



JOSH STEIN
ATTORNEY GENERAL

STATE OF NORTH CAROLINA
DEPARTMENT OF JUSTICE

SETH DEARMIN
CHIEF OF STAFF

July 22, 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 Report on Settlement Agreement for
Nostrum Laboratories, Inc.

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.

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

The settlement resolves allegations that from October 1, 2018 through March 31, 2020, Nostrum failed to pay the required rebate amounts owed for Nitro OS.

Under the terms of North Carolina's settlement, the State of North Carolina will recover \$155,171.71. Of that amount the federal government will receive \$89,201.84 for North Carolina's federal portion of Medicaid recoveries. The North Carolina Medicaid Program will receive \$61,859.95 as restitution. Pursuant to G.S. § 1-608(c), the North Carolina Department of Justice will receive \$4,109.92 for investigative costs.

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

Very truly yours,

A handwritten signature in black ink, appearing to read 'Seth Dearmin', with a stylized flourish at the end.

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

STATE SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement (the “Agreement”) is entered into between the State of North Carolina (the “State”), Nostrum Laboratories, Inc. (“Nostrum”), and Nirmal Mulye, Ph.D. (“Mulye”) (hereafter all collectively referred to as the “Parties”), through their authorized representatives.

II. PREAMBLE

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

A. In order to obtain federal reimbursement for its covered outpatient drugs under any state Medicaid programs, *see* 42 U.S.C. §§ 1396-1396w-5 (“Medicaid”), all of which the federal government jointly finances with the states, a pharmaceutical manufacturer must opt-in to the Medicaid Drug Rebate Program (“MDRP”). The MDRP’s implementing statute, 42 U.S.C. § 1396r-8 (the “Rebate Statute”), requires such manufacturers to enter into a Rebate Agreement. The Rebate Statute and implementing regulations set forth certain terms of the Rebate Agreement. *See* 42 C.F.R. § 447.510. The Rebate Statute and Rebate Agreement require, among other things, the manufacturer pay to each state Medicaid program a quarterly amount that potentially includes an inflation-adjusted “additional rebate” for each “dosage form and strength” of a covered outpatient drug. *See* 42 U.S.C. § 1396r-8(c)(2)(A). For example, for “a covered outpatient drug that is first marketed as a drug other than a single source drug or an innovator multiple source drug after April 1, 2013,” manufacturers must also pay an inflation-based rebate equaling the difference, if any, between the drug’s current quarter average manufacturer’s price (“AMP”) and its AMP in the “applicable quarter” (which is defined as the “fifth full calendar quarter after which

the drug is first marketed”) adjusted by the rate of inflation. 42 U.S.C. § 1396r-8(c)(3). The AMP that serves as the starting point for the additional rebate calculation is commonly called the “Base Date AMP,” and the quarter with which that price is associated is referred to as the “Base Date AMP quarter.” The Rebate Agreement requires manufacturers to make the proper rebate payments “not later than 30 days after receiving the state rebate invoice” and also requires manufacturers to “comply with the conditions of the [Rebate Statute], changes thereto, implementing regulations, agency guidance, and [the Rebate Agreement].”

B. At all relevant times, Nostrum, a New Jersey corporation with its principal places of business in Missouri and New Jersey and an office in New York, marketed and manufactured pharmaceutical products, including Nitrofurantoin Oral Suspension (“Nitro OS”) in the United States under Abbreviated New Drug Application (“ANDA”) number 201355. Nitro OS is an oral suspension antibacterial agent. On or about August 16, 2016, Nostrum entered into a Rebate Agreement with the United States Department of Health and Human Services (“HHS”).

C. Another manufacturer secured the Food and Drug Administration’s (“FDA”) approval for Nitro OS in August 2013 and began to market it in January 2014. Nostrum then acquired exclusive rights to manufacture and market Nitro OS in 2015. At all relevant times, Nostrum sold Nitro OS under National Drug Code (“NDC”) number 70408-239-32 and marketed it under ANDA number 201355. Nitro OS is a “noninnovator multiple source drug” for purposes of the MDRP.

