs with no HCPCS code accounted for 35 percent of Cleveland Clinic's total 340B benefit, Humira accounted for 14 percent, Ocrevus accounted for six percent, and Stelara accounted for four percent.[50]

Cleveland Clinic 340B Benefit by Top 10 Drugs		
Drug	**340B Benefit**	**Percentage of Total 340B Benefit**
Drugs with no HCPCS Code	$327,682,268	35.09%
Humira	$126,732,711	13.57%
Ocrevus	$57,109,802	6.12%
Stelara	$40,248,315	4.31%
Keytruda	$39,884,546	4.27%
Neulasta	$28,625,771	3.07%
Tysabri	$22,579,650	2.42%
Entyvio	$21,784,926	2.33%
Ruxience	$21,338,345	2.29%
Prolia	$17,450,221	1.87%

[48] Cleveland Clinic Nov. 17, 2023 Letter, *supra* note 33, at attach. CCF_0001201 (on file with Committee).
[49] *Id.*
[50] *Id.*

2. BSMH and Cleveland Clinic do not pass 340B discounts directly to their patients and differ on how patients receive discounts on their 340B drugs.

In responses to Chairman Cassidy's letter, both BSMH and Cleveland Clinic assert that Congress did not design the 340B Program to provide direct savings to patients.[51] BSMH explained that it "does not directly pass on all savings generated from the 340B [P]rogram to patients at [RCH] in the form of savings on health care expenses," stating that the legislative purpose of the Program is broader.[52] According to BSMH:[53]

> For the reasons noted in our responsive letter, BSMH does not directly pass on all savings generated from the 340B program to patients at Richmond Community Hospital in the form of savings on health care expenses. *Directly reducing patients' drug expenses is not the purpose of the 340B Program,* as reflected in the federal fraud and abuse laws that prohibit copay waivers and other direct cost-sharing subsidies in the absence of an individualized financial need assessment. If 340B acquisition cost pass-through were mandated, we expect that many safety-net providers would be forced to close because they, like RCH use the savings generated by the 340B Program to subsidize the significant broader costs associated with providing high quality health care in a legally compliant manner and implement the 340B Program in a manner that complies with HRSA OPA's expectations.

While BSMH does not directly pass on 340B savings to patients, it does have a financial assistance policy "to help ensure cost isn't a barrier to care."[54] This policy uses a sliding fee scale and presumptive eligibility criteria to provide a discount on care, and it extends to drugs dispensed through BSMH's wholly-owned pharmacies.[55] Under this policy, patients whose income is below 200 percent of the Federal Poverty Level (FPL), and patients who are otherwise presumptively eligible under the criteria, are provided with 100 percent financial assistance.[56] At RCH, patients whose income is between 200 and 400 percent FPL are provided with 76 percent financial assistance, and uninsured and self-pay patients who do not otherwise qualify for financial assistance are provided with 40 percent financial assistance, regardless of income level.[57] BSMH asserts that this policy provides better outcomes for patients than a direct pass-through of the 340B discount because a direct pass-through "would only reduce, and not eliminate, the cost of some drugs."[58]

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[51] However, BSMH provides financial assistance on 340B drugs to some low-income, uninsured patients while Cleveland Clinic does not provide any drug discounts to its patients.
[52] BSMH Nov. 1, 2023 Letter, *supra* note 33, at 16 (attached at App. 18).
[53] *Id.* (emphasis in original).
[54] *Id.* at 2 (attached at App. 4); *id.* at exhibit 1 (on file with Committee).
[55] *Id.* at 7–8 (attached at App. 9–10).
[56] *Id.* at exhibit 1 (on file with Committee).
[57] *Id.*
[58] *Id.* at 2 (attached at App. 4). BSMH states, "[i]t should be noted that this [financial assistance policy] leads to better, more equitable outcomes than a direct pass-through of the 340B discount. Although the 340B discount is substantial, it does not reduce the cost of a drug to $0. RCH's Financial Assistance Policy does for patients who need it." *Id.* at 7–8 (attached at App. 9–10).

Cleveland Clinic similarly explained that it does not pass 340B discounts directly to patients because "there is no dollar-for-dollar 'pass on' requirement to patients under the 340B statute" and the statute "was intentionally left general to provide safety net providers with latitude on how they use their savings in the ever-changing health care industry."[59] Cleveland Clinic stated that it applies its 340B benefit "to the health system's overall operating expenses and revenues in order to offset the cost of providing health care services to the communities [it] serve[s] and to maintain and invest in programs that enhance patient services and access to care."[60]

Cleveland Clinic also has a financial assistance policy available to uninsured patients with income up to 400 percent FPL, but it only covers hospital care and services provided by employed physicians[61]—it does not extend to dispensed drugs like RCH's financial assistance policy does. This policy similarly uses a sliding fee scale and presumptive eligibility criteria to provide a discount on medical care. Uninsured patients whose income is up to 250 percent FPL are provided with 100 percent financial assistance. Uninsured patients whose income is between 251 and 400 percent FPL are provided varying discounts based on income level.[62] While Cleveland Clinic's policy does not cover dispensed drugs, Cleveland Clinic says that it provides "extensive pharmacy-related benefits at minimal to no additional cost to patients or payers," including a patient assistance program that refers patients and providers to programs for free medication, a pharmacy discharge prescription delivery service to process and deliver a patient's discharge prescription to the patient's room to avoid additional trips to the pharmacy, and transitions of care pharmacists to contact high-risk patients post-discharge to perform medication reconciliation, counsel patients, and address medication access barriers.[63]

3. BSMH and Cleveland Clinic do not specifically account for 340B revenue and savings in their operating budgets, but both use their 340B benefit on capital improvement projects and community benefit programs.

Both BSMH and Cleveland Clinic explain that their 340B benefit becomes part of their overall operating budget and they do not specifically account for 340B revenue or savings. However, both hospitals state that the 340B benefit is vital for them to provide indirect benefits to patients through the financial support provided for broader health care initiatives. These include offsetting shortfalls in government reimbursements through Medicare and Medicaid, funding community benefit programs, offering financial assistance, and investing in capital improvements to medical facilities.

BSMH does not allocate or earmark 340B revenue or savings as a unique part of its operating budget, stating that "revenue is revenue, and all revenue is used to pay for expenses incurred in pursuit of our mission."[64] BSMH was therefore unable to provide a detailed breakdown on any direct and indirect patient savings through the 340B Program. However, BSMH stated that "the savings provided by the 340B Program have allowed RCH to remain open, despite operating at a substantial loss for decades" and allow it to make investments in community organizations and

[59] Cleveland Clinic Nov. 17, 2023 Letter, *supra* note 33, at 6 (attached at App. 42).
[60] *Id.*
[61] *Id.* at 3 (attached at App. 39).
[62] *Id.* at attach. CCF_0000026 (on file with Committee).
[63] *Id.* at 8–9 (attached at App. 44–45).
[64] BSMH Nov. 1, 2023 Letter, *supra* note 33, at 23 (attached at App. 25).

supported services that continue to operate at a loss.[65] This includes offsetting shortfalls in Medicare and Medicaid reimbursements, offering financial assistance, investing in capital improvements to medical facilities, and funding community benefit programs. From 2022 through 2023, RCH invested $25.4 million for capital improvements to its medical facilities.[66] Furthermore, from 2019 through 2023, BSMH invested $18.3 million in community benefit programs in the Richmond area, including programs addressing chronic disease, behavioral health, affordable housing, education, and economic equity.[67]

Similarly, Cleveland Clinic states that "[r]egardless of whether the 340B benefit is accrued as a reduced expense (savings) or limited revenue through contract pharmacy, such benefit is not 'spent' by Cleveland Clinic," instead, "reduced pharmaceutical expense and contract pharmacy revenue flow to the Income Statement, like any other expense or revenue, without being independently segregated, distributed or allocated."[68] Cleveland Clinic explains that it uses its 340B revenue and savings to "offset the cost of providing health care services . . . and to maintain and invest in programs that enhance patient services and access to care."[69] For example, Cleveland Clinic says that 340B revenue and savings assisted the hospital in offsetting $1.7 billion in unpaid care in 2022 and contributed to the hundreds of millions of dollars it spends annually on subsidizing health services, community health improvement, medical education, and medical research.[70] The hospital also invested $1.05 billion in capital improvements from 2020 through 2024, with 55 percent of this investment associated with its Main Campus hospital (which is its 340B parent site).[71] Furthermore, Cleveland Clinic invested tens of millions of dollars in community benefit programs from 2019 through 2022, including programs addressing safe housing, mental health treatment and recovery, access to food, local job creation, and education.[72]

B. FQHC Covered Entities

On November 16, 2023, Chairman Cassidy continued his investigation into the 340B Program and sent letters to Sun River Health (Sun River) and Yakima Valley Farm Workers Clinic (Yakima Valley or Yakima) regarding the FQHCs' participation in the 340B Program and how patients benefit from it. These FQHCs were selected for this investigation because each are one of the top 10 largest FQHCs in the United States that provide primary care services to medically underserved populations, regardless of their ability to pay, as required by law.[73]

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[65] *Id.* at 1–2, 8 (attached at App. 3–4, 10).
[66] *Id.* at exhibit 7 (on file with Committee).
[67] *Id.* at exhibit 5 (on file with Committee).
[68] Cleveland Clinic Nov. 17, 2023 Letter, *supra* note 33, at 6 (attached at App. 42).
[69] *Id.*
[70] *Id.* at 7 (attached at App. 43). This unpaid care includes $109 million in incurred costs for which the hospital never received payment, $1.4 billion in Medicare and Medicaid reimbursement shortfalls, and $212 million in financial assistance to patients (charity care). *Id.*
[71] *Id.* at 9 (attached at App. 45).
[72] *Id.* at 7–8 (attached at App. 43–44).
[73] Yakima Valley was also specifically selected based on a Definitive Healthcare report from April 2023 that ranked Yakima as having the highest compensation among all FQHCs in the nation. Letter from Sen. Bill Cassidy, Ranking Member, S. Comm. on Health, Educ., Lab., & Pensions, to Christy Trotter, Chief Exec. Officer, Yakima Valley Farm Workers Clinic 2 (Nov. 16, 2023), https://www.help.senate.gov/imo/media/doc/yakima_workers_clinic_letter.pdf. In Yakima's response to Chairman Cassidy, it argued that Definitive Healthcare's data was "grossly inaccurate." Letter from Christy Trotter, Chief Exec. Officer, Yakima Valley Farm Workers Clinic, to Sen. Bill

1. Sun River and Yakima Valley generated significant revenue from the 340B Program with a few therapeutic drug classes accounting for a majority of this revenue.

Based on written responses and the accompanying documents produced pursuant to Chairman Cassidy's investigation, both FQHCs generated significant revenue from the 340B Program, driven primarily by a few therapeutic classes of drugs. The data highlights differences in revenue earnings of Sun River and Yakima under the 340B Program, including differences in patient populations and health care needs.

From January 2019 through December 2022, Sun River reports that it generated $37.4 million in net 340B revenue from self-administered drugs dispensed through third-party contract pharmacies.[74] However, Sun River did not provide information as to how it calculated its net revenue. According to its financial statements, Sun River's gross 340B revenue generated over this time period was $105.1 million.[75] HIV/AIDS therapy drugs accounted for the largest amount of 340B revenue, totaling 54 percent of revenue during this time period.[76] Non-insulin hypoglycemic agents to treat Type 2 diabetes were the second largest revenue source, totaling 13 percent of revenue.[77] Miscellaneous antivirals, including hepatitis C virus (HCV) drugs, ranked third, representing 10 percent of revenue, while miscellaneous antipsychotics were the fourth highest, accounting for nine percent.[78] Furthermore, three of Sun River's 30 clinic locations generated 50 to 56 percent of its 340B revenue each year during this time period.[79]

Cassidy, Ranking Member, S. Comm. on Health, Educ., Lab., & Pensions 4–5 (Jan. 22, 2024) (attached at App. 74–75). Definitive Healthcare later confirmed that it inadvertently inflated Yakima's compensation due to miscalculations and removed the data from its website. *Id.* at app. B (on file with Committee). Yakima also produced its IRS Form 990 from 2021, which confirmed that its compensation was $167.2 million, well lower than the $1.5 billion reported by Definitive Healthcare. *Id.* at app. C (on file with Committee).

[74] Letter from Anne K. Nolan, Chief Exec. Officer, Sun River Health, to Sen. Bill Cassidy, Ranking Member, S. Comm. on Health, Educ., Lab., & Pensions, at attach. B (Jan. 31, 2024) (on file with Committee) [hereinafter Sun River Jan. 31, 2024 Letter].

[75] *See Sun River Health, Inc. and Subsidiaries (formerly known as Hudson River Healthcare, Inc. and Subsidiaries) Consolidated Financial Statements*, COHNREZNICK (Dec. 31, 2022), https://projects.propublica.org/nonprofits/display_audit/20246820221 ($22,859,447 in 340B pharmacy revenue); *Hudson River HealthCare, Inc. (d/b/a Sun River Health) and Subsidiaries Consolidated Financial Statements*, COHNREZNICK (Dec. 31, 2021), https://projects.propublica.org/nonprofits/display_audit/20246820211 ($25,177,338 in 340B pharmacy revenue); *Hudson River HealthCare, Inc. (d/b/a Sun River Health) and Subsidiaries Consolidated Financial Statements*, COHNREZNICK (Dec. 31, 2020), https://projects.propublica.org/nonprofits/display_audit/20246820203 ($29,089,955 in 340B pharmacy revenue); *Hudson River HealthCare, Inc. and Subsidiaries Consolidated Financial Statements*, COHNREZNICK (Dec. 31, 2019), https://projects.propublica.org/nonprofits/display_audit/20246820191 ($27,949,267 in 340B pharmacy revenue).

[76] Sun River Jan. 31, 2024 Letter, *supra* note 74, at attach. B (on file with Committee).

[77] *Id.*

[78] *Id.*

[79] *Id.* These clinic locations were: Inwood Health Center in Bronx, NY; 75 Washington A28 in Poughkeepsie, NY; and Sutphin Health Center in Queens, NY. *Id.*

Sun River 340B Revenue by Top 10 Therapeutic Classes		
Therapeutic Class	**340B Revenue**	**Percentage of Total 340B Revenue**
HIV/AIDS Therapy	$20,288,239	54.25%
Non-Insulin Hypoglycemic Agents	$4,955,896	13.25%
Miscellaneous Antivirals	$3,661,215	9.79%
Miscellaneous Antipsychotics	$3,271,944	8.75%
Miscellaneous Pulmonary Agents	$2,475,853	6.62%
Insulin Therapy	$1,959,263	5.24%
Narcotic Antagonists	$1,296,203	3.47%
Anticoagulants	$846,141	2.26%
Smoking Deterrents	$392,300	1.05%
Inhaled Corticosteroids	$373,304	1.00%

Between August 2020 and December 2023, Yakima Valley generated $146.1 million in 340B revenue net of dispensing fees and administrative fees paid to contract pharmacies from self-administered drugs dispensed through its closed-door entity-owned pharmacies and third-party contract pharmacies.[80] Antidiabetics, including insulins, were its the leading 340B revenue generator, accounting for 45 percent of revenue during this time period.[81] Anti-asthmatic and bronchodilator agents were the second highest, contributing 11 percent of revenue.[82] Antivirals, likely including HCV drugs, and anti-inflammatory analgesics (painkillers) followed, each totaling seven percent of revenue.[83] Yakima did not provide a breakdown of 340B revenue by clinic location.

Yakima Valley 340B Revenue by Top 10 Therapeutic Classes		
Therapeutic Class	**340B Revenue**	**Percentage of Total 340B Revenue**
Antidiabetics	$63,157,555	44.98%
Antiasthmatic and Bronchodilator Agents	$15,196,793	10.82%
Antivirals	$10,605,959	7.55%
Analgesics - Anti-Inflammatory	$10,375,494	7.39%
Anticoagulants	$6,152,037	4.38%
Dermatologicals	$4,324,561	3.08%
ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants	$1,919,120	1.37%
Antipsychotics/Antimanic Agents	$1,841,966	1.31%
Anticonvulsants	$1,563,286	1.11%
Psychotherapeutic and Neurological Agents	$1,546,520	1.10%

[80] Letter from Christy Trotter, Chief Exec. Officer, Yakima Valley Farm Workers Clinic, to Sen. Bill Cassidy, Ranking Member, S. Comm. on Health, Educ., Lab., & Pensions, 7-8 (Jan. 22, 2024) (on file with Committee) [hereinafter Yakima Valley Jan. 22, 2024 Letter].
[81] *Id.* at app. D (on file with Committee).
[82] *Id.*
[83] *Id.*

2. Sun River exclusively uses contract pharmacies to dispense 340B drugs, while Yakima Valley relies almost entirely on its closed-door entity-owned pharmacies, demonstrating a key difference in how FQHCs utilize contract pharmacies.

Sun River exclusively uses third-party contract pharmacies to dispense 340B drugs to its patients, while Yakima Valley relies almost entirely on its closed-door entity-owned pharmacies, which the latter says is "somewhat unique" amongst FQHCs.

Sun River exclusively uses third-party contract pharmacies to dispense 340B drugs and does not have any entity-owned or wholly-owned pharmacies.[84] Three contract pharmacies—Paramount Pharmacy, Maxor Pharmacy, and Walgreens—consistently accounted for 64 to 68 percent of Sun River's 340B revenue each year.[85] Sun River states that its "contracting approach ensures that dispensing fees across all contracts, geographies, and populations are reasonable and within the industry standard," and that in 2022, its "average dispensing fee across all independent pharmacies was $27 per prescription."[86]

By contrast, Yakima Valley relies minimally on third-party contract pharmacies and generates its 340B revenue primarily from its 13 closed-door entity-owned retail pharmacies.[87] To illustrate, Yakima's "contract pharmacy relationships only account for 4% of the total [340B] funds generated."[88] Among its contract pharmacy-generated 340B revenue, however, it is similar to Sun River in that three contract pharmacies—Walgreens, Safeway, and Rite-Aid—accounted for 66 percent of this revenue each year.[89] Yakima notes that it is "somewhat unique in that it does not rely heavily on contract pharmacies to reach its patients" and says that it uses contract pharmacies to "expand access to care for its patients when patient choice, location, or payor policies dictate that prescriptions are filled at non-[Yakima] pharmacies."[90] Yakima also highlighted challenges arising from vertical integration among health insurers, pharmacy benefit managers (PBMs), and third-party administrators (TPAs), which have resulted in "an increasing amount of prescriptions that [Yakima] cannot fill in-house due to payor-imposed restrictions, as well as changes to fee structures."[91]

3. Sun River and Yakima Valley both leverage 340B revenue to provide significant discounts on 340B drugs but have notable differences in their drug discount programs.

Sun River and Yakima Valley both leverage revenue from the 340B Program to provide significant discounts to patients on 340B drugs. Both FQHCs provide some patients a discount on 340B drugs based on a sliding fee scale in addition to the sliding fee scale they are required by law to provide for medical services, but the price paid by patients varies between the two. Sun River and Yakima

[84] Sun River Jan. 31, 2024 Letter, *supra* note 74, at attach. B (on file with Committee).
[85] *Id.*
[86] *Id.* at 2 (attached at App. 68).
[87] Yakima Valley Jan. 22, 2024 Letter, *supra* note 80, at 8 (attached at App. 78).
[88] *Id.*
[89] *Id.* at 7–8 (attached at App. 77–78).
[90] *Id.* at 3, 8 (attached at App. 73, 78).
[91] *Id.* at 3 (attached at App. 73).

also have different policies for when their sliding fee scale discounts apply, and Sun River has additional discount programs for uninsured patients.

In 2022, 97 percent of Sun River's patients had incomes below 200 percent FPL and 23 percent of its patients were uninsured.[92] Sun River provides two primary programs for uninsured patients to receive free or low-cost 340B drugs: (1) its Walgreens Uninsured Program and (2) its ProAct Uninsured Program.[93] In addition to these two programs, Sun River also has a Patient Assistance Program, which is available to all patients who face significant barriers to accessing their medications, regardless of insurance status, that further subsidizes prescriptions based on recommendations from its medical providers.[94] Sun River notes that Medicaid beneficiaries "consistently access low-cost medications" through the state Medicaid program, but Sun River no longer participates in the 340B Program as it pertains to Medicaid since the State of New York changed its Medicaid pharmacy program to a fee for service program in 2023.[95]

Sun River's Walgreens Uninsured Program allows uninsured patients who fill their prescription at a contracted Walgreens pharmacy to access 340B drugs at "the 340B acquisition cost plus a nominal administrative fee and dispensing fee."[96] According to Sun River's pharmacy services agreement with Walgreens, the administrative fee is $0.50 and the dispensing fee is $15.[97] Sun River reports that between 2019 and 2022, the Walgreens Uninsured Program provided its patients with $19.5 million in savings off the retail price of the drug.[98] Sun River's ProAct Uninsured Program allows uninsured patients who fill their prescription at participating contract pharmacies to access 340B drugs "on a sliding fee scale with discounts from the negotiated rate based on their federal poverty level and subsidized by Sun River," with a maximum subsidy of $250 per prescription.[99] The sliding fee scale applies to uninsured patients whose income is 200 percent FPL and below.[100] Patients with income at or below 200 percent FPL who cannot afford to pay the amount calculated can be referred to the Patient Assistance Program.[101] Uninsured patients over

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[92] Letter from Anne K. Nolan, Chief Exec. Officer, Sun River Health, to Sen. Bill Cassidy, Ranking Member, S. Comm. on Health, Educ., Lab., & Pensions 7 (Dec. 22, 2023) (attached at App. 61) [hereinafter Sun River Dec. 22, 2023 Letter].
[93] *Id.* at 8 (attached at App. 62).
[94] *Id.* at 4 (attached at App. 58).
[95] *Id.* at 1, 8 (attached at App. 55, 62).
[96] *Id.* at 8 (attached at App. 62). Sun River notes that if the 340B price plus the fee exceeds the Walgreens retail price for the drug, the patient is billed the lowest possible price. *Id.* According to its pharmacy services agreement with Walgreens, dated March 1, 2011, uninsured patients pay the 340B acquisition cost plus a $0.50 administrative fee and a $15 dispensing fee for each prescription filled. Letter from Timothy C. Wentworth, Chief Exec. Officer, Walgreens Boots All., Inc., to Sen. Bill Cassidy, Chairman, S. Comm. on Health, Educ., Lab., & Pensions, at attach. WLGRN-HELP-00000039 (Jan. 16, 2025) (on file with Committee).
[97] Letter from Timothy C. Wentworth, Chief Exec. Officer, Walgreens Boots Alliance, Inc., to Sen. Bill Cassidy, Chairman, S. Comm. on Health, Educ., Lab., & Pensions, at attach. WLGRN-HELP-00000039 (Jan. 16, 2025) (on file with Committee).
[98] Sun River Dec. 22, 2023 Letter, *supra* note 92, at 4 (attached at App. 58).
[99] *Id.* at 3 (attached at App. 57). The sliding fee scale discount is as follows: patients below 100 percent FPL pay a $5 copay for generic drugs and a $15 copay for brand drugs, patients between 101 and 133 percent FPL pay a 25 percent copay for both generic and brand drugs, patients between 134 and 168 percent FPL pay a 50 percent copay for both generic and brand drugs, and patients between 169 and 200 percent FPL pay a 75 percent copay for both generic and brand drugs. All of these copays are capped at $250 per prescription. *Id.*
[100] *Id.*
[101] *Id.*

200 percent FPL are "able to access medications at the group purchasing rate that ProAct has negotiated which is below the standard medication price."[102] Sun River reports that between 2019 and 2022, the ProAct Uninsured Program provided its patients with $1.4 million in savings off the retail price of the drug.[103] Sun River's Patient Assistance Program provided its patients with $64,139 in savings off the retail price of the drug during this time period.[104]

Sun River Drug Discount Programs				
Program	**Available To**	**Drug Discount**		
Walgreens Uninsured Program	Uninsured patients filling prescriptions at Walgreens pharmacies	Patient pays the 340B acquisition cost, plus a $0.50 administrative fee and a $15 dispensing fee		
ProAct Uninsured Program	Uninsured patients filling prescriptions at participating contract pharmacies	Sliding fee scale discount with a maximum subsidy of $250 per prescription:	Generic Copay	Brand Copay
		At or below 100% FPL	$5	$15
		101-133% FPL	25%	25%
		134-168% FPL	50%	50%
		169-200% FPL	75%	75%
		Over 200% FPL	100%	100%
Patient Assistance Program	All patients facing significant barriers to accessing medications, regardless of insurance status	Subsidized prescriptions based on recommendations from Sun River medical providers		

In 2022, 90 percent of Yakima Valley's patients had incomes below 200 percent FPL and 12 percent of its patients were uninsured.[105] Yakima Valley uses a sliding fee scale to provide discounts on 340B drugs for both insured and uninsured patients at its entity-owned pharmacies.[106] The sliding fee discount is available to qualifying uninsured and underinsured patients, and can be used by insured patients for a discount applied to any deductible or coinsurance amount not covered by their insurance, but cannot be applied to a copayment amount.[107] The sliding fee scale applies to all patients whose income is 200 percent FPL and below.[108] Depending on their income level, these patients pay a $2 to $5 fee plus the 340B acquisition cost, however the policy notes that "inability to pay at time of service will not prevent the patient from receiving the medication."[109] Patients whose income is above 200 percent FPL do not receive any discount on their 340B drugs.[110] Yakima reports that between 2019 and 2023, the sliding fee scale provided its patients with $51.6 million in savings off the retail price of self-administered drugs dispensed at its entity-owned pharmacies, which amounted to an average savings rate of 92 percent.[111] In addition, while Yakima did not disclose having an Uninsured Program with Walgreens like Sun River, its pharmacy services agreement with Walgreens similarly provides that self-pay patients

[102] *Id.* at 3–4 (attached at App. 57–58).
[103] *Id.* at 4 (attached at App. 58).
[104] *Id.*
[105] Yakima Valley Jan. 22, 2024 Letter, *supra* note 80, at 9, 13 (attached at App. 79, 83).
[106] *Id.* at 3 (attached at App. 73).
[107] *Id.* at app. H (on file with Committee).
[108] *Id.*
[109] *Id.*
[110] *Id.*
[111] *Id.* at app. E (on file with Committee).

(including uninsured patients) also pay the 340B price of the drug along with a $0.50 administrative fee and $13 dispensing fee at the pharmacy.[112]

Yakima Valley Drug Discount Programs			
Program	**Available To**	**Drug Discount**	
Sliding Fee Scale Discount	Insured, underinsured, or uninsured patients at or below 200% FPL at Yakima pharmacies	Sliding fee scale discount:	All Drugs
		At or below 100% FPL	$2 fee plus 340B acquisition cost
		101-150% FPL	$3 fee plus 340B acquisition cost
		151-180% FPL	$4 fee plus 340B acquisition cost
		181-200% FPL	$5 fee plus 340B acquisition cost
		Over 200% FPL	No discount
Walgreens Agreement	Self-pay patients filling prescriptions at Walgreens pharmacies	Patient pays the 340B acquisition cost, plus a $0.50 administrative fee and a $13 dispensing fee	

C. Contract Pharmacies and Third-Party Administrators

On January 17, 2024, Chairman Cassidy sent letters to CVS Health and Walgreens to understand how these companies generate revenue from the 340B Program either as a contract pharmacy or as a TPA. These companies were selected because they represent the two largest contract pharmacy participants based on the total number of relationships with 340B covered entities (as of 2023).[113] After both companies initially refused to provide all of the requested information, Chairman Cassidy sent their CEOs a private letter demanding production of the requested records by December 20, 2024.[114]

Following extended negotiations, both CVS Health and Walgreens agreed to produce copies of their 340B contract pharmacy services agreements with Cleveland Clinic, Sun River, and Yakima Valley to Chairman Cassidy in January 2025.

The agreements detail the terms of pharmacy services provided by retail, specialty, and mail service pharmacies; additional services elected by covered entities; and administrative services provided by TPAs. The agreements' provisions address operational procedures for drug

[112] Letter from Timothy C. Wentworth, Chief Exec. Officer, Walgreens Boots All., Inc., to Sen. Bill Cassidy, Chairman, S. Comm. on Health, Educ., Lab., & Pensions, at attach. WLGRN-HELP-00000059 (Jan. 16, 2025) (on file with Committee).
[113] Adam J. 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.
[114] Letter from Sen. Bill Cassidy, Ranking Member, S. Comm. on Health, Educ., Lab., & Pensions, to David Joyner, Chief Exec. Officer, CVS Health (Nov. 21, 2024) (attached at App. 102–03); Letter from Sen. Bill Cassidy, Ranking Member, S. Comm. on Health, Educ., Lab., & Pensions, to Tim Wentworth, Chief Exec. Officer, Walgreens Boots All., Inc. (Nov. 21, 2024) (attached at App. 114–15).

purchasing, title, shipment, and billing; patient and covered entity 340B Program eligibility determinations; pharmacy dispensing and fees; administrative services and fees; inventory tracking, replenishment, and fees; claims processing, invoices, payments, and financial reconciliation; regulatory compliance, recordkeeping, audits, and inspections; and confidentiality and reporting requirements, among other terms.

1. CVS Health and Walgreens charge a complex range of fees for pharmacy services to covered entities that generally increase each year.

According to the pharmacy services agreements produced, CVS Health and Walgreens charge varying types of complex fees for pharmacy and administrative services to covered entities under the 340B Program. These fees vary by payment source (i.e., third-party insurer or self-pay), pharmacy category (i.e., retail, specialty, or mail-order), type and amount of drug (i.e., brand, generic, or specialty, and number of days), and method of calculation (i.e., set amount, percentage of reimbursement, or a combination). A breakdown of CVS Health and Walgreens's dispensing fees with Cleveland Clinic, Sun River, and Yakima Valley follows, along with a chart to visualize this data at the end of the section.

CVS Health – Cleveland Clinic

In January 2021, CVS Health entered into a pharmacy services agreement with Cleveland Clinic.[115] The agreement establishes three separate contract pharmacy arrangements with the company's retail, specialty, and mail service pharmacy divisions.[116]

Under its terms, CVS provides retail pharmacy services to 340B eligible patients in exchange for dispensing fees on brand drugs at its retail pharmacies, covering insured and non-insured patients.[117] For patients with third-party prescription insurance coverage, the dispensing fee for brand drugs is $35 for a 1-30 day supply, $60 for a 31-60 day supply, and $85 for a 61-90 day supply.[118] For patients without third-party prescription insurance coverage, the dispensing fee for brand drugs is $15.[119] There is no dispensing fee listed for generic drugs for these patients.[120]

The agreement provides for mandatory annual increases in the retail pharmacy dispensing fee between 0.5 and five percent each year based on increases in the Medical Care Commodities Index (CPI-U-MCC).[121] It also incorporates direct and indirect remuneration (DIR) fees in the retail pharmacy dispensing fee, based on the retail pharmacy's agreements with third-party payers. It provides that the dispensing fee may be increased each year in an amount commensurate with the increase in DIR fees if the DIR fees increased by 25 percent or more the previous year.[122]

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[115] Letter from CVS Health to Sen. Bill Cassidy, Chairman, S. Comm. on Health, Educ., Lab., & Pensions, at attach. CVS000102 to CVS000161 (Jan. 16, 2025) (on file with Committee) [hereinafter CVS Jan. 16, 2025 Letter].
[116] *Id.* at attach. CVS000102 (on file with Committee).
[117] *Id.* at attach. CVS000118 (on file with Committee).
[118] *Id.*
[119] *Id.*
[120] *Id.* at attach. CVS000119 (on file with Committee).
[121] *Id.* at attach. CVS000118 (on file with Committee).
[122] *Id.*

For specialty pharmacies, the agreement only covers "Branded Drugs dispensed to patients who are covered by payers included in Pharmacy Services by Specialty Pharmacy,"[123] and the agreement provides that the dispensing fee is 13 percent of the negotiated reimbursement rate with the third-party payer for insured patients.[124] For patients whose reimbursement is paid under a medical benefits plan or certain direct-contract payers, the dispensing fee is a "Specialty Pharmacy-determined rate."[125] Unlike the retail pharmacy agreement, there is no provision for the dispensing fee for specialty pharmacies to increase annually.[126]

The mail service pharmacy agreement only covers drugs "which are included on the 340B Mail Formulary dispensed to patients who are covered by payers included in Pharmacy Services by Mail Service Pharmacy,"[127] and the agreement provides that the dispensing fee is $35 for a 1-30 day supply of drugs, $60 for a 31-60 day supply, and $85 for a 61-90 day supply.[128] This dispensing fee, like the retail pharmacy dispensing fee, also must increase annually based on the CPI-U-MCC, and, in contrast to the retail pharmacy dispensing fee, there is no cap on the fee increase.[129]

The agreement also specifically requires Cleveland Clinic to use a CVS Health subsidiary, Wellpartner, LLC, as its 340B administrative services provider (TPA) for contract pharmacy services for 340B transactions at CVS pharmacies and to pay related administrative fees, adding another layer of revenue for the parent pharmacy company (CVS).[130] The agreement further entitles Wellpartner to receive separate/additional payments from Cleveland Clinic for optional services beyond those specified in the base agreement.[131]

Walgreens – Cleveland Clinic

Walgreens executed a pharmacy services agreement with Cleveland Clinic on April 1, 2020, which provides for retail and specialty pharmacy services to 340B eligible patients.[132]

Walgreens sets the same schedule of dispensing fees for self-pay and private insurer patients for its retail pharmacies and the agreement covers both brand drugs and generic drugs.[133] For both self-pay patients and patients with private insurance at retail pharmacies, there is a $15 dispensing fee for each 340B transaction for both brand and generic drugs.[134]

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[123] *Id.* at attach. CVS000127 (on file with Committee) (internal quotations omitted).
[124] *Id.* at attach. CVS000126 (on file with Committee).
[125] *Id.*
[126] *Id.* at attach. CVS000126 (on file with Committee).
[127] *Id.* at attach. CVS000136 (on file with Committee).
[128] *Id.* at attach. CVS000135 (on file with Committee).
[129] *Id.*
[130] *Id.* at attach. CVS000103 (on file with Committee).
[131] *Id.* at attach. CVS000141 to CVS000150 (on file with Committee).
[132] Letter from Timothy C. Wentworth, Chief Exec. Officer, Walgreens Boots All., Inc., to Sen. Bill Cassidy, Chairman, S. Comm. on Health, Educ., Lab., & Pensions, at attach. WLGRN-HELP-00000001 to WLGRN-HELP-00000024 (Jan. 16, 2025) (on file with Committee) [hereinafter Walgreens Jan. 16, 2025 Letter].
[133] *Id.* at attach. WLGRN-HELP-00000017 (on file with Committee).
[134] *Id.*

The specialty pharmacy agreement only covers patients with private insurance.[135] For patients with private insurance at specialty pharmacies, there is a $65 dispensing fee.[136]

All of the dispensing fees for retail and specialty pharmacies are indexed to increase annually based on the then-current Consumer Price Index-All Urban Consumers, All Items for the region where the covered entity is located.[137]

CVS Health – Sun River

On April 17, 2023, CVS Health entered into a pharmacy services agreement with Sun River.[138] The agreement establishes three separate contract pharmacy arrangements with the company's retail, specialty, and mail service pharmacy divisions.[139]

CVS sets a separate schedule of dispensing fees for self-pay and private insurer patients for its retail pharmacies.[140] Similar to its agreement with Cleveland Clinic, the dispensing fees at retail pharmacies for brand name drugs for patients with third-party prescription insurance are $35 for a 1-30 day supply, $60 for a 31-60 day supply, and $85 for a 61+ day supply.[141] There is no dispensing fee listed for generic drugs for insured patients.[142] For patients without third-party prescription insurance, the dispensing fee for each brand name, multi-source, or generic drug is $15.[143]

Also similar to its agreement with Cleveland Clinic, the specialty pharmacy agreement only covers "Branded Drugs dispensed to patients who are covered by payers included in Pharmacy Services by Specialty Pharmacy,"[144] and the dispensing fee at specialty pharmacies is 13 percent of the negotiated reimbursement rate with the third-party payer for insured patients.[145] For patients whose reimbursement is paid under a medical benefits plan or certain direct-contract payers, the dispensing fee is a "Specialty Pharmacy-determined rate."[146]

The mail service pharmacy agreement, like the agreement with Cleveland Clinic, only covers drugs "which are included on the 340B Mail Formulary dispensed to patients who are covered by payers included in Pharmacy Services by Mail Service Pharmacy,"[147] and the agreement provides that the dispensing fee is $35 for a 1-30 day supply of drugs, $60 for a 31-60 day supply, and $85 for a 61+ day supply.[148]

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[135] *Id.* at attach. WLGRN-HELP-00000009 (on file with Committee).
[136] *Id.* at attach. WLGRN-HELP-00000017 to WLGRN-HELP-00000018 (on file with Committee).
[137] *Id.* at attach. WLGRN-HELP-00000018 (on file with Committee).
[138] CVS Jan. 16, 2025 Letter, *supra* note 114, at attach. CVS000003 to CVS000064 (on file with Committee).
[139] *Id.*
[140] *Id.* at attach. CVS000019 (on file with Committee).
[141] *Id.*
[142] *Id.*
[143] *Id.*
[144] *Id.* at attach. CVS000029 (on file with Committee) (internal quotations omitted).
[145] *Id.* at attach. CVS000028 (on file with Committee).
[146] *Id.*
[147] *Id.* at attach. CVS000040 (on file with Committee).
[148] *Id.* at attach. CVS000039 (on file with Committee).

CVS's agreement with Sun River provides for an optional annual increase in all of these dispensing fees based on increases to the CPI-U-MCC, increases to DIR fees, or "a significant change in drug mix or average day supply."[149] There is no cap on the annual fee increase.[150] This is a notable difference from CVS's agreement with Cleveland Clinic, which provided for a mandatory dispensing fee increase for both retail and mail service pharmacies.

Like its agreements with Cleveland Clinic, the agreement also specifically requires Sun River to use CVS's Wellpartner (a TPA) as its 340B administrative services provider for CVS contract pharmacy services and to pay related administrative fees.[151] The agreement further entitles Wellpartner to receive separate/additional payments from Sun River for optional services beyond those specified in the base agreement.[152]

Walgreens – Sun River

On March 1, 2011, Walgreens entered into a pharmacy services agreement with Hudson River Health Care, Inc. (which is now Sun River).[153] The agreement provides for retail pharmacy services to 340B eligible patients. Like its agreement with Cleveland Clinic, Walgreens sets the same schedule of dispensing fees for self-pay and privately insured patients.[154]

For both self-pay and privately insured patients, there is a dispensing fee of $15 per 340B prescription for both brand and generic drugs.[155] Self-pay patients must also pay the 340B price of the drug at the pharmacy, pursuant to Walgreens's Uninsured Program with Sun River Health.[156] However, Walgreens only retains the dispensing and administrative fees and remits the payment for the 340B drug itself back to Sun River.[157] Unlike its agreement with Cleveland Clinic, there is no provision for the dispensing fees to increase annually.

CVS Health – Yakima Valley

On March 31, 2021, CVS Health entered into a pharmacy services agreement with Yakima Valley.[158] The agreement establishes two separate contract pharmacy arrangements with the company's "Careplus" retail pharmacy and its specialty pharmacy divisions.[159] Careplus is a retail specialty pharmacy that is distinct from CVS's Specialty Pharmacy. This agreement did not originally contain mail service pharmacy services.

[149] *Id.* at attach. CVS000019, CVS000028, CVS000039 (on file with Committee).
[150] *Id.*
[151] *Id.* at attach. CVS000004 (on file with Committee).
[152] *Id.* at attach. CVS000045 to CVS000054 (on file with Committee).
[153] Walgreens Jan. 16, 2025 Letter, *supra* note 131, at attach. WLGRN-HELP-00000025 to WLGRN-HELP-00000043 (on file with Committee).
[154] *Id.* at attach. WLGRN-HELP-00000039 (on file with Committee).
[155] *Id.*
[156] *Id.*
[157] *Id.*
[158] CVS Jan. 16, 2025 Letter, *supra* note 114, at attach. CVS000231 to CVS000281 (on file with Committee).
[159] *Id.*

Under the agreement, the dispensing fee for Careplus retail pharmacy services for patients with third-party prescription insurance is 13 percent of the contracted reimbursement rate with a $35 minimum for each prescription.[160] There is no dispensing fee listed for any drugs for uninsured patients.[161]

The specialty pharmacy services agreement, like CVS's agreements with Cleveland Clinic and Sun River, only covers "Branded Drugs dispensed to patients who are covered by payers included in Pharmacy Services by Specialty Pharmacy,"[162] and the dispensing fee at specialty pharmacies is 14 percent of the negotiated reimbursement rate with the third-party payer for insured patients.[163] For patients whose reimbursement is paid under a medical benefits plan or certain direct-contract payers, the dispensing fee is a "Specialty Pharmacy-determined rate."[164]

On April 14, 2022, CVS Health and Yakima Valley agreed to an amendment to the aforementioned pharmacy services agreement which added two additional contract pharmacy arrangements with CVS's retail pharmacy and mail service pharmacy divisions.[165]

Under the amended agreement, unlike its agreements with Cleveland Clinic and Sun River, CVS charges the same dispensing fee for both private insurer and self-pay patients.[166] For brand drugs, the dispensing fee at retail pharmacies for both private insurer and self-pay patients is $35 for a 1-30 day supply, $60 for a 31-60 day supply, and $85 for a 61+ day supply.[167] There is no dispensing fee listed for generic drugs.[168] The Careplus dispensing fees remained the same as listed above.[169]

Also under the amended agreement, the mail service pharmacy agreement only covers drugs "which are included on the 340B Mail Formulary dispensed to patients who are covered by payers included in Pharmacy Services by Mail Service Pharmacy,"[170] and the agreement provides that the dispensing fee is $35 for a 1-30 day supply of drugs, $60 for a 31-60 day supply, and $85 for a 61+ day supply.[171] These provisions are the same as CVS's mail service pharmacy agreements with Cleveland Clinic and Sun River.

Like its agreement with Sun River, CVS's agreement with Yakima Valley provides for an optional annual increase in all of these dispensing fees based on increases to the CPI-U-MCC, increases to DIR fees, or "a significant change in drug mix or average day supply."[172] There is no cap on the annual fee increase.[173]

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[160] *Id.* at attach. CVS000245 (on file with Committee).
[161] *Id.* at attach. CVS000245 (on file with Committee).
[162] *Id.* at attach. CVS000255 (on file with Committee) (internal quotations omitted).
[163] *Id.* at attach. CVS000254 (on file with Committee).
[164] *Id.*
[165] *Id.* at attach. CVS000285 to CVS000298 (on file with Committee).
[166] *Id.* at attach. CVS000290 (on file with Committee).
[167] *Id.*
[168] *Id.*
[169] *Id.*
[170] *Id.* at attach. CVS000295 (on file with Committee).
[171] *Id.* at attach. CVS000294 (on file with Committee).
[172] *Id.* at attach. CVS000245, CVS000254 (on file with Committee).
[173] *Id.*

Also like its agreements with Cleveland Clinic and Sun River, CVS's agreement with Yakima Valley specifically requires Yakima to use CVS's Wellpartner (a TPA) as its 340B administrative services provider for CVS contract pharmacy services and to pay related administrative fees.[174] The agreement further entitles Wellpartner to receive separate/additional payments from Yakima Valley for optional services beyond those specified in the base agreement.[175]

Walgreens – Yakima Valley

On April 1, 2023, Walgreens entered into a pharmacy services agreement with Yakima Valley to establish a contract pharmacy arrangement with the company's retail pharmacies.[176] Like its agreements with Cleveland Clinic and Sun River, Walgreens sets the same schedule of dispensing fees for self-pay and privately insured patients.[177]

For both self-pay and private insurer patients, there is a dispensing fee of $13 per 340B prescription for both brand and generic drugs,[178] which is $2 lower than the dispensing fee charged to Cleveland Clinic and Sun River. However, even though Yakima Valley did not disclose having an Uninsured Program with Walgreens like Sun River did, its agreement with Walgreens similarly provides that self-pay patients must also pay the 340B price of the drug plus dispensing and administrative fees at the pharmacy.[179] Like its agreement with Sun River, Walgreens only retains the dispensing and administrative fees and remits the payment for the 340B drug back to Yakima Valley.[180] There is no provision for the dispensing fees to increase annually, but the agreement does state that the dispensing fees can be increased with mutual agreement by both parties.[181]

[174] *Id.* at attach. CVS000232 (on file with Committee).
[175] *Id.* at attach. CVS000261 to CVS000270 (on file with Committee).
[176] Walgreens Jan. 16, 2025 Letter, *supra* note 131, at attach. WLGRN-HELP-00000044 to WLGRN-HELP-00000063 (on file with Committee).
[177] *Id.* at attach. WLGRN-HELP-00000059 (on file with Committee).
[178] *Id.*
[179] *Id.*
[180] *Id.*
[181] *Id.* at attach. WLGRN-HELP-00000060 (on file with Committee).

	CVS Dispensing Fees			
	Insured Patients		Uninsured Patients	
Cleveland Clinic	**Brand Drugs**	**Generic Drugs**	**Brand Drugs**	**Generic Drugs**
Retail Pharmacy	$35 for a 1-30 day supply $60 for a 31-60 day supply $85 for a 61-90 day supply	-	$15	-
Specialty Pharmacy	13% of the negotiated reimbursement rate	-	-	-
Mail Service Pharmacy	$35 for a 1-30 day supply $60 for a 31-60 day supply $85 for a 61-90 day supply	$35 for a 1-30 day supply $60 for a 31-60 day supply $85 for a 61-90 day supply	-	-
Sun River	**Brand Drugs**	**Generic Drugs**	**Brand Drugs**	**Generic Drugs**
Retail Pharmacy	$35 for a 1-30 day supply $60 for a 31-60 day supply $85 for a 61+ day supply	-	$15	$15
Specialty Pharmacy	13% of the negotiated reimbursement rate	-	-	-
Mail Service Pharmacy	$35 for a 1-30 day supply $60 for a 31-60 day supply $85 for a 61+ day supply	$35 for a 1-30 day supply $60 for a 31-60 day supply $85 for a 61+ day supply	-	-
Yakima Valley	**Brand Drugs**	**Generic Drugs**	**Brand Drugs**	**Generic Drugs**
Retail Pharmacy	$35 for a 1-30 day supply $60 for a 31-60 day supply $85 for a 61+ day supply	-	$35 for a 1-30 day supply $60 for a 31-60 day supply $85 for a 61+ day supply	-
Careplus Retail Pharmacy	13% of the negotiated reimbursement rate with a $35 minimum	-	-	-
Specialty Pharmacy	14% of the negotiated reimbursement rate	-	-	-
Mail Service Pharmacy	$35 for a 1-30 day supply $60 for a 31-60 day supply $85 for a 61+ day supply	$35 for a 1-30 day supply $60 for a 31-60 day supply $85 for a 61+ day supply	-	-

	Walgreens Dispensing Fees			
	Insured Patients		Uninsured Patients	
Cleveland Clinic	**Brand Drugs**	**Generic Drugs**	**Brand Drugs**	**Generic Drugs**
Retail Pharmacy	$15	$15	$15	$15
Specialty Pharmacy	$65	-	-	-
Sun River	**Brand Drugs**	**Generic Drugs**	**Brand Drugs**	**Generic Drugs**
Retail Pharmacy	$15	$15	$15	$15
Yakima Valley	**Brand Drugs**	**Generic Drugs**	**Brand Drugs**	**Generic Drugs**
Retail Pharmacy	$13	$13	$13	$13

2. CVS Health and Walgreens charge additional TPA fees on top of contract pharmacy dispensing fees, retaining even more 340B revenue.

Both CVS Health and Walgreens have provisions in their pharmacy services agreements with covered entities that require payment of an administrative fee for TPA services. In CVS's agreements, the administrative fees for its TPA, Wellpartner, are included in a "340B Administrative Services Addendum" to each agreement. In Walgreens's agreements, the administrative fees for its TPA, 340B Complete, to provide "Inventory Maintenance Services" are listed alongside its dispensing fees in the "Fee Schedule."

As discussed above, CVS requires covered entities to use its TPA, Wellpartner, for the 340B drugs it dispenses through its pharmacies, but it does not require covered entities to use Wellpartner when dispensing 340B drugs through other contract pharmacies.[182] Specifically, Wellpartner helps covered entities with "eligibility determinations, replenishment of drugs for eligible prescriptions, technology support, and compliance" as well as helps "adjust to ongoing changes from pharmaceutical manufacturers and evaluate opportunities to add contract pharmacies [and] assist[] clients with [electronic medical record support for public health (ESP)] data submission and HRSA audit preparation."[183]

As detailed in the "340B Administrative Services Addendum" in each of the pharmacy services agreements produced, Wellpartner charges a set of fees for each 340B transaction and these fees increase over time. In its agreement with Sun River, for the first contract year, Wellpartner charges an administrative fee of the greater of $4 or 10 percent of the total amount paid for a 340B drug (regardless of who paid, i.e., third-party payer, patient, or covered entity) minus the 340B price of the drug.[184] In the second contract year, the fee rises to the greater of $4 of 12 percent of the total amount paid minus the 340B price.[185] In the third contract year and each year thereafter, the fee is the greater of $4 or 14 percent of the total amount paid minus the 340B price.[186] In its agreements with both Yakima Valley and Cleveland Clinic, for the remainder of the first contract year, Wellpartner charges an administrative fee of the greater of $4 or 10 percent of the total amount paid minus the 340B price.[187] For the second contract year and every year thereafter, the fee rises to the greater of $4 or 14 percent of the total amount paid minus the 340B price."[188]

In contrast to CVS, Walgreens states that it does not require covered entities to use its TPA, 340B Complete, when dispensing 340B drugs at any contract pharmacy, including those owned by Walgreens.[189] However, included in Walgreens's pharmacy services agreements with covered entities is a provision stating that 340B Complete will be used as an electronic tracking software

[182] Letter from CVS to Sen. Bill Cassidy, Ranking Member, S. Comm. on Health, Educ., Lab., & Pensions 3 (Feb. 16, 2024) (attached at App. 87).
[183] *Id.*
[184] CVS Jan. 16, 2025 Letter, *supra* note 114, at attach. CVS000055 (on file with Committee).
[185] *Id.*
[186] *Id.*
[187] *Id.* at attach. CVS000152, CVS000271 (on file with Committee).
[188] *Id.*
[189] Letter from Walgreens to Sen. Bill Cassidy, Ranking Member, S. Comm. on Health, Educ., Lab., & Pensions 3 (Feb. 6, 2024) (attached at App. 109) [hereinafter Walgreens Feb. 6, 2024 Letter].

providing TPA-like services.[190] These services are not the totality of what 340B Complete can provide covered entity clients,[191] but the pharmacy services agreements provide for an "Administrative Fee" for "Inventory Management Services,"[192] which is presumably to pay for the services 340B Complete provides pursuant to those agreements. The administrative fee is in addition to the dispensing fee.

