Josh Stein
Attorney General

State of North Carolina
Department of Justice

Seth Dearmin
Chief of Staff

May 2, 2024

North Carolina Senate President Pro Tempore Phil Berger
North Carolina House of Representatives Speaker Tim Moore
Co-Chairs, Joint Legislative Commission on Governmental Operations

Senator Danny Earl Britt, Jr.
Senator Warren Daniel
Representative Ted Davis, Jr.
Representative Dudley Greene
Representative Charles W. Miller
Representative Carson Smith
Co-Chairs, Appropriations Subcommittee on Justice and Public Safety

North Carolina General Assembly
Raleigh, North Carolina 27601-1096

RE: G.S. §114-2.5; Report on Settlement Agreement for Lincare, Inc. and Mako Medical Laboratories, LLC

Dear Members:

Section 114-2.5 of the North Carolina General Statutes requires the Attorney General to report to the Joint Legislative Commission on Governmental Operations and the Chairs of the Appropriations Subcommittees on Justice and Public Safety regarding all settlements and court orders which result in more than $75,000.00 being paid to the State. Pursuant to that statute, I am writing regarding the settlement of claims for Medicaid reimbursement to the state and federal governments in the above-referenced matter. Pursuant to federal law (42 C.F.R. § 433.320) recoveries in these cases are shared on a pro rata basis by the state and federal governments.

<u>Lincare, Inc.</u>

A settlement has been executed between Lincare, Inc. and the State of North Carolina.

The settlement resolves allegations that from January 1, 2013, through February 29, 2020, Lincare provided non-invasive ventilators that were not medically necessary.

Under the terms of North Carolina's settlement, the State of North Carolina will recover \$83,802.61. Of that amount the federal government will receive \$47,267.20 for North Carolina's federal portion of Medicaid recoveries. Pursuant to G.S. § 1-610, the qui tam plaintiffs whose whistleblower actions brought this matter to the government's attention will receive \$7,053.69 of North Carolina's recovery. The North Carolina Medicaid Program will receive \$14,015.11 as restitution and interest. In addition, pursuant to Article IX, Section 7 of the North Carolina Constitution and G.S. § 115C-457.1, the penalty portion of the settlement in the amount of \$14,298.93 will be paid to the Civil Penalty Forfeiture Fund for the support of North Carolina public schools. Pursuant to G.S. § 115C-457.2 and G.S. § 1-608(c), the North Carolina Department of Justice will receive \$1,167.68 for investigative costs and costs of collection.

Mako Medical Laboratories, LLC

A settlement has been executed between Mako Medical Laboratories, LLC and the State of North Carolina.

The settlement resolves allegations that from January 1, 2018 through December 31, 2022, Mako submitted false claims to the Medicaid program for medically unnecessary definitive urine drug tests that Mako simultaneously reported with presumptive urine drug tests to healthcare providers.

Under the terms of North Carolina's settlement, the State of North Carolina will recover \$2,140,685.00. Of that amount the federal government will receive \$1,303,891.23 for North Carolina's federal portion of Medicaid recoveries. The North Carolina Medicaid Program will receive \$400,778.05 as restitution and interest. In addition, pursuant to Article IX, Section 7 of the North Carolina Constitution and G.S. § 115C-457.1, the penalty portion of the settlement in the amount of \$403,098.03 will be paid to the Civil Penalty Forfeiture Fund for the support of North Carolina public schools. Pursuant to G.S. § 115C-457.2 and G.S. § 1-608(c), the North Carolina Department of Justice will receive \$32,917.69 for investigative costs and costs of collection.

We will be happy to respond to any questions you may have regarding this report.

Very truly yours,

Seth Dearmin
Chief of Staff

LB:ng

cc: Sean Hamel, NCGA Fiscal Research Division
Mark White, NCGA Fiscal Research Division
Morgan Weiss, NCGA Fiscal Research Division

SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into between the North Carolina Office of the Attorney General on behalf of the State of North Carolina ("North Carolina" or "State") and Mako Medical Laboratories LLC ("Mako"), a North Carolina Medicaid Provider. Each of the above is hereafter referred to as "the Parties" through their authorized representative.

RECITALS

A. Mako is a North Carolina limited liability company headquartered in Raleigh, North Carolina. Mako has been a Medicaid Provider since at least 2014 and operates a clinical laboratory and offers clinical laboratory services for Medicaid beneficiaries in and around the State of North Carolina, including but not limited to urine drug testing ("UDT"). Medicaid Providers may submit claims to the North Carolina Medicaid Program for services that are medically necessary for the care of Medicaid beneficiaries and which comply with Medicaid Clinical Policy.

