



IN THE MATTER OF:

Case No. A-2019-0193
I-2018-2645-B

Shady Arafa, RPh
4945 Lakota Woods Dr.
Liberty Twp., OH 45044

License No. 03-131648

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 Shady Arafa for the purpose of resolving all issues between the parties relating to the Board's inspection conducted at a pharmacy previously owned by Arafa and at which he served as a staff pharmacist. Together, the Board and Shady Arafa are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to R.C. 4729.16 and the rules adopted thereunder, the Board has the authority to suspend, revoke, or refuse to grant or renew any license issued pursuant to R.C. 4729.16 to practice pharmacy in the State of Ohio.
2. Shady Arafa is a licensed pharmacist in the State of Ohio under license number 03-131648.

FACTS

1. The Board initiated an investigation of Shady Arafa, pharmacist license number 03-131648, related to an inspection conducted at a pharmacy previously owned by Arafa and at which he served as a staff pharmacist.
2. On or about September 18, 2020, the Board sent a Notice of Opportunity for Hearing to Shady Arafa, which outlined the allegations and provided notice of his right to a hearing, his rights in such hearing, and his right to submit contentions in writing.

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. Shady Arafa neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated September 18, 2020; 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. Shady Arafa agrees to pay to the Board the amount of amount of \$1,000.00. This fine will be attached to the license record and must be paid no later than 30 days from the effective date of this Agreement. To pay this fine, login to www.license.ohio.gov and process the items in the cart.
4. Shady Arafa must obtain, within six months from the effective date of this Agreement, six hours of approved continuing pharmacy education (0.6 CEUs), which may not also be used for license renewal. One hour (0.1 CEU) must be the Responsible Person Roundtable. Copies of completed CEUs must be e-mailed to legal@pharmacy.ohio.gov.
5. Shady Arafa agrees that, should he ever resume holding a position of executive decision-making authority at a facility licensed by the Board (E.g., as an owner, operator, or RP at a Terminal Distributor of Dangerous Drugs or other Board-licensed facility) and as determined by the Board, he must, within three months after assuming such role, engage an independent third party to review the facility's policies and procedures for compliance with all relevant state and federal law and provide a written report of such review to the Board.
6. Shady Arafa understands that he has the right to be represented by counsel for review and execution of this agreement.
7. Shady Arafa agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction in which he currently holds a professional license, including to the Board on renewal applications or applications for a new license.
8. Shady Arafa waives an opportunity to be heard pursuant to R.C. Chapter 119. and waives any right to an appeal.
9. 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.
10. All parties to this Agreement understand that this document is a public record pursuant to R.C. 149.43.
11. 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.
12. This Agreement shall become effective upon the date of the Board President's signature below.

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:


Shady Arafa, Respondent


Levi Tkach, Attorney for Respondent


Jennifer Rudell, RPh, President,
State of Ohio Board of Pharmacy


Henry Appel, Ohio Assistant Attorney General

1/14/21

Date of Signature

1/14/21

Date of Signature

02.02.2021

Date of Signature

02.02.2021

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: 09/18/2020

-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-2019-0193
I-2018-2645-B

Shady Arafa, RPh
4945 Lakota Woods Dr.
Liberty, Twp., OH 45044

License No. 03-131648

September 18, 2020

Dear Mr. Arafa:

You are hereby notified, in accordance with the provisions of Ohio Revised Code ("ORC") 119.07, the State of Ohio Board of Pharmacy ("Board") proposes to take action against your license for violations of ORC Chapter 4729. and Ohio Administrative Code ("OAC") 4729 under authority of ORC 4729.16.

JURISDICTION

1. Pursuant to ORC 4729.16(A)(1) (effective April 6, 2017), the Board may impose any one or more of the following sanctions on a pharmacist or pharmacy intern if the Board finds the individual engaged in any of the conduct set forth in division (A)(2) of this section:
 - a. Revoke, suspend, restrict, limit, or refuse to grant or renew a license, ORC 4729.16(A)(1)(a); and/or
 - b. Reprimand or place the license holder on probation, ORC 4729.16(A)(1)(b); and/or
 - c. Impose a monetary penalty or forfeiture not to exceed in severity any penalty designated under the Revised Code for a similar offense or in the case of a violation of a section of the Revised Code that does not bear a penalty, impose a monetary penalty or forfeiture of not more than \$500, ORC 4729.16(A)(1)(c).
2. OAC 4729:1-4-01 provides that the Board may discipline or deny the issuance of a certificate of registration or an identification card to practice pharmacy as a pharmacist in Ohio.
3. Shady Arafa is a licensed pharmacist in the state of Ohio under license number 03-131648.

