STATE OF NEW HAMPSHIRE
OFFICE OF PROFESSIONAL LICENSURE AND CERTIFICATION

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BOARD OF PHARMACY

In Re: Dr. Melissa Siciliano, Phar. License #R2536	Docket No.:22-PHAR-002 **NARRATIVE ORDER VACATING EMERGENCY SUSPENSION – 04/20/22**

I. ATTENDEES:

John R. Genovese, R.Ph - President (Recused, did not participate in the proceedings or deliberation)
David A. Rochefort, R.Ph. - Vice President
Nicole J. Harrington, R.Ph. - Member
Karl Peicker, R.Ph. – Member
Eric Lessard, PharmD, R.Ph.- Member
Lindsey Laliberte, R.Ph. - Member (Did not participate in deliberation)
Candace Bouchard, Public Member (Outgoing)
Dan Gross – Public Member (Incoming and did not participate in the proceedings or deliberation)
Attorney John Garrigan, Hearing Counsel and Chief Prosecutor, OPLC
Attorney Collin Phillips, Hearing Counsel, OPLC
Attorney Rick Fradette, Counsel for Licensee
Dr. Melissa Siciliano, PharmD, Licensee
Christine Horne, Board Administrator
Shana Warriner, Board Administrator
Attorney Nikolas K. Frye, Hearings Examiner, OPLC
Sheri Phillips, Esq., Board Counsel

II. CASE SUMMARY/PROCEDURAL HISTORY:

On or about 01/31/22 and 02/04/22, the Office of Professional Licensure and Certification, Division of Enforcement ("Enforcement"), acting on behalf of the Board of Pharmacy ("Board"), received complaints relative to diversion of Fentanyl from the Intensive Care Unit at Cheshire Medical Center in Cheshire, New Hampshire. Enforcement's investigation into those complaints later implicated Melissa

Siciliano ("Licensee"), Pharmacist in Charge ("PIC") at the Hospital. On 03/30/22, the Board held an emergency meeting pursuant to RSA 318:30-a, and N.H. Code Admin. R., Title Ph 204.06 ("Rules") and voted to suspend Licensee's license on an emergency basis. A hearing on that emergency suspension occurred on 04/20/22. A marginal order dated 04/21/22 vacated the emergency suspension and explained that a narrative order would be forthcoming. This Narrative Order Vacating Emergency Suspension-04/20/22 follows.

III. SUMMARY OF THE EVIDENCE AND PRELIMINARY MATTERS:

The Board received the following evidence pursuant to RSA 541-A:33 and Rule 102.02(b):

A. Exhibits were submitted by Hearing Counsel, labeled as follows:

1. Enforcement Complaint Form – Alexandra Towle
2. 02/04/22 Email from Alexandra Towle to NH Board of Pharmacy
3. 02/02/22 NH Controlled Drug Loss Form
4. 02/02/22 Letter from Melissa Siciliano to NH Board of Pharmacy
5. 03/08/22 NH Controlled Drug Loss Form (rev. for 02/02/22)
6. 03/07/22 Letter from Melissa Siciliano to NH Board of Pharmacy
7. NH Controlled Drug Loss Form undated (rev. for 02/02/22)
8. 03/29/22 Letter from Staci Hermann to the NH Board of Pharmacy
9. Controlled Substances Policy: Policy ID: 16267
10. Medication Security, Control and Access Policy: Policy ID: 13698
11. 03/30/22 Confidential Memo from Kaitlyn Simoneau to the NH Board of Pharmacy
12. 02/02/22 Cheshire Medical Center: Investigation Form – Confidential: Interview of Alexandra Towle, RN; summary provided by Jessica Lussier, RN
13. 02/02/22 Lisa Sandstrum's notes from Alexandra Towle Interview
14. 02/07/22 Cheshire Medical Center: Investigation Form – Confidential: Interview of Stephanie Morse, RN; summary provided by Lisa Sandstrum
15. 01/09/22 Video 1607.avi
16. 01/13/22 Video 0250.avi
17. 01/09/22 Video 1912.avi
18. 01/11/22 Video 0905.avi
19. 01/12/22 Video 0205.avi
20. 01/12/22 Video 1835.avi
21. 01/12/22 Video 2107.avi
22. 01/12/22 Video 2309.avi
23. 04/14/22 Letter from Staci Hermann to NH Board of Pharmacy
24. 04/15/22 NH Controlled Drug Loss Form (rev. for 02/02/22)
25. 04/15/22 NH Controlled Drug Loss Form (rev. for 03/08/22)

B. Exhibits were submitted by Licensee, labeled as follows:

A. CV of Dr. Melissa Siciliano
B. CV of Dr. Matthew J. Maughan
C. CV of Dr. David P. LaCoste
D. CV of Dr. David W. Depiero
E. "What Pharmacists Should Know about Drug Diversion", Patrick Yoder, PharmD, 05/26/21

Hearing Counsel listed the following witnesses:

