

## 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), Kelly Wolfe, Regency, Inc., and Condra Albright (hereafter collectively referred to as “the Parties”), through their authorized representatives.

### RECITALS

A. Kelly Wolfe owned and operated Regency, Inc. (“Regency”), a Durable Medical Equipment (“DME”) billing and consulting company in Largo, Florida, which is within the Middle District of Florida. Regency provided consulting services, including the creation and sale of “turn-key” DME supply companies to clients in the Middle District of Florida, the Southern District of Florida, the Southern District of California, and elsewhere. As part of these services, Regency assisted clients with the accreditation and Medicare-enrollment process, and established numerous DME supply companies that then submitted claims for DME to Medicare.

B. On March 20, 2019, Condra Albright (Relator) filed an action in the United States District Court for the Middle District of Florida captioned *United States and the State of Florida ex rel. Condra Albright v. Regency Inc., Magic Medical, Inc., Kelly L. Wolfe, Does 1-300, and John and Jane Does 1-300*, Case No. 8:19-cv-686-T-30AEP, pursuant to the qui tam provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the Civil Qui Tam Action). The Civil Qui Tam Action alleges that Wolfe and Regency submitted and/or caused to be submitted false and/or fraudulent claims for payment to Medicare and other government payors, by falsifying documentation in order to fraudulently establish Durable Medical Equipment corporations to bill for medically unnecessary DME equipment and engaging in improper marketing practices that violate the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b.

C. On April 4, 2019, the United States filed, pursuant to 18 U.S.C. § 1345, a Complaint for Temporary Restraining Order and Preliminary and Permanent Injunction, along with an Emergency *Ex Parte* Motion for Temporary Restraining Order and Preliminary Injunction against Wolfe, Regency, and others (*United States v. Regency, Inc., et al.*, Case No. 8:19-cv-803-T-33AEP) (the Civil Injunctive Action). The same day, Honorable Virginia Covington, United States District Judge for the Middle District of Florida, entered a Temporary Restraining Order (“TRO”) against Wolfe, Regency, and others, enjoining them from committing health care fraud offenses, freezing their assets, ordering them to preserve business, financial, and accounting records, as well as medical records related to their business operations, and requiring them to make financial disclosures to the Government. Wolfe and Regency each stipulated to Preliminary Injunctions, which were entered by the Court. These Preliminary Injunctions bar Wolfe and Regency from submitting false claims to Medicare or committing any other Federal healthcare offenses, and prohibit the dissipation of certain assets.

D. The United States contends that Wolfe and Regency submitted or caused to be submitted false claims for payment to the Medicare Program.

E. The United States contends that it has certain civil claims against Wolfe and Regency arising from them submitting, or causing to be submitted, claims for orthotic braces to the Medicare program between October 2017 and April 2019 that were false because they were medically unnecessary and/or ordered by physicians in violation of the Anti-Kickback Statute. Specifically, the United States contends that:

i. Wolfe and Regency, with co-conspirators, including client-conspirators, engaged in trickery and deception to establish numerous DME supply companies, or “DME fronts” for their clients in the Middle District of Florida, the Southern District of Florida, the Southern

District of California, and elsewhere to facilitate the conspirators' submission of illegal DME claims to Medicare.

ii. Wolfe and Regency established hundreds of DME fronts through deceit, craft, and trickery during the credentialing process that Medicare required for billing privileges, including by knowingly including false information on CMS Forms-855S submitted to Medicare.

iii. Once established by Wolfe and Regency, the DME fronts, many of which had been sold to client-conspirators, provided unlawful kickbacks through telemedicine companies, created fraudulent telemedicine orders for DME supplies, including medically unnecessary orthotic braces, and then submitted claims to Medicare for reimbursement.

iv. Wolfe and Regency also employed other tricks and devices to dupe Medicare into approving DME billing privileges for the DME fronts, including the use of a drop-shipping company called "Magic Medical," that Wolfe and Regency used to execute sham inventory contracts with DME fronts. Thereafter, the Magic Medical contracts—which were necessary for any DME company without its own inventory to meet the requirements for Medicare billing privileges pursuant to 42 C.F.R. § 424.57(c)—were planted at DME fronts. Wolfe, Regency, and others also planted fake patient files for bogus DME sales at the fronts.

v. As part of their billing services for their client-conspirators, Wolfe and Regency submitted, or caused the submission of, thousands of false DME claims to Medicare for medically unnecessary DME or DME prescriptions that were generated through unlawful kickbacks to telemedicine companies and physicians.

