

**DECISION OF THE HEARING COMMITTEE**

**PROVINCE OF NOVA SCOTIA  
HALIFAX REGIONAL MUNICIPALITY**

**IN THE MATTER OF:**     The *Pharmacy Act*, R.S.N.S. 2011, c.55 and Regulations  
                                  made thereunder

-and-

**IN THE MATTER OF:**     Nicole O'Donnell, Pharmacist

The Hearing Committee met on June 20, 2024, to consider the proposed Settlement Agreement (attached) being recommended for acceptance by the Investigation Committee regarding Nicole O'Donnell.

On June 26, 2024 the Hearing Committee received additional information from Ms. O'Donnell and the College in response to additional inquiries raised by the Hearing Committee ("additional information").

The Hearing Committee met again on August 7, 2024 to consider the proposed Settlement Agreement and additional information.

After careful review of the proposed Settlement Agreement and additional information, the Hearing Committee hereby approves the Settlement Agreement as recommended by the Investigation Committee, without amendment, on the basis that the Settlement Agreement meets the requirements of s. 68 of the *Regulations*, is consistent with the purposes of the College as set out in a. 3 of the *Pharmacy Act*, and falls within a reasonable range of dispositions of the Complaint.

The Settlement Agreement is hereby approved.

Dated at Halifax this 7<sup>th</sup> day of August, 2024.

  
Harriet Davies (Chair)

On behalf of Hearing Committee Members:  
Tena Taylor and Desiree Jones

Attachment (Settlement Agreement)

IN THE MATTER OF:      The *Pharmacy Act*, SNS, 2011, c.11

IN THE MATTER OF:      Nicole O'Donnell, Registrant #1939

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### SETTLEMENT AGREEMENT

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Nicole O'Donnell, pharmacist in the Province of Nova Scotia and member of the College of Pharmacists (the "**College**"), hereby agrees with, and consents to, the following in accordance with the provisions of the *Pharmacy Act*.

#### THE COMPLAINT

1. On June 15, 2023, a complaint was filed by the Registrar, pursuant to the *Pharmacy Act* and the *Regulations* made thereunder.
2. The complaint alleged that the Shoppers Simply Pharmacy, #3006, located at 1276 South Park Street, Halifax (the "**Pharmacy**"), had been conducting sterile compounding in contravention of the National Association of Pharmacy Regulatory Authorities Model Standards for Pharmacy Compounding of Hazardous and/or Non-Hazardous Sterile Preparations.
3. In her response dated July 4, 2023, Ms. O'Donnell stated that the Pharmacy underwent renovations 17 years prior, to upgrade their sterile compounding facilities, and that she had travelled to Texas in 2006 and Vancouver in 2013 for training. Ms. O'Donnell stated that she received a pilot inspection report from the College on June 4, 2018, and understood it was to act as a guideline to help the Pharmacy work towards meeting the required standards. Ms. O'Donnell stated there was no deadline given to correct the identified deficiencies. Ms. O'Donnell stated she was told at the pilot inspection that it was the College's goal to work with the Pharmacy to ensure they were taking steps toward meeting the standards. Ms. O'Donnell identified certain changes made by the Pharmacy following the first report. Ms. O'Donnell attributed the Pharmacy's inability to become fully compliant with the required standards to the planned demolition of the VG hospital and the Covid-19 pandemic. Ms. O'Donnell stated the Pharmacy was at all times upfront with the College regarding the delays and hurdles in becoming compliant. Once the Pharmacy was able to secure a new lease in 2023, they started moving forward to become compliant with the required standards.
4. Following investigation, the Investigation Committee of the College, pursuant to section 50(4)(c)(iii) of the *Pharmacy Act*, referred the complaint to a Hearing Committee for a formal hearing to consider allegations against Ms. O'Donnell regarding professional misconduct.