In its agreement with Sun River, Walgreens charges an administrative fee of $0.50 per 340B drug for self-pay patients and an administrative fee of eight percent of the contracted reimbursement rate for privately insured patients at its retail pharmacies.[193] In its agreement with Yakima Valley, Walgreens charges an administrative fee of $0.50 per 340B drug for self-pay patients and an administrative fee of 13 percent of the contracted reimbursement rate for privately insured patients at its retail pharmacies.[194] In its agreement with Cleveland Clinic, Walgreens charges an administrative fee of $0.50 for self-pay patients and an administrative fee of 20 percent of the contracted reimbursement rate for privately insured patients at both its retail and specialty pharmacies.[195]

3. These fees, which are often indexed to automatically increase on an annual basis, drive significant growth in revenue for contract pharmacies.

Contract pharmacies benefit greatly from the structure of these agreements by indexing fees to automatically, annually increase, typically based on a standard measure such as the CPI-U-MCC. The CPI-U-MCC measure is designed to reflect the higher rate of medical cost growth compared to overall consumer prices. From 2000 to 2024, for example, the price of medical care (including drugs, medical equipment, services, and insurance) increased by 121.3 percent, compared to an 86.1 percent increase in the same period for all consumer goods and services.[196]

These fees are a significant revenue source for contract pharmacies. For example, Wellpartner's TPA fees generated $1.6 billion in revenue from covered entities from 2019 to 2023, as detailed further below:[197]

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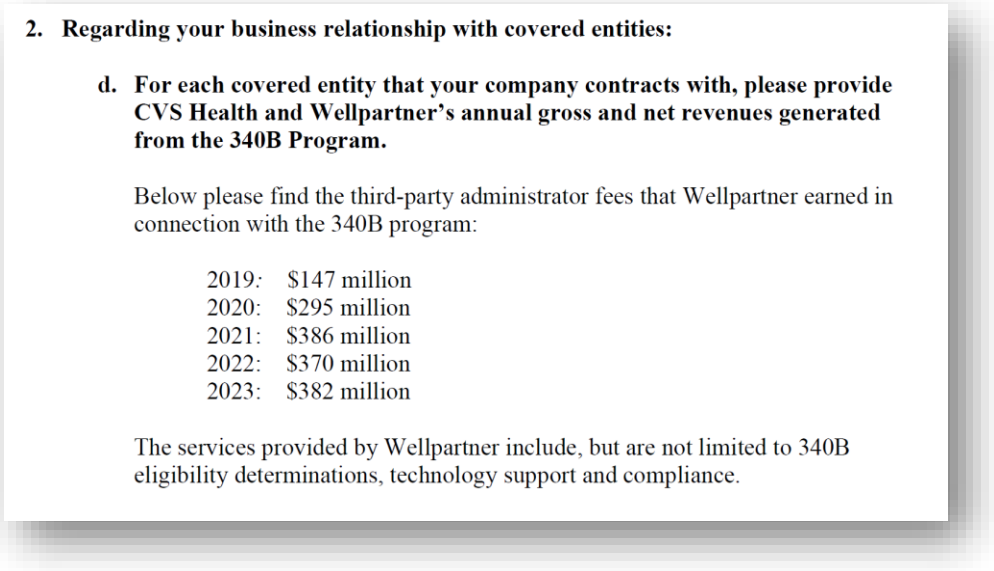
[190] Walgreens Jan. 16, 2025 Letter, *supra* note 131, at attach. WLGRN-HELP-00000007 to WLGRN-HELP-00000008 (on file with Committee).
[191] *See* Walgreens Feb. 6, 2024 Letter, *supra* note 188, at 2–3 (attached at App. 108–09) (listing all of the 340B administrative support services 340B Complete provides to covered entities).
[192] *E.g.* Walgreens Jan. 16, 2025 Letter, *supra* note 131, at attach. WLGRN-HELP-00000017 (on file with Committee) (all three pharmacy services agreements produced to the Committee contain this provision).
[193] *Id.* at attach. WLGRN-HELP-00000039 (on file with Committee).
[194] *Id.* at attach. WLGRN-HELP-00000059 (on file with Committee).
[195] *Id.* at attach. WLGRN-HELP-00000017 to WLGRN-HELP-00000018 (on file with Committee).
[196] Shameek Rakshit et al., *How does medical inflation compare to inflation in the rest of the economy?*, PETERSON-KFF HEALTH SYSTEM TRACKER (Aug. 2, 2024), https://www.healthsystemtracker.org/brief/how-does-medical-inflation-compare-to-inflation-in-the-rest-of-the-economy.
[197] CVS Jan. 16, 2025 Letter, *supra* note 114, at 3 (attached at App. 106).



2. Regarding your business relationship with covered entities:

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.

Below please find the third-party administrator fees that Wellpartner earned in connection with the 340B program:

2019: $147 million
2020: $295 million
2021: $386 million
2022: $370 million
2023: $382 million

The services provided by Wellpartner include, but are not limited to 340B eligibility determinations, technology support and compliance.

Walgreens did not provide the annual revenue 340B Complete generates as a TPA in the 340B Program, but based on the administrative fees in its pharmacy services agreements, it can be assumed it generates significant revenue. For example, Walgreens charges covered entities an administrative fee of anywhere between eight and 20 percent of the contracted reimbursement rate for private insurer patients each time its contract pharmacies fill a 340B prescription, leading to significant revenue considering total 340B sales were $124.1 billion at WAC in 2023.[198]

The agreements also generally include provisions to account for the payment of separate fees for additional administrative services to covered entities. Those additional services typically have not been incorporated to date under the agreements reviewed, or they were included at no additional expense. The provisions nonetheless offer another business option for contract pharmacies and TPAs, which could increase their future revenues as covered entities request more services.

Overall, the agreements between the contract pharmacies, TPAs, and covered entities reflect a proliferation of fees across various services and settings. With multiple for-profit entities receiving substantial financial benefits, the incentives are aligned to exert more payment pressure on covered entities, thereby diverting resources from the 340B Program's intended purpose of allowing covered entities to stretch scarce federal resources as far as possible.

4. Covered entities argue rising fees charged by contract pharmacies and TPAs strain financial resources, making it increasingly challenging to deliver essential services and care to patients.

During Chairman Cassidy's investigation, covered entities expressed concerns about the rising fees charged by contract pharmacies and TPAs. Covered entities argue the increasing fees collected by these for-profit entities limit covered entities' ability to serve patients effectively

[198] Rory Martin & Harish Karne, *The 340B Drug Discount Program Grew to $124B in 2023*, IQVIA 2 (2024), https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2024/iqvia-update-on-size-of-340b-program-report-2024.pdf.

because they take a sizable percentage of the total 340B revenue the covered entities would otherwise retain, thus reducing their ability to provide services to their patients.

BSMH highlighted this issue, noting that the escalating fees imposed by contract pharmacies are creating significant financial pressure on covered entities like RCH. As BSMH explained:[199]

> We also note that for the 19% of claims that are handled by third-party pharmacies, most of them go through Accredo Specialty Pharmacy. Covered Entities such as RCH face pressure from for-profit third parties such as Accredo as those entities continually increase their fees. This issue is compounded by vertical integration in the drug distribution system. For instance, Accredo is owned by ExpressScripts, a national pharmacy benefit manager that earns rebates from drug manufacturers when its beneficiaries use their drugs. ExpressScripts, in turn, is owned by Cigna, which also operates a specialty wholesaler (CuraScriptSD) and a 340B third-party administrator (Verity Solutions), which charges fees for data-matching services that facilitate contract pharmacy relationships. This type of vertical integration allows Cigna and its competitors to demand ever-increasing fees from Covered Entities, reducing the Entities' ability to care for their communities.

Sun River provided a summary of its TPA fees by calendar year, which showed that the TPA fees it had to pay constituted 5.9 percent of its total 340B revenue in 2019, 9.3 percent in 2020, nine percent in 2021, and 8.7 percent in 2022.[200] Sun River also provided the share of 340B revenue retained by each TPA for each 340B transaction. [201]

TPA Fees % of Gross Revenue				
TPA	2019	2020	2021	2022
Walgreens	8%	8%	8%	8%
RXS	2%	2%	1%	1%
HHHN	1%	2%		
Equiscripts		37%	37%	34%

Sun River notes that its TPA fees for the for-profit TPA, Equiscript, are so high because it provides additional services to Sun River patients, such as "identify[ing] patients who are at risk of poor health outcomes because of barriers associated with filling their medications on a regular and reliable basis[,] . . . [and] identif[ying] patients that may suffer barriers to care and direct telephone-based outreach by Equiscript personnel to these patients to ensure they have access to care."[202] Equiscript also coordinates home delivery pharmacy services with Sun River's contract pharmacies and serves as the TPA for the home delivery pharmacies providing the underlying delivery services.[203]

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[199] BSMH Nov. 1, 2023 Letter, *supra* note 33, at 18 (attached at App. 20).
[200] Sun River Jan. 31, 2024 Letter, *supra* note 74, at attach. C (on file with Committee).
[201] *Id.*
[202] *Id.* at 4 (attached at App. 70).
[203] *Id.*

Yakima Valley explained that "[v]ertical integration among payors, [PBMs] and TPAs have led to an increasing amount of prescriptions that [Yakima Valley] cannot fill in-house due to payor-imposed restrictions, as well as changes to fee structures."[204]

For its part, CVS contends that the "dispensing fees are meant to compensate pharmacies because they agree to forego their traditional revenue source (i.e., payments from insurers) when participating as a 340B contract pharmacy."[205] Outside of the 340B Program, pharmacies like CVS purchase full-priced drugs and are then reimbursed by insurers at the negotiated reimbursement rate. In the 340B Program, because the covered entity purchases the drug to be dispensed at a contract pharmacy, the contract pharmacy remits the insurer reimbursement to the covered entity and only retains the dispensing and administrative fees.

D. Pharmaceutical Manufacturers

On September 23, 2024, Chairman Cassidy sent letters to Eli Lilly and Company (Eli Lilly) and Amgen Inc. (Amgen) regarding each company's participation in the 340B Program between 2018 and 2023. The inquiry included requests for information on the types of drugs sold under the 340B Program, pricing information, the companies' decisions to impose limitations on the number of contract pharmacies each covered entity could use, the inventory replenishment model used by contract pharmacies, how the companies identify duplicate discounts, and audits that the companies undergo. These drug manufacturers were selected based on each company's large volume of drug sales under the 340B Program. In addition, Johnson & Johnson (J&J) voluntarily produced data to the Committee responding to the questions sent to Eli Lilly and Amgen. Eli Lilly and J&J produced data on all of their drugs sold under the 340B Program, while Amgen only produced data for its drug Enbrel. Because J&J's voluntary production included top-line data and findings without the underlying data, this report uses its information only where it can be directly compared to Eli Lilly and Amgen.

1. Eli Lilly, Amgen, and J&J provide billions of dollars in discounts to covered entities on their drugs under the 340B Program.

Based on the written responses and the accompanying documents produced pursuant to Chairman Cassidy's investigation, Eli Lilly, Amgen, and J&J provide billions of dollars in discounts on drugs through the 340B Program.

Between 2018 and 2023, Eli Lilly sold 22.23 million drug packages to covered entities, amounting to $7.453 billion in sales at the 340B price.[206] However, the total cost of these drugs at WAC would have been $16.928 billion.[207] WAC is the manufacturers' list price for a drug to wholesalers or direct purchasers outside the 340B setting. This means Eli Lilly provided covered entities $9.475 billion in 340B discounts (a 44 percent discount off WAC). Some of Eli Lilly's highest discounted

[204] Yakima Valley Jan. 22, 2024 Letter, *supra* note 80, at 3 (attached at App. 73).
[205] Letter from CVS to Sen. Bill Cassidy, Ranking Member, S. Comm. on Health, Educ., Lab., & Pensions 4 (Mar. 11, 2024) (attached at App. 93).
[206] Letter from Eli Lilly to Sen. Bill Cassidy, Ranking Member, S. Comm. on Health, Educ., Lab., & Pensions, at attach. Cassidy Response Question 1 (Oct. 31, 2024) (on file with Committee) [hereinafter Eli Lilly Oct. 31, 2024 Letter].
[207] *Id.*

drugs included Forteo, Prozac, and Strattera—each with an average 340B discount of over 95 percent off WAC during that period of time.[208] The average 340B discount for its insulin products ranged dramatically. Humalog and Insulin Lispro were sold at over a 96 percent discount off WAC, Lyumjev and Basaglar Tempo were sold at a 23 percent discount off WAC, and the rest of its insulin products fell in between those ranges.[209] Eli Lilly's lowest discounted drugs included Omvoh, Jaypirca, and Baqsimi—each with an average 340B discount of about 23 percent off WAC.[210]

Between 2018 and 2023, Amgen sold 825,069 packages of Enbrel to covered entities, amounting to $145.3 million in sales at the 340B price.[211] However, the total cost of these drug sales at WAC would have been $4.718 billion.[212] This means Amgen provided covered entities $4.573 billion in 340B discounts on Enbrel over this timeframe. For the five dosage types of Enbrel that Amgen primarily sold from 2018 until 2021,[213] the average 340B discount was 94.6 percent off WAC.[214] For the five dosage types of Enbrel primarily sold from 2019 through 2023,[215] the average 340B discount was 97 percent off WAC.[216] Overall, Amgen generally continued to increase the 340B discount it provided covered entities for the different dosage types of Enbrel from 2018 to 2023, allowing covered entities to generate massive 340B revenue on the drug.

The information provided by J&J demonstrates large growth in both its 340B sales and discounts since the 340B Program expanded precipitously in the wake of the Affordable Care Act and HRSA's 2010 guidance allowing for covered entities to use an unlimited number of contract pharmacies. In 2009, J&J had $824 million in 340B gross sales at WAC, while in 2021, 340B gross sales ballooned to $9.76 billion at WAC.[217] At the same time, J&J's average 340B discount for its drugs was 48 percent off WAC in 2009, before increasing to an average of 65.8 percent off WAC in 2021.[218] Put another way, J&J notes that its 340B gross sales at WAC have grown 1,083 percent since 2009 and 340B discounts (on a dollar basis) have grown 1,520 percent over the same time period.[219] In 2021 alone, J&J provided covered entities $6.42 billion in 340B discounts on its drugs.[220]

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[208] *Id.*
[209] *Id.*
[210] *Id.*
[211] Letter from Amgen to Sen. Bill Cassidy, Ranking Member, S. Comm. on Health, Educ., Lab., & Pensions, at attach. AMGEN-00001, AMGEN-00002, AMGEN-00004, AMGEN-00007 (Nov. 13, 2024) (on file with Committee) [hereinafter Amgen Nov. 13, 2024 Letter].
[212] *Id.*
[213] The five dosage types were: ENBREL Mini 50 mg/mL, 4pk; ENBREL 25 mg, 0.51 mL syringe, 4pk; ENBREL 50 mg, 0.98 mL AI, 4pk; ENBREL 50 mg, 0.98 mL syringe, 4pk; and ENBREL 25 mg vial, 4 pk. *Id.*
[214] *Id.*
[215] The five dosage types were: ENBREL 25 mg, 0.5mL Vial, 4pk; ENBREL Mini 50 mg, 1mL CTG, 4pk; ENBREL 50 mg, 1mL AI, 4pk; ENBREL 50 mg, 1mL syringe, 4pk; and ENBREL 25 mg, 0.5mL syringe, 4pk. *Id.*
[216] *Id.*
[217] *Response Letter to Senator Cassidy's Office, J&J Data*, JOHNSON & JOHNSON 17 (Dec. 19, 2024) (on file with Committee) [hereinafter J&J Dec. 19, 2024 Letter].
[218] *Id.*
[219] *Id.*
[220] *Id.*

2. Despite providing billions in discounts, manufacturers have difficulty ensuring 340B Program integrity.

To prevent the diversion of 340B drugs to ineligible patients, covered entities and contract pharmacies use two inventory models: (1) separate physical inventory or (2) virtual inventory/product replenishment. With the rise of contract pharmacy use in the 340B Program, most covered entities now use the virtual inventory/product replenishment model to dispense 340B drugs. This model does not physically separate 340B and non-340B drugs in the pharmacies' inventory. Instead, pharmacies dispense non-340B-priced drugs to 340B patients and then replenish their inventory with 340B-priced drugs covered entities purchase once an entire package of drugs is dispensed. Once purchased by covered entities, manufacturers ship these drugs directly to the contract pharmacy under a "ship to/bill to" model.

Amgen notes that "[h]istorically, HRSA provided that 340B-priced drugs may only be dispensed to 340B patients presenting a 340B prescription," but under the virtual inventory/product replenishment model, "there is no physical separation of 340B and non-340B drugs, and there is no requirement that a pharmacy verify that a customer is a 340B patient at the time the drug is dispensed."[221] Eli Lilly claims the model creates "an unlawful diversion [of 340B drugs] to a non-patient" because, when the covered entity buys 340B drugs to replenish the contract pharmacy's stock of the drug, the 340B drug itself may be dispensed to a non-340B patient since it goes into the pharmacy's general inventory.[222] Eli Lilly also says that this model "makes identifying unlawful duplicate discounts extremely difficult."[223]

Both Eli Lilly and Amgen criticize the model's lack of transparency and incentives for profit-driven manipulation of eligibility algorithms. Eli Lilly argues this model allows covered entities and TPAs to "go back and reclassify purchases using [accumulator] software or 'harvest claims,'" which can let covered entities retroactively change the definition of what constitutes an eligible patient and decide that the covered entity is "owed more 340B-priced medicines by reclassifying prior non-340B prescriptions as 340B eligible."[224] Similarly, Amgen contends that this model provides "a clear incentive for the contract pharmacy to utilize an algorithm that favors '340B-eligible' transactions based on dubious relationships between patients and covered entities."[225] Both Eli Lilly and Amgen critique the model for a lack of transparency, with Eli Lilly saying it "is completely opaque and unauditable"[226] and Amgen saying it is "cloaked in secrecy and incentivized by commercial profit-taking."[227]

Additionally, Eli Lilly points out that that smaller covered entities face delays in realizing 340B revenue, as replenishment orders require dispensing a full package size.[228] For slow moving or rarely dispensed drugs, the remaining product may sit on the shelf until it expires, meaning the full package will not be dispensed and "the covered entity never actually realizes the value of the

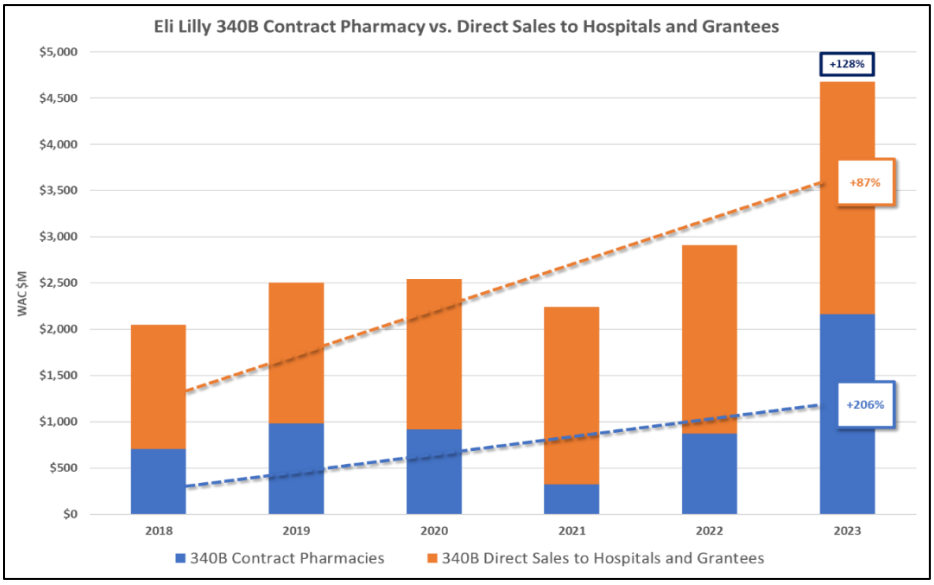
[221] Letter from Amgen to Sen. Bill Cassidy, Ranking Member, S. Comm. on Health, Educ., Lab., & Pensions, 7 (Oct. 31, 2024) (attached at App. 142) [hereinafter Amgen Oct. 31, 2024 Letter].
[222] Eli Lilly Oct. 31, 2024 Letter, *supra* note 205, at 8–9 (attached at App. 125–26).
[223] *Id.* at 9 (attached at App. 126).
[224] *Id.*
[225] Amgen Oct. 31, 2024 Letter, *supra* note 220, at 7 (attached at App. 142).
[226] Eli Lilly Oct. 31, 2024 Letter, *supra* note 205, at 9 (attached at App. 126).
[227] Amgen Oct. 31, 2024 Letter, *supra* note 220, at 8 (attached at App. 143).
[228] Eli Lilly Oct. 31, 2024 Letter, *supra* note 205, at 9 (attached at App. 126).

340B price concession."[229] The pharmacy services agreements produced by CVS and Walgreens confirm that transactions for undispensed packages may be voided after 120 days (for CVS) or 180 days (for Walgreens). At that time, covered entities are forced to return their 340B revenue from those sales to the contract pharmacy.[230]

3. Eli Lilly and J&J have seen significant increases in 340B sales to contract pharmacies compared to direct sales to hospitals and grantees.

The data produced by Eli Lilly and J&J show that both drug manufacturers have seen a significant increase in 340B sales to contract pharmacies compared to direct sales to hospitals and grantees. Amgen did not produce sufficient data to determine how its 340B sales to contract pharmacies relate to its direct sales to hospitals and grantees, but it noted the "prolific use of contract pharmacies in the 340B setting" and said that the massive growth in the 340B Program is "driven in substantial part by the replenishment activities of contract pharmacies."[231]

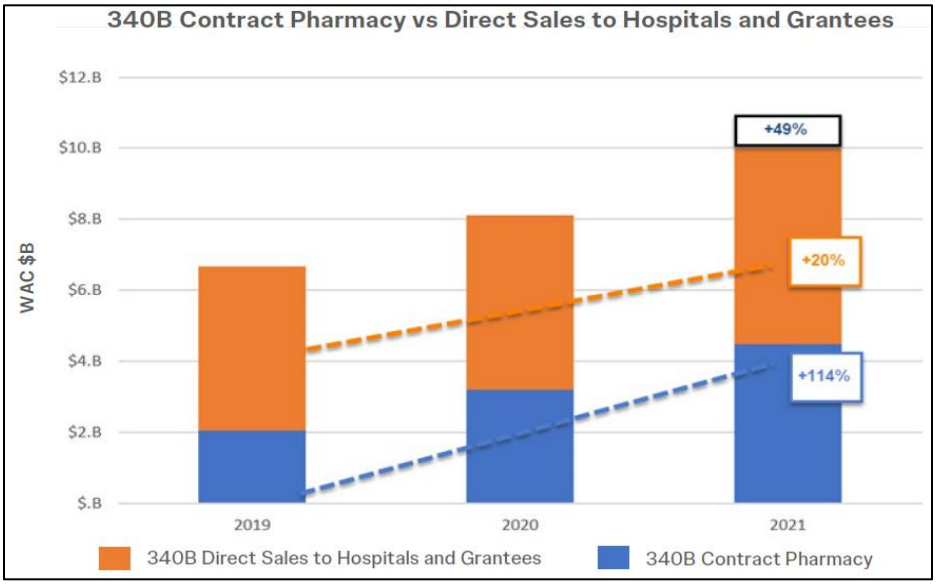
Eli Lilly's data shows that since 2018, its total 340B sales to contract pharmacies (including entity-owned contract pharmacies) has grown 206 percent, from $706 million at WAC in 2018 to $2.16 billion at WAC in 2023.[232] By comparison, Eli Lilly's direct sales to hospitals and grantees has grown 87 percent since 2018, from $1.34 billion at WAC in 2018 to $2.51 billion at WAC in 2023.[233] Given that Eli Lilly's total 340B sales at WAC have grown by 128 percent overall since 2018, the data demonstrates that much of this growth has been fueled by the use of contract pharmacies.



Source: Chart created by Committee staff based on data produced by Eli Lilly.[234]

[229] *Id.*
[230] *See, e.g.*, CVS Jan. 16, 2025 Letter, *supra* note 114, at attach. CVS000022 (on file with Committee) (all of the pharmacy services agreements produced to the Committee contained these provisions); Walgreens Jan. 16, 2025 Letter, *supra* note 131, at attach. WLGRN-HELP-00000003 (on file with Committee) (same).
[231] Amgen Oct. 31, 2024 Letter, *supra* note 220, at 5, 8 (attached at App. 140, 143).
[232] Eli Lilly Oct. 31, 2024 Letter, *supra* note 205, at attach. Cassidy Response Question 1 (on file with Committee).
[233] *Id.*
[234] *Id.*

J&J has seen a similar trend of sales to contract pharmacies growing at a much higher rate than direct sales to hospitals and grantees. From 2019 to 2021, J&J's 340B sales to contract pharmacies has grown 114 percent.[235] This is compared to 340B direct sales to hospitals and grantees growing by 20 percent in the same time period.[236] Again, given that J&Js total 340B sales growth during this time period was 49 percent, its sales to contract pharmacies was the primary driver of this increase.



Source: Chart provided to Committee staff by J&J.[237]

4. Amgen, Eli Lilly, and J&J claim that restrictions on covered entities' use of contract pharmacies have not led to a meaningful decline in 340B utilization of their drugs.

Amgen, Eli Lilly, and J&J have all implemented various restrictions on covered entities' use of contract pharmacies since the summer of 2020. However, the data these companies produced to the Committee shows that these policies have not led to a meaningful decline in 340B utilization of their drugs. What follows is an illustration of how Amgen, Eli Lilly, and J&J's contract pharmacy restrictions have impacted 340B utilization of their drugs.

Amgen

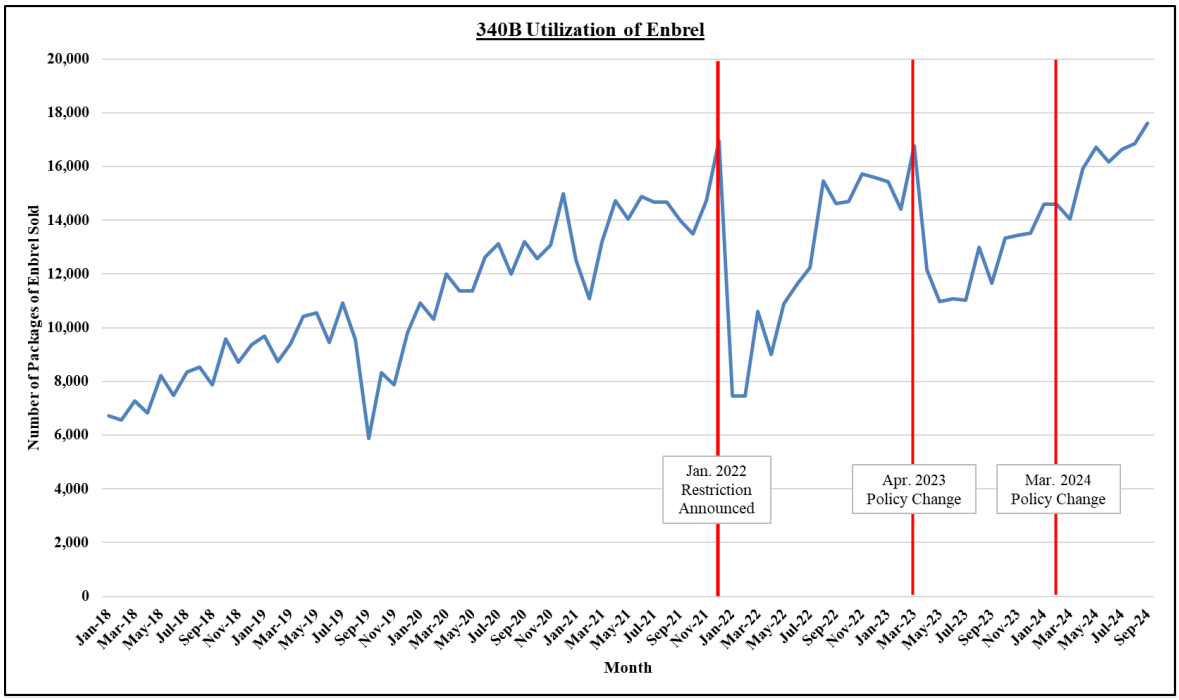
In January 2022, Amgen first announced restrictions on covered entities' use of contract pharmacies to dispense 340B drugs. Under the policy, Amgen stated that it would no longer distribute four types of 340B drugs to contract pharmacies for hospital covered entities, except that it would distribute the drugs to a single contract pharmacy if the hospital did not have an in-house pharmacy location.[238] However, Amgen continued to allow an unlimited number of contract

[235] J&J Dec. 19, 2024 Letter, *supra* note 216, at 18 (on file with Committee).
[236] *Id.*
[237] *Id.*
[238] Amgen Oct. 31, 2024 Letter, *supra* note 220, at 5 (attached at App. 140).

pharmacies if the hospital provided the manufacturer with appropriate claims data.[239] Federal grantee covered entities were exempt from this policy.[240] Then, in April 2023, Amgen announced that it would only distribute 340B drugs to a single contract pharmacy located within 40 miles of a 340B-parent site (the main 340B-eligible covered entity registered with HRSA) for hospital covered entities with no in-house pharmacy.[241] In March 2024, Amgen announced that it was expanding the same policy to federal grantees, including FQHCs.[242] The current policy, last updated in August 2024, applies to six drugs (including Enbrel),[243] and requires any covered entity using a single contract pharmacy to provide claims level data for both their in-house pharmacy (if applicable) and the designated single contract pharmacy.[244] Amgen said these restrictions were in response to the fact that "there are no safeguards in place to require that 340B priced drugs are provided only to 340B patients at contract pharmacies" and in the wake of government reports "demonstrating that the use of contract pharmacies exacerbates program integrity violations."[245]

Amgen states that "[d]espite the adoption of reasonable restrictions on the delivery of 340B-priced drugs to contract pharmacies, 340B covered entities are purchasing more Enbrel[] than ever before."[246] Amgen notes that 340B sales for Enbrel decreased significantly after the initial restriction was announced in January 2022, but have since recovered and 340B utilization of Enbrel is now at 162 percent of its September 2021 level.[247] According to the data Amgen produced to the Committee, in the 12 months preceding January 2022, covered entity 340B utilization of Enbrel averaged 14,082 packages per month.[248] Utilization then dropped to about 7,460 per month in the two months following the announcement of the restriction, before returning to previous levels a few months later.[249] Similarly, after the April 2023 change to Amgen's policy, 340B utilization of Enbrel dropped by about 1,500 packages per month in the first four months following the change, before returning to previous utilization levels.[250] Finally, since Amgen included federal grantees in the policy in March 2024, 340B utilization of Enbrel did not decrease and actually continued to increase, with September 2024 marking the highest monthly 340B utilization of Enbrel ever.[251] The chart below visualizes the impact of Amgen's contract pharmacy policies on 340B utilization of Enbrel:

[239] *Id.*
[240] *Id.*
[241] *Id.* at 6 (attached at App. 141).
[242] *Id.*
[243] The six drugs included in the policy are: Repatha, Enbrel, Otezla, Aimovig, Tezspire, and Amjevita. *Id.*
[244] *Id.*
[245] *Id.* at 6–7 (attached at App. 141–42).
[246] *Id.* at 6 (attached at App. 141).
[247] *Id.*
[248] Amgen Nov. 13, 2024 Letter, *supra* note 210, at attach. AMGEN-00039 (on file with Committee).
[249] *Id.*
[250] *Id.*
[251] *Id.*



Source: Chart created by Committee staff based on data produced by Amgen.[252]

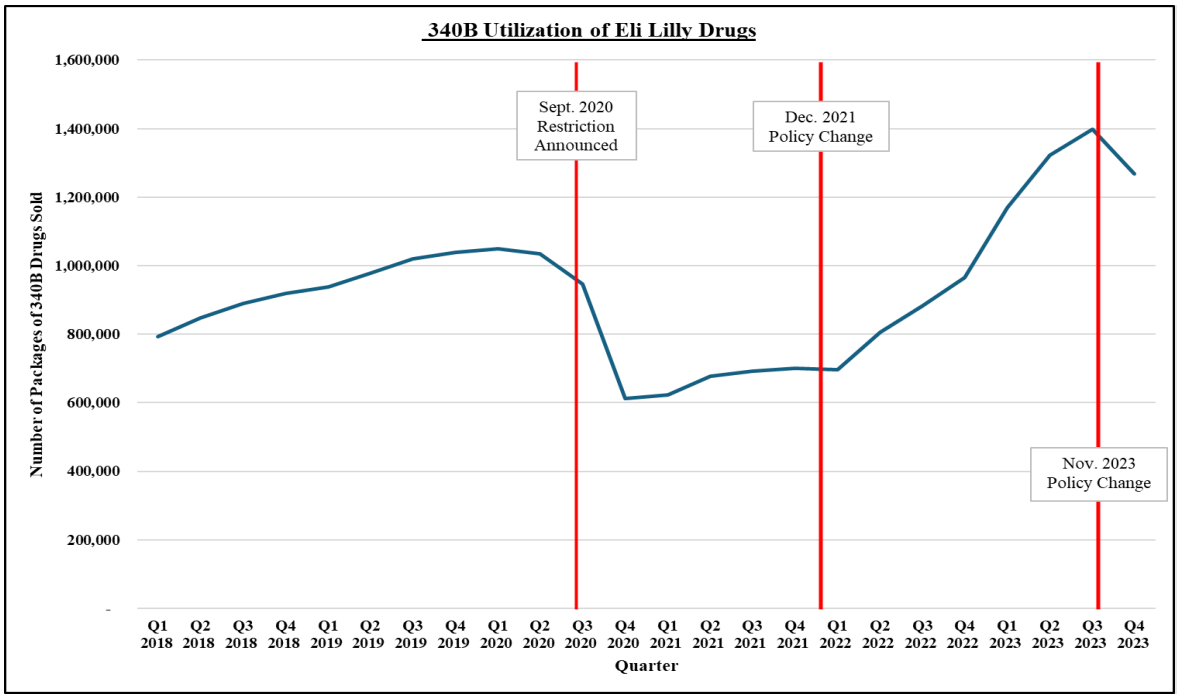
Eli Lilly

In September 2020, Eli Lilly first announced its policy placing limitations on covered entities' use of contract pharmacies. The policy stated that Eli Lilly would no longer distribute 340B drugs directly to contract pharmacies and that it would distribute these drugs only to covered entities and associated child sites.[253] In December 2021, Eli Lilly subsequently announced it would permit 340B drugs to be distributed directly to an unlimited number of contract pharmacies so long as covered entities submit certain claims-level data directly to Eli Lilly.[254] However, in November 2023, Eli Lilly reverted to its previous policy of limiting 340B drug distribution to only covered entities, associated child sites, and pharmacies wholly owned by the covered entity.[255] Most recently, in July 2024, Eli Lilly announced further contract pharmacy restrictions, prohibiting 340B drug distribution to wholly-owned pharmacies and only allowing 340B drugs to be

[252] *Id.* at attach. AMGEN-00001 to AMGEN-00040 (on file with Committee).
[253] *Limited Distribution Plan Notice for Eli Lilly and Company Products*, ELI LILLY & CO. (Sept. 1, 2020), https://www.amerisourcebergen.com/-/media/assets/amerisourcebergen/340b/manf-letters/200901-eli-lilly-and-company_limited-distribution-plan_public-notice.pdf.
[254] *Update to Eli Lilly and Company Contract Pharmacy Policy*, ELI LILLY & CO. (Dec. 10, 2021), https://www.amerisourcebergen.com/-/media/assets/amerisourcebergen/340b/manf-letters/lilly-340b-announcement---updated-010321.pdf.
[255] *Notice of Reinstatement of Lilly's Prior Contract Pharmacy Limited Distribution System*, ELI LILLY & CO. (Nov. 6, 2023), https://www.amerisourcebergen.com/-/media/assets/amerisourcebergen/340b/manf-letters/2023116-update-eff-20231116.pdf.

distributed directly to covered entities and their child sites.[256] Covered entities that do not have an in-house retail pharmacy may designate a single contract pharmacy for 340B drug distribution.[257]

The data produced by Eli Lilly revealed a trend similar to Amgen: 340B utilization of its drugs markedly declined after its initial restriction was announced in September 2020 but then steadily rose to 122 percent of the level prior to its enactment of the initial restriction.[258] In the first full quarter with the restriction in place, utilization dropped from 1.034 million packages in the second quarter of 2020 to 611,685 packages in fourth quarter of 2020, a 40 percent decrease.[259] Utilization then slowly increased each quarter until Eli Lilly's December 2021 policy change, when 340B utilization dropped slightly in the subsequent quarter.[260] From the second quarter of 2022, 340B utilization for Eli Lilly's drugs continued to consistently increase through the third quarter of 2023, before dropping modestly again in the fourth quarter of 2023 after the November 2023 policy change.[261] However, the 340B utilization in the fourth quarter of 2023 was still the third-highest ever of any quarter.[262] The chart below visualizes the impact of Eli Lilly's contract pharmacy policies on 340B utilization of its drugs:



Source: Chart created by Committee staff based on data produced by Eli Lilly.[263]

[256] *Update to Lilly's Contract Pharmacy Limited Distribution System*, ELI LILLY & CO. (June 19, 2024), https://www.amerisourcebergen.com/-/media/assets/amerisourcebergen/340b/manf-letters/20240619-lilly-claims-requirement-eff-20240701.pdf.
[257] *Id.*
[258] Eli Lilly Oct. 31, 2024 Letter, *supra* note 205, at attach. Cassidy Response Question 1 (on file with Committee).
[259] *Id.*
[260] *Id.*
[261] *Id.*
[262] *Id.*
[263] *Id.*

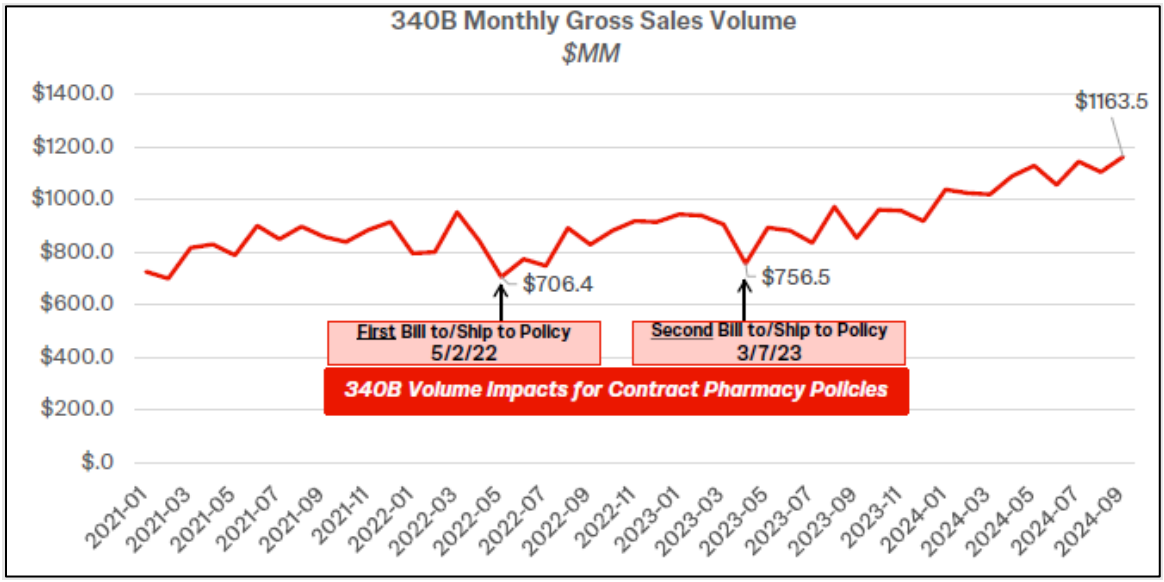
Johnson & Johnson

In May 2022, J&J enacted its first restrictions on covered entities' use of contract pharmacies to dispense 340B drugs. Under this policy, J&J stated that it would no longer distribute 29 types of drugs to contract pharmacies for hospital covered entities unless the hospital submitted pharmacy claims data. Federal grantees, including FQHCs, were unaffected.[264] J&J stated that the policy "will help to reduce diversion and inappropriate claims for discounts and rebates" and "improve 340B Program integrity and compliance."[265] Then, in March 2023, J&J updated its policy to limit hospital covered entities to use of one contract pharmacy within 40 miles of the parent site, and continued to require the submission of pharmacy claims data when using a contract pharmacy. Federal grantees remained unaffected.[266] Finally, in August 2024, J&J announced a 340B rebate model policy in which disproportionate share hospital covered entities would only be able to obtain a 340B discount on Stelara and Xarelto through a rebate and not at the time of purchase.[267] However, HRSA notified J&J that the rebate model policy was in violation of the 340B statute and ordered J&J to cease implementation.[268] J&J then announced that it would forgo implementation of its rebate model before it was set to take effect, but defended its legality under the 340B statute.[269]

J&J states that "Contract Pharmacy policy updates and restrictions only temporarily impacted purchasing volume" of its 340B drugs.[270] The company also says that while it has implemented two contract pharmacy restriction policies "that caused brief decreases in 340B sales, demand quickly rose again as [covered entities] established alternate policies."[271] According to the data provided by J&J to the Committee, 340B monthly gross sales dropped from about $950 million per month prior to the first contract pharmacy policy to $706 million per month after the first policy was enacted in May 2022.[272] The monthly gross sales then gradually recovered over the next year and reached about $900 million per month before dropping again to $757 million per month after the second policy was enacted in March 2023.[273] J&J's 340B monthly gross sales subsequently continued to rise significantly, reaching a record high of $1.16 billion in September

[264] *Notice to 340B and Non-340B End Customers Regarding Bill To/Ship To Orders*, JOHNSON & JOHNSON (Mar. 21, 2022), https://www.dropbox.com/scl/fi/rb337ktt5pu7cjy1gvim7/JJHCS-Notice-to-End-Customers-Regarding-Bill-To-Ship-To-Orders.pdf?rlkey=7uxj9k189jh8rtd0rot3t1mhd&e=1&dl=0.
[265] *Id.*
[266] *Notice to 340B and Non-340B End Customers Regarding Updates to 340B Delivery Limitations*, JOHNSON & JOHNSON (Feb. 15, 2023), https://static.innovativemedicine.jnj.com/f0/e0/a2b4a75a455392428d5f4dbd6aca/jjhcs-notice-to-end-customers-regarding-updates-to-340b-delivery-limitations-9-3-24.pdf.
[267] *Notice to 340B End Customers Regarding Purchases of STELARA and XARELTO*, JOHNSON & JOHNSON (Aug. 23, 2024), https://static.innovativemedicine.jnj.com/ca/ce/2f1a3426491aa7a15a35241a3bd3/johnson-johnson-innovative-medicine-340b-rebate-model-policy-update-9-30-2024.pdf.
[268] Letter from Carole Johnson, Adm'r, Health Res. & Servs. Admin., to Joaquin Duato, Chairman & Chief Exec. Officer, Johnson & Johnson (Sept. 17, 2024), https://www.hrsa.gov/sites/default/files/hrsa/opa/sept-17-2024-hrsa-letter-johnson-johnson.pdf.
[269] Letter from Scott White, Chief Operations Officer, North America Innovative Medicine, Johnson & Johnson, to Carole Johnson, Adm'r, Health Res. & Servs. Admin. (Sept. 30, 2024), https://340breport.com/wp-content/uploads/2024/09/jj-letter-in-response-to-hrsa-9.30.24.pdf.
[270] J&J Dec. 19, 2024 Letter, *supra* note 216, at 20 (on file with Committee).
[271] *Id.* at 5 (on file with Committee).
[272] *Id.* at 20 (on file with Committee).
[273] *Id.*

2024.[274] J&J provided the following chart showing how its contract pharmacy policies impacted 340B monthly gross sales volume:



Source: Chart provided to Committee staff by J&J.[275]

Amgen, Eli Lilly, and J&J are not unique in implementing limitations on covered entities' use of contract pharmacies in the 340B Program, with at least 20 drug manufacturers enacting such restrictions since 2020.[276] While the legality of these restrictions on contract pharmacies plays out in court, the data produced by Amgen, Eli Lilly, and J&J show that their restrictions did not substantially impact long-term 340B utilization of their drugs, despite utilization temporarily decreasing in the wake of their announcements of new restrictions.

III. Conclusion

Chairman Cassidy conducted this investigation to better understand how patients benefit from the 340B Program. In pursuit of the facts, Chairman Cassidy did not single out one covered entity, contract pharmacy, TPA, or drug manufacturer, but requested information from eight different program participants to understand the unique relationship each has with the 340B Program.

This investigation underscores that there are transparency and oversight concerns that prevent 340B discounts from translating to better access or lower costs for patients. Congress needs to act to bring much-needed reform to the 340B Program, including:

1) **Requiring covered entities to provide detailed annual reporting on how 340B revenue is used to ensure direct savings for patients, providing a more transparent link between program savings and patient benefit;**

[274] *Id.*
[275] *Id.*
[276] *See* Hannah-Alise Rogers, *Litigation Continues Over Use of Contract Pharmacies in 340B Drug Discount Program*, CONG. RSCH. SERV. (May 23, 2024), https://crsreports.congress.gov/product/pdf/LSB/LSB11163.

2) **Addressing potential logistical challenges caused by increased administrative complexity, leading to burdens that may impede patient benefit from the program;**

3) **Investigating the types of financial benefits contract pharmacies and TPAs receive for administering the 340B Program to ensure that increasing fees do not disadvantage covered entities and patients;**

4) **Requiring transparency and data reporting for entities supporting participants in the 340B Program (i.e., contract pharmacies and TPAs); and**

5) **Providing clear guidelines to ensure that manufacturer discounts actually benefit 340B-eligible patients, including examining legislative changes to the definition of eligible patient and contract pharmacies' use of the inventory replenishment model.**

This investigation brings Congress and the public one step closer to better understanding the reforms needed to the 340B Program. However, there is more work to be done. Chairman Cassidy looks forward to continuing his efforts to bring transparency and improvements to the 340B Program.

APPENDIX

October 24, 2023

VIA ELECTRONIC TRANSMISSION
[redacted]

The Honorable Bill Cassidy, M.D.
Ranking Member
U.S. Senate Committee on Health,
Education, Labor, and Pensions

Re: Information Request on 340B

Dear Ranking Member Cassidy:

Over the past several weeks, we have been working with your Chief Counsel of Investigations and Oversight, [redacted], to ensure we understand the requests included in your September 28, 2023, letter and to develop a timeline for responding to them. As we discussed with [redacted], we are working diligently toward providing a comprehensive response, inclusive of document production, by November 1, 2023. Between outside assistance and our own staff members, we have already devoted several hundred hours to this project.

[redacted] asked that we provide an estimate of the number of pages to be included in our production. That metric is difficult to quantify since our response will include, per your request, Excel-format workbooks containing more than 100,000 rows of information which we will summarize to aid in your review. We are also collecting policies, procedures, and other documents in response to your questions. We expect that, if printed, the response would span several thousand pages. Given that volume, we are working diligently to summarize and contextualize the information we provide.

As we prepare our responsive document, we would appreciate additional clarification regarding at least one of the questions. Your letter requests a "complete accounting of the funds Bon Secours generated from the 340B Program from Richmond Community Hospital." Since the 340B Program is a discount program, accurately responding to this request requires us to calculate the difference between what we paid for a 340B drug and what we would have otherwise paid. However, a key challenge faced by Bon Secours Richmond Community Hospital ("RCH") and other 340B covered entities is the lack of clarity around what price information can be shared publicly.

The 340B ceiling price is ostensibly confidential. In fact, were it not for an amendment to the 340B Statute, not even Covered Entities would be able to know the ceiling price.[1] The HRSA system that we use to access these prices, https://340bpricing.hrsa.gov/login, warns that "Unauthorized or

[1] *See* 42 U.S.C. § 256b(d)(1)(B)(iii); *see also* 42 U.S.C. § 1396r-8(b)(3)(D) (prohibiting the Secretary of Health & Human Services from disclosing information provided by manufacturers under their National Drug Rebate Agreements).

improper use of this system is prohibited and may result in disciplinary action and/or civil and criminal penalties," but does not specify the authority under which such penalties might be imposed.