D. Mulye is the founder and chief executive officer of Nostrum. Mulye maintains ultimate control of Nostrum and, either directly or through other entities he maintains a 90% ownership interest in Nostrum.

E. Nostrum and Mulye have entered into a separate civil settlement agreement (the “Federal Settlement Agreement”) with the “United States of America” (the “United States”).

F. The State contends (1) that Nostrum and Mulye submitted or caused to be submitted claims for payment to Medicaid for Nitro OS; (2) that Nostrum entered into a Rebate Agreement with the Secretary of HHS in exchange for Medicaid’s coverage of Nitro OS; (3) that Nostrum, under the Rebate Agreement and Rebate Statute, was required to submit pricing information on a quarterly basis to the Centers for Medicare and Medicaid Services (“CMS”) regarding Nitro OS and pay the correct quarterly rebates to state Medicaid programs per unit of Nitro OS dispensed to Medicaid beneficiaries, as determined by the statutory formula set forth in the Rebate Statute, and based on which rebate invoices are sent by State Medicaid programs to Nostrum.

G. The State contends that it has certain civil and administrative causes of action against Nostrum and Mulye from October 1, 2018 through March 31, 2020, for failing to pay the required rebate amounts owed for Nitro OS as required by the Rebate Statute and Rebate Agreement and as invoiced by the State Medicaid program.

H. Nostrum and Mulye admit, acknowledge, and accept their responsibility for the following facts:

Nostrum acquired Nitro OS from another manufacturer in December 2015 and continued to market the product pursuant to Nitro OS’s preexisting FDA approval, ANDA Number 201355. In response to January 2018 FDA updated guidance tightening tolerances for elemental impurities in various drug products, Nostrum ceased manufacturing and marketing Nitro OS temporarily because the amount of lead in Nitro OS, resulting from Nostrum’s formulation at the time, did not comply with the 2018 FDA guidance. Nostrum resumed manufacturing and marketing Nitro OS in August 2018, after having adjusted its Nitro OS formulation to address the new FDA impurities guidance by reducing lead levels and modifying quantities of two inactive ingredients. Nostrum has characterized the relaunched version of Nitro OS as a “reformulation.” Nostrum did not add or subtract any ingredients and the active ingredients remain unchanged; Nitro OS also remained in the same dosage form and strength as it did prior to 2018. Nostrum continues to market this newer version of Nitro OS under the same FDA Approval, ANDA

201355, as the pre-2018 version and maintains with the FDA that it is legal to do so because no major changes have been made to the drug.

After relaunching Nitro OS in August 2018, Nostrum increased its price from \$474.75 to \$2,392.32 per bottle. Beginning with the third quarter of 2018, Nostrum received invoices from state Medicaid Programs reflecting significantly increased Medicaid rebates owed. Based on its later investigation, Nostrum found out that these larger rebate invoices were on account of the Nitro OS price increase triggering the inflation-based Medicaid rebate. Nostrum paid these increased rebates as invoiced by the states for the third quarter of 2018. Thereafter, Nostrum and Mulye did not pay the entire amount of the invoiced amounts due, which included amounts that accounted for the price increase. Nostrum wrote to CMS arguing that it should not have to pay the inflation-based amount because its Nitro OS is a “new” drug after its 2018 relaunch and, therefore, should not have to pay rebates based upon the “old” version of Nitro OS’s 2015 Base Date AMP. In a subsequent teleconference and in correspondence with CMS personnel, including the director of the pertinent CMS division, Nostrum and Mulye understood that: 1) CMS did not agree with Nostrum’s position; and 2) that CMS’s position was that Nostrum should pay its calculated rebate amount going forward, based upon the Q2 2015 Base Date AMP, and that Nostrum should repay any underpayments so far. Nostrum did not and instead chose to terminate the applicable Rebate Agreement, effective March 30, 2020, with partial balances due for Q4 2018 through Q1 2020.

I. The foregoing conduct in Paragraphs G–H is hereinafter referred to as the “Covered Conduct.”

J. Nostrum admits and agrees that the correct Base Date AMP Quarter for Nitro OS is Q2 2015 and that, accordingly, the Base Date AMP for Nitro OS is Nitro OS’s AMP from Q2 2015.

