

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”); the Defense Health Agency (“DHA”), acting on behalf of the TRICARE program; and the Office of Personnel Management (“OPM”), which administers the Federal Employees Health Benefits Program (“FEHBP”); and Dr. Ashish Pal and his practice Interventional Cardiology and Vascular Consultants (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. Dr. Ashish Pal is a physician who owns and operates the medical practice Interventional Cardiology and Vascular Consultants, PLC (“ICVC”), with locations in Orlando, Sebring, and Davenport, Florida. Dr. Ashish Pal and Interventional Cardiology and Vascular Consultants are collectively referred to as “Dr. Pal” below.

B. The United States contends that Dr. Pal 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”); the TRICARE Program, 10 U.S.C. §§ 1071-1110b (“TRICARE”); and the FEHBP, 5 U.S.C. §§ 8901-8914.

C. The United States contends that it has certain civil claims against Dr. Pal arising from the submission of claims for payment for medically unnecessary ablations and vein stents to the Medicare and TRICARE programs and FEHBP during the period from January 1, 2013, through December 31, 2019. In particular, the United States contends that Dr. Pal: (1) performed ablations and stent procedures on veins that did not qualify for treatment under accepted standards of medical practice; (2) overstated the degree of reflux and the diameter of veins in

medical records to make the ablations appear to meet generally recognized medical standards, when, in fact, they did not; (3) falsely documented patient symptoms and conservative therapy measures in medical records to justify the ablation and stent procedures; (4) performed ablations on asymptomatic patients for cosmetic purposes; and (5) placed vein stents in patients in excess of the contemporaneous standards of medical practice. In addition, the United States contends that, in many instances, ablations were performed either exclusively or primarily by one or more ultrasound technicians outside their scope of practice. This conduct is referred to below as the “Covered Conduct.”

D. On May 29, 2020, the Centers for Medicare & Medicaid Services (“CMS”) suspended Medicare payments to Dr. Pal pursuant to 42 C.F.R. § 405.371(a)(2) based upon credible allegations of fraud. The total amount held by the United States as the result of the suspension of Medicare payments to Dr. Pal is one million, eight hundred forty-five thousand, six hundred fifty-five dollars and eighty-nine cents (\$1,845,655.89) and will be referred to herein as the “Suspended Amount.”

E. This Settlement Agreement is neither an admission of liability by Dr. Pal 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. Pal shall pay or relinquish to the United States a total of six million seven hundred and fifty thousand dollars (\$6,750,000) (“Settlement Amount”) plus interest, as follows:
 - a) Dr. Pal will pay four million, nine hundred four thousand, three hundred forty four dollars and eleven cents (\$4,904,344.11) plus interest at a rate of 1.5% per

annum from July 30, 2021, to be paid no later than 14 days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the Civil Division of the United States Department of Justice; and

- b) The United States will retain the Suspended Amount of one million, eight hundred forty-five thousand, six hundred fifty-five dollars and eighty-nine cents (\$1,845,655.89). Dr. Pal hereby agrees that the United States shall retain the Suspended Amount forevermore. Dr. Ashish Pal and ICVC expressly relinquish any and all rights of any kind that they may have with respect to those 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 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 Dr. Ashish Pal or ICVC may have to challenge the withholding or the suspension in any respect.

Of the Settlement Amount, three million three hundred and seventy-five thousand (\$3,375,000) constitutes restitution.

2. Subject to the exceptions in Paragraph 6 below, and upon the United States' receipt of the Settlement Amount plus interest due under Paragraph 1, the United States releases Dr. Pal 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 Dr. Pal in this Agreement and the Integrity Agreement (IA), entered into between OIG-HHS and Dr. Pal, and upon the United States' receipt of full payment of the Settlement Amount plus interest due under Paragraph 1, 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 Dr. Pal 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 6, below. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Dr. Pal 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 6, below.

4. In consideration of the obligations of Dr. Pal set forth in this Agreement, and upon the United States' receipt of full payment of the Settlement Amount, DHA shall release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from the TRICARE Program against Dr. Pal under 32 C.F.R. § 199.9 for the Covered Conduct, except as reserved in this paragraph and in Paragraph 6, below. DHA expressly reserves authority to exclude Dr. Pal from the TRICARE Program under 32 C.F.R. §§ 199.9 (f)(1)(i)(A), (f)(1)(i)(B), and (f)(1)(iii) (mandatory exclusion), based upon the Covered Conduct. Nothing in this paragraph precludes DHA or the TRICARE Program from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 6, below.

5. In consideration of the obligations of Dr. Pal in this Agreement, and upon the United States' receipt of full payment of the Settlement Amount, plus interest due under Paragraph 1, OPM shall release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from the FEHBP against Dr. Pal under 5 U.S.C. § 8902a or 5 C.F.R. Part 890 Subpart J or Part 919 for the Covered Conduct, except as reserved in this paragraph and in Paragraph 6, below, and except if excluded by the OIG-HHS pursuant to 42 U.S.C. § 1320a-7(a). OPM expressly reserves all rights to comply with any statutory obligation to debar Dr. Pal from the FEHBP under 5 U.S.C. § 8902a(b) (mandatory exclusion) based upon the Covered Conduct. Nothing in this paragraph precludes OPM from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 6, below.

