BEFORE THE NEW HAMPSHIRE BOARD OF PHARMACY CONCORD NH 03301

In the Matter of: Cheshire Medical Center Permit #0069 Docket No. 2022-PHARM-003

SETTLEMENT AGREEMENT

In order to avoid the delay and expense of further proceedings and to promote the best interests of the public and the practice of pharmacy, the New Hampshire Board of Pharmacy ("Board") and Cheshire Medical Center ("Permittee"), a hospital with an inpatient pharmacy permitted in the State of New Hampshire, agree to resolve certain allegations of professional misconduct now pending before the Board in accordance with the following terms and conditions:

1. Pursuant to RSA 318:30, RSA 318:31, RSA 310-A:1-j, RSA 310-A:1-l, and RSA 541-A:31, V, the Board has jurisdiction and authority to investigate and commence a disciplinary proceeding pertaining to allegations of professional misconduct committed by Permittee. Pursuant to RSA 318:31, IV, RSA 310-A:1-k, III and RSA 541-A, V, the Board may at any time before or during a disciplinary proceeding resolve allegations of professional misconduct by a written Settlement Agreement approved by the Board and permittees provided the complainant has an opportunity to comment upon the terms of the Settlement Agreement before the Settlement Agreement has been executed.

- On 01/01/1975, the Board first granted Permittee Pharmacy Permit #0069 to operate a
 pharmacy at 580 Court St., Keene, NH 03431. Permittee's permit has an expiration date
 of 12/31/2022.
- On 02/02/2022, the Board received information from Permittee of diversion and significant loss of fentanyl from the Intensive Care Unit at Permittee. After further investigation, Permittee reported additional fentanyl loss that occurred between 04/10/22 and 5/12/22.
- 4. In response to the information received, the Board commenced an investigation on their own motion and obtained information from various sources including Permittee pertaining to whether Permittee's conduct constitutes misconduct pursuant to the Board's statutes and rules. On 05/25/22, the Board voted to initiate a disciplinary action against Permittee and issued a notice of hearing for a disciplinary hearing.
- 5. Permittee stipulates that if a disciplinary proceeding were to take place, Hearing Counsel could prove that Permittee engaged in misconduct pursuant to at least one of the following provisions RSA 318:29, II(c) and (d); RSA 318:29, V(c) and (g); Ph 308.01(a) and (b); Ph 703.03; Ph 704.11(b)(1), (2), (3), (4), (5), (6), (7), (9), (10), and (11); Ph 705.01; Ph 709.04; and/or Ph 709.05 according to the following facts:
 - a. Permittee holds permit #0069 issued by the Board. Permittee is located in Keene, NH.
 - b. On or about 01/01/2021, Permittee began the transition from Pyxis Automated Dispensing Machines ("ADM") to Omnicell ADM.
 - c. In November 2021 through January 2022, Permittee experienced a significant surge of COVID 19 patients which created logistical and unprecedented challenges within the clinical operating environment.

- d. Before 02/01/2022, Nurse Alexandra Towle committed numerous acts of diversion of controlled substances including 50mL bags of fentanyl 50mCg/1mL.
- e. On 02/01/2022, Permittee discovered the diversion and informed the Board the following day of significant loss of fentanyl due to diversion by Nurse Towle. As Permittee investigated the incident further, undertaking a retrospective audit of all fentanyl bag use, and gained information about the scope of Ms. Towle's diversion, Permittee continually updated the Board.
- f. On 02/04/2022, Permittee, on its own initiative, began enacting a corrective action plan to address and strengthen security, education, and procedure issues that permitted an opportunity for Nurse Towle to divert fentanyl.
- g. On 03/08/2022, Permittee reported to the Board that in addition to Nurse Towle's diversion, a reportable loss also occurred due to nurses failing to sufficiently document the administration or waste of fentanyl using Baxter IV pumps.
- h. On 05/12/2022 and despite Permittee's ongoing corrective measures, Permittee informed the Board that additional loss of fentanyl occurred between 04/10/22 and 05/12/22. Permittee attributed this additional loss to nurses failing to sufficiently document the administration and/or waste of fentanyl using Baxter IV pumps.
- Since 05/12/2022, Permittee has taken additional corrective measures to strengthen security, education, and procedures including ceasing fentanyl infusions using Baxter IV pumps.
- j. On 06/08/2022, the NH Department of Health and Human Services conducted an onsite visit of Permittee and determined there were no deficiencies pertaining to 42 CFR 482.23 Nursing Services and 42 CFR 482.25 Pharmaceutical Services.

