

SETTLEMENT AGREEMENT

This Settlement Agreement (“Agreement”) is entered into between 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 Ethos Holding Corp., d/b/a Ethos Laboratories (“Ethos”) (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. Ethos, based in Newport, Kentucky, is a clinical testing laboratory that performs, inter alia, presumptive and definitive urine drug testing (“UDT”) and Foundation Pain Index (“FPI”) testing. Ethos performs UDT and FPI and submits claims for payment for UDT and FPI to the Medicare Program (“Medicare”), Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll.

B. The United States contends that it has certain civil claims against Ethos for submitting false claims for medically unnecessary UDT and FPI to Medicare.

C. On July 18, 2023, the Centers for Medicare & Medicaid Services (“CMS”) suspended Ethos’s Medicare payments pursuant to 42 C.F.R. § 405.371(a)(2) (the “CMS Suspension”). The term “Suspended Amount” refers to the funds held in suspense by CMS from the date of implementation of the suspension through the Effective Date of this Agreement. As of August 22, 2024, the Suspended Amount was \$7,685,493.44.

D. The term “Settlement Amount” refers to six million five hundred thousand dollars (\$6,500,000).

E. Ethos admits, acknowledges, and accepts responsibility for the following facts. From January 1, 2017, to July 15, 2024, Ethos routinely submitted claims for presumptive and definitive UDT. During this timeframe, Ethos submitted claims for presumptive and definitive

UDT for the same patient on the same date of service using the same urine sample. Ethos billed for presumptive testing using Current Procedural Terminology (“CPT”) code 80307 and definitive UDT using Healthcare Common Procedure Coding System (“HCPCS”) codes G0480, G0481, G0492, and G0483 for the same substances without using the presumptive testing results to inform the necessity of definitive testing and regardless of the presumptive testing results. Ethos also submitted claims for UDT conducted pursuant to blanket orders. In some of those blanket orders, the ordering provider ordered the same test panels for all patients in the provider’s practice without providing patient-specific orders and without any individualized determination of medical necessity by the ordering provider. In some instances, these panels included substances with positivity rates below 0.01%. Ethos also submitted claims for presumptive UDT even when it submitted claims for payment for sufficient definitive UDT to reach the maximum reimbursement tier under G0483, resulting in further payment to Ethos for a less effective test.

Additionally, from November 12, 2020, to October 6, 2023, Ethos submitted or caused the submission of claims to Medicare for its proprietary urine test for biomarkers for chronic pain, marketed by Ethos as the FPI. In some instances, Ethos submitted claims for FPI testing (using CPT Code 0117U) for patients in a provider’s practice without any individualized determination of medical necessity by the ordering provider, and, in some cases, without the provider’s knowledge that FPI testing was being ordered. Ethos also submitted claims for FPI testing at high frequencies, including testing some patients multiple times in the same month. The foregoing conduct in paragraph E is hereinafter referred to as the “Covered Conduct.”

In consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Ethos hereby agrees that the United States shall retain the Settlement Amount of \$6,500,000 from the Suspended Amount (the Settlement Amount is herein also referred to as the “Retained Funds”) forevermore, with the remainder of the Suspended Amount applied according to 42 C.F.R. § 405.372(e), including to reduce or eliminate any outstanding overpayments.

Ethos expressly relinquishes any and all rights of any kind that it may have with respect to those Retained Funds, 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 Retained 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 Ethos may have to challenge the withholding or the CMS Suspension in any respect. Of the Settlement Amount, \$6,500,000 is restitution.

2. Subject to the exceptions in Paragraph 4 (concerning reserved claims) below, and subject to Paragraph 5 (concerning disclosure of assets), Paragraph 13 (concerning default), and Paragraph 14 (concerning bankruptcy) below, and upon the execution of this Agreement, the United States releases Ethos 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. In consideration of the obligations of Ethos in this Agreement and the Corporate Integrity Agreement (CIA), entered into between OIG-HHS and Ethos, and upon execution of the Agreement, and effectuation of its payment terms, the OIG-HHS shall 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 Ethos 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 reserved claims), below. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Ethos 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 the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 4, below.

4. 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 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; and
- f. Any liability of individuals.

5. Ethos has provided sworn financial disclosures and supporting documents (together “Financial Disclosures”) to the United States and the United States has relied on the accuracy and completeness of those Financial Disclosures in reaching this Agreement. Ethos

warrants that the Financial Disclosures are complete, accurate, and current as of the Effective Date of this Agreement. If the United States learns of asset(s) in which Ethos had an interest of any kind as of the Effective Date of this Agreement (including, but not limited to, promises by insurers or other third parties to satisfy Ethos's obligations under this Agreement) that were not disclosed in the Financial Disclosures, or if the United States learns of any false statement or misrepresentation by Ethos on, or in connection with, the Financial Disclosures, and if such nondisclosure, false statement, or misrepresentation changes the estimated net worth set forth in the Financial Disclosures by \$650,000 or more, the United States may at its option: (a) rescind this Agreement and reinstate its suit or file suit based on the Covered Conduct or (b) collect the full Settlement Amount in accordance with the Agreement plus one hundred percent (100%) of the net value of Ethos's previously undisclosed assets. Ethos agrees not to contest any collection action undertaken by the United States pursuant to this provision, and agrees that it will immediately pay the United States the greater of (i) a ten-percent (10%) surcharge of the amount collected in the collection action, 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, pursuant to this paragraph rescinds this Agreement, Ethos waives and 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 120 calendar days of written notification to Ethos that this Agreement has been rescinded, and (b) relate to the Covered Conduct, except to the extent these defenses were available on December 7, 2022.

