

IN THE MATTER OF:

CASE NO. A-2023-0345

Nashat Y. Gabrail, M.D., Inc.
c/o Nashat Y. Gabrail, M.D.
4875 Higbee Ave., N.W.
Canton, OH 44718

License No. 02-1234600

SETTLEMENT AGREEMENT WITH THE OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the Ohio Board of Pharmacy (Board) and Nashat Y. Gabrail, M.D., Inc. for the purpose of resolving all issues between the parties relating to the Board investigation of the improper storage and administration of expired lidocaine 2% to patients from February to March, 2023. Together, the Board and Nashat Y. Gabrail, M.D., Inc. are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.57 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit or refuse to grant or renew any license issued pursuant to Section 4729.54 of the Ohio Revised Code.
2. Nashat Y. Gabrail, M.D., Inc. is a licensed Terminal Distributor of Dangerous Drugs under license number 02-1234600.

FACTS

1. The Board initiated an investigation of Nashat Y. Gabrail, M.D., Inc., Terminal Distributor of Dangerous Drugs license number 02-1234600, related to Nashat Y. Gabrail, M.D., Inc.'s improper storage and administration of expired lidocaine 2% to patients from February to March 2023.
2. On or about February 22, 2024, the Board sent a Notice of Opportunity for Hearing to Nashat Y. Gabrail, M.D., Inc., which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.
3. On or about February 26, 2024, Nashat Y. Gabrail, M.D., Inc., timely requested an administrative hearing, which was subsequently scheduled for October 8, 2024. WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative proceedings.

TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

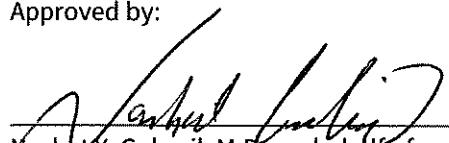
1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.
2. Nashat Y. Gabrail, M.D., Inc. neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated February 22, 2024; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.
3. Nashat Y. Gabrail, M.D., Inc. agrees to pay to the Board a monetary penalty the amount of \$500.00. This fine will be attached to your license record and must be paid no later than 180 days from the effective date of this Agreement. To pay this fine you must login to www.license.ohio.gov and process the items in your cart.
4. The Board hereby imposes a written reprimand on Nashat Y. Gabrail, M.D., Inc.'s TDDD license, number 02-1234600.
5. Nashat Y. Gabrail, M.D., Inc. agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.
6. Nashat Y. Gabrail, M.D., Inc. agrees to comply with all federal and state requirements related to Terminal Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729, and the Rules adopted thereunder, Chapter 3719, and the Rules adopted thereunder, Chapter 3715, and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by Nashat Y. Gabrail, M.D., Inc. of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to Nashat Y. Gabrail, M.D., Inc. by the Board and will NOT discharge Nashat Y. Gabrail, M.D., Inc. from any obligation under the terms of this Agreement.
7. Nashat Y. Gabrail, M.D., Inc. agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.
8. Nashat Y. Gabrail, M.D., Inc. understands that it has the right to be represented by counsel for review and execution of this agreement.

9. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom Nashat Y. Gabrail, M.D., Inc. will operate.
10. Nashat Y. Gabrail, M.D., Inc. explicitly withdraws its request for a hearing, waives its right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code, and waives any right to an appeal.
11. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.
12. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.
13. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.
14. If any of the provisions, terms, or clauses of this Agreement are declared illegal, unenforceable, or ineffective by an authority of competent jurisdiction, those provisions, terms, and clauses shall be deemed severable, such that all other provisions, terms, and clauses of this Agreement shall remain valid and binding upon both Parties.
15. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:

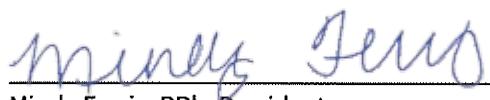


Nashat Y. Gabrail, M.D., on behalf of,
Nashat Y. Gabrail, M.D., Inc., Respondent

8.9.2024

Date of Signature

Attorney for Respondent (if applicable)



Mindy Ferris, RPh, President,
Ohio Board of Pharmacy

Date of Signature

08.13.2024

Date of Signature



**STATE OF
OHIO**
BOARD OF PHARMACY

-THIS IS A RED INK STAMP-

I certify this to be a true and exact copy of the original document on file with the Ohio State Board of Pharmacy.

