

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”) (collectively, the “United States”), and the State of North Carolina, acting through the Medicaid Investigation Division of the North Carolina Department of Justice, Office of the Attorney General (“North Carolina”), and Joint Active Systems, Inc. (“JAS”), (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. JAS is a manufacturer of range-of-motion therapy devices with its principal place of business being located in Effingham, Illinois.

B. The United States and the State of North Carolina contend that JAS submitted or caused to be submitted claims for payment to the North Carolina Medicaid Program, 42 U.S.C. §§ 1396-1396w-5 (“Medicaid”).

C. The United States and the State of North Carolina contend that they have certain civil claims against JAS arising from the submission of false claims for durable medical equipment (“DME”) and/or orthotic devices to North Carolina Medicaid, by way of JAS bypassing North Carolina Medicaid regulations and requirements and causing its “EZ” range-of-motion devices (“JAS EZ Devices”) to be improperly claimed as custom-fabricated orthotics during the period from **January 6, 2012** through **January 29, 2021**, with JAS paying local North Carolina orthotic and prosthetic providers to make improper claims to North Carolina Medicaid on JAS’s behalf.

Specifically, the United States and the State of North Carolina allege that between **January 6, 2012** through **January 29, 2021**:

- (i) JAS bypassed North Carolina Medicaid requirements by entering into arrangements with local North Carolina orthotics and prosthetics providers to improperly submit claims for JAS EZ devices as “L-Code” claims under the Healthcare Common Procedure Coding System (“HCPCS”).
- (ii) Certain “L-Code” HCPCS coded claims (e.g. L1844, L1846, L1970, L3730, L3740, L3766, L3905, L3921 and L3973) are designated for orthotics, including custom-fabricated orthotics. JAS EZ devices do not qualify as being reimbursed as “L-Code” orthotics under North Carolina Medicaid and the JAS EZ devices were not listed as reimbursable devices on the North Carolina Medicaid fee schedule.
- (iii) JAS was unable to directly bill North Carolina Medicaid for its devices as JAS was unable to meet North Carolina Medicaid requirements and/or lacked credentials necessary to do so.
- (iv) JAS bypassed its inability to bill North Carolina Medicaid directly by entering into an arrangement with local North Carolina orthotics and prosthetics providers to improperly bill its JAS EZ devices. Under this arrangement, JAS would direct the local North Carolina orthotics and prosthetics provider to improperly bill North Carolina Medicaid for a JAS EZ device as an “L-Code,” bypassing any medical necessity reviews and/or authorization processes that may have otherwise taken place. Once the improper “L-Code” claim was paid to the local North Carolina orthotics and prosthetics provider, JAS would then pay the local orthotics and prosthetics provider by allowing the provider to retain a certain amount of the claim for billing the device as an “L-Code” on JAS’s behalf.

- (v) A review of records support that JAS EZ devices were being improperly billed as “L-Code” devices in North Carolina, while JAS also received an official coding verification from the Centers for Medicare and Medicaid Services (“CMS”) in 2006, with a consensus coding decision also being made following a re-review by CMS in 2007, that designated one of JAS’s EZ devices, the JAS EZ Toe Device, as an “E-Code” DME device – not as an “L-Code” device. Nevertheless, JAS continued to bill its JAS EZ devices as “L-Code” devices to North Carolina Medicaid, bypassing North Carolina Medicaid regulations and requirements, and utilizing local orthotics and prosthetics providers to do so; with JAS making payments to those local orthotics and prosthetics providers by allowing the providers to retain a certain amount of the claim for billing the device as an “L-Code” on JAS’s behalf.

That above-described conduct is referred to herein as the “Covered Conduct.” As a result of the Covered Conduct, the United States and the State of North Carolina contend that JAS caused false claims to be submitted to the North Carolina Medicaid Program.

D. This Settlement Agreement is neither an admission of liability by JAS nor a concession by the United States or North Carolina that their claims are not well founded.

E. JAS denies the allegations in Paragraph C, above.

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. JAS shall pay to the United States and to the State of North Carolina a total amount of **Five-Hundred-Thousand Dollars (\$500,000.00)** ("Settlement Amount"), of which \$249,523.81 is restitution, no later than 60 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 Eastern District of North Carolina. If JAS defaults on the payment terms or on any other term in this Agreement, then interest shall continue to accrue on the outstanding balance of the Settlement Amount at an annual rate of 12 percent (compounded daily), and the United States and the State of North Carolina may take any and all action permitted by law, including as set forth in Paragraphs 5 and 6 below.

2. Subject to the exceptions in Paragraph 3 (concerning reserved claims) below, and upon the United States' receipt of the Settlement Amount, the United States and the State of North Carolina release JAS, together with its current and former parent corporations, direct and indirect subsidiaries, divisions, current or former corporate owners, and the corporate successors and assigns of any of them, from any civil or administrative monetary claim the United States and the State of North Carolina have 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; the North Carolina False Claims Act, N.C.G.S. § 1-605 - § 1-618, 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 and rights of the United States and the State of North Carolina 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) and the State of North Carolina (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;
- 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 civil or administrative liability that any person or entity, including JAS, has or may have to the Government or to individual consumers or federal or state program payors under any statute, regulation, or rule not expressly covered by the release in Paragraph 2 above, including but not limited to, any and all of the following claims:
 - (i) State or federal antitrust violations;
 - (ii) Claims involving unfair and/or deceptive acts and practices and/or violations of consumer protection laws;
- i. Any liability for failure to deliver goods or services due;
- j. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct;