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



ALLEGATIONS

1. On or about March 6, 2019, you were a staff pharmacist at Econo Pharmacy located at 11534 Springfield Pike Springdale, Ohio 45246. Board staff conducted an inspection which discovered the following violations related to the practice of pharmacy:
 - a. The following violations related to positive identification were discovered:
 - i. You were not dating original prescriptions.
 - ii. You were using a signature stamp instead of a wet-ink signature on original prescriptions.
 - iii. You were signing the backtag, not the actual prescription.
 - iv. You were not signing and dating hard copy prescriptions to capture positive identification for drug utilization review ("DUR").
 - v. You were not signing and dating prescriptions appropriately to capture positive ID for dispensing.
 - b. Econo Pharmacy had one refrigerator and one freezer, each without a thermometer or temperature log.
 - c. The following violations related to improper dispensing were discovered:
 - i. You admitted to Board staff that you were not checking the Ohio Automated Rx Reporting System ("OARRS") for patients who presented prescriptions for controlled substances "like you should."
 - ii. Prescriptions were dispensed without proper DUR being completed.
 - iii. Prescriptions were dispensed in a one-time quantity greater than the physician directions indicated.
 - d. The following violations related to drug stock bottles containing more tablets than the package indicates were discovered:
 - i. Paroxetine 40mg 100 tablet bottles contained 110 tablets.
 - ii. Propranolol 40 mg 100 tablet bottle contained 107 tablets.
 - e. Expired medications were discovered within Econo Pharmacy's active drug stock, including Humulin 70/30 KwikPen, with an expiration date of 2/2018, found in the refrigerated drug stock.
 - f. The following violations related to improper record keeping for non-sterile compounded drugs were discovered:
 - i. Compounded drug labels did not have a beyond use date.

- ii. Compounding records did not indicate any specific beyond use date for any compounded product.
 - g. Compounded products did not have proper labels. Board staff observed 3 syringes of methimazole P-O compounded gel in the refrigerator with no labels. Records indicated that this product was compounded and expired in 2015. Labels for all compounded products did not contain the phrasing "compounded drug product."
- h. The following compounding components were expired but present in active stock:
 - i. Metronidazole powder, expired 9/2018
 - ii. Baclofen powder, expired 7/2018
 - iii. Beef flavor powder, expired 2/2018
 - iv. Tuna flavor powder, expired 7/2018
- i. Econo Pharmacy could not produce a controlled substance inventory for the pharmacy for 2017 or 2018.

POTENTIAL VIOLATIONS OF LAW

- 1. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of ORC 4729.08(B), not of good moral character, punishable by a maximum penalty of \$500.
- 2. Such conduct, as set forth in the Allegations Section, if proven, constitutes a violation of ORC 4729.16(A) (as effective September 29, 2017), each violation constituting a minor misdemeanor, each punishable by a maximum penalty of \$150:
 - a. Engaged in dishonesty or unprofessional conduct in the practice of pharmacy, ORC 4729.16(A)(2)(b); and/or
 - b. Violated, conspired to violate, attempted to violate, or aided and abetted the violation of any of the provisions of this chapter, ORC 3715.75 to 3715.72, ORC Chapters 2925. or 3719., or any rule adopted by the Board under those provisions, ORC 4729.16(A)(2)(e); and/or
 - c. Engaged in any conduct for which the Board may impose discipline as set forth in rules adopted under ORC 4729.26, ORC 4729.16(A)(2)(l).
- 3. Such conduct, as set forth in the Allegations Section, if proven, each constitutes the following violations of OAC 4729:1-4-01(B)(2) (as effective May 1, 2018), each violation punishable by a maximum penalty of \$500:
 - a. Engaged in dishonesty or unprofessional conduct in the practice of pharmacy, OAC 4729:1-4-01(B)(2)(b); and/or