The conduct in this Paragraph E is hereinafter referred to as the "Covered Conduct."

F. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above disputed claims, and defenses asserted by Wolfe and Regency, and in consideration of the mutual promises and obligations of this Agreement, the Parties agree and covenant as follows.

### **TERMS AND CONDITIONS**

1. Wolfe and Regency agree the United States shall receive \$20,332,516 (the Settlement Amount) out of the assets that will be forfeited pursuant to the plea agreement with Wolfe dated January 5, 2021 (the Plea Agreement). The assets forfeited pursuant to the plea agreement, following the expiration of the time for appeal of the forfeiture and, if applicable, the resolution in the United States' favor of any final such appeal, shall hereinafter be referred to as the Forfeited Assets (the Forfeited Assets).

2. Upon a court order that Kelly Wolfe pay restitution pursuant to the Plea Agreement and upon the administrative or judicial forfeiture to the United States of at least \$20,332,516 of the Forfeited Assets, the United States Attorneys' Office for the Middle District of Florida shall pay \$4,676,478, to Relator by electronic funds transfer. In the event that the Forfeited Assets are less than \$20,332,516, the United States Attorneys' Office for the Middle District of Florida shall pay 23% of the amount of the Forfeited Assets to Relator by electronic funds transfer. The amount owed by the United States to the Relator pursuant to this Paragraph shall hereinafter be referred to as the Relator's Share. (Relator's Share).

3. Subject to the exceptions in Paragraph 5 (concerning reserved claims), and subject to Paragraph 7 (concerning disclosure of assets), below and upon the administrative or judicial forfeiture to the United States of the Forfeited Assets, the United States releases Wolfe and Regency 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.

4. Subject to the exceptions in Paragraph 5 (concerning reserved claims), and subject to Paragraph 7 (concerning disclosure of assets), below and once the Forfeited Assets pursuant to the Plea Agreement are administratively or judicially forfeited, and any final appeal is resolved in favor of the United States, Relator, for herself and for her heirs, successors, attorneys, agents, and assigns, releases Wolfe, Regency, and Regency's officers, agents, and employees from any civil monetary claim the Relator has on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733 and from any liability to Relator arising from the filing of the Civil Qui Tam Action, or under 31 U.S.C. § 3730(d) for expenses or attorneys' fees and costs.

5. Notwithstanding the releases given in Paragraph 3 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 other than Wolfe;

- 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;
- i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

6. Relator and her heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). Conditioned upon Relator's receipt of the Relator's Share, Relator and her heirs, successors, attorneys, agents, and assigns 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 Qui Tam 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 Qui Tam Action.

7. Wolfe and Regency have 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. Wolfe and Regency warrant 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 Wolfe or Regency 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 Wolfe's or Regency'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 Wolfe or Regency 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 \$500,000 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 Wolfe or Regency's previously undisclosed assets. Wolfe and Regency agree not to contest any collection action undertaken by the United States pursuant to this provision, and agree that they 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, Regency and Wolfe waive and agree 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 Wolfe or Regency that this Agreement has been rescinded, and (b) relate to the Covered Conduct, except to the extent these defenses were available on March 20, 2019.

8. Wolfe and Regency waive and shall not assert any defenses Wolfe or Regency 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.

9. Wolfe and Regency fully and finally release 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 Wolfe or Regency have 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, including the Civil Injunction Action.

10. Wolfe and Regency fully and finally release the Relator from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Wolfe or Regency have asserted, could have asserted, or may assert in the future against the Relator, related to the allegations in the Civil Qui Tam Action and the Relator's investigation and prosecution thereof.

11. 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 Wolfe and Regency agree 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.

12. Wolfe and Regency 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 Wolfe and Regency, their present or former officers, directors, employees, shareholders, and agents in connection with:

i. the matters covered by this Agreement and any related plea agreement;

ii. the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;

iii. Wolfe's or Regency'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);

iv. the negotiation and performance of this Agreement and any Plea Agreement; and

v. the payment Wolfe or Regency makes to the United States pursuant to this Agreement and any payments that Wolfe or Regency may make to Relator, including costs and attorneys' 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: Unallowable Costs shall be separately determined and accounted for by Wolfe and Regency, and Wolfe and Regency 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 Wolfe or Regency or any of their subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Wolfe and Regency 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 Wolfe or Regency 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. Wolfe and Regency agree that the United States, at a minimum, shall be entitled to recoup from Wolfe and Regency 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.

d. 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 Wolfe and Regency or any of their subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on Wolfe, Regency, or any of their subsidiaries or affiliates' cost reports, cost statements, or information reports.