K. 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. Nostrum and Mulye agree to pay to the United States and the Medicaid Participating States (as defined in paragraph 3 and subject to the non-participating state deduction

provision of paragraphs 4 and 5 below), collectively, the sum of Three Million Eight Hundred Twenty-Five Thousand dollars (\$3,825,000.00), as specified in sub-paragraphs 1(a) and 1(b) below (the “Total Fixed Settlement Amount”). In addition, Nostrum shall make any payments due under sub-paragraphs 1(a)(i)–(iv) and Mulye shall make any payments due under sub-paragraphs 1(b)(i)–(iii) (collectively, “Contingency Payments”). However, no further Contingency Payments from either Nostrum or Mulye are due once the Total Fixed Settlement Amount paid plus any Contingency Payments paid exceed Fifty Million dollars (\$50,000,000.00). The Total Fixed 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 settled by payments to the United States and the Medicaid Participating States under the following terms and conditions:

(a) Nostrum shall pay to the United States and the Medicaid Participating States collectively Two Million Three Hundred Twenty-Five Thousand dollars (\$2,325,000.00) in nine installments pursuant to the payment schedule described in Exhibit A (“Nostrum Fixed Settlement Amount”). Of the Nostrum Fixed Settlement Amount, Nostrum shall pay a total of One Million Two Hundred Thirty-Two Thousand Two Hundred Fifty dollars (\$1,232,250.00) to the United States (“Nostrum Federal Fixed Settlement Amount”), by electronic funds transfer pursuant to written instructions to be provided by the Office of the United States Attorney for the District of Massachusetts, and Nostrum shall pay a total of One Million Ninety-Two Thousand Seven Hundred Fifty dollars (\$1,092,750.00) to the Medicaid Participating States pursuant to the terms of the Medicaid State Settlement Agreements (“Nostrum State Fixed Settlement Amount”). In addition to the Nostrum

Fixed Settlement Amount, Nostrum shall make any additional payments as required by sub-paragraphs (i) through (iv) below (“Nostrum Contingency Payments”), collectively, to the United States and Medicaid Participating States, divided on the same pro-rata basis as the Nostrum Fixed Settlement Amount is divided between the Nostrum Federal Fixed Settlement Amount and Nostrum State Fixed Settlement Amount and using the same payment method. The Nostrum Fixed Settlement Amount plus any Nostrum Contingency Payments due are hereinafter referred to as the “Nostrum Settlement Amount.”

(i) If, in any of the first five full years that conclude following the Effective Date of this Settlement Agreement (each year of which is a “Measurement Period”), Nostrum achieves earnings before interest, taxes, depreciation, and amortization for such Measurement Period as set forth in its annual financial statements prepared on an audited basis by independent certified public accountants selected by Nostrum (“EBITDA”), Nostrum shall pay the United States and the Medicaid Participating States, collectively, an amount equal to 5% of its EBITDA for such Measurement Period (each referred to as a “Performance Contingency Payment”). Within 120 days of the end of each Measurement Period, Nostrum shall submit to the United States Department of Justice, Civil Division, annual audited financial statements and a calculation of the EBITDA and any Performance Contingency Payment Amount (“Annual Financials”). The calculation of EBITDA and any Performance Contingency Payment shall be certified as true and accurate by Nostrum’s Chief Executive Officer and Chief Financial Officer. Nostrum shall pay any owed Performance Contingency Payments within 150 days of the end of each Measurement Period.

(ii) Nostrum agrees to provide 15 business days advance, written notice to the United States of any sale, transfer, merger, or liquidation of any Nostrum assets or any other property, entity, or venture in which Nostrum has an ownership interest in excess of \$10 million, except its pharmaceutical products sold in the ordinary course of its business, in any of the first five full years that conclude after the Effective Date of the Federal Settlement Agreement (“Sale Event”). Upon the occurrence of a Sale Event and within seven business days of the closing on the Sale Event, Nostrum shall pay the United States and the Medicaid Participating States, collectively, an amount equal to 10% of the net proceeds generated from the Sale Event (“Sale Contingency Payment”).