B. North Carolina contends that it has certain civil claims against Mako arising from the following conduct, during the dates of January 1, 2018, through December 31, 2022, for Mako's submission of claims to the North Carolina Medicaid Program for medical services, to wit, as follows:

> To wit, Mako offered its healthcare provider ("HCP") clients the option to order both presumptive and definitive UDTs. For those HCP clients who submitted orders to Mako for both presumptive and definitive UDTs, Mako performed both presumptive and definitive UDTs on the same sample at or near the same time, for the same or similar substances, often providing overlapping information for presumptive and definitive UDTs. Mako performed definitive testing at a level of at least 22 plus classes of drugs per sample (CPT G0483) without alteration as to the level of testing performed by Mako throughout the duration of the Medicaid beneficiaries' treatment, irrespective of the results and progression, or lack

thereof, by the beneficiary in terms of his/her treatment for substance abuse. Mako then reported both the presumptive and definitive UDT results back to the HCPs at the same time. Absent HCP-designated reflex order(s) in certain situations or clear orders from HCPs, this definitive testing was not medically necessary or reasonable under North Carolina Medicaid policy. Yet, from January 1, 2018, through December 31, 2022, Mako billed, or caused to be billed, Medicaid for medically unnecessary definitive UDTs that Mako simultaneously reported with presumptive UDT results to HCP clients. This conduct is hereafter referred to as the "Covered Conduct."

C. North Carolina contends that Mako's submission of such claims for payment to the North Carolina Medicaid Program (Medicaid), Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v, violates the North Carolina False Claims Act, N.C.G.S. §§ 1-605, et seq., and the Medical Assistance Provider Claims Act, N.C.G.S. §§ 108A-70.10, et seq.

D. Mako denies the allegations in Paragraphs B. and C. This Agreement is neither an admission of liability by Mako nor a concession by the State that its claims are not well founded.

E. 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:

TERMS AND CONDITIONS

1. Mako shall pay to North Carolina the aggregate principal amount of two million one hundred thousand dollars ($2,100,000.00) (the "Settlement Amount"), of which $1,050,000.00 is restitution. No later than thirty (30) days after full execution of this Agreement, Mako shall pay to the State of North Carolina the amount of $1,100,000.00 to be credited by the State towards the Settlement Amount. Thereafter, over a period of no more than eighteen (18) months ("Payment Period") after the Initial Payment, Mako will pay the remaining $1,000,000.00, plus interest at

4.125% per annum, pursuant to the payment schedule attached as Exhibit A (the "Payments Over Time") by 5 p.m. U.S. E.T. on or before each due date. The Settlement Amount may be prepaid, in whole or in part, without penalty or premium. Said payments shall be made by **certified check**, payable to the North Carolina Fund for Medical Assistance, and **delivered** to the Medicaid Investigations Division ("MID"), 5505 Creedmoor Road, Suite 300, Raleigh, NC 27612. Upon any default by Mako of the terms contained in Paragraph 1 or any other terms of this Agreement, North Carolina shall have the unconditioned right to accelerate payment and require that the full Settlement Amount then-outstanding be immediately due and payable. In addition, Mako will execute a Confession of Judgment for the outstanding balance which is to be held by NCDOJ/MID and filed in the appropriate Court of Jurisdiction only in the event of a breach of this Agreement by Mako. Said Confession is attached hereto as Exhibit B to the Settlement Agreement.

2. Subject to the exceptions in Paragraph 4 (concerning excluded claims) below, and conditioned upon Mako's full payment of the Settlement Amount, North Carolina releases Mako from the North Carolina Medical Assistance Provider Fraud Claims Act, N.C.G.S. 108A-70.10, et seq.; the North Carolina False Claims Act, N.C.G.S. § 1-605, et seq.; the common law theories of payment by mistake, unjust enrichment, and fraud; and any other right to recoupment or recovery of the Medicaid payments related to the Covered Conduct.

3. In the event that Mako fails to pay any amount as provided in Paragraph 1, above, within five (5) business days of the date upon which such payment is due, Mako shall be in default of their payment obligations ("Default"). North Carolina will provide written notice of the Default, and Mako shall have an opportunity to cure such Default within thirty (30) business days from the date of the receipt of the notice. Notice of Default will be delivered via certified mail to Mako, or to such other representative as Mako shall designate in advance in writing. If Mako fails to cure the Default within thirty (30) business days of receiving the Notice of Default, the remaining unpaid

balance of the Settlement Amount shall become immediately due and payable, and interest shall accrue at the rate of 12% per annum compounded daily from the date of Default on the remaining unpaid total (principal, balance, and interest due). In the event of a Default, the State may, in its sole discretion, choose to set aside the Agreement and bring an action against Mako for the Covered Conduct.

