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 Fresenius Medical Care Holdings, Inc. ("Fresenius") (hereafter "the Parties"), through their authorized representatives.

RECITALS

A. Fresenius, through affiliates and subsidiaries, provides dialysis-related services to more than 130,000 end stage renal disease ("ESRD") patients in the United States. Fresenius has its United States headquarters in Waltham, Massachusetts. At all relevant times, Fresenius subsidiaries or affiliates were providers under the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 ("Medicare"), and Fresenius subsidiary Spectra Laboratories submitted claims to and received reimbursement from Medicare for laboratory testing associated with hemodialysis services provided to Medicare beneficiaries.


C. The United States contends that it has certain civil claims against Fresenius arising from conduct alleged in the United States’ Complaint in Intervention. This conduct is referred to below as the "Covered Conduct."
D. The United States did not intervene with respect to all of the conduct the Relator alleged in his First Amended Complaint. This conduct is referred to below as the "Non-Intervened Conduct."

E. This Agreement is made in compromise of disputed claims. This Agreement is not an admission of facts or liability by Fresenius, and Fresenius denies that it engaged in any wrongful conduct in connection with the Covered Conduct or the Non-Intervened Conduct. This Agreement is not a concession by the United States that its claims are not well-founded, nor a concession by Fresenius its defenses are not well-founded. Neither this Agreement, nor the performance of any obligation arising under it, including any payment, nor the fact of settlement, is intended to be, or shall be understood as, an admission of liability or wrongdoing, by Fresenius.

F. Relator claims entitlement under 31 U.S.C. § 3730(d) and pursuant to 31 U.S.C. §3730(c)(5) to (1) a share of the proceeds of this Agreement and to (2) Relator's reasonable expenses, attorneys' fees and costs. Fresenius denies those claims by Relator to the extent they implicate or impact Fresenius. The United States represents that it has reached an agreement with Relator described in Paragraph 2 that would resolve Relator's claims under (1).

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

TERMS AND CONDITIONS

1. Under the alternate remedy provision of the False Claims Act, 31 U.S.C. § 3730(c)(5), Fresenius shall pay to the United States $5,200,000.00 ("Settlement Amount"), of which $5,200,000.00 is restitution, and interest on the Settlement Amount at a rate of 2.250% from June 14, 2019, no later than 7 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 Massachusetts.

2. Conditioned upon the United States receiving the Settlement Amount from Fresenius and as soon as feasible after receipt, the United States represents that it has agreed with Relator to pay Relator $1,430,000 pursuant to 31 U.S.C. §§ 3730(d)(1) and (2), plus a 27.5% share of any accrued interest at the rate set forth above to Relator by electronic funds transfer.

3. Subject to the exceptions in Paragraph 5 (concerning excluded claims) below, and conditioned upon Fresenius’s full payment of the Settlement Amount, the United States releases Fresenius 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. Nothing in this Agreement constitutes a release by the United States of any rights to retain the monies recouped by the United States or paid provisionally by Fresenius to the United States as a result of OIG Audit A-01-08-00511; nor does this Agreement constitute a release by Fresenius of the claims it has made to recover such recouped or provisionally paid sums through administrative appeals arising from or related to OIG Audit A-01-08-00511, including but not limited to:

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<th>OMHA #</th>
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<td>1-3700964809</td>
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<td>7/23/2016</td>
</tr>
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4. The Parties are advised and understand that, following the Effective Date, Relator and his counsel will seek by motion to the court an award of expenses, fees, and costs against Fresenius, and that Fresenius may oppose such an award on any ground or basis that it deems appropriate; may in its discretion seek an award of expenses, fees, and costs against Relator or his counsel; or both.

5. 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; and
   f. Any liability of individuals.

6. The United States represents that the United States has entered into a separate agreement with the Relator pursuant to which the Relator and his heirs, successors, attorneys, agents, and assigns confirm: that this Agreement is fair, adequate, and reasonable under all the circumstances and within the meaning of 31 U.S.C. § 3730(c)(2)(B); that they do not object to this Agreement; and, conditioned upon their receipt of the payment from the United States described in Paragraph 2, that they fully and finally release, waive, and forever discharge the United States, its agencies, officers, agents, employees, and servants, from any claims arising
from the filing of the Civil Action or under 31 U.S.C. § 3730, and from any claims to a share of
the proceeds of this Agreement and/or the Civil Action.

7. Fresenius waives and shall not assert any defenses Fresenius 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 any such criminal prosecution or
administrative action.

8. Except for any claims or rights that it has raised or may hereafter raise in
connection with the administrative appeals described in Paragraph 3, or any collateral civil
litigation related to or arising from such appeals, Fresenius 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 Fresenius 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 Fresenius agrees not to resubmit to any Medicare contractor or any state payer any
previously denied claims related to the Covered Conduct, and agrees not to appeal any such
denials of claims. Consistent with Paragraph 3, this paragraph does not implicate or require
Fresenius’s withdrawal of its administrative appeal of Docket Number 1-3700964809 presently
awaiting a hearing by an Administrative Law Judge.
10. Fresenius 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 Fresenius, 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) Fresenius’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 Fresenius makes to the United States pursuant to this Agreement and any payments that Fresenius may make to Relator, including costs and attorney’s fees;
   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:** Fresenius shall not charge 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 after the Effective Date of this
Agreement by Fresenius or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

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

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. Fresenius 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. Upon receipt of the payment described in Paragraph 1, above, Relator and the United States shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal of the Civil Action pursuant to Rule 41(a)(1). The United States will dismiss with prejudice all claims based upon the Covered Conduct and dismiss without prejudice all claims based upon the Non-Intervened Conduct. The Relator will dismiss with prejudice all claims based upon the Covered Conduct and the Non-Intervened Conduct; provided however, that Relator will not dismiss his claim for attorney’s fees, expenses, and costs pursuant to Paragraph 4, above, until such issue is finally resolved. It is a condition of this Agreement that the United States’ Complaint in Intervention and the Relator’s First Amended Complaint are dismissed with prejudice.

14. The Parties agree that the United States District Court shall have continuing jurisdiction to issue orders with regard to any disputes between Fresenius and Relator over the
amounts for expenses, attorneys’ fees and costs. As between themselves, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

15. 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.

16. 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 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.

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

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

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

20. This Agreement is binding on Fresenius’s successors, transferees, heirs, and assigns.

21. All Parties consent to the disclosure of this Agreement, and information about this Agreement, to the public.

22. 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: 10/7/2019 BY: ABRAHAM R. GEORGE
STEVEN SHAROBEM
JESSICA J. WEBER
KRIS BASIL
Assistant U.S. Attorneys
U.S. Attorney's Office for the District of Massachusetts

DATED: 10/4/2019 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
FRESENIUS MEDICAL CARE HOLDINGS, INC.,
D/B/A FRESENIUS MEDICAL CARE NORTH AMERICA – DEFENDANT

DATED: 10/3/2019 BY: 

RONALD L. CASTLE
Senior Vice President and Deputy General Counsel
Fresenius Medical Care North America

DATED: 10/3/2019 BY: 

WILLIAM KETTLEWELL
Counsel for Fresenius Medical Care North America