



IN THE MATTER OF:

CASE NO. A-2023-0091

Premier Pharmacy
c/o Joel Gause, RPh
PO Box 78
Berlin, Ohio 44610

License No. 02-2886200

SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and Premier Pharmacy for the purpose of resolving all issues between the parties relating to the Board investigation of administration of Covid-19 vaccinations. Together, the Board and Premier Pharmacy 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. Premier Pharmacy is a licensed Terminal Distributor of Dangerous Drugs under license number 02-2886200.

FACTS

1. The Board initiated an investigation of Premier Pharmacy, Terminal Distributor of Dangerous Drugs license number 02-2886200, related to Premier Pharmacy's administration of Covid-19 vaccinations.
2. On or about June 13, 2023, the Board sent a Notice of Opportunity for Hearing to Premier Pharmacy, 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 June 28, 2023, Premier Pharmacy timely requested an administrative hearing. This matter was settled via this Agreement prior to hearing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative proceedings.

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



TERMS

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

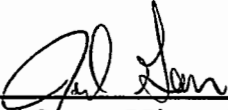
- 1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.**
- 2. Premier Pharmacy neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated June 13, 2023; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.**
- 3. Premier Pharmacy 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.elicense.ohio.gov and process the items in your cart.**
- 4. The Board hereby imposes a written reprimand on Premier Pharmacy' TDDD license, number 02-2886200.**
- 5. Premier Pharmacy 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. Premier Pharmacy 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 Premier Pharmacy 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 Premier Pharmacy by the Board and will NOT discharge Premier Pharmacy from any obligation under the terms of this Agreement.**
- 7. Premier Pharmacy agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.**
- 8. Premier Pharmacy 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 Premier Pharmacy will operate.
10. Premier Pharmacy 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:



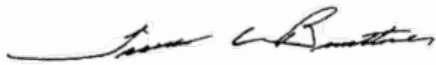
Joel Gause, RPh, on behalf of,
Premier Pharmacy, Respondent

July 13, 2023

Date of Signature

Attorney for Respondent (if applicable)

Date of Signature



Trina Buettner, RPh, President,
State of Ohio Board of Pharmacy

07.25.2023

Date of Signature



**STATE OF
OHIO**
BOARD OF PHARMACY



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

IN THE MATTER OF:

CASE NO. A-2023-0091

Premier Pharmacy
c/o Joel Gause, RPh
PO Box 78
Berlin, Ohio 44610

License No. 02-2886200

June 13, 2023

Dear Premier Pharmacy and Mr. Joel Gause:

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 under authority of Section (TDDD) 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, reprimand, or refuse to grant or renew any license issued pursuant to Section 4729.55 of the Ohio Revised Code to practice as a TDDD in the state of Ohio. Additionally, Section 4729.57 of the 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 Revised Code.
2. Premier Pharmacy, located at 4925 West Main Street, Berlin, Ohio, has an active TDDD license with the Board under license number 02-2886200, which lists Joel Gause, RPh as the Responsible Person.

ALLEGATIONS

1. On or about October 11, 2022, Joel Gause, Responsible Person at Premier Pharmacy, located at 4925 West Main Street, Berlin, Ohio, self-reported to the Board that 78 patients received sub-therapeutic doses of Moderna bivalent Covid-19 vaccine on four dates between September 13, 2022 and October 4, 2022. The patients received 0.25mL of the vaccine instead of 0.5mL as instructed by the bivalent vaccine labeling.
 - a. Mr. Gause reported that he incorrectly vaccinated six patients, and two of his pharmacy technicians incorrectly vaccinated 72 patients.

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- b. Mr. Gause was the pharmacist of record for all 78 patients who were incorrectly vaccinated.
 - c. Mr. Gause contacted the patients, and 60 patients were revaccinated with the full dose of Moderna bivalent Covid-19 vaccine as directed by the Ohio Department of Health (ODH). Eighteen of the patients refused to be revaccinated.
2. On or about February 6, 2023, Joel Gause, RPh was interviewed by an agent of the Board. He admitted:
- a. The patients had appointments and the vaccine doses were all drawn up by either Layla Gause, Registered Pharmacy Technician/RN, or by himself the morning of the vaccinations. He checked all the syringes.
 - b. He was later told by the health department it was inappropriate to draw up all the doses at the beginning of the day, so this practice stopped. The current process is to draw up each dose of vaccine as the patient arrives within the regular workflow.
 - c. He was unaware the dose of the bivalent booster changed from 0.25mL (like the original booster) to 0.5mL. When this was discovered, he self-reported the mistake to the Board and ODH.
 - d. He contacted every patient to explain the error and notify them the Centers for Disease Control and Prevention and ODH recommendation is to revaccinate. Most of the patients were revaccinated.
 - e. The pharmacy updated its policies and procedures to prevent similar instances happening in the future.

POTENTIAL VIOLATIONS OF LAW

1. Such conduct as set forth in the Allegations Section, if proven, also constitutes a violation of Rule 4729:5-5-08(A)(5) of the OAC, as effective December 1, 2020, Incorrect drug dosage, punishable by a maximum penalty of \$1,000.
2. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Rule 4729:1-3-02(C) of the OAC as effective December 1, 2020, each violation punishable by a maximum penalty of \$1,000: Failure to adhere to the standard of care for administration of an immunization shall be considered a violation of this rule and may subject a pharmacist to discipline in accordance with rule 4729:1-4-01 of the Administrative Code.
3. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Rule 4729:5-2-01(A) of the OAC as effective April 25, 2022, each violation punishable by a maximum penalty of \$1,000:
 - a. The responsible person shall be responsible for the practice of the profession of pharmacy, 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(A)(2); and/or
 - b. The person to whom the terminal distributor of dangerous drugs license has been issued and all pharmacists on duty are responsible for compliance with all state and federal laws, regulations,

and rules governing the distribution of drugs and the practice of pharmacy, OAC Rule 4729:5-2-01(A)(3).

4. Such conduct as set forth the Allegations Section, if proven, constitutes a violation of section 4729.55(D) of the ORC, as effective March 31, 2021, adequate safeguards are assured to carry on the business of a TDDD in a manner that allows pharmacists and pharmacy interns employed by the terminal distributor to practice pharmacy in a safe and effective manner punishable by a maximum penalty of \$1,000.
5. 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. Ceasing to satisfy the qualifications of a TDDD set forth in section 4729.55 of the Revised Code, ORC Section 4729.57(B)(7); and/or
 - d. 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).
6. 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. 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).

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 mailing 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 MAILING 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 mailing of this notice, the State of Ohio 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

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