4. Notwithstanding the releases given in paragraph 2 of this Agreement, or any other term of this Agreement, the following claims 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 government health care programs;

d. Any liability to North Carolina (or its agencies) for any conduct other than the Covered Conduct;

e. Any civil or administrative liability 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) claims involving unlawful or illegal conduct based on State or federal antitrust violations; and (ii) claims involving unfair and/or deceptive acts and practices and/or violations of consumer protection laws, and;

f. Any liability based upon obligations created by this Agreement.

5. Mako waives and shall not assert any defenses it 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 proceeding or administrative action. This Agreement bars

those defenses in such a criminal prosecution or administrative action. Beyond these defenses, which are specifically waived, Mako retains and reserves their rights to assert any other defenses in any criminal prosecution or administrative action that might be brought.

6. Mako fully and finally releases 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 Mako has asserted, could have asserted, or may assert in the future against North Carolina, and its agencies, employees, servants, and agents, related to the Covered Conduct and North Carolina's investigation and prosecution thereof.

7. The Settlement Amount shall not be decreased as a result of the denial of claims for payment and which are now being withheld from payment by the Medicaid Program or any Medicaid contractor or intermediary or any state payor on behalf of the Medicaid Program, related to the Covered Conduct; and Mako agrees not to resubmit to the Medicaid Program, any state payor or any of the other above entities acting on behalf of the Medicaid Program, any previously denied claims related to the Covered Conduct, and agrees not to appeal any such denials of claims related to the Covered Conduct.

8. Mako 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 Mako, its present or former officers, directors, employees, shareholders, and agents in connection with:

(1) The matters covered by this Agreement;

(2) The Governments' audit(s) and investigation(s) of the matters covered by this Agreement;

(3) Mako's investigation, defense, and corrective actions undertaken in response to the Governments' audit(s) and 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 payments Mako makes to North Carolina 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 Mako, and Mako 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 4830-6716-3041.1 6 statement, or payment request submitted by Mako or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Mako 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 Mako 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. Mako agrees that the United States, or any affected State Medicaid program, at a minimum, shall be entitled to recoup from Mako 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 or any affected State Medicaid program pursuant to the direction of the Department of Justice and/or the affected State Medicaid agencies. The United States and any affected State Medicaid program reserve their rights to disagree with any calculations submitted by Mako or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on Mako 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 any affected State Medicaid Program to audit, examine, or re-examine Mako's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.

9. 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 as provided in this paragraph. Mako agrees that it waives and shall not seek payment for any of the health care billings related to the Covered Conduct from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third-party payors based upon the claims defined as Covered Conduct.

10. Mako warrants that it has reviewed its financial situation and that it is currently solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and shall, to the fullest extent possible, remain solvent during payment to North Carolina of the Settlement Amount. Further, the Parties warrant that, in evaluating whether to execute this Agreement, they (a) have intended that the mutual promises, covenants, and obligations set forth constitute a contemporaneous exchange for new value given to Mako within the meaning of 11 U.S.C. § 547(c)(1), and (b) conclude that

these mutual promises, covenants, and obligations due, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which either Mako was or became indebted to on or after the date of this transfer, within the meaning of 11 U.S.C. § 548(a)(1).

11. If within 91 days of the Effective Date of this Agreement or of any payment made under this Agreement, Mako commences, or a third party commences, any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors (a) seeking to have any order for relief of Mako's debts, or seeking to adjudicate Mako as bankrupt or insolvent; or (b) seeking appointment of a receiver, trustee, custodian, or other similar official for Mako, or for all or any substantial part of Mako's assets, Mako agrees as follows:

a. Mako's obligations under this Agreement may not be avoided pursuant to 11 U.S.C. § 547, and Mako shall not argue or otherwise take the position in any such case, proceeding, or action that: (i) Mako's obligations under this Agreement may be avoided under 11 U.S.C. § 547; (ii) Mako was insolvent at the time this Agreement was entered into, or became insolvent as a result of the payment made to North Carolina; or (iii) the mutual promises, covenants, and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to Mako.

