ATTORNEY GENERAL OF THE STATE OF NEW YORK HEALTH CARE BUREAU LAW ENFORCEMENT MISCONDUCT INVESTIGATIVE OFFICE

In the Matter of

Assurance No. 25-053

Investigation by LETITIA JAMES, Attorney General of the State of New York, of

PrimeCare Medical of New York, Inc.,

Respondent.

**ASSURANCE OF DISCONTINUANCE** 

The Office of the Attorney General of the State of New York ("OAG") commenced an investigation pursuant to N.Y. Exec. Law §§ 63(12) and 75 into the Respondent PrimeCare Medical of New York, Inc.'s ("PrimeCare") prescribing through standing order the opioid antagonist medication nalmefene (brand name Opvee) for administration by non-medical personnel employed by the Broome County Sheriff's Office ("BCSO"). This Assurance of Discontinuance ("Assurance") contains the findings of the OAG's investigation as to PrimeCare and the relief agreed to by OAG and PrimeCare, whether acting through its respective directors, officers, employees, representatives, agents, affiliates, or subsidiaries, etc. (collectively, the "Parties").

#### APPLICABLE LAW

1. In New York, only persons authorized to prescribe, dispense, and administer prescription medications may do so. Unless otherwise authorized, non-medical personnel are not permitted to prescribe, dispense, or administer prescription medications, and doing so risks

running afoul of New York licensing statutes prohibiting the unauthorized practice of medicine.

N.Y. Educ. Law § 6512.

- 2. For the purposes of opioid overdose prevention, New York law permits health care professionals to prescribe and distribute opioid antagonists to non-medical persons, including law enforcement personnel, through a non-patient specific standing order. These individuals who are not health care providers may then administer opioid antagonists to any individual who is believed to be experiencing an opioid overdose. N.Y. Pub. Health Law § 3309. N.Y. Pub. Health Law § 3309(3)(a)(i) specifically restricts the opioid antagonist that may be used by non-medical persons "to naloxone and other medications approved by the department [of health] for such purpose."
- 3. Naloxone (brand name Narcan) is the only medication approved by the New York State Department of Health ("DOH") as an opioid antagonist pursuant to N.Y. Pub. Health Law § 3309, its implementing regulations in 10 NYCRR § 80.138, and DOH's Guide for New York State's Registered Opioid Overdose Prevention Programs. Nalmefene/Opvee has not been approved by DOH for use through the opioid overdose prevention statute.

#### **OAG's FACTUAL FINDINGS**

- 4. PrimeCare, based in Harrisburg, PA, provides professional contract management services to the New York professional corporation Professional Care Medical Practice, P.C. ("PCMP"), which in turn provides medical and mental health care services to Broome County's incarcerated population and acts as BCSO's agent in providing health care services that Broome County is required to provide those in its custody.
- 5. The Physician Medical Director at Broome County Sheriff's Correctional Division is employed by PCMP.

- 6. Through its investigation, OAG learned that PrimeCare was aware that the use of nalmefene by standing order was not authorized by DOH within N.Y. Pub. Health Law § 3309 and its implementing regulations. PrimeCare consulted with Indivior and worked at the direction of BCSO to obtain Opvee and distribute it through a standing order that PCMP issued to BCSO personnel.
- 7. The OAG learned that between January and April 2024, PrimeCare was in contact with BCSO and Indivior in order to facilitate the purchase and use of Opvee. These communications included an Indivior presentation to PrimeCare's Chief Medical Officer ("CMO") Dr. Pamela Rollings-Mazza and its President Brent Bavington in January 2024. When President Bavington was subsequently contacted by the BCSO sheriff seeking to use Opvee, Bavington explained that Opvee is "not approved by NY DOH such as Narcan," but stated, "we need to get up to speed with some policy" and that he believed "[w]e will be able to fulfill your request/order very quickly."
- 8. In March, 2024, PrimeCare's CMO had another discussion with Indivior regarding the provision of Opvee.
- 9. On March 15, 2024, PrimeCare President Bavington emailed the Physician Medical Director at Broome County Sheriff's Correctional Division ("BCSCD"), an employee of PCMP, asking to speak with him "regarding this life saving medication that Broome County is looking to deploy."
- 10. That same month, PrimeCare communicated with Indivior about coordinating site education for use of Opvee.
- 11. On April 1, 2024, President Bavington requested Indivior provide PrimeCare with a sample standing order.

