KIRSTEN A. HART (SBN 258433)
kirsten.hart@afslaw.com
DOUGLAS A. GRIMM (*Pro Hac Vice forthcoming*)
douglas.grimm@afslaw.com
ARENTFOX SCHIFF LLP
555 S. Flower St., 43rd Floor
Los Angeles, CA 90071
Telephone: 213.629.7400
Facsimile: 213.629.7401

Attorneys for Plaintiff
SAGEBRUSH HEALTH SERVICES

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF VENTURA

SAGEBRUSH HEALTH SERVICES, a Nevada nonprofit foundation,

Plaintiff,

v.

AMGEN INC., a Delaware corporation; and DOES 1-10, inclusive,

Defendants.

Case No. 2025CUBT056917

COMPLAINT FOR:

1) CONVERSION;
2) INTENTIONAL INTERFERENCE WITH CONTRACT;
3) INTENTIONAL INTERFERENCE WITH PROSPECTIVE ECONOMIC ADVANTAGE;
4) VIOLATION OF PENAL CODE § 496; and
5) VIOLATION OF BUSINESS & PROFESSIONS CODE § 17200

JURY TRIAL DEMANDED

Plaintiff Sagebrush Health Services hereby brings this Complaint against Defendant Amgen Inc. and DOES 1-10, inclusive, and alleges in support of its causes of action as follows:

NATURE OF THE CASE

1. This action arises from a dispute between participants in a federal drug discount program, specifically the 340B Drug Pricing Program ("340B Program"), codified at 42 U.S.C. § 256b. The 340B Program was created to increase access to medical care and leverage federal resources efficiently. Under the 340B Program, drug manufacturers, in exchange for the benefit of selling their products at full price to federal health insurance programs (including Medicare and Medicaid), are required to sell certain drugs at discounted prices to eligible health care providers, known as "covered entities."

2. Under the 340B Program, drug manufacturers who elect to enjoy the benefit of selling their drugs to Medicare and Medicaid at full price are required to sell certain drugs at a discount to qualified health care providers.

3. The 340B Program requires participating drug manufacturers to sell 340B drugs to each covered entity at or below a discounted price, documented through a Pharmaceutical Pricing Agreement ("PPA") with the Department of Health and Human Services ("HHS").

4. The Health Resources and Services Administration ("HRSA"), an agency of HHS, has sole authority to regulate covered entity status and program compliance.

5. Participating drug manufacturers have no regulatory or police authority as pertains to the implementation of the 340B Program.

6. Rather, the 340B Program provides a mandatory Administrative Dispute Resolution process ("ADR Process") that drug manufacturers must use to challenge covered entity compliance. The ADR Process - subject to HRSA's prior approval - may be invoked after the manufacturer completes an independent audit of a covered entity that indicates a potential violation of the 340B prohibitions on duplicate discounts or diversion.

7. Defendant Amgen Inc. ("Amgen") is a global pharmaceutical manufacturer and participant in the 340B Program.

8. Amgen contests HRSA's implementation of the 340B Program. In December 2024,

Amgen filed suit against HRSA in federal court claiming, in relevant part, that HRSA's oversight of covered entities is inadequate, leading to HRSA's over-designation of healthcare providers as covered entities. The sum of Amgen's position in its complaint is that, as a 340B drug manufacturer participant, Amgen should enjoy the latitude of selling its drugs to Medicare and Medicaid at full price while not being burdened by the requirements of its PPA to sell its drugs at discounted prices to covered entities that it - in its sole discretion - deems unqualified.[1]

9. Amgen's approach is multi-pronged. Outside the federal judiciary, without utilizing the ADR Process, and with no legal authority whatsoever, Amgen unilaterally determined that Plaintiff Sagebrush Health Services ("Sagebrush"), a nonprofit healthcare provider and HRSA-approved covered entity, should not qualify as a 340B covered entity, despite HRSA's approval and Sagebrush's ongoing qualified status. As such, in January 2024, Amgen began clawing back Sagebrush's 340B Program savings to keep for itself.[2] To date, Amgen has successfully clawed back at least $7,000,000 in Sagebrush's 340B Program savings.

10. Amgen's unlawful actions caused severe financial harm to Sagebrush and interfered with Sagebrush's provision of patient care.

11. Sagebrush brings this action to recover from such unlawful conduct.

PARTIES

12. At all relevant times, Sagebrush has been and is a nonprofit organized and existing under the laws of the State of Nevada with its principal place of business in Las Vegas, Nevada.

13. Amgen Inc. is organized and exists under the laws of the State of Delaware with its principal place of business in Thousand Oaks, California.

14. The true names and capacities of Defendants DOES 1 through 10 are currently unknown to Sagebrush. Therefore, Sagebrush will seek leave of court to amend this Complaint to allege such names and capacities once they are ascertained through discovery or other means.

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[1] Amgen Inc. v. Becerra, No. 1:24-cv-3571 (D.D.C. Dec. 20, 2024).