b. If Mako'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, North Carolina, at its sole option, may rescind the releases in this Agreement and bring any civil and/or administrative claim, action, or proceeding against Mako, for the claims that would otherwise be covered by the releases provided in Paragraph 5 above. Mako agrees that (i) any such claims, actions, or proceedings brought by North Carolina are not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) as a result of the action, case, or proceedings described in the first clause of this Paragraph, and Mako shall not argue or otherwise contend that North Carolina's claims, actions, or proceedings are subject to an automatic stay; (ii) Mako 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 claims, actions, or proceeding that are brought by North Carolina within sixty (60) calendar days of written notification to Mako that the releases have been rescinded pursuant to this Paragraph, except to the extent such defenses were available on the Effective Date of this Agreement and (iii) North Carolina may pursue its claim in the case, action, or proceeding referenced in the first clause of this Paragraph, as well as in any other case, action, or proceeding.

c. Mako acknowledges that its agreement in this Paragraph is provided in exchange for valuable consideration provided in this Agreement.

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

13. Each of the parties and signatory to this Agreement represents that they freely and voluntarily enter into this Agreement without any degree of duress or compulsion.

14. 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 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. If any term or provision of this Agreement is invalid, illegal, or unenforceable, such term or provision be excluded and stricken from this Agreement to the extent of such invalidity, illegality, or unenforceability; all other terms and provisions herein shall remain in full force and effect.

19. Mako agrees to cooperate fully and truthfully with any State investigation of individuals or entities not released in this Agreement. Upon reasonable notice of such an investigation, Mako 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 Mako. Upon request, Mako 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. Mako shall be responsible for all costs it may incur in complying with this paragraph.

20. This Agreement is binding on the Parties' successors, transferees, heirs, and assigns.

21. All parties consent to the disclosure by North Carolina or any other disclosure required by law 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 (the "Effective Date" of this Agreement). Facsimiles, PDFs, or similar electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

STATE OF NORTH CAROLINA

Dated: 2/23/2024

F. EDWARD KIRBY, JR.
Director, Medicaid Investigations Division
Office of the Attorney General

NC DEPARTMENT OF HEALTH & HUMAN SERVICES,

DIVISION OF HEALTH BENEFITS

DocuSigned by:
Jay Ludlam
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Dated: 02/23/24 | 11:35 AM EST

Jay Ludlam
Deputy Secretary, NC Medicaid
NC Department of Health & Human Services, Division of Health Benefits

MAKO MEDICAL LABORATORIES, LLC

Dated: 02/21/24

CHAD PRICE, as Founder and CEO, Mako
Medical Laboratories, LLC

Dated: 2/23/2024

JOE W. HARPER, Counsel for Mako Medical
Laboratories, LLC

STATE SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement (the "Agreement") is entered into between the State of North Carolina ("the State") and Lincare Inc., "the Parties."

II. PREAMBLE

As a preamble to this Agreement, the Parties agree to the following:

A. At all relevant times, Lincare Inc. ("Lincare"), a Delaware corporation headquartered in Clearwater, Florida, supplied durable medical equipment ("DME"), including respiratory equipment such as non-invasive ventilators ("NIVs"), to approximately 1 million patients across the United States.

B. On January 29, 2018, Sandra Gauch and Michelle McNeill (the "Relators") filed a complaint under the *qui tam* provisions of the False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.*, and related state statues against Lincare captioned *United States of America et al., ex rel. Sandra Gauch and Michelle McNeill v. Lincare, Inc.et al*, Civil Action No. 18-CV 783 in the United States District Court for the Southern District of New York, alleging, *inter alia*, that Lincare violated the FCA, comparable state false claims statutes, and the Anti-Kickback Statute (the "AKS"), 42 U.S.C. § 1320a-7b(b), by billing Medicaid for rentals of NIVs that were not being used by patients. This *qui tam* action will be referred to as the "Civil Action."

C. Lincare entered 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.

D. The State contends that Lincare caused claims for payment to be submitted to the State's Medicaid Program (42 U.S.C. Chapter 7 Subchapter XIX), including "managed care entities" as defined by 42 U.S.C. § 1396u-2.