## THE ALLEGATIONS

5. The Notice of Hearing dated February 27, 2024, alleges:

- i. That Nicole O'Donnell engaged in professional misconduct as a pharmacist, licensed at all material times to practice pharmacy in the Province of Nova Scotia and working as the pharmacy manager at the Shoppers Simply Pharmacy located at 1276 South Park Street, Halifax (the "**Pharmacy**"), by failing to address and correct deficiencies identified during an inspection of the Pharmacy conducted by the Nova Scotia College of Pharmacists (the "**College**") on May 1, 2018, including identified failures to comply with the National Association of Pharmacy Regulatory Authorities Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations, adopted by Council of the College effective as of June 30, 2016, and the National Association of Pharmacy Regulatory Authorities Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations, adopted by Council of the College effective as of February 27, 2017, (collectively, the "**NAPRA Standards**"), and which deficiencies remained unaddressed at a follow-up inspection, conducted by the College on May 16, 2023, which activity constituted a breach of:
  - a. Section 12(2) of the *Pharmacy Act*;
  - b. Section 21(1) of the *Pharmacy Practice Regulations*; and/or
  - c. Section 21(2)(a) of the *Pharmacy Practice Regulations*.
- ii. That Nicole O'Donnell engaged in professional misconduct as a pharmacist, licensed at all material times to practice pharmacy in the Province of Nova Scotia and working as the pharmacy manager at the Pharmacy, by performing sterile compounding in the Pharmacy between 2018 and 2023, without having maintained the required training according to the NAPRA Standards, which activity constituted a violation of the standards of practice and performing activities that she was not competent to perform, in breach of:
  - a. Section 21(2)(a) of the *Pharmacy Practice Regulations*;
  - b. Section 12(2) of the *Pharmacy Act*; and/or
  - c. Section 35(3) of the *Pharmacy Act*.
- iii. That Nicole O'Donnell engaged in professional misconduct as a pharmacist, licensed at all material times to practice pharmacy in the Province of Nova Scotia and working as the pharmacy manager at the Pharmacy, by permitting staff working at the Pharmacy who did not have the required training according to the NAPRA Standards to perform sterile compounding in the Pharmacy between 2018 and 2023, which activity constituted a failure to confirm the competency of the person to whom a duty or responsibility is delegated, in breach of Sections 12(2) and 35(2) of the *Pharmacy Act*.
- iv. That Nicole O'Donnell engaged in professional misconduct as a pharmacist, licensed at all material times to practice pharmacy in the Province of Nova Scotia

and working as the pharmacy manager at the Pharmacy, by, between 2018 and 2023, failing to ensure the Pharmacy was adequately equipped to provide safe and proper medication compounding, dispensing, and preparation of medication orders, including failing to comply with the NAPRA Standards respecting cleaning, by:

1. not having sterile isopropyl alcohol to clean;
2. not using sporicidal agent to clean;
3. using shedding gauze to clean;
4. failing to use proper techniques to clean;
5. failing to consistently complete a monthly deep clean;

each of which individually is in breach of:

- a. Section 12(2) of the *Pharmacy Act*;
- b. Section 24(5) of the *Pharmacy Practice Regulations*;
- c. Section 21(1) of the *Pharmacy Practice Regulations*; and/or
- d. Section 21(2)(a) of the *Pharmacy Practice Regulations*.

- v. That Nicole O'Donnell engaged in professional misconduct as a pharmacist, licensed at all material times to practice pharmacy in the Province of Nova Scotia and working as the pharmacy manager at the Pharmacy, by, between 2018 and 2023, preparing hazardous drugs when the Pharmacy was not aware the drug in question was hazardous and the Pharmacy did not compound hazardous drugs in a safe manner, which activity was in violation of the NAPRA Standards and constituted a failure to be adequately equipped to provide safe and proper medication compounding, dispensing and preparation of medical orders, in breach of:

- a. Section 12(2) of the *Pharmacy Act*;
- b. Section 24(5) of the *Pharmacy Practice Regulations*;
- c. Section 21(1) of the *Pharmacy Practice Regulations*; and/or
- d. Section 21(2)(a) of the *Pharmacy Practice Regulations*.