1. Michael Porter, Investigations Bureau Chief, OPLC
2. Elsa Croteau, Pharmacy Compliance Inspector, OPLC
3. Kaitlyn Simoneau, Pharmacy Compliance Inspector, OPLC
4. Dr. Melissa Siciliano, Licensee

Licensee listed the following witnesses:

1. Dr. David LaCoste, Cheshire Hospital
2. Dr. Matthew Maughan, Dartmouth Medical and Research Center
3. Dr. David DePiero, Concord Hospital
4. Dr. Melissa Siciliano, Licensee

IV. PRELIMINARY MATTERS:

Before the hearing, a quorum of the Board had a non-meeting to seek legal advice from Board Counsel pertaining to the following motions filed by Licensee: 04/18/22 "Motion for the Board of Pharmacy to Designate Its Vice President to Preside as the Hearing Officer in the Absence of the President For the April 20, 2022 Hearing Pursuant to RSA 318:5, and Order the Reinstatement of Her License to Practice Pharmacy" and an 04/18/22 "Motion to Strike Emergency Order Pursuant to RSA 318:2, and Order the Immediate Reinstatement of Her License to Practice Pharmacy". When the Board came out of nonmeeting, it voted to deny all prayers for relief contained therein and appoint Nikolas Frye as Presiding Officer, pursuant to Rule 201.02(g). Nikolas Frye was not present for either the non-meeting or Board vote. When the hearing began, the parties were informed of the Board's orders on the filed motions. The Licensee asked for the Board to hear oral argument from the parties on the motions and reconsider its

orders of denial. The Board granted the request, heard oral arguments, and then, again, denied all prayers for relief contained in the motions.

The Presiding Officer then began the proceeding by accepting offers of proof from the parties as to their anticipated witnesses and exhibits to determine their admissibility pursuant to Rule 204.11. With respect to Hearing Counsel's proposed witnesses and exhibits, the parties stipulated to the full admission of Exhibits 1 through 14 and 23 through 25. The parties further agreed that Exhibits 15 through 22 should be excluded. Hearing Counsel then stated an intent to call Michael Porter, Elsa Croteau, and Licensee (if she was not testifying in her case-in-chief) as witnesses. The parties stipulated to those proposed witnesses testifying. After consideration, the Presiding Officer admitted the stipulated to exhibits and determined the witnesses would provide material and relevant testimony. Additionally, and though not required, the Presiding Officer asked Kaitlyn Simoneau, who was listed as a potential OPLC witness, to make herself available in the event one of Hearing Counsel's witnesses provided hearsay testimony of which she had firsthand knowledge and Licensee desired to cross examine her. Finally, Hearing Counsel indicated his case-in-chief would take approximately 40 to 45 minutes, exclusive of cross and Board examination questions. Licensee's counsel approximated 15 to 20 minutes for cross examination of all Hearing Counsel's witnesses.

The Presiding Officer next inquired about the general admissibility of Licensee's witnesses and exhibits. Hearing Counsel objected to the admissibility of testimony from David LaCoste, Matthew Maughan, and David DePiero based upon relevance and materiality. He argued none of those witnesses had any personal knowledge of the facts related to the order of emergency suspension and that the expert witness (DePiero) was not necessary because the Board's rules and hospital's policies establish the practice standards and duties of the Licensee. Licensee argued that David LaCoste would testify to the practice of pharmacy at Cheshire Hospital DH under the supervision of the Licensee; Matthew Maughan

would testify to the practice of pharmacy at Cheshire Hospital DH in the temporary absence of Licensee, and David Depiero would testify to the duties and practice standards of a Director of Pharmacy/PIC in New Hampshire. The Presiding Officer ruled that David LaCoste's testimony was relevant and material insofar as it would cover the timeframe at Cheshire Hospital discussed in the emergency suspension order. The Presiding Officer ruled that Matthew Maughan's proposed testimony was not relevant or material because it did not establish a fact of consequence as to whether the Licensee's actions, as described in the emergency suspension order, posed an imminent danger to life or health. *See In re Gina D.*, 138 N.H. 697, 700 (1994).

Finally, the Presiding Officer began his determination that David DePiero's intended testimony did not appear to be admissible. Rule 704.11(b) sets the standards and duties for a pharmacist in New Hampshire, and the Presiding Officer did not think the proposed expert testimony would assist the Board, as trier of fact, given the Board authors the relevant rules. *In re Gina D.* 138 N.H. at 700. During the Presiding Officer's explanation, Board Members indicated that their understanding was that they would be deciding which witnesses testify. The Presiding Officer explained that the admission of evidence is handled by the Presiding Officer in his or her sole discretion pursuant to Rule 204.11. Nonetheless, the Board Members' comments indicated they did not intend to delegate that authority. Therefore, the Presiding Officer conferred with the Board on what witnesses it believed would provide relevant and material evidence. After a brief nonmeeting to consult with Board Counsel, the Board excluded the testimony of David DePiero and allowed testimony from David LaCoste and Matthew Maughan. The Board explained the purpose of the testimony of those two witnesses should be to provide context as to what was happening in Cheshire Hospital during the relevant time period and insight into the role and responsibilities of a pharmacist in charge at a hospital.[1] Based upon the Board's decisions and the parties'