We have collected, and intend to provide, a line-by-line accounting of the difference between the 340B purchase price and the price that would otherwise be available to RCH. As such, unless we hear otherwise from your office before our submission on November 1st, we assume that RCH is permitted to disclose this information to your office, in response to your request, as part of an "authorized use" of the HRSA OPA system. Please let us know in advance of that date if this detailed, non-aggregated information will be made publicly available in a manner inconsistent with this requirement. If we do not hear from your office before then, we will assume it will be kept confidential consistent with HRSA OPA expectations. We believe this should be the case because making individually identifiable price information available to covered entities but not members of Congress would seem to be contrary to the public interest.

Thank you for your interest in this matter and please let me know if you should have any questions.

Very Truly Yours,

BON SECOURS MERCY HEALTH

Bon Secours Mercy Health, Inc.

BON SECOURS MERCY HEALTH

November 1, 2023

Via Electronic Transmission to [redacted] ([redacted])

The Honorable Bill Cassidy, M.D.
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

Dear Ranking Member Cassidy:

By this letter and its enclosed materials, Bon Secours Mercy Health ("BSMH") is providing its complete response to your September 28, 2023 letter requesting information regarding Bon Secours Richmond Community Hospital ("RCH") and its participation in the 340B drug discount program ("340B Program"). We wish to thank you and the Committee staff for the productive discussions we have had while collecting information in response to your letter. We also thank you for this opportunity to comprehensively highlight the work RCH has done to support the Richmond community and to address the inaccurate narratives regarding how the 340B Program operates which have been put forth by the pharmaceutical industry and amplified by various media outlets.

As mentioned in our status update letter, BSMH devoted several hundred hours of employees' and outside experts' time in responding to this request. Much of that time was spent collecting and analyzing financial information and preparing updates on initiatives begun before and after the publication of the New York Times article you referenced. This also included time spent analyzing the prevalent, misplaced belief that safety-net hospitals such as RCH are somehow failing the American public by using the 340B Program as Congress intended it to be used. Ultimately, the discourse around the 340B Program pits drug manufacturers' self-interest against hospitals and clinics acting consistent with their charitable, nonprofit missions. Your letter has afforded RCH and 340B Covered Entities like it an opportunity to be heard, and for that we are grateful.

Document Summary

This letter proceeds by describing the 340B Program from the perspective of a nonprofit Catholic health care system with dozens of hospitals, hundreds of non-hospital health care facilities, and tens of thousands of employees. This includes a brief summary of the numerous, and sometimes discordant, laws, regulations, and other authorities that we must harmonize in pursuit of our nonprofit mission. The letter also discusses RCH and its role in the community, identifying the many ways that it supports those living in the East End. Finally, the letter addresses each of the questions you asked, describes the materials produced in response to them, and summarizes our analysis of them.

We are proud of the role that RCH plays in the Richmond health care space and believe it is important to tell an accurate narrative about RCH and its operations, specifically as a fully compliant 340B Program participant. As you will see in this correspondence, the savings

provided by the 340B Program have allowed RCH to remain open, despite operating at a substantial loss for decades. This Program is essential to ensure the East End has access to a key community provider of high-quality, affordable behavioral health, primary care and specialty services.

It is also important to note that as a health care ministry, we respond to the needs of the communities we serve. As such, we conduct Community Health Needs Assessments (CHNA) every three years and create robust and focused action plans to meet the identified needs. At RCH, our CHNA has identified behavioral health as a significant need, which has led to additional programs and services to help ensure the health and well-being of the community.

Finally, our mission compels us to care for every person who comes through our doors, and we will not waiver from this commitment. RCH, like all BSMH tax-exempt hospitals, offers a robust Financial Assistance Policy to help ensure cost isn't a barrier to care. Our policy provides a full discount on care for individuals under 200% of the federal poverty level, with a 76% discount for patients up to 400% of the federal poverty level. This is above and beyond any requirements or the commitments of other health care systems in the area, and it extends to drugs dispensed through BSMH's pharmacies, too. In contrast, a requirement that Covered Entities pass through the 340B discount to their patients would only reduce, and not eliminate, the cost of some drugs. RCH is committed to continuing to give back to the community through improved facilities, community grants and programs, uncompensated care and more.

History and Background on the 340B Program

A common refrain used by critics is that the 340B Program has "strayed from its purpose." The reality, however, is that the 340B Program has and continues to achieve Congress's intended goal to stretch scarce Federal resources as far as possible by limiting the avarice of drug manufacturers.

The 340B Program's Purpose Is to Control Drug Costs for Safety-Net Providers and Their Patients

Originally drafted as an amendment to the Medicaid Act,[1] Congress enacted the 340B statute to prevent drug manufacturers from exploiting their market power to the detriment of our nation's health care safety net. In 1990, Congress enacted the Omnibus Budget Reconciliation Act of 1990 ("OBRA 90") which, among other things, required drug manufacturers to provide their "best price" to state Medicaid agencies under the Medicaid Drug Rebate Program ("MDRP"). This had unintended consequences. *Prior to OBRA 90, many drug manufacturers offered discounts and other concessions to safety-net providers. To avoid having to offer these same discounts to every state Medicaid agency, many manufacturers*

[1] *See* Medicaid and Department of Veterans Affairs Drug Rebate Amendments of 1992 (102nd Congress, H.R. 2890).

raised their prices. A study cited in a 1992 House Committee report found that in the wake of the MDRP, "[h]ospital costs for the drugs included in the study increased, on average, by 32 percent, far in excess of the historical 5 to 9 percent annual increases in drug prices experienced by public hospitals."[2]

Congress decided this was a problem:

> It is evident that OBRA 90 has achieved its objective of generating savings for the Medicaid program. However, other entities–notably the DVA, Federally-funded clinics, and public hospitals, have continued to experience substantial increases in their outpatient drug costs. The Committee is persuaded that, without intervention, the DVA and Federally-funded clinics may continue to experience substantial drug price increases as manufacturers try to limit their rebates to Medicaid. *In the view of the Committee, the Federal government simply cannot continue to allow the DVA, Federally-funded clinics, and their patients to remain unprotected against manufacturer price increases.*[3]

One Senator put it succinctly: "Clearly, the intent of the Medicaid rebate law is to reduce government expenditures for the $5 billion Medicaid prescription drug program—not shift them to other public health programs."[4] So, while the 340B statute enables Covered Entities to "stretch scarce Federal resources as far as possible,"[5] the statute was not intended to create new obligations for these entities. Instead, it recognized that without "access to price reductions,"[6] Federal funds already dedicated to providing health care would be diverted to drug manufacturers.

RCH in Context

Richmond Community Hospital serves a vital role in Richmond's East End, but its place in the community must be considered in the appropriate context. RCH itself is a relatively small hospital with 64 licensed acute care beds and 40 licensed psychiatric beds, but it serves a disproportionately important role in providing mental health care in the community that could otherwise go unaddressed.[7] In 2020, RCH experienced 490 medical/surgical

[2] H.R. Rep. No. 102-384(II), *10 (hereinafter "1992 House Report").

[3] *Id.*, * 11 (emphasis added).

[4] Floor Statement of Sen. Edward Kennedy on S. Amd. 3372 (Oct 1, 1992) (Cong. Rec. vol. 138, pt. 20, p. Sen. 29,485).

[5] 1992 House Report, *12.

[6] *Id.*

[7] VHI Financial Reports for Bon Secours Richmond Community Hospital (Sept. 1, 2018-Aug. 31, 2019; Jan. 1, 2020-Dec. 31, 2020).

discharges as compared to over 1,000 psychiatric discharges.[8] In fact, despite its small size, Virginia Health Information found RCH provided 7.5% of all hospital-level psychiatric care in Central Virginia in 2020.[9] These efforts include a dedicated behavioral health clinical pharmacist who staffs RCH's general and acute behavioral health beds, rounding with physicians to enhance patient care. In 2022, RCH added a Partial Hospitalization Program, the first of its kind in the East End of Richmond. With an average daily census of 16 patients, the partial hospitalization program provides structured intervention for patients both before and after they experience behavioral health crises.

Commitment to Quality

RCH has expanded its behavioral health offerings while continuing to be recognized for its high achievement in patient experience and safety. In 2022, RCH earned a Leapfrog Safety Grade "A" and was designated a Leapfrog Top General Hospital, one of only 32 hospitals in the Country, and the only one in the Commonwealth of Virginia, to earn this commendation. These accomplishments and others are echoed by the Virginia Hospital & Healthcare Association recognizing RCH as #1 in Overall Patient Experience in 2022. These awards and recognitions belie the New York Times' narrative that RCH is a hospital in crisis. Its safety and quality scores and achievements[10] arise, in part, from effective and widely used safety reporting systems. In the wake of the New York Times article, RCH leaders investigated some of its more egregious claims; they found, for instance, that the safety reporting system used at RCH did not have any record of a report about a lack of surgical tools as alleged in the article. Furthermore, shortly after the article was published, CMS investigated the article's claim that RCH did not treat or transfer patients consistent with its EMTALA obligations. An unannounced, two-day, three-investigator survey was completed three weeks after the article was published, and not only was the specific complaint "determined to be unsubstantiated due to lack of evidence", but the investigators identified "no deficiencies," and RCH was found to be in compliance with the attendant regulatory requirements.[11] A copy of the survey report is enclosed for your review.

Financial Transparency and Position in the Market

Against this backdrop, RCH's financial condition must be addressed. Medicare and Medicaid beneficiaries make up a huge portion of RCH's payor mix, with Medicaid leading the

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[8] *Id.*

[9] Virginia Health Information, *2020 Service Line Summary for Bon Secours Richmond Community Hospital* (https://vhi.org/Bon%20Secours%20Richmond%20Community%20Hospital.html?tab=&?=h9880/) (last accessed Nov. 1, 2023).

[10] RCH internally-reported safety statistics as of October 6, 2023: 1,218 days without a CLABSI (central line-associated bloodstream infection); 1,497 days without a CAUTI (catheter-associated urinary tract infection); 366 days without *C. diff*; 1,198 days without MRSA; 325 days since the last Serious Safety Event.

[11] CMS EMTALA Survey Report for RCH, December 2022.

way. After uninterrupted yearly increases for at least the past five years, RCH now finds itself in a position where Medicaid beneficiaries account for 53% of its inpatient admissions while an additional 14% of its Medicare patients are SSI beneficiaries. Despite this high level of care provided to government beneficiaries, RCH's Medicare disproportionate patient percentage is capped by law at 12%.[12] Without this cap, RCH's 2020 DSH percentage would have been a staggering 44.02%. That is an almost unheard-of level of public commitment, driven by the fact almost 60% of RCH's inpatients qualified for Medicaid or SSI benefits in 2020. *RCH provides care to every one of these patients at a loss that is subsidized by the 340B Program* savings primarily earned at its accredited hospital outpatient departments located within and beyond the East End. *Without a way to generate revenue, such as through its outpatient infusion centers, RCH would literally be unable to exist as a hospital, and Richmond's East End would be without access to a key community provider of behavioral health, primary care and other services.*

The foregoing sits in stark contrast to the narrative in the New York Times article, which specifically faults RCH for closing its intensive care unit and not providing specialty care such as gastroenterology, intensive cardiology, or nephrology thereby creating a health care desert in Richmond's East End. This strawman criticism fails to account for the complex nature of how health care services are delivered and the environment in which RCH operates.[13]

Less than two miles down the road from RCH is VCU Medical Center, a government-owned, 340B-participating academic medical center with 693 beds, including 253 intensive care or specialized intensive care beds. Additionally, the Chippenham campus of CJW Medical Center, which is also a Level I Trauma Center,[14] and HCA Henrico Doctors' Hospital Forest Campus, which is a Level II Trauma Center, are both less than 10 miles from RHC.[15] Based on their Trauma Center designations, these three enormous hospitals—three of the five largest in the Commonwealth of Virginia—are all required to have cardiologists on call, and two are required to have nephrologists and gastroenterologists on call, 24 hours a day.

With robust trauma, cardiology, nephrology, and gastroenterology services readily available nearby, it would be financially and practically irresponsible for RCH to maintain the

[12] 42 C.F.R. § 412.106(d)(2)(iii)(C)(3).

[13] For example, under the Virginia State Trauma Plan, certain hospitals have taken on the responsibility of providing hospital-level care in certain medical specialties. Offering these services and meeting other criteria lead to a "Trauma Center" designation. Level I and II Trauma Centers are required to have cardiologists on call and promptly available 24 hours a day. Level I Trauma Centers are required to have gastroenterologists and nephrologists at the same level of availability. Further, EMS providers are required to transport trauma designated patients to the nearest trauma center.

[14] ODEMSA Trauma Triage Performance Improvement Plan, FY 22 (Mar. 16, 2022), p. 21. (https://odemsa.net/wp-content/uploads/2022/04/ODEMSA-Regional-Trauma-Triage-Plan-2022.pdf) (last accessed Nov. 1, 2023).

[15] *Id.*

duplicative capabilities identified in the New York Times article. In fact, maintaining these services may put patients at risk, because clinicians and nurses need cases to maintain their skills. Yet despite the lack of these medical specialties at RCH, almost 98% of the patients who present at RCH's emergency department are treated at RCH rather than being transferred to another hospital such as VCU Medical Center or one of RCH's sister facilities located throughout the Richmond community. Simply put, just because an entity participates in the 340B Program should not require it to offer every medical specialty available, especially when patients have access to other local options for intensive care and academic medical center level specialties are readily available to support complex patient care needs. In fact, being required to duplicate such services would be clinically and financially irresponsible.

Infusion Centers Keep RCH Open

The New York Times article faults RCH for operating off-campus infusion centers, characterizing them as a way that RCH transfers the 340B benefit from the poorer residents of Richmond's East End to wealthy insured individuals in the suburbs. This is in every way inaccurate and highlights a misunderstanding of how the 340B Program works in general and how it was implemented at RCH.

RCH's 53% Medicaid payor mix (over 65% Medicaid and SSI) means it must find ways to generate revenue to sustain its operations. In general, Medicaid pays less than the cost of care, with some analyses finding that it reimburses only 88 cents on the dollar.[16] Nevertheless, implicit in the assertion contained in the New York Times article is the idea that 340B Covered Entities should pass through the entirety of all 340B discounts directly to patients. *Doing so would likely lead to the closure of facilities like RCH, because their reduced drug costs allow them to maintain access to services that RCH, in particular, provides at a loss of more than $33 million annually*. To suggest that one hundred percent of all 340B savings should be passed through to patients is not only unjustified under the 340B statute, and the other laws on which it relies, but would be operationally infeasible. Stated more plainly, to require direct savings pass-through to patients would negate the benefit of the 340B Program for Covered Entities, ultimately harming patients. We also note that, from a more technical perspective, the federal fraud and abuse laws prevent an entity from offering price reductions to Medicare and Medicaid beneficiaries in the absence of an individualized assessment of financial need, so passing through 340B savings without a financial needs assessment could lead to civil or criminal penalties.[17]

[16] *See, e.g.,* Ford, Tiffany and Michener, Jamila (June 16, 2022), *Medicaid Reimbursements are a Racial Justice Issue*, The Commonwealth Fund ("for example, in 2020 hospitals received only 88 cents for every dollar spent caring for Medicaid patients. This amounted to a $24.8 billion underpayment").

[17] 42 U.S.C. §§ 1320a-7a(a)(5) (prohibiting remuneration that may incentivize a patient to receive Medicare- or Medicaid-reimbursable services from a particular provider or supplier), 1320a-7b(b) (prohibiting

Committed to Caring for the Community

RCH has a robust financial assistance program that helps it provide care regardless of a patient's ability to pay. **RCH's Financial Assistance Policy provides for a *full discount* on hospital services for individuals under 200% of the federal poverty guidelines, with a 76% discount for patients up to 400% of the federal poverty guidelines**. In 2023, these thresholds are $60,000 and $120,000, respectively, for a family of four.[18] In addition, RCH's Financial Assistance Policy includes a number of categories for presumptive eligibility, including for patients who live in low-income or subsidized housing, are Medicaid-eligible, are discharged to a SNF, are on state-funded prescription programs, are homeless or received care from a homeless clinic, participate in Women, Infants, and Childrens ("WIC") or food stamps programs, or are eligible for free school lunches.[19] *In fact, in 2022, BSMH provided $645 million in community benefit services despite losses of $1.2 billion.* This means that across the system, more than half of BSMH's "losses" came from pursuit of its charitable mission, including in the East End of Richmond. While these expenditures might count as financial losses, they are critical to BSMH's mission.

RCH's financial assistance program is more generous than that of the VCU Medical Center, which tops out at 300% of the federal poverty level, as well as that of HCA Virginia, which tops out at 200%.[20] We note that, as provider-based hospital departments, *the infusion centers maligned by the New York Times are covered by the RCH Financial Assistance Policy.* If they were freestanding locations, they would be covered by the BSMH Medical Group Financial Assistance Policy, which could be seen as less generous because, like the VCU Medical Center policy, it tops out at 300% of the federal poverty level.

Financial assistance extends, also, to BSMH's wholly-owned Harness Health Pharmacies, some of which are contract pharmacies for RCH. If a patient is eligible under BSMH's Financial Assistance Policy for hospitals, the patient will receive the same level of discount at the BSMH pharmacy.[21] It should be noted that this leads to better, more equitable

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remuneration in exchange for federal health care program business); 42 C.F.R. §§ 1003.110 (defining "remuneration" to exclude waivers of copays and deductibles when, among other things, a provider conducts an individualized financial needs assessment), 1001.952(k)(3) (creating a safe harbor under the Anti-Kickback Statute for waivers of copays and deductibles when, among other things, a pharmacy conducts an individualized financial needs assessment).

[18] *See* HHS Office of the Assistant Secretary for Planning and Evaluation, *Poverty Guidelines* (https://aspe.hhs.gov/topics/poverty-economic-mobility/poverty-guidelines) (last accessed Nov. 1, 2023).

[19] BSMH Financial Assistance Policy for Hospital Services.

[20] HCA Virginia is the for-profit entity over Chippenham Hospital, and Henrico Doctors' Hospital. VCU Health Patient Financial Assistance Policy (2023); HCA Virginia Patient Financial Assistance Statement (retrieved Nov. 1, 2023). We note that HCA's Financial Assistance Statement implies that assistance may be available for patients with documented incomes of up to 400% of the federal poverty level, but does not provide detail on the level of assistance or additional conditions that are placed on that assistance.

[21] BSMH Harness Health Pharmacy Charity Care Policy.

outcomes than a direct pass-through of the 340B discount. Although the 340B discount is substantial, it does not reduce the cost of a drug to $0. RCH's Financial Assistance Policy does for patients who need it.

RCH's 340B savings has allowed it to embed patient financial coordinators in its clinics, which led to reduced patient payment amounts of more than $5.5 million from January through August, 2023, and more than $27.5 million from 2019 through 2023. These coordinators help patients evaluate the cost of care and identify sources of assistance, including BSMH's Financial Assistance Policy, as well as need-based assistance from independent foundations and manufacturers themselves. So, while the payor mix in the neighborhoods where most of RCH's off-campus infusion centers are located allows it to sustain its operations by providing infusion services, this does not come at the expense of financially vulnerable patients. *As such, the 340B Program and provider-based status in fact allow enhanced access to charity care to the RCH community.*

It is within this context that we acknowledge that RCH's provider-based outpatient infusion centers generate revenue for the RCH. However, without this revenue, the hospital would likely have been closed years ago. A patient mix with 56% Medicare and Medicaid beneficiaries is simply not sustainable in light of the other health care resources available in the region. By opening provider-based departments such as an infusion center in a community with a more favorable payor mix, RCH has been able to stay in the community and continue pursuing its charitable, nonprofit mission: "To extend the compassionate ministry of Jesus by improving the health and well-being of our communities and bring good help to those in need, especially people who are poor, dying and underserved."

To that end, BSMH and RCH have translated this revenue into substantial community investments and supported services that continue to operate at a loss. These commitments include:

- Primary care and specialty medical groups which staff RCH and physician clinics in the area

- A retail pharmacy which, until recently, was the only one within walking distance of the East End

- A Care-a-Van mobile service to make primary and preventive care more accessible in the community

- Development of the Sarah Garland Jones Center for Healthy Living

- Community Benefit Investments in the East End. Over the past 5 years, we have committed substantially to increasing access to care, behavioral health needs, community livability, educational achievement, and economic activity. Below are total donation figures for East End nonprofits from 2018-2023:

  - Access to Care - $1,170,000
  - Behavioral Health - $394,000
  - Community Livability - $3,182,000
  - Educational Achievement - $1,867,000
  - Economic Equity - $1,924,500
- $1.6 million donation to the Salvation Army Boys and Girls Club for construction of a gymnasium and fitness center
- $200,000 partnership with the Greater Richmond Transit Company to build sheltered bus stops along Richmond's city bus lines
- $156,000 to support a Play60 playground for Richmond youth

The impact that RCH makes on its community is immense, diffuse, and only possible because of the revenue generated through RCH's outpatient infusion centers and the 340B Program.

We would address, also, the New York Times article's conclusion that RCH was the most profitable hospital in the Commonwealth in 2020, showing a 44% profit margin in Virginia Health Information data. It is true that a limited data set showed those numbers, but the article failed to acknowledge that as of January 1, 2020, all of the physicians that had previously been employed by RCH were moved to BSMH's affiliated medical groups. As with many such decisions, this restructuring was spurred by Federal policy choices: here, the federal fraud and abuse laws. By organizing the providers under a medical group instead of a hospital, BSMH could have more options to recruit physicians to the area under the Stark Law's group practice exception.[22] As a result of this restructuring, though, the costs associated with employing these physicians (who continue to staff the hospital) were moved off of RCH's books. Today, BSMH's medical groups that serve the Richmond Community operate at a net loss of over $100 million per year, with the shortfall made up by BSMH hospitals in the community, including RCH. Rather than subverting the 340B Program's intent, then, this exemplifies it: RCH reduced its costs and found opportunities to earn revenue, enabling it to provide primary and specialty care in the East End community.

In the wake of the New York Times article, RCH and BSMH leadership evaluated RCH's commitment to the community, identified substantial ways in which that commitment had been acted on since before the article was published, and convened meetings with local leaders to understand how RCH may have fallen short. These efforts contributed to the

[22] 42 U.S.C. § 1395nn(e)(7).

development of RCH's **Community Today, Community Tomorrow** plan through which it is focusing, amplifying, and extending its commitment to the community.[23] A more complete description of this plan is enclosed for your review.

340B Program Participation Is Highly Regulated by HRSA and Other Authorities

The New York Times article referenced in your letter also raised a common criticism that the 340B Program is "unregulated." This misses the mark. In reality, Covered Entities must comply with a wide array of Federal and state legal requirements, accreditation standards, and contractual commitments to establish 340B Program eligibility and to use 340B-priced drugs.

It is true that Congress decided not to give HHS substantial new rulemaking authority when it created the 340B statute. Instead, Congress requires Covered Entities to demonstrate, on demand, their compliance with the 340B statute's prohibition on duplicate discounts and diversion of 340B drugs[24] through audits by HHS or manufacturers themselves.[25] These audits dive deep into a Covered Entity's implementation of the 340B Program; just the initial data request from HRSA's 340B Prime Vendor spans nine (9) printed pages and requires the Covered Entity to produce, among other things, tailored descriptions of its 340B Program implementation, claims-level pharmacy and hospital encounter data, Medicare cost report information including trial balances and work papers, provider lists, and contracts for each of contract pharmacy locations with highlights per the auditors' specifications.[26] During a full-day on-site audit, one of HRSA's on-site auditors sits side-by-side with Covered Entity personnel while they review patient charts, medical staff rosters, pharmacy purchasing data, and insurance claims to determine whether the Covered Entity limited its use of 340B drugs to only its patients, as is required under the 340B statute. HRSA performs about 200 of these audits each year. In addition to requiring repayment to manufacturers where noncompliance is found, HRSA's audit reports include Areas for Improvement to help a Covered Entity fortify its internal controls, reducing the likelihood of future noncompliance.

HRSA's audits add to the substantial list of legal requirements that Covered Entities must meet, and continue to meet, to achieve and maintain 340B eligibility. For instance, any urban acute-care hospital that participates in the Program must, as a threshold matter, participate in both the Medicare and Medicaid programs and treat a substantial number of low-income

[23] Community Today, Community Tomorrow program description.

[24] 42 U.S.C. § 256b(a)(5).

[25] 42 U.S.C. § 256b(a)(5)(C).

[26] *See* 340B Prime Vendor (Apexus), Sample HRSA 340B Audit Data Request List (DRL) for Covered Entities, (https://www.340bpvp.com/Documents/Public/340B%20Tools/sample-hrsa-340b-audit-data-request-for-covered-entities.pdf) (last accessed Nov. 1, 2023).

patients.[27, 28] Complying with Medicare and Medicaid program requirements is no easy task, as acknowledged by Federal judges who colorfully (but accurately) describe these statutes as "among the most completely impenetrable texts within human experience. Indeed, one approaches them at the level of specificity herein demanded with dread, for not only are they dense reading of the most tortuous kind, but Congress also revisits the area frequently, generously cutting and pruning in the process and making any solid grasp of the matters addressed merely a passing phase."[29].

Rather than creating new administrative burdens, Congress sensibly relied on Medicare program requirements as a threshold for 340B Program eligibility. Each year, hospital administrators must certify under threat of administrative, civil, and even criminal penalty that the hospital is in material compliance with each and every one of Medicare requirements upon which 340B Program eligibility is predicated.[30] The Medicare Act mandates discipline and intentionality for all aspects of hospital 340B Covered Entity operations, setting minimum requirements for services offered,[31] provider credentialing and self-governance,[32] patients' rights,[33] and hospital administration.[34] This certification is made on the first page of the hospital's annual cost report, a form which HHS estimates to take, on average 674 hours to complete each year for each hospital.[35] Layer onto the Medicare Act any requirements that the state imposes through its licensing regime, its Medicaid program, its public health laws, and fiscal initiatives such as state hospital taxes (which are often applicable even if, as addressed next, the hospital is tax exempt under federal law), and the burden of simply *being* a 340B-eligible hospital comes into focus.

As an additional layer of financial accountability, the 340B statute limits Program participation to government or "nonprofit" hospitals, which is often construed to mean

[27] 42 U.S.C. § 256b(a)(4)(L) (permitting a "subsection (d) hospital" to participate in the 340B Program if its disproportionate share percentage is higher than 11.75%, where both "subsection (d) hospital" and "disproportionate share percentage" are defined by cross-reference to Title XVIII of the Social Security Act (also called the Medicare Act)).

[28] As described in further detail below, RCH far exceeds the minimum required for caring for low-income beneficiaries.

[29] *Abraham Lincoln Mem'l Hosp. v. Sebelius*, 698 F.3d 556, 541 (7th Cir. 2012) (*citing Rehab. Ass'n of Va. v. Kozlowski*, 42 F.3d 1444, 1450 (4th Cir. 1994)).

[30] *See* CMS Hospital Cost Report Worksheet S, Part II (Form CMS-2552-10).

[31] 42 C.F.R. §§ 482.21-482.45.

[32] 42 C.F.R. § 482.22.

[33] 42 C.F.R. § 482.13.

[34] 42 C.F.R. § 482.12.

[35] 87 Fed. Reg. 37,337, 37,338 (June 22, 2022).

hospitals that are tax-exempt under the Internal Revenue Code.[36] To maintain tax-exempt status, a hospital must not only comply with the multitude of requirements applicable to all tax-exempt entities under Section 501(c) and the various rules interpreting it,[37] but they must also meet the community benefit requirements under Section 501(r). At a minimum, this means the hospital must perform a community health needs assessment, offer financial assistance through a publicly accessible financial assistance policy, limit its charges to persons eligible for assistance under that policy to the amounts generally billed to those with insurance, and verify that the individual is not eligible for assistance under the policy before attempting to collect payment. Outside of CMS and the IRS, a hospital must be cognizant of, and actively comply with, requirements imposed by the Drug Enforcement Agency,[38] HHS Office for Civil Rights, [39] the HHS Office of Inspector General, [40] the Food and Drug Administration,[41] OSHA and state and federal Departments of Labor,[42] as well as accrediting agency standards and others.

Entire industries are built around compliance with these regulatory regimes, and Covered Entities such as RCH devote substantial resources to ensuring that they meet these obligations. They are subject to audit by HRSA, by manufacturers, by CMS and OIG and the IRS; they face unannounced accreditation surveys and accept reimbursement under Federal payment programs which permit any person with direct knowledge of a violation to sue on the government's behalf and collect a portion of any settlement or judgment. The simple story that the 340B Program is wayward, unregulated, or a failure is simply untrue.

Drug Manufacturers Profit from 340B Program Participation

As alluded to above, drug manufacturers agree to participate in the 340B Program because without it, the Federal government would not pay for their drugs through Medicare Part B or Medicaid. Manufacturers could cease their participation in the 340B Program at any time; as their contracts with the government only require them to provide 60 days' notice. **Instead, drug manufacturers stay in the 340B Program because it is extremely profitable for them to do so**. Figures recently made public show that the federal government and Medicare beneficiaries spent more than $175 billion on Part B drugs from

[36] *See* 340B Prime Vendor (Apexus), Sample HRSA 340B Audit Data Request List (DRL) for Covered Entities, p. 3 (https://www.340bpvp.com/Documents/Public/340B%20Tools/sample-hrsa-340b-audit-data-request-for-covered-entities.pdf) (last accessed Nov. 1, 2023).

[37] Estimated to take, on average, 107 hours to complete, *see* Internal Revenue Services, 2022 Instructions for Form 990, p. 51.

[38] Regulating a hospital's handling of controlled substances.

[39] Regulating a hospital's use of patient protected health information, among other things.

[40] Regulating a hospital's financial relationships with physicians and other potential referral sources.

[41] Regulating a hospital's drug supply chain.

[42] Regulating workplace safety and worker relations.

2017 to 2021, and state Medicaid programs spent more than $367 billion on drugs in the same time frame.[43] Just for the 25 drug manufacturers that have restricted drug shipments to Covered Entities' contract pharmacies Medicare and Medicaid paid them $86 billion and $219 billion, respectively, in the same 2017-2021 time frame. We note that the Medicaid figures provided here do not take into account the rebates that manufacturers paid back under the MDRP, because CMS does not publish data that would allow us to deduct these rebates.[44]

The "best price" provision in the 340B statute holds manufacturers accountable for their own pricing decisions (as discussed below). This is not unreasonable. A recent MACPAC study concluded that Medicaid drug rebates reduced Medicaid gross drug spending by over half.[45] A recent MACPAC study found that **almost half of all brand drugs had their Medicaid rebate amount set through the statute's "best price" provision, meaning the manufacturer affirmatively chose to offer a better discount on the drug to a purchaser other than state Medicaid agencies, 340B Covered Entities, or Federal agencies like the Department of Veterans Affairs.**[46] These drugs represented more than two-thirds of all claims and led to a basic rebate of more than 50% of the drug's average sales price.[47] When the inflationary rebate was added, the final Medicaid rebate averaged to more than 76%.[48] This is not surprising considering that manufacturers have (as described by PhRMA) "entire departments devoted to the calculation of government-reportable prices."[49] They "enlist expensive and sophisticated computer systems to track sales, customers, adjustments, discounts, rebates, price concessions, and other data just for this purpose."[50] Finally, they "employ legal and compliance offers specifically trained in the administration of pricing reporting requirements, who issue and oversee detailed internal policies and procedures."[51] In short, manufacturers are highly sophisticated organizations that are

[43] Figures calculated from data.cms.gov databases, *Medicare Part B Spending by Drug* (2021) and *Medicaid Spending by Drug* (2021).

[44] This lack of transparency is a common challenge faced by Covered Entities. Enclosed with this letter is an Excel workbook that incorporates these CMS data sources, but you will see that we had to rely on sources from the FDA, a CMS contractor, and our external legal counsel to tie payment amounts to manufacturers.

[45] Chris Park, *Trends in Medicaid Drug Spending and Rebates*, MACPAC, 16 (https://www.macpac.gov/wp-content/uploads/2022/10/07_Trends-in-Medicaid-Drug-Spending-and-Rebates-Chris.pdf) (last accessed Nov. 1, 2023).

[46] *Id.*, 25.

[47] *Id.*

[48] *Id.*

[49] Brief of Pharmaceutical Research and Manufacturers of America (PhRMA) as *Amicus Curiae* in Support of Petitioners at 17, *Astra USA, Inc. v. County of Santa Clara*, 563 U.S. 110 (2010) (No. 09-1273), 2010 WL 2101767.

[50] *Id.*

[51] *Id.*

capable of, and responsible for, managing their own sales practices. So to the extent that the 340B discount and Medicaid rebate exceed the statutory minimum, it is solely because of manufacturers' choices to further maximize profits.

These figures tell a clear story of the relentless pursuit of profits by multinational drug manufacturers that make billions from public payors while dealing sharply with RCH and other Covered Entities to limit the reach of the 340B Program. Further, the data that led to these insights was hidden even from MACPAC, Congress's own advisor, until 2021.[52] It is noteworthy, then, that Covered Entities have substantial reporting obligations under Medicare, Medicaid, federal grant programs, and the Internal Revenue Code, while manufacturers' price information is apparently so sensitive that it takes an act of Congress for Congress's own advisory agency to receive it.

The 340B Discount Is Driven Solely By Manufacturers' Pricing Decisions

Finally, your letter asked RCH to provide a full accounting of the 340B benefit it realized from 2018 through 2023. This is difficult to quantify, but we have done our best and shown our work in the enclosed Excel workbook. We note that our estimates are based on information currently known to RCH, and that these estimates will likely not reflect the actual 340B discount for any particular drug.[53] As you know, the minimum 340B discount is 23.1% for brand-name drugs and 13% for generic drugs, both based on manufacturers' "average sales price" in a calendar quarter.[54] However, if the manufacturer of a brand-name drug offers a better price (the "best price") to another purchaser, they must honor that price for Covered Entities and Medicaid agencies.[55] In addition, price increases for 340B and Medicaid purchasers are capped at the rate of inflation.

We have used our own purchase data to estimate the difference between the price we paid for a drug and the price we may have paid at the time if RCH had not participated in the 340B Program. This measurement should not be interpreted to be the "cost" manufacturers incur for participating the Program. One way to calculate that "cost" would be to measure the actual 340B discount and MDRP rebate amounts as provided in the MDRP statute, but the underlying data is, by law, not provided to Covered Entities.[56] It would also be important to offset that "cost" against the revenues manufacturers earn through the Medicaid and

[52] MACPAC, *Trends in Medicaid Drug Spending and Rebates* (https://www.macpac.gov/publication/trends-in-medicaid-drug-spending-and-rebates/) (last accessed Nov. 1, 2023) ("In 2021, Congress gave MACPAC access to the price benchmarks used to calculate Medicaid rebates and the actual rebate amounts for individual drugs.").

[53] This is because the factors affecting the 340B price are not available to Covered Entities. This is an area where we would welcome greater Congressional or regulatory guidance.

[54] 42 U.S.C. § 1396r-8(c).

[55] *Id.*

[56] 42 U.S.C. § 1396r-8(b)(3)(D).

Medicare Part B programs, which are the "carrot" that causes them to accept the 340B and MDRP "stick". As detailed near the end of this letter, those revenues are monumental.

Conclusion

We would like to formally invite you and your colleagues to visit RCH. We would be proud to take you on a tour of our facilities as well as sit down to openly and honestly discuss how the 340B Program continues to make important and necessary care possible in the East End. These conversations are important, because the 340B Program exists at the confluence of two remarkably complex domains: the drug distribution system, and the health care delivery system. Here, even capable, diligent, and earnest inquiry can lead to mistaken conclusions. Intentionally or not, the New York Times article and other public critiques of the 340B Program press a normative argument that Covered Entities should ***do more***, often failing to account for important context along the way. As shown in the enclosed materials, RCH has done, and continues to do, many good things to improve the lives of those in the East End and in Richmond. The 340B Program is instrumental to that work. As you and your colleagues evaluate the 340B Program, we urge you to be wary of simple stories, because the truth is never simple in the American health care system.

Sincerely,

BON SECOURS MERCY HEALTH, INC.

John M. Starcher, Jr., Esq., CEO

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#	**Request**	**Response**	**Supporting Enclosures**
1	Does Bon Secours pass on all savings generated from the 340B Program to patients at Richmond Community Hospital in the form of savings on health care expenses? If not, why not? Please explain in detail.	For the reasons noted in our responsive letter, BSMH does not directly pass on all savings generated from the 340B program to patients at Richmond Community Hospital in the form of savings on health care expenses. *Directly reducing patients' drug expenses is not the purpose of the 340B Program,* as reflected in the federal fraud and abuse laws that prohibit copay waivers and other direct cost-sharing subsidies in the absence of an individualized financial need assessment. If 340B acquisition cost pass-through were mandated, we expect that many safety-net providers would be forced to close because they, like RCH use the savings generated by the 340B Program to subsidize the significant broader costs associated with providing high quality health care in a legally compliant manner and implement the 340B Program in a manner that complies with HRSA OPA's expectations. Patients receiving care at RCH are eligible for financial assistance consistent with the attached BSMH Financial Assistance Policy. Consistent with 26 U.S.C. § 501(r), this policy, a plain language summary of the policy, and financial assistance forms are available on the BSMH website in English, Spanish, Arabic, Chinese, French, Haitian Creole, Hindi, Korean, Nepali, Portuguese, Russian, and Vietnamese.	1, 2
2a	Please provide a complete accounting of the funds Bon Secours generated from the 340B Program from Richmond Community Hospital. This information should be provided in Excel format. In addition, please include the following information: a. The total dollar amount generated from the 340B Program categorized by: i. Site of service.	Calculating the value of savings facilitated by the 340B Program is a persistent challenge for Covered Entities because it requires engaging in a counterfactual examination of past practices. That is, the Covered Entity must determine what it would have paid for a drug if it had not been purchased under the 340B Program. In the case of DSH hospitals like RCH, participating in the Program means giving up the ability to purchase covered outpatient drugs through a Group Purchasing Organization ("GPO") or other group arrangement. So, the GPO price should be used as the "price that would have been paid" when calculating the 340B Program benefit.	3, 4

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	ii. Therapeutic class of drugs. iii. HCPC or CPT code (as applicable). iv. Name and address of dispensing pharmacy. If the dispensing pharmacy was an onsite pharmacy, please note whether the pharmacy is wholly or partially owned by Bon Secours.	Enclosed are Excel workbooks attempting to calculate the 340B benefit along with the supporting data you requested. We performed these calculations using the price we paid at the time of purchase, which may be the 340B price or a sub-340B price available through HRSA's 340B Prime Vendor. This means that we implemented a conservative approach and the savings described is higher than mandated under the 340B Program. We subtracted the purchase price from the GPO price that would have been available at the time if RCH were not subject to the GPO prohibition. Under this formulation, *BSMH saved approximately $232.1 million on drug purchases from September 2018 through September 2023*, with substantially all of the savings occurring within the provider-based outpatient infusion centers. We emphasize that **this figure represents savings, not revenues**. With respect to contract pharmacy arrangements, the vast majority of RCH's contract pharmacy claims are dispensed through BSMH's wholly owned retail, specialty and home-delivery pharmacies, which helps ensure that patients receive high-level care for conditions treated with medication that requires special handling, monitoring for dangerous side effects, or is otherwise unsuited to being stocked in a community pharmacy. These pharmacies operate under the "Harness Health Pharmacy" brand, and they accounted for 84% of all of RHC's contract pharmacy claims between September 2018 and September 2023. In this time frame, RCH generated approximately $39.4 million in revenue from 340B drugs dispensed through our contract pharmacies. As you know, drug manufacturers began restricting their shipments to contract pharmacies in 2020. We believe these restrictions are unlawful, but manufacturers have capitalized on HHS's unwillingness to terminate their Pharmaceutical Pricing Agreements or impose civil monetary penalties under existing legal authority, leading to one Court of Appeals decision that, unfortunately, favors their position. Since that opinion was issued in January 2023, manufacturers have stacked	

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		restrictions on one another, making it nearly impossible for some Covered Entities to receive covered outpatient drugs at their contract pharmacies. Due to these increasing manufacturer restrictions, we expect the revenue that RCH generates through the Harness Health pharmacies to figure to drop significantly in the next year. This will, unfortunately, have a very real impact on our ability to continue care-related subsidies. We also note that for the 19% of claims that are handled by third-party pharmacies, most of them go through Accredo Specialty Pharmacy. Covered Entities such as RCH face pressure from for-profit third parties such as Accredo as those entities continually increase their fees. This issue is compounded by vertical integration in the drug distribution system. For instance, Accredo is owned by ExpressScripts, a national pharmacy benefit manager that earns rebates from drug manufacturers when its beneficiaries use their drugs. ExpressScripts, in turn, is owned by Cigna, which also operates a specialty wholesaler (CuraScriptSD) and a 340B third-party administrator (Verity Solutions), which charges fees for data-matching services that facilitate contract pharmacy relationships. This type of vertical integration allows Cigna and its competitors to demand ever-increasing fees from Covered Entities, reducing the Entities' ability to care for their communities.	
2b	The specific dollar amount directly passed on to patients at Richmond Community Hospital, excluding offsite outpatient facilities registered as child sites, each year, categorized as: i. Direct-to-patient savings on prescription medications, as defined as a discount on the total medical billings that patients otherwise would have been	As noted above, the 340B Program is not intended to directly reduce drug costs for patients. Its purpose is to prevent drug manufacturers from siphoning off federal funds that Congress has devoted to public health goals. Direct pass-through would undercut those goals, as demonstrated by HHS's own analysis. In late 2020, HHS published a rule which required federally qualified health centers ("FQHC") that participate in the 340B Program to make assurances that they charged low-income patients no more than the 340B price, plus an administration fee, for insulin and	5, 6

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	billed. Total medical billings should already include applicable federal programs, charity care, discounts, and adjustments from private and public health insurance programs. ii. Direct-to-patient savings on medical billings other than prescription medications, as defined as a discount on the total medical billings that patients otherwise would have been billed. Total medical billings should already include applicable federal programs, charity care, discounts, and adjustments from private and public health insurance programs. iii. Indirect patient savings. Please provide significant justification as to the form of the indirect patient savings, and how the patient was able to benefit from these savings.	epinephrine.[57] Less than a year later, HHS rescinded the rule "because the overall impact of the additional administrative costs and burden that [it] would have placed on health centers would have harmed health centers and the patients they serve."[58] As explained below, BSMH was unable to calculate the savings in exactly the way it was requested. However, BSMH is providing community benefit information for RCH, broken down as reported on BSMH's publicly available tax returns. BSMH was unable to break down its community benefit information in the way that was requested for several reasons. First, to the extent that the question includes medical (hospital-administered) as well as pharmacy (dispensed) claims, prescription drugs are often paid in conjunction with medical services as part of a bundled payment. For Medicare Part B outpatient services, these payments are based on the "Ambulatory Payment Classification" assigned to a group of services the hospital provides. It is unclear whether the Centers for Medicare and Medicaid Services publishes data that would allow a hospital to assign costs to only the drugs included in an APC payment; if that data is available, BSMH was unable to identify internal or external resources with the ability to use it in the time provided. Second, the nature of prescription drug transactions makes it very difficult to determine the extent to which a patient is ultimately responsible for payment. Public policy favors patient copay and deductible benefit design as a means of ensuring some reasonable barriers to access remain in place when the patient decides whether to fill a prescription, ask for alternatives, etc. In this environment, manufacturers routinely set exorbitant prices for their breakthrough products, then evade these	

[57] 85 Fed. Reg. 83,822 (Dec. 23, 2020).

[58] 86 Fed. Reg. 54,390, 54,391 (Oct. 1, 2021).

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		copays and deductibles by offering financial assistance to patients who are well above the federal poverty line. AbbVie, for example, offers financial assistance for patients up to six (6) times the federal poverty level.[59] Manufacturers often provide this financial assistance in the form of copay cards or through other means that are not apparent to the dispensing pharmacy and which may cause a patient not to pursue financial assistance from the pharmacy. Finally, we note that providing direct-to-patient savings outside of a patient-specific financial assistance determination could violate state or federal law prohibiting kickbacks and beneficiary inducement. To evade these laws, manufacturers routinely exclude Medicare and Medicaid beneficiaries from their patient assistance programs.[60] RCH, of course, does not.	
2c	The specific dollar amount spent on capital improvement, executive compensation, or other expenditures associated with: i. Richmond Community Hospital, excluding offsite outpatient facilities. Please explain in detail how those funds were spent. ii. Offsite outpatient facilities registered as a child site of Richmond Community	Attached is a breakdown of capital investments at RCH from 2013-2022, as well as a separate breakdown from 2022-2023. It shows that in that time, RCH invested nearly $800,000 to renovate its emergency room, more than $385,000 to provide digital mammography services, and more than $1,750,000 to build the Sarah Garland Jones Center for Healthy Living. This community center is located across the street from RCH and offers hands-on cooking classes, group-based therapy sessions for adolescent behavioral health, and wellness therapies for hypertension, diabetes, and cardiac conditions. More recently, *RCH has committed more than $25 million to capital improvements*	7, 8, 9

[59] *See, e.g.*, AbbVie, myAbbVieAssist Income Criteria, which offer assistance to a single patient with an income of up to $87,480 or less (https://www.abbvie.com/patients/patient-support/patient-assistance/income-criteria.html) (last accessed Nov. 1, 2023); *see also* AbbVie, *Savings Card* (https://www.abbvie.com/patients/patient-support/patient-assistance/savings-card.html) (last accessed Nov. 1, 2023).

[60] *See id.*

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	Hospital, including primary care centers, community health centers, imaging centers, specialty care centers, and any other facilities. Please explain in detail how those funds were spent. iii. Offsite outpatient facilities, medical centers, and other facilities offering health or medical services in the Richmond area as part of the Bon Secours system. Please explain in detail how those funds were spent.	*in the East End, which includes $16.5 million spent constructing a medical office building.* While the New York Times article implied that RCH continually dragged its feet on this project, the reality is that RCH completed the project in accordance with its designated timeline. Other commitments include $4.3 million for an MRI suite, $1.85 million to construct an urgent care center, $365,000 to further enhance its 3D mammography capabilities, and $71,000 on pediatric dental equipment. Also attached is a list of RCH's 340B child sites, which include infusion centers, three oncology clinics, a gynecologic oncology clinic, a rheumatology clinic, and a hepatology clinic. Total capital investments in these locations from 2018-2023 has been $3.3 million. As to investments in other capital projects in the Richmond market, attached is a written narrative describing the investments.	
3	Please provide copies of all documentation governing the relationship between Richmond Community Hospital and its offsite outpatient facilities registered as child sites, including how 340B revenue is generated and distributed throughout the Bon Secours system.	Each of the child sites is a provider-based department of RCH, meaning that they are fully part of RCH and are not administered separately from the rest of RCH. This is required by law. Under CMS's provider-based regulations, a hospital is prohibited from treating an off-site facility as provider-based unless, among other things, it is operated under the same organizational documents as the main provider and has a reporting relationship that has the same frequency, intensity, and level of accountability as in the relationship between the main provider and its on-campus departments.[61] Although CMS does not require it, RCH chose to submit documentation demonstrating that its off-campus infusion centers met these and the many other	10

[61] 42 C.F.R. § 413.65(e).

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		criteria that apply to provider-based departments when it converted those departments to provider-based status in 2016. CMS approved these attestations. Furthermore, at the time the off-campus infusion centers were added to RCH's Medicare provider enrollment, RCH officials attested, under penalty of perjury, that each provider-based location met these standards. A consequence of provider-based status is that an off-campus department is subject to all the same standards that apply to the main hospital. *RCH is accredited by the Joint Commission, having completed its most recent recertification in 2021, when it was found to be in full compliance with the applicable accreditation standards.* In this light, RCH has been unable to collect information directly responsive to this request, because the documents requested govern all of RCH's operations. These documents would include, for example, Medical Staff Bylaws, patient care policy and procedure manuals, financial reporting workpapers, Medicare Cost Report working papers, trial balances and other work papers, Medicare enrollment forms including the CMS Form 855A and 855B, Medicaid enrollment forms, operational policies and procedures, and many others. Given the significant workload involved with identifying these materials, we would request additional clarification regarding this inquiry and would be happy to provide additional information if necessary. To be certain, though, neither BSMH nor RHC has policies which contemplate allocating 340B Program-related savings or revenue for particular purposes.	
4	Please explain in detail how Bon Secours spends the revenue it generates from the 340B Program. In addition, please provide the following: a. Copies of all internal guidance documents and other policies and procedures explaining how Bon Secours	RCH and BSMH allocate all revenue consistent with a large number of legal requirements including IRS tax exemption standards, CMS cost reporting standards, state hospital operations laws, and the federal fraud and abuse laws. *RCH's robust charity care policy, developed in conjunction with legal counsel to ensure compliance with laws that prohibit kickbacks and beneficiary inducement, allow us to reduce the cost of care for financially at-risk and needy patients.* Certainly, revenues from our contract pharmacy and outpatient infusion centers enable us to	See narrative

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	spends 340B revenue. To the extent Bon Secours has any unwritten relevant policies or procedures, please explain them in detail. b. A list of all Bon Secours officials who have authority over how the health system spends the revenue it generates from the 340B Program. c. All records, including written and electronic communications, involving Bon Secours' senior leadership related to the expenditure of revenue generated from the 340B Program.	provide this care. With that being said, RCH and BSMH do not allocate or earmark 340B savings in any structured way. In short, revenue is revenue, and all revenue is used to pay for expenses incurred in pursuit of our mission.	
5	Please provide all written and electronic communications in which Bon Secours communicated with its provider staff in regard to the 340B Program. These communications should include all instances in which Bon Secours communicated (whether directly or indirectly) about provider incentives as it related to the 340B Program.	We would appreciate clarification on this question, if possible, and would further appreciate any information you have regarding provider incentives that may create legal or reputational risk for BSMH or RHC. BSMH has policies, procedures, and controls governing employed and non-employed provider compensation, and the 340B Program plays no role in these decisions. The federal Anti-Kickback Statute and the Physician Self-Referral ("Stark") Law drive many decisions related to provider compensation. BSMH's employed providers are compensated on a productivity, salary, or shift model. In general, providers within the same specialty and market will be compensated under the same model. To help ensure that it complies with the Anti-Kickback Statute and the Stark Law, BSMH proactively monitors provider compensation using industry-standard provider compensation and productivity survey data. Consistent with guidance from the Centers for Medicare and Medicaid Services and the HHS Office of Inspector General, BSMH also developed a Strategic Care	See narrative

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		Initiative through which employed providers can receive appropriately scaled additional compensation if they meet objective, clinically vetted quality metrics. These metrics focus on areas such as Patient Safety/Quality/Reliability, Value-Based Care, Health Care Disparities, Coding Compliance Training, MaGICQ Core Measures, and Ongoing Quality and Access. Non-employed provider arrangements have standard contract terms and compensation methodologies in accordance with BSMH policy. Typically, these arrangements will compensate providers based on time or productivity. As with our employed providers, the 340B Program plays no role in these decisions.	

