

**SETTLEMENT AGREEMENT**

This Settlement Agreement (“Agreement”) is made and entered into by and between the United States of America, acting through the United States Department of Justice and its Drug Enforcement Administration (“DEA”) (collectively, the “United States”) and Northeast Hospital Corporation (“Northeast”). The United States and Northeast are each referred to herein as a “Party” and collectively as the “Parties.”

**RECITALS**

A. Northeast is a Massachusetts charitable corporation that owns and operates a hospital at multiple locations in Massachusetts. Northeast does business as Beverly Hospital in Beverly, Massachusetts; Lahey Outpatient Center Danvers, in Danvers, Massachusetts; BayRidge Hospital, in Lynn, Massachusetts; and Addison Gilbert Hospital, in Gloucester, Massachusetts.

B. Each of these four locations at which Northeast conducts business is separately registered with the DEA as follows:

| <b>Name on Registration</b>                       | <b>DEA Registration Number</b> |
|---|--------------------------------|
| Beverly Hospital                                  | ██████████                     |
| Beverly Hospital<br>DBA Lahey Outpatient, Danvers | ██████████                     |
| Beverly Hospital<br>DBA BayRidge Hospital         | ██████████                     |
| Addison Gilbert Hospital                          | ██████████                     |

C. Every DEA registrant is required to conduct its operations in accordance with the Controlled Substances Act, 21 U.S.C. § 801, et seq. (the “CSA”), and the regulations promulgated thereunder. One purpose of the recordkeeping requirements of the CSA is to track controlled substances from a manufacturer to a purchaser and to the ultimate user or consumer because misuse of controlled substances can result in overdose or other harm.

D. The DEA is the Department of Justice component agency primarily responsible for enforcing the CSA, and is vested with the responsibility of investigating violations of the CSA.

E. The United States Attorney General, through the United States Attorney's Office, has primary authority to bring civil actions to enforce the CSA. *See* 21 U.S.C. § 871 and 28 C.F.R. § 0.55(c).

F. Northeast admits, acknowledges, and accepts its responsibility for the following facts:

(a) On March 22, 2018, Northeast reported to the DEA and the Massachusetts Department of Public Health a diversion of controlled substances by one of its employees. A pharmacy technician diverted 17,846 dosage units<sup>1</sup> of controlled substances, including Percocet, oxycodone, dextroamphetamine, fentanyl, and MS Contin, over an at least 13-month period.

The pharmacy technician took the controlled substances from automated dispensing machines, recorded the withdrawn controlled substances as "expired," and did not return the controlled substances to Northeast's pharmacy located at Beverly Hospital. Northeast discovered the diversion in the course of implementing improvements to Northeast's pharmacy operations and controlled substances accountability procedures and promptly suspended the pharmacy technician. DEA subsequently investigated Northeast's diversion report and Northeast fully cooperated with DEA's investigation;

(b) On April 20, 2018, DEA counted certain controlled substance dosage units in automated drug-dispensing machines within Northeast's Beverly and Danvers locations. DEA

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<sup>1</sup> This total includes 17,754 total tablets and capsules of medications in solid forms, plus 92 milliliters of medications in liquid forms. The total could alternatively be accurately reported as 17,776 dosage units by counting the 22 containers of liquid medications in place of the 92 milliliters of medications contained within them.

maintains that, after comparing these counts with Northeast's most recent biennial inventory and other documentation, it found discrepancies in the amounts of twelve types of controlled substances that it counted at one location and four types of controlled substances that it counted at the other location;

(c) 21 C.F.R. § 1304.21(b) provides that "[s]eparate records shall be maintained by a registrant for each registered location except as provided in § 1304.04(a)." Beverly Hospital; Beverly Hospital DBA Lahey Outpatient, Danvers; Beverly Hospital DBA BayRidge Hospital; and Addison Gilbert Hospital are each separately registered with the DEA, as set forth above. From April 19, 2016 through December 2019, Northeast used a "SECTION" designator column to differentiate inventory by location within combined inventory spreadsheets that covered the four locations, collectively;

(d) From April 19, 2016 through December 2019, on at least 4,283 occasions, Northeast delivered Schedule II controlled substances that had been ordered and received by Northeast under one of the DEA registrations listed above to one of the other locations listed above (each of which had a separate DEA registration, as noted above) all part of Northeast, without completing DEA transfer forms (Forms 222);

(e) On or about March 27, 2018, two Forms 222 related to a reverse distribution of controlled substances (i.e., a return of the controlled substances to the distributor, which occurs routinely, typically when a controlled substance has expired) were completed incorrectly by hand writing in the "Date Shipped" section a date of "3/27/19", when the reverse distribution shipment likely occurred on March 27, 2018;

(f) From April 19, 2016 through December 2019, on at least 6,099 occasions, Northeast delivered Schedule III-V controlled substances that had been ordered and received by

Northeast under one of the DEA registrations listed above to one of the other locations listed above (each of which had a separate DEA registration, as noted above), all part of Northeast, without recording on the documentation related to each such delivery the DEA registration number of the location that received the dosage units; and

(g) During the period from April 19, 2016 through December 2019, Northeast delivered more than 5% of its total controlled substances purchased in each calendar year from Beverly Hospital to Beverly Hospital DBA Lahey Outpatient, Danvers; Beverly Hospital DBA BayRidge Hospital; and Addison Gilbert Hospital. Northeast has never been registered with the DEA as a distributor.

The foregoing conduct set out in subparagraphs (a) through (g) is referred to below as the "Covered Conduct."