[1] No Board Members of the quorum were pharmacists in charge at a hospital.

oral arguments on the exhibits, the Presiding Officer admitted Licensee's Exhibits A, B, C, and E.[2] Exhibit D was excluded. Throughout the hearing, the Presiding Officer deferred to the Board on whether it thought certain pieces of opinion testimony from David LaCoste and Matthew Maughan that Hearing Counsel objected to would assist them as trier of fact.[3]

V. CONDUCT OF THE HEARING AND EVIDENCE PRESENTED:

Pursuant to Rule 205.03, Hearing Counsel has the burden of proving its case by a preponderance of the evidence. As such, Hearing Counsel presented its case-in-chief first, followed by Licensee. All witnesses were sworn in under oath by the Presiding Officer before testifying. Rule 204.11(e). The credible evidence presented at the hearing allows the Board to find the following facts.

A. Testimony for Hearing Counsel's Case-in-Chief

1. Michael Porter, Investigations Bureau Chief, OPLC

Michael Porter first briefly testified he has worked at OPLC since 2018, first as an investigator and later as Investigations Bureau Chief, a position he has held since 2020. His testimony then shifted to facts pertaining to the Board's Order of Emergency Suspension of 03/30/22. Investigator Porter explained that on or about 02/04/22, OPLC Division of Enforcement received, on behalf of the New Hampshire Board of Nursing, a complaint filed by Cheshire Hospital ("Hospital"), which he identified as Exhibit 1. Exhibit 1 shows that Amy Matthews, DNP, RN filed the complaint for the Hospital. The complaint generally alleges that a nurse at the Hospital had been diverting Fentanyl solution bags since October of 2021; the Hospital had determined that at least 23 bags were removed by the nurse without being wasted or provided to patients; and the Hospital's internal investigation was ongoing. Investigator Porter clarified that each of the missing bags contained 2500 micrograms of Fentanyl.

[2] Exhibit E was admitted with the understanding it would be discussed by one of the witnesses. This never occurred.

[3] The purpose of doing this was to ensure that the Presiding Officer honored what authority the Board intended to delegate to him, as his authority derives from the Board. *See* Rule 201.02(g).

Investigator Porter next testified that on the same day OPLC Enforcement received a complaint from the Hospital, the nurse who was the subject of the complaint, Alexandra Towle, RN, filed a self-report with OPLC. Investigator Porter identified Exhibit 2 as an email chain containing an 02/04/22 12:30 PM email from Nurse Towle with a subject line stating "Self-Reporting to the Board of Nursing". Nurse Towle admits in the email to diverting Fentanyl from the Hospital's Omnicell for her own use as a way of coping with the stress of working during the pandemic. However, as Investigator Porter testified to on cross examination, Nurse Towle's representation in that email differs from what was provided to the Hospital by Nurse Towle, which was that she had given 12 bags of Fentanyl to a friend. Exh. 1.

Investigator Porter explained the investigation into diversion of Fentanyl at the Hospital is "ongoing and rolling" and that the numbers continue to shift. He noted that the investigation covers the time period from September of 2021 through January of 2022 and not all bags of Fentanyl unaccounted for are attributable to Nurse Towle. At the time the Board issued its Order of Emergency Suspension, the approximate number of Fentanyl bags unaccounted for was 700, which equated to approximately 10 gallons of Fentanyl. While the amount of unaccounted for bags continued to rise at that time, the total attributed to Nurse Towle was remaining steady. Investigator Porter explained that because the Licensee is the PIC for the Hospital, she is responsible for the security and disposition of controlled substances. He acknowledged that the matter is an ongoing investigation, involving multiple jurisdictions and agencies, including the DEA. He agreed that there was currently no evidence that the Licensee had diverted any of the missing controlled substances but reaffirmed the investigation was ongoing.

On cross examination, Investigator Porter acknowledged that before or contemporaneous with the time the complaints from the Hospital and Nurse Towle came to OPLC, the Licensee had reported the loss of controlled substances. *Compare* dates on Exhs. 1 and 2 to Exhs. 3 and 4. Board questioning then revealed that there are currently about 280 bags of unaccounted for Fentanyl not attributable to Nurse

Towle's actions. In comparison, there are currently about 303 bags of Fentanyl missing that are attributable to Nurse Towle. Investigator Porter testified that he did not know whether the diversion was still ongoing, only that the information he currently had indicated the pharmacy's role in the matter appears to be that it failed in preventing large scale diversion over an extensive period. He additionally noted that he was unaware of any new Fentanyl loss at the Hospital.