- vi. That Nicole O'Donnell engaged in professional misconduct as a pharmacist, licensed at all material times to practice pharmacy in the Province of Nova Scotia and working as the pharmacy manager at the Pharmacy, by, between 2018 and 2023, failing to maintain up to date policies and procedures specific to sterile compounding, as required by the NAPRA Standards, and which activity constituted a failure to manage the preparation and distribution of drugs and devices in response to the needs and desired health outcomes of patient to ensure the safety, accuracy and quality of supplied products, in breach of:

- a. Section 12(2) of the *Pharmacy Act*;
- b. Standard 2 of the *Standards of Practice: General Pharmacy Practice*;
- c. Section 21(1) of the *Pharmacy Practice Regulations*;
- d. Section 21(2)(a) of the *Pharmacy Practice Regulations*; and/or

e. Section 21(2)(c) of the *Pharmacy Practice Regulations*.

vii. That Nicole O'Donnell engaged in professional misconduct as a pharmacist, licensed at all material times to practice pharmacy in the Province of Nova Scotia and working as the pharmacy manager at the Pharmacy, by, between 2018 and 2023, failing to implement appropriate techniques as required by the NAPRA Standards, including:

1. failing to ensure airflow from the laminar flow workbench (LAFW) was not blocked by the compounder;
2. failing to ensure the compounder did not rest their elbows on the LAFW;
3. failing to ensure the compounder applied sterile alcohol to their hands each time hands left the LAFW;
4. failing to ensure the compounder allowed alcohol to dry on gloves;
5. failing to ensure the compounder re-gowned with new PPE after leaving and returning to clean the room;

each of which individually is in breach of:

- a. Section 12(2) of the *Pharmacy Act*;
- b. Standard 2 of the *Standards of Practice: General Pharmacy Practice*;
- c. Section 32(1)(c) of the *Pharmacy Act*;
- d. Section 21(1) of the *Pharmacy Practice Regulations*; and/or
- e. Section 21(2)(a) of the *Pharmacy Practice Regulations*.

viii. That Nicole O'Donnell engaged in professional misconduct as a pharmacist, licensed at all material times to practice pharmacy in the Province of Nova Scotia and working as the pharmacy manager at the Pharmacy, by, between 2018 and 2023, not undergoing air and surface sampling, which activity violated the NAPRA Standards and constituted a failure to compound products according to product specifications and in accordance with recognized standard and a failure to perform compounding activities in an environment that is consistent with the requirements for the product, in breach of:

- a. Section 12(2) of the *Pharmacy Act*;
- b. Standard 2.2.2 of the *Standards of Practice: General Pharmacy Practice*;
- c. Section 32(1)(c) of the *Pharmacy Act*;
- d. Section 21(1) of the *Pharmacy Practice Regulations*; and/or
- e. Section 21(2)(a) of the *Pharmacy Practice Regulations*.

ix. That Nicole O'Donnell engaged in professional misconduct as a pharmacist, licensed at all material times to practice pharmacy in the Province of Nova Scotia and working as the pharmacy manager at the Pharmacy, by, between 2018 and 2023, failing to consistently complete filter testing for high-risk compounds, which activity violated the NAPRA Standards and constituted a failure to compound products according to product specifications and in accordance with recognized

standards and a failure to perform compounding activities in an environment that is consistent with the requirements for the product, in breach of:

- a. Section 12(2) of the *Pharmacy Act*;
  - b. Standard 2.2.2 of the *Standards of Practice: General Pharmacy Practice*;
  - c. Section 32(1)(c) of the *Pharmacy Act*;
  - d. Section 21(1) of the *Pharmacy Practice Regulations*; and/or
  - e. Section 21(2)(a) of the *Pharmacy Practice Regulations*.
- x. That Nicole O'Donnell engaged in professional misconduct as a pharmacist, licensed at all material times to practice pharmacy in the Province of Nova Scotia and working as the pharmacy manager at the Pharmacy, by, between 2018 and 2023, not utilizing the Pharmacy's Compounding Aseptic Isolator, which would have mitigated the fact that the Pharmacy did not have an anteroom, and which activity violated the NAPRA Standards and constituted a failure to use equipment that is consistent with the needs of the procedure and meets accepted standards, in breach of:
  - a. Section 12(2) of the *Pharmacy Act*;
  - b. Standard 2.2.2 of the *Standards of Practice: General Pharmacy Practice*;
  - c. Section 32(1)(c) of the *Pharmacy Act*;
  - d. Section 21(1) of the *Pharmacy Practice Regulations*; and/or
  - e. Section 21(2)(a) of the *Pharmacy Practice Regulations*.
- xi. That Nicole O'Donnell engaged in professional misconduct as a pharmacist, licensed at all material times to practice pharmacy in the Province of Nova Scotia and working as the pharmacy manager at the Pharmacy, by, between 2018 and 2023, failing to monitor temperature during the transportation of refrigerated sterile compounds, which activity violated the NAPRA Standards and constituted a failure to perform compounding activities in an environment that is consistent with the requirements of the product, in breach of:
  - a. Section 12(2) of the *Pharmacy Act*;
  - b. Standard 2.2.3 of the *Standards of Practice: General Pharmacy Practice*;
  - c. Section 32(1)(c) of the *Pharmacy Act*;
  - d. Section 21(1) of the *Pharmacy Practice Regulations*; and/or
  - e. Section 21(2)(a) of the *Pharmacy Practice Regulations*.
- xii. That Nicole O'Donnell engaged in professional misconduct as a pharmacist, licensed at all material times to practice pharmacy in the Province of Nova Scotia and working as the pharmacy manager at the Pharmacy, by, between 2018 and 2023, not providing adequate safety procedures for hazardous drug sterile compounding, which activity violated the NAPRA Standards and constituted a failure to compound products in accordance with recognized standards and a failure to perform compounding activities in an environment that is consistent with the requirements for the product, in breach of:

- a. Section 12(2) of the *Pharmacy Act*;
  - b. Standard 2.2.2 of the *Standards of Practice: General Pharmacy Practice*;
  - c. Section 32(1)(c) of the *Pharmacy Act*;
  - d. Section 21(1) of the *Pharmacy Practice Regulations*; and/or
  - e. Section 21(2)(a) of the *Pharmacy Practice Regulations*.
- xiii. That Nicole O'Donnell engaged in professional misconduct as a pharmacist, licensed at all material times to practice pharmacy in the Province of Nova Scotia and working as the pharmacy manager at the Pharmacy, by, between 2018 and 2023, failing to do required calculations that caused the strength of the product to be inaccurate, which activity violated the NAPRA Standards and constituted a failure to accurately perform and document calculations, in breach of:
  - a. Section 12(2) of the *Pharmacy Act*;
  - b. Standard 2.2.2 of the *Standards of Practice: General Pharmacy Practice*;
  - c. Section 32(1)(c) of the *Pharmacy Act*;
  - d. Section 21(1) of the *Pharmacy Practice Regulations*; and/or
  - e. Section 21(2)(a) of the *Pharmacy Practice Regulations*.
- xiv. That Nicole O'Donnell engaged in professional misconduct as a pharmacist, licensed at all material times to practice pharmacy in the Province of Nova Scotia and working as the pharmacy manager at the Pharmacy, by, between 2018 and 2023, assigning the wrong beyond use dates to certain compounds causing them to be used beyond the recommended date, which activity violated the NAPRA Standards and constituted a failure to compound products according to product specifications and in accordance with recognized standards and a failure to use only materials and procedures that maximize the integrity of the product, in breach of:
  - a. Section 12(2) of the *Pharmacy Act*;
  - b. Standard 2.2.2 of the *Standards of Practice: General Pharmacy Practice*;
  - c. Section 32(1)(c) of the *Pharmacy Act*;
  - d. Section 21(1) of the *Pharmacy Practice Regulations*; and/or
  - e. Section 21(2)(a) of the *Pharmacy Practice Regulations*.
- xv. That Nicole O'Donnell engaged in professional misconduct as a pharmacist, licensed at all material times to practice pharmacy in the Province of Nova Scotia and working as the pharmacy manager at the Pharmacy, by failing to comply with the NAPRA Standards as particularized in charges 1-15 above, thereby placing the public in harm and failing to hold the health and safety of each patient of primary importance, which activity constituted a breach of Value I, Code of Ethics.

