

## **STATE SETTLEMENT AGREEMENT**

### **I. PARTIES**

This Settlement Agreement (the “Agreement”) is entered into between the State of California (“the State”) and Medicrea USA Inc. (“MUSAC”) and Medicrea International (“MI”), (collectively “Medicrea”) hereinafter collectively referred to as “the Parties.”

### **II. PREAMBLE**

The Parties agree to the following:

A. Medicrea manufactures- and markets and sells within the United States and elsewhere, including in the Eastern District of Pennsylvania- medical devices used to treat spinal diseases, including scoliosis and other disorders requiring spinal fusion.

B. MI, the parent company of MUSAC, is headquartered in Lyon, France. MUSAC is headquartered in the State of New York.

C. The State contends that Medicrea caused claims to be submitted for payment to the Medicaid Program (“Medicaid”) (42 U.S.C. §§ 1396-1396w-5), and to the State Medicaid Program, including “managed care entities” as defined by 42 U.S.C. § 1396u-2, which provides health insurance for certain persons with limited income and resources.

D. In mid-to-late September 2013, Medicrea hosted a variety of events surrounding meetings at the Scoliosis Research Society’s Congress in Lyon, France (“the 2013 SRS Conference”). Medicrea provided certain transportation, meals, drinks, and entertainment to  
*Medicrea USA Corp. #596*

various United States-based physicians (“U.S.-based physicians”) who attended the 2013 SRS Conference as well as some of these Medicrea-hosted events in France.

E. The following conduct is referred to in this Agreement as the “Covered Conduct”:

1. The State contends that it has certain civil claims against Medicrea arising from the companies’ provision of benefits—specifically meals, alcoholic beverages, entertainment, and travel expenses—to U.S.-based physicians who attended events in France surrounding the 2013 SRS Conference and occurring between September 18 and 21, 2013, in return for some of the physicians purchasing or ordering—or arranging for or recommending the purchasing or ordering of—Medicrea’s medical devices that were to be paid for, in whole or in part, under a federal healthcare program. The State contends that this conduct violated the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(1)(B) (“AKS”) and the related State false claims act statutes, and resulted in claims submitted to, or purchases made by, the state Medicaid Program between October 1, 2013 and December 31, 2015.

F. On April 27, 2016, Dory Frain, (the “Relator”) filed a *qui tam* action in the United States District Court for the Eastern District of Pennsylvania—captioned *United States of America, et al., ex rel. Dory Frain v. Medicrea USA Corporation*, Civil Action No. 16-1986—under the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) and related State statutes (the “Civil Action”). In her *qui tam* complaint, Relator alleged, among other things, that MUSAC—in order to induce referrals, recommendations, and arrangements for purchase of the companies’ spinal products—violated the AKS and related state statutes by providing to surgeons various benefits

and perquisites that included not only paid travel to France but also meals and beverages for surgeons and some of their family members. Relator further alleged that these and other violations caused the submission of false and fraudulent claims to state health care programs. This *qui tam* action will be referred to as the “Civil Action.”

G. Medicrea entered, or will be entering into, a separate civil settlement agreement (the “Federal Settlement Agreement”) with the “United States of America” (the “United States”) as that term is defined in the Federal Settlement Agreement.

H. This Agreement is neither an admission of facts or liability by Medicrea nor a concession by the State that its allegations are not well founded.

I. 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 Agreement, the Parties agree and covenant as follows:

### III. TERMS AND CONDITIONS

1. Medicrea agrees to pay to the United States and the Medicaid Participating States (as defined in sub-paragraph (c) and subject to the non-participating state deduction provision of sub-paragraph (d) below), collectively, the sum of Two Million Dollars (\$2,000,000.00) plus accrued interest at the rate of 0.75% per annum, calculated monthly, from October 23, 2020, and continuing until and including the date of payment, (the “Settlement Amount”).<sup>1</sup> The Settlement Amount shall constitute a debt immediately due and owing to the United States and the Medicaid Participating States on the “effective date” of the Federal Settlement Agreement, as defined therein

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<sup>1</sup> Of the \$2,000,000.00 recovery, \$1,000,000.00 is attributed to federal health care programs, including Medicaid. The remaining \$1,000,000.00 recovery is attributed violations of the Open Payments Program, which affects the Medicare Program, but not the Medicaid Program.

and subject to the terms of this Agreement. The debt shall forever be discharged by payments to the United States and the Medicaid Participating States under the following terms and conditions:

(a) Medicrea shall pay to the United States the sum of \$2,000,000.00 plus accrued interest pursuant to the terms of the Federal Settlement Agreement.

