

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, the Defense Health Agency (“DHA”), acting on behalf of the TRICARE program (collectively, the “United States”); and Ellen Boyle Duncan, M.D., and Ellen Boyle Duncan, PLLC, d/b/a Duncan Medical Group (collectively, “the Defendants”) (hereafter collectively referred to as “the Parties”) through their authorized representatives.

RECITALS

A. Ellen Boyle Duncan, M.D. (“Dr. Duncan”) is a Texas-licensed physician specializing in pain management practicing in the San Antonio Metro Area. Dr. Duncan, via her professional limited liability entity, Ellen Boyle Duncan, PLLC d/b/a Duncan Medical Group (“Duncan PLLC”) was previously contracted to provide medical services through Consultants in Pain Medicine, PLLC d/b/a Consultants in Pain Medicine, PA (“CPM”), a professional limited liability company located at 45 NE Loop 410 Suite 560, San Antonio, Texas 78216.

B. Dr. Duncan, via Duncan PLLC and CPM, provided medical services to individuals, including beneficiaries of federal and state healthcare payer programs. Until January 2022, Dr. Duncan’s medical services were billed to government programs and private insurers through CPM.

C. The United States contends Dr. Duncan and Duncan PLLC submitted or caused to be submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. 1395-1395lll (“Medicare”) and the TRICARE Program, 10 U.S.C. 1071-1110b (“TRICARE”).

D. The United States contends that it has certain civil claims against Dr. Duncan and Duncan PLLC for claims submitted by CPM for medical services provided by Dr. Duncan through Duncan PLLC to Medicare and TRICARE between January 1, 2020, and May 31, 2021. Specifically, the United States contends the Defendants submitted or caused the submission of claims for certain experimental and investigational uses of Fluid Flow, aka Fluid GF, an acellular amniotic fluid allograft, that were not reasonable and necessary for the diagnosis or treatment of an illness or injury, contrary to 42 U.S.C. § 1395y(a)(1)(A), and thus were not covered by Medicare or TRICARE. The United States contends the Defendants submitted or caused the submission of false claims for Medicare and TRICARE beneficiaries for injections of Fluid Flow using HCPCS Code Q4206.

E. The United States contends Dr. Duncan became aware in or around late 2021 that their use of the Fluid Flow injectable product was not covered by Medicare or TRICARE as reasonable and medically necessary. The United States contends Dr. Duncan ignored or otherwise took steps to avoid returning the improperly paid funds as overpayments to the Medicare or TRICARE program within the 60-day time frame from the date of overpayment identification provided by 42 C.F.R. § 401.305(b). The United States contends it has civil claims against Dr. Duncan and Duncan PLLC for this conduct under 31 U.S.C. § 3729(a)(1)(G).

F. The conduct described in Recitals D-E is collectively referred to below as the Covered Conduct.

G. Dr. Duncan and Duncan PLLC expressly deny the claims identified as the Covered Conduct.

H. This Settlement Agreement is neither an admission of liability by the Defendants 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. Dr. Duncan, individually and on behalf of Duncan PLLC, shall pay \$3,440,538.65 ("Settlement Amount") to the United States, of which \$1,756,705.97 is restitution to Medicare and \$103,044.65 is restitution to TRICARE, via electronic funds transfer pursuant to written instructions to be provided by the Office of the United States Attorney for the Western District of Texas. The Settlement Amount shall be paid in full within 90 days of the Effective Date of this Agreement.

2. Subject to the exceptions in Paragraphs 3 (concerning reserved claims), 8 (concerning default), and 9 (concerning bankruptcy) below, and upon the United States' receipt of the Settlement Amount, the United States releases the Defendants 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.

3. Notwithstanding the release given in Paragraph 2 of this Agreement, or any other term of this Agreement, the following claims and rights 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 or enforcement right, 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 except Dr. Duncan;
- 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; and
- i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct;

4. The Defendants waive and shall not assert any defenses the Defendants 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.

5. The Defendants fully and finally release 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 the Defendants have asserted, could have asserted,

or may assert in the future against the United States, and its agencies, officers, agents, employees, and servants related to the Covered Conduct and the United States' investigation and prosecution thereof.

6. 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); any TRICARE contractor, fiscal intermediary, or carrier; or any state payer, related to the Covered Conduct; and the Defendants agree not to resubmit to any Medicare contractor, TRICARE 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 withdrawal any such pending appeals.