ENCLOSURES

No.	Description	Purpose	Medium
1	BSMH Financial Assistance Policy for Hospital Services	Responsive to request 1	PDF
2	BSMH Harness Health Pharmacy Charity Care Policy	Responsive to request 1	PDF
3	Excel workbook calculating 340B benefit for physician-administered drugs, including source data and pivot tables	Responsive to request 2a	Excel workbook, encrypted and password-protected
4	Excel workbook calculating 340B benefit for dispensed drugs, including source data and pivot tables	Responsive to request 2a	Excel workbook, encrypted and password-protected
5	Summary of RCH's community benefit spend, 2019-2023	Responsive to request 2b	PDF
6	Tax returns applicable to RCH for 2018-2021 (2020 covered on 2021 form; 2022 form not yet finalized)	Responsive to request 2b	PDF (multiple)
7	Summary of RCH's capital expenditures, 2013-2023	Responsive to request 2c	PDF
8	RCH's record from the 340B Office of Pharmacy Affairs Information System ("OPAIS")	Responsive to request 2c	.XLSX
9	Summary of BSMH's capital expenditures for its RCH, its 340B child sites, and other Richmond facilities, 2018-2023	Responsive to request 2c	PDF

No.	Description	Purpose	Medium
10	CMS Form 855A	Substantiates response to request 3	PDF
11	MACPAC Presentation, *Trends in Medicaid Drug Spending and Rebates* (Oct. 27, 2022)	Demonstrates that manufacturers' own pricing strategies inflate the 340B discount because they offer higher rebates to entities other than the Department of Veterans Affairs, Department of Defense, state Medicaid agencies, other government purchasers, and 340B Covered Entities.	PDF
12	VCU Health Patient Financial Assistance Policy (2023)	Comparator for BSMH's financial assistance policy	PDF
13	HCA Virginia Patient Financial Assistance Statement (retrieved Oct. 24, 2023)	Comparator for BSMH's financial assistance policy	PDF
14	VHI Financial Reports for Bon Secours Richmond Community Hospital (Sept. 1, 2018-Aug. 31, 2019; Jan. 1, 2020-Dec. 31, 2020).	Demonstrates that $10 million in costs were removed from RCH's books when employed physicians were moved into an affiliated medical group instead of being directly employed by the hospital.	PDF

No.	Description	Purpose	Medium
15	Excel workbook containing: Medicare Part B drug purchase data, 2017-2021 (data.cms.gov) Medicaid drug purchase data, 2017-2021 (data.cms.gov) Labeler code registry (FDA) HCPCS-NDC crosswalk (Palmetto GBA, a Medicare Administrative Contractor) List of 340B-participating manufacturers (HRSA OPA)	Substantiates BSMH's claim that notwithstanding their voluntary participation in the 340B Program and MDRP, manufacturers collect billions of dollars in payments from Medicare, Medicaid, and their beneficiaries. Demonstrates the difficulty of performing robust analysis of manufacturers' benefit from 340B and MDRP participation due to gaps in data collected and reported.	.XLSX
16	CMS EMTALA Survey Report for RCH, December 2022	Demonstrates that the claims in the New York Times article which may have indicated noncompliance with the Emergency Medical Treatment and Active Labor Act were unsubstantiated and that RCH otherwise complied with its EMTALA obligations, as determined through an unannounced, two-day, three-investigator survey.	PDF
17	Community Today, Community Tomorrow program description	Demonstrates RHC's substantial giving and continuing commitment to Richmond's East End	PDF

No.	Description	Purpose	Medium
18	RCH Cost Reports Covering Sept. 2019-Current	Background information demonstrating costs and charges associated with operating RCH. Substantiates BSMH's claim that RCH cares for a disproportionate number of low-income patients (see Worksheet E, Part A)	PDF (multiple)

BON SECOURS MERCY HEALTH

May 15, 2024

Via Electronic Transmission to [redacted] ([redacted])

The Honorable Bill Cassidy, M.D.
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

Dear Ranking Member Cassidy:

By this letter and its enclosed materials, Bon Secours Mercy Health ("BSMH") is providing its complete response to follow-up questions that we received from [redacted] on March 25, 2024 regarding Bon Secours Richmond Community Hospital ("RCH") and its participation in the 340B drug discount program ("340B Program"). We wish to thank you and the Committee staff for the time spent analyzing the information we provided on November 1, 2023 in response to your earlier request. We appreciate the opportunity to clarify and continue our discussion of the ways in which the 340B Program allows RCH and BSMH to provide high-quality, compassionate care in Richmond and throughout the communities we serve.

Below are the questions posed by your staff, each immediately followed by our response.

1. **Why do financial assistance policies vary by a hospital's location in BSMH's network?**

BSMH has adopted a system-wide Healthcare Financial Assistance Policy that applies to all BSMH hospitals located in the United States. In accordance with its system-wide FAP, all BSMH hospitals use the same sliding scale methodology to offer discounts to FAP-eligible patients with income levels up to 400% of the federal poverty guidelines ("FPG"). Any FAP-eligible patient between 0-200% FPG receives emergency and medically necessary services at zero cost at all BSMH hospitals. Any FAP-eligible patient between 201-400% FPG receives a discount that varies by hospital facility to align with the Amounts Generally Billed ("AGB") for the service. However, the AGB varies from facility to facility. These differences arise from the Tax Code.

As a tax-exempt organization that operates multiple hospitals, BSMH is considered a "hospital organization" under the Federal Tax Code. Section 501(r) of the Tax Code provides that a hospital organization must meet certain requirements related to patient financial assistance to maintain its tax-exempt status. As applicable here, a hospital organization must charge patients no more than the "amounts generally billed" ("AGB") for emergency and medically necessary care provided under its FAP.[1] However, the Tax Code requires that the AGB be calculated separately for each "hospital facility" that a hospital organization

[1] 26 C.F.R. § 1-501(r)-5(a).

operates.[2] The AGB is based on a hospital facility's actual experience with claims allowed by patients' insurers.[3] Both negotiated payment rates and patient characteristics vary from facility to facility, so the AGB varies from facility to facility, leading to differences seen in the system-wide FAP.

2. Why do out-of-pocket patients receive an across-the-board 40% discount regardless of a hospital's location?

To clarify, it is not the case that all out-of-pocket patients receive an across-the-board 40% discount. This self-pay discount is extended only to patients who do not qualify for financial assistance. If a patient qualifies for assistance under the BSMH FAP, they receive discounts that are universally more generous than the 40% self-pay discount.

Self-pay discounts are common in the healthcare industry. In BSMH's case, a self-pay patient is one who is either uninsured or simply chooses not to bill their insurance plan for a particular service. Patients can choose this approach for a wide variety of reasons. For example, they may have a high-deductible health plan where their insurer's negotiated rate would be more expensive than if the patient chooses the self-pay option.

Since the self-pay discount is not means-tested, it falls outside the scope of the 501(r) requirements, so BSMH is able to provide a uniform discount across its hospital facilities. See the attached BSMH Uninsured/Self-Pay Discount Policy for more information.

3. How much revenue did BSMH generate from patients without insurance?

BSMH's net patient revenue in calendar year 2023 was nearly $11,000,000,000 ($11 billion). Of this amount, less than 0.7% came from uninsured patients, totaling about $64,600,000 ($64 million). In calendar year 2022, BSMH's net patient revenue was about $10,200,000,000 ($10.2 billion). Of this amount, less than 1.0% came from uninsured patients, totaling about $100,000,000 ($100 million). These figures are reported in the audited consolidated financial statements prepared by KPMG.

4. BSMH did not produce financial statements for FY 2021-2023 (or past September 2020). Please produce these materials.

The audited consolidated financial statements for calendar years 2021-2023, prepared by KPMG, are attached. The first file covers 2021 and 2022, and the second file covers 2022 and 2023. These files are password-protected, and we will provide the password under separate cover.

[2] *Id.*

[3] *See id.* at § 1-501(r)-5(b)(3)(i).

5. **BSMH alleges that it incurred losses of $1.2 billion in 2022, but it did not produce financial statements for that time period. How does BSMH account for these losses? Please produce supporting documents.**

The audited consolidated financial statement covering 2022 and 2023 shows on page 6 a deficit of $1,204,784,000 for 2022. This loss is a combination of operating losses (totaling $402,905,000) and losses that are recorded as investment losses (totaling $925,329,000). However, it is important to note that these "investments" are principally held in BSMH's long-term operating portfolio, which is the collection of relatively liquid assets in which BSMH maintains its days-cash-on-hand. BSMH is required to meet certain thresholds of days-cash-on-hand due to bond commitments, and it otherwise maintains a cash balance to weather market disruptions outside of its control, such as the recent Change Healthcare ransomware event that significantly interrupted cashflow for many hospitals and health systems across the country.

6. **Please produce IRS Form 990s for FYs 2022 and 2023.**

A copy of the FY 2022 Form 990 is attached here. BSMH's 2023 Form 990 will not be filed until November 2024.

7. **Regarding the information produced on charity care. Do these figures also include financial assistance payments?**

Yes, they do.

8. **Between September 2018 and September 2023, how much savings did RCH generate in 340B drug purchases?**

The table below reflects 340B savings between September 2018 and September 2023.

Year	340B Savings (Hospital-Administered Drugs)	340B Benefit (Pharmacy Dispenses)	Total
2018	$12,435,271	$438,668	$12,873,939
2019	$43,146,926	$4,604,307	$47,751,233
2020	$47,507,055	$8,727,490	$56,234,545
2021	$45,257,703	$10,276,889	$55,534,592
2022	$45,817,423	$12,380,705	$58,198,128
2023	$37,962,759	$7,978,395	$45,941,154
Total	**$232,127,137**	**$44,406,454**	**$276,533,591**

These figures come from Exhibits 3 and 4 to our November response.

In a follow-up question, [redacted] asked for a breakdown of the $39.4 million of 340B benefit described in our November response. In calculating that figure, we added together the "340B Benefit" for years 2020-2023, excluding 2018 and 2019. When preparing our November response, we determined that the underlying contract pharmacy data for 2018 and 2019 may be incomplete, so we excluded them from the aggregate calculation. The full supporting data (including the available data for 2018 and 2019) is available in Exhibits 3 and 4 of our November response. We regret any confusion this caused.

9. Does RCH track its utilization of 340B revenue generated from its 340B wholly-owned contract pharmacies*?* If so, how?

RCH does not track its utilization of 340B savings generated from wholly-owned contract pharmacies.

10. Between September 2018 and September 2023, please produce information concerning types and amount of fees payed to third-party administrators.

BSMH is not able to provide this information due to confidentiality provisions contained in its contracts with its third-party administrators. Please see the attached response received from one of BSMH's third-party administrators, the Craneware Group, in which the third-party administrator enforced the confidentiality provision despite BSMH's request that it be waived. Macro Helix, another third-party administrator, also enforced a confidentiality provision in a legacy agreement. That correspondence is also attached.

11. Between September 2018 and September 2023, please produce your contracts with third-party administrators.

As stated above, BSMH is unable to provide these documents because its TPAs refused to waive applicable confidentiality provisions.

12. Does an uninsured patient pay the list price for the prescription, the 340B price, or the GPO negotiated price?

The answer depends on the pharmacy location. In general, the price that a patient pays for a prescription dispensed by a pharmacy (as opposed to a drug administered in a clinical care setting) is not directly related to the list price, the 340B price, or the GPO negotiated price, which all describe the price the pharmacy pays for the drug (*i.e.* the wholesale price).

In some cases, when a patient is uninsured or chooses to self-pay for a prescription drug dispensed through one of BSMH's wholly owned contract pharmacies, the pharmacy team works with the patient to reduce out-of-pocket costs by searching for coupon cards from a manufacturer or a third party such as GoodRx and, if applicable, referring the patient to BSMH financial assistance resources. As described in Exhibit 2 to our November response, financial assistance is available to patients through BSMH's wholly owned contract pharmacies. When financial assistance is unavailable and the patient is uninsured, the on-

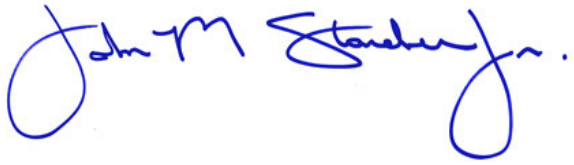
site contract pharmacy at RCH uses a "cost-plus" model where the patient is asked to pay the pharmacy's acquisition cost for the drug plus a nominal dispense fee. As shown in Exhibit 4 to our November response, this pharmacy ("Bon Secours – Virginia Healthsource Inc. DBA Bon Secours Good Health Pharmacy at Rich" [*sic*]) actually incurred a 340B savings loss of $1,768 for RCH from 2018-2023. Despite this loss and overall net operating losses incurred by this particular pharmacy location, BSMH continues to support the pharmacy because without it, members of the community may be unable to access their medications.

Conclusion

Thank you again for the time you have devoted to this matter. If you have further questions, we would be happy to set up a meeting with you and your staff to discuss this important issue. Finally, we take this opportunity to renew our invitation for you and your staff to visit RCH to see how it supports its community and exemplifies our commitment to providing much-needed care to vulnerable patients.

Sincerely,

BON SECOURS MERCY HEALTH, INC.



John M. Starcher, Jr., Esq., CEO

Enclosures

JONES DAY

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[redacted]

November 17, 2023 CONFIDENTIAL

VIA ELECTRONIC MAIL

[redacted]
Committee on Health, Education, Labor, and Pensions
United States Senate
428 Senate Dirksen Office Building
Washington, D.C. 2051

RE: Senator Cassidy's September 28, 2023 Letter to Cleveland Clinic

Dear [redacted]:

Enclosed is Cleveland Clinic's response to Senator Cassidy's letter of September 28, 2023, requesting certain information concerning Cleveland Clinic's participation in the 340B Drug Pricing Program. You should also be receiving from our office an FTP to a production of documents referenced in the enclosed response. The password to open the underlying 7-zip file containing the document production will be: [redacted]

The produced documents comprise 1,212 pages of information and have been Bates stamped CCF_0000001–CCF_0001212. Included in the production are four Excel files in native format. The inclusion of any document subject to the attorney-client privilege, the attorney work-product doctrine, or any other applicable privilege or protection from disclosure available by rule of evidence, statute, or common law is inadvertent and is not intended to waive the privilege or protection from disclosure.

Cleveland Clinic respectfully requests that its response and any produced documents remain confidential. In the event that a determination is made to publish or otherwise disclose to a third party any documents from Cleveland Clinic's production, Cleveland Clinic requests that you or your staff provide us notice and an opportunity to be heard.

If you have any questions about this production, please contact me.

Respectfully,

[redacted]

Enclosures

CLEVELAND CLINIC'S RESPONSE TO SENATOR CASSIDY'S SEPTEMBER 28, 2023 LETTER

Thank you, Senator Cassidy, for your letter of September 28, 2023, concerning Cleveland Clinic's participation in the 340B Drug Pricing Program (340B Program or Program). We welcome this opportunity to clarify certain points about the 340B Program raised in your letter and to respond to your requests for records and information about Cleveland Clinic's participation in the Program. Your interest in 340B Program oversight is sincerely appreciated; from Cleveland Clinic's entrance into the Program, we have complied with the Program's legal requirements strictly. We thus look forward to reasonably cooperating with your efforts.

This response begins with a background discussion of Cleveland Clinic[1] and its 340B Program participation, and then provides information specifically responsive to the requests set forth in your September 28 letter. We wish to stress from the outset, however, that Cleveland Clinic's participation in the 340B Program—although limited in time—has been critical in helping us better serve our patient communities. Consistent with Congress's goal to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services," the 340B Program has provided Cleveland Clinic meaningful cost savings that we have leveraged for our patients by preserving access to critical health care services in the face of fiscal headwinds.

Indeed, Cleveland Clinic's care extends from its Main Campus hospital located in Cleveland, Ohio, to more than 230 community-based locations and hospitals in areas throughout Ohio that also serve the state's Medicaid patients, Amish population, and other rural communities. While Cleveland Clinic may seem different from traditional "safety net" hospitals, which serve their communities by ensuring access to more routine hospital care, we provide an important and unique type of safety net with the high-quality tertiary and quaternary care we are renowned for; in some cases, we may be among a few providers in the country—or even the only provider—to offer certain specialty care. The cost savings Cleveland Clinic has realized from its participation in the 340B Program have allowed us to ensure that these highly specialized services are available for all patients in need, including those with limited financial means.

Lastly, Cleveland Clinic respectfully requests that this response and any produced records remain confidential. In the event that a determination is made to publish or otherwise disclose to a third party any documents from Cleveland Clinic's production, Cleveland Clinic requests that you or your staff provide us notice and an opportunity to be heard.

[1] Cleveland Clinic is a d/b/a of The Cleveland Clinic Foundation. We refer to The Cleveland Clinic Foundation throughout this letter as "Cleveland Clinic." The Main Campus is located in Cleveland and is the Cleveland Clinic location that is registered as the parent site for the 340B Program. Cleveland Clinic also has other community-based locations throughout surrounding communities in Ohio and is the parent of several other hospitals. When we reference Cleveland Clinic and these affiliated hospitals collectively in this letter, we refer to them as the "Health System."

I. BACKGROUND ON THE CLEVELAND CLINIC

Cleveland Clinic is a physician-led institution with a focus on world-class, highly specialized care. We are consistently recognized in the United States and throughout the world for our expertise. The patients we see have the highest acuity among major teaching hospitals in the country; at the same time, we are a significant provider of primary care, including being the largest provider of Medicaid outpatient visits in the state of Ohio. We operate across the United States with a footprint in Northeast Ohio, Florida, and Nevada with 20 hospitals, including our Main Campus, and more than 260 outpatient locations. From our founding in 1921 to the present, Cleveland Clinic has employed and salaried our physicians and Ph.D. scientific investigators; our compensation model further distinguishes us from other health systems that routinely incentivize physician productivity.

Cleveland Clinic is the largest employer in Ohio, and we employ 74,000 employees in the United States, including approximately 8,000 salaried physicians, researchers and trainees, and more than 30,000 registered nurses, nursing support personnel and advanced practice providers, representing 140 medical specialties and subspecialties. Last year, our Health System provided 12.8 million outpatient visits, 303,000 hospital admissions and observations, and 270,000 surgeries and procedures. Patients came for treatment from every state and from 128 other countries. Still, our mission remains that of our founders: caring for life, researching for health, and educating those who serve.

Specialization and sub-specialization have characterized the practice and growth of Cleveland Clinic, while our commitment to the integration of research and education into a dynamic health care practice has allowed Cleveland Clinic and our physicians and researchers to make many important contributions to the practice of medicine over the years. In over 100 years since our founding, we have pioneered many medical breakthroughs, including coronary artery bypass surgery; the first successful larynx transplant; the transcatheter aortic valve replacement; the first face transplant in the United States; and the first deep brain stimulation (DBS) surgery for stroke recovery. We also were the first major medical center to publish treatment outcomes for thoracic and cardiovascular surgery, demonstrating a commitment to quality, transparency, and accountability.

Our focus on research and offering the latest options means our patients can find a wide range of clinical trials and other care that they could not find elsewhere. These include a novel study for a vaccine aimed at eventually preventing triple-negative breast cancer and the use of gene therapies to treat sickle cell disease and to address the leading cause of hypertrophic cardiomyopathy. Last year, Cleveland Clinic launched the largest clinical study ever for brain disease, which will involve collecting data from up to 200,000 neurologically healthy individuals over a 20-year period to identify brain disease biomarkers and targets for preventing and curing neurological disorders. We recently cared for the youngest surviving premature twins born at Cleveland Clinic, who spent 138 days in the neonatal intensive care unit (NICU) following their birth at 22 weeks, were discharged and have continued to progress. Cleveland Clinic also serves as a national referral center for patients with substance use disorders (SUD) who suffer from ineffective endocarditis (IE), serving as one of the few providers in the country that will undertake surgery to replace these highly complex patients' damaged heart valves because of the significant potential for relapse and recurrence of the IE, leading to death. In response, we developed the Management of Substance Use Disorder and Heart Infections in Cardiovascular Patients (MOSAIC) Project, which is an interdisciplinary approach to address the unique and complex

care needs of these patients, recognizing that it is important to treat the root cause of the IE—the SUD—along with the heart.

A. 340B SAVINGS ARE CRITICAL TO OUR HEALTH SYSTEM PROVIDING ACCESS TO CARE

Cleveland Clinic's policy is to provide emergency and medically necessary care on a non-profit basis, without regard to a patient's ability to pay. Notably, a majority of the patients we serve—around 65%—are covered by government insurance (Medicare and/or Medicaid). In 2022, Cleveland Clinic was the largest provider of Medicaid outpatient visits and the second largest provider of Medicaid inpatient days in Ohio; our ability to preserve access to care to this population is particularly important as several Cleveland-area hospitals that served a significant percentage of underserved patients have recently closed. We also offer a generous financial assistance policy that is available to uninsured patients with family income up to 400% of the federal poverty level (and even higher in some catastrophic circumstances) and that covers both hospital care and services provided by employed physicians.

The patient care the Health System provides to government-insured patients (i.e., Medicare and Medicaid), which represents over 60% of our gross revenues, is reimbursed below costs.[2] In 2022, the Health System incurred $615 million in additional costs that were unreimbursed by Medicaid, which included care to children, pregnant women, parents, seniors, individuals with disabilities, and low-income adults. The Health System also experienced a shortfall of $800 million between the cost we incurred in providing care to patients covered by Medicare and the reimbursement we received in 2022.[3]

Further, in 2022, the Health System provided $109.8 million in unpaid care to the uninsured/under-insured ("bad debt"),[4] that was incurred beyond our financial assistance policy. Combined with the $212 million in charity care that we provided under our financial assistance policy and the shortfalls we experience for patients with Medicare and Medicaid coverage, the Health System provided $1.7 billion in unreimbursed services in 2022.

Over the past several years, Cleveland Clinic has encountered financial challenges because of the high cost of providing the highly specialized care for which we are known. Overall, the Health System yields an operating margin hovering at or below breakeven; absent the cost saving benefits of the 340B Program (and COVID relief in some years), we would have sustained operating losses in two out of the three years since the Main Campus enrolled in the Program.[5] (See Cleveland Clinic Health System Operating Income Overview, attached as CCF_0000001). While demand for patient care is strong, we are experiencing high costs for supplies, pharmaceuticals and contracted workers. Given the fact that

[2] Despite the persistent underpayment by Medicare and Medicaid, we invest significant resources in striving to be good stewards of taxpayer dollars by achieving efficiencies via Medicare and Medicaid alternative payment models. For example, in 2022 the Cleveland Clinic Medicare Accountable Care Organization (CCMACO) reduced spending for Medicare beneficiaries in the model by $30 million, netting a savings to Medicare of $15 million (Cleveland Clinic shared in $15 million of the overall savings achieved).

[3] This Medicare shortfall is not included in the community benefit reported by Cleveland Clinic; only Medicaid shortfall is included in community benefit reporting, in compliance with Internal Revenue Service (IRS) requirements.

[4] These unpaid services are on top of Community Benefit support.

[5] While the Sept. 28 letter referred to net income for Cleveland Clinic, only a portion of net income is attributable to operations. The vast majority is non-operating income, which is earmarked annually for debt service/to support capital investments and to fund Cleveland Clinic's defined benefit pension plan and which may provide a financial backstop when revenues do not cover expenses.

government rates of reimbursement have not increased in correlation to the rising cost of providing health care services, the 340B Program is one way the government can help health care providers—at no additional taxpayer expense—save resources that otherwise would have been spent on purchasing pharmaceuticals but can now be directed to providing health care services.

Because pharmaceuticals are a recognized driver of cost for health care providers, the 340B Program helps providers save on the cost of drugs with the assistance of pharmaceutical manufacturers that choose to participate. Since inception over 30 years ago, the 340B pricing framework and subsequent discounts have been governed by the 340B statute, which mandates that pharmaceutical manufacturers enrolled in the Medicaid Drug Rebate Program must offer their products to covered entities at an amount calculated as the average manufacturer price minus a predefined discount.[6] This discount is the larger of a predetermined percentage or the difference between the manufacturer's average price and the best price the manufacturer offers.

Furthermore, when manufacturers consistently increase drug prices above the Consumer Price Index (CPI) in consecutive quarters, they are obligated to provide additional discounts. In some cases, this can result in the drug's price being discounted to nearly zero due to extensive price increases in the market, demonstrating how important the 340B Program is to counter otherwise rapidly increasing drug prices. It is important to reiterate that these discounts are voluntarily authorized by manufacturers as a trade-off to gain access to the Medicare Part B and Medicaid markets and that the magnitude of the discount is directly influenced by manufacturer-driven factors—specifically, their external price negotiations and the degree to which they increase prices for the drugs they offer.

While hospitals routinely work to negotiate drug price discounts, this remains a significant challenge due to pharmaceutical price increases that are triple the rate of inflation since 1990.[7] In 2019, the United States House of Representatives' Ways and Means Committee found that drug prices in the United States were nearly four times higher than the average prices in comparable countries, far exceeding the discounts offered through the 340B Program.[8] This emphasizes the vital role that the 340B Program plays in mitigating the soaring costs of pharmaceuticals and addressing this price disparity.

B. CLEVELAND CLINIC USES 340B PROGRAM SAVINGS IN COMPLIANCE WITH THE LAW

As explained in greater detail in response to your information requests below, Cleveland Clinic's use of the savings resulting from its participation in the 340B Program is consistent with the intent of the Program: to allow participants to use generated savings to stretch resources further and provide additional critical health care services for their communities, including underserved populations within those communities.

By design, the 340B Program provides covered entities flexibility and discretion to use their cost savings in a way that they deem best meets the unique needs of the patients they serve. At Cleveland

[6] 42 U.S.C. § 256b(a)(1).

[7] Drug prices outpaced inflation since the 1990s (updated Oct. 5, 2023), *available at* https://usafacts.org/articles/drug-prices-outpaced-inflation-since-the-1990s.

[8] House Ways & Means Committee Majority Staff Rept., *A Painful Pill to Swallow: U.S. vs. International Prescription Drug Prices*, (Sept. 2019), *available at* https://democrats-waysandmeans.house.gov/sites/evo-subsites/democrats-waysandmeans.house.gov/files/documents/U.S.%20vs.%20International%20Prescription%20Drug%20Prices_0.pdf.

Clinic, 340B Program savings directly further our core mission: to preserve access to the unique offering of high-quality, highly specialized clinical expertise we provide to patients. In light of our tight financial picture, the 340B Program benefits have helped make it possible for Cleveland Clinic to support access to this often life-saving care for patients in our communities and beyond—without additional cost to taxpayers. Cleveland Clinic also invests significantly in the community, providing $1.42 billion in community benefit across our Health System in 2022.

The cost savings also have helped us fulfill our strong commitment to our workforce: as other organizations pursued savings through pay cuts, furloughs, and layoffs during the COVID-19 pandemic, we were able to keep our employees whole. As Ohio's largest employer, our employees' continued employment helped maintain their quality of life and positively impacted the economies where our caregivers live. Retaining our employees has also allowed us to maintain seamless levels of care within our communities, as a robust workforce is critical to our ability to serve patients.

C. CLEVELAND CLINIC'S 340B PROGRAM INTEGRITY

As we noted at the outset of this response, Cleveland Clinic places a high priority on its 340B Program compliance and has thus implemented a series of comprehensive compliance initiatives. (*See* Cleveland Clinic's 340B Compliance Policy and Appendix A (Contract Pharmacies) attached as CCF_0000002- CCF_0000025.) To strengthen program integrity, we established stringent qualification rules to link our 340B web-based system with our Electronic Medical Records (EMR), consulting with the Health Resources and Services Administration (HRSA) 340B Program Prime Vendor,[9] Apexus, prior to 340B enrollment to incorporate best practices with a focus on statutory compliance. Ongoing engagement with the Prime Vendor is a priority, with all Cleveland Clinic 340B team members earning and maintaining Apexus Advanced 340B Operations Certification.

To ensure compliance, we conduct extensive manual audits, totaling over 27,000 audits at our Main Campus alone and more than 73,000 audits across our Health System. Furthermore, we have conducted annual mock HRSA audits. Our contract pharmacy program undergoes thorough evaluation on nine distinct measures by our Internal Control Evaluation team. In addition, we cooperate fully and transparently with HRSA and its auditor. Training and education for all individuals interfacing with the 340B Program are pivotal components of our compliance strategy. These initiatives collectively underscore our dedication to upholding a compliant and effective 340B Program within our organization.

II. SEPTEMBER 28 REQUESTS

Below we have sought to provide information and records to reasonably accommodate the requests set forth in your September 28 letter. These responses have been prepared on the basis, and consistent with the format, of information as it is currently maintained by Cleveland Clinic in the regular course of business and for various required reporting activities. In the event Cleveland Clinic either does not maintain information in a manner responsive to a particular request or has not retained information for as many years as the request seeks, Cleveland Clinic has endeavored to provide as much relevant

[9] The 340B Prime Vendor is a contract awarded by HRSA to provide education and technical assistance to 340B stakeholders. The Prime Vendor negotiates pricing discounts with participating manufacturers, provides education and resources such as 340B University, and offers technical assistance through Apexus Answers.

information as reasonably possible. The responses have been group based on specific subject matter (not request number) to provide you a more understandable, cohesive response.

A. CLEVELAND CLINIC'S USE OF 340B PROGRAM SAVINGS

As briefly discussed above, the 340B Program is a point-of-sale drug discount program that allows covered entities to save money by purchasing discounted drugs from pharmaceutical manufacturers who voluntarily choose to participate and sell the drugs at the statutorily set discounted price.

The Program reduces covered entity drug expense, creating 340B Program "savings" but not generating "revenue"—except in the limited contract pharmacy setting where reimbursement is remitted back to the covered entity by the contract pharmacy, less the contract pharmacy's fees. In recent years, contract pharmacy revenues have been nearly eradicated by drug manufacturers' refusal to honor these arrangements despite HRSA requiring them to do so. Notwithstanding the contract pharmacy issue, which continues to be litigated in federal court, the primary benefit of the 340B Program remains its reduction in an otherwise increasing drug expense (savings) for 340B covered entities that serve a higher proportion of low-income patients.

Regardless of whether the 340B benefit is accrued as a reduced expense (savings) or limited revenue through contract pharmacy, such benefit is not "spent" by Cleveland Clinic. As part of normal operations, reduced pharmaceutical expense and contract pharmacy revenue flow to the Income Statement, like any other expense or revenue, without being independently segregated, distributed or allocated. Cleveland Clinic considers total net income/loss generated by the organization as a whole, and if positive, decides how the operating income will be reinvested back into the organization and community. This approach is consistent with law and meets all 340B Program requirements.

Since 340B Program expense/revenue is not separately tracked and allocated, there exist no internal guidance documents, policies or procedures that specifically address this topic as requested in 4(a). Cleveland Clinic has procurement and payment policies as well as a payment authorization matrix that demonstrate how procurement/payment is made by Cleveland Clinic in general, without regard to whether the expense/revenue is related to the 340B Program.

When Congress created the 340B Program, it did not mandate that covered entities apply their 340B Program benefits in a certain way. The 340B statute was intentionally left general to provide safety net providers with latitude on how they use their savings in the ever-changing health care industry. Therefore, there is no dollar-for-dollar "pass on" requirement to patients under the 340B statute. Instead, Congress recognized that first and foremost, covered entities are safety net providers that need flexible assistance (expense reduction) to help support operations and continue to serve their local community in the ways they know best.

At Cleveland Clinic, we do this by applying the benefit derived from the 340B Program to the health system's overall operating expenses and revenues in order to offset the cost of providing health care services to the communities we serve and to maintain and invest in programs that enhance patient services and access to care. We understand our community and its needs best, and undoubtedly, the 340B Program is critical to Cleveland Clinic's ability to provide the depth and breadth of services to low-income patients that we do.

The Health System provides a significant amount of free or discounted care to patients, and the 340B Program is an important savings measure that assists us in covering the cost of doing so. In 2022, we provided $1.7 billion in unpaid care. This includes:

- **$109 million** in incurred costs for services for which we never received payment (bad debt).
- **$1.4 billion** representing the difference between the cost of caring for patients with Medicare and Medicaid and the payment we receive (Medicare/Medicaid shortfall).
- **$212 million** in financial assistance (charity care). The represents the cost of providing free or discounted medically necessary care to patients unable to pay some or all their medical bills.

Cleveland Clinic offers a generous financial assistance policy that is available to patients with family income up to 400% of the federal poverty level (and even higher in some catastrophic circumstances); this policy is unique among hospitals in that it covers both hospital care and services provided by employed physicians. A copy of our financial assistance policy is attached as CCF_0000026-CCF_0000035.

The Health System also provides benefit to the community beyond this unpaid care. In 2022, this includes:

- $57.8 million in subsidized health services; these are clinical services which are provided to meet the needs of the community, despite creating a financial loss. Examples include behavioral health, obstetrics, and chronic disease management services.
- $69.7 million in community health improvement; these programs are designed to serve vulnerable and at-risk populations, as well as the broader population in our communities. They address documented health needs of our communities and align with our Community Health Needs Assessments.
- $338.2 million in medical education; this includes a wide range of high-quality medical education, including accredited training programs for residents, physicians, nurses, and other allied health professionals. We maintain one of the largest graduate medical education programs in the nation. At the postgraduate level, the Center of Continuing Education has developed one of the largest and most diverse continuing medical education programs in the world.
- $128.9 million in medical research; this includes research activities supported by government and foundation sources; corporate and other grants are excluded from community benefits. Cleveland Clinic uses internal funding to cover shortfalls in outside resources for research.

Our community benefit reports for the Health System for 2018 through 2022 are attached as CCF_0000036- CCF_0000047. We are dedicated to building a healthy community for everyone through *healing* as a leader in public health and high-quality patient care; *hiring* by developing the local workforce and developing meaningful connections with youth; and *investing* through community benefit and charitable partnerships. Examples of this commitment include:

- Expansion of the Langston Hughes Community Health Center to include primary care services for local residents in an underserved neighborhood near our Main Campus.
- Pledging $52.5 million with the City of Cleveland and local institutions to make homes lead safe.
- Pledging $2.5 million towards the expansion of new residential treatment and recovery housing for the Hitchcock Center for Women in Cleveland.

- Creating a new Infant and Maternal Health Center to support families by addressing health disparities and social determinants associated with infant mortality.
- Expanding access to mental health, vision and primary care services to local youth in the community through school-based care programs.
- Employing 10 community health workers through the Cleveland Clinic Center for Community Health Workers at seven Cleveland Clinic locations across Northeast Ohio. These newly added caregivers collaborate closely with patients to identify and remove barriers to social and medical needs. The largest cohorts include infant and maternal health followed by primary care and emergency medicine, respectively.
- Connecting patients with health and social organizations across Northeast Ohio to reduce barriers to care through the Unite Us program.
- Supporting development of a 40,000-square-foot Meijer grocery market in a food desert
- Pledging $10 million to support construction of an 82-unit mixed-income apartment building near Cleveland Clinic's Main Campus to help revitalize the neighborhood.
- Supporting groups that share our commitment to social determinants of health, including the Greater Cleveland Food Bank, Digital-C, Lead Safe Cleveland Coalition and United Way.
- Joining forces with local institutions to launch the Evergreen Cooperative to create jobs and build community wealth for our neighbors.
- Graduating more than 41 apprentices from Cleveland Clinic's caregiver apprenticeship program, which recently expanded to offer apprenticeship programs in ophthalmology, epilepsy and sleep. Apprentices are paid as full-time employees, working in the field with the support of a manager, and they receive education that leads to a credential or associate degree.
- Addressing opportunity gaps and increased diversity in healthcare through the ASPIRE Nurse Scholars Program. Twenty-five students enroll in ASPIRE each year, and at least five program graduates are employed by Cleveland Clinic.
- Becoming a founding member of OneTen, a coalition of large United States employers formed to train, hire and promote one million Black Americans into family-sustaining jobs with opportunities for advancement. Since 2021, Cleveland Clinic has hired and promoted more than 2,000 caregivers who are black.

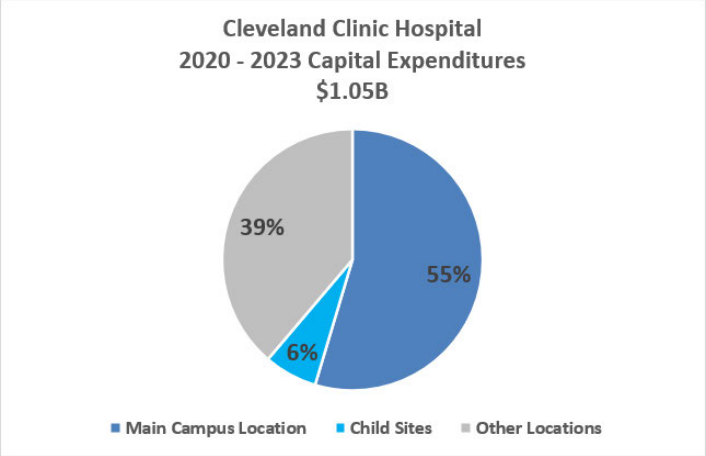
Further, Cleveland Clinic Pharmacy provides extensive pharmacy-related benefits at minimal to no additional cost to patients or payers, such as:

- Over 73 dedicated full time equivalent employees (FTEs) support a diverse range of services, including primary care, anticoagulation, transitional care, specialty clinics, and value-based care. For example:
    - The primary care pharmacy team conducts referral-based visits for a variety of conditions including diabetes and hypertension as well as obesity, COPD, and heart failure.
    - In 2020, a remote monitoring and telemanagement program was developed to support patients with chronic diseases during the COVID-19 pandemic. This multidisciplinary program utilized a combination of telephone calls and digital outreach to monitor patients' health status and assess changes in a patient's condition. Pharmacists answer patients' medication questions and address concerning symptoms; this contributed to a

35% reduction in the rate of inpatient admissions due to any cause among patients who were engaged by a pharmacist via this program.
    - The pharmacy anticoagulation clinic has provided anticoagulation management services for over 25 years. Pharmacists perform point-of-care international normalized ratio (INR) testing and telemanagement services for lab and home meter INR results for approximately 4,500 patients. Approximately 35% of patients are managed via telemanagement services since its implementation in 2020, and this has greatly increased patient satisfaction. The pharmacy team continues to maintain target of > 65% time in therapeutic range (TTR).
    - Pharmacy support of specialty clinics includes endocrinology, geriatrics, rheumatology, gastroenterology, pulmonology, solid organ transplant, pharmacogenomics, primary care, heart failure, HIV/PrEP clinics, travel medicine, epilepsy, anticoagulation clinic, pain management, oncology, and virtual transitional care.
- Transitions of care pharmacists contact high risk patients post-discharge to perform medication reconciliation, counsel patients, address medication access barriers and provide recommendations for adjustments to discharge medications.
- In January 2023, we opened a patient assistance program for patients within our primary care pharmacy clinics who are not able to afford certain brand-name medications. This referral-based service is managed by pharmacy technicians who connect patients and providers with programs for free medication. In 2023, 111 new referrals were placed, along with 300 renewals, to support patients with affordability issues.
- Pharmacy Discharge Prescription Delivery Services are available across all hospitals in Northeastern Ohio at no cost to our patients. This program supports processing and delivering of a patient's discharge prescription(s) to the patient's room following discharge orders, with over 30 Pharmacy Technicians employed to maintain this service. This program is a convenient patient and provider satisfier, saving additional trips to the pharmacy after discharge from the hospital. In 2023, over 32,000 patients have already received this valuable service.
- As a part of our commitment to curbing the epidemic of prescription drug misuse, Cleveland Clinic supports 18 medication disposal kiosks within our outpatient pharmacies. In 2022, we collected over 7,000 pounds of unutilized medication within our disposal kiosks.

B. <u>CLEVELAND CLINIC EXPENDITURES</u>

Your September 28 letter requests information about Cleveland Clinic's capital expenditures at its Main Campus, child sites, and in the Cleveland area. A detailed accounting of capital expenditures by Cleveland Clinic at each of these locations from January 1, 2020, through June 30, 2023, is attached as CCF_0000048. To summarize, Cleveland Clinic's capital expenditure from 2020–2023 was $1.05 billion dollars. Fifty-five percent (55%) of such expenditure was associated with the Main Campus hospital. Six percent (6%) was associated with the child sites, excluding the Main Campus hospital, and the other thirty-nine percent (39%) was associated with other locations (i.e., non-340B).



These figures demonstrate that Cleveland Clinic continues to invest heavily in its Main Campus, which is located in a medically underserved area. This includes investing in buildings, equipment and technology to better serve its patients. For example, Cleveland Clinic is building a new Neurological Institute on Main Campus to accommodate the expansion of patient care, research and education. The new facility is approximately 400,000-square-feet, and its offering of patient services will include digitized patient evaluations, imaging, neuro-simulation training, infusion therapy, neurodiagnostics and brain-mapping suites. Cleveland Clinic also is expanding its Cole Eye Institute, adding more than 100,000 square feet to the existing building to accommodate growing patient eye care and research needs. The new addition will feature an ophthalmic surgical center with operating rooms and new exam rooms, a new Center of Excellence in Ophthalmic Imaging, an expanded simulation center for education and training of residents and fellows and an ophthalmic research center to promote eye research. Other major capital expenditures include investment in replacement of hospital beds and other equipment involved in patient care, as well as improvements to information technology.

The executive compensation also requested by your September 28 letter is included in the salary, wages and benefits on the Cleveland Clinic Statement of Revenues and Expenses for 2020 through 2022, attached as CCF_0000049. Cleveland Clinic uses a thorough and rigorous process to set executive compensation. All executive compensation is reviewed by, and must be approved by, the Board Compensation Committee, comprised of independent Board members from the community. This committee is authorized by the Board of Directors to make compensation decisions for the executive team, including physician executives. Cleveland Clinic engages a nationally known independent compensation firm to advise on executive compensation. This includes benchmarking against similar organizations and providing opinions as to the reasonableness of the compensation. This process complies with Internal Revenue Service (IRS) requirements.

All “other expenditures” appear as the other expenses listed on this Statement as well. For convenience, executive compensation is further broken out on CCF_0000050. Additional detail on expenditures is provided in the System’s Audited Financial Statements from 2018-2022 and the Management Discussion & Analysis (MD&A) from our quarterly financial filings for fourth quarter 2018 through second quarter 2023, attached as CCF_0000051- CCF_0000425 and CCF_0000426, respectively.

C. ACCOUNTING OF FUNDS GENERATED FROM THE 340B PROGRAM

Your September 28 letter seeks an accounting of funds generated from the 340B Program. When calculating the total financial impact of the 340B Program, Cleveland Clinic utilizes the industry standard calculation as defined by the American Hospital Association (AHA) (see chart below).

Calculating Estimated 340B Program Savings - Basic Method with Compliance/Administrative and GPO Prohibition Costs

(A) GPO or other Estimated Acquisition Costs	Minus -	(B) Actual 340B Acquisition Costs	Equal =	(C)Total Est. 340B Savings (before adjustments)	Minus -	(D) Wholesale Acquisition Costs (WAC) Variance	Plus +	(E) Benefit from Contract Pharmacy Arrangement (if applicable)	Minus -	(F) Compliance and Administrative Costs	Equals =	(G) Estimated Savings of 340B Program
			TOTAL								Total Estimated Savings of 340B Program	
			Optional								Optional; Compare 340B Estimated Savings to Total Drug Expenditures	

Under AHA's formula, we calculate our 340B benefit as the difference between our standard medication list price (e.g., group purchasing organization (GPO) price) and our 340B purchase price; this estimates the cost to replenish the drug if we were not enrolled in the Program. In addition, the formula accounts for any expense incurred due to administrative costs associated with Program management.

Finally, we account for the benefit of our contracts with external pharmacies (i.e., contract pharmacies), which the 340B Program allows us to enter in order to reach more Cleveland Clinic patients.

Based on this formula, we have prepared a summary of the 340B benefit from the time Main Campus enrolled in the Program (4/1/2020) through June 2023. These data have been summarized by dispensing pharmacy, and all attempts were made to define the benefit based on HCPCS and therapeutic class as defined by our purchasing wholesaler. Some medications dispensed do not have a HCPCS code defined by the Centers for Medicare & Medicaid Services (CMS); these have been listed as null. A detailed accounting by dispensing pharmacy (including address), therapeutic class, and HCPCS has been provided as CCF_0001201.

We are unable to provide a detailed accounting of site of service, since a single dispensing pharmacy may service multiple sites of service. However, we have established a location relationship between the dispensing pharmacy and whether it is located within our parent facility at 9500 Euclid Ave or located offsite and therefore associated with our child sites. In addition, our retail, specialty and contract pharmacy locations are listed separately since they may serve both our parent location and child sites.

The chart below summarizes the 340B benefit derived from 2020, when Cleveland Clinic entered the Program, through June 2023. Pharmacies serving our parent location in Cleveland comprised 24% of our total benefit, while pharmacies at the Cleveland Clinic locations in surrounding communities, i.e., child sites, accounted for 18% of the total benefit. These represent clinic/physician-administered medications, which are administered directly to patients during their visit. The remainder of the benefit was accounted for between our internally owned retail/home delivery/specialty pharmacy operations and our contract pharmacy locations.

Cleveland Clinic Hospital 340B Benefit				
	2020*	2021	2022	2023 Jun YTD
Total	**$ 137,227,542**	**$ 309,283,806**	**$ 313,405,123**	**$ 173,831,806**
Parent Location	$ 42,313,565	$ 73,234,906	$ 68,543,038	$ 39,242,533
Off Site	$ 29,774,768	$ 53,675,228	$ 57,175,714	$ 31,414,774
Retail	$ 8,780,717	$ 22,289,876	$ 28,562,178	$ 17,951,449
Home Delivery/Specialty	$ 28,874,621	$ 60,424,713	$ 69,328,621	$ 42,291,308
Contract Pharmacy	$ 27,483,872	$ 99,659,083	$ 89,795,572	$ 42,931,744

*Overall benefit lower due to partial year enrollment

D. CHILD SITES

Your September 28 letter also requests information regarding the relationship between Main Campus and its offsite outpatient facilities registered as child sites. Main Campus and its offsite outpatient facilities that are registered as child sites are all part of one corporate entity—Cleveland Clinic. Cleveland Clinic's Main Campus and its child sites are all locations of the same Medicare/Medicaid provider. Cleveland Clinic's Main Campus and all of the child sites are clinically and financially integrated as one provider. Further, all of these locations are under the same Joint Commission accreditation. This means that Cleveland Clinic is responsible for ensuring that the Main Campus and all of the child sites meet the Conditions of Participation for Medicare. Because these locations are part of one entity, there are no documents governing the relationship.

Your September 28 letter suggests that Cleveland Clinic's Main Campus has opened child sites in areas with higher income levels than our Main Campus to maximize benefit from the 340B Program. **To clarify, 99% of our child sites were already operational and owned by Cleveland Clinic prior to the time Cleveland Clinic registered for the 340B Program and thus were not acquired after Cleveland Clinic became eligible for 340B. In fact, Cleveland Clinic does not consider 340B when deciding where to locate; locations are placed in communities to ensure patients have access to our services.**

Additionally, the location of a site is not determinative of the patient population served. Our Main Campus is located in an area that is unarguably economically underserved, with lower median household income ($26,399) and higher rates of households below poverty (15.9%) compared to Cuyahoga County, in which it is located ($61,111 and 6.8% respectively), and the State of Ohio ($68,626 and 6.1% respectively).[10] Further, in total, nearly 50% of our 340B locations are in a medically underserved area. To further extend services into the community, Cleveland Clinic also operates ancillary outpatient clinics, called Family Health Centers, which provide primary care and select specialty care services in convenient settings in support of our mission. These Family Health Centers often house multiple Cleveland Clinic child sites. While some Family Health Centers are in areas that have higher income levels and lower poverty rates than the neighborhood around our Main Campus, a majority of the patients they see are covered by a government payer.

For example, our Beachwood Family Health Center is located in a zip code (44122) east of our Main Campus that has a median household income of $89,016 and 3.5% of households below poverty. But among the patients it serves, 50% have a government payer, compared to 36% with commercial insurance. Our Strongsville Family Health Center is in a zip code west of our Main Campus (44136) with a

[10] Internal analysis based on Sg2/Truven data.

median household income of $87,788 and 2% of households below poverty; 52% of the patients seen at this location have a government payer, compared to 38% with commercial coverage. Finally, our Independence Family Health Center, located to the south of our main campus (44131), has a median household income of $93,620 and 1.5% of households below poverty. At this location, 59% of patients are covered by Medicare or Medicaid, with 32% having commercial coverage.[11]

Finally, your September 28 letter also describes how some 340B entities may acquire hematology-oncology or other practices that generate higher 340B savings due to the 340B Program benefits. We cannot opine on other providers, but this is not true of Cleveland Clinic.[12] As noted above, we do not factor in 340B savings into acquisition decisions, and it would not be prudent to do so since eligibility in the 340B Program is reassessed throughout the year and could change.