(b) The total recovery for government healthcare programs under this Agreement is \$1,000,000.00 consisting of \$414,971.10 for the states pursuant to this Agreement and \$585,028.90 for the United States pursuant to the Federal Settlement Agreement. Medicrea shall pay to the Medicaid Participating States the sum of \$414,971.10 plus accrued interest on that amount at the rate of 0.75% per annum commencing on October 23, 2020 and continuing to and including the day payment is made under this Agreement (the “Medicaid State Settlement Amount”), subject to the non-participating state deduction provision of sub-paragraph (d) below (the “Medicaid Participating State Settlement Amount”), no later than seven (7) business days after the expiration of the 60-day opt-in period for Medicaid Participating States described in Sub-paragraph (c) below. The Medicaid Participating State Settlement Amount shall be paid and immediately deposited by electronic funds transfer to the New York State Attorney General’s National Global Settlement Account pursuant to written instructions from the state negotiating team (the “State Team”), which written instructions shall be delivered to counsel for Medicrea. The electronic funds transfer shall constitute tender and negotiation of the State Amount as defined in Paragraph III. 1. (d) below.

(c) Medicrea shall execute a State Settlement Agreement with any State that executes such an Agreement in the form to which Medicrea and the State Team have agreed, or in a form otherwise agreed to by Medicrea and an individual State. The State shall constitute a Medicaid

Participating State provided this Agreement is fully executed by the State and delivered to Medicrea's attorneys within 60 days of receiving this Agreement. Medicrea's offer to resolve this matter with the State shall become null and void absent written agreement between counsel for Medicrea and the State Team to extend the 60-day period.

(d) The total portion of the amount paid by Medicrea in settlement for the Covered Conduct for the State is \$154,768.56, consisting of a portion paid to the State under this Agreement and another portion paid to the United States as part of the Federal Settlement Agreement. The amount allocated to the State under this Agreement is the sum of \$92,861.14 plus applicable interest (the "State Amount"), of which \$44,010.02 is restitution or an amount to come into compliance with law. If the State does not execute this Agreement within 60 days of receiving this Agreement, the State Amount shall be deducted from the Medicaid State Settlement Amount and shall not be paid by Medicrea absent written agreement between counsel for Medicrea and the State Team to extend the time period for executing this Agreement.

2. Contingent upon receipt of the State Amount, the State agrees to dismiss with prejudice any state law claims which the State has the authority to dismiss currently pending against Medicrea in State or Federal Courts for the Covered Conduct, including any supplemental state law claims asserted in the Civil Action, with the exception of claims arising under California's Insurance Fraud Protection Act (California Insurance Code §§1871.7, *et seq.*). Contingent upon receipt of the State Amount, the State, if served with the Civil Action and liable to pay a relator's share, agrees to pay the Relator, as soon as feasible after such receipt, such amounts as have been or will be negotiated with the Relator in the Civil Action, which shall be set forth in side letters issued to and executed by the Relator in the Civil Action.

3. Subject to the exceptions in Paragraph 4 below, in consideration of the obligations of Medicrea set forth in this Agreement, and conditioned upon tender and negotiation of the State Amount, the State agrees to release Medicrea USA Corp., together with their current and former parent corporations entities; direct and indirect subsidiaries; brother or sister corporations; divisions; current or former corporate owners; and the corporate successors and assigns of any of them. (collectively, the “Medicrea Released Entities”), from any civil or administrative monetary cause of action that the State has for any claims submitted or caused to be submitted to the State’s Medicaid Program as a result of the Covered Conduct.

4. Notwithstanding the releases given in Paragraph 3 of this Agreement, or any other term of this Agreement, the following claims of the State are specifically reserved and are not released:

- (a) any criminal, civil, or administrative liability arising under state revenue codes;
- (b) any criminal liability;
- (c) any civil or administrative liability that any person or entity, including the Medicrea Released Entities, has or may have to the State or to individual consumers or state program payors under any statute, regulation, or rule not expressly covered by the release in Paragraph 3 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; and (iii) violations of California’s Insurance Fraud Protection Act (California Insurance Code §§1871.7, *et seq.*);
- (d) any liability to the State for any conduct other than the Covered Conduct;
- (e) any liability based upon obligations created by this Agreement;

(f) except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusions from the State's Medicaid Program;

(g) any liability for expressed or implied warranty claims or other claims for defective or deficient products and services, including quality of goods and services;

(h) any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct;

(i) any liability for failure to deliver goods or services due; or

(j) any liability of individuals.

5. In consideration of the obligations of Medicrea set forth in this Agreement, and conditioned on receipt by the State of the State Amount, the State agrees to release and refrain from instituting, recommending, directing, or maintaining any administrative action seeking exclusion from the State's Medicaid Program against Medicrea for the Covered Conduct, except as reserved in Paragraph 4 above. Nothing in this Agreement precludes the State from taking action against Medicrea in the event that Medicrea is excluded by the federal government, or for conduct and practices other than the Covered Conduct.

6. Medicrea waives and shall not assert any defenses it may have to criminal prosecution or administrative action for the Covered Conduct, which defenses may be based in whole or in part on a contention, under the Double Jeopardy Clause of the Fifth Amendment of the U.S. Constitution or the Excessive Fines Clause of the Eighth Amendment of the U.S. Constitution, that this Agreement bars a remedy sought in such criminal prosecution or administrative action.

