

SETTLEMENT AGREEMENT

This Settlement Agreement (Agreement) is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General (OIG-HHS) of the Department of Health and Human Services (HHS), (collectively, the “United States”) and Osteo Relief Institute of Colorado Springs, LLC f/k/a Osteo Relief of Colorado Springs, Inc. (COSPGS), (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. COSPGS is a Colorado limited liability corporation that formerly operated two medical practices in Denver and Colorado Springs, specializing in the treatment of osteoarthritis of the knee. COSPGS was owned by Jeffrey J. Keller, D.C. Keller and his company COSPGS operated the two locations under a licensing agreement with Anti-Gravity Effects (AGE), a company owned and operated by Mathias Berry, D.C. Both COSPGS locations closed in November 2017, following Jeffrey Keller’s death.

B. The United States contends that COSPGS submitted or caused to be submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 (“Medicare”).

C. The United States contends that it has certain civil claims against COSPGS arising from COSPGS knowingly submitting, or causing to be submitted, false claims to Medicare as a result of the following conduct between January 1, 2012 through May 30, 2017:

(1) COSPGS provided fluoroscopic-guided viscosupplementation injections that were medically unnecessary because they were provided to patients who did not need any injections, they were provided bilaterally when the treatment was indicated for only one knee, and they were provided to patients who had just completed an earlier series of injections and thus did not need additional

treatment for several months, if at all; (2) COSPGS also knowingly purchased and provided to patients hyaluronic acid distributed in foreign markets and reimported to the United States. The reimported hyaluronic acid had not received final marketing approval by the Food and Drug Administration (FDA) and contained packaging and labeling different than that approved by the FDA for domestic versions; and (3) COSPGS provided expensive custom-fitted and custom-fabricated knee braces that were medically unnecessary, where a standard, less expensive brace or no brace at all was indicated. This conduct is referred to below as the "Covered Conduct."

D. The term "Suspended Amount" shall be defined as the amount held in suspense as of the Effective Date of this Agreement pursuant to the Medicare payment suspension that the Centers for Medicare & Medicaid Services (CMS) put in place for COSPGS effective August 14, 2017. The Suspended Amount as of February 5, 2019, is approximately \$1,130,797.71.

E. This Settlement Agreement is neither an admission of liability by COSPGS nor a concession by the United States that its claims are not well founded.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. COSPGS hereby agrees that the United States shall retain the Suspended Amount forevermore. The Suspended Amount constitutes the "Settlement Amount," subject to the contingency described in Paragraph 2 below. The Settlement Amount constitutes restitution to the United States. COSPGS expressly relinquishes any and all rights of any kind that it may have with respect to the Suspended Amount, including, but not limited to: any and all claims or rights to have an overpayment determined under 42 C.F.R. § 405.372(c), any and all rights to payment of those funds, and any and all rights to appeal, whether formally or informally and

whether administratively or judicially, the right of the United States and/or CMS to retain those funds, and any other rights COSPGS may have to challenge the Withholding or the Suspension in any respect.

2. COSPGS further agrees that, in the event there is a positive asset balance in excess of \$40,000 upon the completed winding down and dissolution of COSPGS within five years of the Effective Date of this Agreement, COSPGS will notify the United States and pay the United States 50% of such balance prior to any scheduled disbursement to the Estate of Jeffrey Keller. Payment shall be made by electronic funds transfer pursuant to written instructions provided by the United States.

3. Subject to the exceptions in Paragraph 4 (concerning excluded claims) below, and conditioned upon COSPGS's full payment of the Settlement Amount and subject to Paragraph 16, below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment made under this Agreement), the United States releases COSPGS 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; 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.

4. Notwithstanding the releases given in Paragraph 3 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;

- c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory or permissive exclusion from Federal health care programs;
- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon obligations created by this Agreement;
- f. Any liability of individuals;
- g. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- h. Any liability for failure to deliver goods or services due;
- i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct;

5. COSPGS has provided financial statements (Financial Statements) to the United States and the United States has relied on the accuracy and completeness of those Financial Statements in reaching this Agreement. COSPGS warrants that the Financial Statements are complete, accurate, and current. If the United States learns of asset(s) in which COSPGS had an interest at the time of this Agreement that were not disclosed in the Financial Statements, or if the United States learns of any misrepresentation by COSPGS on, or in connection with, the Financial Statements, and if such nondisclosure or misrepresentation changes the estimated net worth set forth in the Financial Statements by \$150,000.00 or more, the United States may at its option: (a) rescind this Agreement and file suit based on the Covered Conduct, or (b) let the Agreement stand and collect the full Settlement Amount plus one hundred percent (100%) of the value of the net worth of COSPGS previously undisclosed. COSPGS agrees not to contest any

collection action undertaken by the United States pursuant to this provision, and immediately to pay the United States all reasonable costs incurred in such an action, including attorney's fees and expenses.

6. In the event that the United States, pursuant to Paragraph 5 (concerning disclosure of assets), above, opts to rescind this Agreement, COSPGS agrees not to plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims that (a) are filed by the United States within 90 calendar days of written notification to COSPGS that this Agreement has been rescinded, and (b) relate to the Covered Conduct, except to the extent these defenses were available on the Effective Date of the Agreement.

7. COSPGS waives and shall not assert any defenses COSPGS 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 Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

8. COSPGS fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that COSPGS has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct and the United States' investigation and prosecution thereof.