D. COMMUNICATION TO PROVIDER STAFF REGARDING 340B

Your September 28 letter asks about Cleveland Clinic's communication with our provider staff in regard to the 340B Program. In short: Cleveland Clinic did not communicate with our provider staff regarding the 340B Program; the 340B Program is not relevant to the medical staff nor to any individual practitioner's practice of medicine.

Cleveland Clinic does not provide any incentives to providers as it relates to the 340B Program.[13] Cleveland Clinic providers make prescribing decisions based on their medical judgment and what is best for the care of the patient. Accordingly, Cleveland Clinic does not have knowledge of any communications related to incentives related to the 340B Program. As explained in Section I.C. (Program Integrity) above, the Cleveland Clinic employees who interact directly with the 340B Program receive training and education regarding the 340B Program, none of which include anything related to incentives.

E. RURAL REFERRAL CENTER APPLICATION

Your September 28 letter seeks greater information regarding Cleveland Clinic's decision to apply to qualify as a rural referral center. As we note above, Cleveland Clinic provides over a billion dollars in care to patients that goes unreimbursed or is under-reimbursed. At the same time, the number of patients who are uninsured or underinsured are growing as are the costs we incur to provide care to patients. As a result, the Cleveland Clinic regularly evaluates ways to mitigate expenses—such as pharmaceutical spending—that drive the cost of care, especially as those costs are rising at a pace much faster than reimbursement for services, and as more patients are uninsured or underinsured. In 2019, Cleveland Clinic realized the value that participating in the 340B Program not only could have in mitigating our increasing patient care costs, but also could bring in enhanced access to care for our patients. Therefore, we pursued enrollment in the 340B Program via a statutorily approved process that involves an urban hospital being reclassified as rural and then seeking classification as a Rural Referral Center (RRC).

[11] Other patients may be covered by Cleveland Clinic's Employee Health Plan or be self-pay.
[12] In fact, Cleveland Clinic has not acquired any hematology-oncology practices since it enrolled in 340B.
[13] As previously noted, it is not our practice to provide incentives generally; this distinguishes us from other health systems that routinely incentivize productivity.

The first step in the process was to submit an application to the CMS Regional Office requesting rural reclassification based on satisfaction of applicable statutory criteria. Urban hospitals meeting certain criteria have a right guaranteed by statute to obtain rural status.[14] The statue specifically states that CMS shall treat a hospital that is located in an urban area as rural if the hospital applies for such reclassification, and the hospital would qualify as an RRC. Cleveland Clinic applied to CMS for rural reclassification on August 19, 2029 (*see* August 19, 2019 letter from Cleveland Clinic to CMS, attached as CCF_0001202-CCF_0001205). CMS approved Cleveland Clinic's request for reclassification from an urban area to a rural area because Cleveland Clinic would qualify as a RRC or sole community hospital if it was located in a rural area (*see* October 4, 2019 letter from CMS to Cleveland Clinic, attached as CCF_0001206). As required by regulations, CMS determined that the reclassification to rural was effective as of August 20, 2019, the date CMS received the application.[15]

Then, on October 4, 2019, Cleveland Clinic submitted a request to CMS for classification as an RRC (*see* October 4, 2019 letter from Cleveland Clinic to the CMS Regional Office, attached as CCF_0001207- CCF_0001211). 42 C.F.R. Section 412.96(b) sets for the criteria for classification as an RRC. Cleveland Clinic meets the criteria set forth in Section 412.96(b)(1)(ii), which says a hospital may qualify as a RRC if it is located in a rural area and has 275 or more beds listed on its most recently completed cost reporting period.[16] At the time of its application to CMS for RRC status, Cleveland Clinic reported 1,285 acute care beds on its 2018 Medicare cost report. CMS determined that Cleveland Clinic met the criteria to qualify for RRC status because it had received urban to rural reclassification effective August 20, 2019, based on the criteria at 42 CFR 412.103(a)(3); and it met the minimum requirement of 275 beds (*see* CMS letter attached as CCF_0001212). The RRC status was effective as of January 1, 2020 (the start of Cleveland Clinic's cost reporting period).

The next step was enrolling in the 340B Program. The 340B Program statute allows various categories of hospitals to enroll in the 340B Program, all of which are some form of safety-net hospital. By statute, hospitals that qualify as RRCs, by having a disproportionate share adjustment percentage equal to or greater than 8% and an agreement with the State or local government (i.e., Medicare or Medicaid participation), are allowed to participate in the 340B Program.[17] At the time of its enrollment in the 340B Program, Cleveland Clinic had a disproportionate share percentage of 9.29% and has exceeded the 8% threshold each year since enrollment.

As your letter notes, our Main Campus is located just outside downtown Cleveland, Ohio. **Despite its location, Cleveland Clinic prides itself on providing care to a significant number of patients from rural areas. In 2022–2023, patients from rural counties represented 12.3% of inpatient admissions. We drew patients from 579 rural counties in the United States, including all rural counties in Ohio, Pennsylvania, New York, Indiana, Michigan, West Virginia, and Kentucky.** We also strive to bring critical care directly to our rural patients for whom access to care is limited. As part of our commitment to the 340B Program's congressionally stated mission to provide more comprehensive care to more patients, we invest significant resources to ensure rural patients in the communities we serve

[14] Social Security Act Section 1886(d)(8)(E) and 42 C.F.R. Section 412.103.
[15] 42 C.F.R. Section 412.103(d)(1).
[16] Social Security Act Section 1886(d)(5)(c)(i) and 42 C.F.R. Section 412.96 identify the criteria for obtaining RRC status. 65 Fed. Reg. 47026, 47031 (Aug. 1, 2000) states that a hospital with acquired rural status can use that to obtain RRC status.
[17] PHSA Section 340B(a)(4).

have access to care. For example, Cleveland Clinic is the only health system in Northeast Ohio with a forensic nurse on call 24/7 who will drive to meet a victim of sexual assault at any of our rural hospitals. In contrast, other local hospitals and health systems require a victim of sexual assault from a rural location to drive to downtown Cleveland to meet a forensic nurse.

* * *

As stated at the start of this response, Cleveland Clinic appreciates this opportunity to provide you and your staff more information about its participation in the 340B Program. Our participation in the Program has been a critical component in our Health System's ability to deliver on our mission and continually deliver top-quality care to our patients—regardless of means—during a period of significant constraints. We welcome further engagement with you and your staff to reasonably accommodate any questions you may have.

JONES DAY

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[redacted]

CONFIDENTIAL

July 23, 2024

VIA ELECTRONIC MAIL

[redacted]
Committee on Health, Education, Labor, and Pensions
United States Senate
428 Senate Dirksen Office Building
Washington, DC, 20510

RE: Senator Cassidy's Follow-Up Questions to Cleveland Clinic

Dear [redacted]:

Enclosed please find Cleveland Clinic's response to Senator Cassidy's follow-up questions relating to Cleveland Clinic's prior submission of November 17, 2023. Cleveland Clinic respectfully requests that its response remain confidential. In the event a determination is made to publish or otherwise disclose to a third party any information set forth in the response, Cleveland Clinic requests that it be provided notice and an opportunity to be heard.

Respectfully,

[redacted]

Enclosure

CLEVELAND CLINIC'S RESPONSE TO SENATOR CASSIDY'S FOLLOW-UP QUESTIONS ABOUT NOVEMBER 17, 2023 SUBMISSION

Senator Cassidy, we thank you for your questions, conveyed over two emails from [redacted] on your staff, following up on Cleveland Clinic's original submission of November 17, 2023 (Initial Submission), concerning its participation in the 340B Drug Pricing Program (340B Program or Program).

In 2019, Cleveland Clinic identified that participating in the 340B Program could help mitigate our increasing patient care costs secondary to escalating drug prices and enable us to enhance access to care for our patients. To enroll, we followed the 340B application process for hospitals that qualify under statute to be designated as rural referral centers; upon approvals by the Centers for Medicare and Medicaid Services (CMS) and the Health Resources and Services Administration (HRSA), we began participation in the Program in April 2020, *see* CCF_0001201. Further information in this regard can be found on pages 13-15 of our Initial Submission. *See also* CCF_0001202-CCF_0001205, CCF_0001206, CCF_0001207-CCF_0001211 & CCF_0001212.

For a detailed listing of Cleveland Clinic's 340B benefit that includes both savings and revenue, please refer to the chart at the top of page 12 of the Initial Submission. *See also* CCF_0001201 (summarizing 340B benefit April 2020 through June 2023). To offer further clarity, we note that the 340B Program reduces covered entity drug expense, which in turn, creates 340B Program "savings" but does not generate "revenue"—except in the limited contract pharmacy setting where reimbursement is remitted back to the covered entity by the contract pharmacy, less the contract pharmacy's fees. *See* Initial Submission 6-11. Accordingly, only the Contract Pharmacy row of the chart on page 12 of the Initial Submission represents *revenue*; all of the other rows—for the Parent Location, Off Site, Retail, and Home Delivery/Specialty—represent 340B *savings* only.

From April 2020 to June 2023, Cleveland Clinic received $259,870,271 in revenue from contract pharmacy, after fees and pharmaceutical costs were calculated (net revenue). For the full 2023 calendar year, Cleveland Clinic's 340B contract pharmacy revenue was $60,390,188. Notably, as a result of increasing manufacturer restrictions, Cleveland Clinic's annual contract pharmacy revenue will be reduced by more than 90% since 2022 and is estimated at $9.8 million for 2024.

Consistent with Appendix A to the Cleveland Clinic 340B Compliance Policy, CCF_0000021-CCF_0000025, Cleveland Clinic has contracted with six separate contract pharmacy vendors. Those six contracts account for all of the contract pharmacy revenue. While the underlying contracts between Cleveland Clinic and these six vendors contain confidential business information subject to express limitations on disclosure, we can state that these six vendors provide pharmaceutical services for our patients at a total of 164 pharmacy store locations—representing approximately 1% of the over 16,000 pharmacy locations to which Cleveland Clinic sent prescriptions in 2023. Some of the contract pharmacy vendors also operate as third-party administrators (TPAs), determining eligibility and processing 340B-eligible claims. They may increase fees for these services via contractually negotiated annual increases and/or ad-hoc

notices, which has led to fee increases over the course of Cleveland Clinic's participation in the 340B Program.

Cleveland Clinic also owns and operates nineteen (19) distinct ambulatory/retail pharmacies. Four (4), or 21%, of our pharmacies operate as contract pharmacies for 340B covered entities within the Cleveland Clinic Health System. These pharmacies do not serve as contract pharmacies for any entities outside of the Cleveland Clinic Health System.

As to revenue generated from the 340B Program, we apply the benefit derived from the Program—including both savings and contract-pharmacy revenue—to the Cleveland Clinic Health System's overall operating expenses and revenues in order to offset the cost of providing healthcare services to the communities we serve and to maintain and invest in programs that enhance patient services and access to care. This directly furthers Cleveland Clinic's core mission: to preserve access to the unique offering of high-quality, highly specialized clinical expertise we provide to patients. 340B Program benefits have helped make it possible for Cleveland Clinic to support access to often life-saving care for patients in our communities and beyond—without additional cost to taxpayers. *See* CCF_0000036- CCF_0000047 (community benefit reports).

In cases where patients pay for medications when they do not have—or choose not to use—insurance, our retail pharmacies offer a sliding-scale discount based on the Average Wholesale Price or AWP. For uninsured hospital patients who qualify for financial assistance under our Financial Assistance Policy, *see* CCF_0000026-CCF_0000035 (policy), medications administered in the inpatient or outpatient hospital setting are provided free of charge or discounted by an amount that is recalculated annually based on I.R.S. regulations, resulting in a discount of 72.6% for 2024.

* * *

We thank you once again for the opportunity to address questions about Cleveland Clinic's participation in the 340B Program—which undoubtedly has been critical in Cleveland Clinic's ability to continually deliver top-quality care to patients, regardless of their financial status, during a period of serious pressures on our system. *See* Initial Submission at 3-4; CCF CCF_0000001 (Operating Income Overview).

Sun River Health

Sun River Health
Executive Office
1200 Brown Street, Peekskill, NY 10566
[redacted]
sunriver.org

December 22, 2023

The Honorable Senator William Cassidy, MD
Ranking Member
US Senate Committee on Health, Education, Labor and Pensions
Washington, DC 20510-6300

Dear Senator Cassidy,

I am writing on behalf of Sun River Health, in response to your inquiry dated November 16, 2023, requesting information on Sun River Health's (Sun River) participation in the 340B program. We appreciate your acknowledgment of the essential role that community health centers play in the nation's health care safety net and our care for the medically underserved and vulnerable through our comprehensive services offered on a sliding fee scale.

The 340B drug discount program is an important program for Sun River for two major reasons. First, the program allows us to increase access to critical prescription drugs to help improve health outcomes, and second, we can utilize the savings to support key programs and services for all our patients under the HRSA section 330 program. We are eager to demonstrate how this program is of incredible value to our patients and communities. We hope that our response contributes to your and the Committee's understanding of the 340B program and aids your review.

As we have discussed with [redacted] and [redacted], of your staff, we are including information in response to Questions 3, 4, 5, 7, and 8 in this initial submission. We will provide additional responses in 2024 for the remaining questions and data requests. We also thank your team for their understanding the rationale for refining the dates covered by your inquiry to include the years 2019 – 2022.

By way of background and rationale for this refinement, Hudson River Health Care, Inc. finalized a merger with Bright Point Health in December of 2018. In 2020, following the merger, Hudson River Health Care, the legacy name of the merged organizations, rebranded as Sun River Health. You will see materials in this submission under both Sun River Health and Hudson River Health Care, depending on the date the materials were generated. Sun River Health maintains a DBA for Hudson River HealthCare (HRHCare). A second reason for a refinement in years is that in 2023, the State of New York changed its pharmacy program from a Medicaid Managed Care program (premium-based) to an FFS program; as such, Sun River Health no longer participates in the 340B program as it pertains to Medicaid beneficiaries. NYS reverted to a Fee-for-Service (FFS) program on March 31, 2023. Both of the above changes make the respective years of 2018 and 2023 significantly different and less comparable.

Question 3: Does Sun River Health have processes and procedures in place to audit how it uses 340B savings? If so, please describe these audit processes and procedures. If not, why not?

Sun River Health has been a recipient of government funding for nearly 50 years and has a solid and sustained track record of high compliance based on designing and carrying out programs in accordance with the requirements of government contracts and regulations. As a longtime Health Resources and Services Administration (HRSA) Health Center Program grantee, Sun River Health has accrued decades of experience in carefully managing public funding. Sun River Health has in place the robust information and fiscal management systems necessary to ensure compliance with the terms, conditions, and requirements of public funding. Business transactions are recorded in conformity with GAAP, and all HRSA Department-wide grants administration rules set forth in 45 CFR Part 75 and associated cost principles and Single Audit Act requirements. The reporting system's integrity is based on an internal control and reconciliation system that ensures complete, timely, and accurate data. Sun River completes an annual audit with an external auditing firm to review and affirm financial reporting is in compliance with all state and federal laws and regulations.

Sun River Health is committed to ensuring compliance with the 340B program regulations and expectations. In addition to the robust policy development and board and staff oversight, Sun River Health has engaged with SpendMed for an annual 340B compliance audit, utilizing the HRSA Audit standards (Program Integrity | HRSA). Sun River has recently successfully completed a 2023 audit, helping to ensure our ongoing adherence to HRSA program expectations for covered entities.

Sun River's use of 340B revenue is guided by federal regulation:

- Section 330 requires that patient revenue be used to maintain or expand services to the population served; however, neither Section 330, nor the 340B statute, require specific accounting of 340B revenue separately from other sources of revenue.
- Specifically, Sun River is required to "use any non-grant funds as permitted under section 330, and may use such funds for such other purposes as are not specifically prohibited under section 330, if such use furthers the objectives of the [health center] project[1]".
- The Bureau of Primary Health Care requires health centers to maintain an accurate scope of project. A health center's scope of project defines the health center's approved service sites, services, providers, service area, and target populations[2].

To ensure maximum transparency and clarity regarding the use of 340B revenue by Sun River, the Board of Directors passed a resolution guiding the use of 340B revenue:

- HRHCare shall implement a 340B program and the revenue secured through the 340B program be utilized to expand the capacity and volume of services within HRHCare's

[1] Section 330(e)(5)(D) of the PHS Act, 42 USC 254b(e)(5)(D

[2] (https://bphc.hrsa.gov/sites/default/files/bphc/compliance/pin-2008-01-project-scope.pdf).

approved scope of project for underserved populations as required by the Health Resources and Services Administration (HRSA) of the United States Department of Health and Human Services.

- Attachment A: Board Resolution on 340B Revenue
- Attachment B: Policy on Use of Funds

Question 4: For each year beginning in 2018, please produce an excel document with a detailed accounting of how revenue generated from the 340B Program is used, including:

a) Direct-to-patient savings;
b) Indirect patient savings; and,
c) Programs supported by revenue generated from the 340B Program.
d) For direct-to-patient and indirect patient savings please delineate between patients with private insurance, patients on public insurance (differentiating between Medicaid, Medicare, or another public insurance program), and uninsured patients.

Direct-to-patient savings: Sun River defines direct-to-patient savings for purposes of this inquiry, as savings to the patient from the retail price of the drug, provided either directly at the pharmacy for the patient, or subsidized by Sun River through our 340B and pharmacy assistance programming.

There are three components to the direct-to-patient savings:

- Sun River Health has negotiated an uninsured program with Walgreens. Prescriptions for uninsured patients are transmitted to Walgreens with a special barcode to indicate eligibility for the Sun River Health uninsured prescription program. Patients can access these prescribed medications at the 340B acquisition cost plus a nominal administrative fee and dispensing fee. If the 340B price plus the fees exceeds the Walgreens retail price for the medication, the patient will be billed the lowest possible price. Due to the large geographic spread of Sun River patients, this program with Walgreens ensures that patients throughout the service area have access to the lowest possible drug pricing. These transactions happen directly at the pharmacy and occur outside of Sun River's financial tracking and accounts.
- Sun River has established an uninsured program through ProAct to maximize access for our patients and to further ensure availability throughout the large geography of our service area. Sun River provides uninsured patients with a discount card based on their income and family size. When this card is presented at participating contract pharmacies, patients can access prescription medications on a sliding fee scale with discounts from the negotiated rate based on their federal poverty level and subsidized by Sun River[3]. While those over 200% of the poverty level do not receive further subsidy,

[3] The slide categories are set based on income and family size with Slide A as those below 100% of the federal poverty level; Slide B as those between 101-133% of the federal poverty level; Slide C those between 134% - 168% of the federal poverty level; Slide D for those between 169% - 200% of the federal poverty level; Slide E & F are for those over 200% of the federal poverty level.

they are able to access medications at the group purchasing rate that ProAct has negotiated which is below the standard medication price.

	Generic Copay	Brand Copay
Slide A	$5*	$15*
Slide B	25% *	25%*
Slide C	50%*	50%*
Slide D	75%*	75%*
Slide E & F	100% ^	100% ^

*Max per prescription of $250

^ For Slides E & F the patient pays the discounted ProAct negotiated price, typically a substantial discount off retail pharmacy rates

- Attachment C: Staff Education Uninsured Program on 340B

- Finally, Sun River has a Patient Assistance program to further subsidize prescriptions that are urgently needed by our patients, but where significant barriers to accessing those medications exist. Medical providers make recommendations for the use of this fund, and it is available to all patients, regardless of insurance status, who face access barriers.

Uninsured Benefit				
	2019	**2020**	**2021**	**2022**
Proact	290,326	396,988	410,415	335,985
Maxor PAF	4,668	25,436	18,836	15,199
Walgreens	2,933,622	4,199,688	5,869,364	6,497,938
Total	3,228,615	4,622,112	6,298,615	6,849,122

- Attachment D: Direct Patient Savings Excel Document

Indirect patient savings: Sun River defines indirect patient savings as indirect patient benefits as additional programming available to patients that has been made possible by 340B net revenue.

As discussed above, Sun River's Board of Directors has resolved its understanding, pursuant to HRSA, that 340B Program's intent is for "covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services[4]."

Sun River Health's scope of services includes community health center locations and community-based locations throughout New York's Hudson Valley, New York City, and Long Island regions. This network, serving nearly 250,000 patients in 48 locations and 400 clinicians and support teams provides comprehensive primary and preventive care to all who seek it, including medical, dental, behavioral health, and specialty care. (A comprehensive description of our organization, service area, and patients is available in the response to Question 7 below.) Sun River Health includes the 340B net revenue in the organizational operating budget to support the full scope of services offered across Sun River's federally approved scope of project.

- The Bureau of Primary Health Care requires federally qualified health centers, like Sun River Health, to be compliant with the sliding scale program, specifically:
    - The health center must prepare a schedule of fees or payments for the provision of its services consistent with locally prevailing rates or charges and designed to cover its reasonable costs of operation and must prepare a corresponding schedule of discounts [sliding fee discount schedule (SFDS)] to be applied to the payment of such fees or payments, by which discounts are adjusted on the basis of the patient's ability to pay[5].
    - The health center's schedule of discounts must provide for a full discount to individuals and families with annual incomes at or below those set forth in the most recent Federal Poverty Guidelines (FPG) [100% of the FPG], except that nominal charges for service may be collected from such individuals and families where the imposition of such fees is consistent with project goals.
    - In 2022, Sun River Health provided 116,259 visits to uninsured patients, nearly 18% of all visits.

In addition to supporting access to comprehensive care for all Sun River Health patients, we have also included a list of examples of the programming made possible with 340B net revenue.

- ***New Community Health Centers (non-330 funded new access points)***: Sun River Health's Board of Directors continues to be responsive to patients' and communities' needing, in our service area, improved access to affordable, high-quality care. Through a rigorous

[4] 1 The House Report accompanying the original 340B Program legislation states the following intent: "[i]n giving these 'covered entities' access to price reductions the Committee intends to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."

[5] *Section 330(k)(3)(G) of the PHS Act; 42 CFR 51c.303(f), 42 CFR 51c.303(g), 42 CFR 51c.303(u), 42 CFR 56.303(f), 42 CFR 56.303(g), and 42 CFR 56.303(u))*.

planning and community development process, Sun River Health has opened new health center locations in underserved areas. This follows a robust application process to include the new location in the Bureau of Primary Health Care's approved scope of project for Sun River. During the inquiry period, Sun River has added centers in new cities/locations of White Plains, New Rochelle, Copiague, Huntington, the Bronx, and Queens.

- ***Mobile Health***: Many individuals in our service area face barriers to care, including homelessness, transportation, and often lack of awareness of available services and how to navigate health care services. Sun River Health utilizes its mobile medical vans in both urban and rural areas to help break down these barriers to care. Mobile Health allows us to bring a medical team to community-based locations, engage new patients in care, and connect them to a Sun River medical home. Our mobile teams visit schools, senior centers, behavioral health centers, community events, food pantries, and many other community-based organizations (CBOs). These teams provide screenings, vaccinations, enrollment in health care, education, and medical services, among many others, to community members most in need.

- ***Enabling and Supportive Services***: Barriers to health care disproportionately impact the ability of high-need patients to access the services, often resulting in poorer health outcomes, complications, and delays in care. Sun River is committed to addressing these barriers faced by our patients and helping patients access critical services. Sun River staff link patients to community-based services through a dynamic navigation system and portal, Unite UsÒ, to help facilitate referrals to food pantries, homeless shelters, educational resources, and others. In addition, Sun River Health provides numerous transportation services to enable patients to get to their medical appointments. Sun River supports transportation needs by helping utilize insurance-provided transportation, navigating public transportation, shuttles directly operated by Sun River, and through travel vouchers. These services help ensure that our patients can attend their appointments at the health center and access lab and radiology services. Additionally, Sun River provides translation services in the health centers. Communication with the medical team in a patient's primary language is critical to safe and quality care. Sun River provides nearly 2,000,000 minutes of translated medical care each year.

- ***Navigation Services***: The health care system can be complex to navigate for many individuals, and for those with multiple chronic conditions or who face multiple barriers it can be overwhelming. When patients cannot navigate the system, they often miss primary care appointments, diagnostic tests and imaging, specialty appointments, etc.,

which contributes to additional morbidity and mortality and high health care utilization and costs. Sun River Health provides health navigation and care coordination to our patients with programs that range in intensity and support based on the needs of the patients. These navigation services include referral coordination for both medical and social service needs; post-hospitalization care management to reconnect patients with primary care and address medication reconciliation; housing application assistance; and behavioral health follow-up and connection to services.

- ***After-Hours Access***: Sun River Health has 24-hour, seven-day-a-week access for our patients. During the hours when the health center itself is not open, we have after-hours nurse and medical clinician support for patients with medical emergencies and concerns.

- ***Intensive Chronic Care Management***: Sun River provides health care for over 20,000 patients with diabetes. Many of these patients have elevated HbA1C levels that indicate poorly controlled diabetes and a higher risk for complications and poor outcomes. Lowering these levels is complex and difficult. Sun River has added nutrition and certified diabetes educators to our clinical teams to provide additional clinical and educational support for our patients to help them reduce their HbA1C levels and improve their health outcomes. In addition, patients with asthma often visit the emergency room during exacerbations and flare ups. Successful management of asthma requires continuous awareness and readiness to reduce the chances of hospitalization and other complications. Sun River has implemented a comprehensive Asthma Action Planning Program to support our patients and their families. AirNYC, another CBO with whom Sun River has a contractual relationship, receives referrals from Sun River to provide home health and other services so that patients do not over-use hospital-based emergency services when their care is better delivered in the community.

- ***Maternal Health Support***: Sun River Health cares for over 3,000 pregnant women annually. Ensuring ongoing prenatal care, access to diagnostic testing and imaging, post-partum care, and pediatric care for these families helps improve health outcomes. Sun River Health provides supportive services in all these areas, including coordination in the hospital post-delivery to support women in connecting back to post-partum care and ongoing primary care for their infants.

Question 5: Does Sun River give eligible patients access to 340B drugs at the discounted rate? If so, please describe the patient population (i.e., uninsured, low-income) that has access to these drugs.
Sun River provides care to all who seek it, regardless of ability to pay. Currently, 97.42% of patients are below 200% of poverty and 23.36% of patients are uninsured (2022 UDS Data). All patients have access

to the Sun River Health 340B program, and as described above, all of Sun River's uninsured patients have access to discounted drugs through multiple programs. Medicaid covered patients are able to consistently access low-cost medications through the NYS Medicaid program, which sets copays and formularies. In our 340B Program, patient eligibility is defined as those who have had a visit with a Sun River Health provider within the last 24 months (about two years). All patients on our sliding fee program have access to our ProAct program to further subsidize their medication costs at participating pharmacies. As shared above, please see additional details about our patient programs.

Sun River Health's Uninsured Program for 340B:

Every uninsured patient that presents to Sun River Health is given options to receive free or low-cost medications through one of our two primary programs.

- Sun River Health has negotiated an uninsured program with Walgreens. Prescriptions for uninsured patients are transmitted to Walgreens with a special barcode to indicate eligibility for the Sun River uninsured prescription program. Patients can access these prescribed medications at the 340B acquisition cost plus a nominal administrative fee and dispensing fee. If the 340B price plus the fees exceeds the Walgreens retail price for the medication, the patient will be billed the lowest possible price. Due to the large geographic spread of Sun River Health patients, this program with Walgreens ensures that patients throughout the service area have access to the lowest possible drug pricing.
- In addition, Sun River has established an uninsured program through ProAct and provides uninsured patients with a discount card based on their income and family size. When this card is presented at participating contract pharmacies, patients can access prescription medications on a sliding fee scale with discounts off the negotiated rate based on their poverty level and subsidized by Sun River Health.

	Generic Copay	Brand Copay
Slide A	$5*	$15*
Slide B	25% *	25%*
Slide C	50%*	50%*
Slide D	75%*	75%*
Slide E & F	100% ^	100% ^

*Max per prescription of $250

^ For Slides E & F the patient pays the discounted ProAct negotiated price, typically a substantial discount off retail pharmacy rates

- See attached 340B Uninsured Program, Attachment E

Question 7: Please describe your patient population and the communities that you serve.

Sun River Health, Inc. is a New York State licensed Article 28 diagnostic and treatment center and federally qualified health center (FQHC) providing comprehensive primary, preventive, behavioral and oral health care, and a full range of enabling and support services for approximately 250,000

predominantly low-income patients living throughout a 16-county region of southeastern New York State encompassing the Hudson Valley, New York City, and Long Island. For more than 47 years, Sun River has provided innovative programs and services to meet the needs of the most vulnerable residents of medically underserved communities throughout our catchment area. Throughout this time, the Sun River has been steadfast in our commitment to our mission *to increase access to comprehensive primary and preventive health care and to improve the health status of our communities, especially for the underserved and vulnerable*. To this end, Sun River Health provides care to all who seek it regardless of insurance or ability to pay.

Sun River Health serves vulnerable, hard-to-reach populations living in rural, urban, and suburban underserved communities located throughout southeastern New York State. The patients served by the Sun River are largely impoverished and almost entirely low-income – 88.88% of patients whose poverty status is known have incomes below 100% of the federal poverty level (FPL), and 97.42% live below 200% FPL. As is common in low-income and medically underserved communities, many of these patients are Medicaid beneficiaries (50.91%), Medicare enrolled (11.38%), or uninsured (23.36%). Furthermore, the Health Center also serves a highly diverse patient population within the targeted counties, which includes substantial representation from racial and ethnic minority communities. Indeed, 81.26% of our patients are people of color, predominantly those who identify as Hispanic/Latino in ethnicity (53.75%) and non-Hispanic Black/African American (28.92%). In addition, our patient population includes individuals who are members of special populations with unique health care and enrollment needs including, 9,959 migrant and seasonal agricultural workers and their dependents, 19,398 people experiencing homelessness, and 982 veterans. Overall, Sun River Health patients experience many barriers that challenge their ability to enroll in health insurance or obtain assistance in the enrollment process. These include low incomes, low levels of educational attainment, limited functional and health literacy, and a general lack of access to health care and enrollment services within their communities. In addition, many Health Center patients in the targeted counties struggle with additional challenges related to insurance enrollment, including:

- *Patients with Limited English proficiency* – In total, 42.3% of Sun River Health patients in the targeted counties are best served in a language other than English. These individuals face additional challenges in accessing linguistically appropriate information on available health insurance options, enrollment forms, and assistance in their preferred language.

- *Rural populations* – Sun River Health currently sees 10,783 patients through 28,887 visits annually at service sites located in rural areas, specifically in Sullivan County, NY, and eastern Dutchess County, NY. Several factors create significant barriers to accessing primary care and other health-related services in these geographically isolated and frequently economically depressed areas. Given the limitation on public transportation, cross-county and intra-county travel is virtually impossible for area residents who lack financial resources or personal vehicles. These limitations also contribute to the difficulty in recruiting qualified medical providers, social workers, home health aides, and others

to work in the area. As a result, economic and transportation issues have a twofold effect on accessing care – they inhibit patients from seeking care and discourage providers from coming to the area. While there are a few group and individual practices in these highly rural service areas, very few providers are willing to accept Medicaid patients, provide enrollment assistance, and/or offer a sliding fee scale for those who are uninsured.

- *Marginalized populations* – Sun River Health delivers services to populations that include disproportionate representation from marginalized populations, including individuals of color, those with diverse cultural identities or ethnicities, and people who identify as *LGBTQAI+.* The Health Center has considerable experience with and an unyielding commitment to addressing the unique and often complex needs of these populations. Indeed, to ensure that services are responsive to these needs, the SRH prioritizes cultural competence and applies the National Standards for Culturally and Linguistically Appropriate Services (CLAS) to "advance health equity, improve quality, and help eliminate health care disparities" in hiring and training staff, designing programs, and delivering services. All Sun River Health staff undergo training on cultural competency, which includes a broad definition of culture that recognizes that clients may define themselves by "membership" in multiple groups based on socioeconomics, culture, language, religion, gender, age, sexual orientation, physical and mental capacity, and health-related experiences and issues.

- *Black / African American Patients* – Sun River sees a substantial number of patients identifying as non-Hispanic, Black /African American (28.92 %), and has recognized the real and potential disparities that may affect these individual. Since 2020, Sun River has tracked disparities in health outcomes, launching dedicated efforts to address the national disparity in birth outcomes among African American women.

- *Patients with Chronic Conditions* – Sun River Health sees patients with a wide array of chronic conditions including over 20,000 with diabetes mellitus, over 10,000 with asthma, and over 30,000 with hypertension. Chronic conditions are the leading causes of death and disability in the United States and the primary drivers of health care costs. Patients of Federally Qualified Health Centers, including Sun River Health, have 35% higher odds of having any chronic condition and 31% higher odds of having two or more chronic conditions as compared to non-FQHC providers[6]. As such, Sun River Health has developed substantial care management supports to improve outcomes and reduce the total cost of care.

[6] Corallo B, Proser M, Nocon R. Comparing Rates of Multiple Chronic Conditions at Primary Care and Mental Health Visits to Community Health Centers Versus Private Practice Providers. J Ambul Care Manage. 2020 Apr/Jun;43(2):136-147. doi: 10.1097/JAC.0000000000000324. PMID: 32011414; PMCID: PMC7329234.

- *Patients with HIV, HCV, and OUD* – Sun River Health sees 2,997 individuals with Human Immunodeficiency Virus (HIV), 300 with Hepatitis C (HCV), and 1,019 with Opioid Use Disorder (OUD). The Health Center has developed a comprehensive, integrated, multi-disciplinary model of care and treatment for individuals with these conditions designed to meet the complex needs of these individuals, including care management, support services, seamless linkage to responsive referral care networks, and routine review of prescribed therapeutic regimens. In addition, Sun River provides community based mobile health services in partnership with community-based organizations serving hard to reach populations at high risk for Hepatitis C and HIV, including out patient and short term drug treatment programs, methadone programs, homeless shelters and domestic violence shelters. Sun River's team, led by an infectious disease boarded physician, coordinates screening, assessment, entry into care, treatment, access to medications, and coordination with specialists.

Sun River Health's Sliding Fee Discount Program (SFDP) and associated Sliding Fee Discount Schedules (SFDS) apply uniformly to all patients seeking care at the Health Center, regardless of income or insurance status, and to all services within the Health Center's approved scope of project. To this end, Sun River Health informs all individuals seeking care at the Health Center of the SFDP. All patients, including those who are insured and/or are members of special populations, are asked to provide information on their household income and family size for the purposes of calculating their poverty level (as a percentage, based on federal poverty guidelines) and corresponding position on the sliding fee schedule to determine their eligibility for discounted services. To receive discounted services, patients must disclose their household income and family size and provide documentation to verify their income annually.

- Sun River Health's Board is responsible for ensuring that the organization has financial policies that follow federal and State laws and FQHC requirements, including the mandate that the Health Center implement a sliding fee discount program (SFDP),a which assures that our patients have access to all services in our federally-approved scope of project, regardless of their ability to pay. Sun River Health has a system to determine eligibility for, and application of, a sliding fee discount program. The income gradations are based on the most recently available Federal Poverty Guidelines (FPG) and are reviewed annually by the Board of Directors and adjusted accordingly. This system ensures that every service within Sun River Health's federally approved scope of project for which the Health Center has established a charge, regardless of the service type or mode of service delivery, will be made available to all Health Center patients regardless of ability to pay.

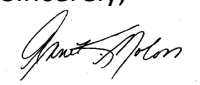
I. Question 8

- Please produce a copy of your drug cost-sharing policy for uninsured patients.

- See 340 Program description in Question 5 above

If you have any further questions, please feel free to reach out to me at [redacted] or at [redacted].

Sincerely,



Anne K. Nolon
CEO

cc: [redacted]

The Honorable Senator William Cassidy, MD
Ranking Member
US Senate Committee on Health, Education, Labor and Pensions
Washington, DC 20510-6300

Dear Senator Cassidy,

I am writing again on behalf of Sun River Health, in response to your inquiry dated November 16, 2023, requesting information on Sun River Health's (Sun River) participation in the 340B program. We hope that our initial response provided in December was helpful in your inquiry. As discussed with your staff, we are providing additional materials in response to Questions 1, 2 and 6 in this package.

As we shared in our last response, the 340B drug discount program is an important program for Sun River Health and is of incredible value to our patients and communities. We hope that this response further contributes to your understanding of the 340B program. Consistent with our first response, the information contained herein pertains to the calendar years 2019-2022. As noted previously, New York State implemented a pharmacy carve out for 340B on April 1, 2023, and Medicaid 340B is no longer a component of Sun River Health's 340B program.

Question 1: For each year beginning in 2018, please produce unredacted copies of Sun River Health's 340B pharmacy services agreements with contract pharmacies.

Sun River has included unredacted copies of the contracts for the following pharmacies in Attachment A:

PHARMACY	DBA/LOCAL NAME
WAL-MART PHARMACY 10-5997	
MERU PHARMACY INC	DBA SUNRISE PHARMACY
31ST & 3RD PHARMACY INC	DBA: AVITA PHARMACY 1063
SMS1 PHARMACY CORP.	MEDICAL CENTER PHARMACY OF WYANDANCH
POPULAR PHARMACY INC	DBA: BROOKHAVEN PHARMACY
PEEKSKILL PHARMACY INC	DBA: BAXTER'S PHARMACY
CIVA DRUGS CORP	DBA: BRENTWOOD PHARMACY
BENZER NY 1 LLC	AMENIA DRUGS
ESCO DRUG CO INC	ESCO DRUG CO INC
AVS RX	DBA: RUBIN CHEMISTS
TOMPKINSVILLE PHARMACY INC	TOMPKINSVILLE PHARMACY INC
BRIGHT PHARMA INC	DBA: BRIGHT AID
MAXOR NATIONAL PHARMACY SERVICES, LLC	DBA: BRIGHTPOINT PHARMACY
ALLURE SPECIALTY PHARMACY	ALLURE SPECIALTY PHARMACY
JEWEL OF FLUSHING RX INC.	JEWEL OF FLUSHING RX INC.
FEDCO CHEMIST PHARMACY CORP.	FEDCO CHEMIST PHARMACY CORP.

ACCREDO HEALTH GROUP INC / EXPRESS SCRIPTS PHARMACY,	ACCREDO HEALTH GROUP INC
OPTUM PHARMACY 702, LLC / GENOA HEALTHCARE LLC	OPTUM PHARMACY 702, LLC
MYTH SERVICES INC	DBA: SALUD CARE SPECIALTY PHARMACY
AMAZON PHARMACY #001 / PILLPACK, LLC	DBA: PILLPACK AMAZON PHARMACY #001

It is Sun River Health's intent to ensure access to the 340B program for our full patient population and to contract with pharmacies to ensure comprehensive access in all communities. Our contracting approach ensures that dispensing fees across all contracts, geographies, and populations are reasonable and within industry standard; specifically for 2022, our average dispensing fee across all independent pharmacies was $27 per prescription. This rate is well within the industry standard considering the mix of specialty drugs included in Sun River Health's program[1]. These contract arrangements create a consistent patient experience and work in tandem with our uninsured programs to provide access to additional support for patients who face barriers to access care. Specifically, Sun River Health has negotiated significantly lower fees for our uninsured transactions in our contracts.

Sun River Health's initial submission included a thorough description of our uninsured medication program, included here again for reference:

- Sun River has established an uninsured program through ProAct to maximize access for our patients and to further ensure availability throughout the large geography of our service area. Sun River provides patients with a discount card based on their income and family size. When this card is presented at participating contract pharmacies, patients can access prescription medications on a sliding fee scale with discounts from the negotiated rate based on their federal poverty level and subsidized by Sun River[2]. While those over 200% of the poverty level do not receive further subsidy, they are able to access medications at the group purchasing rate that ProAct has negotiated which is below the standard medication price.

	Generic Copay	Brand Copay
Slide A	$5*	$15*
Slide B	25% *	25%*
Slide C	50%*	50%*
Slide D	75%*	75%*
Slide E & F	100% ^	100% ^

*Max per prescription of $250

^ For Slides E & F the patient pays the discounted ProAct negotiated price, typically a substantial discount off retail pharmacy rates

[1] https://www.nacds.org/pdfs/pharmacy/2020/NACDS-NASP-NCPA-COD-Report-01-31-2020-Final.pdf

[2] The slide categories are set based on income and family size with Slide A as those below 100% of the federal poverty level; Slide B as those between 101-133% of the federal poverty level; Slide C those between 134% - 168% of the federal poverty level; Slide D for those between 169% - 200% of the federal poverty level; Slide E & F are for those over 200% of the federal poverty level.

- Sun River has a Patient Assistance program to further subsidize prescriptions that are urgently needed by our patients, but where significant barriers to accessing those medications exist. Medical providers make recommendations for the use of this fund, and it is available to all patients, regardless of insurance status, who face access barriers.

Question 2: For each year beginning in 2018, please produce an excel document with a detailed accounting of the funds Sun River Health generated from the 340B Program. This excel document must include:

The total dollar amount generated from the 340B Program:
i. Per calendar year;
ii. Per payer (e.g. Medicare, Medicaid, Private Insurance, Uninsured);
iii. Site of service;
iv. Therapeutic Class of Drugs; and,
v. Name and address(es) of dispensing pharmacy.

See Attachment B

As described in our initial submission, Sun River Health's Walgreens agreement provides the full 340B discount to patients at the point of the pharmacy transaction. We have included the value of that discount in *Attachment B, "Uninsured Benefit,"* as it is a significant and real savings that Sun River Health patients receive. This savings is not included in the 340B revenue totals because these funds do not flow through Sun River Health accounts.

- Sun River Health has negotiated an uninsured program with Walgreens. Prescriptions for uninsured patients are transmitted to Walgreens with a special barcode to indicate eligibility for the Sun River Health uninsured prescription program. Patients can access these prescribed medications at the 340B acquisition cost plus a nominal administrative fee and dispensing fee. If the 340B price plus the fees exceeds the Walgreens retail price for the medication, the patient will be billed the lowest possible price. Due to the large geographic spread of Sun River patients, this program with Walgreens ensures that patients throughout the service area have access to the lowest possible drug pricing. These transactions happen directly at the pharmacy and occur outside of Sun River's financial tracking and accounts.

Question 6: Do you use a third-party administrator (TPA) to assist in administering the 340B Program?

a. For each year beginning in 2018, please produce unredacted copies of Sun River Health's TPA agreements.
b. For each year beginning in 2018, please provide the total amount of fees and/or revenue sharing Sun River has paid annually to its TPA. Please provide this information as a total dollar amount and as a percentage of the revenue generated from the 340B Program.

Sun River Health utilizes several 340B third party administrators to support our 340B program and to ensure compliance with program regulations. These vendors provide support in tracking 340B transactions, maintaining inventory, managing payments with pharmacies and supporting pharmacies with program implementation. Sun River Health utilized four TPAs during the period of inquiry: Walgreens, Hudson Headwaters, Equiscript, and RX Strategies. All our 340B TPA agreements include confidentiality clauses requiring mutual authority to release the contract. We have not received approval to release unredacted copies of these contracts and therefore, we have not included those contracts with this submission.

Please see Attachment C for a summary of fees.

As you will see in Attachment C, in addition to standard TPA services, Equiscript provides additional services for Sun River Health patients. In late 2018, Sun River Health entered into an agreement with Equiscript, LLC to identify patients who are at risk of poor health outcomes because of barriers associated with filling their medications on a regular and reliable basis. Sun River Health's patient population includes patients who may not be able to reliably access a pharmacy for various reasons. Equiscript's service includes the identification of patients that may suffer barriers to care and direct telephone-based outreach by Equiscript personnel to these patients to ensure they have access to care. If the patient asks for assistance with receiving their medications at home, Equiscript services can include: the coordination of home delivery pharmacy services through a pharmacy contracted with Sun River Health; coordination with Sun River Health clinical staff and contracted pharmacy personnel to ensure the patient receives their medications; and direct follow up calls to the patient to ensure the patient understands their prescription benefits and receives their medications on a reliable schedule. Under this service, Equiscript also serves as the third-party administrator for the home delivery pharmacies providing the underlying delivery service.

If you have any further questions, please feel free to reach out to me at [redacted] or at [redacted].

Sincerely,

Anne K. Nolon
CEO

cc: [redacted]

Yakima Valley Farm Workers Clinic

January 22, 2024

VIA EMAIL: [redacted]

The Honorable Bill Cassidy, M.D.
Ranking Member
U.S. Senate Committee on Health, Education, Labor, and Pensions

Dear Ranking Member Dr. Cassidy,

On behalf of Yakima Valley Farm Workers Clinic ("YVFWC"), a non-profit Federally Qualified Health Center ("FQHC") with headquarters in Toppenish, WA, I am formally submitting this letter in response to your request for information dated November 16, 2023 ("340B Inquiry Letter"). This response supplements our correspondence dated December 29, 2023. We included our narratives and responses to questions 3, 5, 7, and 8 from our December 29, 2023 correspondence herein. Thank you for allowing YVFWC the opportunity to describe the significant impact the 340B Program has on the communities we serve. We are happy to continue the dialogue so the scope of the 340B Program remains as it is today.

Please be advised that the information provided contains competitively sensitive data. It is our understanding that your office views the disclosure of this data, including 340B pricing data, as a permitted disclosure under the 340B Office of Pharmacy Affairs Information System authorized user guidelines ("OPAIS Guidelines"). We have password protected the Appendices to preserve confidentiality. We expect that your office will keep this information confidential and will not publicly disclose any of the data. Also, if we do not hear from your office, we will assume that this disclosure is permitted under OPAIS Guidelines. YVFWC removed all protected health information consistent with HIPAA and our discussion.

Overview of the 340B Program

As you know, the 340B Program was created in 1992 in response to skyrocketing drug costs following implementation of the Medicaid Drug Rebate Program ("MDRP").[1] When Congress passed Section 340B of the Public Health Service Act, it recognized that drug costs were soaring as drug manufacturers offset the cost of rebates required under the MDRP. At that time, safety-net providers faced drug price increases of 32 percent, on average.[2] Congress created the 340B Program to curtail manufacturer cost-shifting to safety-net providers in recognition of the critical role that such safety-net providers play in their respective communities. The Congressional record explains "the Federal government simply cannot continue to allow…Federally-funded clinics…and their patients to remain unprotected against manufacturer price increases.[3] The 340B Program was designed to curtail manufacturer pricing behavior for the benefit of covered entities and their patients. YVFWC values its ability to participate in the 340B Program as it provides us with invaluable resources to support the needs of our patient population that consists largely of

[1] *See* 42 U.S.C. 1396r–8.
[2] House Energy and Commerce Report on The Medicaid Drug Rebate Amendments of 1992 to the Veterans Health Care Act of 1992, P.L. 102-585, H.R. REP. 102-384(11), at 10 (1992). Citing a study conducted by New York University regarding the cost increases safety-net providers faced, the House Energy and Commerce Committee noted "Hospital costs for the drugs included in the study increased, on average, by 32 percent, far in excess of the historical 5 to 9 percent annual increases in drug prices experienced by public hospitals."
[3] *Id*. at 11.

low-income patients. Simply put, many of the programs and services that we offer would not be possible, or at the very least would be a significant challenge to develop, absent 340B funds as they are not covered fully by our grant funding or payments for services. Notwithstanding, we understand the interest in 340B Program reform focused on transparency to ensure that communities are appropriately supported by the 340B Program as Congress intended when it created the program over 30 years ago. YVFWC is here to support that cause while ensuring that its patients are not adversely impacted by any reform.

The Congressional record went on to state that "in giving these 'covered entities' access to price reductions the [House Energy and Commerce] Committee intends to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[4] YVFWC has created a network for its patients to receive primary care services and other substantial community benefits due to the 340B Program, as Congress intended.

The 340B Program was, in fact, created to enable *covered entities* to stretch their resources to reach more patients and provide more services. Therefore, any proposed reform should not shift onerous obligations to covered entities that ultimately result in taking resources away from covered entities and their patients. This would significantly alter our ability to treat our patient population that largely consists of low-income patients. YVFWC provides substantial direct savings to its low-income, uninsured, and underinsured patients as discussed below, and it invests appropriate resources and time to maintain a compliant program. These investments in our people and our communities would not be possible without the 340B Program. Our patients are the beneficiaries of the 340B Program, so we urge Congress to maintain the current scope of the program while requiring manufacturers to provide their products at or below the 340B ceiling price in all settings where our patients are treated, including contract pharmacies, as the 340B statute intended to accomplish.

Congress, safety-net providers, and communities remain aligned on drug pricing matters – soaring drug costs are a significant barrier to patient care. Drug manufacturers have not changed their pricing behavior in any way that benefits taxpayers such that programs like 340B or MDRP should be curtailed. The MDRP, the 340B Program, and other critical programs continue to work, as designed, by allowing our healthcare delivery system to properly function for the benefit of our communities and low-income patients therein. We greatly appreciate the opportunity to demonstrate the important work that YVFWC does for its communities, and to contribute to the discussion about the good that the 340B Program does for our patients. We also understand the interest in assessing the good that the 340B Program does for communities throughout this country, so we are happy to provide your office with further insight on how critical the 340B Program is to our patients.