G. The United States contends that it has claims for civil monetary penalties and injunctive relief against Northeast under the CSA and its implementing regulations based upon the Covered Conduct. Such civil claims under the CSA include violations of 21 USC § 822(a)(1), 21 USC § 827(b)(1), 21 USC § 828(a), 21 USC § 843(a)(1), 21 USC § 842(a)(2), 21 USC § 842(a)(5) and the following implementing regulations: 21 C.F.R. §§ 1301.71, 1301.76(b), 1304.11(a) and (c), 1304.21, 1304.22(c), 1304.22(f)(2)(i), 1304.22(f)(2)(v), 1305.03, 1305.13(b), and 1307.11(a)(iv).

In consideration of the mutual promises and obligations of this Agreement and with full authority to enter into this Agreement and to be bound thereby, the Parties agree as follows:

#### **TERMS AND CONDITIONS**

1. As set forth below, Northeast shall pay to the United States the sum of one million

nine hundred thousand dollars (\$1,900,000.00) plus interest at a rate of 1.875% per annum from February 9, 2022, and continuing until and including the date of payment (the "Settlement Amount"), none of which is restitution. On the Effective Date of this Agreement, this sum shall constitute a debt due and immediately owing to the United States, for which Northeast is liable.

2. Northeast shall make payment of the Settlement Amount, pursuant to written instructions to be provided by the United States Attorney's Office for the District of Massachusetts, no later than ten days after the Effective Date of this Agreement.

3. No later than five business days after the Effective Date of this agreement, Northeast and the DEA will enter into the Corrective Action Plan ("CAP") that is attached.

4. Subject to the exceptions in Paragraph 5 (concerning reserved claims) below, and conditioned upon the United States' receipt of the Settlement Amount and Northeast complying with Paragraph 3, the United States releases Northeast (including its predecessors, current and former parents, divisions, subsidiaries, successors, and assigns), from any civil or administrative claims the United States has, could have, or may assert in the future, related to the Covered Conduct under the CSA and associated DEA regulations.

5. Notwithstanding the release given in Paragraph 4 of this Agreement, or any other term of this Agreement, the following claims and rights of the United States 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. Any administrative liability or enforcement right, including the suspension and debarment rights of any federal agency, other than DEA, as to the Covered Conduct;

- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon obligations created by this Agreement; or
- f. Any liability of individuals not a party to this Agreement.

6. The United States reserves the right to seek injunctive relief pursuant to 21 U.S.C. § 843(f) if Northeast fails to pay the Settlement Amount or comply with the obligations of the CAP.

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

8. Northeast releases the United States and its agencies, officers, agents, employees, and servants from any claims (including for attorneys' fees, costs, and expenses of every kind and however denominated) that Northeast has asserted, could have asserted, or may assert in the future against the United States or its agencies, officers, agents, employees, or servants, related to the Covered Conduct and the United States' investigation and prosecution thereof.

9. The obligations imposed upon Northeast pursuant to this Agreement are in addition to, and not in derogation of, all requirements imposed upon Northeast pursuant to all applicable federal, state, and local laws and regulations, including but not limited to the requirements set forth in Title 21 of the United States Code and the regulations promulgated thereunder.

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

11. Each Party represents that it freely and voluntarily enters into this Agreement without any duress or compulsion.

12. Except as otherwise provided herein, 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 otherwise provided herein.

13. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the District of Massachusetts. This Agreement shall be deemed to have been drafted by all Parties to this Agreement and, therefore, shall not be construed against any Party for that reason in any subsequent dispute.

14. The Agreement, including the CAP, contains the entire agreement between the Parties regarding the alleged claims at issue herein. The Agreement may be amended only by a writing signed by both Parties.

15. This Agreement is binding on Northeast's successors, transferees, and assigns.

16. The undersigned represent and warrant that they are fully authorized to execute this Agreement on behalf of the Parties.

17. This Agreement may be executed in counterparts, each of which constitutes an original and both of which constitute one and the same agreement, but shall become final and binding only upon signing by all representatives listed below for both Parties.

18. The Parties may execute this Agreement via facsimile and/or by portable document format (.pdf), both of which shall be deemed the equivalent of an original signature.

19. The Parties consent to the United States' disclosure to the public of this Agreement and information about this Agreement, except that DEA Registration Numbers shall be

redacted and not disclosed to the public.

20. This Agreement shall become effective on the date of the signature of the last signatory to the Agreement (“Effective Date of this Agreement”).

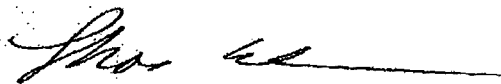
SIGNATURES TO FOLLOW ON NEXT PAGE



THE UNITED STATES OF AMERICA

DATED: November 22, 2022

BY:



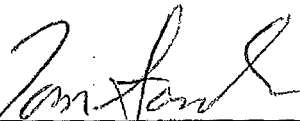
THOMAS E. KANWIT  
Assistant U.S. Attorney  
United States Attorney's Office  
District of Massachusetts

NORTHEAST HOSPITAL CORPORATION

DATED:

11/29/2022

BY:

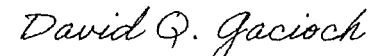


TOM SANDS  
President

DATED:

11/29/2022

BY:



SARAH E. WALTERS  
DAVID Q. GACIOCH  
McDermott Will & Emery LLP  
Counsel for Northeast Hospital Corporation

David  
Quinn  
Gacioch

Digitally signed  
by David Quinn  
Gacioch  
Date: 2022.11.29  
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