- b. Violated, conspired to violate, attempted to violate, or aided and abetted the violation of any of the provisions of ORC Chapter 4729., ORC 3715.52 to 3715.72, ORC Chapters 2925., 3796., 3719. or 4752., or any rule adopted by the Board under those provisions, OAC 4729:1-4-01(B)(2)(e); and/or
 - c. Violated any state or federal law, regulation or rule regardless of the jurisdiction in which the acts were committed, except for minor traffic violations..., OAC 4729:1-4-01(B)(2)(m); and/or
 - d. Failed to conform to prevailing standards of care of similar pharmacists under the same or similar circumstances, whether or not actual injury to a patient is established, OAC 4729:1-4-01(B)(2).
- 4. Such conduct, as set forth in paragraphs (1)(d), (1)(e), (1)(f), (1)(g), and/or (1)(h) of the Allegations Section, if proven, constitutes a violation of ORC 3715.52(A)(2), the adulteration or misbranding of any food, drug, devise or cosmetic, constituting a misdemeanor of the fourth degree, punishable by a maximum fine of \$250.
- 5. Such conduct, as set forth in paragraphs (1)(f) and/or (1)(g) of the Allegation Section, if proven, constitutes a violation of ORC 3715.64(A)(1), misbranded drug – its labeling is false or misleading in any particular, a misdemeanor of the fourth degree, punishable by a maximum fine of \$250.
- 6. Such conduct, as set forth in paragraph (1)(d) of the Allegation Section, if proven, constitutes a violation of ORC 3715.64(A)(2), misbranded drug – its labeling does not contain an accurate statement of the quantity of the contents..., a misdemeanor of the fourth degree, punishable by a maximum fine of \$250.
- 7. Such conduct, as set forth in paragraphs (1)(f) and/or (1)(g) of the Allegation Section, if proven, constitutes a violation of ORC 3715.64(A)(10)(a), misbranding – it is a drug and its container is so made, formed, or filled as to be misleading, a misdemeanor of the fourth degree, punishable by a maximum fine of \$250.
- 8. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following paragraphs of OAC 4729-5-11 (as effective February 17, 2017), each violation punishable by a maximum penalty of \$500:
 - a. Failure of the person to whom the TDDD license has been issued and all pharmacists on duty to be responsible for compliance with all state and federal laws, regulations, and rules regulating the distribution of drugs and the practice of pharmacy, OAC 4729-5-11(A)(3).
- 9. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following OAC 4729:5-2-01(A) (as effective March 1, 2019), each violation punishable by a maximum penalty of \$500:
 - a. 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 4729:5-2-01(A)(3).
- 10. Such conduct, as set forth in the Allegations Section, if proven, constitutes a violation of the following paragraphs of OAC 4729-5-20(D), punishable by a maximum penalty of \$500: Prior to dispensing an outpatient prescription for a reported drug as listed in OAC 4729-37-02, at a minimum, a pharmacist shall request and review an OARRS report covering at least a one year time period, including a border state's

information when the pharmacist is practicing in a county bordering another state if that state's information is available, in any of the following circumstances:

- a. A patient adds a different or new reported drug to their therapy that was not previously included, OAC 4729-5-20(D)(1); and/or
- b. An OARRS report has not been reviewed for that patient during the preceding twelve months, as indicated in the patient profile, OAC 4729-5-20(D)(2); and/or
- c. A prescriber is located outside the usual pharmacy geographic area, OAC 4729-5-20(D)(3); and/or
- d. A patient is from outside the usual pharmacy geographic area, OAC 4729-5-20(D)(4); and/or
- e. A pharmacist has reason to believe the patient has received prescriptions for reported drugs from more than one prescriber in the preceding three months, unless the prescriptions are from prescribers who practice at the same physical location, OAC 4729-5-20(D)(5); and/or
- f. Patient is exhibiting signs of potential abuse or diversion. This includes, but is not limited to, over-utilization, early refills, appears overly sedated or intoxicated upon presenting a prescription for a reported drug, or an unfamiliar patient requesting a reported drug by specific name, street name, color, or identifying marks, OAC 4729-5-20(D)(6).

