

SETTLEMENT AGREEMENT

This Settlement Agreement (“Agreement”) is entered into among: (a) the United States of America, acting through the United States Department of Justice and on behalf of the Department of Health and Human Services, Office of Inspector General (“HHS-OIG”) (collectively, “United States”); (b) the State of California, acting through the California Department of Justice, Office of the Attorney General, Division of Medi-Cal Fraud and Elder Abuse, and through the California Department of Health Care Services (“DHCS”) (collectively, “California”) (the United States and California are collectively referred to as “the Governments”); and (c) Pomona Valley Hospital Medical Center (“Pomona Valley”) (hereinafter the United States, California, and Pomona Valley are collectively referred to as “the Parties” and each is a “Party”) through their authorized representatives.

RECITALS

A. Pomona Valley is a general acute care hospital that participates in the California Medicaid program (“Medi-Cal”), wherein it provides Medi-Cal patients with outpatient prescription drugs. Pomona Valley purchases drugs under the federal 340B Drug Pricing Program (“340B Program”), pursuant to California Welfare and Institutions Code § 14105.46.

B. Prior to 2009, Medi-Cal generally reimbursed 340B Program providers, including Pomona Valley, for outpatient drugs provided to a Medi-Cal beneficiary at the lower of the provider’s “usual and customary” (“U&C”) rates or rates established by DHCS. That year, California enacted a statute requiring 340B Program providers to submit claims for drugs they dispensed at rates not to exceed the covered entity’s “actual acquisition cost” (“AAC”). *See* California Welfare and Institutions Code § 14105.46.

C. Following its enactment in 2009, the statute was challenged on multiple grounds, including that Medi-Cal had not received approval from the federal Centers for Medicare & Medicaid Services for the change in the billing requirement and associated reimbursement. Although the United States District Court for the Central District of California preliminarily issued an injunction preventing implementation of the AAC requirement, that injunction was later vacated by the United States Court of Appeals for the Ninth Circuit, effective December 1, 2016. *See AHF v. Douglas*, Nos. 14-56333, 14-56368 (9th Cir. 2016).

D. Pomona Valley, however, continued to bill Medi-Cal for outpatient prescription drugs at U&C rates, rather than AAC rates. The use of U&C rates resulted in higher reimbursement to Pomona Valley than if it had billed Medi-Cal using AAC rates.

E. By letter dated August 17, 2021, Pomona Valley submitted a voluntary self-disclosure report to HHS-OIG regarding Pomona Valley's billing practice under the 340B Program. By e-mail dated April 26, 2023, Pomona Valley supplemented this disclosure with additional information.

F. Pomona Valley's voluntary self-disclosure revealed, among other things, the following (hereinafter referred to as "the Covered Conduct"):

From December 1, 2016 through September 7, 2021, Pomona Valley improperly billed Medi-Cal by charging higher U&C prices, rather than the lower AAC that was required, for drugs purchased by Pomona Valley under the 340B Program and reimbursed by Medi-Cal. During this time period, the amount of Pomona Valley's overcharge was \$1,399,789.

G. As noted, Pomona Valley voluntarily self-disclosed the Covered Conduct to the

United States. Pomona Valley furthermore has cooperated fully with the Governments' investigation.

H. This Agreement is neither an admission of liability or wrongdoing by Pomona Valley nor a concession by the Governments that their claims are not well founded.

I. To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the foregoing dispute, and in consideration of the mutual promises and obligations of this Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Payment to the Governments. Not later than the later of either December 31, 2023 or ten (10) calendar days after the Effective Date of this Agreement (as defined in paragraph 24 of this Agreement), Pomona Valley shall pay the Governments \$2,099,684 ("Settlement Amount"): (a) \$873,730 to the United States by electronic funds transfer pursuant to written instructions to be provided by the United States Attorney for the Central District of California (\$582,486 of this amount is restitution); and (b) \$1,225,954 to California pursuant to written instructions to be provided by the California Attorney General's Office (\$817,303 of this amount is restitution).