[2] Amgen contemporaneously announced its refusal to sell discounted drugs to Sagebrush going forward, in violation of Amgen's obligations under the 340B program. However, this case is limited to California state law claims sounding in contract and tort and in no way seeks to adjudicate Amgen's failure to abide by the strict tenets of the 340B program, including by refusing to sell discounted drugs to Sagebrush, a covered entity.

15. On information and belief, at all relevant times mentioned herein, each defendant, including DOES 1 through 10, was acting as the agent, employee, alter ego, partner, or joint venturer of the other defendants, and was acting within and in furtherance of the purposes and scope of such agency, representation, employment, joint venture, partnership, corporate structure, and/or association, whether actual or ostensible.

JURISDICTION AND VENUE

16. This Court has subject matter jurisdiction over this civil action. This Court has personal jurisdiction over Amgen because Amgen is headquartered in California and conducts substantial business in this state. This Court has personal jurisdiction over DOES 1–10 to the extent they transact business in California or are otherwise subject to this Court's jurisdiction. A substantial portion of the events and omissions giving rise to these claims occurred in or were directed from Ventura County, California.

17. Venue is proper in this Court under Code of Civil Procedure § 395(a) because Amgen maintains its principal place of business in Thousand Oaks, Ventura County, California.

FACTUAL BACKGROUND

The 340B Drug Pricing Program

18. Congress created the 340B Drug Pricing Program ("340B Program"), codified at 42 U.S.C. § 256b, to increase access to medical care and stretch federal resources as far as possible. H.R. Rep. No. 102-384, pt. II, at 12 (1992).

19. Under the 340B Program, drug manufacturers who seek the benefit of selling their products at full price to federal health insurance programs (including Medicare and Medicaid) are required to sell drugs at discounted prices to eligible health care providers, known as "covered entities." Sagebrush is one such covered entity.

20. Participating drug manufacturers are required to sell 340B drugs to each covered entity at or below the price set by a formula that results in a significantly discounted price. 42 U.S.C. § 256b(a)(1). Participating manufacturers enter into an agreement with HHS that, among other things, requires compliance with this statutory "must-offer" duty, including honoring purchases by covered entities and processing chargebacks (effectively reimbursing the drug

purchaser for the difference between the 340B statutory discounted price and the wholesale price) accordingly (titled the Pharmaceutical Pricing Agreement ("PPA")). See 42 U.S.C. § 256b(d)(2)(B)(iv).[3] Executing and complying with the terms of the PPA is a condition of the manufacturer's participation in the Medicare and Medicaid programs. *See* 42 U.S.C. §§ 256b(a)(1); 1396r-8; 1395w-3a.

21. The difference between the 340B Program statutory discounted price and the wholesale acquisition cost (WAC) price is referred to as the covered entity's "savings."

22. Additionally, manufacturers are required to maintain pricing and sales records sufficient to demonstrate compliance with the 340B Program and are subject to audit by HRSA, an agency of HHS. 42 U.S.C. §§ 256b(a)(5)(C), (d)(1)(B)(i). HHS may impose civil monetary penalties for "knowing and intentional" overcharges of items and services reimbursed as part of federally funded health care programs. 42 U.S.C. § 256b(d)(1)(B)(vi); 42 C.F.R. § 10.11.

23. HRSA has sole authority to determine an entity's eligibility for qualification as a covered entity, oversee a certification and recertification process for certain covered entities, conduct audits to ensure compliance with statutory requirements, and terminate entities from the 340B Program. The 340B Program's governing statute details the scope of HRSA's authority to perform each of these actions.

24. One category of covered entity eligible to participate in the 340B Program is an "entity receiving funds . . . through a State or unit of local government" under Section 318 of the Public Health Service Act ("PHSA") "relating to sexually transmitted diseases" (a "Section 318 Subawardee"). 42 U.S.C. § 256b(a)(4)(K). Such an entity may gain access to the 340B Program only after certification of eligibility by HRSA. 42 U.S.C. § 256b(a)(7)(A). HRSA is required to annually recertify the 340B eligibility of a Section 318 Subawardee. 42 U.S.C. § 256b(a)(7)(E).

25. At all times relevant to this litigation, HRSA certified each of Sagebrush's medical clinics in Nevada and Connecticut ("Sites") as "covered entities" because each was a Section 318

[3] *See* King & Spalding on behalf of Amgen, Letter to The Honorable Bill Cassidy, M.D., Ranking Member, Committee on Health, Education, Labor, and Pensions, App. at 136–50 (Oct. 31, 2024), reprinted in Congress Must Act to Bring Needed Reforms to the 340B Drug Pricing Program, S. Comm. on Health, Education, Labor, and Pensions, 119th Cong., Majority Staff Report (Apr. 2025) (Exhibit A, the "King & Spalding Letter").

Subawardee. 42 U.S.C. § 256b(a)(4)(K). Accordingly, at all times relevant to this litigation Sagebrush had the right to purchase certain drugs at discounted prices from participating drug manufacturers, including Amgen.

Horizon

26. Horizon Therapeutics plc ("Horizon") was a global biopharmaceutical company that specialized in medicines treating rare diseases.