Steven W. Schierholt

Steven W. Schierholt, Esq., Executive Dir.
Date: Feb 22, 2024

-MUST HAVE BOARD SEAL TO BE OFFICIAL-

**NOTICE OF OPPORTUNITY FOR HEARING
PROPOSAL TO TAKE DISCIPLINARY ACTION AGAINST LICENSEE**

IN THE MATTER OF:

CASE NO. A-2023-0345

Nashat Y. Gabrail, M.D., Inc.
c/o Nashat Y. Gabrail, M.D.
4875 Higbee Ave., N.W.
Canton, OH 44718

License No. 02-1234600

February 22, 2024

Dear Nashat Y. Gabrail, M.D., Inc. and Nashat Y. Gabrail, M.D.:

You are hereby notified, in accordance with the provisions of Section 119.07 of the Ohio Revised Code the State of Ohio Board of Pharmacy (Board) proposes to take action against your license as a Terminal Distributor of Dangerous Drugs (TDDD) under authority of Section 4729.57 of the Revised Code.

JURISDICTION

1. Pursuant to section 4729.57 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, or refuse to grant or renew any license issued pursuant to section 4729.55 of the ORC to practice as a TDDD in the state of Ohio. Additionally, Section 4729.57 of the Ohio Revised Code grants the Board the authority to impose a monetary penalty or forfeiture not to exceed in severity any fine designated under the Revised Code for a similar offense or \$1,000 if the acts committed have not been classified as an offense by the ORC.
2. Nashat Y. Gabrail, M.D., Inc., located at 4875 Higbee Ave., N.W., Canton, OH 44718, has an active TDDD license with the Board under license number 02-1234600, which lists Nashat Y. Gabrail, M.D., as the Responsible Person.

ALLEGATIONS

1. From on or about February 2, 2023, through on or about March 6, 2023, Nashat Y. Gabrail, M.D., Inc. (TDDD 02-1234600), located at 4875 Higbee Ave., N.W., Canton, Ohio, failed to store expired lidocaine 2% in a separate and secure area apart from the storage of drugs used for administration and eleven doses of expired lidocaine 2% were administered to nine patients.

77 South High Street, 17th Floor, Columbus, Ohio 43215

T: (614) 466.4143 | F: (614) 752.4836 | contact@pharmacy.ohio.gov | www.pharmacy.ohio.gov



POTENTIAL VIOLATIONS OF LAW

1. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following divisions of Rule 4729:5-2-01, as effective April 25, 2022, Responsible person – terminal distributor, each violation punishable by a maximum penalty of \$1,000:
 - a. The responsible person to whom the terminal distributor of dangerous drugs license has been issued and all licensed health professionals on duty are responsible for compliance with all state and federal laws, regulations, and rules governing the distribution of dangerous drugs, OAC Rule 4729:5-2-01(E)(4); and/or
 - b. The responsible person shall be responsible for ensuring the terminal distributor of dangerous drugs requirements are met, including, but not limited to, the supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs and maintaining all drug records otherwise required, OAC Rule 4729:5-2-01(E)(6).
2. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following divisions of Rule 4729:5-19-03, as effective February 4, 2021, Security, control and storage of dangerous drugs, each violation punishable by a maximum penalty of \$1,000:
 - a. The security and control of dangerous drugs is the responsibility of the responsible person on the terminal distributor of dangerous drugs license and the terminal distributor of dangerous drugs, OAC Rule 4729:5-19-03(A); and/or
 - b. Adulterated drugs, including expired drugs, shall be stored in accordance with rule 4729:5-3-06 of the Administrative Code, OAC Rule 4729:5-19-03(M).
3. Such conduct as set forth in the Allegations section, if proven, constitutes a violation of the following sections of Rule 4729:5-3-06 of the OAC, as effective March 1, 2019, Storage of adulterated drugs - To prevent their use, adulterated drugs, as defined in agency 4729 of the Administrative Code, shall be stored in a separate and secure area apart from the storage of drugs used for dispensing, personally furnishing, compounding and administration, each violation punishable by a maximum penalty of \$1,000.
4. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of section 3715.52(A)(2) of the ORC, the adulteration or misbranding of any food, drug, device, or cosmetic, a misdemeanor of the fourth degree, punishable by a maximum penalty of \$2,000 if committed by an organization.
5. Such conduct as set forth in Allegations Section, if proven, constitutes a violation of the following division of Section 4729.55 of the ORC, as effective March 31, 2021, TDDD license requirements, each violation punishable by a maximum penalty of \$1,000:
 - a. A pharmacist, licensed health professional authorized to prescribe drugs, animal shelter licensed with the state board of pharmacy under section 4729.531 of the Revised Code, or a laboratory as defined in section 3719.01 of the Revised Code will maintain supervision and control over the

possession and custody of dangerous drugs that may be acquired by or on behalf of the applicant, ORC 4729.55(B).