(iii) Nostrum shall pay the United States and the Medicaid Participating States, collectively, an amount equal to 50% of any repayment Nostrum receives, within five years of the Effective Date of the Federal Settlement Agreement, of a loan Nostrum issued to Asia Pacific Investment Holdings Limited (“Asia Pacific”), an affiliate of Nalinkant Rathod (“Nostrum Loan Contingency Payment”). Nostrum shall make any Nostrum Loan Contingency Payment within 10 business days of the date upon which it receives any repayment on the Asia Pacific loan.

(iv) Nostrum shall pay to the United States and Medicaid Participating States, collectively 25% of the amount of any payment from any insurance coverage, policy, plan, or claim Nostrum receives within five years of the Effective Date of the Federal Settlement Agreement relating to the substance of litigation, disputes, or claims relating to the Covered Conduct or the governments’

investigation relating thereto (excluding coverage for legal fees and expenses) (“Nostrum Insurance Payout Contingency Payment”).

(b) Mulye shall pay to the United States and the Medicaid Participating States collectively One Million Five Hundred Thousand dollars (\$1,500,000.00) (“Mulye Fixed Settlement Amount”) in nine installments pursuant to the payment schedule described in Exhibit B. Of the Mulye Fixed Settlement Amount, Mulye shall pay a total of Seven Hundred Ninety-Five Thousand dollars (\$795,000.00) to the United States (the “Mulye Federal Fixed Settlement Amount”) by electronic funds transfer pursuant to written instructions to be provided by the Office of the United States Attorney for the District of Massachusetts, and Mulye shall pay a total of Seven Hundred Five Thousand dollars (\$705,000.00) to the Medicaid Participating States pursuant to the terms of the Medicaid State Settlement Agreements (“Mulye State Fixed Settlement Amount”). In addition to the Mulye Fixed Settlement Amount, Mulye shall make any additional payments as required by sub-paragraphs 1(b)(i) through (iii) below (“Mulye Contingency Payments”), collectively, to the United States and Medicaid Participating States, divided on the same pro-rata basis as the Nostrum Fixed Settlement Amount is divided between the Nostrum Federal Fixed Settlement Amount and Nostrum State Fixed Settlement Amount and using the same payment method. The Mulye Fixed Settlement Amount plus any Mulye Contingency Payments due are hereinafter referred to as the “Mulye Settlement Amount.”

(i) Mulye shall pay to the United States and the Medicaid Participating States, collectively, any payments or 1099 income received from the government as specified in a letter from counsel for the United States to counsel for Mulye dated

October 24, 2023, within 14 days of receiving any such funds (“Government Funds Contingency Payment”).

(ii) Mulye shall pay the United States and the Medicaid Participating States, collectively, an amount equal to 50% of any repayment Mulye receives, within five years of the Effective Date of the Federal Settlement Agreement, of a loan Nostrum issued to Asia Pacific (“Mulye Loan Contingency Payment”). Mulye shall make any Mulye Loan Contingency Payment within 10 business days of the date upon which he receives any repayment on the Asia Pacific loan.

(iii) Mulye shall pay to the United States and Medicaid Participating States, collectively, 25% of the amount of any payment from any insurance coverage, policy, plan, or claim Mulye receives within five years of the Effective Date of this Agreement relating to the substance of litigation, disputes, or claims relating to the Covered Conduct or the governments’ investigation relating thereto (excluding coverage for legal fees and expenses) (“Mulye Insurance Payout Contingency Payment”).

2. Payments of the Nostrum State Fixed Settlement Amount made pursuant to the schedule described in Exhibit A and the Mulye State Fixed Settlement Amount made pursuant to the schedule described in Exhibit B (collectively, “the Medicaid State Fixed Settlement Amount”) shall be 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 Nostrum and Mulye. The State shall be deemed to have been paid its state-specific share of each installment payment by Nostrum in satisfaction of the obligations in Paragraph 4 and by Mulye in satisfaction of the

obligations in Paragraph 5 upon receipt and deposit of their respective installment payments via the electronic fund transfers into the New York State Attorney General's National Global Settlement Account. Each electronic fund transfer shall constitute tender and negotiation of an installment payment of the North Carolina Fixed Settlement Amounts as defined in Paragraphs 4 and 5 below.

