



**STATE OF  
OHIO**  
BOARD OF PHARMACY

**IN THE MATTER OF:**

**CASE NO. A-2020-0637**

**RC Compounding**  
c/o Emily Carlson, RPh  
3030 Center Road  
Poland, OH 44514

**License No. 02-1678950**

### **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 RC Compounding for the purpose of resolving all issues between the parties relating to the Board investigation of an error in dispensing. Together, the Board and RC Compounding 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. RC Compounding is a licensed Terminal Distributor of Dangerous Drugs under license number 02-1678950.

#### **FACTS**

1. The Board initiated an investigation of RC Compounding, Terminal Distributor of Dangerous Drugs license number 02-1678950, related to RC Compounding's error in dispensing.
2. On or about April 7, 2022, the Board sent a Notice of Opportunity for Hearing to RC Compounding, 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 May 4, 2022, RC Compounding, through counsel Brandon Smith, timely requested an administrative hearing, which was subsequently scheduled for August 8, 2022. This matter was settled via this Agreement prior to hearing.

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

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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. RC Compounding neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated April 7, 2022; 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. RC Compounding agrees to pay to the Board a monetary penalty the amount of \$1,000. 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](http://www.elicense.ohio.gov) and process the items in your cart.
4. The Board hereby imposes a written reprimand on RC Compounding's TDDD license, number 02-1678950.
5. RC Compounding 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. RC Compounding 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 RC Compounding 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 RC Compounding by the Board and will NOT discharge RC Compounding from any obligation under the terms of this Agreement.
7. RC Compounding agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.
8. RC Compounding 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 RC Compounding will operate.
10. RC Compounding 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:

Emily Carlson  
Emily Carlson, RPh, on behalf of,  
RC Compounding, Respondent

7/20/2022  
Date of Signature

B. L. M. Smith 0096701  
Brandon Smith, Attorney for Respondent

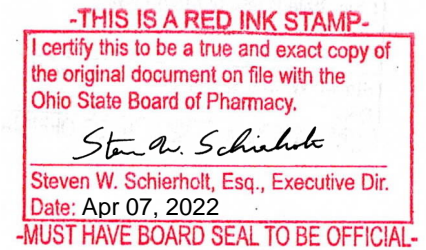
20 July 2022  
Date of Signature

Shawn Wilt  
Shawn Wilt, RPh, President,  
State of Ohio Board of Pharmacy

08.10.2022  
Date of Signature

N/A  
Henry Appel, Ohio Assistant Attorney General

N/A  
Date of Signature



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

**IN THE MATTER OF:**

**CASE NO. A-2020-0637**

**RC Compounding**  
c/o Emily Carlson, RPh  
3030 Center Road  
Poland, OH 44514

**License No. 02-1678950**

April 7, 2022

Dear RC Compounding and Mr./Ms.:

**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. RC Compounding, located at 3030 Center Road, Poland, Ohio, has an active TDDD license with the Board under license number 02-1678950, which lists Emily Carlson, RPh as the Responsible Person.

**ALLEGATIONS**

1. On or about March 11, 2020, prescriptions #188064CR and #186293R were compounded at RC Compounding for Patient 1. On or about March 12, 2020, prescription #188064CR for Biest 80/20 0.25 mg + 0.25 mg testosterone and prescription #186293R for progesterone 30 mg/0.5 ml were dispensed to Patient 1; however, the prescription labeled as progesterone 30 mg/0.5 ml, contained testosterone 26 mg/0.5ml.
2. The investigation revealed, on or about March 11, 2020, the certified pharmacy technician who compounded the medications chose testosterone powder instead of progesterone powder prior to

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compounding the cream labeled as progesterone 30 mg/0.5 ml. A positive ID indicates Michael Martinelli, RPh, verified and took responsibility for the dispensing of the prescriptions after the compounding was complete. Mr. Martinelli reviewed each of the compounding records and found the weights, calculations, and records to be accurate. However, pursuant to RC Compounding's standard operating procedure, he did and not verify the compounding ingredients prior to the compounding taking place.