## STATEMENT OF FACTS

6. Ms. O'Donnell became a licensed pharmacist in Nova Scotia in 2004.

7. Ms. O'Donnell was licensed to practice pharmacy in the Province of Nova Scotia at all material times.
8. At the time of events described in the complaint, Ms. O'Donnell was the pharmacy manager at the Pharmacy and participated in the sterile compounding at the Pharmacy between 2018 and 2023.
9. On May 1, 2018, the Pharmacy underwent an onsite pilot inspection conducted by Katie Busroe, a sterile compounding inspector contracted by the College. The inspection revealed numerous deficiencies which were identified in a report prepared by Ms. Busroe. Ms. Busroe's report is attached to this Settlement Agreement as Appendix "A".
10. On June 4, 2018, the May 2018 inspection report and summary documents were provided to Ms. O'Donnell, as well as the owner of the Pharmacy, with instruction that the documents could serve as an action plan as the Pharmacy worked towards compliance with the NAPRA Standards. No date was given to Ms. O'Donnell to correct the deficiencies or for follow up.
11. On November 19, 2018, the College contacted Ms. O'Donnell and the owner of the Pharmacy via email to follow up on the progress made toward compliance with the NAPRA Standards. The College did not receive a response to its inquiry. Ms. O'Donnell says that she did not receive the College's email and that she would have responded had she received it.
12. The College planned to do a follow-up inspection in the Summer of 2020; however, this was not communicated to Ms. O'Donnell and was then cancelled due to the Covid-19 pandemic.
13. On February 11, 2021, the College contacted Ms. O'Donnell to inform her that due to the ongoing pandemic, which prevented Ms. Busroe from visiting the Pharmacy, the Pharmacy would be inspected via a self-assessment to ensure that it was practicing in compliance with the NAPRA Standards.
14. On June 3, 2021, the Pharmacy was provided a self-assessment to complete and advised that any action required would be communicated back to the Pharmacy.
15. On June 29, 2021, Ms. O'Donnell returned the self-assessment to the College. The College provided the self-assessment to Ms. Busroe.
16. On January 10, 2022, the College received Ms. Busroe's review of the self-assessment, which noted numerous outstanding deficiencies, which she summarized in a report. Attached as Appendix "B" is Ms. Busroe's report.
17. On March 30, 2022, the College contacted Ms. O'Donnell and the owner of the Pharmacy noting that the findings from the self-assessment were unacceptable. The Pharmacy was asked to submit an identified list of policies immediately, but failed to do so and, as of the date of the complaint, the College had not received the requested policies.

18. Following the March 30, 2022, communication, Ms. O'Donnell contacted the College by phone to request further information regarding the findings. The College staff member assigned to the matter was scheduled to retire the next day and, as a result, Ms. O'Donnell spoke to a different staff member who was assigned to take over. Ms. O'Donnell was told that the new staff member responsible needed to familiarize herself with the information and would contact Ms. O'Donnell in a couple of weeks. Ms. O'Donnell did not hear back from her.

19. Due to the failure to correct the deficiencies, the College moved forward with a second onsite inspection.

20. Ms. O'Donnell contacted the College prior to the second onsite inspection to request that the inspection be postponed as the Pharmacy was booked for external training and assessment the month following the scheduled inspection. The College denied Ms. O'Donnell's request as the inspector was booked to come from out of the country. Ms. O'Donnell says she was told the scheduled training would be taken into account during the inspection.

21. On May 16, 2023, Katie Busroe attended the Pharmacy to conduct a second onsite inspection. The Pharmacy continued to be in breach of numerous sections of the NAPRA Standards, having failed to rectify the majority of the deficiencies noted in 2018. Attached as Appendix "C" is Ms. Busroe's report.

22. On May 23, 2023, the College requested that the Pharmacy discontinue all sterile compounding as per the recommendation from Ms. Busroe.

23. On May 24, 2023, all standing orders for sterile compounding at the Pharmacy were transferred to other pharmacies.

24. East Coast Apothecary was one of the pharmacies that received prescription transfers. When reviewing the prescriptions received, that pharmacy identified to the College a number of errors and concerns.

25. On May 31, 2023, Ms. O'Donnell and the owner of the Pharmacy signed an Undertaking with the College that there would be no further sterile compounding at the Pharmacy until the College is satisfied that it is safe to do so.

26. The Registrar's complaint was filed on June 15, 2023.

## ADMISSIONS

27. Ms. O'Donnell admits the allegations set out in the Notice of Hearing and the facts described herein and admits that her actions constitute professional misconduct, as set out in the *Pharmacy Act*.