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

4. The portion of the Total Fixed Settlement Amount paid by Nostrum in settlement for the Covered Conduct for the State is \$94,320.10, 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 \$40,099.35 (the "Nostrum North Carolina Fixed Settlement Amount"), of which \$40,099.35 is restitution. If the State does not execute this Agreement within 60 days of receiving this Agreement, the Nostrum North Carolina Fixed Settlement Amount shall be deducted from the Medicaid State Fixed Settlement Amount and shall not be paid by Nostrum absent written agreement between counsel for Nostrum and the State Team to extend the time period for executing this Agreement.

5. The portion of the Total Fixed Settlement Amount paid by Mulye in settlement for the Covered Conduct for the State is \$60,851.61, 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 \$25,870.52 (the “Mulye North Carolina Fixed Settlement Amount”), of which \$25,870.52 is restitution. If the State does not execute this Agreement within 60 days of receiving this Agreement, the Mulye North Carolina Fixed Settlement Amount shall be deducted from the Medicaid State Settlement Fixed Amount and shall not be paid by Mulye absent written agreement between counsel for Mulye and the State Team to extend the time period for executing this Agreement.

6. The Medicaid State Fixed Settlement Amount, or any portion thereof, may be prepaid without premium or penalty.

7. Subject to the exceptions in Paragraph 9 (concerning reserved claims) below, and subject to Paragraph 10 (concerning disclosure of assets), Paragraph 11 (concerning default), and Paragraph 20 (concerning bankruptcy) below, and upon receipt of the Nostrum North Carolina Fixed Settlement Amount, the State releases Nostrum, together with its current and former parent corporations or entities; direct and indirect subsidiaries; and brother or sister corporations or entities; and their respective divisions, current or former corporate owners; and the corporate or entity successors and assigns of any of them (the “Nostrum 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.

8. Subject to the exceptions in Paragraph 9 (concerning reserved claims) below, and subject to Paragraph 10 (concerning disclosure of assets), Paragraph 11 (concerning default), and Paragraph 20 (concerning bankruptcy) below, and upon receipt of the Mulye North Carolina Fixed

Settlement Amount, the State releases Mulye 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.

9. Notwithstanding the releases given in Paragraphs 7 and 8 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 Nostrum Released Entities and Mulye, 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 releases in Paragraphs 7 and 8 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; and

(j) any liability of individuals other than Mulye.

10. Nostrum and Mulye each have provided sworn financial disclosures and supporting documents (together "Financial Disclosures") to the United States, and the State has relied on the accuracy and completeness of those Financial Disclosures in reaching this Agreement. Nostrum and Mulye each warrant that the Financial Disclosures are complete, accurate, and current as of the date provided. If the State learns of asset(s) in which Nostrum or Mulye had an interest of any kind at the time of this Agreement (including, but not limited to, promises by insurers or other third parties to satisfy Nostrum or Mulye's obligations under this Agreement) that were not disclosed in the Financial Disclosures, or if the State learns of any false statement or misrepresentation by Nostrum or Mulye 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 State may at its option: (a) rescind this Agreement and file suit based on the Covered Conduct; or (b) collect the full North Carolina Fixed Settlement Amount in accordance with the Agreement plus 100% of the net value of Nostrum or Mulye's previously undisclosed assets. Nostrum and Mulye agree not to contest any collection action undertaken by the State pursuant to this provision and agree that they will immediately pay to the State the greater of (i) a 10% surcharge of the amount collected in the collection action, or (ii) the State's reasonable attorneys' fees and expenses incurred in such a collection action. In the event that the State, pursuant to this paragraph rescinds this Agreement, Nostrum and Mulye 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 State within 120 calendar days of written notification to Nostrum and/or Mulye that this Agreement has been rescinded, and (b) relate to the Covered Conduct, except to the extent these defenses were available on the Effective Date of this Agreement.