27. Horizon manufactured two drugs, Tepezza and Krystexxa, that Sagebrush purchased in limited quantities as they had limited utility within Sagebrush's patient population.

28. Horizon participated in the 340B Program.

Amgen

29. Amgen advertises itself as a global pharmaceutical manufacturer and has a presence in approximately 100 countries. It is one of the 30 companies that comprise the Dow Jones Industrial Average® and is also part of the Nasdaq-100 Index®, which includes the largest non-financial companies listed on the Nasdaq Stock Market based on market capitalization.[4] Amgen's total revenues in fiscal year 2024 were $33.42 billion. Amgen projects 2025 total revenues in the range of $34.3 billion to $35.7 billion.[5]

30. On October 6, 2023 Amgen acquired Horizon.

Sagebrush and its Participation in the 340B Program

31. Sagebrush is a Nevada nonprofit foundation that collaborates with medical clinics in Nevada and Connecticut (each a "Site") to provide essential health services, including to people with infectious diseases and those in underserved communities.

32. At all times relevant to this case, the Sites were duly registered as 340B covered entities and their participation in the 340B program had not been suspended, terminated, or otherwise limited by HRSA. 42 U.S.C. § 256b(a)(4)(K).

33. As such, Sagebrush, on behalf of each of its Sites, is authorized to purchase certain

[4] *See* https://www.amgen.com/about (last visited Dec. 30, 2025).

[5] *See* https://www.amgen.com/newsroom/press-releases/2025/02/amgen-reports-fourth-quarter-and-full-year-2024-financial-results (last visited Dec. 30, 2025).

drugs at significantly reduced prices from participating drug manufacturers, such as Amgen, through wholesalers and others.

34. From June 2022 to September 2022 and again from early 2023 until January 2024, Sagebrush purchased limited quantities of the drug Krystexxa from Horizon through wholesalers. Sagebrush paid the discounted 340B price for these drugs, as required by federal law.

35. From June 2022 to January 2024, Sagebrush purchased $3,500,227 in drugs from Amgen through authorized drug wholesalers. Sagebrush paid the discounted 340B price for these drugs, as required by federal law.

The Role of Wholesalers

36. Sagebrush purchases both 340B drugs and non-340B drugs from drug manufacturers through various drug distributors, including Cencora (formerly AmerisourceBergen) ("Cencora"), Cardinal Health ("Cardinal"), and CuraScript SD ("Cura") (each a "Wholesaler" or collectively the "Wholesalers"). A "chargeback" is a financial transaction where a wholesaler, after selling a 340B-discounted drug to a covered entity at a price lower than what the wholesaler paid the manufacturer, submits a claim to the manufacturer for reimbursement of that price difference. The manufacturer then reimburses the wholesaler, ensuring the covered entity receives the drug at the correct 340B price.

37. Sagebrush's orders are charged against credit lines that it maintains with each Wholesaler. Sagebrush makes regular payments on outstanding invoices so as to not exceed its credit limit because failing to do so impacts its ability to make future drug orders.

38. Sagebrush has valid and binding contracts with each of the Wholesalers for the sale of drugs to Sagebrush and its patients. Sagebrush routes all of its orders for pharmaceuticals through the Wholesalers regardless of whether the orders are for 340B or non-340B drugs. Sagebrush maintains lines of credit with each Wholesaler and all orders placed by Sagebrush are charged against these credit lines. Sagebrush's lines of credit vary depending on the Wholesaler.

39. The covered entities purchase drugs from wholesalers at the discounted 340B price. Wholesalers typically buy drugs from manufacturers at the Wholesale Acquisition Cost ("WAC") price (which is the non-340B price). When a covered entity orders a drug at the 340B price, the

wholesaler sells it to the covered entity at the discounted rate, which is lower than the price the wholesaler paid the manufacturer. To recover the difference, the wholesaler submits a chargeback to the manufacturer for the delta between the WAC price and the 340B discounted price. The manufacturer reimburses the wholesaler for this difference, ensuring the covered entity receives the drug at the correct 340B price. The amount reimbursed constitutes the chargeback.

40. Amgen is well aware of this process and the contracts between Sagebrush and its Wholesalers as Amgen never sold 340B-priced drugs directly to Sagebrush. Rather, at all times relevant to this case, a wholesaler (e.g., Cura, Cencora, or Cardinal) placed orders with Amgen on behalf of Sagebrush using Sagebrush's unique 340B identifier.

41. Prior to Amgen's implementation of the chargeback reversals, Sagebrush consistently maintained its lines of credit in good standing with the Wholesalers through regular payments so as to not exceed its credit limits. Exceeding the limits would impact Sagebrush's ability to obtain drugs for its patients - 340B-eligible and otherwise.

42. From June 2022 to January 2024, Sagebrush purchased 340B drugs from Horizon and Amgen through the Wholesalers. These drugs had a wholesale acquisition cost (WAC or "non-340B price") of approximately $10.6 million, while Sagebrush paid the statutorily mandated 340B discounted price of approximately $3.5 million. The difference between the WAC price and the 340B price for Amgen drugs was at least $7,000,000 in Sagebrush's "savings." Sagebrush reinvested this amount in its operations and sexual healthcare programming for qualified patients as required by federal law.