3. Patient 1 used the topical medications as prescribed and experienced changes in behavior and appearance consistent with an excessive amount of testosterone. Patient 1 also experienced unusually high total testosterone blood levels collected on 3/24/20 (1277 ng/dl) and 4/20/20 (1384 ng/dl). The normal range of total testosterone in a female the same age as Patient 1 is 2-45 ng/dl.
4. On or about May 12, 2020 an agent of the Board spoke with Ray Carson, RPh, owner of RC Compounding, Mike Basista, RPh, and Emily Carson. They stated an internal investigation of the compounding and dispensing found no errors.
5. On or about July 7, 2020, agents of the Board conducted a non-sterile compounding inspection at RC Compounding. The inspection revealed the pharmacy's process is for the pharmacist to verify the contents of the compound and the correctness of the compounding process *after* the compounding has been completed by a technician. The pharmacist does not verify the ingredients and proper weight prior to the technician compounding. It was explained to agents of the Board the pharmacy had already changed their standard operating procedure to include pharmacist verification of ingredients during the compounding process.
6. RC Compounding provided to the Board a July 7, 2020 internal report summarizing the error in dispensing and stating the isolated event was likely caused by the technician mistakenly choosing a bottle containing testosterone instead of progesterone. The report also included changes to the pharmacy's standard operating procedures including a step for pharmacists to verify the ingredients of compounds prior to the technician completing the compounding process.

#### **POTENTIAL VIOLATIONS OF LAW**

1. 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 \$250.
2. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of section 3715.64(A)(1), Misbranded drug – its labeling is false or misleading in any particular, punishable by a maximum penalty of \$150.
3. Such conduct as set forth in the Allegations Section, if proven, constitutes the following violations of divisions (A)(10) of section 3715.64 of the ORC, Misbranding, each violation punishable by a maximum penalty of \$150:
  - a. It is a drug and its container is so made, formed, or filled as to be misleading, ORC Section 3715.64(A)(10)(a); and/or

- b. The drug sold or dispensed is not the brand or drug specifically prescribed or ordered or, when dispensed by a pharmacist upon prescription, is neither the brand or drug prescribed nor a generically equivalent drug, ORC Section 3715.64(A)(10)(d).
- 4. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of each of the following divisions of Rule 4729-16-03 of the OAC as effective February 15, 2016, each violation punishable by a maximum penalty of \$500:
  - c. 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 (9/10/2015); OAC Rule 4729-16-03(A); and/or
  - d. For all compounded prescriptions, the pharmacist shall: Inspect and approve the compounding process; OAC Rule 4729-16-03(G)(1).
- 5. Such conduct as set forth the Allegations Section, if proven, constitutes a violation of section 4729.55(D) of the ORC, as effective April 6, 2017, 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.
- 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
  - a. 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
  - 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).
- 7. Such conduct as set forth in Allegations Section, if proven, constitutes a violation of the following sections of Rule 4729:5-4-01 of the OAC, as effective March 1, 2019, 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).

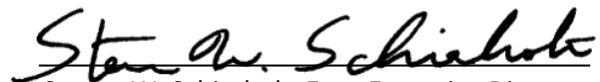
YOU ARE FURTHER NOTIFIED, in accordance with the provisions of Chapters 119. and 4729. of the Ohio Revised Code, that you are entitled to a hearing before the State of Ohio Board of Pharmacy, if you request such a hearing within thirty 30 days of the date of the mailing of this notice.

**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, 17<sup>th</sup> Floor, Columbus, Ohio 43215-6126 or an e-mail request may be sent to [legal@pharmacy.ohio.gov](mailto:legal@pharmacy.ohio.gov) (please note faxes will not be accepted). **YOUR REQUEST MUST BE RECEIVED ON OR PRIOR TO THE 30<sup>TH</sup> 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 30<sup>th</sup> 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](mailto: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/alg/kll

Enclosure: Patient ID Key

CMRRR: 9414 7118 9956 1605 7449 95