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Steven W. Schierholt, Esq., Executive Dir.
Date: 6/6/2025
-MUST HAVE BOARD SEAL TO BE OFFICIAL-

ORDER OF THE OHIO BOARD OF PHARMACY
Case Number A-2025-0082

In The Matter Of:

Rejuv and Renew Wellness Spa DBA R&R Wellness
f.k.a. Rejuvenation and Relaxation Wellness Spa
DBA Rejuv & Renew Wellness Spa
c/o Patricia Cantrell and Lindsey Midkiff
2906 W US Highway 22 And 3 Unit 2
Mainville, Ohio 45039

License No. 02-62001568

INTRODUCTION

The Matter of Rejuv and Renew Wellness Spa DBA R&R Wellness f.k.a. Rejuvenation and Relaxation Wellness Spa DBA Rejuv & Renew Wellness Spa (R&R Wellness) came for hearing on June 2, 2025 and June 3, 2025, before the following members of the Ohio Board of Pharmacy (Board): Mindy Ferris, RPh, *Presiding*; Jeff Huston, RPh, Vice President; Anthony Buchta, Sr., RPh; Trina Buettner, RPH; Jason George, RPh; T.J. Grimm, RPh; Leonard Hubert, *Public Member*; and Rich Miller, RPh.

Christine Pfaff, RPh; Absent. Anthony Buchta, Sr., RPh; Absent on June 3, 2025.

R&R Wellness was represented by Levi Tkach. The State of Ohio was represented by Henry Appel, Assistant Attorney General.

SUMMARY OF EVIDENCE

State's Witnesses:

1. Patricia Cantrell, MSN-Ed, RN-BC
2. Nicole Walker, PA
3. Sarah Nash – Board Specialist
4. Drew Bouza – Board Agent

Respondent's Witnesses:

1. Patricia Cantrell, MSN-Ed, RN-BC
2. Lindsey Midkiff, LMT
3. Sheilah Rauh, RN, CNP

State's Exhibits:

1. Notice Letter
2. Request for Hearing
3. Scheduling Order
4. Inspection Report 3/14/2025
5. Response to Inspection Report 3/14/2025 (part 1)
6. Response to Inspection Report 3/14/2025 (part 2)
7. Inspection Report 3/20/2025
8. Inspection Report 4/22/2025
9. Response to Inspection Report 4/22/2025
10. Botox Packing List
11. E-mail 3/17/2025 from Abbvie
12. Photos
13. Inspection Report from Choosi Spa 3/25/2025
14. Statement of S.G.*
15. Botox Administration Spreadsheet*
16. Facebook Post
17. Facebook “Friend” List
18. Botox Package Insert

*Filed under Seal

Respondent's Exhibits**:

A. Resume of Patricia Cantrell
B. Resume of Lindsey Midkiff
C. Text messages with Dr. Hall (March 22, 2025)
D. Destruction Logs
E. Letter of Support, Diana M. Young
F. Letter of Support, Lisa Knabb
G. Letter of Support, Rebecca Y. Madariaga

**Respondent’s Exhibits A-E were admitted into evidence on June 22, 2025; however, these exhibits were not testified to by any of the witnesses. On June 23, 2025, Respondent withdrew Exhibits A-E and entered new Exhibits A-G. Exhibits A-G are listed above.

FINDINGS OF FACT

After hearing the testimony, observing the demeanor of the witnesses, considering the evidence, and weighing the credibility of each, the Board finds portions of Patricia Cantrell's testimony on June 2, 2025 and June 3, 2025, not to be credible.

Ms. Cantrell repeatedly stated she wants to comply with the rules and set an example for how a good medical spa should operate; however, her actions and testimony did not align with these statements. She repeatedly blamed R&R Wellness' Responsible Person(s)- whom she hired - for not providing the medical spa with proper information, and justified her actions by claiming other medical spas in Ohio were committing the same practice violations. The egregiousness of the violations and the continued willingness to blame others casts doubt that Ohio and Federal rules and laws that are in place to ensure patient safety will be routinely complied with.