Mandatory ADR Procedure For Disputes Arising Under the 340B Program

43. Disputes arising under the 340B Program are subject to a mandatory administrative dispute resolution ("ADR") process. 42 U.S.C. § 256b(d)(3); 89 Fed. Reg. 28,643 (Apr. 19, 2024).

44. The 340B statute and HRSA regulations establish specific remedies available to manufacturers: (1) request and conduct a HRSA-approved audit upon reasonable cause; and (2) if a dispute remains, invoke the ADR process. *See* 42 U.S.C. § 256b(d)(3); Manufacturer Audit Guidelines and Requirements, 61 Fed. Reg. 65,406, 65,408–10 (Dec. 12, 1996); Final Rule on Administrative Dispute Resolution Process, 89 Fed. Reg. 28,643, 28,645 (Apr. 19, 2024). *See also*

Ex. A, King & Spalding Letter, App. 143–47.

45. As Amgen has acknowledged, the rationale is plain: "the 340B program is not designed to permit even this modest level of manufacturer oversight." *See* Ex. A, King & Spalding Letter, App. 143–44.

46. At no time did Amgen (or Horizon, prior to its acquisition by Amgen) initiate the mandatory ADR process with respect to Sagebrush.

Amgen's Unlawful Clawbacks

47. In late 2022, Horizon for the first time informed Sagebrush that Horizon disagreed with HRSA's determination of Sagebrush's covered entity status. Of course, the 340B Program vests in participating drug manufacturers no authority to determine whether a healthcare provider participating as a "covered entity" in the 340B Program appropriately qualifies for such status.

48. As part of this same series of communications, Horizon further decreed that Sagebrush would no longer be permitted to access Horizon drugs at 340B-discounted pricing. This unilateral declaration violated its PPA and 42 U.S.C. § 256b(a)(1).

49. Tellingly, Horizon circumvented the federally mandated procedures for initiating a dispute regarding implementation of the 340B Program.

50. As such, from September 2022 through December 2022 Sagebrush was unable to purchase drugs from Horizon at 340B Program prices through Cura, the only Wholesaler who was then selling Horizon's drugs to Sagebrush.

51. In early 2023, Sagebrush regained access to Horizon drugs at 340B prices through different wholesalers, Cardinal and Cencora.

52. Following Amgen's October 2023 acquisition of Horizon, in or about January 2024 Amgen unilaterally ceased honoring Sagebrush's 340B covered entity status by (1) refusing to sell both legacy Horizon and Amgen 340B discounted drugs to Sagebrush going forward[6] and (2) reaching through the Wholesalers to claw back at least $7,000,000 in savings that Sagebrush had properly realized on both Horizon and Amgen 340B drug purchases made during 2022–2024.

[6] This lawsuit does not seek to address Amgen's violations of its 340B Program obligations and is limited to seeking compensation for Amgen's unlawful taking of at least $7,000,000 from Sagebrush.

53. Not once prior to this unlawful taking had Amgen initiated mandatory 340B Program ADR measures contesting Sagebrush's covered entity status.

54. Not once prior to this unlawful taking had Amgen notified Sagebrush in any way that it disputed Sagebrush's covered entity status.

55. Rather, after its acquisition of Horizon, Amgen adopted Horizon's historical position, contrary to law, that Sagebrush was not a properly designated covered entity.

56. Amgen knowingly used Horizon's dated communications contesting Sagebrush's covered entity designation, despite their inaccuracy and legal insignificance, as a lever against the Wholesalers to recoup for itself Sagebrush's savings from both Horizon and Amgen drugs. Amgen did so by reversing the chargebacks and reissuing dozens of invoices ("Rebills") charging Sagebrush the WAC price for orders that Sagebrush made for both Horizon and Amgen drugs at 340B prices dating back over a year.

57. Amgen's refusal to sell at 340B pricing and its clawing back of at least $7,000,000 in chargebacks from the Wholesalers to reverse previously honored 340B transactions - all while itself enjoying the benefit selling its drugs at full price to federal health insurance programs - constitute violations of the PPA's must-offer obligation and 42 U.S.C. § 256b. *See* Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed. Reg. 65,406, 65,408 (Dec. 12, 1996) ("[n]ot until the entity is found guilty of prohibited activity and a decision is made to remove the entity from the covered entity list, will the manufacturers no longer be required to extend the discount.").

58. In sum, Amgen clawed back through the Wholesalers at least $7,000,000 in Sagebrush savings via unexpected and unauthorized chargeback reversals for 340B drugs purchased during the period 2022–2024 from both Horizon and Amgen.

59. Roughly half of the rebilled amounts were from historical Horizon drug purchases while the other half were from Amgen drug purchases.