9. 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 contractor (e.g., Medicare

Administrative Contractor, fiscal intermediary, carrier or any state payer), related to the Covered Conduct; and COSPGS agrees not to resubmit to any Medicare contractor or any state payer 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.

10. The Parties hereby acknowledge that appeal numbers 1-6468725164 (MAS NPI 1164861613) and 1-5366245188 (MAS NPI 1063781474), currently pending before Administrative Law Judge – Central Operations (collectively the “Administrative Actions”), include claim lines that fall within the Covered Conduct, hereinafter referred to as “Overlapping Claims.” The Overlapping Claims will not be used as an off-set against, or otherwise applied to reduce, any separate or remaining liability to the United States. COSPGS agrees to waive any and all appeals and withdraw any pending appeals related to the Covered Conduct, including but not limited to the aforementioned appeal numbers, upon execution of this Agreement. Upon execution of this Agreement and COSPGS’s withdrawal of any pending appeals, the United States agrees to withdraw its overpayment demands associated with the Administrative Actions. The parties agree that the Settlement Amount will satisfy the claims included in the Administrative Actions.

11. COSPGS agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of COSPGS, its present or former officers, directors, employees, shareholders, and agents in connection with:

(1) the matters covered by this Agreement;

- (2) the United States' audit(s) and civil investigation(s) of the matters covered by this Agreement;
- (3) COSPGS's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);
- (4) the negotiation and performance of this Agreement; and
- (5) the payment COSPGS makes to the United States pursuant to this Agreement,

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by COSPGS, and COSPGS shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by COSPGS or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: COSPGS further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information

reports, or payment requests already submitted by COSPGS or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. COSPGS agrees that the United States, at a minimum, shall be entitled to recoup from COSPGS any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by COSPGS or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on COSPGS or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine COSPGS's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

12. COSPGS agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, COSPGS shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. COSPGS further agrees to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of

interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf.

13. 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 Paragraph 14 (waiver for beneficiaries paragraph), below.

14. COSPGS agrees that it waives and 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.

15. COSPGS 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 United States 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 COSPGS, 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 COSPGS was or became indebted to on or after the date of this transfer, within the meaning of 11 U.S.C. § 548(a)(1).

16. If within 91 days of the Effective Date of this Agreement or of any payment made under this Agreement, COSPGS commences, or a third party commences, any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors (a) seeking to have any order for relief of COSPGS's debts, or seeking to adjudicate

COSPGS as bankrupt or insolvent; or (b) seeking appointment of a receiver, trustee, custodian, or other similar official for COSPGS or for all or any substantial part of COSPGS's assets, COSPGS agrees as follows:

a. COSPGS's obligations under this Agreement may not be avoided pursuant to 11 U.S.C. § 547, and COSPGS shall not argue or otherwise take the position in any such case, proceeding, or action that: (i) COSPGS's obligations under this Agreement may be avoided under 11 U.S.C. § 547; (ii) COSPGS was insolvent at the time this Agreement was entered into, or became insolvent as a result of the payment made to the United States; or (iii) the mutual promises, covenants, and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to COSPGS.

b. If COSPGS's obligations under this Agreement are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the United States, at its sole option, may rescind the releases in this Agreement and bring any civil and/or administrative claim, action, or proceeding against COSPGS for the claims that would otherwise be covered by the releases provided in Paragraph 2, above. COSPGS agrees that (i) any such claims, actions, or proceedings brought by the United States are not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) as a result of the action, case, or proceedings described in the first clause of this Paragraph, and COSPGS shall not argue or otherwise contend that the United States' claims, actions, or proceedings are subject to an automatic stay; (ii) COSPGS shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claims, actions, or proceeding that are brought by the United States within 90 calendar days of written notification to COSPGS that the releases have been rescinded pursuant to this Paragraph, except to the extent such defenses were available on the Effective Date of the

Agreement; and (iii) the United States has a valid claim against COSPGS in the amount of \$26,460,759.00, and the United States may pursue its claim in the case, action, or proceeding referenced in the first clause of this Paragraph, as well as in any other case, action, or proceeding.

c. COSPGS acknowledges that its agreements in this Paragraph are provided in exchange for valuable consideration provided in this Agreement.

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

18. Each party and signatory to this Agreement represents that it freely and voluntarily enters in to this Agreement without any degree of duress or compulsion.

19. 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 District of Minnesota. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

20. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

21. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

22. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

23. This Agreement is binding on COSPGS's successors, transferees, heirs, and assigns.

24. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

25. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: 4/26/19

BY: 

CHRISTOPHER G. WILSON
CLAIRE L. NORSETTER
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____

BY: _____

CHAD A. BLUMENFIELD
Assistant United States Attorney
United States Attorney's Office
for the District of Minnesota

DATED: _____

BY: _____

LISA M. RE
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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CLAIRE L. NORSETTER
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice


DATED: _____

BY: _____

CHAD A. BLUMENFIELD
Assistant United States Attorney
United States Attorney's Office
for the District of Minnesota

DATED: 04/26/2017


BY: _____


LISA M. RE
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

OSTEO RELIEF OF COLORADO SPRINGS, LLC - DEFENDANT

DATED: 4/24/19

BY:



Craig A. Keller
Personal Representative
Estate of Jeffrey J. Keller

DATED: 4-25-19

BY:



Thomas W. Berners
Hogan Lovells US LLP
Counsel for Osteo Relief Institute of Colorado Springs, LLC