11. The Nostrum North Carolina Fixed Settlement Amount plus the Nostrum Contingency Payments (the “Nostrum State Settlement Amount”) and the Mulye North Carolina Fixed Settlement Amount plus the Mulye Contingency Payments (the “Mulye State Settlement Amount”) represent the amounts the State is willing to accept in compromise of its civil claims arising from the Covered Conduct, due solely to Nostrum and Mulye’s financial condition as reflected in the Financial Disclosures referenced in Paragraph 10.

(a) In the event that Nostrum fails to pay any portion of the Nostrum State Settlement Amount or in the event that Mulye fails to pay any portion of the Mulye State Settlement Amount, the party failing to make such payment (“Defaulting Party”) shall be in default of their payment obligations under this Agreement (“Default”). In such event, the State will provide the Defaulting Party with a written “Notice of Default,” and the Defaulting Party shall have an opportunity to cure such Default (the “Cure Payment”) within 14 calendar days from the date of receipt of the Notice of Default by making the payment due under the payment schedule. The Notice of Default will be delivered to the Defaulting Party, or to such other representative as Defaulting Party shall designate in advance in writing. If the Defaulting Party fails to cure the Default within 14 calendar days of receiving the Notice of Default and in the absence of an agreement with the State to a modified payment schedule (“Uncured Default”), then without further notice, the unpaid balance of the Defaulting Party’s settlement amount thereunder shall become immediately

due and payable, subject to and in accordance with their respective terms, and interest on the remaining unpaid balance shall thereafter accrue at the rate of 5% per annum, compounded daily from the date of Default, on the remaining unpaid total (principal and interest balance).

(b) In the event of an Uncured Default, the Defaulting Party agrees that the State, at its sole discretion, may: (i) retain any payments previously made, rescind this Agreement, or bring any civil and/or administrative claim, action, or proceeding against the Defaulting Party for the claims that would otherwise be covered by the releases provided in Paragraphs 7 and 8 above, with any recovery reduced by the amount of any payments previously made by the Defaulting Party to the State under this Agreement; (ii) take any action to enforce this Agreement; (iii) offset the remaining unpaid balance of the State Settlement Amount from any amounts due and owing to the Defaulting Party and/or affiliated companies by any department, agency, or agent of the State at the time of Default or subsequently; and/or (iv) exercise any other right granted by law, or under the terms of this Agreement, or recognizable at common law or in equity. The State shall be entitled to any other rights granted by law or in equity by reason of Default, including referral of this matter for private collection. In the event the State pursues a collection action, the Defaulting Party agrees immediately to pay the State the greater of (i) a 10% surcharge of the amount to be collected, or (ii) the State's reasonable attorneys' fees and expenses incurred in such an action, in each case, to the extent allowed under applicable law. In the event that the State opts to rescind this Agreement pursuant to this paragraph, Nostrum and Mulye waive, and agree not to plead, argue, or otherwise raise, the defenses of res judicata and collateral estoppel or any defenses under the theories of statute of limitations, laches,

waiver, discharge, estoppel, release, accord and satisfaction, or similar theories in response to any civil or administrative claims that are (i) filed by the State against Nostrum and/or Mulye within 120 calendar days of written notification by the State that this Agreement has been rescinded, and (ii) relate to the Covered Conduct, except to the extent these defenses were available on the Effective Date of this Agreement. Nostrum and Mulye agree not to contest any offset, recoupment, and/or collection action undertaken by the State pursuant to this paragraph, either administratively or in any state or federal court, except on the grounds of actual payment to the State.

(c) In the event of an Uncured Default, the State may exclude the Defaulting Party from participating in the State Medicaid Program until the Defaulting Party pays the State Settlement Amount, with interest, as set forth above ("Exclusion for Default"). The State will provide written notice of any such exclusion to the Defaulting Party. The Defaulting Party waives any further notice of the exclusion under state law 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, the Defaulting Party wishes to apply for reinstatement, it must submit a written request for reinstatement to the State in accordance with the provisions of state law. The Defaulting Party will not be reinstated unless and until the State approves such request for reinstatement. The option for Exclusion for Default is in addition to, and not in lieu of, the options identified in this Agreement or otherwise available.