- 12. On April 3, 2024, the Physician Medical Director of BCSCD completed the purchase order for Opvee by providing his medical license information to Indivior and signing a certification that he would be responsible for an Opvee shipment to BCSO. BCSO ultimately purchased 300 units of Opvee for \$22,500 from Indivior.
- 13. On or about the same day, the Physician Medical Director of BCSCD signed an undated, non-patient-specific standing order for use of Opvee by staff of BCSO and Broome County-affiliated health care provider personnel.

#### **CONCLUSIONS OF LAW**

- 14. OAG finds that PrimeCare violated N.Y. Exec. Law § 63(12), N.Y. Pub. Health Law § 3309, 10 NYCRR § 80.138, and N.Y. Educ. Law § 6512.
- 15. PrimeCare admits paragraphs (1)-(13) above and that its actions violated the statutory provisions cited above.
- 16. The OAG finds the relief and agreements contained in this Assurance appropriate and in the public interest.
- 17. Respondent has agreed to this Assurance in settlement of the violations described above and to avoid the time, expense, and distraction of litigation.
- 18. The OAG finds the relief and agreements contained in this Assurance appropriate and in the public interest.

THEREFORE, OAG is willing to accept this Assurance pursuant to N.Y. Exec. Law § 63(15), in lieu of commencing a statutory proceeding for violations of N.Y. Exec. Law § 63(12) and 75 and N.Y. Educ. Law § 6512.

IT IS HEREBY UNDERSTOOD AND AGREED, by and between the Parties:

#### RELIEF

19. General Injunction: PrimeCare shall not engage, or attempt to engage, in conduct in violation of any applicable laws, including but not limited to N.Y. Exec. Law § 63(12), N.Y. Pub. Health Law § 3309, N.Y. Educ. Law § 6512, and 10 NYCRR § 80.138, and expressly agrees and acknowledges that any such conduct is a violation of the Assurance, and that OAG thereafter may commence the civil action or proceeding contemplated in the Conclusion, *supra*, in addition to any other appropriate investigation, action, or proceeding.

## 20. Programmatic Relief:

- a. PrimeCare shall prepare a corrective memo and distribute it to all employees of PrimeCare and of Professional Care Medical Practice, P.C. of New York, that states that:
  - Clinical decisions concerning the Broome County Jail Facility
     ("the Facility") shall be the sole providence of the Physician
     Medical Director of the Facility and shall not be
     countermanded by non-clinicians;
  - The Physician Medical Director at the Facility shall make final medical decisions for the Facility;
  - iii. The Physician Medical Director at the Facility has authority to issue standing orders pursuant to the opioid overdose prevention statute, N.Y. Pub. Health Law § 3309, only for opioid antagonists that are approved by DOH for opioid overdose prevention.

- iv. All Physician Facility Medical Directors and all PrimeCare executive staff shall be trained on the issues detailed in this paragraph and on the details and requirements of standing orders under N.Y. Pub. Health Law § 3309.
- b. Acceptance of this Assurance by OAG is not an approval or endorsement by OAG of any of PrimeCare's policies, practices or procedures, and PrimeCare shall make no representation to the contrary.

## 21. Oversight:

- a. Certification of Compliance: PrimeCare shall provide OAG with a certification affirming its compliance with the requirements set forth in this Assurance, paragraph 20, to be submitted to OAG within sixty (60) days following the Effective Date. This certification shall be in writing and be signed by an appropriate authorized individual on behalf of PrimeCare.
- b. PrimeCare expressly agrees and acknowledges that a default in the performance of any obligation under this paragraph is a violation of the Assurance, and that OAG thereafter may commence the civil action or proceeding contemplated, *supra*, in addition to any other appropriate investigation, action, or proceeding, and that evidence that the Assurance has been violated shall constitute prima facie proof of the statutory violations described in paragraphs 1 through 14, pursuant to N.Y. Exec. Law §§ 63(12) and 75.

