



**STATE OF
OHIO**
BOARD OF PHARMACY

IN THE MATTER OF:

Case No. A-2021-0085

Clark LowCost Pharmacy
c/o Adam Abukater, RPh
3107 Clark Avenue
Cleveland, OH 44109

License No. 02-2004150

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 Clark LowCost Pharmacy for the purpose of resolving all issues between the parties relating to the Board investigation of improper storage of COVID-19 vaccines. Together, the Board and Clark LowCost 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. Clark LowCost Pharmacy is a licensed Terminal Distributor of Dangerous Drugs under license number 02-2004150.

FACTS

1. The Board initiated an investigation of Clark LowCost Pharmacy, Terminal Distributor of Dangerous Drugs license number 02-2004150, related to Clark LowCost Pharmacy's improper storage of COVID-19 vaccines.
2. On or about December 10, 2021, the Board sent a Notice of Opportunity for Hearing to Clark LowCost 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 December 15, 2021, Clark LowCost Pharmacy, through counsel, timely requested an administrative hearing, which was subsequently scheduled for June 6, 2022.

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WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial 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. Clark LowCost Pharmacy neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated December 10, 2021; 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. Clark LowCost Pharmacy agrees to pay to the Board a monetary penalty the amount of \$1,000.00. This fine will be attached to the license record and must be paid no later than 180 days from the effective date of this Agreement. To pay this fine, login to www.elicense.ohio.gov and process the items in the cart.
4. The Board hereby imposes a written reprimand on Clark LowCost Pharmacy's TDDD license, number 02-2004150.
5. Clark LowCost 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. Clark LowCost 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 Clark LowCost 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 Clark LowCost Pharmacy by the Board and will NOT discharge Clark LowCost Pharmacy from any obligation under the terms of this Agreement.
7. Clark LowCost 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. Clark LowCost 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 Clark LowCost Pharmacy will operate.
10. Clark LowCost 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:



Adam Abukater, RPh, on behalf of,
Clark LowCost Pharmacy, Respondent

4-6-2022

Date of Signature



Brandon Smith
Attorney for Respondent

7 Apr. 2022

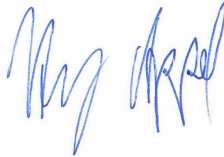
Date of Signature



Rich Miller, RPh, President,
State of Ohio Board of Pharmacy

04.14.2022

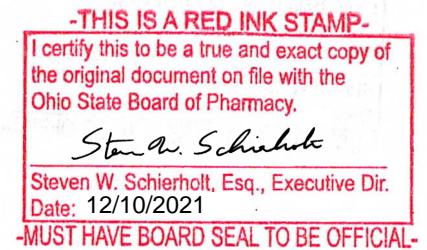
Date of Signature



Henry Appel, Ohio Assistant Attorney General

04.14.2022

Date of Signature



**NOTICE OF OPPORTUNITY FOR HEARING
PROPOSAL TO TAKE DISCIPLINARY ACTION AGAINST
TERMINAL DISTRIBUTOR OF DANGEROUS DRUGS LICENSEE**

IN THE MATTER OF:

Case No. A-2021-0085

Clark LowCost Pharmacy
c/o Adam Abukater, RPh
3107 Clark Avenue
Cleveland, OH 44109

License No. 02-2004150

December 10, 2021

Dear Clark LowCost Pharmacy and Adam Abukater, RPh:

You are hereby notified, in accordance with the provisions of Ohio Revised Code 119.07, 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 R.C. 4729.57.

JURISDICTION

1. Pursuant to R.C. 4729.57 and the rules adopted thereunder, the Board has the authority to suspend, revoke, or refuse to grant or renew any license issued R.C. 4729.55 to practice as a TDDD in the state of Ohio. Additionally, R.C. 4729.57 grants the Board the authority to impose a monetary penalty or forfeiture not to exceed in severity any fine designated under the Ohio Revised Code for a similar offense or \$1,000 if the acts committed have not been classified as an offense by the Ohio Revised Code.
2. Clark LowCost Pharmacy has an active TDDD license with the Board under license number 02-2004150, which presently lists Adam Abukater, RPh, as the Responsible Person.

ALLEGATIONS

1. On or about January 27, 2021, during a Board-inspection, Board agents discovered that Clark LowCost Pharmacy was administering COVID-19 vaccines. At that time, Clark LowCost Pharmacy had received at least 2 shipments of the Moderna COVID-19 vaccine, each shipped in a cold-pack/freezer carton containing 10 multi-dose vials. Upon receipt, the vaccines were stored in a refrigerator in the pharmacy, along with various other dangerous drugs. A thermometer was hanging inside the refrigerator and displayed a temperature of 49 degrees Fahrenheit, outside the acceptable range for a refrigerated vaccine. The thermometer did not have a minimum/maximum range, did not have memory capabilities, alarms, or the ability to track out of range temperatures. Further, although Responsible Person Adam Abukater, RPh, stated that the pharmacy was conducting temperature checks each day, the pharmacy's temperature log had not been updated since May 2020. As a result, the COVID-19 vaccines on-hand at

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the pharmacy that day were subsequently deemed not for use in patients because their proper storage could not be confirmed.