60. Amgen's unlawful conduct snowballed from there: since Sagebrush was suddenly operating at a huge deficit with each of the Wholesalers due to the clawbacks, the Wholesalers placed holds on all Sagebrush orders, refusing to sell Sagebrush any drugs, regardless of

manufacturer, until the chargeback reversal amounts were paid or payment plans established, and also reduced Sagebrush's credit lines. The Wholesalers also demanded aggressive repayment terms from Sagebrush to the extent permitted by their contracts.

61. For example, Sagebrush was forced to make the reversal payments in addition to regular payments on its existing lines of credit as well as a $56,500 interest payment to Cardinal. Sagebrush found itself in the untenable position of being unable to supply any of its Sites with any drugs from any of the Wholesalers until the credit lines were re-established by fully repaying the reversal amounts or entering into payment plans to fully repay the reversal amounts.

62. In fact, Sagebrush was forced to return some of the Amgen drugs not yet dispensed to its patients so as to reduce the now staggeringly high debit balance it held with the Wholesalers.

63. These actions were the direct result of Amgen's unilateral refusal to honor 340B pricing and chargeback processing, in violation of 42 U.S.C. § 256b(a)(1) and Business and Professions Code § 17200 et seq.

64. Amgen's refusal to honor the covered entity status of Sagebrush's registered Sites and its direction to the Wholesalers to seek the unlawful repayments from Sagebrush caused Sagebrush financial harm, intentionally and wrongfully disrupted, interfered with, and substantially impaired Sagebrush's contractual relationships with the Wholesalers, materially increased the cost of the Sagebrush Program, and interfered with Sagebrush's ability to service its patients.

Amgen's Failure To Request an Audit or Request ADR

65. At no point did Amgen (or Horizon) initiate or complete a HRSA-approved manufacturer audit of Sagebrush, nor did Amgen (or Horizon) file an ADR petition as required by law. *See* 42 U.S.C. § 256b(d)(3); 89 Fed. Reg. 28,643 (Apr. 19, 2024); *see also* Ex. A, King & Spalding Letter, App. 143–47. In fact, Sagebrush did not learn of Amgen's determination until after the Wholesalers began issuing Rebills.

66. Instead, Amgen suspended Sagebrush's 340B pricing and orchestrated Rebills—all while admitting publicly that manufacturers have limited authority and that the audit process or ADR are the prescribed pathways for disputes. *See* Ex. A, King & Spalding Letter. This violates the PPA and the 340B statute. Amgen's unilateral withholding of 340B pricing and direction to

reverse chargebacks, absent HRSA action, constitutes self-help contrary to the 340B Program statutory framework.

67. Amgen's conduct is not excused by its disagreement with Sagebrush's eligibility. Eligibility determinations rest exclusively with HRSA, not drug manufacturers. *See* 42 U.S.C. § 256b(a)(7), (d)(2)(B)(iv); *see also* Ex. A, King & Spalding Letter, App. 143–44. Amgen's PPA does not permit self-help suspensions of 340B pricing to an approved covered entity.

68. But Sagebrush is not suing Amgen here for its multiple violations of federal law governing the 340B Program or to adjudicate Sagebrush's 340B covered entity eligibility.

69. Rather, Sagebrush is suing Amgen for the damage it caused by wrongfully taking Sagebrush's millions in 340B savings and keeping it for its own profits.

Amgen's Admissions Confirm It Lacked Authority and Failed to Use the Statutory Pathway

70. In the King & Spalding Letter to the HELP Committee, Amgen laments:

- "Amgen does what it can," but "the 340B program is not designed to permit even [a] modest level of manufacturer oversight," and HRSA limits manufacturer audits and data access. App. 144–45.
- Amgen claims that manufacturers "are not equipped or permitted to police compliance" and that "the audit process is expensive, time-consuming, and often ineffective." App. 146, 149.
- Amgen admitted that it "*has not undertaken an internal audit specific to the company's participation in [the] 340B program in the past five years*." App. 149 (emphasis added).

71. These admissions confirm that Amgen lacks independent authority to adjudicate covered entity status, lacks a unilateral pathway to deny sales to covered entities, and must utilize HRSA's audit and ADR processes when Amgen has unresolved concerns regarding covered entities. Amgen knew HRSA's audit and ADR processes were the only lawful pathway to resolving any disputes. Amgen did not use them, thereby violating the law.

72. As a result, Sagebrush has suffered tremendous direct and proximate harm, only

beginning with the over $7,000,000 Amgen wrongfully clawed back for its own benefit. Amgen's conduct has also caused substantial and concrete harm to Sagebrush's business operations and patient care capabilities. Namely, the restrictions on Sagebrush's ability to utilize its lines of credit with the Wholesalers have impaired Sagebrush's ability to purchase drugs necessary to keep its clinics fully stocked. And Sagebrush was forced to return some previously purchased Amgen drugs to further mitigate the amounts it had to repay the Wholesalers. Additionally, Sagebrush relied on its 340B drug savings to fund its programming. As a result of Amgen's conduct and on information and belief, Sagebrush has been forced to reduce its patient treatment capacity compared to previous levels. Sagebrush hereby seeks recompense for all damages suffered due to Amgen's wrongful conduct.

