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 the Oncology Practice of Dr. Kenneth D. Nahum, D.O., P.C. ("the Practice"), Dr. Kenneth D. Nahum ("Nahum"), and Ann Walsh ("Walsh") (collectively, the Practice, Nahum, and Walsh shall be referred to as "the Practice Parties") through their authorized representatives. Hereafter, all of the persons and entities named above shall be collectively referred to as "the Parties."

RECITALS

- A. Nahum and Walsh are husband and wife. During the relevant time period, Nahum was the owner of the Practice, a New Jersey corporation that had offices in Howell, New Jersey, and Wall, New Jersey. Nahum is an oncologist who offered his services through the Practice, including chemotherapy infusion services. Walsh was a registered nurse at the Practice and was responsible for ordering drugs at the Practice.
- B. The United States contends that the Practice 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 the Practice

 Parties arising from the Practice submitting claims for payment to Medicare for chemotherapy

 drugs and infusion services where the chemotherapy drugs that were administered had not been

 approved by the U.S. Food & Drug Administration ("FDA") for sale in the United States and

 were obtained from a foreign distributor. Dates of service for the claims encompassed the period

from April 1, 2010, to January 31, 2011. That conduct is referred to below as the "Covered Conduct."

- D. This Settlement Agreement is neither an admission of liability by the Practice Parties nor a concession by the United States that its claims are not well founded.
 - E. The Practice Parties deny the United States' allegations in Paragraph C.

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. The Practice Parties shall pay to the United States One Million Seven Hundred Thousand Dollars (\$1,700,000) ("Settlement Amount") and interest on the Settlement Amount at a rate of 2.375% from December 22, 2016 ("Interest") no later than ten business days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the Office of the United States Attorney for the District of New Jersey. The Settlement Amount plus interest described above shall hereafter be referred to as the "Settlement Proceeds."
- 2. Subject to the exceptions in Paragraph 3 (concerning excluded claims) below, and conditioned upon the Practice Parties' full payment of the Settlement Proceeds, the United States releases the Practice Parties 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 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;
 - 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 any other individuals; and
 - g. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.
- 4. The Practice Parties waive and shall not assert any defenses the Practice Parties 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. Nothing in this paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Proceeds for purposes of the Internal Revenue laws, Title 26 of the United States Code.

- 5. The Practice Parties 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 Practice Parties 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 Proceeds 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 the Practice Parties agree not to resubmit to any Medicare contractor or any state payer any previously denied claims related to the Covered Conduct, agree not to appeal any such denials of claims, and agree to withdraw any such pending appeals.
 - 7. The Practice Parties agree to the following:
- a. <u>Unallowable Costs Defined</u>: 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-I and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of the Practice Parties, its present or former officers, directors, employees, shareholders, and agents in connection with:
 - (1) the matters covered by this Agreement and any related plea agreement;
 - (2) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;
 - (3) the Practice Parties' 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 attorney's fees);
- (4) the negotiation and performance of this Agreement and any plea agreement; and
- (5) the payment the Practice Parties 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. <u>Future Treatment of Unallowable Costs</u>: Unallowable Costs shall be separately determined and accounted for by the Practice Parties, and the Practice Parties 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 Practice Parties or any of their subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.
- c. Treatment of Unallowable Costs Previously Submitted for Payment: The Practice Parties further agree that within 90 days of the Effective Date of this Agreement they 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 Practice Parties or any of their 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 Practice Parties agree that the United States, at a minimum, shall be entitled to recoup from the Practice Parties 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 Practice Parties or any of their subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on the Practice Parties or any of their 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 Practice Parties' books and records to
 determine that no Unallowable Costs have been claimed in accordance with the provisions of this
 Paragraph.
- 8. The Practice Parties agree to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, the Practice Parties shall encourage, and agree not to impair, the cooperation of their directors, officers, and employees, and shall use their 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. The Practice Parties further agree to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in their possession, custody, or

control concerning any investigation of the Covered Conduct that they have undertaken, or that has been performed by another on their behalf.

- 9. 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 10 (waiver for beneficiaries paragraph), below.
- 10. The Practice Parties agree that they waive 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.
- 11. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.
- 12. Each party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.
- 13. 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 New Jersey. 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.
- 14. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.
- 15. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.
- 16. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

- 17. This Agreement is binding on the Practice Parties' successors, transferees, heirs, and assigns.
- 18. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.
- 19. 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: 2/16/17

BY:

ANDREW A. CAPPEREY, III

Assistant United States Attorneys

District of New Jersey

BY:

JACOB T. ELBERG

Chief, Health Care and Government Fraud Unit

United States Attorney's Office

District of New Jersey

DATED: 02/13/17

BY: (

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

PRACTICE PARTIES

DATED: 2/1/17

BY:

Dr. Kenneth D. Nahum

DATED: <u>7/7/17</u>

BY:

Michael B. Himmel Matthew M. Oliver Lowenstein Sandler LLP 65 Livingston Avenue

Roseland, New Jersey 07068

Counsel for Dr. Kenneth D. Nahum

DATED: 277

BY:

The Oncology Practice of Dr. Kenneth D. Nahum, D.O.,

P.C.

DATED: 3/7/7

BY:

Michael B. Himmel

Matthew M. Oliver Lowenstein Sandler LLP

65 Livingston Avenue Roseland, New Jersey 07068

Counsel for The Oncology Practice of Dr. Kenneth D.

Nahum, D.O., P.C.

DATED: 2 7 12. BY:

Ann Walsh

DATED: 107/17 BY:

See Tast

Salvatore T. Alfano Salvatore T. Alfano, P.A. 55 Washington St # 400

Bloomfield, NJ

Counsel for Ann Walsh