2. Elsa Croteau, Pharmacy Compliance Inspector, OPLC

Hearing Counsel's second witness was Elsa Croteau. She first testified that she has worked as an Inspector for OPLC for seven and a half years, previously worked for UVM Medical, and is a certified pharmacist technician and sterile compounder. Her current work duties include routine inspections of pharmacies, issuing permits, and administering the New Hampshire PIC exams. Inspector Croteau next relayed she became involved in this matter when she received the initial 02/02/22 NH Loss of Controlled Substance form from Cheshire Hospital on 02/03/22. Inspector Croteau identified the Licensee as the individual who filed the form and an accompanying letter, which are marked as Exhibits 3 and 4, respectively. According to Exhibit 4 and Inspector Croteau's testimony, the Hospital had determined there were 23 bags or 1,150 ml of Fentanyl diverted by Nurse Towle. The letter explained that the investigation was ongoing, and the Hospital anticipated the numbers would change.

Inspector Croteau next testified as to the contents of Exhibits 5 and 6, which she explained were an 03/08/22 NH Controlled Drug Loss Form from the Hospital and an accompanying letter from the Licensee. According to Inspector Croteau's testimony and Exhibits 5 and 6, the Hospital had identified a cumulative 22,300 ml of Fentanyl lost by 03/08/22. The Hospital had attributed 283 lost bags of Fentanyl to Nurse Towle but still could not account for 163 bags. Inspector Croteau testified, and Exhibit 6 shows, that the Hospital did not believe those 163 bags were diverted but rather the challenges of the Hospital work setting brought about by the COVID-19 winter surge "impacted the ability of nursing staff to

consistently document Fentanyl infusion and administration." Exh. 6. Inspector Croteau's testimony further elucidated that the Hospital's investigation was ongoing as of 03/08/22.

Inspector Croteau's testimony also revealed that OPLC received another updated New Hampshire Controlled Drug Loss Form from the Hospital on or about 03/29/22, along with a cover letter from Staci A. Hermann, Chief Pharmacy Officer at Dartmouth-Hitchcock Health.[4] The letter explains that the form "supplements the [03/08/22] report … concerning controlled substances loss associated with… Alexandra Towle." Exh. 8. As Ms. Croteau explained and the form shows, there was a reported loss of 15,200 ml of Fentanyl identified. The updated list also includes other missing controlled substances, but the amounts are comparatively small. Inspector Croteau followed up her testimony concerning the 03/29/22 report by referencing Exhibits 23, 24, and 25. The exhibits are, respectively, a 04/14/22 letter from Staci Hermann and two controlled drug loss forms dated 04/14/22. The first form updates the 02/02/22 report, Exh. 3, and the second form updates the 03/08/22 form, Exh. 5. Inspector Croteau testified these documents helped her determine the most recent cumulative loss determination of Fentanyl at the Hospital is 583 bags of Fentanyl, or approximately 7.7 gallons.

Inspector Croteau's testimony also provided insight on a 03/08/22 meeting she attended among the Licensee, nursing administrators, and Hospital legal staff. She testified those at the meeting explained the spike in critically ill COVID-19 patients during the 2021-2022 winter surge resulted in controlled substance procedures not being enforced. Inspector Croteau also learned from the meeting that the pharmacist who addressed the Hospital's controlled substance discrepancies was Richard Crowe. According to Inspector Croteau's testimony, the Hospital's transition from the Pyxis to Omnicell system

[4] Cheshire Hospital is affiliated with Dartmouth-Hitchcock (aka Dartmouth Health) and Licensee was on leave at this time for a scheduled surgery.

had created technological issues in reconciling controlled substance issues.[5] Nonetheless, the Licensee had explained during the meeting that the employees had received initial and additional training on the new software, including Dr. Crowe. Inspector Croteau also recalled the Licensee stating that when she would check in with Dr. Crowe to see if the reconciliation process was working, he would say he was busy and handling it. According to Inspector Croteau, the Licensee indicated that she had established a level of trust with Dr. Crowe and did not verify his representations by reviewing his work. The interview also resulted in Ms. Croteau learning that there were, at that time, 144 controlled substance discrepancies at the Hospital that Dr. Crowe had addressed without documentation. She explained, however, that the Hospital's investigation was still ongoing.

Inspector Croteau last addressed Exhibits 9 and 10 which are, respectively, the Hospital's current Controlled Substances Policy and Medication Control and Secure Access Policy. She identified the Licensee, in her role as PIC, as being one of the individuals responsible for how controlled substances are documented and secured at the Hospital under the policies.

Cross examination revealed that during Ms. Croteau's investigation, Licensee had been cooperative, involved, and timely with her reports of loss. Ms. Croteau acknowledged she had no evidence that Licensee failed to report controlled substance losses after she discovered the issue. Inspector Croteau also clarified the process that was in place at the Hospital if a controlled substance discrepancy originated in nursing between September of 2021 through January of 2022. According to her testimony, nursing was supposed to attempt to reconcile the issue first and only turn it over to pharmacy if it could not. Inspector Croteau explained nursing had a hard time understanding the reports, so they were sent to Dr. Crowe, who then reconciled the issues. Finally, Ms. Croteau acknowledged on cross that the Hospital policies

[5] Pyxis and Omnicell provide automated systems for medication management in various healthcare settings, as well as supporting software used by pharmacies.

submitted as evidence were approved after the alleged conduct noted in the Emergency Suspension Order of 03/30/22 occurred.