POTENTIAL VIOLATIONS OF LAW

1. Such conduct, as set forth in the Allegations Section, if proven, constitute violations of Ohio Adm.Code 4729:5-5-02(E)(2) (effective December 1, 2020), All areas where drugs and devices are stored and prepared shall be dry, well-lit, well-ventilated, and maintained in a clean, sanitary and orderly condition. Storage areas shall be maintained at temperatures and conditions which will ensure the integrity of the drugs prior to their dispensing or administering as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling, each violation punishable by a maximum penalty of \$1,000.
2. Such conduct, as set forth in the Allegations Section, if proven, constitute violations of Ohio Adm.Code 4729:5-5-23(B) (effective December 1, 2020), Prescription Processes, each violation punishable by a maximum penalty of \$1,000:
 - a. Refrigerators and freezers used for the storage of dangerous drugs shall. . . maintain either of the following to ensure proper refrigeration and/or freezer temperatures are maintained:
 - i. Temperature logs with, at a minimum, daily observations, Ohio Adm.Code 4729:5-5-23(B)(1)(a); and/or
 - ii. A temperature monitoring system capable of detecting and alerting staff of a temperature excursion, Ohio Adm.Code 4729:5-5-23(B)(1)(b); and/or
 - b. The terminal distributor shall develop and implement policies and procedures to respond to any out-of-range individual temperature readings or excursions to ensure the integrity of stored drugs, Ohio Adm.Code 4729:5-5-23(B)(2).
3. Such conduct, as set forth in the Allegations Section, if proven, constitutes a violation of each of the following paragraphs of R.C. 4729.55, TDDD License Requirements (effective March 22, 2020), each violation punishable by a maximum penalty of \$1,000:
 - a. The applicant is equipped as to land, buildings, and equipment to properly carry on the business of a terminal distributor of dangerous drugs within the category of licensure approved by the Board, R.C. 4729.55(A); and/or
 - b. A pharmacist, licensed health professional authorized to prescribe drugs, other person authorized by the Board, animal shelter licensed under R.C. 4729.531, or laboratory will maintain supervision and control over the possession and custody of dangerous drugs and controlled substances that may be acquired by or on behalf of the applicant, R.C. 4729.55(B); and/or
 - c. Adequate safeguards are assured that the applicant will carry on the business of a TDDD in a manner that allows pharmacists and pharmacy interns employed by the TDDD to practice pharmacy in a safe and effective manner, R.C. 4729.55(D); and/or

4. Such conduct, as set forth in Allegations Section, if proven, constitutes a violation of each of the following paragraphs of R.C. 4729.57 (effective September 29, 2017), each violation punishable by a maximum penalty of \$1,000:
 - a. Violating any rule of the Board, R.C. 4729.57(A)(2); and/or
 - b. Violating any provision of this chapter, R.C. 4729.57(A)(3); and/or
 - c. Ceasing to satisfy the qualifications of a TDDD set forth in R.C. 4729.55, R.C. 4729.57(A)(7); and/or
 - d. Any other cause for which the Board may impose discipline as set forth in rules adopted under R.C. 4729.26 , R.C. 4729.57(A)(10).
5. Such conduct, as set forth in Allegations Section, if proven, each constitutes a violation of the following paragraphs of Ohio Adm.Code 4729:5-4-01 (effective March 1, 2019), each violation punishable by a maximum penalty of \$1,000 if committed by an organization:
 - a. Violating any rule of the Board, Ohio Adm.Code 4729:5-4-01(B)(2); and/or
 - b. Violating any provision of R.C. Chapter 4729., Ohio Adm.Code 4729:5-4-01(B)(3); and/or
 - c. Ceasing to satisfy the qualifications of a TDDD set forth in R.C. 4729.55, Ohio Adm.Code 4729:5-4-01(B)(7); and/or
 - d. The method used by the terminal distributor to store, possess or distribute dangerous drugs poses serious harm to others, Ohio Adm.Code 4729:5-4-01(B)(25).

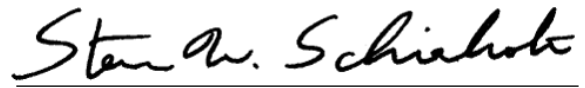
YOU ARE FURTHER NOTIFIED, in accordance with the provisions of Chapters 119. and 4729. of the Ohio Revised Code, that you are entitled to a hearing before the State of Ohio Board of Pharmacy, if you request such a hearing within thirty 30 days of the date of the mailing of this notice.

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.** 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 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.

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

A handwritten signature in black ink, reading "Steven W. Schierholt". The signature is fluid and cursive, with the first name "Steven" and last name "Schierholt" clearly legible. The middle initial "W." is smaller and less distinct.

Steven W. Schierholt, Esq., Executive Director

SWS/mls/kl

CMRRR: 9414 7118 9956 1357 3902 66