11. Such conduct, as set forth in paragraphs (1)(a)(iv) and/or (1)(c) of the Allegations Section, if proven, constitutes a violation of OAC 4729-5-20(G), Prospective drug utilization review, each violation punishable by a maximum penalty of \$500.
12. Such conduct, as set forth in paragraph (1)(a) of the Allegations Section, if proven, constitutes a violation of OAC 4729-5-21(C)(2), Manner of issuance of a prescription, punishable by a maximum penalty of \$500.
13. Such conduct as set forth in paragraph (1)(a) of the Allegations Section, if proven, constitutes a violation of the following paragraphs of OAC 4729-5-27(A), Record Keeping, each violation punishable by a maximum penalty of \$500: There must be positive identification of the pharmacist or pharmacists responsible for performing all activities relating to the practice of pharmacy including, but not limited to:
 - a. Prescription information entered into the record keeping system, OAC 4729-5-27(A)(1); and/or
 - b. Prospective drug utilization review, OAC 4729-5-27(A)(2); and/or
 - c. Dispensing, OAC 4729-5-27(A)(3).
14. Such conduct as set forth in paragraph (1)(b) of the Allegations Section, if proven, constitutes a violation of OAC 4729-9-11(D), Security and Control of Dangerous Drugs, each violation punishable by a maximum penalty of \$500.
15. Such conduct, as set forth in paragraph (1)(i) of the Allegations Section, if proven, constitutes the following violations of OAC 4729-9-14(A), punishable by a maximum penalty of \$500: Each prescriber or terminal distributor of dangerous drugs shall keep a record of all controlled substances received, administered, personally furnished, dispensed, sold, destroyed, or used. The acts of prescribing, administering,

dispensing, and destroying of a controlled substance must be documented with the positive identification of the responsible individual pursuant to OAC 4729-5-01(N). These records may be kept electronically if the method is approved by the Board and the records are backed-up each business day.

- a. Records of receipt shall contain a description of all controlled substances received, the kind and quantity of controlled substances received, the name and address of the persons from whom received, and the date of receipt, OAC 4729-9-14(A)(1); and/or
- b. Records of administering, dispensing, personally furnishing or using controlled substances shall contain a description of the kind and quantity of the controlled substance administered, dispensed, personally furnished or used, the date, the name and address of the person to whom or for whose use, or the owner and identification of the animal for which, the controlled substance was administered, dispensed, or used, OAC 4729-9-14(A)(2).

16. Such conduct as set forth in paragraphs (1)(f), (1)(g), and/or (1)(h) of the Allegations Section, if proven, constitutes a violation of OAC 4729-16-03(A), Drugs compounded in the pharmacy, for all non-sterile compounded drug products, the pharmacy shall comply with the United States pharmacopeia chapter <795>, USP 38-NF 33, or any official supplement thereto, each violation is punishable by a maximum penalty of \$500.

17. Such conduct as set forth in paragraphs (1)(f), (1)(g), and/or (1)(h) of the Allegations Section, if proven, constitutes a violation of the following paragraphs of OAC 4729-16-03(O), Drugs compounded in the pharmacy, labels for a compounded drug product that is prepared in anticipation of a prescription drug order shall contain, but not be limited to, the following, each violation is punishable by a maximum penalty of \$500:

- a. The name, strength, and quantity of each drug used in the compounded drug product, OAC 4729-16-03(O)(1); and/or
- b. The identification of the repackager by name, by the final seven digits of its terminal distributor of dangerous drugs license number, or any other board approved identifier, OAC 4729-16-03(2) and/or
- c. The pharmacy control number, OAC 4729-16-03(O)(3); and/or
- d. The pharmacy's expiration date or beyond use date, OAC 4729-16-03(O)(4); and/or
- e. "Compounded Drug Product" or other similar statement, OAC 4729-16-03(O)(5).

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.

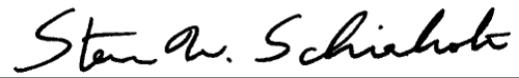
IF YOU DESIRE A HEARING, such request shall either be mailed to the State of Ohio Board of Pharmacy, Attn: Legal, 77 South High Street, 17th Floor, Columbus, Ohio 43215-6126 or an e-mail request may be sent to legal@pharmacy.ohio.gov (please note faxes will not be accepted). **YOUR REQUEST MUST BE RECEIVED 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.

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



Steven W. Schierholt, Esq., Executive Director

SWS/mls/kll

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