2. The Governments' Releases of Pomona Valley

a. Release of Pomona Valley by the United States. Subject to the exceptions in Paragraph 4 (concerning excluded claims) below, and conditioned upon Pomona Valley's full payment of the Settlement Amount, the United States releases Pomona Valley and its current and former subsidiaries and parents, successors and assigns from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. § 3729-3733, both pre-amendment and as amended by the Fraud Enforcement and

Recovery Act of 2009, Pub. L. 111-21, 123 Stat. 1617 (2009); the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. § 3801-3812; or the common law theories of payment by mistake, unjust enrichment, and fraud.

b. Release of Pomona Valley by California. Subject to the exceptions in Paragraph 4 (concerning excluded claims) below, and conditioned upon Pomona Valley's full payment of the Settlement Amount, California releases Pomona Valley and its current and former subsidiaries and parents, successors and assigns from any civil or administrative monetary claim California has for the Covered Conduct under the California False Claims Act, Cal. Government Code §§ 12650-12656; or the common law theories of payment by mistake, unjust enrichment, and fraud.

3. Administrative Actions

a. HHS-OIG. In consideration of the obligations of Pomona Valley in this Agreement, and conditioned upon Pomona Valley's full payment of the Settlement Amount, HHS-OIG agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Pomona Valley under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in this Paragraph and in Paragraph 4 (concerning excluded claims), below. HHS-OIG expressly reserves all rights to comply with any statutory obligations to exclude Pomona Valley from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes

HHS-OIG from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 4, below.

b. California. In consideration of the obligations of Pomona Valley in this Agreement and Pomona Valley's full payment of the Settlement Amount, California agrees to release Pomona Valley from, and to refrain from instituting, directing, or maintaining against Pomona Valley, any administrative action seeking permissive exclusion from Medi-Cal for the Covered Conduct. California expressly reserves all rights to comply with any mandatory statutory obligations to suspend or exclude Pomona Valley from Medi-Cal or any other program based upon the Covered Conduct.

4. Exceptions to the Governments' Releases. Notwithstanding the releases given in this Agreement, or any other term of this Agreement, the following claims of the Governments are specifically reserved and are not released:

- a. Any liability arising under Title 26, U.S. Code ("Internal Revenue Code") or under California's Taxation and Revenue Code;
- b. Any criminal liability;
- c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from federal or state health care programs;
- d. Any liability to the United States (or its agencies) or to California (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon obligations created by this Agreement;
- f. Any liability for express or implied warranty claims or other claims for

defective or deficient products or services, including quality of goods and services;

g. Any liability for failure to deliver goods or services due;

h. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct; and

i. Any liability of individuals.

5. Release of the Governments by Pomona Valley. Pomona Valley fully and finally releases the Governments and their respective agencies, officers, agents, employees, and servants from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Pomona Valley has asserted, could have asserted, or may assert in the future against the Governments and their respective agencies, officers, agents, employees, and servants related to, or arising out of, the Covered Conduct, the Governments' review of the Covered Conduct, and any ensuing civil prosecution.

6. Double Jeopardy and Excessive Fines Clauses. Pomona Valley waives and shall not assert any defenses it may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the United States Constitution, the Excessive Fines Clause in the Eighth Amendment of the United States Constitution, or under Article 1, §§ 15 and 24 of the California Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

7. No Characterization of Settlement Amount for the Purpose of Internal Revenue Laws. Nothing in this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of

the U.S. Code.

8. Denial of Claims. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare carrier or intermediary or Medi-Cal, related to the Covered Conduct; and Pomona Valley agrees not to resubmit to any Medicare carrier or intermediary or Medi-Cal any previously denied claims related to the Covered Conduct, agrees not to appeal any such denials of claims, and agrees to withdraw any such pending appeals.

9. Dispensing Fees. In computing the overpayment amount that resulted in the Settlement Payment, Pomona Valley included professional dispensing fees in the aggregate amount of \$145,464.05, thereby reducing the overpayment amount by this sum. In the event DHCS wishes to dispute the allowability of a professional dispensing fee to Pomona Valley in connection with the Covered Conduct, DHCS may issue a demand for repayment of all or part of the aggregate professional dispensing fee. DHCS will use its best efforts to deliver any such demand for payment within six months of the execution of this Agreement. Pomona Valley shall have the right to appeal any such repayment demand pursuant to the provider audit appeal process set forth in Article 1.5 of Title 22 of the California Code of Regulations.

10. Nothing in this Settlement Agreement shall be construed as preventing DHCS from auditing Pomona's cost reports and disallowing costs DHCS determines are not allowable under the applicable cost reimbursement principles.

11. Benefit of the Parties. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in the Paragraph immediately below (waiver for beneficiaries).