6. Ethos waives and shall not assert any defenses Ethos 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.

7. Ethos fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Ethos 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 or the United States' investigation or prosecution thereof.

8. 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 Ethos 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.

9. Ethos 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. §§ 1395-1395lll and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Ethos, 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) or criminal investigation(s) of the matters covered by this Agreement;
- (3) Ethos's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal

investigation(s) in connection with the matters covered by this Agreement (including attorneys' fees);

- (4) the negotiation and performance of this Agreement;
- (5) the payment Ethos makes to the United States pursuant to this Agreement; and
- (6) the negotiation of, and obligations undertaken pursuant to the CIA to: (i) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and (ii) prepare and submit reports to the OIG-HHS

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). However, nothing in Paragraph 9.a.(6) that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to Ethos.

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Ethos, and Ethos 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 Ethos or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

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

10. Ethos agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, Ethos 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. Ethos 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.

11. 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 12 (waiver for beneficiaries paragraph), below.

12. Ethos 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.

13. The Settlement Amount represents the amount the United States is willing to accept in compromise of its civil claims arising from the Covered Conduct due solely to Ethos's financial condition as reflected in the Financial Disclosures referenced in Paragraph 5.

a. In the event that Ethos fails to pay the Settlement Amount as provided in the payment schedule set forth in Paragraph 1 above, Ethos shall be in Default of Ethos's payment obligations ("Default"). The United States will provide a written Notice of Default, and Ethos 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 up to the date of payment. Notice of Default will be delivered to Ethos, or to such other representative as Ethos shall designate in advance in writing. If Ethos 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).

b. In the event of Uncured Default, Ethos agrees that the United States, at its sole discretion, may (i) retain any payments previously made, rescind this Agreement and pursue the Civil Action or bring any civil and/or administrative claim, action, or proceeding against Ethos for the claims that would otherwise be covered by the releases provided in Paragraph 2 above, with any recovery reduced by the amount of any payments previously made by Ethos to the United States under this Agreement; (ii) take any action to enforce this Agreement in a new action or by reinstating the Civil Action; (iii) offset the remaining unpaid balance from any amounts due and owing to Ethos 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, Ethos agrees 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, Ethos 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 Ethos 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 December 7, 2022. Ethos agrees 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.

c. In the event of Uncured Default, OIG-HHS may exclude Ethos from participating in all Federal health care programs until Ethos pays the Settlement Amount, with interest, as set forth above (Exclusion for Default). OIG-HHS will provide written notice of any such exclusion to Ethos. Ethos waives any further notice of the exclusion under 42 U.S.C. § 1320a-7(b)(7), and agrees 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, Ethos wishes to apply for reinstatement, it must submit a written request for reinstatement to OIG-HHS in accordance with the provisions of 42 C.F.R. §§ 1001.3001-.3005. Ethos 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.

14. In exchange for valuable consideration provided in this Agreement, Ethos acknowledges the following:

a. Ethos has reviewed its financial situation and warrants that it 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 and return of the remaining Suspended 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 Ethos, 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 Ethos was 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 Ethos's 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, Ethos 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 Ethos's debts, or to adjudicate Ethos as bankrupt or insolvent; or seeking appointment of a receiver, trustee, custodian, or other similar official for Ethos or for all or any substantial part of Ethos'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 Ethos for the claims that would otherwise be covered by the release provided in Paragraph 2 above; and

(ii) the United States has an undisputed, noncontingent, and liquidated allowed claim against Ethos in the amount of twenty-one million, six-hundred thousand dollars (\$21,600,000), 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 Ethos, a receiver, trustee, custodian, or other similar official for Ethos.

f. Ethos agrees that any civil and/or administrative claim, action, or proceeding brought by the United States under Paragraph 14.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. Ethos 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). Ethos waives 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 Ethos that the releases have been rescinded pursuant to this paragraph, except to the extent such defenses were available on December 7, 2022.

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

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

17. 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 District of Massachusetts. 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.

18. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties. Forbearance by the United States from pursuing any remedy or relief available to it under this Agreement shall not constitute a waiver of rights under this Agreement.

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

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

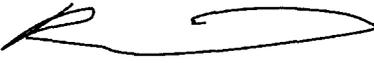
21. This Agreement is binding on Ethos's successors, transferees, heirs, and assigns.
22. Ethos consents to the United States' disclosure of this Agreement, and information about this Agreement, to the public.
23. This Agreement is effective on the date of signature of the last signatory to the Agreement (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: ABRAHAM GEORGE Digitally signed by ABRAHAM GEORGE
Date: 2024.11.07 15:32:57 -05'00'
ABRAHAM R. GEORGE
Chief, Civil Division
Assistant United States Attorney
District of Massachusetts

DATED: 11/01/24 BY: SUSAN GILLIN Digitally signed by SUSAN GILLIN
Date: 2024.11.01 16:12:32 -04'00'
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

ETHOS

DATED: 10/30/24 BY: 
BRIAN KINCAID
Ethos Laboratories
Chief Executive Officer

DATED: 10/30/24 BY: 
ANDREW SOLINGER
SHALYN WATKINS
JEREMY STERNBERG
Holland & Knight LLP
Counsel for Ethos Laboratories