(d) Any rights or remedies with respect to default granted to the federal government under the Federal Settlement Agreement not otherwise provided to the State herein shall be granted to the State.

12. Nostrum and Mulye each waive and shall not assert any defenses they may have to criminal prosecution or administrative action for 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.

13. In consideration of the obligations of the State set forth in this Agreement, the Nostrum Released Entities and Mulye each 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 Nostrum Released Entities and Mulye 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.

14. The amounts that Nostrum and Mulye must pay to the State pursuant to Paragraphs 4 and 5 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 Nostrum and Mulye agree 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.

15. Nostrum and Mulye 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 based upon the claims defined as Covered Conduct.

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

17. 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.

18. 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.

19. 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.

20. In exchange for valuable consideration provided in this Agreement, Nostrum and Mulye acknowledge the following:

(a) Nostrum and Mulye have each reviewed their financial situation and warrant that they are currently solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and shall remain solvent following payment to the Medicaid Participating States of the Medicaid State Fixed Settlement Amount.

(b) In evaluating whether to execute this Agreement, the Parties (i) intend that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to Nostrum and Mulye, within the meaning of 11 U.S.C. § 547(c)(1), and (ii) conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange.

(c) 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.

(d) The Parties do not intend to hinder, delay, or defraud any entity to which Nostrum and Mulye 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).

(e) If any of Nostrum and/or Mulye's payments or 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 applicable Total Fixed Settlement Amount is paid in full, Nostrum and/or Mulye 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 Nostrum's and/or Mulye's debts, or to adjudicate Nostrum and/or Mulye as bankrupt or insolvent; or an Order is entered appointing a receiver, trustee, custodian, or other similar official for Nostrum and/or Mulye or for all or any substantial part of Nostrum's and/or Mulye's assets, the State may rescind the releases in this Agreement and bring any civil and/or administrative claim, action, or proceeding against the entity or person to whom this subparagraph applies (*i.e.*, the "Avoiding Defendant") for the claims that would otherwise be covered by the releases provided in Paragraphs 7 and 8 above.

(f) Nostrum and Mulye agree that any civil and/or administrative claim, action, or proceeding brought by the State under Paragraph 20(e) is not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) because it would be an exercise of the State's police and regulatory power. Nostrum and Mulye shall not argue or otherwise contend that the

State's 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). Nostrum and Mulye 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 State within 120 days of written notification to Nostrum and Mulye that the releases have been rescinded pursuant to this paragraph, except to the extent such defenses were available on the Effective Date of the Agreement.

(g) Should this Agreement be assumed in any bankruptcy proceeding, Nostrum and Mulye shall submit the following language to be included in any Order confirming any Plan of Reorganization: "In the event of any conflict between this Agreement and the Confirmation Order, this Agreement shall govern." For the avoidance of doubt, the discharge provisions of the Confirmation Order shall not affect the terms of this Agreement.

21. 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.

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

23. 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.

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

25. 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.

26. 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. Forbearance by the State from pursuing any remedy or relief available to it under this Agreement shall not constitute a waiver of rights under this Agreement.

State of North Carolina

By: F. Edward Kirby, Jr. Dated: 2/22/2024

F. Edward Kirby, Jr.
Name

Director
Title

NCDOJ Medicaid Investigations Division
Organization


By: DocuSigned by:
Jay Ludlam
06565C1C2A8F4C8... Dated: 02/26/24 | 3:41 PM EST

Jay Ludlam
Name

Deputy Secretary, NC Medicaid
Title

NC DHHS, Division of Health Benefits
Organization

NOSTRUM LABORATORIES, INC.

By:  Dated: 5.27.24
Nirmal Mulye, Ph.D., Chairman and
Chief Executive Officer

By:  Dated: 5.16.24
[Attorney Name]
Counsel to Nostrum Laboratories

NIRMAL MULYE, Ph.D.

By:  Dated: 5.27.24
Nirmal Mulye, Ph.D.


By:  Dated: 5.16.24
[Attorney name]
Counsel for Nirmal Mulye, Ph.D.