## 26. Monetary Relief:

- a. Monetary Relief Amount: Respondent shall pay to the State of New York \$35,000 in penalties (the "Monetary Relief Amount"). Payment of the Monetary Relief Amount shall be made in full within ten [10] business days of the effective date of this Assurance.
- b. Payments shall be made by attorney check, corporate or certified check, or bank draft, which shall be made payable to the "State of New York", and shall reference Assurance No. 25-053; payments shall be addressed to the attention of Assistant Attorney General Susan Lambiase, State of New York, Office of the Attorney General, Health Care Bureau, 28 Liberty Street, New York, NY 10005.

#### **MISCELLANEOUS**

# 27. Subsequent Proceedings:

- a. PrimeCare expressly agrees and acknowledges that OAG may initiate a subsequent investigation, civil action, or proceeding to enforce this Assurance, for violations of the Assurance, or if the Assurance is voided pursuant to paragraph 30, and agrees and acknowledges that in such event:
  - any statute of limitations or other time-related defenses are tolled from and after the effective date of this Assurance;
  - ii. the OAG may use statements, documents or other materials
     produced or provided by PrimeCare prior to or after the effective
     date of this Assurance;
  - iii. any civil action or proceeding must be adjudicated by the courts of the State of New York, and that PrimeCare irrevocably and

- unconditionally waives any objection based upon personal jurisdiction, inconvenient forum, or venue.
- iv. evidence of a violation of this Assurance shall constitute prima facie proof of a violation of the applicable law pursuant to Executive Law § 63(15).
- a. If a court of competent jurisdiction determines that PrimeCare has violated the Assurance, PrimeCare shall pay to OAG the reasonable cost, if any, of obtaining such determination and of enforcing this Assurance, including without limitation legal fees, expenses, and court costs.

# 28. <u>Effects of Assurance:</u>

- a. All terms and conditions of this Assurance shall continue in full force and effect on any successor, assignee, or transferee of PrimeCare. PrimeCare shall include any such successor, assignment or transfer agreement a provision that binds the successor, assignee or transferee to the terms of the Assurance. No party may assign, delegate, or otherwise transfer any of its rights or obligations under this Assurance without the prior written consent of OAG.
- Nothing contained herein shall be construed as to deprive any person of any private right under the law.
- c. Any failure by OAG to insist upon the strict performance by PrimeCare of any of the provisions of this Assurance shall not be deemed a waiver of any of the provisions hereof, and OAG, notwithstanding that failure, shall have the right thereafter to insist upon the strict performance of any and all of the provisions of this Assurance to be performed by PrimeCare.

## 29. Communications:

a. All notices, reports, requests, and other communications pursuant to this Assurance must reference Assurance No. 25-053, and shall be in writing and shall, unless expressly provided otherwise herein, be given by hand delivery; express courier; or electronic mail at an address designated in writing by the recipient, followed by postage prepaid mail, and shall be addressed as follows:

If to PrimeCare, to: Thomas Weber, CEO at <a href="mailto:tweber@primecaremedical.com">tweber@primecaremedical.com</a>, or Brent Bavington, President at <a href="mailto:bwbavington@primecaremedical.com">bwbavington@primecaremedical.com</a>,, or in their absence, to the person holding the title of General Counsel. If to the OAG, to: Susan Lambiase <a href="mailto:susan.lambiase@ag.ny.gov">susan.lambiase@ag.ny.gov</a> or Tina Peng at <a href="mailto:tina.peng@ag.ny.gov">tina.peng@ag.ny.gov</a> or, in their absence, to Darsana Srinivasan at <a href="mailto:darsana.srinivasan@ny.ag.gov">darsana.srinivasan@ny.ag.gov</a> or the person holding the title of Bureau Chief, Health Care Bureau.