Despite claiming she attempted to follow all laws and rules of the Board, Ms. Cantrell admitted she spent minimal time navigating the Board's website as it contained "too much legal jargon" and admitted she did not review the inspection guides on the Board's website. Ms. Cantrell represents herself as a "master prepared registered nurse" (Respondent's Exhibit A) who teaches others how to administer neurotoxins yet admitted she did not understand the basic principles of the law that she was required to follow. During the hearing and/or during conversations with Board inspectors, Ms. Cantrell admitted to the following:

- She purchased 20 vials of Botox from a dentist in the Bay area of California; however, was not willing to share his name nor his specific location, upon request by the Board inspector. Ms. Cantrell admitted not knowing where the dentist had obtained the purchased product.
- She did not look at the vials- which were in Turkish- close enough to notice they were in a foreign language, from the months of September through March. She "threw out" the package inserts without reading them.
- She testified that she paid $300 to $350 per vial of Botox; however, Botox normally costs around $678 per vial. She stated similar prices to a Board inspector during an inspection. This cost saving was suspicious and should have put Ms. Cantrell on notice.

The Board further finds that Ms. Cantrell's testimony at hearing that she "found" the Liporase in a box of bands that she purchased from a closed medical spa is inconsistent with her original responses to the Board, during and following the March 14, 2025 inspection, that she purchased the Liporase from a closed medical spa, not that she had found it in a box.

Of particular concern to the Board was the testimony from a physician assistant, Nicole Walker, that she put Ms. Cantrell on notice over one month prior to the Board's first inspection, that the Botox she observed at R&R Wellness looked different than Botox she had used (in her practice as a physician assistant). She went as far as to tell Ms. Cantrell this and verbalized her concerns that something was not right. Instead of looking into this concern, Ms. Cantrell blatantly ignored the warning and continued to administer counterfeit drugs to her patients.

The Board further finds the following to be fact:

1. On or about March 14, 2025, a Board Agent and a Board Specialist (Board inspectors) conducted an inspection at R&R Wellness (fka Rejuvenation and Relaxation Wellness Spa DBA Rejuv & Renew Wellness Spa), located at 2906 W US Highway 22 And 3, Unit 2, Mainville, Ohio. Upon arrival, Board inspectors met with Patty Cantrell, Registered Nurse (RN), license no. RN.397952. RN Cantrell stated she is a co-owner of R&R Wellness, along with her business partner Lindsey Midkiff.

2. The inspection revealed R&R Wellness was in possession of the following dangerous drugs which were suspected to be counterfeit:

    a. A partial vial of Botox. The vial was opened and had been used.

        i. The vial did not have a National Drug Code (NDC), nor did it have the manufacturer's hologram on the front.

    b. Seven vials of Liporase (Hyaluronidase).

        i. Each vial had characters of an unknown language on the label.

3. During the inspection, Patty Cantrell, RN stated the following to the Board inspectors when asked about the suspected counterfeit drugs:

    a. RN Cantrell explained she purchased the Botox from a dentist in the Bay area of California who was part of a buying group called "CARE."

        i. RN Cantrell was not willing to share the name of the dentist or the specific location from which she ordered/he shipped from. She said she knew him from high school and considered him a friend.

    b. RN Cantrell explained she purchased the Liporase (lip filler dissolver) from a salon in Dayton, Ohio that had abruptly closed sometime in the Fall of 2024 or January 2025.

        i. She described the purchases as "cash purchases."

        ii. She ordered these drugs off of Facebook.

        iii. She did not have invoices or documentation of the purchases.

    c. She asked that "if" the Xeomin was found to be real, could she get the money back. She stated the product taken was worth $1,000.00 and she did not want to lose the money. She was able to produce invoices for the Xeomin.

    d. R&R Wellness has a second location in Franklin, Ohio which was not licensed by the Board.

        i. RN Cantrell stated she and other nurses employed by the clinic injected Botox at R&R Wellness and the business' second location in Franklin, Ohio.

ii. RN Cantrell stated the Franklin location stores Botox and derma fillers (Botox is a dangerous drug and requires a TDDD license to order/possess).

iii. Note: as of the date of issuance of this Summary Suspension, "Rejuv and Renew Wellness Spa – Franklin" has a website advertising the following services, all of which require a Board-issued TDDD license:

1. Botox Allergan, Semaglutide, Trizepatide, Xeomin, injection shots (Lipolean, B12, Vitamin C, Vitamin D), Hylaronidase (filler dissolver), etc.