Board questioning of Inspector Croteau uncovered that the last biannual inventory for the Hospital pharmacy was 05/01/21. Additionally, the Board learned that the relevant Hospital reports relative to the period of diversion indicate that the patients being treated with Fentanyl received their prescription, even though Fentanyl was being diverted. Inspector Croteau explained that the Omnicell system allowed the nurses to use a physician's order to access the machine and dispense Fentanyl for the patient. This provided an opportunity to divert Fentanyl bags because the pockets of the Omnicell dispensing machine contained more bags then were necessary to fill the prescription of the patient. Ms. Croteau also testified that she had no evidence that the Licensee was diverting drugs but reminded the investigation was ongoing. She explained that Licensee did have a responsibility to oversee the security of the medications under both the hospital policies and the Board's 700 Rules. When directly asked by a Board Member if she believed the Licensee currently poses an imminent danger to the public, Ms. Croteau responded "no." On redirect by Hearing Counsel, she clarified that Licensee, as PIC, was responsible for the controlled substances at the Hospital.

B. Testimony for Licensee's Case-in-Chief[6]

1. David P. LaCoste, Pharm.D

Dr. LaCoste began his testimony by explaining his relationship to the Licensee. He explained that he had retired as a pharmacist eighteen months before September 2021 but had later decided to return to Cheshire Hospital as a part-time clinical coordinator working two days per week. He testified that he came back before September of 2021 at the behest of Dr. Siciliano, whom he holds in high regard. The Hospital

[6] Before presenting her case-in-chief, the Licensee requested the Board find that Hearing Counsel had failed to prove that 1) Licensee had diverted substances and 2) failed to report ongoing diversion. The request was reserved by a quorum of the Board until the close of the record.

environment between the time of his return and September of 2021 he described as being the "status quo"—85 to 86 patients with a couple on ventilators. Dr. LaCoste then juxtaposed that with the conditions of the Hospital between September of 2021 and January of 2022. He described this period as a "war zone", nothing he had ever seen before. He explained that there was an influx of severely ill COVID-19 patients and all 10 ICU beds at the Hospital were filled with individuals on ventilators. At one point, Dr. Lacoste said, the Hospital had to open a makeshift ICU with 4 additional beds because it was beyond capacity. He noted all these critically ill COVID-19 patients were on multiple IV medications, including Fentanyl, and were being treated at doses he had never seen before. The Hospital treated some of these COVID-19 patients for months.

Dr. LaCoste next testified as to his previous experience as a pharmacist and working under Dr. Siciliano. He stated he had previously acted as a Director of Pharmacy and as an Assistant Director for 15 years. He described his time working under Dr. Siciliano in positive terms. He described her as "run[ning] a tight ship", "never avoiding conflict or controversy", "physically always there", "not a micromanager", having "everyone's back", and prioritizing "the safety of the patients". For these reasons, he "trusted her." He further relayed that Dr. Siciliano had won some pharmacy and leadership awards while at the Hospital. As to Dr. Siciliano's decision to appoint Dr. Richard Crowe to fulfill the duty of operational manager at the Hospital, Dr. LaCoste stated he was not surprised. He explained that he knew Dr. Crowe very well, he could do multiple tasks, and he always wanted to help.

Dr. LaCoste's testimony then shifted to provide some more insight into the reason why the Hospital bought more Fentanyl between September and January of 2022. He explained that it was not unusual for each COVID-19 patient to receive 3 to 4 bags of Fentanyl per day. He testified that during the surge the Hospital ran out of IV bags and vials and was making its own bags due to supply issues. He testified that the real "ramp up" of manually processing bags occurred between November 2021 and

February 2022, when the spike in COVID-19 cases occurred. During this portion of his testimony, Dr. LaCoste also provided information on how controlled substances go from the Omnicell to the patient at the Hospital. He testified that the Omnicell is an automated dispensing cabinet with multiple drawers that contain all the medications a patient may need. Orders for a patient prescription first come from the patient's physician and go to the pharmacy, which then transcribes the order into the computer. That order then goes to the nurse's computers and Omnicell. Dr. LaCoste explained that as far as he knew, despite the diversion occurring, patients were receiving their prescribed Fentanyl. He testified that what appeared to be occurring was that a nurse would take from the Omnicell the prescribed amount of Fentanyl for a patient and administer it, while simultaneously diverting some amount of Fentanyl. The chaos of the COVID-19 surge made it difficult to notice the diversion sooner because documentation was poor.

Dr. LaCoste's testimony then focused on the system that allowed for the diversion to occur. He noted that there was no evidence that he had come across that indicates Dr. Siciliano diverted Fentanyl or other controlled substances from the Hospital. He explained Cheshire had policies and procedures in places that Dr. Siciliano enforced and which had been updated since the diversion. He testified those changes included the revision of the Hospital's reconciliation policy, a locked second door to the medication room, and third party software reimplemented to discover diversion. He contextualized the responsibilities of the Hospital's PIC in terms of the COVID-19 surge. He explained Dr. Siciliano oversaw multiple Omnicell dispensing machines located around the hospital to which hundreds of professionals have access. He noted policies and procedures are important but even with them diversion can occur. He thought it was reasonable for a Hospital PIC, with so many responsibilities, to delegate authority as Dr. Siciliano had done in the case of handling the reconciliation of controlled substances. Finally, he testified that he would have no issue with having himself or a patient he knew admitted at the Hospital with Dr. Siciliano operating as PIC.