6. Such conduct as set forth in Allegations Section, if proven, constitutes a violation of each of the following divisions of Section 4729.57(B) of the ORC, as effective September 29, 2017, each violation punishable by a maximum penalty of \$1,000:

- a. Violating any rule of the board, ORC Section 4729.57(B)(2); and/or
- b. Violating any provision of this chapter, ORC Section 4729.57(B)(3); and/or
- c. Except as provided in section 4729.89 of the Revised Code, violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, or Chapter 3715. of the Revised Code, ORC Section 4729.57(B)(4); and/or
- d. Ceasing to satisfy the qualifications of a terminal distributor of dangerous drugs set forth in section 4729.55 of the Revised Code, ORC Section 4729.57(B)(7); and/or
- e. Any other cause for which the board may impose discipline as set forth in rules adopted under section 4729.26 of the Revised Code, ORC Section 4729.57(B)(10).

7. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-4-01 of the OAC, as effective April 25, 2022, each violation punishable by a maximum penalty of \$1,000:

- a. Violating any rule of the board, OAC Rule 4729:5-4-01(B)(2); and/or
- b. Violating any provision of Chapter 4729. of the Revised Code, OAC Rule 4729:5-4-01(B)(3); and/or
- c. Except as provided in section 4729.89 of the Revised Code, violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, or Chapter 3715. of the Revised Code, OAC Rule 4729:5-4-01(B)(4); and/or
- d. Ceasing to satisfy the qualifications of a terminal distributor of dangerous drugs set forth in section 4729.55 of the Revised Code, OAC Rule 4729:5-4-01(B)(7); and/or
- e. The method used by the terminal distributor to store, possess or distribute dangerous drugs poses serious harm to others, OAC Rule 4729:5-4-01(B)(23).

YOU ARE FURTHER NOTIFIED, in accordance with the provisions of Chapters 119. and 4729. of the Ohio Revised Code, that you are entitled to a hearing before the State of Ohio Board of Pharmacy, if you request such a hearing within thirty (30) days of the date of the service of this notice.

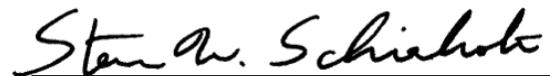
IF YOU DESIRE A HEARING, such request shall either be mailed to the State of Ohio Board of Pharmacy, Attn: Legal, 77 South High Street, 17th Floor, Columbus, Ohio 43215-6126 or an e-mail request may be sent to legal@pharmacy.ohio.gov (please note faxes will not be accepted). **YOUR REQUEST MUST BE RECEIVED ON OR PRIOR TO THE 30TH DAY FOLLOWING THE SERVICE DATE OF THIS NOTICE.** Please note that if you submit a request via email, your request will be acknowledged within one business day of receipt. If you do not receive an

acknowledgment, please contact the Board offices at 614-466-4143 and request the legal department. You may appear at such hearing in person, by your attorney, or by such other representative as is permitted to practice before the agency, or you may present your position, arguments or contentions in writing; and, at this hearing, you may also present evidence and examine any witnesses appearing for and against you. **If you are a business entity, including but not limited to a corporation, limited liability company, or a limited partnership, you must be represented at the hearing by an attorney licensed to practice in the state of Ohio.**

YOU ARE FURTHER ADVISED that if there is no request for such a hearing received by the Board on or prior to the 30th day following the service of this notice, the State of Board of Pharmacy, upon consideration of the aforementioned allegations against you, may take action without such a hearing, and may adopt a final order that contains the board's findings. In the final order, the board may impose any of the sanctions listed in division RC 4729.57(A).

If you have questions regarding the Chapter 119. Administrative Hearing process, please e-mail your questions to legal@pharmacy.ohio.gov or call the Board office at 614-466-4143 and ask for the legal department.

BY ORDER OF THE STATE BOARD OF PHARMACY



Steven W. Schierholt, Esq., Executive Director

SWS/zas/kll

Encl: Patient Identifier Key