7. The Defendants agree 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. §§ 1395-1395lll and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of the Defendants, 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) The Defendant'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 attorneys' fees);

- (4) the negotiation and performance of this Agreement; and
- (5) the payment the Defendants make 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 the Defendants, and the Defendants 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 the Defendants or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: The Defendants further agree 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 the Defendants 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. The Defendants agree that the United States, at a minimum, shall be entitled to recoup from the Defendants 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 the Defendants or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on the Defendants 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 the Defendants' books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.

8. In the event the Defendants fail to pay the Settlement Amount as provided in Paragraph 1 above, Defendants shall be in Default of their payment obligations ("Default"). The United States will provide a written Notice of Default, and Defendants shall have an opportunity to cure such Default within seven (7) calendar days from the date of receipt of the Notice of Default by making the payment due under the payment schedule and paying any additional interest accruing under the Settlement Agreement as described in Paragraph 1(C) up to the date of payment. Notice of Default will be delivered to Defendants, or to such other representative as Defendants shall designate in advance in writing. If Defendants fails to cure the Default within seven (7) calendar days of receiving the Notice of Default and in the absence of an agreement with the United States to a modified payment schedule ("Uncured Default"), the remaining unpaid balance of the Settlement Amount shall become immediately due and payable, and interest on the remaining

unpaid balance shall thereafter accrue at the rate of 12% per annum, compounded daily from the date of Default, on the remaining unpaid total (principal and interest balance).

a. In the event of Uncured Default, Defendants agree that the United States, at its sole discretion, may (i) retain any payments previously made, rescind this Agreement and pursue the Covered Conduct or bring any civil and/or administrative claim, action, or proceeding against Defendants for the claims that would otherwise be covered by the releases provided in Paragraphs 2, 3, and 4 above, with any recovery reduced by the amount of any payments previously made by Defendants to the United States under this Agreement; (ii) take any action to enforce this Agreement in a new action or by reinstating the Covered Conduct; (iii) offset the remaining unpaid balance from any amounts due and owing to Defendants and/or affiliated companies by any department, agency, or agent of the United States at the time of Default or subsequently; and/or (iv) exercise any other right granted by law, or under the terms of this Agreement, or recognizable at common law or in equity. The United States shall be entitled to any other rights granted by law or in equity by reason of Default, including referral of this matter for private collection. In the event the United States pursues a collection action, Defendants agree immediately to pay the United States the greater of (i) a ten-percent (10%) surcharge of the amount collected, as allowed by 28 U.S.C. § 3011(a), or (ii) the United States' reasonable attorneys' fees and expenses incurred in such an action. In the event that the United States opts to rescind this Agreement pursuant to this paragraph, Defendants waives and agrees not to plead, argue, or otherwise raise any defenses of statute of limitations, laches, estoppel or similar theories, to any civil or administrative claims that are (i) filed by the United States against Defendants within 120 days of written notification that this Agreement has been rescinded, and (ii) relate to the Covered Conduct, except to the extent these defenses were available on August 1, 2025. Defendants agree not to contest any offset,

recoupment, and /or collection action undertaken by the United States pursuant to this paragraph, either administratively or in any state or federal court, except on the grounds of actual payment to the United States.

b. In the event of Uncured Default, OIG-HHS may exclude Defendants from participating in all Federal health care programs until Defendants pay the Settlement Amount, with interest, as set forth above (Exclusion for Default). OIG-HHS will provide written notice of any such exclusion to Defendants. Defendants waive any further notice of the exclusion under 42 U.S.C. § 1320a-7(b)(7) and agree not to contest such exclusion either administratively or in any state or federal court. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, Defendants wish to apply for reinstatement, Defendants must submit a written request for reinstatement to OIG-HHS in accordance with the provisions of 42 C.F.R. §§ 1001.3001-.3005. Defendants will not be reinstated unless and until OIG-HHS approves such request for reinstatement. The option for Exclusion for Default is in addition to, and not in lieu of, the options identified in this Agreement or otherwise available.