Hearing Counsel cross examined Dr. LaCoste on the dangers of Fentanyl. Dr. LaCoste testified that Fentanyl is a Schedule II drug under the federal guidelines and therefore requires strict control. Dr. LaCoste explained that Fentanyl can cause an individual to suffer respiratory arrest and/or die. He acknowledged this is the reason that only prescribers with the proper training and experience (such as nurses, physicians, and pharmacists) are charged with administering Fentanyl. While Dr. LaCoste agreed that any amount of diversion is a problem, he reaffirmed his previous testimony that Dr. Siciliano's responsibilities as a PIC had to be contextualized in light of the fact that she acts in a large, complex hospital setting and the chaos caused by the COVID-19 surge in which the diversion took place. Dr. LaCoste testified that it was his experience that Dr. Siciliano held everyone accountable, followed-up, and was well-prepared for committees. He explained this is what he meant by saying she ran "a tight ship".

Board questioning of Dr. LaCoste first focused on how reconciliation issues were addressed at the Hospital during the period of diversion. Dr. LaCoste testified nursing initially tried to resolve any discrepancy and, if it could not, the problem was sent to Dr. Crowe and Dr. Siciliano. Dr. Crowe was then tasked with attempting to reconcile the discrepancy. Dr. LaCoste explained that Dr. Siciliano assisted in the process by ensuring her employees received proper training with the new software, appointing Dr. Crowe operational manager to reconcile issues, keeping abreast of identified discrepancies, and following up on matters with Dr. Crowe.

Board questioning also revealed the various types of reports produced to uncover potential diversion. Dr. LaCoste testified that there was an IV Fentanyl bag report, which documented what was dispensed and hung by the nurses. That report would have to be reviewed manually. Next, he explained there was an override report generated every day showing medications that were overridden by individuals administering them. He stated that report goes to pharmacy and presumed, if Fentanyl was shown on a report, the matter would be escalated. On redirect, Dr. LaCoste clarified that, as PIC, the Licensee would

see that reports were being reconciled. He believed it was reasonable for a PIC to trust the professional to whom they had delegated the reconciliation authority. Dr. LaCoste admitted he could do no more than speculate as to what happened to the missing bags given the reconciliation reports appeared fine.

2. Matthew J. Maughan, Pharm.D, MHCDS

Licensee next called Dr. Matthew J. Maughan, who first testified as to his credentials. He stated he previously acted in a quasi-director of pharmacy position at a children's hospital in South Carolina. He described his current position with Dartmouth as a resource to other hospitals. He testified that he came to the Hospital on 03/07/22 to assist with the diversion problem. At the time he arrived, Richard Crowe was no longer the operational manager at the Hospital, but the Licensee was still working there. He worked alongside the Licensee until she left on medical leave a week later, and then stayed to keep the progress of the investigation and remedial measures moving forward. Dr. Maughan's testimony also elucidated that he was impressed with the Licensee and had empathy for her situation. He found her to be knowledgeable, competent, organized, and concerned with putting patient safety first. He next offered insight into the limitations of the reports produced for monitoring potential diversion during the relevant time frame. He stated that he was satisfied the Hospital had implemented appropriate remediations to improve their ability to detect diversion. His testimony placed the Licensee at the forefront of creating and instituting those new remedial measures.

Dr. Maughan then shifted his testimony to the investigation he conducted into diversion at the Hospital as part of his duties. He explained that he spoke with the Licensee and others at the Hospital, as well as reviewed reports and email correspondence from Richard Crowe upon which Licensee had been copied. While he stated that he had not finished reviewing all the correspondence between Licensee and Mr. Crowe concerning reconciliation, he opined what he has reviewed fails to demonstrate any noticeable abnormalities in the process. Further, Mr. Crowe's correspondence to Licensee suggests he was competent and understood what he was doing. Based upon his review of the aforementioned, Dr. Maughan testified

that he had seen no evidence that the Licensee had diverted any controlled substance. Based upon what he had reviewed and his training and experience, he additionally concluded that he had no evidence that she had failed to provide sufficient oversight as PIC. He explained that it was reasonable for her to delegate authority of reconciliation to Dr. Crowe, given the sheer volume of reports involved and the significant number of responsibilities assigned to Licensee as both Hospital PIC and Director of Pharmacy. He finished his direct testimony by emphasizing that the electronic reports from the various software used by the Hospital do not tell the individual reviewing them if diversion is occurring. They produce information that may raise a "red flag" for the reviewer. Sometimes these reports might need to be read in conjunction with chart reconciliation to detect diversion.