- k. On 06/22/2022, The Joint Commission conducted an onsite visit and determined the services at Permittee were in "substantial compliance with the Medicare Conditions [of participation for hospitals]" and noted there were "no requirements for improvement" identified. The Joint Commission granted Permittee "an accreditation decision of Accredited with an effective date of June 23, 2022." The Joint Commission also recommended Permittee "for continued Medicare certification effective June 23, 2022."
- In total, Permittee had reportable losses over a period of months due to diversion or lack of documentation of the equivalent of approximately 670 50mL bags of fentanyl 50mCg/1mL.
- Permittee acknowledges that the conduct set forth in paragraph 5 d., g., h., and l. could constitute grounds for the Board to impose disciplinary sanctions against Permittee pursuant to RSA 318:29.
- 7. WHEREFORE, Permittee consents to the Board imposing the following discipline and penalties pursuant to RSA 318:29, RSA 310-A:1-m, and Ph 710:
 - a. Permittee is **REPRIMANDED** for the loss of significant quantities of controlled substances at Permittee's facility.
 - b. Permittee's permit is **RESTRICTED** subject to the following terms and conditions:
 - i. Permittee's permit is restricted for a period of three (3) years (the "Restriction Period") beginning on the date the Board approves this Settlement Agreement (the "Effective Date").

- ii. Within six (6) months of the Effective Date, Permittee's Pharmacist-in-Charge and Director of Pharmacy shall be two different individuals.
- iii. Permittee shall independently employ a third-party monitor (selected by Permittee and approved by the Board) to conduct Controlled Substance Audits in a manner similar to audits conducted by the Board's pharmacy inspectors pursuant to Board Order dated 06/17/2022, beginning no later than October 2022 (to afford Permittee adequate time to engage a thirdparty monitor). More specifically, the Controlled Substance Audits will include Permittee Invoice to CSM reconciliation audit; CSM Exception Report audit; Omnicell Override Report audit for controlled substances; Omnicell Pick List Report audit; Omnicell Dose Rec. Report audit; Controlled Substance Infusion audit; Physical Inventory audit; and Diversion Training audit. Permittee will make available to the monitor all information reasonably requested by the monitor to enable it to carry out the Controlled Substance Audits. For the first four months of the Restriction Period, the Controlled Substance Audits shall be performed every other week. For the subsequent eight months of the Restriction Period, the Controlled Substance Audits shall be performed monthly. For the remaining 24 months of the Restriction Period, the Controlled Substance Audits shall be performed quarterly. Between the Effective Date and the date the thirdparty is approved and commences monitoring activities, the Board's pharmacy inspectors shall undertake further Controlled Substance Audits as

- set forth above with reasonable notice to Permittee, not to exceed two such audits per month.
- iv. Permittee shall be responsible for the cost of employing a third-party monitor but may share such costs with a third-party.
- v. All Controlled Substance Audits shall be reported to the Board and OPLC
 Enforcement within 7 business days of completion of the audit.
- vi. Permittee shall appear before the Board at regularly scheduled status hearings to discuss the results of the audits and to answer any questions from Board members. For the first 6 months of the Restriction Period, the status meetings shall occur at each of the regularly scheduled monthly Board meetings. For the subsequent 30 months of the Restriction Period, they shall be held quarterly at a regularly scheduled monthly Board meeting. All such status hearings shall be open to the public.
- vii. The Permittee shall allocate \$10,000.00 per year during the Restriction Period to community outreach and awareness initiatives related to substance use disorder and/or diversion. This may include internal resources and training directed toward its staff, and/or community benefit support or outreach programs directed toward the local community. Permittee shall report such community outreach and awareness initiatives at status conferences pursuant to paragraph 7 b. vi.
- viii. After 2 years, Permittee may petition the Board to lift the restrictions and monitoring contained in paragraph 7 upon a showing of good cause and good faith compliance with this Settlement Agreement

- c. Permittee shall pay an ADMINISTRATIVE FINE in the amount of two hundred and twenty-five thousand dollars (\$225,000.00) representing one-hundred and fifty (150) days of violations occurring between 09/01/2021 and 02/02/2022 at three hundred dollars (\$300.00) per day for five (5) offenses per day less the amounts allocated in paragraph 7.b.vii where all but forty-five thousand dollars (\$45,000.00) is suspended provided Permittee complies with all provisions of this Settlement Agreement and the Board makes no additional finding of misconduct following a hearing for conduct occurring during the Restriction Period. If the Board makes no such finding of misconduct subject to RSA 332-G:9 statute of limitations, the suspended portion shall terminate. Forty-five thousand dollars (\$45,000.00) is due and payable within thirty (30) days from the Effective Date of this Settlement Agreement and according to the terms in paragraph 7.e.
- d. Permittee shall pay COST OF INVESTIGATION AND PROSECUTION in the amount of ten thousand dollars (\$10,000.00) which is due and payable within thirty (30) days from the Effective Date of this Settlement Agreement and according to the terms in paragraph 7.e.
- e. All payments shall be in the form of a check or money order made payable to the Treasurer, State of New Hampshire. The payment of the administrative fine shall be made separate from any required payment of the costs of investigation and prosecution. Each payment shall specify on the memo line whether the payment is for "PHARM Administrative Fine" or "PHARM Costs of Investigation and Prosecution." Each payment shall be mailed with a printed copy of this Settlement Agreement. All payments shall be sent to:

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ATTN: OPLC Finance and Board of Pharmacy

Office of Professional Licensure and Certification

7 Eagle Sq.

Concord, NH 03301

8. Permittee shall cooperate with the investigation of and any hearing relating to controlled

drug loss or diversion at Permittee.