E. The State contends that it has certain civil and administrative causes of action against Lincare for engaging in the following conduct (the "Covered Conduct"):

The State alleges that, from January 1, 2013, to February 29, 2020, Lincare violated the FCA and related state statutes by knowingly submitting false claims for payment to the Medicaid program for NIV rentals (i) when the NIVs were not medically necessary or reasonable due to the lack of continued use or continued need; (ii) when Lincare did not maintain sufficient documentation to show (or otherwise verify) continued use or continued need; in violation of the FCA and related state statutes and of Lincare's own applicable internal policies; or (iii) when Lincare approved, at the Regional Vice President-level, waivers of coinsurance payments that Medicaid beneficiaries were required to pay to induce the beneficiaries to rent the NIVs based on factors other than the patient's financial need, in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), comparable state anti-kickback laws, and Lincare's own applicable internal policies.

F. Except as set forth in Paragraph 1 below, this Agreement is neither an admission of facts or liability by Lincare, nor a concession by the State that its allegations are not well founded.

G. The Parties mutually desire to reach a full and final settlement as set forth below.

III. TERMS AND CONDITIONS

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants and obligations set forth in this Agreement, and for good and valuable consideration as stated herein, the Parties agree as follows:

1. Defendant admits, acknowledges, and accepts responsibility for the following conduct:

a. Lincare is a DME supplier and operates approximately 700 local Lincare-operated locations, known as Centers, throughout the United States.

b. In 2015, Lincare targeted growth of its NIV business as a strategic imperative on account of, among other things, technological improvements with NIVs and expected reimbursement cuts by Medicare that would affect Lincare's other business lines. During the Covered Period, the number of patients who rented Lincare's NIVs increased substantially.

c. Lincare, through its local Centers, leased NIVs to a substantial number of patients covered by the Medicaid health care program pursuant to prescriptions written by physicians, and submitted claims to those programs to obtain reimbursement for those NIV rentals. In Lincare's marketing to physicians, Lincare asserted that its clinical programs endeavored to offer clinical support to patients at least every sixty days through home visits to support patient progress and to ensure compliance with the physicians' prescriptions. Such prescriptions generally identify periods of the day the patients should use the NIVs, often noting that the patient should use the NIV while she or he slept at night.

d. The Medicaid health care program maintains billing requirements for DME rental items like NIVs. Those requirements provide, as applicable here, that NIV rentals must be reasonable and medically necessary. Lincare understood that claims submitted to the Medicaid health care programs seeking reimbursement for NIV rentals must comply with these requirements.

<u>Failure to Ensure All NIV Rentals Were Reasonable and Medically Necessary</u>

e. Lincare knew that patients needed to use their NIVs to receive the benefits of NIV therapy. Lincare also knew that it was responsible for monitoring the utilization of NIVs, and that the Medicaid health care program requires providers to discontinue billing when rental items are no longer medically necessary and are no longer being used by beneficiaries.

f. Lincare relied on Center clinical staff as well as outreach through its clinical programs to monitor patients' usage of their NIVs. According to Lincare's internal protocols for its Centers, clinical staff were expected to regularly follow up with NIV patients—including through home visits at least every sixty days—to ensure patient progress and compliance with physicians' orders.

g. In violation of Lincare's internal protocols, Lincare's Center clinical staff frequently failed to visit NIV patients every sixty days to confirm that the patients were using their NIVs as directed by their physicians. Some Centers lacked sufficient staff to adequately monitor patient progress and confirm that patients were using the devices as directed by their physicians. On many occasions, clinical staff did not perform home visits for NIV patients for several months.

h. In addition to conducting patient visits, Lincare had the ability to remotely monitor certain patients' NIV usage for certain newer NIV models through online cloud-based platforms. However, Lincare did not use these systems to confirm that those patients were using the devices as directed.

i. Lincare continued to seek monthly payments from the Medicaid health care program for NIV rentals in many instances when its staff had not verified that patients were still using their NIVs or had not maintained documentation showing that the patient continued to use the devices.

j. In some instances, Lincare continued to seek monthly payments from the Medicaid health care program when it was aware that patients were not using the devices.

k. In addition, certain of Lincare's internal audits, including a 2018 internal audit, indicated that certain beneficiaries were not regularly using their NIVs.

l. As a result of the above-referenced conduct, Lincare received reimbursements from the Medicaid health care program for some NIV rental claims that did not comply with all of those programs' billing rules and guidance.

2. Lincare has agreed to pay to the United States and agrees to pay the Medicaid Participating States (as described in sub-paragraph (c) and subject to the non-participating state deduction provision of sub-paragraph (d) below), collectively, the sum of $25,500,000.00 plus

accrued interest (the "Settlement Amount"). 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 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) Lincare has agreed to pay to the United States the sum of $24,228,517.96 plus accrued interest pursuant to the terms of the Federal Settlement Agreement.