9. In exchange for valuable consideration provided in this Agreement, Defendants acknowledge the following:

a. Dr. Duncan has reviewed her and Duncan PLLC's financial situations and warrants that they are 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.

b. In evaluating whether to execute this Agreement, the Parties intend that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to Defendants, within the meaning of 11 U.S.C. § 547(c)(1), and the Parties

conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange.

c. The mutual promises, covenants, and obligations set forth herein are intended by the Parties to, and do in fact, constitute a reasonably equivalent exchange of value.

d. The Parties do not intend to hinder, delay, or defraud any entity to which Defendants were or became indebted to on or after the date of any transfer contemplated in this Agreement, within the meaning of 11 U.S.C. § 548(a)(1).

e. If any of Defendants' payments or 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) or if, before the Settlement Amount is paid in full, Dr. Duncan, Duncan PLLC, or a third party commences a case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors seeking any order for relief of Defendants' debts, or to adjudicate Defendants as bankrupt or insolvent; or seeking appointment of a receiver, trustee, custodian, or other similar official for Defendants or for all or any substantial part of Defendant's assets:

(i) the United States may rescind the releases in this Agreement and bring any civil and/or administrative claim, action, or proceeding against Defendants for the claims that would otherwise be covered by the releases provided in Paragraph 2 above;

(ii) the United States has an undisputed, noncontingent, and liquidated allowed claim against Defendants in the amount of \$13,234,031.86, less any payments received pursuant to Paragraph 1 of this Agreement, provided, however, that such payments are not otherwise avoided and recovered from the United States by Defendants, a receiver, trustee, custodian, or similar official for Defendants;

(f). Defendants agree that any civil and/or administrative claim, action, or proceeding brought by the United States under Paragraph 9(e) is not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) because it would be an exercise of the United States' police and regulatory power. Defendants shall not argue or otherwise contend that the United States' claim, action, or proceeding is subject to an automatic stay and, to the extent necessary, consents to relief from the automatic stay for cause under 11 U.S.C. § 362(d)(1). Defendants waive and 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 claim, action, or proceeding brought by the United States within 120 days of written notification to Defendants that the releases have been rescinded pursuant to this paragraph, except to the extent such defenses were available on August 1, 2025.

10. 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 11 (waiver for beneficiaries paragraph), below.

11. The Defendants agree that they waive and shall not seek payment for any of the health care billings covered by this Agreement from any healthcare beneficiaries or their parents, sponsors, legally responsible individuals, or third-party payors based upon the claims defined as Covered Conduct.

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

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

14. Each Party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

15. This Agreement is governed by the laws of the United States. The exclusive venue for any dispute relating to this Agreement is the United States District Court for the Western District of Texas, San Antonio Division. 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.

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

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

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

19. This Agreement is binding on the Defendant's successors, transferees, heirs, and assigns.

20. All Parties consent to the disclosure of this Agreement, and information about this Agreement, by either the United States or Dr. Duncan, to the public.

21. 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: _____

BY: _____

ERIN VAN DE WALLE Digitally signed by
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ERIN M. VAN DE WALLE
Assistant United States Attorney
Western District of Texas

DATED: _____

BY: _____

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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

DATED: _____

BY: _____

SALVATORE M. MAIDA
General Counsel
Defense Health Agency
United States Department of War

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____

ERIN M. VAN DE WALLE
Assistant United States Attorney
Western District of Texas

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

DATED: 6/3/2026

BY: _____

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For

SALVATORE M. MAIDA
General Counsel
Defense Health Agency
United States Department of War

ELLEN BOYLE DUNCAN, M.D.
ELLEN BOYLE DUNCAN PLLC d/b/a DUNCAN MEDICAL GROUP

DATED: 6/5/26

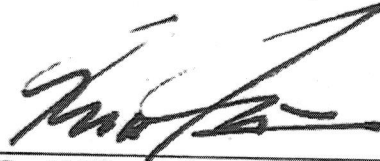
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Ellen Boyle Duncan, M.D.
Individually and on behalf of Ellen Boyle Duncan PLLC
d/b/a Duncan Medical Group

DATED: 6/5/26

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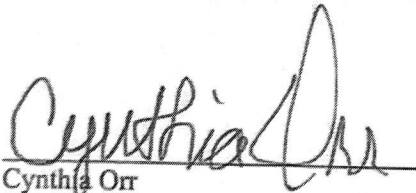


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DATED: 6/5/26

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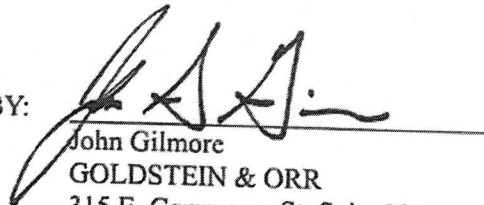


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DATED: 6/5/26

BY:



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