7. In consideration of the obligations of the State set forth in this Agreement, the *Medicrea Released Entities* waive and discharge the State and any of its agencies, departments, and personnel including, but not limited to, officials, employees, and agents, whether current or former in their official and individual capacities from any causes of action (including attorneys' fees, costs, and expenses of every kind and however denominated) which the *Medicrea Released Entities* have against the State and any of its agencies, departments, and personnel as previously referenced arising from the State's investigation and prosecution of the Covered Conduct.

8. The amount that Medicrea must pay to the State pursuant to Paragraph III.1. above will not be decreased as a result of the denial of any claims for payment now being withheld from payment by the State's Medicaid Program, or any other state program payor, for the Covered Conduct; and Medicrea agrees not to resubmit to the State's Medicaid Program or any other state program payor, any previously denied claims, which denials were based on the Covered Conduct.

9. Medicrea shall not seek payment for any claims for reimbursement to the State's Medicaid Program covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third-party payors.

10. Medicrea expressly warrants that it has reviewed its financial condition and that it is currently solvent, meaning that a fair valuation of its property (exclusive of exempt property) exceeds the sum of its debts.

11. The Parties each represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

12. Medicrea agrees to cooperate fully and truthfully with any State investigation of individuals or entities not released in this Agreement as to the Covered Conduct. Upon reasonable



notice of such an investigation, Medicrea shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its 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 and of Medicrea. Upon request, Medicrea agrees to furnish to the State complete and unredacted copies of all non-privileged documents including, but not limited to, reports, memoranda of interviews, and records in its possession, custody or control, concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf, as well as complete and unredacted copies of any other non-privileged documents in its possession, custody, or control relating to the Covered Conduct. Medicrea shall be responsible for all costs it may incur in complying with this paragraph.

13. Except as expressly provided to the contrary in this Agreement, each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

14. Except as otherwise stated in this Agreement, this Agreement is intended to be for the benefit of the Parties only, and the Parties do not release any liability as to any other person or entity. 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.

15. Nothing in this Agreement constitutes an agreement by the State concerning the characterization of the amounts paid hereunder for purposes of the State's revenue code.

16. In addition to all other payments and responsibilities under this Agreement, Medicrea agrees to pay the State Team's reasonable expenses and fees, including travel costs, consultant expenses, and administrative fees. Medicrea will pay this amount by separate check made payable to the National Association of Medicaid Fraud Control Units, after the Medicaid Participating States execute their respective Agreements, or as otherwise agreed by the Parties.

17. This Agreement is governed by the laws of the State, and venue for addressing and resolving any and all disputes relating to this Agreement shall be the state courts of appropriate jurisdiction of the State.

18. The undersigned Medicrea signatories represent and warrant that they are authorized as a result of appropriate corporate action to execute this Agreement. The undersigned State signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement on behalf of the State through their respective agencies and departments.

19. The Effective Date of this Agreement shall be the date of signature of the last signatory to this Agreement. Facsimiles of signatures shall constitute acceptable binding signatures for purposes of this Agreement.

20. This Agreement shall be binding on all successors, transferees, heirs, and assigns of the Parties.

21. This Agreement constitutes the complete agreement between the Parties with respect to this matter and shall not be amended except by written consent of the Parties.

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

23. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by the Parties to this Agreement and shall not, therefore, be construed against any of the Parties for that reason.

**STATE OF CALIFORNIA**



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RANDAL L. GLASER  
Deputy Attorney General  
California Attorney General's Office

Date: May, 5, 2021



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WILL LIGHTBOURNE  
Director  
California Department of Health Care Services

Date: 4/15/2021

MEDICREA USA, INC.

DATED: April 28, 2021 BY: \_\_\_\_\_

*Nadège*

Nadège Bourdois  
Directrice Juridique et Ressources Humaines  
Medicrea International

DATED: April 28, 2021 BY: \_\_\_\_\_

*Marc S. Raspanti*

Marc S. Raspanti, Esquire  
Pamela Coyle Brecht, Esquire  
Erik R. Giannitrapani, Esquire  
Pietragallo Gordon Alfano  
Bosick & Raspanti, LLP

**MEDICREA INTERNATIONAL**

DATED: April 28, 2021

BY:

Nadège Bourdois  
Nadège Bourdois  
Directrice Juridique et Ressources Humaines  
Medicrea International

DATED: April 28, 2021

BY:

Marc Raspanti  
Marc S. Raspanti  
Pamela Coyle Brecht  
Erik R. Giannitrapani  
Pietragallo Gordon Alfano  
Bosick & Raspanti, LLP

MEDICREA USA, INC.

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

NAME  
TITLE  
Medicrea USA, Inc.

DATED: 5-10-2021

BY: Marc S. Raspanti

Marc S. Raspanti, Esquire  
Pamela Coyle Brecht, Esquire  
Erik R. Giannitrapani, Esquire  
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