FIRST CAUSE OF ACTION

CONVERSION

(Against all Defendants)

73. Sagebrush incorporates the allegations set forth in all Paragraphs of this Complaint as if fully set forth herein.

74. Sagebrush's Sites each qualified as a covered entity during 2022–2024. HRSA had not taken any adverse action depriving the Sites of their covered entity status during this period. Therefore, Sagebrush was legally entitled to purchase 340B drugs from participating manufacturers at 340B prices. As a direct result of these legitimate 340B purchases, Sagebrush had a right to possess and retain at least $7,000,000 in savings realized from its participation in the 340B Program.

75. Amgen's contention regarding Sagebrush's ineligibility to participate in the 340B Program is legally irrelevant; it contravenes the 340B statute, the PPA, and HRSA's requirements, as HRSA is the sole authority for such determinations.

76. Amgen's demand to the Wholesalers to reverse legitimate historical 340B chargebacks and re-invoice ("Rebill") transactions at WAC resulted in an unauthorized assumption and exercise of dominion over Sagebrush's property, specifically its entitled 340B savings, in violation of California law.

77. Amgen's actions constituted substantial interference with Sagebrush's property rights. As a direct result of Amgen's wrongful acts, Sagebrush has been deprived of its legal right to dominion and control over at least $7,000,000.

78. Amgen intended to deprive Sagebrush of these rightful savings and to unlawfully reclaim at least $7,000,000. Amgen is a longtime participant in the 340B program and well aware of both its must-offer obligations and mandatory dispute resolution mechanisms. Amgen intentionally did not honor the former, while at no point availing itself of the latter.

79. Amgen's intentional acts caused Sagebrush at least $7,000,000 in damages from Amgen's wrongful taking of Sagebrush's 340B savings. Amgen's conduct as described herein was malicious, oppressive, and/or fraudulent within the meaning of Civil Code § 3294, which warrants the imposition of punitive damages against Amgen in addition to the foregoing relief requested.

SECOND CAUSE OF ACTION

INTENTIONAL INTERFERENCE WITH CONTRACT

Against all Defendants

80. Sagebrush incorporates the allegations set forth in all Paragraphs of this Complaint as if fully set forth herein.

81. Sagebrush entered into valid and binding agreements with each of the Wholesalers for the provision of drugs to Sagebrush and its patients, which included terms for purchasing 340B-eligible drugs at discounted prices from various manufacturers, such as Amgen. Amgen is a manufacturer and vendor of pharmaceutical products supplied to the Wholesalers and therefore had knowledge of the ongoing contractual relationships between Sagebrush and each of the Wholesalers, including their obligation to process 340B orders.

82. Amgen was also aware that Sagebrush's Sites were, at all relevant times, recognized as covered entities under the 340B Program by HRSA. Amgen lacked any legal authority to terminate Sagebrush's right to purchase Amgen drugs at 340B prices, nor to direct the Wholesalers to reverse legitimate chargebacks and claim the unlawful reversal amounts from Sagebrush.

83. Amgen's views on Sagebrush Sites' 340B status are legally irrelevant; only HRSA possesses the authority to make such determinations. Amgen's actions, therefore, constitute an

impermissible self-help measure, directly violating the 340B statute, the applicable PPA, and HRSA's regulations.

84. Amgen engaged in intentional acts designed to disrupt the contractual relationship between Sagebrush and the Wholesalers, without privilege or justification, by instructing them to immediately obtain repayment of its unlawful chargeback reversals. Due to the volume and timing of Amgen's Rebill orders, Sagebrush was forced to operate under narrow measures deployed by the Wholesalers. These measures included holds on all Sagebrush orders, refusing to sell Sagebrush any drugs regardless of manufacturer until Amgen's unlawful reversal amounts were paid, and reducing Sagebrush's credit limits, all intended to force Sagebrush to pay the reversal amounts.

85. Because Amgen demanded immediate repayment of these unwarranted reversals, Sagebrush was forced to make substantial payments in a short timeframe. As a result, Sagebrush paid Cardinal $56,500 in interest on the outstanding reversal amounts, an expense it would not have otherwise incurred but for Amgen's actions. Amgen's coercive actions materially impaired Sagebrush's ability to purchase drugs necessary to maintain its required inventory (from Amgen and other drug manufacturers) and rendered Sagebrush's performance under its agreements with the Wholesalers with respect to all drug manufacturers significantly more expensive and burdensome.

86. Sagebrush has been damaged by Amgen's actions described herein in an amount according to proof at trial.

87. Amgen's conduct as described herein was malicious, oppressive, and/or fraudulent within the meaning of Civil Code § 3294, warranting the imposition of punitive damages against Amgen in addition to compensatory damages.

THIRD CAUSE OF ACTION

INTENTIONAL INTERFERENCE WITH PROSPECTIVE ECONOMIC ADVANTAGE

(Against all Defendants)

88. Sagebrush incorporates the allegations set forth in all Paragraphs of this Complaint as if fully set forth herein.

89. Sagebrush's patients originate from predominantly underserved populations. By

participating in the 340B Program, Sagebrush has provided affordable access to prevention and treatment medications for its patients. Many patients would not be able to afford medications critical for their health without the 340B Program. The entire *raison d'être* of the 340B Program is to support covered entities as they support their underserved and financially disadvantaged patients.