Covered entities utilize the 340B Program by purchasing covered outpatient drugs at a discount that varies based on the type of drug, the manufacturer, and other factors (*e.g.*, generic products may have a low discount). HRSA permits covered entities to purchase 340B drugs for dispensing to the covered entities' patients in the retail setting.[5] Under the 340B Program, manufacturers are statutorily required to offer the discount. In short, 340B covered entities buy discounted drug products that ultimately create savings that are used to provide additional care to patients and increase access to care all *without increasing costs to taxpayers*.

[4] *Id*. at 12.
[5] 75 Fed Reg. 10272 (March 5, 2010); *See also* 61 Fed. Reg. 43549 (August 23, 1996).

YVFWC dedicates significant time and resources to maintaining a compliant 340B Program that provides significant benefits to the communities and low-income patients it serves. YVFWC enlists several 340B vendors to assist with compliance, including third party administrators ("TPA") that manage inventories and electronic track 340B patient eligibility. YVFWC also contracts with retail and specialty pharmacies to expand access to care for its patients when patient choice, location, or payor policies dictate that prescriptions are filled at non-YVFWC pharmacies.[6] These various avenues allow YVFWC to generate funds to invest in the communities and serve its patients consistent with the intent of the 340B Program.

Overview of Yakima Valley Farm Workers Clinic

YVFWC is a non-profit, grant-funded FQHC[7] with over 40 locations across Washington and Oregon that serve over 197,000 patients. YVFMC is deeply committed to serving its communities as evident by the tremendous amount of patient-centered care it provides to low-income patients. In calendar year 2022 alone, 90% of YVFWC's patients fell below 200% of the Federal Poverty Level with nearly 58% of its patients at 100% or below the Federal Poverty Level. (See Appendix A – YVFWC Community Benefit Report 2022). These patients qualified for substantial financial assistance ranging from a 25% discount to a 100% discount with a nominal fee per YVFWC's Sliding Fee Discount and Federal Poverty Level Policy ("FPL Policy"). Additionally, 65% of YVFWC's patients are Medicaid beneficiaries, and 12% of the patients have no insurance. This clearly demonstrates YVFWC's commitment to providing care to medically underserved and vulnerable patients regardless of their ability to pay.

YVFWC's patient population varies in characteristics with 64.2% Hispanic/Latino, 39.4% monolingual non-English speaking representing multiple ethnicities and races; 49.9% are adults vs. 42.7% pediatrics; and 14.1% are seasonal agricultural workers to whom YVFWC provides regular care during their season in its region. YVFWC is proud to provide culturally competent healthcare to its patients and communities in a manner that meets the social, cultural, and whole person needs of diverse populations.

YVFWC's central function is providing primary care services to its patients located throughout Washington and Oregon, regardless of their ability to pay. Consistent with its patient-centered focus, YVFWC also provides other medical, dental, pharmacy, Women, Infants, and Children (WIC), and enabling services regardless of an individual's ability to pay. Although FQHCs are required to provide primary health care services to patients, YVFWC takes it further and provides services beyond the required services of an FQHC. These additional services include behavior health and other community benefits such as nutrition assistance, employment training, unhoused services, and citizenship classes. YVFWC strongly believes that by providing the community benefits beyond the required FQHC services, the patients overall health will improve. We could not do this without resources from the 340B Program.

As an FQHC, YVFWC is often the anchor healthcare center for patients. Our patients, clients, and the communities in which YVFWC serves depend upon the FQHC to not only provide high quality care and

[6] Vertical integration among payors, pharmacy benefit managers ("PBM") and TPAs have led to an increasing amount of prescriptions that we cannot fill in-house due to payor-imposed restrictions, as well as changes to fee structures.

[7] A "health center" under Section 330 of the Public Health Service Act is "an entity that serves a population that is medically underserved, or a special medically underserved population comprised of migratory and seasonal agricultural workers, the homeless, and residents of public housing, by providing, either through the staff and supporting resources of the center or through contracts or cooperative arrangements…required primary health services." 42 USC 254b(a)(1).

services, but to continuously improve, evolve, and adapt. The ability to actively reinvest 340B revenue as well as other revenue streams into YVFWC's scope in a manner that supports a multidisciplinary model of care has allowed YVFWC to bolster community-aligned, evidence-based programs while also expanding access and newer service lines in a manner that supports *whole* person healthcare in historically underserved communities. Here are a few examples of personal success stories made possible by savings from YVFWC's 340B Program:

- A 72-year-old patient of YVFWC for more than 20 years who spent most of their life working in the agricultural community and has very limited income now qualifies for the YVFWC sliding fee at the 100% poverty level for clinical and pharmacy services. This allows the patient to receive care and medications at a nominal fee without fear of denials or snowballing medical bills they are unable to afford. The patient was recently diagnosed with metastatic cancer to their liver in addition to their multiple other comorbidities. As the patient navigates this new diagnosis, they require additional medications beyond the nine prescriptions they currently have for their health. Their current prescription medications cost approximately $28 per month because they receive YVFWC's sliding fee discount and pays only a nominal fee. The patient will continue to pay the nominal fee for all prescriptions due to YVFWC's sliding fee policy that they are able to provide due to the 340B Program savings. The patient has expressed their gratitude for these discounts as they would not be able to afford the care or medications without these programs.

- A 53-year-old healthcare professional who is both a patient and an employee of YVFWC was diagnosed with type 2 diabetes in 2016. As part of their treatment plan, the patient enrolled in diabetes education courses offered by YVFWC and took advantage of the available community health services related to their diabetes. The patient lost more than 150 pounds and improved their health through appropriate diet and exercise utilizing the education and tools provided through the YVFWC community programs. The patient did not use surgical or pharmaceutical modalities to lose weight or to gain control of their health. As a result of utilizing the YVFWC programs and increasing their overall health, the patient's endocrinologist removed diabetes as a diagnosis in 2023 and declared the patient is cured. The patient expressed their gratitude and desire to partner with the community services teams to share their journey with others. YVFWC can offer educational courses and programs beyond the traditional clinic visits for patients to utilize as a result of the 340B Program savings.

Clarification of Inaccurate Definitive Healthcare Data Cited in the 340B Inquiry Letter

YVFWC is pleased to participate in this exercise to offer greater insight into the importance of 340B Program including the good that it does for our community and our patients, and to correct certain misconceptions. To that end, the 340B Inquiry Letter states: "Your health system is also ranked as having the highest compensation among all CHCs in the nation" and cites to data published by Definitive Healthcare in April 2023.[8] However, the data published by Definitive Healthcare was grossly inaccurate.

After the 340B Inquiry Letter brought this data to YVFWC's attention, YVFWC notified Definitive Healthcare of the data inaccuracies, and Definitive Healthcare confirmed that it inadvertently inflated

[8] YVFWC is not affiliated with, nor has it provided data to Definitive Healthcare.

YVFWC's compensation due to miscalculations and removed the data from its website. Please see a statement prepared by Definitive Healthcare enclosed as Appendix B confirming Definitive's data was incorrect. This letter explains how Definitive Healthcare was unaware of the long-standing nuanced Medicare Cost Reporting methods for FQHCs with multiple sites which resulted in Definitive Healthcare aggregating and inflating data when each Medicare Cost Report contained previously reported data for the same sites.

To put the gravity of this incorrectly reported information into perspective, Definitive Healthcare's data suggested that total compensation paid by YVFWC was $1,487,343,665. However, as reported on its 2021 IRS Form 990, YVFWC's total reported expenses across the entire organization, inclusive of compensation, supplies, rent, etc., was approximately $251M.[9] (See Appendix C – YVFWC 2021 IRS Form 990).

Recent 340B Development Impacts on YVFWC

YVFWC relies heavily on the 340B Program to be able to expand and reinvest in its communities so that its patients can live healthier lives, but recent actions by drug manufacturers are limiting the availability of resources that can be reinvested. As you may be aware, in 2020, drug manufacturers began implementing contract pharmacy restriction policies, which unlawfully deny access to drugs at the 340B price when delivered to and dispensed by contract pharmacy locations to a covered entity's 340B eligible patients.

As an FQHC that provides predominantly primary care to patients as opposed to specialty care (*e.g.*, it does not provide infusion), YVFWC relies on retail pharmacies to assist with treating YVFWC patients by meeting their outpatient medication needs. As noted in responses that follow, fortunately YVFWC relies on its entity-owned pharmacies for most medication needs, but there are some instances where we are required to send prescriptions to certain external contract pharmacies. This dynamic has led us to strategically identify and contract with certain pharmacies to ensure we are appropriately utilizing the 340B Program. In short, manufacturer restrictions inhibit our community's ability to access 340B resources in certain contract pharmacies. We encourage Congress to resolve this issue so we do not face further restrictions.

Drug Pricing Transparency

Participating in this exercise has shed light on an area that we believe needs attention. Many stakeholders have long pushed for greater transparency in the 340B Program with an emphasis on covered entity transparency. Through this process, YVFWC faced significant challenges when preparing the data in the form and for the date range requested in the 340B Inquiry Letter. In large part, this was due to vendors, like drug wholesalers, limiting access to historical drug pricing and purchasing data.

YVFWC greatly appreciates [redacted] accommodation on the date range and flexibility on timing as we worked diligently to prepare our submission. In light of the above challenges, we respectfully request that Ranking Member Cassidy and other members of Congress consider that transparency measures, if used, need to be directed at all 340B stakeholders in the drug supply chain.

[9] YVFWC 2021 IRS Form 990.

Yakima Valley Farm Workers Clinic

We appreciate the opportunity to convey the importance of the 340B Program to YVFWC and the communities we serve. We hope this information provides the Committee with greater insight into how the 340B Program operates and how it benefits communities across the United States.

Please feel free to contact me if you need additional information or have any questions.

Sincerely,

Christy Trotter

Christy Trotter,
Chief Executive Officer
Yakima Valley Farm Workers Clinic

Yakima Valley Farm Workers Clinic

RESPONSE TO 340B QUESTIONNAIRE

1. **For each year beginning in 2018, please produce unredacted copies of Yakima Valley's 340B pharmacy services agreements with contract pharmacies.**

   YVFWC is unable to provide copies of its contract pharmacy services agreements due to the confidential information contained in them. These contract pharmacy services agreements contain a confidentiality section, which specify that the agreement itself is confidential and cannot be disclosed. As such, to continue its relationship with its partners and remain in compliance with the agreements, YVFWC has not provided copies.

2. **For each year beginning in 2018, please produce an excel document with a detailed accounting of the funds Yakima Valley generated from the 340B Program. This excel document must include:**

   a. **The total dollar amount generated from the 340B Program:**
      i. **Per calendar year;**
      ii. **Per payer (e.g. Medicare, Medicaid, Private Insurance, Uninsured);**
      iii. **Site of service;**
      iv. **Therapeutic Class of Drugs; and,**
      v. **Name and address(es) of dispensing pharmacy.**

   Please see Appendix D (included in the appendices attachment(s) accompanying this letter) compromised of the requested data. Appendix D presents data from YVFWC's entity-owned retail pharmacies and their contract pharmacies. Appendix D contains high level summaries of funds generated by pharmacy relationship along with underlying source data.

   As discussed and agreed upon with [redacted], the data in Appendix D ranges from August 2020 – December 2023. Our wholesalers and other supply chain partners place restrictions on historical pricing and other data, so YVFWC is unable to provide data from 2018- July 2020. Our total 340B funds generated from August 2020 to December 2023 were approximately $146,178,844.65. Please see below summary table of 340B funds generated:

TABLE 1: DOLLARS GENERATED FROM 340B PROGRAM (AUG 2020 – 2023)

Pharmacy	Total (2020 – 2023)
Contract Pharmacies[10]	
Accredo (includes ESI)	$ 161,821.72
Columbia Memorial Hospital	$ 376,844.09
CVS	$ 410,458.25
Elfers	$ 315,646.33
Healthy Options Inc.	$ 24,745.61

[10] YVFWC calculated dollars generated in the contract pharmacy setting net of dispensing fees and other administrative fees paid to contract pharmacies. The dollars generated do not factor in YVFWC's internal operational costs, including oversight staffing, compliance, legal, etc. As such, although the question requests dollars generated, the totals reflected do not reflect the net revenue realized by YVFWC.

Kroger (includes Fred Meyer)	$ 368,643.94
Optum	$ 45,065.97
PillPack (includes Overlake)	$ 24,120.84
TruePill	$ 759.06
Rite-Aid	$ 595,136.54
Rick's Hi-School	$ 244,869.68
Safeway	$ 780,408.75
Walgreens	$ 2,409,043.82
Pharmacies (13) Owned by YVFWC	
YVFWC Entity-Owned Retail	$ 140,421,281.00[11]
TOTAL	**$146,178,845.60**

As Appendix D depicts, the total funds generated through the 340B Program are primarily from YVFWC's entity-owned retail pharmacies. YVFWC's contract pharmacy relationships only account for 4% of the total funds generated. YVFWC operates 13 of its own retail pharmacies that exclusively serve YVFWC patients (known as closed-door pharmacies). YVFWC's closed-door pharmacies provide a critical access point to its patients who are often on multiple medications that treat multiple chronic conditions. These pharmacies allow YVFWC to treat the whole person and ensure that patients are adhering to their treatment regimen.

YVFWC is somewhat unique in that it does not rely heavily on contract pharmacies to reach its patients. YVFWC contract pharmacies serve a critical supplemental role where patient choice or PBM/payor policies mandate use of specific pharmacies, including those owned by the PBMs. Further, by relying on our own closed-door pharmacies to treat our patients, YVFWC pharmacy staff have real-time access to the patient's medical record so they can verify 340B patient eligibility at the time of dispense.

3. **Does Yakima Valley have processes and procedures in place to audit how it uses 340B savings? If so, please describe these audit processes and procedures. If not, why not?**

While YVFWC has multiple layers of auditing processes related to the 340B program including verification controls to ensure compliance and risk mitigation and submitting to external audits of our practices, we do not specifically link a dollar amount saved with direct funding to a program or service line. YVFWC's 340B Program complies with the 340B statute and HRSA guidance, which do not include having processes or procedures in place to audit 340B savings. Congress never intended to direct the use of 340B savings in any specific way or to any specific patients, so the statute does not require covered entities to audit their savings. Mandating this level of auditing and reporting may require vast resources that are not currently available.

Notwithstanding, YVFWC does produce annual public-facing community benefit reports and IRS Form 990s that summarize how VVFWC supports its communities.

[11] YVFWC's entity-owed pharmacy calculation is a gross dollars generated calculation. The figure in Table 1 and Appendix D does not include bad debt and other uncollectable debt. Therefore, the figure presented in Table 1 is higher than actual dollars received. The calculation also does not include staffing, rent, technology and other costs of operating YVFWC's 13 pharmacies which are significant.

4. **For each year beginning in 2018, please produce an excel document with a detailed accounting of how revenue generated from the 340B Program is used, including:**

    a. **Direct-to-patient savings;**

Please see Appendix E, which includes detail on direct-to-patient savings that YVFWC provides through its Sliding Fee Discount and Federal Poverty Level Policy within its entity-owned pharmacies. YFVWC provided patient savings information as far back as the data permitted. Also, please see Appendix F for direct-to-patient savings for clinic-administered drugs. YVFWC is able to provide these discounts in large part because of 340B funds consistent with Congress's intent when it enacted the 340B Program. More than 90% of YVFWC's patients qualify for significant discounts under this policy, and the funds generated from the 340B Program provide the mechanism to YVFWC to provide these discounts and stretch its scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services consistent with Congressional intent.

    b. **Indirect patient savings; and,**
    c. **Programs supported by revenue generated from the 340B Program.**

As discussed with [redacted], we do not see a clear distinction between questions 4b and 4c. Therefore, we are providing a consolidated response to those questions. Please see Appendix G for specific projects supported by 340B funds. These projects would not have been possible or would have had to be significantly reduced in scope without the 340B Program.

As you know, YVFWC is an FQHC that receives federal funding under Section 330 of the Public Health Service Act ("Section 330"). Section 330 requires YVFWC to provide comprehensive primary care services regardless of the patient's ability to pay. YVFWC's focus is to provide primary care and enabling services to uninsured and underinsured populations, ensuring comprehensive care. YVFWC's patient population has seen a minimum of about 5% growth year-over-year for the last ten years. Ensuring our organization can not only provide ongoing care but also expand access to primary care and support services entails vast operational and capital investment costs.

In addition to the direct and indirect expenditures captured in Appendices E and F, YVFWC also provides significant support within its community through unfunded or underfunded programs, many of which do not result in billable services or result in largely clinic subsidized services such as integrated registered dieticians, clinical pharmacists, and other licensed independent professionals providing direct patient services. Additionally, YVFWC has invested heavily in education, housing assistance and other programs targeting whole person health and community outcomes. YVFWC does not have a mechanism to track the expense of these programs to 340B funding on a dollar-for-dollar basis. Notwithstanding, YFVWC expends significant resources providing these value-add services to ensure its patients can live comfortable lives with access to resources necessary to stay healthy. Below are several examples of how YVFWC utilizes its 340B savings for programs that benefit its community and fulfill YVFWC's mission. Each of these examples highlights the different forms of investment YVFWC contributes to its communities.

- Enhanced Medical Services: YVFWC has an active role in assuring the health of the communities it serves. To increase access and improve the health of its communities, YVFWC has invested in innovations and new care team models to enhance the way care is delivered and increase access. This includes adding additional behavioral health services, integrated registered dieticians, additional population health programs, and increased specialty care services for pediatric patients with special health and developmental needs among other clinical improvements. Although YVFWC receives reimbursement from state and federal prospective payment systems, each state operates differently in how these rates are adjusted. This complexity can leave certain disciplines or services heavily subsidized because the rate cannot be automatically adjusted to reflect the cost of the service.

- Educational Services: YVFWC provides several educational programs that patients can take advantage of to learn more about their health and how to better self-manage it. YVFWC has identified common diagnoses to provide these self-management courses to patients, including asthma, diabetes, and chronic diseases. In addition to medical-focused education services, YVFWC also provides patients with other courses that focus on other social determinants of health to improve patients' overall health. Examples of these courses involve improving reading to children and parenting classes. These educational courses are provided on a consistent schedule to ensure patients remain consistent with their education and implementing what they learn from the courses into their everyday routines.

- Citizenship and English as a Second Language (ESL) Services: YVFWC offers assistance with preparing for citizenship tests and also learning and improving English for individuals whose primary language is not English. This includes reading, writing, speaking, and listening to English.

- Housing Support Services – HEN: HEN provides essential needs items to low-income individuals who cannot work for at least 90 days due to their physical and/or mental health. These services provided may include move-in costs, personal health and hygiene items, cleaning supplies, and transportation assistance. Additionally, emergency hotel/motel vouchers are also available during extreme weather for patients who are experiencing homelessness. Patients who qualify for the vouchers are at or below 80% of the median area income.

- Weatherization & Utility Assistance Services: YVFWC assists with bills for low-income families living around the Lower Yakima Valley area. Clients who qualify can get up to $1000 worth of aid each year to help pay bills for electricity, natural gas, propane, heating oil, and wood for heating. Clients who own their homes can also receive assistance with repairing or replacing heating equipment in their homes.

- Support Services: YVFWC provides a variety of services to complement its FQHC offering, including the following:
    - Outreach services
        - The overarching goal is to assist patients in navigating the larger systems to increase the probability of access to a service or support they need. The

goal is to provide guidance and information so they can become self-sufficient. We work to address social determinants of health by completing an assessment in EPIC and referring/connecting to resources. In FY23, outreach workers had 23,398 encounters.

- We host and participate in over 100 events throughout the year in Washington and Oregon; plan and oversee events, including health fairs, state/county fairs, and community parades; participate in community events to enhance visibility for patients in need of care; build and maintain relationships with organizations and members of the community; and create the opportunity to engage new patients during community events.

- Sensory adaptive dental environment - Modifies the standard dental environment for children with sensory sensitivities.
- Social Stories: a tool for patients with autism spectrum disorder - A story with photos used to prepare patients to go to the dentist. This story breaks down the visit step by step, to help patients know what to expect at their visit, avoiding surprises and unexpected activities that can be distressing to patients with autism spectrum disorder.
- De-sensitization visits - These services help children apprehensive about the dentist become more comfortable. These include tours of the dental office and practice dental visits.

- Northwest Community Action Center ("NCAC")
  - Community Education Services
    - 21st Century Learning Centers
      - Provides k-12 students learning opportunities in STEM, art, music, robotics, and community service outside of regular school hours. Students can also get help with homework, learn about careers, take field trips, and do various other activities.
    - SNAP-Ed
      - Program with goal of improving healthy food choices from SNAP participants and making healthy eating easier. This is done through classroom education, food demonstrations, grocery store tours, providing recipes, community-facilitated education, community gardens., and more. This program touches on health living, healthy shopping, food security, and food safety.
    - Adult Education
      - Provided through Safe Haven, we provide a range of adult education classes and activities such as: computer lab, seniors-on-the-go, ESL classes, citizenship classes, and town halls.
    - Adult Exercise

- Housing Support Services – RRH: Helps those who are unhoused to return to stable housing quickly. Clients may receive funds for security deposits, move-in expenses, and rent. This program is meant to provide short-term help to get clients back on their feet and regain self-sufficiency.

- Outdoor Adventure Program: Provides under-served youth with quality opportunities to experience the natural world. Programming focuses on serving youth with the greatest needs and helping them improve their overall academic performance, self-esteem, personal responsibility, community involvement, personal health, and understanding of nature.

d. For direct-to-patient and indirect patient savings please delineate between patients with private insurance, patients on public insurance (differentiating between Medicaid, Medicare, or another public insurance program), and uninsured patients.

For direct-to-patient savings per payor, please see the excel sheet previously provided for question 4a (Appendices E and F).[12] This excel sheet displays the discounts given to patients based on YVFWC's Sliding Fee Discount and Federal Poverty Level Policy.

YVFWC does not track the vast indirect community programing / indirect savings that it provides by payer. The majority of these programs are not driven by payor source and do not result in bills submitted to payors, so YVFWC does not always collect payor insurance information from patients that participate in these programs. Notwithstanding, more than half of YVFWC's patient population is enrolled in Medicaid and 90% are considered low income. YVFWC is committed to its communities and providing care and services needed, regardless of payor.

5. Does Yakima Valley give eligible patients access to 340B drugs at the discounted rate? If so, please describe the patient population (i.e., uninsured, low-income) that has access to these drugs.

The 340B Program was intended for covered entities to access 340B drugs at discounted rates. Consistent with its mission and its FQHC grant funding, and subject to applicable patient inducement legal restrictions, YVFWC has implemented a sliding scale fee discount policy and related procedures that result in significant medical, dental, mental health and prescription drug savings for its patients. Depending on income levels, patients may pay a nominal fee anywhere from $0 - $5 for prescription drugs. These discounts ensure that patients can continue to take their medications on the appropriate schedule. This policy is extremely important for patients with chronic diseases that routinely take multiple high-cost drugs to manage the chronic conditions.

The majority of YVFWC's patient population is eligible for the sliding scale discount policy. 90% of YVFWC's patients are classified as low-income, 65% of the patients are Medicaid beneficiaries, and 12% of the patients have no insurance. YVFWC's patient population varies in characteristics with 64.2% Hispanic/Latino, 39.4% monolingual non-English speaking representing multiple ethnicities and races; 49.9% are adults vs. 42.7% pediatrics; and 14.1% are seasonal agricultural workers to whom YVFWC provide regular care during their season in its region.

6. Do you use a third-party administrator (TPA) to assist in administering the 340B Program?

a. For each year beginning in 2018, please produce unredacted copies of Yakima Valley's TPA agreements.

[12] Appendix E displays all sliding scale fee discounts across all payors in the view provided. There is no further information per-payor as sliding scale discounts are provided to uninsured and underinsured patients.

As discussed with [redacted], contract pharmacy and TPA agreements contain confidentiality provisions, many of which specify that the agreement itself is confidential and cannot be disclosed. Therefore, YVFWC is unable to provide copies of its TPA agreements due to the confidential information contained therein. YVFWC has to rely on its vendors to provide support to its 340B program, so we are not in a position to divulge their confidential information at this time.

b. For each year beginning in 2018, please provide the total amount of fees and/or revenue sharing Yakima Valley has paid annually to its TPA. Please provide this information as a total dollar amount and as a percentage of the revenue generated from the 340B Program.

YVFWC is unable to provide data regarding its TPA fees because this information is confidential under the agreements with TPA vendors.

7. Please describe your patient population and the communities that you serve.

YVFWC is an FQHC with over 40 locations across Washington and Oregon to serve over 197,000 patients with 90% of those patients being low-income, 65% of the patients are Medicaid beneficiaries, and 12% of the patients have no insurance. This number of visits is an increase of nearly 100,000 visits when compared to our 2020 data. In 2022, YVFWC conducted over 778,000 visits to ensure its patient population received the care it needed. YVFWC's patient population varies in characteristics with 64.2% Hispanic/Latino, 39.4% monolingual non-English speaking representing multiple ethnicities and races; 49.9% are adults vs. 42.7% pediatrics; and 14.1% are seasonal agricultural workers to whom YVFWC provide regular care during their season in its region.

8. Please produce a copy of your drug cost-sharing policy for uninsured patients.

Please see YVFWC's FPL Policy at Appendix H. As described in the policy, the fees for drugs are dependent on the patient's income level. Moreover, the discounts apply to both insured and uninsured patients, which further demonstrates YVFWC's commitment to serving its patients.[13] All patients that demonstrate that they are below 200% of the Federal Poverty Level ("FPL") benefit from YVFWC's 340B participation as those patients pay the 340B acquisition cost of the drug plus a nominal dispensing fee.[14] Without the 340B program, we would not be able to offer this significant discount as our acquisition cost would be much higher.

As noted in our above correspondence, Congress's clear intent in developing the 340B program was "in giving these 'covered entities' access to price reductions the [House Energy and Commerce] Committee intends to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. In addition to the drug cost saving measures mentioned above, YVFWC also stretches its resources to benefit its community by offering many other non-drug items and services on a sliding fee scale basis as described in Appendix H.

[13] All patients that receive discounts undergo an individual financial needs assessment.
[14] Per the "Nominal Fee" definition in Appendix D, a patient's ability to obtain care from YVFWC is not dependent on the patient's ability to pay the nominal fee. Patients will not be denied care in such instances.

YVFWC offers medical, behavioral health, substance abuse, and dental service, among others, at a significant discount based on the FPL. For example, YVFWC provides nearly a 100% discount for individuals and families at or below 100% of the FPL. YVFWC only charges a nominal $10.00 (dental services) or $15.00 (medical services) fee. In 2022, approximately 58% of YVFWC families had income below 100% of the FPL. In short, more than half of YVFWC's population qualified for substantial discounts.

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February 16, 2024

VIA EMAIL
CONFIDENTIAL TREATMENT REQUESTED

Senator Bill Cassidy, M.D.
Ranking Member
Committee on Health, Education, Labor and Pensions
United States Senate
428 Senate Dirksen Office Building
Washington, DC, 20510

Re: January 17, 2024 Letter to CVS Health

Dear Ranking Member Cassidy:

On behalf of our client, CVS Health ("CVS Health" or the "Company"), please find enclosed the first voluntary production of documents responsive to Request Nos. 1a, 1b, and 1c of your January 17, 2024 letter.

Please note that the materials enclosed in response to Request Nos. 1a, 1b, and 1c (hereinafter the "Confidential Materials") contain confidential information, and we request Confidential Treatment of those materials. The Confidential Materials concern customarily non-public, confidential, and privileged business and commercial information. CVS Health requests that this letter and the Confidential Materials be maintained in confidence and be used solely for the purposes of this inquiry.

Production of the Confidential Materials is not intended to, and does not, waive any applicable privilege or other legal basis under which information may not be subject to production. If it were found that production of any of the Confidential Materials constitutes disclosure of otherwise privileged matters, such disclosure would be inadvertent. By the production of such documents, CVS Health does not intend to and has not waived the attorney-client privilege or any other protections. CVS Health also reserves the right to supplement these responses, if necessary.

Please let me know if you have any questions, and we look forward to our continued engagement.

Best regards,

[redacted]

[redacted]
of LATHAM & WATKINS LLP

REQUEST No. 1a

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.

Wellpartner is a 340B administrator. The services provided by 340B Administrators include eligibility determinations, replenishment of drugs for eligible prescriptions, technology support, and compliance.

Wellpartner provides 340B program optimization services. Wellpartner helps covered entities adjust to ongoing changes from pharmaceutical manufacturers and evaluate opportunities to add contract pharmacies. Wellpartner also assists clients with ESP data submission and HRSA audit preparation.

REQUEST No. 1b

Regarding your company's participation in the 340B Program: b. Are covered entities required to use Wellpartner as their designated TPA?

Covered entities must use the Company's own contract pharmacy administrative services for CVS Health pharmacies. This integrated approach delivers measurable benefits, including expanding access and output and reducing compliance problems.

The Company does not require covered entities to use a single administrator or to use only Wellpartner. Covered entities can choose to work with the Company's internal administrative services either just for CVS Health pharmacies or for any of their other contract pharmacies. Covered entities can and often do hire other administrators for other contract pharmacies and other services.

The Company does not require hospitals to use just CVS Health pharmacies. Hospitals remain free to contract with other contract pharmacies, including Walgreens, Walmart, Albertsons, Kroger, and many independent pharmacies. Hospitals also remain free to, and in fact frequently do, use multiple 340B administrators. Consistent with CVS Health's open platform approach in other parts of its business, Wellpartner continues to work with hospitals and non-CVS Health pharmacies with appropriate firewalls in place.

REQUEST No. 1c

Regarding your company's participation in the 340B Program: c. Describe the firewalls that exist between: (a) CVS Caremark and Wellpartner; and (b) CVS Caremark and Aetna.

CVS Health has established a Business Information Firewall Policy (the "Firewall Policy") and controls to protect competitively sensitive information held by one business from being inappropriately disclosed to or used by another business. Our Firewall Policy and program have

been reviewed and vetted by numerous regulators and law enforcement agencies, including the Federal Trade Commission, Department of Justice, state attorneys general, and state departments of insurance.

The Firewall Policy restricts CVS Health Business Units from disclosing competitively sensitive information, such as competitor pricing or bid information, contract information, strategic plans, or other competitively sensitive information that may violate our contracts, our policies, or antitrust laws. Compliance with the Firewall Policy is part of our colleague Code of Conduct and all employees with access to competitively sensitive information receive annual training on their obligations to comply with these expectations. CVS Health has also implemented strict data access controls for data systems that carry confidential information to further ensure firewall compliance through technical means, and those access controls are regularly audited.

Application, database, and operating system access is reviewed at least annually, based on risk assessments, to confirm whether rights and privileges are restricted to appropriate personnel based on job responsibilities. The process is performed to assess the appropriateness of users' access rights and privileges, including high privileged access to relevant applications, operating systems, databases, developer access to production, and supporting tools. A segregation of duties review of application access is performed over limited high-risk roles within applications and where applicable across applications at least annually by Finance Operations to confirm that employee access is commensurate with job responsibilities, mitigating controls are established if needed, and remediation steps are taken for conflicting duties.

CVS Health also conducts regular monitoring and auditing of the business unit information firewall standards. On a quarterly basis, the enterprise services team responsible for the Business Firewall Policy selects competitively sensitive data sources to validate that user access is appropriate based on CVS Health Business Firewall Policy/Standards. User Access Listings are compared to human resource listings to confirm that active users report within the appropriate business unit based off the CVS Health Business Firewall Policy/Standards. Any user deemed inappropriate is researched to determine appropriateness (e.g., proper approvals/forms, ability to compete). In the event a user is concluded to have inappropriate access, the users' access is revoked and business and application owners are required to submit a management action plan to remediate the risk to ensure the problem does not occur in the future.

In addition to the Firewall Policy, CVS Health complies with applicable laws protecting the privacy and security of patient data as well as the confidentiality provisions in our client agreements.

This CVS Health Entity	Will Not Share this Competitively Sensitive Data	With this Firewalled off Entity
Wellpartner	Contract pharmacy and administrative fees charged by non-CVS pharmacies and non-Coram infusion providers; reimbursement rates paid by non-Caremark payers to non-CVS pharmacies and non-Coram infusion providers	CVS Pharmacy Providers (Retails, Specialty, and LTC pharmacies), CVS Caremark, Coram
CVS Caremark	Health Plan clients' RFP pricing, bid information, contract terms, financial information or drug claims data	Aetna (including Aetna Affiliate) and SilverScript (SSI)
CVS Caremark Part D Services	Clients' Part D RFP pricing, bid information, contract terms, financial information or drug claims data	Aetna and SilverScript (SSI)
Aetna and SilverScript (SSI)	Contract terms, prices, and financial arrangements Aetna has with non-CVS Payor entities	CVS Caremark

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March 11, 2024

VIA EMAIL
CONFIDENTIAL TREATMENT REQUESTED

Senator Bill Cassidy, M.D.
Ranking Member
Committee on Health, Education, Labor and Pensions
United States Senate
428 Senate Dirksen Office Building
Washington, DC, 20510

Re: January 17, 2024 Letter to CVS Health

Dear Ranking Member Cassidy:

On behalf of our client, CVS Health ("CVS Health" or the "Company"), please find enclosed narrative responses to Request No. 1 and 2 of your January 17, 2024 letter.

Please note that this response (hereinafter the "Confidential Materials") contain confidential information, and we request Confidential Treatment of those materials. The Confidential Materials concern customarily non-public, confidential, and privileged business and commercial information. CVS Health requests that this letter and the Confidential Materials be maintained in confidence and be used solely for the purposes of this inquiry.

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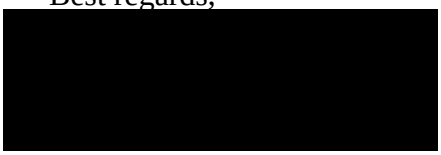
Please let me know if you have any questions, and we look forward to our continued engagement.

Best regards,



[redacted]
of LATHAM & WATKINS LLP

REQUEST No. 1

Regarding your company's participation in the 340B Program…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…f) Does CVS Caremark and/or Wellpartner assist covered entities in sharing 340B discounts with patients? If so, please explain.

1d. Wellpartner uses covered entity data to determine 340B eligibility. Wellpartner receives a) pharmacy dispense data, and b) covered entity encounter (patient and prescriber) data. We determine eligibility by finding dispense vs. encounter data matches (a and b matches). We support a variety of methodologies but these do not deviate from matching covered entity data to pharmacy data.

We also offer covered entities additional eligibility opportunities in the form of our Pending Claims feature. When there are near matches, but not enough for us to assert 340B eligibility, we present these near misses to covered entities who have the opportunity to review and mark them as eligible. The set of Pending Claims that age out are then eligible to be forwarded to their referral vendor partner(s) who may assist in the eligibility determination.

Wellpartner understands and takes seriously our obligations to safeguard the confidential personal health information we receive in connection with our patient and covered entity services. We have implemented robust privacy and security programs to ensure we are in compliance with applicable laws as well as program commitments.

1f. Wellpartner is a strategic partner for 340B Covered Entities (CE) and their mission to help deliver affordable patient access to medications. Our Community Benefit Programs (CBPs) are established and designed by CEs to support under-insured or uninsured members of the community. For those patients that may need the most help, we encourage our CE partners to establish a Community Benefit Program that supports this mission.

We manage CBPs using rigorous methods to ensure that patients are qualified to participate, and provide CEs with transparent reporting and continuous audit support to offer a full picture of drug costs and outcomes.

REQUEST No. 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.

The Company generates revenue from the 340B Program through two separate services. First, Wellpartner earns administrator fees that are structured in accordance with the terms and conditions of its services agreement with Covered Entities (e.g. fixed fee per eligible claim or a percentage of the 340B savings, which is based on the 340B ceiling price set by statute). Second, CVS Health pharmacies that participate as 340B contract pharmacies earn dispensing fees that are structured in accordance with the terms and conditions in the written pharmacy services agreement between the pharmacies and the Covered Entities (e.g. a flat fee based on the days supply of the prescription or a percentage of the claim's value). These dispensing fees are meant to compensate pharmacies because they agree to forego their traditional revenue source (i.e. payments from insurers) when participating as a 340B contract pharmacy. 340B Program revenue is reported in CVS Health's Pharmacy & Consumer Wellness and Health Services Segments.

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April 5, 2024

VIA EMAIL
CONFIDENTIAL TREATMENT REQUESTED

Senator Bill Cassidy, M.D.
Ranking Member
Committee on Health, Education, Labor and Pensions
United States Senate
428 Senate Dirksen Office Building
Washington, DC, 20510

Re: January 17, 2024 Letter to CVS Health

Dear Ranking Member Cassidy:

On behalf of our client, CVS Health ("CVS Health" or the "Company"), please find enclosed our first voluntary production of documents and narrative responses to Request No. 3 of your January 17, 2024 letter.

Please note that this response (hereinafter the "Confidential Materials") contain confidential information, and we request Confidential Treatment of those materials. The Confidential Materials concern customarily non-public, confidential, and privileged business and commercial information. CVS Health requests that this letter and the Confidential Materials be maintained in confidence and be used solely for the purposes of this inquiry.

Production of the Confidential Materials is not intended to, and does not, waive any applicable privilege or other legal basis under which information may not be subject to production. If it were found that production of any of the Confidential Materials constitutes disclosure of otherwise privileged matters, such disclosure would be inadvertent. By the production of such documents, CVS Health does not intend to and has not waived the attorney-client privilege or any other protections. CVS Health also reserves the right to supplement these responses, if necessary.

Please let me know if you have any questions, and we look forward to our continued engagement.

LATHAM & WATKINS LLP

Best regards,

[redacted]

[redacted]
of LATHAM & WATKINS LLP

REQUEST No. 3

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)?

To the best of our knowledge, using calculations based on internal and government records, there were 75,748 contracts involving pharmacies owned or operated by a CVS Health subsidiary ("CVS Health pharmacy") that were active at some point between January 1, 2019, and January 17, 2024. Data on 1) the name of each pharmacy, 2) the location of each pharmacy, and 3) the pharmacy's distance to a covered entity is included in the production at CVS000001. 88 percent of covered entities are located in urban areas or urban clusters.

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.

To the best of our knowledge, using calculations based on internal and government records, there were 8,323 pharmacies owned or operated by a CVS Health subsidiary ("CVS Health pharmacy") with an active 340B contract during that time period.

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May 10, 2024

VIA EMAIL
CONFIDENTIAL TREATMENT REQUESTED

Senator Bill Cassidy, M.D.
Ranking Member
Committee on Health, Education, Labor and Pensions
United States Senate
428 Senate Dirksen Office Building
Washington, DC, 20510

Re: January 17, 2024 Letter to CVS Health

Dear Ranking Member Cassidy:

On behalf of our client, CVS Health ("CVS Health" or the "Company"), please find enclosed narrative responses to Request Nos. 1 and 2 of your January 17, 2024 letter.

Please note that this response (hereinafter the "Confidential Materials") contain confidential information, and we request Confidential Treatment of those materials. The Confidential Materials concern customarily non-public, confidential, and privileged business and commercial information. CVS Health requests that this letter and the Confidential Materials be maintained in confidence and be used solely for the purposes of this inquiry.

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Please let me know if you have any questions, and we look forward to our continued engagement.

Best regards,

[redacted]

[redacted]
of LATHAM & WATKINS LLP

REQUEST No. 1e

1. Describe your company's participation in the 340B Program:

e. Does CVS Caremark and/or Wellpartner offer savings from the 340B Program to your health plan clients? If so, please explain.

Wellpartner offers savings from the 340B Program to its Covered Entity (CE) clients, not CVS Caremark's health plan clients, by maximizing 340B savings for CEs. Wellpartner's customers include urban and rural hospitals and federal grantees of all sizes. CVS Caremark does not participate in the 340B Program, but does offer a variety of PBM services and programs (including utilization management, pharmacy network contracting, and formulary management) designed to reduce the cost of its clients' prescription drug spending, including on prescriptions that may be qualified claims under the 340B Program.

REQUEST No. 2d

2. Regarding your business relationship with covered entities:

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.

As explained in response to 2a and 2b, the Company generates revenue from the 340B Program through two separate services. First, Wellpartner earns administrator fees that are structured in accordance with the terms and conditions of its services agreement with Covered Entities (e.g. fixed fee per eligible claim or a percentage of the 340B savings, which is based on the 340B ceiling price set by statute). Second, CVS Health pharmacies that participate as 340B contract pharmacies earn dispensing fees that are structured in accordance with the terms and conditions in the written pharmacy services agreement between the pharmacies and the Covered Entities (e.g. a flat fee based on the day's supply of the prescription or a percentage of the claim's value). These dispensing fees are meant to compensate pharmacies because they agree to forego their traditional revenue source (i.e. payments from insurers) when participating as a 340B contract pharmacy. 340B Program revenue is reported in CVS Health's Pharmacy & Consumer Wellness and Health Services Segments. As announced in its 10Q on May 1, 2024, CVS Health's operating income and adjusted operating income decreased in part because of a lower contribution from 340B.

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May 15, 2024

VIA EMAIL
CONFIDENTIAL TREATMENT REQUESTED

Senator Bill Cassidy, M.D.
Ranking Member
Committee on Health, Education, Labor and Pensions
United States Senate
428 Senate Dirksen Office Building
Washington, DC, 20510

Re: January 17, 2024 Letter to CVS Health

Dear Ranking Member Cassidy:

On behalf of our client, CVS Health ("CVS Health" or the "Company"), please find enclosed our second voluntary production of documents responsive to Request No. 2 of your January 17, 2024 letter. The materials are Bates stamped CVS000002.

Please note that this response (hereinafter the "Confidential Materials") contain confidential information, and we request Confidential Treatment of those materials. The Confidential Materials concern customarily non-public, confidential, and privileged business and commercial information. CVS Health requests that this letter and the Confidential Materials be maintained in confidence and be used solely for the purposes of this inquiry.

Production of the Confidential Materials is not intended to, and does not, waive any applicable privilege or other legal basis under which information may not be subject to production. If it were found that production of any of the Confidential Materials constitutes disclosure of otherwise privileged matters, such disclosure would be inadvertent. By the production of such documents, CVS Health does not intend to and has not waived the attorney-client privilege or any other protections. CVS Health also reserves the right to supplement these responses, if necessary.

Please let me know if you have any questions, and we look forward to our continued engagement.

LATHAM & WATKINS LLP

Best regards,

[redacted]

[redacted]

of LATHAM & WATKINS LLP

United States Senate

COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS

WASHINGTON, DC 20510–6300

November 21, 2024

VIA ELECTRONIC TRANSMISSION

David Joyner
President and Chief Executive Officer
CVS Health
1 CVS Dr.
Woonsocket, RI 02895

Mr. Joyner:

On January 17, 2024, I sent your predecessor, Karen S. Lynch, a letter as part of my investigation into the 340B Drug Pricing Program (340B Program).[1] This multi-year investigation into covered entities, including hospitals and community health centers, contract pharmacies, and pharmaceutical manufacturers is necessary to ensure proper oversight of the program and that all participants prioritize patients over profits.

The Senate Committee on Health, Education, Labor, and Pensions has primary jurisdiction over the Health Resources and Services Administration, the agency charged with administering and overseeing the 340B Program. As Ranking Member of this Committee, it is necessary that I have a full understanding of CVS Health's participation in the 340B Program, including covered entities' use of Wellpartner, a third-party administrator (TPA) program that offers inventory management, audit and operational support, as well as increased 340B Program savings.

Since sending Ms. Lynch the letter in January, my staff has engaged with your outside counsel for almost a year to remedy my production-related concerns. Despite these repeated attempts, the Committee has yet to receive a satisfactory production from your company. Specifically, CVS Health has failed to respond question 2, subparts (d), (e), and (f), which seek information and records pertaining to the revenue your company generates from the 340B Program and your company's contractual relationships with covered entities. When Ms. Lynch and I discussed these production-related concerns in October, she refused to produce these records, citing confidentiality clauses, refused to engage in good faith, and, at times, was hostile to my inquiries.

CVS Health's unwillingness to provide the documents voluntarily is consistent with an industry-wide pattern of fighting to prevent transparency into the administration of the 340B Program. I

[1] Letter from Sen. Bill Cassidy, Ranking Member, S. Comm. on Health, Educ., Lab., & Pensions, to Karen S. Lynch, President & Chief Exec. Officer, CVS Health (Jan. 17, 2024), https://www.help.senate.gov/imo/media/doc/340b_cvs_letter.pdf.

therefore expect CVS Health to produce all documents, data, and information requested in question 2 and its subparts by **December 20, 2024.** If CVS Health continues to fail to produce the requested documents by the above deadline, I will consider additional tools to force compliance and to obtain this critical information.

Thank you for your prompt attention to this important matter.

Sincerely,

Bill Cassidy, M.D.

Bill Cassidy, M.D.
Ranking Member
U.S. Senate Committee on Health,
Education, Labor, and Pensions

LATHAM & WATKINS LLP

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January 16, 2025

VIA EMAIL
CONFIDENTIAL TREATMENT REQUESTED

Senator Bill Cassidy, M.D.
Chair
Committee on Health, Education, Labor and Pensions
United States Senate
428 Senate Dirksen Office Building
Washington, DC, 20510

Re: January 17, 2024 Letter to CVS Health

Dear Chair Cassidy:

On behalf of our client, CVS Health ("CVS Health" or the "Company"), please find enclosed a narrative response and our third voluntary production of documents. The materials are responsive to Request No. 2 of your January 17, 2024 letter, which was reiterated in your November 21, 2024 letter. The production consists of unredacted TPA and contract pharmacy agreements between Wellpartner and Yakima Valley Farm Workers Clinic, Cleveland Clinic, and SunRiver Valley. The materials are Bates stamped CVS000003 - CVS000309.

Please note that this response (hereinafter the "Confidential Materials") contains confidential information, and we request Confidential Treatment of these materials. The Confidential Materials concern customarily non-public, confidential, and privileged business and commercial information. CVS Health requests that this letter and the Confidential Materials be maintained in confidence and be used solely for the purposes of this inquiry. See Rule XXIX(5). As discussed during our January 6, 2025 call, due to the highly sensitive commercial information contained in the Confidential Materials, CVS respectfully requests that the Committee engage with CVS prior to any potential disclosure of the Confidential Materials discussed herein.

Production of the Confidential Materials is not intended to, and does not, waive any applicable privilege or other legal basis under which information may not be subject to production. If it were found that production of any of the Confidential Materials constitutes disclosure of otherwise privileged matters, such disclosure would be inadvertent. By the production of such documents, CVS Health does not intend to and has not waived the attorney-client privilege or any other protections. CVS Health also reserves the right to supplement these responses, if necessary.

Please let me know if you have any questions, and we look forward to our continued engagement.

Best regards,

[redacted]

[redacted]
of LATHAM & WATKINS LLP

REQUEST No. 2d

2. Regarding your business relationship with covered entities:

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.

Below please find the third-party administrator fees that Wellpartner earned in connection with the 340B program:

2019: $147 million
2020: $295 million
2021: $386 million
2022: $370 million
2023: $382 million

The services provided by Wellpartner include, but are not limited to 340B eligibility determinations, technology support and compliance.

Walgreen Co.
1399 New York Ave., NW
Suite 725
Washington, DC 20005
[redacted]
Walgreens.com

February 6, 2024

The Honorable Bill Cassidy, M.D.
U.S. Senate

Subject: 340B

Walgreens would like to thank you for the opportunity to respond to the January 17th request on the 340B Drug Pricing Program. Our comments are a starting point, and we look forward to further engaging with you to provide thoughtful input on and workable solutions for the program.

Walgreens is an integrated pharmacy and healthcare entity operating nearly 9,000 locations across the United States and serving approximately 9 million customers and patients each day. Nearly half of our locations are in underserved areas. Our healthcare teams play a critical role in the U.S. healthcare system by providing a wide range of pharmacy and healthcare services, including primary care, specialty pharmacy care, post-acute care, home care, and clinical trial facilitation, to uniquely impact the patient care-journey continuum. Through our enhanced offerings, community engagement, and partnerships, we are creating neighborhood health destinations within our stores, featuring interprofessional teams to provide a wider range of healthcare services with the aim of improving patient access and health outcomes and lowering costs. It is our vision to be the leading partner in reimagining local healthcare and well-being for all. This drives all our efforts and addresses the Nation's top priorities of improving access to health care, advancing health equity, and improving the health of all.

The 340B Program allows safety-net providers, "covered entities," including the pharmacies with whom they contract, serving a large population of low-income Medicare, Medicaid, and Supplemental Security Insurance patients, to acquire and dispense outpatient drugs from pharmaceutical manufacturers at discounted prices. According to Congress, the purpose of the 340B program is to enable covered entities "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Walgreens is a dedicated partner in helping the 340B program achieve this goal. As a contract pharmacy under the program, Walgreens has provided pharmacy services to 340B covered entities and their patients for more than a decade. In addition, we provide comprehensive support through our contract pharmacy administrative services solution to help covered entities carry out their program. One of the important functions carried out in this capacity is to support covered entities with audit

requests that help support program integrity. We have provided several covered entities with audit support and to date, all audits have resulted with no adverse findings from HRSA.
The 340B Program facilitates enhanced medical services within resource-stricken communities and ensures continuity of care by increasing access through the ability of covered entities to enter into contractual relationships with pharmacies. This flexibility enables and expands the range of covered entities to effectively reach those in need. Subsequently, the program generates healthcare savings that contribute to funding free or low-cost medications and supporting clinics focused on HIV/AIDS, diabetes, cancer, dental care, and primary healthcare. These clinics serve our most at-risk patients experiencing financial hardships by ensuring their patients have access to necessary medications and specialized care without any financial burdens. Safety net providers work in partnership with contract pharmacies to meet the needs of the community. These providers use their 340B savings towards caring for vulnerable patients, including financially, economically, socially and ethnically diverse populations. In many cases, 340B savings go directly to patients at the point-of-sale to cover or reduce the cost of their prescriptions. Studies have shown that access to reduced-cost medications through the federal 340B Drug Pricing Program is associated with a significant reduction in hospitalizations and emergency department visits for patients while, decreasing patients' utilization of healthcare resources[1].