9. The Board may consider any unresolved reportable loss or diversion occurring after the

Effective Date or any failure to timely report any reportable loss or diversion occurring

after the Effective Date as a basis for further discipline and, additionally, as a basis to not

lift the restrictions and monitoring contained in paragraph 7 before expiration of the

Restriction Period.

10. The Board may consider Permittee's compliance with the terms and conditions herein in

any subsequent proceeding before the Board regarding Permittee's permit. Permittee's

breach of any terms or conditions of this Settlement Agreement may constitute

unprofessional conduct and may serve as a separate and independent basis for further

disciplinary action by the Board.

11. Except as provided herein, this Settlement Agreement shall bar the commencement of

further disciplinary action by the Board against Permittee based upon the facts and

circumstances described above and at issue in this matter, including but not limited to the

diversion of fentanyl by Nurse Towle, losses associated with documentation and related

issues regarding the administration and/or waste of controlled substances, and alleged

violations of state and federal controlled substances laws during the period prior to the

Effective Date. However, the Board may consider such facts as evidence of a pattern of

conduct in the event that similar misconduct is proven against Permittee in the future.

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- 12. This Settlement Agreement shall become a permanent part of Permittee's file, which is maintained by the Board as a public document.
- 13. Permittee voluntarily enters into and signs this *Settlement Agreement* and states that no promises or representations have been made to Permittee other than those terms and conditions expressly stated herein.
- 14. The Board agrees that in return for Permittee's executing this Settlement Agreement, the Board will not proceed with the formal adjudicatory process based upon the facts described herein and otherwise in accordance with the terms of this Settlement Agreement.
- 15. Permittee understands that Permittee's action in entering into this Settlement Agreement is a final act and not subject to reconsideration or judicial review or appeal.
- 16. Permittee has had the opportunity to seek and obtain the advice of an attorney of Permittee's choosing in connection with its decision to enter into this Settlement Agreement.
- 17. Permittee understands that the Board must review and accept the terms of this Settlement Agreement. If the Board rejects any portion, the entire Settlement Agreement shall be null and void. Permittee specifically waives any claims that any disclosures made to the Board during its review of this Settlement Agreement have prejudiced Permittee's right to a fair and impartial hearing in the future if this Settlement Agreement is not accepted by the Board.
- 18. Permittee's Authorized Representative is not under the influence of any drugs or alcohol and is otherwise of sound mind at the time Permittee signs this agreement.
- 19. Permittee certifies that Permittee has read this document titled Settlement Agreement.

 Permittee understands that Permittee has the right to a formal adjudicatory hearing

concerning this matter and that at said hearing Permittee would possess the right to confront and cross-examine witnesses, to call witnesses, to present evidence, to testify on Permittee's own behalf, to contest the allegations, to present oral argument, and to appeal to the courts. Further, Permittee fully understands the nature, quality, and dimensions of these rights. Permittee understands that by signing this *Settlement Agreement*, Permittee waives these rights as they pertain to the misconduct described herein. This *Settlement*

Agreement shall take effect as an Order of the Board on the date it is signed by an

authorized representative of the Board.

FOR PERMITTEE

I, Authorized Representative of Cheshire Medical Center Pharmacy Permit #0069, have reviewed the foregoing Settlement Agreement settling misconduct allegations pending against Permittee and, of my own free will and without duress, and being knowledgeable about all of the consequences, admit to the validity thereof, and agree to all of the terms of this Settlement Agreement. Further, I, Authorized Representative of Cheshire Medical Center Pharmacy Permit #0069, knowingly and freely waive the right to further notice, opportunity for hearing, substantial evidence, and findings and conclusions with regard to the allegations, which have been settled by the terms of this Settlement Agreement.

Dated: July 27, 2022

Signature

Printed Name

Authorized Representative

Cheshire Medical Center Pharmacy Permit #0069

Permittee

On this 27th

day of

2022 personally

appeared the person who subscribe to the following instrument and acknowledged the same as

her/his voluntary act and deed before me.

Justice of the Peace Notary Public

My commission expires:

Notary Public - New Hampshire My Commission Expires December 20, 2022

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FOR THE BOARD

DAVID ROCHEFORT - Vice President (Print Name)

NH Office of Professional Licensure and

Certification

Authorized Representative of the NH Board of Pharmacy