90. Amgen did not have the right to unilaterally terminate Sagebrush's right to purchase Amgen drugs at 340B prices or to reach through the Wholesalers to claim the payments from the unlawful chargeback reversals. Amgen's contention that Sagebrush was ineligible to participate in the 340B Program is irrelevant: only HRSA gets to decide who is a covered entity, and at all relevant times, Sagebrush was a covered entity. Amgen's self-important position contravenes federal 340B statutory and regulatory requirements, the PPA, and HRSA's regulations.

91. Amgen knew or should have known that its implementation of the chargeback reversals and suspension of 340B pricing would substantially disrupt Sagebrush's economic relationships and cause significant economic hardship. Amgen knew and understood that its conduct would hinder Sagebrush's ability to purchase sufficient drugs to fully stock its Sites (both from Amgen and other drug manufacturers), force Sagebrush to return existing inventory of drugs to reduce its expenses, and disrupt Sagebrush's ability to effectively treat its predominantly low-income patients.

92. Amgen's intentional acts have caused a disruption in Sagebrush's economic relationship with its patients, when Amgen knew its actions would disrupt these relationships. As a direct result of Amgen's conduct, Sagebrush has been unable to treat as many of its patients as in the years prior, causing economic harm to Sagebrush. Sagebrush has been damaged by Amgen's actions described herein in an amount to be proven at trial. Amgen's conduct as described herein was malicious, oppressive, and/or fraudulent as defined by Civil Code § 3294, which warrants the imposition of punitive damages against Amgen in addition to the foregoing relief requested.

FOURTH CAUSE OF ACTION

VIOLATION OF PENAL CODE § 496

(Against all Defendants)

93. Sagebrush incorporates the allegations set forth in all Paragraphs of this Complaint as if fully set forth herein.

94. Sagebrush's Sites each qualified as a covered entity during 2022–2024. HRSA had not taken any adverse action depriving the Sites of their covered entity status during this time. Therefore, Sagebrush was entitled to purchase 340B drugs at 340B prices from manufacturers participating in the 340B Program pursuant to 42 U.S.C. § 256b. Sagebrush had a legal right to retain the savings realized from its participation in the 340B Program to fund its operations and the Sagebrush Program.

95. A longtime and active participant in the 340B Program, as well as being a multi-billion-dollar global pharmaceutical company, Amgen was well aware that it had no authority to reclaim Sagebrush's savings in 340B Program savings from its purchase of Horizon and Amgen drugs.

96. Rather, Amgen's contention (piggy-backing off of Horizon's years-prior letter writing campaign) that Sagebrush was ineligible to participate in the 340B Program is mere subterfuge and contravenes the 340B statute, the PPA, and HRSA guidelines. In fact, Horizon and Amgen benefited from selling its drugs to federal insurance programs at full price without bearing any burden of selling its drugs to Sagebrush, a covered entity, at a reduced price. Amgen's behavior intentionally avoids a central tenet of the 340B Program – to encourage large drug manufacturers to sell their necessary products to healthcare providers serving under-served communities who might not have access to critical medicines but for the negotiated rates the drug manufacturers are required to offer.

97. Particularly egregious here, and contrary to the 340B Program's mission, is Amgen's greedy reclamation of Sagebrush's savings from both historical Horizon 340B drug purchases as well as historical Amgen 340B drug purchases.

98. In sum, Amgen wrongfully and intentionally obtained and retained at least

$7,000,000 through conduct constituting theft as defined by California Penal Code § 496.

99. Amgen knowingly and intentionally reached through the Wholesalers to undertake coercive measures, without legal justification or authority, to force Sagebrush to pay the reversal amounts (from both Horizon and Amgen purchases), including by placing holds on all Sagebrush orders, refusing to sell Sagebrush any drugs regardless of manufacturer until Amgen's unlawful reversal amounts were paid, and reducing Sagebrush's credit limit. Amgen's actions also caused Sagebrush to be charged $56,500 in interest by Cardinal on the unlawful reversal amounts, causing further monetary harm.

100. Amgen had actual knowledge that it lacked any legal right to unilaterally take back at least $7,000,000 from Sagebrush on behalf of itself or Horizon, as HRSA had not terminated the Sites' covered entity status and HRSA retained sole authority over such determinations. As a 340B Program participant, Sagebrush was entitled to retain the savings, not Amgen. Amgen acted knowingly and intentionally in receiving and retaining property obtained from Sagebrush in the manner described, within the meaning of Penal Code § 496.

101. Sagebrush has been damaged by Amgen's actions described herein in an amount to be proven at trial. Sagebrush is entitled to and requests mandatory treble damages pursuant to Penal Code § 496(c), as Amgen's conduct constitutes theft under California law. Amgen's conduct as described herein was malicious, oppressive, and/or fraudulent as defined by Civil Code § 3294, which warrants the imposition of punitive damages against Amgen in addition to the foregoing relief requested.