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

13. Wolfe and Regency agree to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, Wolfe and Regency 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. Wolfe and Regency 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 it has undertaken, or that has been performed by another on their behalf.

14. 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 16 (waiver for beneficiaries paragraph), below.

15. Wolfe and Regency 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.

16. 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 Wolfe and Regency's financial condition as reflected in the Financial Disclosures referenced in Paragraph 7.

17. In exchange for valuable consideration provided in this Agreement, Wolfe and Regency acknowledge the following:

a. 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 Wolfe and Regency, 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.

b. 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.

c. The Parties do not intend to hinder, delay, or defraud any entity to which Wolfe or Regency 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).

d. If Wolfe or Regency's 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, Wolfe or Regency 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 Wolfe or Regency's debts, or to adjudicate Wolfe or Regency as bankrupt or insolvent; or seeking appointment of a receiver, trustee, custodian, or other similar official for Wolfe or Regency or for all or any substantial part of Wolfe or Regency'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 Wolfe or Regency for the claims that would otherwise be covered by the releases provided in Paragraph 4 above;

ii. the United States has an undisputed, noncontingent, and liquidated allowed claim against Wolfe and Regency in the amount of \$549,000,000, less any payments received pursuant to this agreement, provided, however, that such payments are not otherwise avoided and recovered from the United States by Wolfe or Regency, a receiver, trustee, custodian, or other similar official for Wolfe or Regency; and

iii. if any payments are avoided and recovered by Wolfe or Regency, a receiver, trustee, custodian, or similar official for Wolfe or Regency, Relator shall, within thirty

days of written notice from the United States to the undersigned Relator's counsel, return any portions of such payments already paid by the United States to Relator pursuant to Paragraph 2.

e. Wolfe and Regency agree that any civil and/or administrative claim, action, or proceeding brought by the United States under Paragraph 17.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. Wolfe and Regency 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). Wolfe and Regency 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 Wolfe or Regency that the releases have been rescinded pursuant to this paragraph, except to the extent such defenses were available on March 20, 2019.

18. Upon execution of this agreement and the administrative or judicial forfeiture to the United States of the Forfeited Assets, the Parties shall promptly sign and file in the Civil Qui Tam Action a Joint Stipulation of Dismissal of the Civil Qui Tam Action pursuant to Rule 41(a)(1).

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

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

21. 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.

22. 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.

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

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

25. This Agreement is binding on Wolfe and Regency's successors, transferees, heirs, and assigns.

26. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.

27. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

28. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement).

29. Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

**FOR THE UNITED STATES OF AMERICA:**

DATED: 1-19-21

BY: Carolyn B. Tapie  
Carolyn B. Tapie  
Assistant United States Attorney  
Middle District of Florida

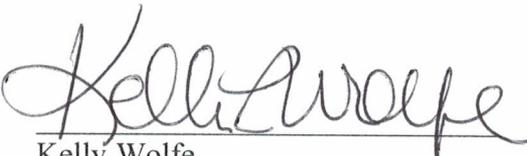
DATED: 1/19/21

BY: Daniel A. Schiffer  
Daniel A. Schiffer  
Trial Attorney, Commercial Litigation Branch  
Department of Justice

DATED: 01/21/21

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

**FOR DEFENDANTS KELLY WOLFE AND REGENCY, INC.**

DATED: 1/19/2021 BY:   
Kelly Wolfe

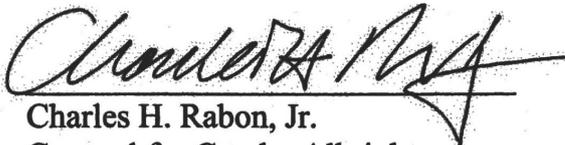
DATED: 1/19/2021 BY:   
Eddie Suarez  
Counsel for Kelly Wolfe and Regency, Inc.

**FOR RELATOR CONDRA ALBRIGHT:**

DATED: 1/15/21

BY:   
Condra Albright

DATED: 1/15/2021

BY:   
Charles H. Rabon, Jr.  
Counsel for Condra Albright