6. Notwithstanding the release given in Paragraphs 2, 3, 4, and 5 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;
- f. Any liability of individuals other than Dr. Pal;
- 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.

7. Dr. Pal waives and shall not assert any defenses Dr. Pal 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. Dr. Pal 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 Dr. Pal has 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.

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), TRICARE or FEHBP carrier or payer, or any state payer, related to the Covered Conduct; and Dr. Pal agrees not to resubmit to any Medicare contractor, TRICARE or FEHBP carrier or payer, 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. Dr. Pal 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 Dr. Ashish Pal, ICVC, or 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) Dr. Pal'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;
- (5) the payment Dr. Pal makes to the United States pursuant to this Agreement; and
- (6) the negotiation of, and obligations undertaken pursuant to the IA to:
 - (i) retain an independent review organization to perform annual reviews as described in Section III of the IA; 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 10.a.(6) that may apply to the obligations undertaken pursuant to the IA affects the status of costs that are not allowable based on any other authority applicable to Dr. Pal.

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

c. Treatment of Unallowable Costs Previously Submitted for Payment: Dr. Ashish Pal and ICVC 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 Dr. Pal 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. Dr. Pal agrees that the United States, at a minimum, shall be entitled to recoup from Dr. Pal 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 Dr. Ashish Pal, ICVC or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on Dr. Ashish Pal, ICVC, 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 Dr. Pal'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, below.

12. Dr. Ashish Pal and ICVC 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.

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 Middle District of Florida. 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 Dr. Pal's successors, transferees, heirs, and assigns.

20. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, 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: 9/10/2021

BY: NICHOLAS PERROS
NICHOLAS C. PERROS
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

Digitally signed by NICHOLAS PERROS
Date: 2021.09.10 13:45:41 -04'00'

DATED: _____

BY: _____
MICHAEL KENNETH
Assistant United States Attorney
Middle District of Florida

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

DATED: _____

BY: _____
SALVATORE M. MAIDA
General Counsel
Defense Health Agency
United States Department of Defense

DATED: _____


BY: _____
PAUL ST. HILLAIRE
Assistant Inspector General
for Legal & Legislative Affairs
Office of the Inspector General
United States Office of Personnel Management

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____
NICHOLAS C. PERROS
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 8/26/21

BY:  _____
MICHAEL KENNETH
Assistant United States Attorney
Middle District of Florida

DATED: _____

BY: _____
LISA M. R
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 Defense

DATED: _____

BY: _____
PAUL ST. HILLAIRE
Assistant Inspector General
for Legal & Legislative Affairs
Office of the Inspector General
United States Office of Personnel Management

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____
NICHOLAS C. PERROS
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____

BY: _____
MICHAEL KENNETH
Assistant United States Attorney
Middle District of Florida

DATED: 9/07/21

BY: Lisa M. Re
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

DATED: _____

BY: _____
SALVATORE M. MAIDA
General Counsel
Defense Health Agency
United States Department of Defense

DATED: _____

BY: _____
PAUL ST. HILLAIRE
Assistant Inspector General
for Legal & Legislative Affairs
Office of the Inspector General
United States Office of Personnel Management

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____
NICHOLAS C. PERROS
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____

BY: _____
MICHAEL KENNETH
Assistant United States Attorney
Middle District of Florida

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

DATED: 08/25/2021

BY: _____
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SALVATORE M. MAIDA
for
General Counsel
Defense Health Agency
United States Department of Defense

DATED: _____

BY: _____
PAUL ST. HILLAIRE
Assistant Inspector General
for Legal & Legislative Affairs
Office of the Inspector General
United States Office of Personnel Management

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____
NICHOLAS C. PERROS
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____

BY: _____
MICHAEL KENNETH
Assistant United States Attorney
Middle District of Florida

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

DATED: _____

BY: _____
SALVATORE M. MAIDA
General Counsel
Defense Health Agency
United States Department of Defense


DATED: _____

BY: **PAUL ST HILLAIRE**
Digitally signed by PAUL ST HILLAIRE
DN: c=US, o=U.S. Government, ou=Office of Personnel
Management, cn=PAUL ST HILLAIRE,
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Date: 2021.09.02 11:11:43 -04'00'

PAUL ST. HILLAIRE
Assistant Inspector General
for Legal & Legislative Affairs
Office of the Inspector General
United States Office of Personnel Management

DATED: _____

BY: EDWARD
DEHARDE



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DEHARDE
Date: 2021.09.02 09:28:18 -04'00'

EDWARD M. DEHARDE
Assistant Director of Federal Employee
Insurance Operations
Healthcare and Insurance
United States Office of Personnel Management

DATED: 8/27/21 BY: Ashish Pal
DR. ASHISH PAL

INTERVENTIONAL CARDIOLOGY AND VASCULAR CONSULTANTS, PLC

DATED: 8/27/21 BY: Ashish Pal
DR. ASHISH PAL
Managing Member