4. JAS waives and shall not assert any defenses JAS 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.

5. If JAS defaults on any of its obligations under this Agreement, the Settlement amount shall become due and payable in full immediately, interest shall accrue at a rate of 12 percent per annum compounded daily, and the United States and the State of North Carolina may take whatever steps it is entitled to take pursuant to law to collect the Settlement Amount (plus all accrued interest) and to enforce the obligations of this Agreement, including but not limited to (a) any and all collection actions, and (b) the filing of a civil action for the Covered Conduct. In the event a complaint is filed pursuant to subsection (b) of this paragraph, JAS agrees not to plead, argue, or otherwise raise any defenses under the theories of statutes of limitation, laches, and estoppel, or similar theories, to the allegations in the complaint, except to the extent such defenses were available to them on the Effective Date of this Agreement. Furthermore, in the event a complaint is filed pursuant to subsection (b) of this paragraph, JAS agrees to sign a consent judgment in the amount of the unpaid balance of the Settlement Amount and all accrued interest, plus continuing interest at a rate of 12 percent per annum compounded daily. JAS further agrees not to contest any collection action taken by the United States or the State of North Carolina, including garnishment, execution, and offsets of federal and/or state benefits and payments (including offsets by the Internal Revenue Service and any other federal or state agency). JAS shall pay to the United States and the State of North Carolina all reasonable costs of collection and enforcement under this paragraph, including attorneys' fees and expenses. In addition, in the event of default, OIG-HHS may exclude JAS from participating in all Federal health care programs until JAS pays the Settlement Amount and reasonable costs as set forth above. OIG-HHS will provide written notice of any such exclusion to JAS. JAS 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 JAS wishes to apply for reinstatement to OIG-HHS in accordance with the provisions of 42 C.F.R. §§ 1001.3001-.3005 JAS will not be reinstated unless and until OIG-HHS approves such request for reinstatement.

6. Furthermore, if JAS defaults on any terms under this Agreement, it agrees to provide full, updated financial disclosures to the United States and to the State of North Carolina. The United States and the State of North Carolina may request, and JAS shall provide, any and all documents relating to its financial condition, including but not limited to state and federal tax returns and the tax returns for any business owned, has an interest in, or participates in, including all schedules and attachments; all bank account statements (including copies of deposits and checks), for every bank account to which JAS has access or an interest (including but not limited to personal accounts, joint accounts, and business accounts); and an updated financial affidavit for any business that JAS owns and/or has an interest in.

7. JAS fully and finally releases the United States, its agencies, officers, agents, employees, and servants, and the State of North Carolina, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that JAS has asserted, could have asserted, or may assert in the future against the United States and/or the State of North Carolina, and their agencies, officers, agents, employees, and servants related to the Covered Conduct and the United States' and the State of North Carolina's investigation and 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 JAS 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. JAS 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. §§ 1395-1395III and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of JAS, 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) JAS'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; and
- (5) the payment JAS makes 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. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by JAS, and JAS 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 JAS or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: JAS 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 JAS 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. JAS agrees that the United States and the State of North Carolina, at a minimum, shall be entitled to recoup from JAS 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 and/or the State of North Carolina pursuant to the direction of the Department of Justice and/or the affected agencies. The United States and the State of North Carolina reserve its rights to disagree with any calculations submitted by JAS or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on JAS 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 or the State of North Carolina to audit, examine, or re-examine JAS's books and

records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.

10. 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 11 (waiver for beneficiaries paragraph), below.

11. JAS 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.

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

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

14. This Agreement is governed by the laws of the United States and the State of North Carolina. The exclusive venue for any dispute relating to this Agreement is the United States District Court for the Eastern District of North Carolina, Raleigh, North Carolina. 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.

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

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

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


18. This Agreement is binding on JAS's successors, transferees, heirs, and assigns.

19. All Parties consent to the United States' and the State of North Carolina's disclosure of this Agreement, and information about this Agreement, to the public.

20. 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

1/27/2023
DATED: _____

BY: 

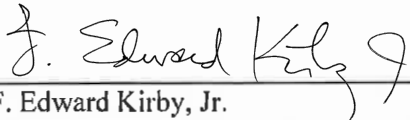
Matthew R. Petracca
Special Assistant United States Attorney
Eastern District of North Carolina

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

THE STATE OF NORTH CAROLINA

DATED: 1/27/2023

BY: 

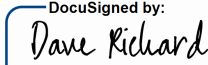
F. Edward Kirby, Jr.
Director, Medicaid Investigations Division
Office of the Attorney General

NC DEPARTMENT OF HEALTH & HUMAN SERVICES,

DIVISION OF HEALTH BENEFITS

01/31/23 | 9:30 AM PST

DATED: _____

BY: 

Dave Richard
11395D232A054A2...
Deputy Secretary, NC Medicaid
NC Department of Health & Human Services,
Division of Health Benefits

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____

Matthew R. Petracca
Special Assistant United States Attorney
Eastern District of North Carolina

DATED: 1/28/2023

BY: _____

SUSAN
EDWARDS

Digitally signed by SUSAN
EDWARDS
Date: 2023.01.28 16:09:04
-05'00'

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

THE STATE OF NORTH CAROLINA

DATED: _____

BY: _____

F. Edward Kirby, Jr.
Director, Medicaid Investigations Division
Office of the Attorney General

NC DEPARTMENT OF HEALTH & HUMAN SERVICES,

DIVISION OF HEALTH BENEFITS

DATED: _____

BY: _____

Dave Richard
Deputy Secretary, NC Medicaid
NC Department of Health & Human Services,
Division of Health Benefits

JOINT ACTIVE SYSTEMS, INC.

DATED: 1/23/2023

BY: Boris Bonutti
Boris Bonutti, President
Joint Active Systems, Inc.

DATED: 1/24/23

BY: Evan Z. Reid
Evan Z. Reid
Counsel for Joint Active Systems, Inc.