12. Waiver for Health Care Beneficiaries. Pomona Valley agrees that it shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

13. Financial Condition. Pomona Valley warrants that it has reviewed its financial situation and that it currently is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I) and shall remain solvent following payment to the Governments of the Settlement Amount. Further, the Parties warrant that, in evaluating whether to execute this Agreement, they (a) have intended that the mutual promises, covenants, and obligations set forth constitute a contemporaneous exchange for new value given to Pomona Valley, within the meaning of 11 U.S.C. § 547(c)(1), and (b) conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which Pomona Valley was or became indebted to on or after the date of this transfer, within the meaning of 11 U.S.C. § 548(a)(1).

14. Costs. Each Party shall bear its own legal and other costs, fees, and expenses incurred in connection with this matter, including the preparation and performance of this Agreement.

15. Voluntary Agreement. Each Party and signatory to this Agreement represents that it and she/he freely, voluntarily, knowingly, and deliberately enters into this Agreement without any degree of duress, compulsion, or misconduct by any of the Parties.

16. Governing Law. This Agreement is governed by the laws of the United States.

The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the Central District of California.

17. Complete Agreement. This Agreement constitutes the entire agreement of the Parties with respect to the subject matter of this Agreement and may not be modified, amended, or terminated except by a written agreement signed by the Parties specifically referring to this Agreement and its relevant portions. Each of the Parties acknowledges that, except as expressly set forth in this Agreement, no representations of any kind or character have been made by any other party or that party's agents, representatives, or attorneys to induce execution or delivery of this Agreement.

18. Agreement Drafted by All Parties. This Agreement shall be deemed to have been drafted by all Parties to this Agreement and therefore shall not be construed against any Party for reasons of drafting.

19. Pomona Valley's Successors. This Agreement is binding on Pomona Valley's successors, transferees, and assigns.

20. Disclosure. All Parties consent to the Governments' disclosure of this Agreement, and information about this Agreement, to the public.

21. Headings. The headings in this Agreement are for convenience only, do not constitute a part of this Agreement, and shall not limit or affect any of its provisions.

22. Capacity to Execute. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below. Each signatory represents that he or she has the full power, authority, and competence necessary to enter into this Agreement.


23. Counterparts and Facsimiles. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement. Facsimiles and electronic versions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

24. Effective Date. This Agreement is effective on the date of signature of the last signatory to the Agreement (“Effective Date of this Agreement”).

In Witness Whereof, the Parties, through their duly authorized representatives, hereunder set their hands.

THE UNITED STATES OF AMERICA

DATED: January 19, 2024

BY: 

JACK D. ROSS
Assistant United States Attorney
Deputy Chief, Civil Fraud Section
Central District of California

DATED: _____

BY: _____
Susan E. Gillin
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human
Services

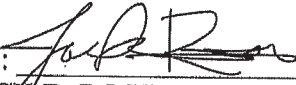
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THE UNITED STATES OF AMERICA

DATED: January 19, 2024

BY: 

JACK D. ROSS
Assistant United States Attorney
Deputy Chief, Civil Fraud Section
Central District of California

DATED: _____


BY: **SUSAN GILLIN**

Susan E. Gillin
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human
Services

Digitally signed by SUSAN
GILLIN
Date: 2024.01.25 11:49:41
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THE STATE OF CALIFORNIA

DATED: 1/22/2024

BY: 
NICHOLAS N. PAUL
Senior Assistant Attorney General
California Department of Justice

DATED: _____

BY: _____
MICHELLE BAASS
Director
California Department of Health Care Services

POMONA VALLEY

DATED: _____

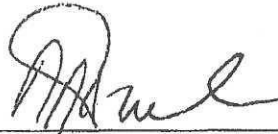
BY: _____
RICHARD E. YOCHUM
President and Chief Executive Officer

DATED: _____

BY: _____
LLOYD A. BOOKMAN
Counsel for Pomona Valley

THE STATE OF CALIFORNIA

DATED: 1/22/2024

BY: 
NICHOLAS N. PAUL
Senior Assistant Attorney General
California Department of Justice

DATED: _____


BY: _____
MICHELLE BAASS
Director
California Department of Health Care Services

POMONA VALLEY

DATED: 1/31/2024

BY: 
RICHARD E. YOCHUM
President and Chief Executive Officer

DATED: 1/31/2024

BY: 
LLOYD A. BOOKMAN
Counsel for Pomona Valley