On cross examination, Dr. Maughan reaffirmed his statement that the responsibilities of the PIC are so vast that they needed to be delegated, and it was reasonable for Licensee to delegate the reconciliation responsibilities. He agreed that delegating the duties exclusively to Dr. Crowe had created a "single point of failure"; however, he noted that it is almost inevitable there will always be some single points of failure in a highly complex environment like a hospital. He testified to his belief that the PIC's duty is to ensure a proper review of reports and "run those down." He explained that "some things are unanswerable" and the focus should be on whether and how the Hospital is documenting the unanswered questions. Dr. Maughan agreed that patient and public safety was paramount for a pharmacist and that pharmacists are bound by the statutes and ethical guidelines governing their behavior. He clarified an earlier statement he had made during direct testimony that the diversion event at the Hospital was a pharmacist's "nightmare". He said he had made the statement because the event had the potential to cause patient harm and cost the Licensee her livelihood.

During Board questioning, Dr. Maughan stated that he did not believe there were any Hospital procedures or policies that the Licensee had not followed. He admitted that losing 600 bags does not

appear as "signal to noise" in the absence of context. With the sheer volume of patients involved and the laxer COVID-19 documentation protocols instituted to deal with the reality of the environment, Dr. Maughan argued it was plausible that detection of those 600 bags over the relevant time span was difficult. He reminded the Board that Dr. Crowe's emails regarding reconciliation "said all the right things" and that there was a "plausible trail that this person [Dr. Crowe] knew what he was doing." He reasoned that he would like to think that the Hospital could detect diversion now with the system that has been implemented but realized that even with remediations in place diversion can occur. Dr. Maughan then reiterated all the various remedial measures that he had previously addressed in his testimony. He then described the Board's current rules for PIC's as an "anachronism", especially in the hospital setting. He noted some reconciliation he has done at the Hospital in relation to this matter has taken upwards of four hours—hardly time a PIC could spare given all the other duties. Finally, Dr. Maughan testified that the Licensee was an integral part of the ongoing investigation and had been so since day one. He opined that Dr. Crowe should be the one to blame, if an individual was singled out, but really the diversion occurred due to all parts of the Hospital's system and a confluence of historical events.

3. Melissa Siciliano, Pharm.D.

The Licensee was the last witness to testify. She began by providing her training and experience background, which is more particularly described in Exhibit A. She then testified as to her duties at the Hospital as PIC and Director of Pharmacy, positions she has held since 2018. She listed, among others: overseeing all pharmacy operations, securing controlled substances, managing the budget, supervising staff, working with disciplines, collaborating with providers, establishing policies and procedures, and creating and implementing improvements, compliance, and quality assurance. She stated that between when she became PIC and Director of Pharmacy in 2018 until the diversion issue related to this hearing there were no insurmountable issues she faced at the Hospital. She relayed that she had always had positive reviews and evaluations from her supervisors and passed inspections by the Board.

Next, the Licensee testified to the context in which the diversion occurred. She explained there were challenges with the COVID-19 surge. Before the recent surge, she worked approximately 50-60 hours per week, but during it closer to 80+ hours. To emphasize her point, she indicated there was a two-week period during the surge where she had not seen her family. She then shifted topics to explain that she had cooperated with the Board's investigation and filed her first report of loss of controlled substances the same day she discovered the diversion. She had even involved Dartmouth, since they have a better ability to investigate the diversion and are affiliated with the Hospital.

The Licensee took the Board through the timeline of the Hospital transitioning controlled substance documentation software from Pyxis to Omnicell. She explained the changes occurred in multiple phases and there were some unanticipated issues, such as having to manually reconcile for a period because the information she had received from the Hospital's IT department had suggested that she could use Pandora software until the Blue Sight software became available. She described the manual reporting as time consuming. The Licensee's testimony also revealed that Dr. Crowe had received training on the new system in January of 2021 and April of 2021. There was then further training provided in August of 2021, as well as informational emails sent to Dr. Crowe. She acknowledged that there was an issue with Anesthesia during Phase 1 of the changeover, but that was because that department needed to reconcile its own reports. The Licensee represented the matter was handled collaboratively.

Licensee also testified as to her communication and dealings with Dr. Crowe with respect to reconciliation. She stated that during the transition to the new software Dr. Crowe never said he could not keep up with the reconciliation. She also noted no other individual at the Hospital reported issues with Dr. Crowe's handling of reconciliations. The Licensee's testimony additionally revealed that she had reached out to the nurse administrators on multiple occasions to learn if they had any issues with the new system. She stated she reached out to Dr. Crowe and her other pharmacy staff for the same feedback, as she was

worried about burnout. She described Dr. Crowe's emails about reconciliation as being concise and accurate. Her testimony indicated she chose him as operations manager because he was always helpful, presented as competent, and she trusted him.

Licensee next testified to the remedial measures that had been implemented at the Hospital since the diversion scheme was uncovered. Some of the remedial measures include: 1) the second floor medication room at the Hospital being permanently locked; 2) a reduction of Fentanyl bags stored in the Omnicell; 3) training of nursing and pharmacy staff on preventing and detecting diversion; 4) practice updates for nursing and pharmacy staff as it relates to controlled substance administration; 5) two pharmacist technicians trained and assigned to the Omnicell reports; 6) working closely with technicians at Dartmouth to review the reports; and 7) reinstitution of ICU dual sign-off at the point of nursing documentation.