## 30. Representations and Warranties:

a. The OAG has agreed to the terms of this Assurance based on, among other things, the representations made to OAG by PrimeCare and their counsel and OAG's own factual investigation as set forth in Findings, paragraphs (4)-(13) above. PrimeCare represents and warrants that neither it nor its counsel has made any material representations to OAG that are inaccurate or misleading. If any material representations by PrimeCare or its counsel are later found to be inaccurate or misleading, this Assurance is voidable by OAG in its sole discretion.

- b. No representation, inducement, promise, understanding, condition, or
  warranty not set forth in this Assurance has been made to or relied upon by
  PrimeCare in agreeing to this Assurance.
- c. PrimeCare represents and warrants, through the signatures below, that the terms and conditions of this Assurance are duly approved.

# 31. General Principles:

- a. Unless a term limit for compliance is otherwise specified within this Assurance, PrimeCare's obligations under this Assurance are enduring. Nothing in this Agreement shall relieve PrimeCare of other obligations imposed by any applicable state or federal law or regulation or other applicable law.
- b. PrimeCare agrees not to take any action or to make or permit to be made any public statement denying, directly or indirectly, any finding in the Assurance or creating the impression that the Assurance is without legal or factual basis.
- c. Nothing contained herein shall be construed to limit the remedies available to OAG in the event that PrimeCare violates the Assurance after its effective date.
- d. This Assurance may not be amended except by an instrument in writing signed on behalf of the Parties to this Assurance.
- e. In the event that any one or more of the provisions contained in this Assurance shall for any reason be held by a court of competent jurisdiction to be invalid, illegal, or unenforceable in any respect, in the sole discretion of OAG, such

- invalidity, illegality, or unenforceability shall not affect any other provision of this Assurance.
- f. PrimeCare acknowledges that it has have entered this Assurance freely and voluntarily and upon due deliberation with the advice of counsel.
- g. This Assurance shall be governed by the laws of the State of New York without regard to any conflict of laws principles.
- h. The Assurance and all its terms shall be construed as if mutually drafted with no presumption of any type against any party that may be found to have been the drafter.
- i. This Assurance may be executed in multiple counterparts by the parties hereto. All counterparts so executed shall constitute one agreement binding upon all parties, notwithstanding that all parties are not signatories to the original or the same counterpart. Each counterpart shall be deemed an original to this Assurance, all of which shall constitute one agreement to be valid as of the effective date of this Assurance. For purposes of this Assurance, copies of signatures shall be treated the same as originals.

  Documents executed, scanned and transmitted electronically and electronic signatures shall be deemed original signatures for purposes of this Assurance and all matters related thereto, with such scanned and electronic signatures having the same legal effect as original signatures.
- j. The effective date of this Assurance shall be September 29 , 2025.

LETITIA JAMES Attorney General of the State of New York 28 Liberty Street New York, NY 10005

By: Darsana Srinivasan Bureau Chief, Health Care Bureau Chief, LEMIO PRIMECARE MEDICAL, OF NEW YORK, INC. By: Brent Bavington President ss.: On the <u>22</u> day of <u>Sept</u> in the year <u>2425</u> before me personally came Brent Bavington, to me known, who, being by me duly sworn, did depose and say that he/she/they reside(s) in Lancaster, PA; that he/she/they is (are) the President duly appointed of PrimeCare Medical of New York, Inc., the corporation described in and which executed the above instrument; that he/she/they know(s) the seal of said corporation; that the seal affixed to said instrument is such corporate seal; that it was so affixed by authority of the board of directors of said corporation, and that he/she/they signed his/her/their names(s) thereto by like authority. day of <u>Sept</u>, 2025 <u>Riveria Rose Und</u> NOTARY PUBLIC

Commonwealth of Pennsylvania - Notary Seal REBECCA ROSE ULRICH - Notary Public **Dauphin County** 

Sworn to before me this

STATE OF

COUNTY OF Dauphin

My Commission Expires November 7, 2026 Commission Number 1342194