While all recognize the 340B program's importance in providing care to vulnerable Americans, it is prudent to evaluate ways in which we can bring improvement to the program to provide greater efficiency and reach to communities in need. Throughout the years, Walgreens has used every opportunity to engage on Congressional, Agency, and other requests seeking ideas to enhance the 340B drug pricing program. In our multiple comments, we have consistently provided feedback and solutions that we believe would provide specific direction on program issues, including patient definition, drug inventory replenishment, duplicate discounts, and the intended crucial role of pharmacy. We are pleased, once again, to offer the below responses to your questions, with the hope that this effort will result in purposeful focus and unequivocal clarity on the program's statutory intent.

.

Responses to the Request

1. **Please describe the types of services 340B Complete provides to covered entities participating in the 340B Program.**

   We provide the following 340B administrative support services:

[1] Taliaferro LM, Dodson S, Norton MC, Ofei-Dodoo S. Evaluation of 340B prescription assistance program on healthcare use in chronic obstructive pulmonary disease. Explor Res Clin Soc Pharm. 2023 Jun 14;11:100295. doi: 10.1016/j.rcsop.2023.100295. PMID: 37404594; PMCID: PMC10315920.

- Implementation and maintenance of covered entity's pharmacy plan design (including sliding copayment schedules) for their eligible patients
- Pharmacy network management, including contract pharmacy staff training on the 340B program
- Establishment and maintenance of covered entity's 340B drug file, eligible prescribers, and eligible sites of care
- Maintenance of patient eligibility available in various options based on the capability of the Covered Entity – ex. barcodes on paper prescriptions and/or electronic prescriptions, electronic data transfer of eligible patients from their Covered Entity's Electronic Medical Records (EMR) system
- Validating the prescriptions that are eligible for 340B services, based on the Covered Entity's selected process, for those covered entities who elect to use Walgreens as their TPA.
- Inventory maintenance and management by dedicated Inventory team members for the covered entity and the contract pharmacy
- Electronic Data Interchange ordering and connectivity with covered entity's wholesaler
- Dedicated IT department to make timely software upgrades to ensure compliance with 340B program requirements
- Covered entity assistance to educate eligible prescribers about the availability of the 340B contract pharmacy network
- Accounting and outstanding receivable management
- Maintenance of secure web portal for covered entity's review of all transactions (24x7), prescriptions dispensed, and orders placed, received, and outstanding
- Reporting capabilities through the secure web portal to ensure compliance review of the covered entity's program
- Use of "sold" prescription data (as opposed to "dispensed") to confirm the eligible patient received the medication prior to placing replenishment orders
- Audit support – pre-audit review and dedicated team member support, including physical on-site presence during actual audit of 340B program compliance
- Account management - dedicated team members for day-to-day operations support and local field account managers for in-person entity support

2. **Are covered entities required to use 340B Complete as their designated TPA?**

   No. Covered entities can choose to work with other TPAs.

3. **How does your 340B Complete identify prescriptions as 340B-eligible vs. noneligible? What level of information is shared? Please describe the mechanisms in place to ensure confidentiality.**

Walgreens operates a retrospective replenishment model. Under this model, we dispense Walgreens purchased products to patients at the point-of-dispensing. Once the prescriptions are sold, for those covered entities who choose to use Walgreens as their TPA, the 340B Complete system will determine if a prescription is 340B eligible based on matching Walgreens pharmacy records to the validation criteria selected by the covered entity, such as location code identifiers, eligible providers, eligible patients, or eligible medication orders from an entity's electronic medical record (EMR) system. For those covered entities who use another party as their TPA, Walgreens (pursuant to a separate contract with that TPA) transmits a dataset of pharmacy records to the TPA for the TPA to determine 340B eligibility. For uninsured patients, our pharmacy personnel are trained to utilize the covered entity's unique 340B plan for eligible prescriptions. If the Walgreens usual and customary (U&C) price (the cash price) is less than the 340B contracted rate, then Walgreens will not convert the prescription to 340B and instead offer the lower price to the patient. Through the 340B Complete web portal, each covered entity has 24/7 access to a complete set of data for all of its 340B program transactions with Walgreens, including patient level prescription data, inventory orders placed, received, and outstanding, and reporting. Walgreens complies with all federal and state laws and regulations related to data security and privacy along with the standards and requirements of HIPAA Rules and other applicable laws relating to the security or confidentiality of PHI.

4. **Does Walgreens or 340B Complete assist covered entities in sharing 340B discounts with patients? If so, please explain.**

   We work with covered entities to implement and maintain the respective entity's patient plan design, which may include various sliding fee scales for low-income or uninsured patients as determined by the entity to best meet their patient's needs. The entity's plan design is then loaded into a claims processor and tested for accuracy prior to the launch date. Utilizing the administrative support capabilities, we are able to dispense 340B drugs to eligible patients using the benefit designed by the covered entity. In addition, covered entities can actively monitor program utilization through our customizable reporting web portal to ensure their program is appropriately tailored for their patients. We work with covered entities to modify their plan design as requested by the covered entity. Any changes made by the covered entity after initial launch will result in additional testing for accuracy prior to the new launch date. In addition, we compare the 340B contracted rate to the U&C price available from that Walgreens location. If the U&C price is lower than the 340B contracted rate, we offer that lower-cost, non-340B option to the patient, thereby ensuring the patient always receives the best available pricing for their pharmacy needs.

5. **Please describe how revenue is generated from the 340B Program for your company. How does 340B Complete account for this revenue in its annual financial statements submitted to the U.S. Securities and Exchange Commission?**

   Our pricing structure includes a pharmacy dispensing fee, and a program administration fee. Each fee is individually negotiated per covered entity and

varies from contract to contract. Through our annual reports and SEC filings (http://investor.walgreens.com) Walgreens provides substantial financial information related to our operations and services, inclusive of 340B services, to the public and to investors. However, as the prescriptions that Walgreens fills under the 340B program represent less than one percent of the prescriptions we fill every year for all patients across the country, those prescriptions are immaterial to our financial disclosures and, as such, we do not report that information separately. In addition, Walgreens, as a publicly traded company, does not report the financial results of individual products or service lines among our business units or pharmacy locations as that information is proprietary, confidential, and competitively sensitive. Regarding the financial arrangement with each 340B entity, we may further be bound by contractual limitations that require us to protect the confidentiality of the arrangements.

6. **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.**

   Walgreens charges covered entities fair market value fees for the services provided. The fee structure includes a flat dollar amount for pharmacy services and a percentage-based fee for administrative services. The fee amounts may vary based on the type of pharmacy services provided, i.e., retail, mail-order, or central specialty pharmacy. The fee amounts also are negotiated and therefore may vary across covered entities.

7. **Please provide a list of all covered entities that contract with 340B Complete to provide 340B pharmacy services.**

   The list of covered entities with which Walgreens contracts can be found in the following file

8. **For each covered entity that your company contracts with, please provide your company's annual gross and net revenues generated from the 340B Program.**

   Through our annual reports and SEC filings (http://investor.walgreens.com) Walgreens provides substantial financial information related to our operations and services, inclusive of 340B services, to the public and to investors. However, as the prescriptions that Walgreens fills under the 340B program represent less than one percent of the prescriptions we fill every year for all patients across the country, those prescriptions are immaterial to our financial disclosures and, as such, we do not report that information separately. In addition, Walgreens, as a

publicly traded company, does not report the financial results of individual products or service lines among our business units or pharmacy locations as that information is proprietary, confidential, and competitively sensitive. Regarding the financial arrangement with each 340B entity, we may further be bound by contractual limitations that require us to protect the confidentiality of the arrangements.

9. **Please produce unredacted copies of all TPA and contract pharmacy agreements between 340B Complete and covered entities.**

   Walgreens is restricted by contract from disclosing the 340B agreements with our covered entity clients and the confidential information therein.

10. **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.**

    Walgreens is restricted by contract from disclosing the 340B agreements with our covered entity clients and the confidential information therein.

11. **Please provide the number of contract pharmacy arrangements between 340B Complete-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)?**

    The list of covered entities with which Walgreens contracts can be found in the file at question 7.

12. **Please provide the number of 340B Complete-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.**

    Any Walgreens pharmacy, including our traditional retail, mail-order, local specialty or central specialty pharmacies, may serve as a 340B contract pharmacy. Each covered entity selects the right mix of pharmacies and pharmacy types that best meet their patients' needs and those pharmacies are included in that covered entity's 340B contract. Below are the number of active contracts in 340B Complete by each Walgreens pharmacy type.

    - 7,686 retail pharmacies have contract arrangements with 2,112 covered entities.
    - 2 mail order pharmacies have contract arrangements with 298 covered entities.
    - 261 local specialty pharmacies have contract arrangements with 1,005 covered entities.
    - 4 central specialty pharmacies have contract arrangements with 940 covered entities.

- 10 Micro-fulfillment centers that do not dispense to patients, and are used only for inventory replenishment

Conclusion

Thank you for the opportunity to comment on these critical matters as the 340B Program, including the existing partnerships between covered entities and community pharmacies, remain a lifeline for many Americans and creates the opportunity to touch lives and mitigate healthcare disparities. We look forward to working with you on improvements to the 340B Drug Discount Program. If we can be of any further assistance, please reach us at [redacted] or via email at [redacted].

Sincerely,

[redacted]

United States Senate

COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS

WASHINGTON, DC 20510–6300

November 21, 2024

VIA ELECTRONIC TRANSMISSION

Tim Wentworth
Chief Executive Officer
Walgreens Boots Alliance, Inc.
108 Wilmot Rd.
Deerfield, IL 60015

Mr. Wentworth:

On January 17, 2024, I sent you a letter as part of my investigation into the 340B Drug Pricing Program (340B Program).[1] This multi-year investigation into covered entities, including hospitals and community health centers, contract pharmacies, and pharmaceutical manufacturers is necessary to ensure proper oversight of the program and that all participants prioritize patients over profits.

The Senate Committee on Health, Education, Labor, and Pensions has primary jurisdiction over the Health Resources and Services Administration, the agency charged with administering and overseeing the 340B Program. As Ranking Member of this Committee, it is necessary that I have a full understanding of Walgreens's participation in the 340B Program, including covered entities' use of Walgreens 340B Complete, a third-party administrator (TPA) program that offers inventory management, audit and operational support, as well as increased 340B Program savings.

Since sending you the letter in January, my staff has engaged with your outside counsel for almost a year to remedy my production-related concerns. Despite these repeated attempts, the Committee has yet to receive a satisfactory production from your company. Specifically, Walgreens has failed to respond to question 2, subparts (d), (e), and (f), which seek information and records pertaining to the revenue your company generates from the 340B Program and your company's contractual relationships with covered entities. When you and I discussed these production-related concerns in May, you told me that Walgreens is willing to produce these records in full, and unredacted, if compelled to do so by a duly authorized subpoena.

Walgreens's unwillingness to provide the documents voluntarily is consistent with an industry-wide pattern of fighting to prevent transparency into the administration of the 340B Program. I therefore expect Walgreens to produce all documents, data, and information requested in question

[1] Letter from Sen. Bill Cassidy, Ranking Member, S. Comm. on Health, Educ., Lab., & Pensions, to Tim Wentworth, Chief Exec. Officer, Walgreens Boots Alliance, Inc. (Jan. 17, 2024), https://www.help.senate.gov/imo/media/doc/340b_walgreens_letter.pdf.

2 and its subparts by **December 20, 2024**. If Walgreens continues to fail to produce the requested documents by the above deadline, I will consider additional tools to force compliance and to obtain this critical information.

Thank you for your prompt attention to this important matter.

Sincerely,

Bill Cassidy, M.D.

Bill Cassidy, M.D.
Ranking Member
U.S. Senate Committee on Health,
Education, Labor, and Pensions

Walgreens Boots Alliance

January 16, 2025

The Honorable Bill Cassidy, M.D.
United States Senate
455 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Senator Cassidy:

I want to start by sending my sincere condolences to you and the great people of New Orleans affected by the senseless violence on New Year's Day. Thank you for your letter dated November 21, 2024. We welcome your ongoing collaboration on efforts to ensure patients are benefiting from the 340B Drug Discount Program.

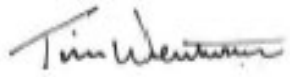
In our previous discussion, we presented information around fee structures, methodologies, and service descriptions as part of our contractual framework with covered entities. To provide additional transparency, attached to this response is a copy of our standard contract pharmacy agreement with covered entities, which describes the terms and conditions of how we operate within the 340B program.

However, we were able to receive permission from three of our covered entity partners—Yakima Valley Farm Workers Clinic, Sun River Health, and Cleveland Clinic—to share with you unredacted copies of our contracts, provided that we request that these contracts remain confidential. The contracts are attached for your reference. Given the sensitive business and competitive information therein, we respectfully request that these contracts remain confidential and that you do not publish or further disclose them to third parties. If there is an intent to publish one or more of the agreements in their entirety, or any proprietary information regarding pricing, fees, ownership, and drug distribution, we ask that your team provides us reasonable notice and the opportunity for Walgreens, Yakima Valley Farm Workers Clinic, Sun River Health, and Cleveland Clinic to work with you to limit such disclosures consistent with applicable law and Senate rules. Walgreen Co. and its clients are being cooperative with this exercise, so we ask that you please provide the parties with the opportunity to preserve the confidential nature of business terms between the cooperating parties.

Your letter also requests information pertaining to the revenue generated by the 340B program. Through our annual reports and SEC filings (http://investor.walgreens.com), Walgreens provides substantial financial information related to our operations and services, inclusive of 340B services, to the public and to investors. However, as the prescriptions that Walgreens fills under the 340B program represent less than one percent of the prescriptions we fill every year for all patients across the country, those prescriptions are immaterial to our financial disclosures and, as such, we do not report that information separately. In addition, Walgreens, as a publicly traded company, does not report the financial results of individual products or service lines among our business units or pharmacy locations as that information is proprietary, confidential, and competitively sensitive.

We look forward to continuing a constructive dialogue and hope this information is helpful in providing more information about our participation in the 340B program and the lengths to which we go to ensure we remain focused on serving the needs of patients and covered entities.

Sincerely,



Timothy C. Wentworth
Chief Executive Officer

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Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.
[redacted]
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October 31, 2024

Submitted via email

The Honorable Bill Cassidy, M.D.
Ranking Member
U.S. Senate Committee on Health, Education, Labor, and Pensions
455 Dirksen Senate Office Building
Washington, DC 20510

Re: Response to September 23, 2024 Letter

Dear Ranking Member Cassidy,

On behalf of Eli Lilly and Company ("Lilly"), I write in response to your letter dated September 23, 2024 regarding Lilly's experience with the federal 340B Program and its limited distribution policy. Before enactment of the 340B program, manufacturers voluntarily sold medicines at lower prices to certain safety-net providers, but due to the enactment of the Medicaid Drug Rebate Program manufacturers would be penalized for continuing this practice. To remedy this unintended consequence, Congress enacted the 340B program.[1] With this in mind, we share your view that this program was initially designed to enable genuine safety-net providers to access medicines at lower prices so that those entities, relieved of acquiring medicines at list prices, could direct more of their funds to broader patient care and provide discounted medicines to vulnerable patients. Unfortunately, the program has morphed over time—becoming a major arbitrage program where highly profitable "non-profit" hospitals and many for-profit intermediaries buy medicine at low prices and charge patients, government programs, and insurers full or marked up prices. This has created a range of bad incentives and unintended consequences, including provider consolidation,[2] shifting care to higher cost sites of care and higher cost medicines,[3] diverting care from low-income areas to focus services with more lucrative profits in wealthier areas,[4] decreasing federal revenues, and increasing federal healthcare program costs.[5]

Moreover, the agency charged with policing this program, the Health Resources and Services Administration (HRSA), appears to be beholden to the very entities it is charged with regulating. Lilly has catalogued its concerns for the agency in a comment letter and invited them to reconsider their approach. *See* Attachment A. Recent threats to remove Johnson & Johnson from all federal healthcare programs for attempting to lawfully (in our view) implement a more transparent and reasonable

[1] *See* Nicholas C. Fisher, *The 340B Program: A Federal Program in Desperate Need of Revision After Two-and-a-Half Decades of Uncertainty*, 22 J. Health Care L. & Pol'y 25, 30 (2019).
[2] *See* Sunita Desai & J. Michael McWilliams, *Consequences of the 340B Drug Pricing Program*, NEJM (Jan. 24, 2018).
[3] *See* Anthony M. DiGiorgio & Wayne Winegarden, *Reforming 340B to Serve the Interests of Patients, Not Institutions*, JAMA (July 26, 2024).
[4] Katie Thomas & Jessica Silver-Greenberg, *Profits Over Patients: How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits*, N.Y. Times (Sept. 24, 2022),
[5] *See* AIR 340B, *340B Impact on the Federal Budget*, (Oct. 2024) (explaining the incentives for patient expansion, vertical integration, and preference for higher list price products produced by the 340B program and their financial impact on the federal government) *available at* https://340breform.org/wp-content/uploads/2024/10/AIR340B-CBO-Memo.pdf.

rebate option—a model Congress expressly contemplated in the 340B statute—demonstrates just how anti-manufacturer this agency has become.[6]

It is against this backdrop that Lilly has been participating in the 340B program and worked to refine distribution via so-called "contract pharmacies."

Why Lilly Implemented a Limited Distribution Program for Contract Pharmacies

The statutory prohibitions against diversion and duplicate discounts are absolute – there are no exceptions and any instance of diversion or duplicate discounting violates the law. 42 U.S.C. § 256b(a)(5). Yet, for more than a decade, both HRSA and the Department of Health and Human Services Office of Inspector General (HHS OIG) have recognized significant and numerous ongoing violations of the prohibitions against diversion and duplicate rebates. Compelling evidence—including in government reports and congressional oversight hearings—demonstrate that these violations occur predominantly at contract pharmacies. The covered entities and HRSA appear fine with that; we are not. Congress should not be either, especially because the concept of contract pharmacies appears nowhere in the law Congress passed when establishing the 340B program.

- 2011 GAO Report: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement: GAO concluded that ***"[o]perating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies."*** GAO further noted the "[i]ncreased use of the 340B program by contract pharmacies and hospitals may result in a greater risk of drug diversion, further heightening concerns about HRSA's reliance on participants' self-policing to oversee the program."[7]

- 2014 HHS OIG Report: Contract Pharmacy Arrangements in the 340B Program: In 2014, HHS OIG reported that ***contract pharmacies create "complications" in preventing diversion because "some covered entities that do dispense 340B-purchased drugs to Medicaid beneficiaries through their contract pharmacies did not report a method to avoid duplicate discounts."*** [8] HHS OIG also concluded, quite troublingly, that findings of noncompliance did not lead to HRSA terminating the covered entities' permission to use multiple pharmacy arrangements.[9]

- 2018 HHS OIG Testimony: Examining Oversight Reports on the 340B Drug Pricing Program: In its testimony, OIG stated that it "has identified ***a number of challenges and inconsistencies arising from the widespread use of contract pharmacy arrangements."*** [10] OIG further stated that "many ***contract pharmacies dispense drugs to all of their customers—340B-eligible or otherwise—from their regular inventory.***"

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[6] *See* HRSA letter to Johnson & Johnson (Sept. 27, 2024), *available at* https://www.hrsa.gov/sites/default/files/hrsa/opa/sept-27-24-hrsa-letter-johnson-johnson.pdf

[7] GAO, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836, (Sept. 23, 2011), *available at* https://www.gao.gov/products/GAO-11-836 (emphasis added).

[8] HHS OIG, *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, at 1-2, 16, OEI-05-13-00431, (Feb. 4, 2014) *available at* https://oig.hhs.gov/documents/evaluation/2914/OEI-05-13-00431-Complete%20Report.pdf. (emphasis added)

[9] *Id*. at 7, 9–15.

[10] OIG Testimony Before the U.S. Senate Committee on Health, Education, Labor, and Pensions (May 15, 2018), at 5.

- 2018 GAO Report: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement: In this report, GAO concluded that "***[t]he identified noncompliance at contract pharmacies raises questions about the effectiveness of covered entities' current oversight practices."***[11] For example, GAO found that approximately two-thirds (66 percent) of diversion findings in HRSA audits (from FY 2012 to FY 2017, based on results posted to HRSA's website as of February 2018), "involved drugs distributed at contract pharmacies."[12] Despite this significant conclusion, GAO further noted that "the number of contract pharmacy oversight findings may be limited by the fact that officials from HRSA's contractor said that its auditors rely on verbal responses from entity officials about any internal review or self-audits conducted by the entity."[13]

- 2018 House Energy and Commerce Committee Report: Review of the 340B Drug Pricing Program: In 2018, the House Energy and Commerce Committee issued a report echoing the findings of HHS OIG, concluding that contract pharmacy arrangements lead to diversion of 340B drugs. The committee's review of HRSA's audit files revealed that many covered entities have engaged in diversion. Further, in one quarter of the audit files reviewed by committee staff, HRSA recommended that the covered entity improve its oversight of their contract pharmacy arrangement to prevent diversion of 340B drugs at the contract pharmacy.[14] The Committee emphasized its concerns by recommending that "[a]ll covered entities should perform independent audits of their contract pharmacies at regular intervals to ensure 340B program compliance."[15] ***The Committee endorsed auditing by manufacturers to stem unlawful diversions***, underscoring how HRSA's limiting the actions that a manufacturer may take to police compliance undermines the program's integrity.

Publicly available audit statistics published by HRSA support these concerns. Notably:

Fiscal Year	Entity Audits	Entities with Contract Pharmacy Adverse Findings (All)	Entities with Contract Pharmacy Adverse Findings (Diversion)
2013	94	31	19
2014	104	45	34
2015	200	92	71
2016	200	77	61
2017	199	81	69
2018	200	64	42
2019	187	52	33

The data collection ends in 2019 because, despite the findings of widespread contract pharmacy noncompliance, HRSA informed GAO in July 2020 that it would no longer issue adverse findings related to contract pharmacy use.[16] And HRSA has rejected GAO's recommendation that HRSA

[11] GAO, *Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, at 44 (June 2018), GAO-18-480, *available at* https://www.gao.gov/assets/700/692697.pdf. (emphasis added)

[12] *Id.* at 44 & n. 64.

[13] *Id.* at 44.

[14] *See* H. Comm. on Energy & Commerce, at 39.

[15] *Id*. at 76.

[16] GAO, *HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements*, at Intro (December 2020), GAO-21-107, *available at* https://www.gao.gov/assets/gao-21-107.pdf.

"provide more specific guidance to covered entities regarding contract pharmacy oversight, including the scope and frequency of such oversight."[17]

Finally, Lilly's own data demonstrate that contract pharmacies are a frequent source of statutory violations.

- 2018-2024 Analysis of Covered Entity and Contract Pharmacy Self-Disclosures: Since 2018, ***Lilly has received 391 self-disclosures involving either duplicate discounts and diversion, the vast majority of which involve contract pharmacies***.

- 2019 Contract Pharmacy Managed Medicaid Duplicate Discount Review: In 2019, Lilly engaged Kalderos, a third-party, to review Managed Medicaid rebate requests from five states (CA, LA, FL, TX and NJ) to identify instances of duplicate 340B discounts for selected covered entities from 2014 to 2018. ***Kalderos identified approximately $12.4M worth of duplicate discounts related to contract pharmacy utilization in connection with just this small sample***.

In addition to these statutory violations, the number of contract pharmacies increased exponentially, growing more than 4000% between 2010 and 2020.[18] The result was that a program Congress intended to be a small cost-savings program is now the second-largest federal drug program, behind only Medicare Part D, and could very soon become the largest.[19] And as described above, HRSA's reaction to this incredible growth was to provide less, not more, oversight, effectively leaving manufacturers to their own devices to ensure compliance.

Lilly's decision to limit distribution through contract pharmacies was also a natural response to disincentives created by the Affordable Care Act (ACA). Specifically, the ACA amended the 340B statute by imposing penalties on manufacturers of up to $5,000 for "each instance" of a 340B overcharge; covered entities face no civil money penalty liability, despite their troubling record of noncompliance.

The rational reaction to a "per instance" risk of liability is to limit the number of "instances" to only those that are absolutely required by the law. Hence, to mitigate the potential liability for CMPs, Lilly logically stopped honoring non-mandatory 340B pricing requests from non-covered entity locations (e.g., contract pharmacies).

Finally, the ACA also requires manufacturers to issue repayment to covered entities upon the routine restatement of certain Medicaid prices (which serve as the basis for the 340B price). Congress tasked HRSA with the obligation to develop a "mechanism" for providing refunds or credits. 42 U.S.C. § 256b(d)(1)(B)(iv)(II). HRSA has never done this, instead it issued a mandate (not a mechanism), which renders this process higher risk for manufacturers. Again, as a logical response to the regulator's decision to shirk its duties under the statute to facilitate repayment, Lilly opted for an approach that limited the number of repayment transactions (and thus the source for potential

[17] *Id.* at 25.
[18] PhRMA, *340B Contract Pharmacy 101* (Sept. 2020) *available at* https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/0-9/340B-Contract-Pharmacy-101-Deck_Sept-2020.pdf
[19] *See* Alliance for Integrity and Reform of 340B, *The Impact of Growth in 340B Contract Pharmacy Arrangements—Six Years Later*, at 8 (Oct. 2020) *available at* https://340breform.org/wp-content/uploads/2021/04/AIR340B_340B-Contract-Pharmacies.pdf.

repayment errors) by limiting its engagement in the 340B program to include only those transactions that were absolutely required.

Lilly's Track Record of Transparency with Regulators and the Regulators' Inaction[20]

Lilly communicated frequently with U.S. Department of Health and Human Services (HHS) and HRSA before implementing the contract pharmacy limited distribution policy. In May 2020, Lilly presented all the evidence of statutory violations to HRSA and stated:

> We believe [instituting a limited distribution program for Cialis contract pharmacies] is prudent, reasonable and lawful, particularly in light of the substantial and ongoing expansion of contract pharmacy participation in the 340B program and the now overwhelming evidence demonstrating that contract pharmacy transactions result in 340B duplicate discounts and diversion. Based on these concerns, coupled with the risk that contract pharmacy transactions may be considered a basis a Civil Money Penalties or subject to onerous repayment obligations, Lilly feels compelled to take this action at this time.[21]

In June 2020, HRSA refused to address Lilly's concern or the overwhelming evidence of statutory violations. HRSA then "strongly urge[d] Lilly to reconsider its position." Notably, HRSA did not assert that the 340B statute requires manufacturers to honor an unlimited number of contract pharmacy relationships.

Because HRSA did not acknowledge Lilly's well-documented and legitimate concerns, let alone try to address them, and because these problems affect all products, Lilly expanded its program from Cialis-only to all products. It communicated this change to its limited distribution policy to HRSA in advance by letter dated August 19, 2020.

Simultaneously, Lilly was engaged and fully transparent with leadership with HHS on this topic as well. Those efforts ultimately culminated in the issuance of an Advisory Opinion from HHS (in December 2020) and an enforcement letter from HRSA directed at Lilly (in March 2021).

As is common when regulated parties disagree with the legal conclusions of the agencies that regulate them, Lilly and other manufacturers sought redress in the courts. While Lilly's case is still pending before the U.S. Court of Appeals for the Seventh Circuit, two other federal appellate courts have rejected HRSA's position that "section 340B prohibits drug manufacturers from imposing any conditions on the distribution of discounted drugs to covered entities."[22]

Why Lilly Revised Its Contract Pharmacy Program

On December 10, 2021, Lilly announced that it would accommodate unlimited contract pharmacy arrangements provided that covered submit readily available claim level detail, that they already

[20] Copies of these communications are included as Attachment B in response to Question 3.
[21] Cialis (tadalafil) is an erectile dysfunction medicine that is not covered by Medicaid or Medicare, but which had been subject to high volume and suspicious purchasing patterns by 340B covered entities, which raised particular concerns above diversion and fraud.
[22] *Novartis Pharms. Corp. v. Johnson*, 102 F. 4th 452, 459 (D.C. Cir. 2024); *see also Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Human Servs.*, 58 F.4th 696 (3d Cir. 2023).

submit to their other vendors, and are required to satisfy audit needs. We reverted back to a more limited approach (still consistent with HRSA's 1996 Contract Pharmacy Guidance) in November 2023 and slightly revised this approach again in July 2024. These changes in policy were precipitated by the learnings that demonstrated the magnitude of noncompliance and game playing we observed when permitting more contract pharmacy participation. These learnings included:

- Visibility into the Magnitude of Duplicate Discounts: For the periods during which Lilly permitted unlimited contract pharmacies, Lilly identified thousands of duplicate Medicaid and 340B claims. We are unable to determine whether it was the state Medicaid program or the covered entity who was at fault for this, but the overall pattern was alarming and the inability to address these clear statutory violations is disturbing and unlawful.

- Covered Entity Responses to Good Faith Inquiries: Lilly thought, perhaps naively, that if there was specific evidence of duplicate discounts, covered entities would respond to good faith inquiries and work collaboratively to address the root cause of these problems. Our experience was the exact opposite. Good faith inquiries were frequently ignored and not a single covered entity repaid Lilly or indicated a desire to understand and correct the processes that might have given rise to Medicaid duplicates. One covered entity, through outside legal counsel, alleged Lilly was violating state criminal law by even making the good faith inquiry.

- Covered Entity Gaming: During the period during which Lilly offered unlimited contract pharmacy networks we observed a number of troubling "gaming" efforts to circumvent the reasonable manufacturer requirements. First, we saw a number of covered entities designate so-called "central fill pharmacies" as their contract pharmacy. Under this scheme, hospital systems have all their medications delivered to one location, claiming this to be an in-house purchase, and then distribute these medications to any number of their entity pharmacies or contract pharmacy partners. This rerouting is hidden from manufacturers. Second, we saw widespread manipulation of how covered entities are designated on the HRSA Covered Entity Database. This database is critical because it is the source of truth for wholesalers, manufacturers, regulators, and covered entities regarding entity eligibility and locations. We observed covered entities simply recharacterizing contract pharmacies as entity-owned "shipping locations"—a clear fraud. Finally, we also encountered numerous instances of two different covered entities claiming the same prescription as their own 340B-eligible patient. This is due to the expansive definition of "patient" employed by some covered entities, including those that take that position that an individual is a patient for purposes of 340B if they ever received treatment from the entity, even if it took place years prior and is unconnected to the prescription at hand.

- Wholesaler Gaming: Lilly also learned that wholesalers were involved in the proliferation of contract pharmacies. For example, Lilly discovered that wholesalers were assisting covered entities in establishing so-called "alternative distribution models" to skirt manufacturer programs whereby 340B priced product is shown as delivered to an in-house pharmacy, but then re-routed with the wholesaler's assistance to a contract pharmacy that was otherwise excluded from the manufacturer's program. We also became aware of wholesalers offering so-called "virtual replenishment" services to contract pharmacies as well. For example, Cencora advertises an "Inventory Synchronization Program" whereby when a 340B dispense is identified, a contract pharmacy is rewarded with a credit in their account with Cencora for the 340B value, as opposed to Cencora shipping 340B priced product to the contract

pharmacy.[23] This substitute for the product replenishment model makes it much more difficult for manufacturers to track what product is sold at 340B and where it was dispensed, allowing covered entities and contract pharmacies to team up with the wholesaler to avoid manufacturer policies. This program also shows that the true motive for 340B access at contract pharmacies is not expanded patient access as is often claimed, but instead is simply to make profit for every entity in the chain. Recent court filings indicate some version of this credit-based virtual replenishment have been in place as early as 2015, unbeknownst to manufacturers.[24]

To summarize, the use of 340B contract pharmacies exploded after 2010, instances of duplicate discounts and diversion skyrocketed, and HRSA, HHS OIG, and Congress have compiled overwhelming evidence of this ongoing fraud and program abuse. Despite these trends, HRSA—the agency charged with ensuring program integrity—has declined to implement improvements proposed by various government watchdogs. Instead, HRSA enabled unlimited contract pharmacy expansion, disregarded blatant contract pharmacy abuses, erected barriers to manufacturer audit and oversights, lowered covered entity compliance standards, and challenged manufacturer attempts to impose reasonable transparency standards.

Responses to Specific Questions

Please find below responses to your specific questions.

1. **For each year beginning in 2018, please produce an Excel document with a detailed accounting of Eli Lilly's participation in the 340B Program, including the following information per calendar year:**

    a. **A list of full packages, identified by National Drug Code (NDC), of drugs sold to covered entities at the 340B ceiling or sub-ceiling price;**
    b. **The price of each of the packages identified in question (1)(a) at the wholesale acquisition cost (WAC);**
    c. **The amount of the 340B price concessions given to covered entities for each of the drug sales identified in question (1)(a);**
    d. **The 340B price paid as a percentage of WAC for each of the drug sales identified; and**
    e. **A denotation of whether each drug was distributed to covered entities and their child sites, wholly-owned pharmacies, or contract pharmacies for each drug sale identified.**

See EXCEL file titled "Cassidy Response Question 1."

2. **For each calendar year beginning in 2018, please produce the above information separately for all 340B drugs sold to the following covered entities: Cleveland Clinic, Bon Secours Mercy Health, Sun River Valley, and Yakima Valley Farm Workers Clinic.**

See EXCEL file titled "Cassidy Response Question 2."

[23] AmerisourceBergen (now Cencora), *Inventory Synchronization Program Guide*, *available at* https://web.archive.org/web/20240426164057/https://www.amerisourcebergen.com/-/media/assets/amerisourcebergen/pdf/hgs-230633-isp-guide-12dec23-v2.pdf.
[24] *See e.g., Fruth, Inc. v. Cardinal Hlth., Inc.*, No. 3:23-cv-801, 2024 WL 3236314 (S.D.W.V. June 28, 2024).

3. **Please provide all internal communications and documents related to Eli Lilly's decision to impose restrictions on distribution of 340B drugs to contract pharmacies and how these policies were created and implemented.**

See PDF file titled "Attachment B – Communications Regarding Contract Pharmcy Policy."

   a. **Please provide numerical data, on a month-by-month basis, on how this policy has affected the volume of your 340B sales since the date of implementation.**
   b. **Please provide numerical data and specific examples of how this policy has resulted in fewer duplicate discounts or diversion of 340B drugs to ineligible patients.**

See EXCEL file titled "Cassidy Response Question 1" for data on Question 3a. Because of the limited insight Lilly has into covered entity purchases, it is impossible for us to quantify the impact of our contract pharmacy policy on the number of duplicate discounts or instances of diversion.

4. **Currently, the vast majority of covered entities purchase 340B drugs through the virtual inventory/replenishment model. Please explain any difficulties this model has for Eli Lilly and if there is a different model that would be more efficient for the sale and distribution of 340B drugs.**

The virtual inventory/product replenishment model is opaque and complex in ways that undermine efforts to drive program integrity. It is the alternative to a straightforward and simplistic "segregated inventory" approach. This approach to administering the 340B program was never announced in any official program rules or guidance documents and stakeholders were never given a chance to weigh in with concerns as to what problems this approach could cause.

Before describing some of the concerns with the virtual inventory/replenishment model it is worth explaining, briefly, what it is. Under the virtual inventory/replenishment approach, a covered entity or a contract pharmacy will dispense a drug not acquired at the 340B price to an individual. Later, that dispense will be characterized as 340B eligible (because it was purportedly dispensed to an eligible patient of a covered entity) or not 340B eligible (reasons for ineligibility could be that the drug was dispensed in an inpatient setting or as a drug reimbursed under a bundled payment methodology, or the individual obtaining the drug might not be an eligible 340B "patient").

The covered entity or contract pharmacy will keep track of the number of these 340B dispenses and when the entity or contract pharmacy has "accumulated" enough units to restock the initial non-340B package it will place a "replenishment" order for a package at the 340B price.

This 340B priced package then goes into "general inventory" for later dispensing, maybe to a 340B eligible patient or maybe not. Neither manufacturers nor HRSA, or the covered entities themselves, really knows.

There are several issues with this approach:

- <u>Replenishment Severs the Link Between the 340B Medicine and the 340B Patient</u>: Because replenishment is simply a way for a covered entity to "pay itself back" for fronting non-340B priced medicine to 340B patients, the link between the 340B medicine and the 340B patient is severed from the beginning. When the entity later "pays itself back" with 340B-priced medicine, it must be dispensing 340B medicine to non-340B patients. This is an unlawful

diversion to a non-patient. Severing the link between the 340B-priced medicine and patient also makes identifying unlawful duplicate discounts extremely difficult.

- Replenishment Relies on Unreliable Software and a Black Box Intermediaries: Replenishment relies on something called an "accumulator" which is a machine or computer program that counts doses. These accumulators are "set up" in various hospital IT systems and there are literally now dozens of vendors that offer these programs and/or consultant services. Lilly has received numerous self-disclosures—and HRSA has made numerous audit findings—indicating that the virtual replenishment programs or software either misclassified or misapplied certain transactions (or both). Moreover, manufacturers have simply no way of knowing or validating how the programming code works or how a given hospital defines what is eligible and what is not. It is completely opaque and unauditable.

- Replenishment Permits Later Recharacterization of Transactions: Covered entities and their "third party administrators" can go back and reclassify purchases using this software or "harvest claims." For example, if a covered entity decides it wants to change its definition of what constitutes an eligible patient, it could choose to do so retroactively and arbitrarily decide that it is owed more 340B-priced medicines by reclassifying prior non-340B prescriptions as 340B eligible. Again, this would not be disclosed to either manufacturers or HRSA.

- Replenishment Leads to Information Asymmetries, Which Breeds Conflict: Because manufacturers do not know or understand how these replenishment programs operate, and because manufacturers have no way to review the "nuts and bolts" of these systems (even in an audit), we have concerns that games are being played.

- Replenishment Requires Entities to Wait to Obtain 340B Prices Until a Full Package Is Dispensed: Manufacturers are not the only entities being harmed by the virtual replenishment model. Covered entities, especially smaller covered entities, are harmed by the need to wait until an entire reorderable package is dispensed before claiming their "replenished" 340B priced order. Moreover, if the product is slow moving or rarely dispensed, that replacement product may sit on the pharmacy or entity shelf until it expires, meaning the covered entity never actually realizes the value of the 340B price concession.

- The Replenishment Model Is Incompatible with the IRA: The replenishment model, combined with the changes made in the Inflation Reduction Act (IRA), will cause the number of unlawful duplicates to dramatically increase. Specifically, the IRA added the Medicare Inflation Rebates program and the Maximum Fair Price (MFP) program, both of which prohibit duplicates with 340B prices. The specific issues are:

    - 340B and MFP Pricing: There is no legally binding mechanism for de-duplicating 340B and MFP claims. CMS announced that it "will not … assume responsibility for nonduplication of discounts between the 340B ceiling price and MFP" and that, at most, it will pass along information about potential 340B duplicates, but only "[t]o the extent dispensing entities *choose to voluntarily and proactively* indicate on a submitted claim that the claim is 340B-eligible."[25] HRSA has not

[25] CMS, "Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027" (Oct. 2, 2024) at 231.

issued any guidance to covered entities on this topic, let alone issued any legally binding requirements. And our experience is that covered entities will not proactively provide such data. Practically, then, this regulatory vacuum leaves the responsibility for avoiding duplicates entirely to manufacturers.

Also, because manufacturers cannot audit for duplicate MFP-340B discounts under either the 340B statute or the IRA, there is simply no way to honor the 340B price "upfront" in time period "one" only to reverse it or claw it back in time period "two," when—or if—the duplicate is identified. There is also no mechanism for manufacturers to compel repayment or refunds from covered entities for causing unlawful duplicates in the first place.

- 340B and Medicare Inflation Rebates: There is similarly no legally binding mechanism for de-duplicating 340B claims and claims for so-called "inflation rebates" for Medicare Part B and Part D utilization. With respect to inflation rebates, CMS has, again, effectively disclaimed oversight for ensuring that the statutory prohibition on 340B-inflation rebate duplicates is applied and enforced.

  Rather than provide a mechanism for identifying duplicates, CMS proposes to estimate the percentage of Part D sales that are 340B using existing data, and then exclude that number of Part D dispenses from the rebate as presumed 340B duplicates.[26] Besides known flaws in the data including relying on an outside vendor's data that HRSA acknowledges is an incomplete reflection of all 340B sales, this reflects an abdication of regulatory responsibility from CMS like the approach taken with MFP deduplication. CMS also refused to provide any dispute resolution process and will only receive comments related to mathematical errors.[27]

  For Part B utilization, although CMS's guidance directs covered entities to use a 340B claims modifier for Part B claims, CMS failed to address commenters' concerns about the accuracy of such modifiers. CMS also rejected requests to create enforcement mechanisms, a claims clearinghouse, or an audit process, simply saying the agency "expects providers to submit accurate claims and utilize correct modifiers."[28]

  For Part B, CMS also rejected calls for a dispute resolution process to adjudicate claims of duplication between Part B inflation rebates and 340B.CMS instead provided that, if a manufacturer believes there was a "mathematical error," the issue can be submitted and "CMS may consider [it] at its discretion."[29] In this same guidance CMS also rejected commenters' request that the 340B modifiers be included in the Preliminary Rebate Reports provided to manufacturers.[30]

[26] 89 Fed. Reg. 61596, 61934-84 (July 31, 2024).
[27] *Id*. at 61979.
[28] CMS, "Medicare Part B Drug Inflation Rebates Paid by Manufacturers: Revised Guidance, Implementation of Section 1847A(i) of the Social Security Act" (Dec. 14, 2023) at 20.
[29] *Id*. at 25.
[30] *Id.* at 40.

> As such, manufacturers will have no insight into the data used to identify duplicate 340B and Part B or Part D inflation rebates out of the IRA and no recourse when duplicate discounts are paid. Accordingly, the only practical option that Lilly has identified to ensure that the appropriate MFP/340B amounts are paid and to avoid duplicate Part B and Part D inflation rebates is through a rebate operated as a cash replenishment option.

Lilly believes either a segregated inventory model or a rebate model would be more transparent and efficient. With respect to a rebate model, this is not actually a wholesale change. The replenishment model is a method of receiving 340B pricing in arrears—product acquired at market prices are later replaced with product acquired at 340B prices. Rebates replace product acquired at market prices with dollars.

Lilly suspects some form of a rebate model will eventually need to replace the virtual inventory/replenishment model. However, HRSA has asserted that its approval is required for such a rebate approach and has recently threatened at least one manufacturer with exclusion from all federal healthcare programs if that manufacturer choses to utilize 340B rebates.[31]

a. How does Eli Lilly identify which purchases are made through 340B under this model?

At present, there is no way to distinguish between replenishment model purchases and purchases made by entities that utilize segregated inventory management systems or other inventory management approaches.

b. How does the use of contract pharmacies versus the use of in-house pharmacies affect this model?

The use of contract pharmacies exponentially increases the noncompliance risk and associated distrust fostered by the virtual inventory/replenishment model because it expands the scale of the 340B program and permits even more liberal "claims harvesting."

5. Please describe Eli Lilly's policies and procedures for identifying duplicate discounts with Medicaid and diversion to ineligible patients.

See Response 8, below.

a. What has been the company's experience in resolving these issues with covered entities, state Medicaid agencies, and/or HRSA?

See Response 8, below.

[31] *See* HRSA letter to Johnson & Johnson (Sept. 27, 2024), *available at* https://www.hrsa.gov/sites/default/files/hrsa/opa/sept-27-24-hrsa-letter-johnson-johnson.pdf.

b. Please provide the financial impact of the identified duplicate discounts and diversions in your response.

As a threshold matter, measuring diversion is nearly impossible because the term "patient" has never been authoritatively defined and manufacturers have no visibility into how any covered entity elects to apply this term.

With respect to Medicaid duplicate discounts, Lilly does have some limited insights. As we noted above:

- 2018-2024 Analysis of Covered Entity and Contract Pharmacy Self-Disclosures: Since 2018, ***Lilly has received 391 self-disclosures involving either duplicate discounts and diversion, the vast majority of which involve contract pharmacies***.

- 2019 Contract Pharmacy Managed Medicaid Duplicate Discount Review: In 2019, Lilly engaged Kalderos, a third-party, to review Managed Medicaid rebate requests from five states (CA, LA, FL, TX and NJ) to identify instances of duplicate 340B discounts for selected covered entities from 2014 to 2018. ***Kalderos identified approximately $12.4M worth of duplicate discounts related to contract pharmacy utilization in connection with just this small sample***.

Since Lilly started collecting claims-level detail on just a portion of covered entities' 340B purchases, we were able to identify with greater precision the frequency of these statutory violations in the context of contract pharmacy arrangements. For the five quarters of data we have the number of duplicate claims grew from 869 claims/10,243 units (Q4 2021), 1,985 claims/21,019 units (Q1 2022), 4,169 claims/42,547 units (Q2 2022), 5,673 claims/55,050 units (Q3 2022), and 9,450 claims/96,438 units (Q4 2022). These total of 22,146 instances of duplicate claims, on just a portion of Lilly's 340B sales during a little more than a year, show that duplicate discounts are a massive problem, and **were worth more than $10 million to Lilly,** solely on contract pharmacies, during this limited time period alone. The prohibition in the 340B statute is absolute, and there is no room in the program for any duplicate discount violations whatsoever.

6. How does your company intend to monitor that 340B pricing is not duplicated with the Inflation Reduction Act's introduction of the Maximum Fair Price and inflation rebate penalties?

Lilly has frequently urged CMS and HRSA to work together to undertake a holistic review of all the statutory prohibitions against duplicate discounts on 340B units. As discussed above, these non-duplication requirements extend to units subject to the Part B inflation rebate, Part D inflation rebate, Medicaid rebates (fee-for-service and managed care), and the MFP.

Moreover, to give CMS's guidance or requirements "teeth," Lilly has also urged CMS to establish a robust audit process for 340B covered entities to confirm the appropriate identification of 340B eligible units and to establish a clearinghouse-type organization to identify 340B units administered to Medicare enrollees. The 340B clearinghouse would act as a claims verifier, reviewing data submitted by 340B covered entities (or entities acting on their behalf) to determine the likelihood that a claim is subject to a 340B agreement, similar to the role played by 340B third-party administrators (TPAs) and split-billing vendors today.[32] Units marked as 340B eligible on either the claim or by the 340B clearinghouse would be excluded from calculation of the Part D inflation rebate.

[32] 340B TPAs and split-billing vendors assist 340B CEs in managing prescriptions. These entities track electronic data feeds (such as inpatient or outpatient status, prescriber eligibility, clinic location, Medicaid

Finally, Lilly supports recent positions expressed by the trade associations PhRMA and BIO, calling on HRSA to endorse, or at least not impede, the implementation of a 340B rebate-style program.[33] As PhRMA noted, manufacturers face "substantial new risks" of duplicate discounts with the introduction of the IRA and HRSA's opposition to a rebate model "fails to appreciate that a 340B rebate could be the only way to implement the [MFP] nonduplication requirement, a critical aspect of the IRA."

7. **How has HRSA's 2010 guidance allowing for an unlimited number of contract pharmacies affected how Eli Lilly conducts compliance audits on covered entities to monitor the occurrence of duplicate discounts and diversion under the 340B Program?**

The 2010 Contract Pharmacy Guidance caused the number of 340B claims to expand exponentially and opened the floodgates to the widespread 340B noncompliance highlighted in the government studies and OIG reports referenced in our letter. More importantly, it changed the entire mindset around 340B. Inviting for-profit entities into the 340B ecosystem created a large and growing industry in developing legal loopholes and exploiting them for profit. HRSA has turned a blind eye to this conduct and has, indeed, enabled it—seeking to enforce against manufacturers who do not simply permit any 340B contract pharmacy transaction to proceed.

Grave concerns that the 2010 Guidance had caused the number of statutory violations to skyrocket led Lilly to audit covered entities. But Lilly quickly learned that manufacturers' ability to use the statutory audit process to check contract pharmacy abuses is entirely illusory. Although enshrined in statute, audit rights are limited by HRSA. The agency requires that manufacturers obtain prior approval, demonstrate "reasonable cause" (i.e., virtually provide proof of noncompliance before the audit has been allowed), and—in the context of contract pharmacies—HRSA has gone so far as to reject Lilly's request to audit these relationships. When HRSA finally did allow that aspect of the audit to proceed, they warned that covered entities would not provide any meaningful information (which was true). HRSA then refused to force the covered entities to comply with an audit of their contract pharmacy relationships, and also declined to assist Lilly by providing contract pharmacy agreements that Lilly needed. It did so even though HRSA possessed the contract pharmacy agreements, and the covered entity being audited did not object to HRSA's providing them. Contract pharmacy relationships are an intentionally unauditable black box.

To be clear, the 2010 Contract Pharmacy Guidance is just one factor that has led to exponential growth of the use of contract pharmacies in the 340B program. In addition to the replenishment model, the lack of a legally enforceable definition of "patient" has resulted in an environment where any transaction involving fulfillment of any prescription by any person who has ever interacted with any covered entity in any way can be defined as an eligible 340B dispense. Lilly appreciates that HRSA published non-binding guidance defining this critical statutory term in 1996, but covered entities—and the industry of vendors who profit from the 340B program—have drifted from that guidance and

payer status, drug identifier, and quantity dispensed) so 340B patient eligibility can be assessed and to virtually separate inventory dispensed to 340BCE patients from inventory dispensed to individuals who are not CE patients.