FIFTH CAUSE OF ACTION

VIOLATION OF BUSINESS & PROFESSIONS CODE § 17200

(Against all Defendants)

102. Sagebrush incorporates the allegations set forth in all Paragraphs of this Complaint as if fully set forth herein.

103. California Business & Professions Code § 17200 (the "UCL") prohibits any "unlawful," "unfair," or "fraudulent" business practices. Amgen's conduct constitutes unlawful and unfair competition under the UCL, causing substantial injury to Sagebrush's business that could

not reasonably have been avoided, and which is not outweighed by countervailing benefits to consumers or competition, in violation of the UCL.

104. Amgen violated the "unfair" prong of the UCL by implementing a systematic scheme to coerce the Wholesalers into demanding chargeback reversal payments from both historical Horizon and Amgen 340B drug purchases, which practice: (1) violates established public policy as embodied in the 340B statute; (2) is immoral, unethical, and oppressive; and (3) is substantially injurious to covered entities like Sagebrush who are legally entitled to 340B Program savings. Amgen directed the Wholesalers to undertake coercive measures to force Sagebrush to pay the reversal amounts despite knowing Sagebrush was entitled to at least $7,000,000 in savings as a covered entity.

105. Amgen violated the "unlawful" prong of the UCL because its wrongful taking of at least $7,000,000 from Sagebrush constituted conversion and violated Penal Code § 496. Amgen knew that Sagebrush was entitled to keep its savings because its Sites had covered entity status at all relevant times. Nevertheless, Amgen orchestrated coercive action to force Sagebrush to pay the unlawful reversal amounts. Amgen wrongfully obtained and retained Sagebrush's savings.

106. Because of Amgen's wrongful acts as alleged in this Complaint, Sagebrush has suffered and will suffer economic injury in the form of monetary damages, including money paid to Amgen's wholesalers at Amgen's direction. As a direct, proximate, and foreseeable result of Amgen's wrongful conduct, Amgen has been and will continue to be unjustly enriched through its unfair competition in violation of Business & Professions Code § 17200 et seq., in an amount to be proven at trial.

PRAYER FOR RELIEF

WHEREFORE, Sagebrush prays for judgment against Amgen as follows:

1. Restitution in an amount to be proven at trial, but not less than Seven Million Dollars ($7,000,000), reflecting the sum of: (a) all amounts paid to the Wholesalers for Amgen's chargeback reversals, and (b) the interest Sagebrush paid to Cardinal due to the reversal amounts, together with prejudgment interest as provided by law.

2. An award of compensatory damages in an amount to be determined at trial, but not less than Seven Million Dollars ($7,000,000), comprising: (a) the amount paid to the Wholesalers for Amgen's chargeback reversals, and (b) the interest Sagebrush paid to Cardinal on the reversal amounts.
3. An order that such compensatory damages be trebled pursuant to Penal Code § 496(c).
4. An award for Sagebrush's reasonable attorneys' fees and costs of suit pursuant to Penal Code § 496(c) and, to the extent applicable, Code of Civil Procedure § 1021.5 and any other applicable fee-shifting provision.
5. Declaratory relief pursuant to Code of Civil Procedure § 1060 declaring that: (a) Amgen's refusal to sell 340B drugs to Sagebrush at or below the 340B discount price while Sagebrush was listed in OPAIS violates Amgen's PPA and 42 U.S.C. § 256b(a)(1); and (b) Amgen may not direct wholesalers to reverse prior chargebacks or otherwise demand repayment or refuse to extend 340B pricing to Sagebrush absent a HRSA-approved audit finding and removal from OPAIS, or final resolution through HRSA's ADR process.
6. Preliminary and permanent injunctive relief pursuant to Code of Civil Procedure § 526, enjoining Amgen, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with them, from directing wholesalers to reverse chargebacks or otherwise demand repayment related to Sagebrush's 340B purchases absent a final determination by HRSA or final resolution through applicable administrative remedies, and requiring Amgen to honor 340B pricing and chargeback processing consistent with 42 U.S.C. § 256b and 61 Fed. Reg. 65,406 (Dec. 12, 1996).
7. For such other and further relief as the Court may deem just and proper.

Dated: December 30, 2025

Respectfully submitted,

ARENTFOX SCHIFF LLP

By: 

Kirsten A. Hart
Douglas A. Grimm
Attorneys for Plaintiff
SAGEBRUSH HEALTH SERVICES

JURY DEMAND

Sagebrush demands a trial by jury of all issues so triable.

Dated: December 30, 2025

ARENTFOX SCHIFF LLP

By: 

Kirsten A. Hart
Douglas A. Grimm
Attorneys for Plaintiff
SAGEBRUSH HEALTH SERVICES

EXHIBIT A

KING & SPALDING

King & Spalding LLP
1700 Pennsylvania Ave NW
Suite 900
Washington, DC 20006
Tel: +1 202 737 0500
Fax: +1 202 626 3737
www.kslaw.com

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.

<u>Request 6:</u> 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.

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[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).