(b) The total Medicaid recovery for the Covered Conduct is $2,968,878.01 consisting of $1,271,482.04 for the states pursuant to this Agreement and $1,697,395.97 for the United States pursuant to the Federal Settlement Agreement. Lincare shall pay to the Medicaid Participating States the total sum of $1,271,482.04 plus interest which shall be compounded annually at a rate of 3.875% accruing from October 6, 2023 and continuing to and include 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 fourteen (14) 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 Lincare. This electronic funds transfer shall constitute tender, and negotiation of the State Amount as defined in Paragraph 2(d) below.

(c) Lincare shall execute a State Settlement Agreement with any State that executes such an Agreement in the form to which Lincare and the State Team have agreed, or in a form otherwise agreed to by Lincare and an individual State. The State shall constitute a Medicaid Participating State provided this Agreement is fully executed by the State and delivered to Lincare's attorneys within 60 days of receiving this Agreement. In the absence of a State Settlement Agreement delivered within that 60-day period, Lincare's offer to resolve this matter with the State shall become null and void absent written agreement between counsel for Lincare and the State Team to extend the 60-day period.

(d) The total portion of the amount paid by Lincare in settlement for the Covered Conduct for the State is $83,439.99 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 $36,172.79 plus applicable interest (the "State Amount"), of which $18,086.40 is restitution. 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 Lincare absent written agreement between counsel for Lincare and the State Team to extend the period for executing this Agreement.

3. 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 Lincare in State or Federal Courts for the Covered Conduct, including any supplemental state law claims asserted in the Civil Action. Contingent upon receipt of the State Amount, the State, if served with the Civil Action and otherwise liable to pay a relator's share, agrees to pay the Relator(s) the amount of $7,053.69 plus applicable interest. This amount is to be paid through the State Team and has been addressed via side letter(s) with the Relator(s) in the Civil Action(s).

4. Subject to the exceptions in Paragraph 5 below, in consideration of the obligations of Lincare set forth in this Agreement, and conditioned upon tender and negotiation of the State

Amount, the State agrees to release Lincare, its predecessors and current and former parents, divisions, subsidiaries, affiliates, successors, transferees, and assigns (collectively, the "Defendant 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 for the Covered Conduct.

5. Notwithstanding the releases given in Paragraph 4 of this Agreement, or any other term of this Agreement, the following claims and rights 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 Lincare 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 4 above, including, but not limited to, any and all of the following claims: (i) claims involving unlawful or illegal conduct based on State or federal antitrust violations; and (ii) claims involving unfair and/or deceptive acts and practices and/or violations of consumer protection laws;

(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 or right, including exclusion 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.

6. Lincare waives and shall not assert any defenses it may have to 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 of the Fifth Amendment of the U.S. Constitution or the Excessive Fines Clause of the Eighth Amendment of the U.S. Constitution, 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 Lincare 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 Lincare 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 Medicaid Participating State Settlement Amount 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 Lincare 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, and agrees to withdraw the appeal of, or not to appeal or cause the appeal of, any such denials of claims.

9. Lincare 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. Lincare 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. Lincare agrees to cooperate fully and truthfully with any State investigation of individuals or entities not released in this Agreement. Upon reasonable notice of such an investigation, Lincare 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 Lincare. Upon request, Lincare 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.

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.

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, Lincare agrees to pay the State Team's reasonable expenses and fees, including travel costs, consultant expenses, and administrative fees. Lincare 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 all disputes relating to this Agreement shall be the state courts of appropriate jurisdiction of the State.

18. The undersigned Lincare 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. The facsimile, email or other electronically delivered signatures of the parties shall be deemed to constitute acceptable binding signatures for purposes of this Agreement, and facsimile or electronic copies shall be deemed to constitute duplicate originals.

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. The recitals in Section I (Parties) and Section II (Preamble) are agreed to by the Parties. The headings of this Agreement are not binding and are for reference only and do not limit, expand, or otherwise affect the contents or meaning of this Agreement.

STATE OF NORTH CAROLINA

By: ______________________ Dated: 1/5/2023

F. Edward Kirby, Jr.
Name

Director
Title

NCDOJ Medicaid Investigations Division
Organization

By: DocuSigned by: Jay Ludlam 06565C1C2A8F4C8... Dated: 01/09/24 | 12:59 PM EST

Jay Ludlam
Name

Deputy Secretary, NC Medicaid
Title

NC Department of Health & Human Services, Division of Health Benefits
Organization

LINCARE INC.

By:____________________________
Name Paul Tripp
Title General Counsel

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