### AGGRAVATING FACTORS

28. In reaching this Settlement Agreement, the College has taken into consideration the following aggravating factors:

- a) Ms. O'Donnell did not demonstrate insight into the importance of making the corrections identified in Ms. Busroe's reports for the sake of public safety.
- b) Ms. O'Donnell was given ample opportunity to correct the deficiencies identified prior to the initiation of a formal complaint.

### MITIGATING FACTORS

29. In reaching this Settlement Agreement, the College has taken into consideration the following mitigating factors:

- a) Ms. O'Donnell was cooperative during the investigation into the complaint.
- b) Ms. O'Donnell has admitted professional misconduct and has agreed to enter into this Settlement Agreement in lieu of a contested hearing.

### DISPOSITION

30. The College and Ms. O'Donnell agree to the following disposition and settlement of this matter:

- a) A letter of reprimand shall be placed on the file of Ms. O'Donnell. The reprimand shall read as follows:

*You are hereby reprimanded for breaching the Pharmacy Act, the Pharmacy Practice Regulations and the Standards of Practice: General Pharmacy Practice by:*

- *Failing to comply with the National Association of Pharmacy Regulatory Authorities Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations, adopted by Council of the College effective as of February 27, 2017, and the National Association of Pharmacy Regulatory Authorities Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations, adopted by Council of the College effective as of June 30, 2016, (collectively, the "NAPRA Standards"); and*
  - *As the pharmacy manager of the Shoppers Simply Pharmacy, #3006, located at 1276 South Park Street, Halifax, failing to ensure the pharmacy was in compliance with the NAPRA Standards.*
- b) Ms. O'Donnell shall pay a fine of \$2,000 to the College within three months of the date of this Settlement Agreement.
  - c) The licence of Ms. O'Donnell to practise pharmacy in Nova Scotia shall be suspended for a period of four weeks. The four weeks must be served consecutively. The period

of suspension shall be completed within six months of the date of this Settlement Agreement.

- d) Ms. O'Donnell shall pay a portion of the College's costs for this matter to the College, fixed at the amount of \$4,000, within six months of the date of this Settlement Agreement.
- e) If Ms. O'Donnell wishes to resume the role of sterile compounding supervisor at any pharmacy at any point in the future, she must undergo two sterile compounding inspections, at her own cost. The first inspection must occur within 4-6 weeks of resuming the supervisor role. The second inspection must occur at a date to be determined by the College. If the inspections do not occur by the required dates, for any reason, or if there are deficiencies identified, Ms. O'Donnell must cease compounding immediately until the deficiencies are corrected and the inspector has confirmed compliance.
- f) Ms. O'Donnell shall compose an essay within 3 months of the date of this Settlement Agreement outlining the lessons she learned throughout this complaint process, including both ethical learnings and clinical learnings regarding proper compounding. The College will review the submitted essay with Ms. O'Donnell to determine if it is acceptable. The essay must be considered acceptable to the College before this requirement will be considered complete. The essay must be a minimum of 750 words.

#### **PUBLICATION**

- 31. The outcome of the Settlement Agreement shall be made public, in accordance with the *Registration, Licensing and Professional Accountability Regulations*, Section 71.

#### **INDEPENDENT LEGAL ADVICE**

- 32. Ms. O'Donnell acknowledges that she has consulted with independent legal counsel, or has had the opportunity to do so, prior to signing this Settlement Agreement. Ms. O'Donnell acknowledges that she has read, understands, and voluntarily consents to the terms of this Settlement Agreement.

#### **EFFECTIVE DATE**

- 33. This Settlement Agreement shall only be effective and binding when it has been recommended for acceptance by the Investigation Committee and approved by the Hearing Committee appointed to hear the matter. The date of this Settlement Agreement shall be deemed to be the date of approval by the Hearing Committee.

**DATED** at Halifax, Nova Scotia, this 27<sup>th</sup> day of may, 2024.

**CONSENTED TO:**



Nicole O'Donnell, Registrant #1939



Beverley Zwicker, CEO and Registrar, NSCP

**RECOMMENDED BY:**



Gerri Allen, Chair, Investigation Committee  
Nova Scotia College of Pharmacists

Date: May 28, 2024

**APPROVED BY:**



Harriet Davies, Chair, Hearing Committee  
Nova Scotia College of Pharmacists

Date: Aug. 7th, 2024