Exhibit A – Nostrum Installment Payment Schedule

Nostrum will pay the Nostrum Fixed Settlement Amount to the United States and the Medicaid Participating States in nine installment payments as follows:

- 1) \$75,000.00 within seven days of the Effective Date of this Agreement (“First Nostrum Installment Payment”), with \$39,750.00 paid to the United States and \$35,250.00 paid to the Medicaid Participating States;
- 2) \$75,000.00 within 60 days of the First Installment Payment (“Second Nostrum Installment Payment”), with \$39,750.00 paid to the United States and \$35,250 paid to the Medicaid Participating States;
- 3) \$175,000.00 within 120 days of the First Installment Payment (“Third Nostrum Installment Payment”), with \$92,750.00 paid to the United States and \$82,250.00 paid to the Medicaid Participating States;
- 4) \$175,000.00 within 180 days of the First Installment Payment (“Fourth Nostrum Installment Payment”), with \$92,750.00 paid to the United States and \$82,250.00 paid to the Medicaid Participating States;
- 5) \$1,070,000.00 within one year of the First Installment Payment (“Fifth Nostrum Installment Payment”), with \$567,100.00 paid to the United States and \$502,900.00 paid to the Medicaid Participating States;
- 6) \$125,000.00 within two years of the First Installment Payment (“Sixth Nostrum Installment Payment”), with \$66,250.00 paid to the United States and \$58,750.00 paid to the Medicaid Participating States;
- 7) \$130,000.00 within three years of the First Installment Payment (“Seventh Nostrum Installment Payment”), with \$68,900.00 paid to the United States and \$61,100.00 paid to the Medicaid Participating States;
- 8) \$250,000.00 within four years of the First Installment Payment (“Eighth Nostrum Installment Payment”), with \$132,500.00 paid to the United States and \$117,500.00 paid to the Medicaid Participating States; and
- 9) \$250,000.00 within five years of the First Installment Payment (“Ninth Nostrum Installment Payment”), with \$132,500 paid to the United States and \$117,500 paid to the Medicaid Participating States.

Exhibit B – Nirmal Mulye Installment Payment Schedule

Mulye will pay the Mulye Fixed Settlement Amount to the United States and the Medicaid Participating States in nine installment payments as follows:

- 1) \$25,000.00 within seven days of the Effective Date of this Agreement (“First Mulye Installment Payment”), with \$13,250.00 paid to the United States and \$11,750.00 paid to the Medicaid Participating States;
- 2) \$25,000.00 within 60 days of the First Installment Payment (“Second Mulye Installment Payment”), with \$13,250.00 paid to the United States and \$11,750.00 paid to the Medicaid Participating States;
- 3) \$75,000.00 within 120 days of the First Installment Payment (“Third Mulye Installment Payment”), with \$39,750.00 paid to the United States and \$35,250.00 paid to the Medicaid Participating States;
- 4) \$125,000.00 within 180 days of the First Installment Payment (“Fourth Mulye Installment Payment”), with \$66,250.00 paid to the United States and \$58,750.00 paid to the Medicaid Participating States;
- 5) \$250,000.00 within one year of the First Installment Payment (“Fifth Mulye Installment Payment”), with \$132,500.00 paid to the United States and \$117,500.00 paid to the Medicaid Participating States;
- 6) \$250,000.00 within two years of the First Installment Payment (“Sixth Mulye Installment Payment”), with \$132,500.00 paid to the United States and \$117,500.00 paid to the Medicaid Participating States;
- 7) \$250,000.00 within three years of the First Installment Payment (“Seventh Mulye Installment Payment”), with \$132,500.00 paid to the United States and \$117,500.00 paid to the Medicaid Participating States;
- 8) \$250,000.00 within four years of the First Installment Payment (“Eighth Mulye Installment Payment”), with \$132,500.00 paid to the United States and \$117,500.00 paid to the Medicaid Participating States;
- 9) \$250,000.00 within five years of the First Installment Payment (“Ninth Mulye Installment Payment”), with \$132,500.00 paid to the United States and \$117,500.00 paid to the Medicaid Participating States.