[33] PhRMA letter to HRSA, (Oct. 11, 2024) *available at* https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/P-R/PhRMA-Letter-to-HRSA-re-340B-Rebates---101024-FINAL28075.pdf; BIO letter to HRSA, (Oct. 10, 2024) *available at* https://www.bio.org/sites/default/files/2024-10/bio_letter_to_hrsa_on_340b_rebate_model.pdf.

now promote an even more elastic definition of "patient" and new methods for "referral capture" of 340B prescriptions. [34]

One emerging practice involves so-called patient "self-referrals," which Lilly learned about through unsolicited reporting from a concerned covered-entity pharmacist. A 340B-eligible-patient "self-referral" occurs when a patient, of his or her volition, seeks and receives services from a provider who is wholly unaffiliated with a covered entity and to whom the covered entity has made no referral. A contract pharmacy will dispense any resulting prescription, and a third-party administrator (or a different vendor) will identify the patient as having an affiliation with a covered entity so that the covered entity can claim 340B pricing for the prescription that resulted from that wholly separate interaction, even though the covered entity played no role in it. This is plainly fraudulent but goes completely unchecked by HRSA.

8. **Please explain the actions that Eli Lilly takes when instances of duplicate discounts and/or diversion are identified. What are the procedures and process by which covered entities remit payments to manufacturers in instances of duplicate discounts and/or diversion?**

Lilly has limited ability to identify duplicate discounts and diversion proactively for various reasons. In some instances, covered entities self-disclose noncompliance or disclose noncompliance and offer repayment pursuant to an audit conducted by HRSA. The process for those recoupments is provided at Attachment C. Where Lilly identifies the noncompliant purchases (as opposed to HRSA or the entity itself) repayment almost never occurs.

- *Diversion:* Absent self-disclosure, it is virtually impossible for Lilly to identify, and recover for, unlawful diversion. With over 25,000 registered covered entities and more than 600 participating manufacturers, the possible variety of "patient" definitions is expansive. And while many stakeholders may still defer to HRSA's 1996 non-binding guidance,[35] more and more covered entities and their consultants/vendors have moved away from that definition and are looking to generate 340B drug pricing profits from new and exotic practices such as "patient capture," "referral capture" and "claims harvesting."[36]

  Moreover, there is evidence that covered entities are seeking to expand their definitions. For example, a consultant for covered entities asked a lawyer advising covered entities, "we hear from clients that are looking to revisit their 'patient' definition in light of the *Genesis* case, I'm curious what are you seeing across clients." The lawyer responded, "we know that some covered entities have gotten more aggressive with their interpretation of the 'patient' definition …. I've heard that there are some very aggressive approaches that are being looked at … one approach to the statute would be to say everybody that we've ever treated at any

[34] *See, Genesis HealthCare v. Becerra*, No. 20-1701 (4th Cir. 2022). According to statements made by a government attorney to the 4th Circuit Court of Appeals referring to the 1996 "patient" definition guidance, "[t]his is non-binding guidance so I suppose Genesis does not have to follow it." Recording available at https://www.youtube.com/watch?v=4SaMlSDuJMc. Covered entities have since relaxed their own definitions of "patient" in recognition of the government's own lax views.
[35] 61 Fed. Reg. 55,156 (Oct. 24, 1996).
[36] *See, e.g.*, 340B Report, "Optimizing 340B Savings through Referral Capture" https://340breport.com/optimizing-340b-savings-through-referral-capture/; "Grow Your Referral Revenue" https://www.capturerx.com/capture-referrals/.

point is our patient and they're eligible for 340B drugs."[37] That is a limitless standard and will certainly result in multiple covered entities claiming the same individual as a "patient" for purposes of generating 340B profits.

Lilly has urged HRSA to resolve this issue through notice-and-comment rulemaking. Nevertheless, HRSA has abdicated its duty to issue a binding "patient" definition by claiming to lack statutory authority to do so. This conclusion is incorrect, and Lilly has submitted to HRSA it has statutory authority under at least four provisions of the law (i.e., to "certify" covered entities, to ensure meaningful audits, and to administer the ADR). However, HRSA may claim to lack the authority to define "patient" so that it can justify its repeated requests to Congress for general rulemaking authority; we sincerely hope that is not the agency's basis for declining to issue regulations for this critical statutory term.

- *Duplicate Discounts in Medicaid*: Prior to implementing its December 2021 contract pharmacy limited distribution policy, Lilly's ability to identify duplicate discounts was limited. Even with these data, challenges remain. Note that for all of the strategies described below, Lilly is dependent on State Medicaid Agencies to make Medicaid rebate data available at the claim level. While many states (or their vendors) provide claim level data, it is not mandatory, so some states still do not. Also, the format of these data often varies from state to state. But where Lilly has Medicaid data, we can employ the following techniques to detect unlawful duplicate discounts:

    - Confirm that the State Is Using an Accurate Medicaid Exclusion File for Fee-For-Service Medicaid: Lilly consults the Medicaid Exclusion File (MEF), which is a list of covered entities that have chosen to use 340B drugs for their Medicaid patients and to bill Medicaid for those drugs (carve-in). When covered entities choose to carve-in for Medicaid, they must provide HRSA with the Medicaid Provider Number/NPI used to bill Medicaid. These provider identifiers are listed in the MEF. Having this information in the MEF indicates to the states and manufacturers which drugs are not subject to Medicaid rebates, and helps ensure the prevention of duplicate discounts, as prohibited by statute.

      While the states are generally reliable in scrubbing their data prior to seeking Medicaid rebates, Lilly "double checks" that states are utilizing accurate version of the MEF. Disputes related to these claims are sent to State Medicaid agencies, not covered entities for resolution.

    - Compare Provider Information on 340B Purchases with State Medicaid Claim Data: Lilly employs a vendor to analyze DEA Numbers, Healthcare Identifier Numbers (HINs), BIN and PCN numbers, and to compare those to National Provider Identification (NPI) numbers to identify duplicate 340B/Medicaid claims based on provider data. Disputes related to these claims are sent to State Medicaid agencies, not covered entities for resolution.

    - Compare Contract Pharmacy Claim Level Data with State Medicaid Claims. Finally, where Lilly has claim level data on 340B contract pharmacy utilization, the company can identify potential Medicaid duplicate discounts by matching on Prescription ID number, Date of

[37] WEBINAR REPLAY "Legal Considerations and Compliance for 340B Program Optimization 340B Insider Q&A session with 340B experts" (minutes 14-16). https://www.cloudmed.com/resource/340b-insider-december-2022/.

Service, and Provider ID. Disputes related to these claims require Lilly to identify which entity—the state or the covered entity is—likely liable for the duplicate discount (based on review of State Medicaid guidance). Whenever Lilly has sought repayment from the entity, those requests have been ignored or denied. Moreover, Lilly has used this data to initiate two HRSA-approved audits. Again, despite clear evidence of noncompliance, Lilly has yet to collect any refunds on these duplicates.

9. Has Eli Lilly undertaken any internal 340B audits on the company's participation in the 340B Program over the past five years? If so, please explain the results in detail. If not, please explain why you did not perform any internal audits.

As discussed above, Lilly is in the process of auditing two covered entities based on contract pharmacy duplicate discounts. These audits are expensive, time consuming, and, while they have generated significant findings related to duplicate discounts and the lack of covered entity controls to prevent them, we do not expect that the audited entities will either pay Lilly back or that we will be able to drive meaningful compliance improvements.

Lilly's recent audit experience shows just how burdensome the HRSA requirements are. Below is a brief timeline that illustrates the time Lilly expending in undertaking two audits. These efforts easily required 100+ hours of Lilly employee time and cost hundreds of thousands of dollars for both the independent auditors and outside legal counsel necessary to initiate these still incomplete audits.

- April 2023 – Lilly initiates good faith inquiries with covered entities to determine if there is reasonable cause
- June 2023 – Lilly meets in-person with HRSA on appropriate audit process
- August 2023 – Covered entity #1 objects to premise of good faith inquiry through outside counsel who alleges Lilly committed a crime by exercising audit rights; Lilly responds through outside counsel
- September 2023 – Lilly identifies covered entities for HRSA to ensure they are not currently under audit and continues communications (through outside counsel) with Covered Entity #1 on premise of good faith outreach
- October 2023 – Lilly hires independent auditor to conduct audits and submits reasonable cause letters with audit workplans to HRSA for approval
- November 2023 – Lilly resubmits reasonable cause letters after HRSA's initial rejection of audit workplans
- December 2023 – Lilly notifies covered entities of HRSA approval of audits and independent auditor attempts to initiate audit
- January 2024 – Both covered entities refuse to comply with HRSA-approved audit workplan, and Lilly submits letter to HRSA escalating issue of non-compliance
- February 2024 – Covered Entity #2 begins producing documents and allows auditor to conduct virtual audit; Covered Entity #1 conditions compliance with audit on completion of an NDA with auditor, which requires Lilly to continue engaging outside legal counsel
- April 2024 – Audit for Covered Entity #2 completed but covered entity rejects findings of duplicate discounts, requiring further interaction; Covered Entity #1 continues to reject audit which requires virtual meeting between HRSA, Lilly, and Covered Entity #1
- May 2024 - Covered Entity #1 eventually produces some, but not all, of documents required for audit and permits virtual onsite audit to occur
- June 2024 – Lilly requests to expand the scope of audit for Covered Entity #1 based on findings in on-site portion of audit; covered entity refuses
- July 2024 – Lilly requests that HRSA authorize expansion of audit and refuses

As demonstrated by this high-level summary, HRSA-created manufacturer audit process is an arduous and expensive endeavor. Lilly has been working continuously for more than a year to complete audits of two 340B covered entities—and those audits are not yet complete.

To date, these two audits have found that the covered entities applied loose controls around prevention of duplicate discounts, particularly in Medicaid Managed Care space. In fact, the auditors concluded that Covered Entity #1 **did not have any controls** in place to prevent duplicate Medicaid Managed Care discounts, and accordingly the same audit showed a 100% occurrence of duplicate discounts. Both Covered Entity #1 and #2 showed a general lack of control over their contract pharmacy partners as well, which led to instances of duplicate discounts in both audits. Neither entity produced copies of their contract pharmacy agreements, with both claiming that they were precluded from releasing these documents due to confidentiality clauses within the agreement that the contract pharmacy refused to waive. Copies of these agreements are integral to determining which entity has the responsibility for taking steps to prevent duplicate discounts, as well as to confirm no unlawful diversion is occurring. The audits are incomplete without these documents and conflict with HRSA instruction that covered entities are to maintain auditable documentation and provide upon request.

Lilly's experience with these contract pharmacy agreements is illustrative of many of the issues facing the 340B program. For starters, HRSA refused to support Lilly's efforts to ensure that the auditors were supplied with the agreements. This was particularly troubling when Covered Entity #1 told Lilly that they authorized HRSA releasing the agreements it had in its possession from an earlier audit, but HRSA refused to provide citing that it did not have permission from the contract pharmacy. During a meeting between HRSA, Lilly, and Covered Entity #1, the CEO for Covered Entity #1 relayed that they had no power to compel their contract pharmacy partners to release the copies of the agreements or otherwise take any affirmative steps related to their 340B agreement. All told, these examples demonstrate that the for-profit contract pharmacies, entities not intended to be beneficiaries in the statute, have an outsize influence on the 340B program and are actively precluding manufacturers from obtaining information required by law through audits.

10. Please explain how the requirements of the 340B Program affect Eli Lilly's contracts with Pharmacy Benefit Managers (PBMs) and the rebates offered outside of the 340B Program.

The 340B program interacts with the PBM business model in a number of ways never intended when this law was enacted.

- Covered Entities Selling 340B Prices and Claiming to be PBMs: In August, the University of North Carolina (UNC), a large 340B covered entity, purported to launch a PBM that would provide "up to 32% in total savings" to (for profit) employers. We believe the UNC business model is to engage in a perfunctory patient interaction, likely via a telehealth interaction, so they can claim a 340B patient relationship with the plan's insured beneficiary and split the 340B profits with the employer plan in the form of a "rebate." If true, this would be egregious, systematic diversion and potentially violate other laws.

- PBMs Own 340B Vendors and Contract Pharmacies, Which Leads to Self-Dealing: There are numerous examples of PBMs owning or controlling entities that profit from the 340B program. For example, in August 2022, the New York Attorney General sued CVS for allegedly violating the Donnelly Act, New York's state antitrust law, by illegally tying access to Contract Pharmacy services at CVS retail and specialty pharmacies to use of CVS third-party administrator (TPA) services through Wellpartner, a company CVS acquired in 2017. PBMs

also own numerous contract pharmacies, especially specialty pharmacies, that often serve as covered entity mail order pharmacies.

- 340B Discounts Affect Manufacturer Rebate Agreements: Because 340B medicines are deeply discounted (sometimes down to one cent), manufacturers often seek to contractually prohibit duplicate discounts on commercial and Part D medicines that would otherwise be eligible for a PBM rebate. When manufacturers identify ineligible 340B claims, often in arrears, and correct, dispute or reprocess prior PBM rebate claims, PBMs may be surprised and in a position where they might have already passed certain rebate dollars through to the plan. These disputes lead to friction with PBMs and may lead PBMs to penalize manufacturers who detect ineligible 340B claims. Again, to avoid interference with these other relationships, more transparency is needed throughout the system.

***

Thank you for the opportunity to provide this response. As the experiences cataloged above make clear, Lilly supports federal legislative reforms to preserve and protect the 340B program. Any legislation should provide, at a minimum, (1) a clear and administrable "patient" definition; (2) data transparency to prevent or correct all statutorily prohibited duplicate discounts; (3) limits on, and meaningful oversight of, contract pharmacy arrangements; and (4) a regular culture of compliance fostered by routine and frictionless manufacturer audits. We are grateful for your attention to this important issue, and we look forward to continuing a dialogue with you and your staff.

Sincerely,

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October 31, 2024

BY EMAIL DELIVERY **Confidential Treatment Requested**
Attn: [redacted]

The Honorable Bill Cassidy, M.D.
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate
Washington, D.C. 20510-6300

Dear Ranking Member Cassidy:

This letter and enclosed information is submitted on behalf of Amgen Inc. ("Amgen" or the "Company") in response to your letter dated September 23, 2024 (the "Letter") regarding the 340B Drug Pricing Progam (see attached Appendix A).

Amgen is providing information regarding the 340B Pricing Program and intends to cooperate with your inquiry, as Ranking Member of the the Senate Health, Education, Labor and Pensions Committee (the "Committee"). We also appreciate the ongoing dialogue with your Committee staff so that Amgen can respond to your Letter in a reasonable and timely manner. In responding to your Letter, Amgen has in good faith tried to be as accurate and responsive as possible based on Amgen's understanding of the objectives of your inquiry and the requests made in your Letter. The representations herein are based on reasonably available information and are not intended to and do not capture all potential information related to your Letter, nor are they an exhaustive response to these requests. Amgen reserves the opportunity to supplement this information. In providing this response, neither Amgen, nor any of its affiliates, waive, nor intend to waive, any rights or privileges that may be applicable with respect to your Letter.

Today's submission contains highly confidential and proprietary, and/or trade secret information of Amgen that is being provided pursuant to your request as Ranking Member of the Committee and pursuant to Rule XXIX.5 of the Standing Rules of the Senate. While Congress

may request such information, the law, as reflected in the Trade Secrets Act (18 U.S.C. §1905), recognizes the critical and sensitive nature of confidential, proprietary, and trade secret information and, as such, protects against the disclosure of such information. The intentional or inadvertent disclosure of information that Amgen has expressly designated as confidential, trade secret, and/or proprietary would likely cause substantial competitive harm to Amgen. Accordingly, this letter is marked with the legend "AMGEN CONFIDENTIAL TREATMENT REQUESTED PURSUANT TO SENATE RULE XXIX.5." Amgen respectfully requests advance notice of any contemplated disclosure of the Company's confidential, trade secret, and/or proprietary information, and a reasonable opportunity to object. As discussed with your staff, we are initially providing certain information related to Requests 1, 2, and 3 in a secure online database, consistent with measures designed to protect against inadvertent disclosure of sensitive information.

If you have any questions regarding this matter, or need additional information, please do not hesitate to contact me.

Sincerely,

[redacted]

[redacted]

October 31, 2024

Appendix A

AMGEN'S SUBMISSION IN RESPONSE TO RANKING MEMBER CASSIDY'S LETTER DATED SEPTEMBER 23, 2024

Amgen is committed to unlocking the potential of biology for patients suffering from serious illness by discovering, developing, manufacturing, and delivering innovative human therapeutics. We use advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology. The medicines we have discovered and developed have reached millions of people around the world in the fight against serious illnesses.

Amgen supports the 340B Program and is committed to maintaining and strengthening its mission to help uninsured and low-income patients gain access to prescription medications at deeply discounted prices. **Since 2018, Amgen has provided over *$5.6 billion* in discounts to 340B covered entities on Enbrel® alone.**

At the same time, Amgen is alarmed by the 340B Program's uncontrolled and explosive growth. This growth has been achieved at the expense of 340B patients and through complicated business arrangements that benefit for-profit pharmacies and other commercial vendors. The 340B Program—which is now larger than the Medicaid Drug Rebate Program from which it emerged—has become a vehicle for improper arbitrage on a massive scale. Covered entities have turned away from using 340B to benefit indigent or uninsured patients at the point of dispense, and they have instead focused on the practice of generating "spread" at every opportunity. By purchasing manufacturers' drugs at deeply discounted prices and then selling them at the full price to pharmacy customers, and by pulling every lever available to maximize the volumes of drugs they subject to this arbitrage, hospital covered entities put at risk the ability of the manufacturing community to support them. The 340B Program is not operating as Congress intended and is failing to best assist vulnerable patient populations.[1]

Amgen is committed to ensuring the long-term viability and sustainability of the 340B Program. To that end, we welcome the opportunity to work with you and your office as you consider ways to ensure the program functions appropriately. We hope the information provided in this submission is helpful.

Request 1: For each year beginning in 2018, please produce an Excel document with a detailed accounting of Amgen's participation in the 340B Program, including the following information per calendar year:

[1]See, e.g., Gov. Howard Dean, *Transparency Needed to Ensure Safety-Net Program Helps Uninsured*, RealClear Health, October 25, 2024 (340B has become a "self-enrichment scheme" that "desperately needs oversight").

a. **A list of full packages, identified by National Drug Code (NDC), of drugs sold to covered entities at the 340B ceiling or sub-ceiling price;**
b. **The price of each of those packages identified in question (1)(a) at the wholesale acquisition cost (WAC);**
c. **The amount of the 340B price concessions given to covered entities for each of the drug sales identified in question (1)(a);**
d. **The 340B price paid as a percentage of WAC for each of those sales; and**
e. **A denotation of whether each drug was distributed to covered entities and their child sites, wholly-owned pharmacies, or contract pharmacies for each drug sale identified.**

As previously discussed with Committee counsel, some of the information sought by Request 1 is not regularly maintained by Amgen in the format requested by the Committee. As a result, we have combined available sources of data to provide information responsive to this Request. In response to 1.a through 1.d, Amgen is providing spreadsheets of responsive data in the electronic reading room (AMGEN-RR-00001 - AMGEN-RR-00008). This confidential and proprietary business information reflects 340B quarterly pricing data for Enbrel® for the period 2018 Q1 through 2024 Q3.

With respect to 1.e, Amgen's policy is to provide 340B prices to all the listed entities, with one caveat: After Amgen implemented its contract pharmacy policy, it imposed reasonable conditions on when it would allow contract pharmacies to access its drugs at the discounted 340B price (e.g., submission of claims data).

Request 2: For each year beginning in 2018, please produce the above information separately for any 340B drugs you sold to the following covered entities: Cleveland Clinic, Bon Secours Mercy Health, Sun River Valley, and Yakima Valley Farm Workers Clinic.

In response to 2.a through 2.d, Amgen is providing spreadsheets of responsive data in the electronic reading room (AMGEN-RR-00009 - AMGEN-RR-00038). This confidential and proprietary business information reflects 340B quarterly pricing data for Enbrel® for each fiscal year between 2018 Q1 through 2024 Q3. In collecting this information, we ran "Entity Name" searches in the HRSA OPAIS database to identify relevant 340B IDs, which we then used to filter PHS chargeback data and obtain responsive information specific to each of the four identified covered entities.

With respect to 2.e, Amgen's policy is to provide 340B prices to all the listed entities. After Amgen implemented its contract pharmacy policy, it placed limits on when Amgen would transfer drugs at discounted prices to those pharmacies.

<u>Request 3:</u> Please provide all internal communications and documents related to Amgen's decision to impose restrictions on distribution of 340B drugs to contract pharmacies and how these policies were created and implemented.

a. **Please provide numerical data, on a month-by-month basis, on how this policy has affected the volume of your 340B sales since it was implemented.**

b. **Please provide numerical data and specific examples of how this policy has resulted in fewer duplicate discounts or diversion of 340B drugs to ineligible patients.**

As the HELP Committee is aware, the Health Resources and Services Administration's ("HRSA") failure to enforce statutory standards (e.g., an enforceable patient definition; mechanisms to track duplicate discounting), combined with the significant growth in contract pharmacy arrangements, has transformed the 340B Program. Of particular concern to Amgen, the growth continues to be fueled by sophisticated business arrangements aimed at maximizing the profits of contract pharmacies and other commercial entities rather than ensuring program integrity. At present, there are no safeguards in place to require that 340B priced drugs are provided only to 340B patients at contract pharmacies. Indeed, under many contract pharmacy arrangements, no effort is made at the point of sale to identify the 340B status of a pharmacy customer. Weeks after the dispense, contract pharmacies and their partners apply an "algorithm" to assign patients to 340B status to justify their demand for manufacturer replenishment at the 340B price. 340B covered entities purchased *$124 billion* in covered outpatient drugs in 2023, driven in substantial part by the replenishment activities of contract pharmacies. To try to control for the perceived abuse, Amgen felt it had no choice but to implement certain reasonable conditions on when it would allow hospital covered entities to seek to transfer its drugs at 340B prices to contract pharmacies.

In January 2022, Amgen altered its approach to the circumstances in which it would allow hospitals to use contract pharmacies to purchase 340B-priced drugs. Under the January 2022 policy, Amgen announced that, while hospital covered entities could continue to purchase Amgen's drugs at the 340B price without restriction, it would facilitate transferring 340B priced drugs to a single contract pharmacy only if a hospital covered entity did not have an in-house pharmacy location, and to an unlimited number of contract pharmacies if the hospital provided appropriate claims data. This policy was limited to four drugs and did not include federal grantees. Importantly, at no time has Amgen limited the number of 340B-priced packages of drugs that any covered entity may purchase, as long as the entity takes possession of the drugs at its location (or as provided in our policy). And because hospital covered entities extend discounts to contract pharmacy patients less than *2% of the time*[2], patients see no benefit at the contract pharmacy counter from covered entities' pervasive use of contract pharmacies.

[2] *See* Rory Martin & Kepler Illich, *Are Discounts in the 340B Drug Discount Program Being Shared with Patients at Contract Pharmacies*, IQVIA (2022), at 11.

In April 2023, Amgen announced that it would provide 340B priced drugs only to a single contract pharmacy located within 40 miles of the parent site if a hospital covered entity does not have an in-house pharmacy. In March 2024, Amgen extended this same policy to federal grantees. Amgen routinely updates this policy, with the most recent modification published on August 28, 2024.

The current policy allows products purchased at the 340B price to be transferred exclusively to locations registered as a 340B covered entity or other locations designated in accordance with Amgen's policy. This policy applies to six drugs: Repatha®, Enbrel®, Otezla®, Aimovig®, Tezspire®, and Amjevita® Highlights from our current contract pharmacy policy follow:

- Any 340B covered entity that does not have an in-house pharmacy capable of dispensing 340B purchased drugs to its patients may designate a single contract pharmacy location within 40 miles of the covered entity parent site.
- Any 340B covered entity that does have an in-house pharmacy capable of dispensing 340B purchased drugs to its patients may designate a single contract pharmacy if (i) the location of the single contract pharmacy is within 40 miles of the covered entity parent site and (ii) the covered entity provides claims data for both the in-house pharmacy and the designated single contract pharmacy.
- Any covered entity may elect to designate any contract pharmacy location registered on the HRSA OPAIS database that is within 40 miles of the covered entity's parent site, regardless of ownership interest, as its single contract pharmacy location so long as the covered entity complies with the claims data submission requirements noted above. Amgen evaluates requests for exceptions to the 40-mile rule on a case-by-case basis.
- Amgen uses 340B ESP™ to effectuate its contract pharmacy policy by enabling covered entities to make contract pharmacy designations and submit 340B claims data.[3]

Each of the policy iterations described above is consistent with federal law. *See Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452 (D.C. Cir. 2024) and *Sanofi Aventis U.S. LLC v. U.S. Dept. of HHS*, 58 F.4th 696 (3d Cir. 2023).

As you can see from the data provided in response to Request 3a. (AMGEN-RR-00039 – AMGEN-RR-00040), gross 340B sales dollars decreased markedly after Amgen instituted its original policy in January 2022. Nevertheless, 340B utilization of Enbrel® quickly recovered and now sits at 162% of its September 2021 level. Despite the adoption of reasonable restrictions on the delivery of 340B-priced drugs to contract pharmacies, 340B covered entities are purchasing more Enbrel® than ever before. Amgen's policies are clearly not an inhibition on access to 340B pricing.

[3]Amgen has exempted contract pharmacies located in certain states due to the enactment of recent state laws prohibiting any restrictions on the use of contract pharmacies (i.e., Arkansas, Mississippi, Missouri, and Maryland).

Amgen instituted its contract pharmacy policy, in part, in reaction to U.S. Government Accountability Office ("GAO") and U.S. Department of Health and Human Services ("HHS") Office of the Inspector General ("OIG") reports demonstrating that the use of contract pharmacies exacerbates program integrity violations.[4] These government reports confirmed what manufacturers had long suspected: contract pharmacies magnify and exacerbate problems in a program already rife with abuse. By restricting when they will allow covered entities to use contract pharmacies consistent with the 340B statute, manufacturers implemented reasonable business conditions on the terms of sale for 340B drugs in the hopes of addressing this abuse. Reducing the number of contract pharmacies is an imperfect tool and one that does not identify specific instances of diversion or duplicate discounting. However, by reasonably limiting the opportunity for abuse – and the mechanism that facilitates improper arbitrage and does not permit patients to obtain our discounts – Amgen has taken a stand in support of 340B program integrity.

Request 4: Currently, the vast majority of covered entities purchase 340B drugs through the virtual inventory/replenishment model. Please explain any difficulties this model has for Amgen and if there is a different model that would be more efficient for the sale and distribution of 340B drugs.

a. How does Amgen identify which purchases are made through 340B under this model?

b. How does the use of contract pharmacies versus the use of in-house pharmacies affect this model?

Historically, HRSA provided that 340B-priced drugs may only be dispensed to 340B patients presenting a 340B prescription. However, under the replenishment model, there is no physical separation of 340B and non-340B drugs, and there is no requirement that a pharmacy verify that a customer is a 340B patient at the time the drug is dispensed. Rather, contract pharmacies dispense full-priced drugs to any customer with a prescription from any prescriber. The customer (and in many cases his or her health plan) pays full price for the drug. Then, the contract pharmacies, their Third-Party Administrators ("TPAs"), and other commercial consultants rely on black-box algorithms to assess, retroactively, whether the dispensed drugs actually went to patients of a covered entity eligible to receive 340B drugs. If the algorithm determines that the patient is likely eligible, then the contract pharmacy authorizes its covered entity partner to "replenish" the pharmacy's general inventory with a new 340B-discounted order. Patients are not retroactively provided any discount. Contract pharmacies are compensated by the covered entity, in part, based on the number of 340B-priced prescriptions they fill. Therefore, there is a clear incentive for the contract pharmacy to utilize an algorithm that favors "340B-eligible" transactions based on dubious relationships between patients and covered entities.

[4] *See* GAO, Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, GAO-18-480 (Jun. 21, 2018), and OIG, Contract Pharmacy Arrangements in the 340B Program, OEI-05-13-00431 (Feb. 4, 2014).

Amgen believes this arrangement—cloaked in secrecy and incentivized by commercial profit-taking—leads to the abuses described above.

The replenishment model established by contract pharmacies does not exist in the commercial marketplace. The only purpose of the replenishment model appears to be to facilitate the prolific use of contract pharmacies in the 340B setting. Amgen does not permit commercial purchasers to back-fill independent dispensaries with discounted product after the fact, as the 340B replenishment model requires.

Were 340B dispensing done by in-house pharmacies at the discount-eligible entities (as was the case for the first eighteen years of the program), the notion of replenishment would never have arisen. Replenishment is not contemplated in the 340B statute or implementing regulations. It is a construct of the post-2010 era in which covered entities, their commercial partners, and HRSA elevated maximizing 340B utilization and covered entities' ability to maximize its profit spread on the purchase and dispensing of 340B-priced drugs over the protection of program integrity.

In light of the evident shortcomings of this replenishment model, Amgen encourages Congress and HRSA to implement common-sense changes to make the system work better for covered entities and manufacturers. At a minimum, prior to dispensing a 340B prescription from a virtual inventory, the covered entity or contract pharmacy must be able to confirm the status of the patient.

<u>Request 5:</u> Please describe Amgen's policies and procedures for identifying duplicate discounts with Medicaid and diversion to ineligible patients.

a. **What has been the company's experience in resolving these issues with covered entities, state Medicaid agencies, and/or HRSA?**

b. **Please provide the financial impact of the identified duplicate discounts and diversions in your response.**

Amgen currently reviews claim level detail against the Medicaid Exclusion file to determine eligible 340B Covered Entities. Chargeback (sales) data is then reviewed to determine if the eligible 340B Covered Entity made purchases at the 340B price. Amgen disputes claims that are determined to likely be duplicate 340B discounts based on this analysis. Historically, resolving disputes for duplicate discounts has been challenging. This can be due to timeliness of updates to the Medicaid Exclusion File and waiting for states to reach out to the Covered Entity and respond back to Amgen on the dispute. States can be very slow to respond to requests for follow-up on disputes, likely due to limited staffing resources.

HRSA's recent audits of covered entities confirm that illegal diversion and duplicate discounting are regularly occurring. An analysis of FY 2021 HRSA audit findings showed that

more than *60 percent* of audited covered entities had at least one adverse finding, and nearly *30 percent* of non-compliant covered entities had two or more adverse findings.[5]

Amgen would very much like to have a robust policy under which reliable and transparent data are reviewed and tested to identify potential diversion and duplicate discounting. This includes being able to scrub 340B data as it does commercial rebate submissions to ensure eligibility of its very significant discounts and identify duplicate discounts with Medicaid and diversion to ineligible patients.

Unfortunately, the 340B program is not designed to permit even this modest level of manufacturer oversight. HRSA does not require covered entities to provide claims level detail to permit review for these abuses and identification of irregularities. The 1996 340B patient definition guidance is so broadly worded that even HRSA cannot successfully audit for diversion. Last year, a federal court in South Carolina enjoined HRSA from enforcing a narrow definition of the term "patient" of a covered entity.[6] How is Amgen to identify dispensing to ineligible patients if the HRSA definition of an eligible patient isn't enforceable and covered entities are not required to publish their policies on patient eligibility?

In theory, covered entities are supposed to track and manage 340B inventory and ensure that the drugs in that inventory are excluded from Medicaid rebate requests. However, HRSA has not "issued guidance on how covered entities should prevent duplicate discounts in Medicaid managed care," and the agency "has indicated that it is not pursuing new guidance."[7] Due to this lack of guidance, HRSA effectively does not require covered entities to address identified instances of duplicate discounts, which is "contrary to federal law."[8] HRSA and Centers for Medicare & Medicaid Services ("CMS") finger-pointing over illegal duplicate discounting does not enable manufacturers like Amgen to perform its own tests.

HRSA does not even permit manufacturers to regularly audit covered entities to uncover program abuse. Instead, manufacturers may only gain access to the data necessary to determine diversion or duplicate discounting after they have demonstrated good cause that such abuses are occurring. But of course, manufacturers aren't provided data that would allow them to uncover the abuses required to ask for an audit. Furthermore, manufacturers can only audit one covered entity at a time, and at the manufacturer's expense. To perform an audit, manufacturers are required to hire outside auditing firms and submit audit work plans to HRSA for approval. This painstakingly slow process makes it almost impossible to effectively monitor covered entities and their contract pharmacies.[9] In short, there is no systematic monitoring of the opaque and

[5]ADVI Insights, *Analysis of FY 2021 HRSA 340B Covered Entity Audits* (Feb. 23, 2023).
[6]*See Genesis Health Care, Inc. v. Becerra*, 701 F. Supp. 3d 312 (D.S.C. 2023).
[7]*GAO, 340B Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement*, GAO-20-212 at 30 (Jan. 2020).
[8]*See id*. at 26.
[9]See 87 Fed. Reg. 73518 (Nov. 30, 2022)(HRSA noting "the historical infrequency of manufacturer audit[s]").

potentially non-compliant processes to police for diversion or duplicate discounting; the only (inadequate) controls are the haphazard and infrequent threats of HRSA audits.

Amgen does what it can. Amgen relies on the 340B ESP™ platform to address 340B Program abuses, including duplicate discounts, through the submission of claims data required under Amgen's contract pharmacy policy. But the utility of this 340B ESP™ platform is limited since only a subset of covered entities submit claims data to Amgen.

Under Amgen's current policy, as explained above, only covered entities that have an in-house pharmacy and wish to designate a single contract pharmacy for delivery of 340B drugs are required to submit claims data through the 340B ESP™ platform. Participating covered entities submit claims data on a rolling basis, twice per month. To allow time for all covered entities to obtain and submit the required data, submissions are made on or before the 1st and 16th days of each month for the prior period. For example, on or before October 1st, all prescriptions identified as eligible under Amgen's 340B policy since a covered entity's last submission on September 16 are submitted. Data submission includes all claims that were identified as eligible under Amgen's 340B policy during this time period regardless of the date of service on the claim. Claims identified as eligible under Amgen's 340B policy between September 1 and September 15, for example, will likely include dates of service prior to September 1. Email reminders are automatically generated from 340B ESP™ and covered entities can monitor claims submission status when logged into the platform.

Request 6: How does your company intend to monitor that 340B pricing is not duplicated with the Inflation Reduction Act's introduction of the Maximum Fair Price and inflation rebate penalties?

While Amgen intends to comply with CMS's request and submit a proposed plan to avoid duplication of the 340B ceiling price and the Maximum Fair Price ("MFP") by September 1, 2025, we remain deeply concerned at the lack of implementation details provided by the Agency. In particular, CMS has declined to assume responsibility for deduplicating discounts and instead proposed that manufacturers implement their own systems based on data *voluntarily* submitted by 340B covered entities. CMS "strongly encourages" that manufacturers "work with dispensing entities, covered entities and their 340B TPAs, and other prescription drug supply chain stakeholders (e.g., wholesaler) to facilitate access to the lower of the MFP and the 340B ceiling price."[10] This punt by CMS undermines Congress' clear directive that manufacturers provide only the *lower* of the 340B price or the MFP, not both simultaneously. Failing an adequate nonduplication mechanism, manufacturers will surely pay MFP rebates on utilization purchased

[10]CMS, Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Section 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027 (Draft Guidance) at 114.

at the 340B price, resulting in many cases in *negative* pricing to the manufacturer (that is, extending more in 340B discount and Medicaid rebate than the full price of the drug).

In August, 2024, Johnson & Johnson ("J&J") attempted to adopt a modest rebate mechanism to extend 340B pricing to disproportionate share hospitals on two products subject to MFP (Stelara and Xarelto). By offering 340B rebates after dispense, J&J would be in a position to assess whether the dispensing pharmacy was owed a 340B discount *or* an MFP discount. J&J proposed to use the rebate mechanism for the narrow purposes of ensuring that purchases are made by an eligible covered entity, discounted drugs are dispensed by an eligible covered entity or contract pharmacy, and claims data are received in a timely fashion.[11] The covered entity community marshaled a furious response, mischaracterizing J&J's proposal as violative of the 340B statute, and calling for J&J to be sanctioned. HRSA quickly capitulated. Not only did HRSA voice objection to J&J's proposed rebate model, but it went so far as to threaten to terminate J&J's participation in federal programs if the company did not immediately ascede to the government's demand.[12] The threat was unprecedented, unwarranted, and out of proportion to the reasonable approach proposed by J&J. J&J was forced—under threat of removal from 340B, Medicaid, and Medicare Part B—to disavow its strategy to comply with the Inflation Reduction Act's ("IRA") nonduplication provision. HHS has thus doubled down on its refusal to provide a means by which manufacturers can avoid being charged twice in this way, in violation of the explicit terms of the IRA.[13]

Amgen is alarmed by the lack of an oversight mechanism to ensure that—at a minimum—covered entities properly report all 340B claims. The absence of which will create additional opportunities for duplicate discounts. As discussed in more detail throughout our responses, manufacturers are not equipped or permitted to police compliance with covered entity reporting requirements.

Accordingly, as described in our comments on the Calendar Year 2025 Physician Fee Schedule Proposed Rule, we encourage CMS to require the use of either a 340B or a non-340B claims modifier, as applicable, for each unit billed under Medicare Part B and to specify that accurate use of such a modifier is necessary for a claim to be considered complete and eligible for reimbursement and should establish a clearinghouse to validate 340B units. Similarly, CMS should require the accurate use of either a 340B or a non-340B claims modifier, as applicable, for each unit billed under Medicare Part D and use a clearinghouse approach to exclude 340B units from the calculation of the Part D inflation rebate.

[11] *See* *Notice to 340B End Customers Regarding Purchases of STELARA and XARELTO*, Aug. 23, 2024.
[12] *See* *HRSA Response to J&J's September 19, 2024 Letter* (Sept. 27, 2024).
[13] 42 U.S.C. § 1320f-2(d)("nonduplication with 340B ceiling price")

Request 7: How has HRSA's 2010 guidance allowing for unlimited numbers of contract pharmacies affected how Amgen conducts compliance audits on covered entities to monitor the occurrence of duplicate discounts and diversion under the 340B Program?

HRSA's 2010 guidance has precipitated an explosion in the number of contract pharmacies and 340B claims, making it almost impossible for manufacturers like Amgen to effectively monitor for duplicate discounts and diversion. Adding to this difficulty are the limited circumstances under which audits are permitted and the burdensome procedures required even when audits are permitted. Moreover, several covered entities noticed for manufacturer audits have recently sued HRSA to stop them, putting the cart squarely before the horse by arguing that manufacturers must prove abuse as a precondition of *initiating* an audit.[14] Covered entities routinely delay cooperation with auditors, or affirmatively deny them access to the data necessary to perform their function. Audits were nearly impossible to undertake before HRSA welcomed commercial pharmacies into the program. Today, with so much more money at stake, the forces of resistance and obfuscation have made auditing an illusory remedy for manufacturers.

In 1996, nearly thirty years ago and prior to the massive growth of the program, HRSA issued manufacturer audit guidelines. Those outdated audit guidelines are still in place, untouched by HRSA in the decades since their publication. Manufacturers must audit covered entities prior to bringing a case through Administrative Dispute Resolution ("ADR"), making the 1996 audit guidelines a significant impediment to manufacturer access to the only dispute resolution process offered in 340B.

In 2010, the Affordable Care Act ("ACA"), authorized HRSA to conduct routine audits and to establish regulations for the ADR process under which manufacturers and covered entities were supposed to settle disputes regarding 340B purchases. In 2012, HRSA implemented its audit program; however, HRSA did not promulgate final rulemaking related to the ADR process until 2020.[15] That ADR rule was litigated, and a revised ADR final rule did not become effective until June 18, 2024—fourteen years after the ACA.[16]

Since 2010, the number of covered entities increased by roughly 50 percent.[17] During that same period, the number of contract pharmacies has increased 25-fold.[18] Despite this explosion in the number of contract pharmacies, there has not been a corresponding increase in audits of covered entities. As far back as 2018, a report by the GAO underscored the shortcomings of HRSA's audit program.[19]

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[14] *See*, *e.g.*, *Children's Nat'l Med. Ctr. v. Johnson*, 24-cv-02563 (D. D.C. 2024).
[15] 85 Fed. Reg. 80632 (Dec. 14, 2020).
[16] 89 Fed. Reg. 28643 (Apr. 19, 2024).
[17] Anthony M. DiGiorgio, Wayne Winegarden, *Reforming 340B to Serve the Interests of Patients, Not Institutions*, JAMA HEALTH FORUM (Jul 26, 2024).
[18] *Id*.
[19] *See GAO, Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* (Jun. 28, 2018).

Although the 340B statute requires covered entities to permit both HHS and manufacturers to audit "the records of the entity that directly pertain to the entity's compliance with" the bars on duplicate discounts, reselling, and transfers, HRSA has imposed a number of significant restrictions that undermine the practical benefit of the audit process.[20] For instance, as described above, manufacturers must hire outside auditing firms, must submit audit work plans for HRSA approval, and may audit only one covered entity at a time.[21] In light of the difficulty and expense of proceeding with an audit, identifying a violation may not be worth the effort. Taken together, the uncontrolled increase in the number of contract pharmacies coupled with resistance to audits by covered entities has rendered it impractical to utilize audits as a mechanism for ensuring program integrity.

Request 8: Please explain the actions that Amgen takes when it identifies instances of duplicate discounts and/or diversion. What are the procedures and process by which covered entities remit payments to manufacturers in instances of duplicate discounts and/or diversion?

As a practical matter, when Amgen identifies potential duplicate Medicaid discounts (a tricky thing to do given the lack of transparency described above), it typically disputes the Medicaid invoice amount with the state. Amgen then asks the state Medicaid agency to work with the covered entity to either provide documentation to validate the claim is not a duplicate discount, or for the state to reverse the claim. There are no payments made by covered entities to Amgen for duplicate discounts; they are either resolved by the states or go unresolved.

When instances of illegal diversion are called to Amgen's attention (most likely as a result of a finding of noncompliance in a HRSA-initiated audit), Amgen typically works with the affected covered entity to process payments from the covered entity in reimbursement. Generally, the amounts received by Amgen are the difference between the 340B ceiling price and the commercial price otherwise available to the covered entity, times the number of units identified. These kinds of reimbursements paid by covered entities are very rare.

Consistent with HRSA guidance, covered entities "should" submit a self-disclosure form to HRSA if they determine that duplicate discounts or diversion occurred and correct the issue.[22] Covered entities are supposed to work with manufacturers like Amgen to submit repayment of identified duplicate discounts or diversions. But, in practice, covered entities are not incentivized to self-disclose due to the lack of enforcement and transparency in the data, which is driven by the income the covered entities gain as a result of acquiring the drugs at the 340B price and selling them at a higher price. Even if a duplicate discount is discovered, the repayment responsibility

[20] Id. § 256b(a)(5)(C).
[21] 61 Fed. Reg. 65,406, 65,409 (Dec. 12, 1996).
[22] *See* *HRSA 340B Pricing FAQs*.

varies: covered entities are responsible for repayment of 340B discounts if a manufacturer pays a duplicate discount on a Medicaid Fee-for-service ("FFS") claim, but states are responsible for repaying the rebates that they receive if a manufacturer pays a duplicate discount on a Medicaid managed care organization ("MCO") contract claim. As a result, covered entities and states often seek to shift the responsibility for duplicate discounts. Moreover, since states have adopted different methods for avoiding duplicate discounts in MCO claims, manufacturers face high costs in navigating these disparate systems—complicating access to reimbursements for duplicate claims. For its part, HRSA has not taken any steps to harmonize reimbursements of MCO claims, and has stated that it has no intention of doing so. Faced with these challenges, certain manufacturers have begun audits of MCO duplicate discount policies, but it is not clear that this strategy can be effective at scale.[23]

Recently, CMS finalized a requirement that MCO contracts incorporate Medicaid-specific identifiers on enrollees' pharmacy cards, including a unique Processing Bank Identification Number and Processor Control Number ("BIN/PCN") combination with a group number identifier. These specific Medicaid identifiers may, in the future, assist states and their managed care plans in avoiding duplicate discounts to the 340B Program and the Medicaid Drug Rebate Program ("MDRP"). Amgen will be monitoring the effect of this new requirement.

Theoretically, Amgen could avail itself of the ADR process after identifying duplicate discounts or diversion through an audit of the covered entity and after attempting good faith negotiations to seek repayments. But, as explained above, the audit process is expensive, time-consuming, and often ineffective.

Request 9: Has Amgen undertaken any internal 340B audits on the company's participation in the 340B Program in the past five years? If so, please explain the results in detail. If not, please explain why you did not perform any internal audits.

Amgen has not undertaken an internal audit specific to the company's participation in 340B program in the past five years. However, Amgen routinely subjects its MDRP function to internal audit to confirm, among other things, that Amgen's MDRP pricing is accurate and consistent with statutory and regulatory requirements. Because the 340B ceiling price is a function of those MDRP prices (specifically, Average Manufacturer Price and Unit Rebate Amount), the accuracy of Amgen's 340B pricing undergoes regular internal audit. The most recent internal audit of the MDRP function was conducted in December, 2020.

Note that Amgen also routinely conducts 340B ceiling price recalculations—often as a result of standard lags in the availability of Best Price data—and notifies covered entities accordingly. For example, in September 2024, Amgen announced that it will refund covered entities that purchased certain products during the third and fourth quarters of 2021 based on

[23]Rich Daly, *Lilly to Conduct HRSA-Approved Audit That Includes First-Time Look for Medicaid MCO Duplicate*, 340B REPORT (Dec. 19, 2023).

updated ceiling price recalculations. Covered entities eligible for a refund of at least $25 will receive a credit via the 340B prime vendor, Apexus. Covered entities eligible for less than $25 in total can obtain a credit upon request to Amgen.[24]

Request 10: Please explain how the requirements of the 340B Program affects Amgen's contracts with Pharmacy Benefit Managers (PBMs) and the rebates offered outside of the 340B Program.

As a threshold matter, pharmacy benefit managers ("PBMs") leverage the 340B Program to increase profit margins through their vast networks of pharmacies. More than 85,000 contracts exist between 340B providers and contract pharmacies under the auspice of the three largest PBMs: OptumRx, Express Scripts, and CVS Health. In addition, more than half the profits contract pharmacies accrue through the 340B Program benefit only four PBM and pharmacy companies: CVS Health, Express Scripts, Walgreens, and Walmart, and those profits are substantial.[25] The average profit margin gained by covered entities and the pharmacies with which they contract on commonly dispensed 340B drugs is around 72 percent compared to a margin of 22 percent for non-340B drugs dispensed through independent pharmacies.[26]

In general, PBMs are reluctant to enter into agreements with manufacturers that include 340B exclusionary language. During the course of contract negotiations, the manufacturer must bargain for duplicate discount protection and PBMs may require higher rebates in exchange. These negotiations are complicated given the lack of 340B data and disparate sources available. For example, PBMs tend to use information from the National Council for Prescription Drug Programs to detect 340B duplicate discount exclusions; however, that data set is incomplete and can lead to discrepancies in revenue.

In sum, covered entities' arbitrage position demands both that manufacturers extend to them extraordinary discounts, and that insurers pay to them the full undiscounted prices in reimbursement. Insurers and their PBM partners seek rebates from manufacturers, who resist being double dipped—often times yielding net prices not just below cost but below zero. This dynamic makes PBMs even more aggressive in their demands for rebates in other areas, raising the costs of care throughout the health care system.

* * *

[24]See HRSA, *Advance Notice Regarding Evenity NDCs*.
[25]*See* CVS Pharmacy 10-K (2022), at 22, (explaining that a reduction in contract pharmacy arrangements "could materially and adversely affect the Company"); Walgreens, Inc. 10-K (2022), at 28, (similar).
[26]Nicole Longo, *PBMs using 340B program to drive profits at patients' expense*, PhRMA Blog (March 28, 2024).

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November 13, 2024

BY EMAIL DELIVERY **Confidential Treatment Requested**
Attn: [redacted]

The Honorable Bill Cassidy, M.D.
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate
Washington, D.C. 20510-6300

Dear Ranking Member Cassidy:

This letter and enclosed information is submitted on behalf of Amgen Inc. ("Amgen" or the "Company") in response to your letter dated September 23, 2024 (the "Letter") regarding the 340B Drug Pricing Progam.

Following up on its October 31, 2024 submission, Amgen is making a supplemental production of information and documents bearing the bates range AMGEN-00001 – AMGEN-00040. In responding to your Letter, Amgen has in good faith tried to be as accurate and responsive as possible based on Amgen's understanding of the objectives of your inquiry and the requests made in your Letter. The representations herein are based on reasonably available information and are not intended to and do not capture all potential information related to your Letter, nor are they an exhaustive response to these requests. Amgen reserves the opportunity to supplement this information. In providing this response, neither Amgen, nor any of its affiliates, waive, nor intend to waive, any rights or privileges that may be applicable with respect to your Letter.

Today's production contains highly confidential and proprietary, and/or trade secret information of Amgen that is being provided pursuant to your request as Ranking Member of the Committee and pursuant to Rule XXIX.5 of the Standing Rules of the Senate. While Congress may request such information, the law, as reflected in the Trade Secrets Act (18 U.S.C. §1905), recognizes the critical and sensitive nature of confidential, proprietary, and trade secret

information and, as such, protects against the disclosure of such information. The intentional or inadvertent disclosure of information that Amgen has expressly designated as confidential, trade secret, and/or proprietary would likely cause substantial competitive harm to Amgen. Accordingly, this letter and the documents in today's submission are marked with the legend "AMGEN CONFIDENTIAL TREATMENT REQUESTED PURSUANT TO SENATE RULE XXIX.5." Amgen respectfully requests advance notice of any contemplated disclosure of the Company's confidential, trade secret, and/or proprietary information, and a reasonable opportunity to object. Please direct such notices to my attention.

If you have any questions regarding this matter, or need additional information, please do not hesitate to contact me.

Sincerely,

[redacted]