Licensee's testimony also addressed some non-policy related changes since the COVID-19 surge. She testified the Hospital no longer need an additional makeshift ICU, had the support of Dartmouth in addressing the diversion issues, and were looking for a new operations manager. She explained that she has been cooperative in both the Board and DEA investigations and took immediate steps to investigate, properly report, and train Hospital staff as soon as she discovered the diversion. Her testimony elucidated that she believes she is now getting the help she needs, and that Dartmouth stands behind her as PIC. She clarified that with the Pandora software being reinstated, she can see anomalous usage. She explained she is not a "micromanager" because her dual roles as PIC and Director of Pharmacy make it impossible not to delegate authority. When delegating, she chooses confident and competent individuals and then follows through with the staff members to ensure things are done. She argued if things "look good" that follow through alone is sufficient oversight. Lastly, the Licensee was adamant that she does not want this to happen again and continues to work on remedial measures toward preventing further incidents.

On cross examination, the Licensee acknowledged Fentanyl is harmful to the public in different ways, including professionals who have access to them, like Nurse Towle. She explained a PIC has a duty to ensure there is a system in place that can assist in detecting diversion. She agreed that she was responsible for control, oversight, and security of controlled substances at the Hospital. Like the other two pharmacists who testified, she agreed that no amount of diversion was an acceptable level but argued she acted appropriately upon discovering the losses. Her testimony also revealed that she had never conducted a random audit of Dr. Crowe's reconciliation work or verified it in any other way beyond checking in with him and keeping herself apprised of his correspondence on the reports. She agreed that it was not good supervision to have 100 "errors" underneath her but explained the 144 reports pertaining to Dr. Crowe were account discrepancies; it was the resolution that was incorrect. She noted nurses removing bags made it difficult to catch the discrepancies during the COVID-19 chaos.

Lastly, Board questioning uncovered that the Licensee has received no internal discipline with respect to this matter. To the contrary, the Hospital had developed a plan to have her come back and assist them with its investigation in a non-pharmacist while her license was suspended. Further, the DEA had spoken with her, but she had not heard back from them or otherwise been arrested and charged. She testified that she had not invoked her Fifth Amendment right against self-incrimination when speaking with the DEA.

V. DISCUSSION AND FINDINGS OF FACTS / CONCLUSIONS OF LAW:

After reviewing all the evidence, and accounting for the presentation and demeanor of all the witnesses, the Board finds that Hearing Counsel has not met its burden of proof, by a preponderance of the evidence, that the Licensee being licensed pending a disciplinary adjudication of this matter presents an "imminent danger to life or health". RSA 318:30-a. While it is certainly not lost on the Board that, according to the most recent controlled substance loss report, this case involves a large quantity of lost or

unaccounted for Fentanyl, the Board is tasked with assessing the imminency of the threat to the public based upon the facts before it. There was no evidence presented at the hearing that the Licensee either diverted controlled substances or failed to report ongoing diversion once she discovered it. Further, and with respect to the Licensee's ability to provide sufficient oversight at the Hospital, the change in context since the period between September of 2021 and January of 2022 is a significant component of this Board's determination. The Hospital is no longer receiving a massive influx of severely ill COVID-19 patients needing Fentanyl. More importantly though, with the assistance of the Licensee and Dartmouth, the Hospital has adopted remedial measures to address the exposed flaws of its diversion detection system and re-implemented Pandora software to detect diversion. The Board cannot say that the Licensee poses an imminent danger to the public life or health under the current circumstances. As noted herein, even the OPLC Inspector admitted as much during Board questioning.

The Board wishes to be very clear that it understands the gravity of what has occurred at the Hospital. At the hearing, the Board's Vice President described the events as a "tragedy" and the record reflects he is right. At the very least, this situation has resulted in a significant amount of lost Fentanyl and a devastating impact on Nurse Towel and her family. *See* Exh. 1. Nonetheless, the sole issue before the Board is whether the Licensee, if licensed, presents an imminent danger to the public life or health pending her disciplinary adjudication. For the aforementioned reasons, a majority of a quorum of the Board concludes that the Licensee does not.

VI. CONCLUSION AND DECISION:

Pursuant to RSA 318:30-a, and Rule 204.06, the Board hereby VACATES its Order of Emergency Suspension in Docket #2022-Pharm-002. The Licensee's license is no longer suspended on an emergency basis, pending adjudication. The Licensee's proposed Findings of Fact and Rulings of Law are granted

insofar as they are made herein. All other of Licensee's proposed Findings of Fact and Rulings of Law are denied.

DATED: 5/3/2022

___/s/ Nikolas K. Frye, Esq._____
Nikolas K. Frye, Esq., Hearings Examiner
Authorized Representative of the Board of Pharmacy-
New Hampshire Office of
Professional Licensure & Certification
7 Eagle Square
Concord, NH 03301