4. The inspection of R&R Wellness conducted by Board inspectors on March 14, 2025, resulted in 8 warnings requiring a written response and multiple warnings, including:

a. The TDDD license does not have a Responsible Person.

i. Dr. Adetoro was the Responsible Person listed on the TDDD license; however, RN Cantrell stated Dr. Adetoro had not been the Responsible Person since October 2024.

ii. Dr. Tiffany Hall assumed the role of Responsible Person in October 2024 but vacated the position on March 11, 2025.

iii. Dr. Rebecca Jones became the Responsible Person on March 11, 2025; the application was submitted to the Board on March 17, 2025.

b. The TDDD failed to submit a Change of Responsible Person form for Dr. Hall and failed to complete an inventory of controlled substances on the effective date of the new Responsible Person.

c. The Responsible Person was not physically present at the medical spa for a sufficient amount of time.

i. RN Cantrell reported Dr. Adetoro was never physically on-site and Dr. Jones had yet to visit the location.

d. The TDDD failed to verify licensure prior to purchasing dangerous drugs at wholesale.

i. There were no records indicating licensure of drug distributors were queried prior to purchase.

ii. RN Cantrell stated the following were drug distributors R&R Wellness purchased drugs from: Allergan, Abbvie, Olympia, Revance, Merz, SKNV and "the CARE Group."

e. The facility stored expired and adulterated drugs on site.

i. Board inspectors observed multiple expired products comingled with the active drug stock. The drugs were not segregated as required.

1. Expiration dates included: September 2023, July 2024, May 2024, February 2024 and November 2023.

f. Drugs were stored longer than one year from the date of adulteration or expiration.

   i. Drugs from 2023 and February 2024 were observed.

g. The TDDD accepted occasional drug transfers from entities that are not permitted to conduct occasional sales or transfers. These "medical spas" are not licensed drug distributors in Ohio.

   i. R&R Wellness purchased Olympia products from a med spa located in Indiana.

   ii. RN Cantrell stated R&R Wellness purchased "Liporase" from a med spa in Ohio that ceased their dangerous drugs services.

h. The refrigerators where drugs are stored does not comply with the Ohio Administrative Code.

   i. Board inspectors observed temperature logs for January 2025 to present. Several dates did not have the temperature documented.

   ii. The weight loss drugs were stored in a refrigerator containing food and beverages.

i. Multi-dose vials are not properly labeled with a beyond-use-date (BUD) or date of puncture.

   i. Board inspectors observed 13 multi-dose vials that had been opened but did not include a date of puncture or BUD. These vials must be destroyed.

j. Records of drug receipt did not contain required information.

   i. Records from the drug distributors did not contain the date of receipt.

k. R&R Wellness did not have records of drug receipt for dangerous drugs for the following drugs, as described by RN Cantrell:

   i. Ketorolac, a dangerous drug, purchased from "STAT DDS," not a drug wholesaler (or entity) licensed with the Board.

   ii. Dangerous drugs purchased from "She's So Pretty," which RN Cantrell stated discontinued services for dangerous drugs and sold to R&R Wellness. "She's So Pretty" is not a drug wholesaler (or entity) licensed with the Board and was not able to be found upon investigation by Board inspectors.

   iii. Botox, a dangerous drug, purchased from "a dentist associated with 'CARE Group' in the Bay Area in California."

l. All records are not readily retrievable and kept on-site for at least three years.

    i. RN Cantrell stated temperature logs are maintained at her personal residence.

m. Compounding of non-hazardous drugs is performed and administered without prescriber oversight.

    i. R&R Wellness compounds and administers IV hydration, including Olympia products Reboot and B-Lean. Both products are compounded by an RN, but the compounding/administration is not overseen by a prescriber.

n. The required documentation of non-hazardous compounding (by a prescriber) was not observed; the Responsible Person was not overseeing the requirements.

o. A Registered Nurse compounds and administers the compounded preparations, but there is no final or visual check of the drugs by a prescriber prior to the drug being administered.

p. The compounding of immediate-use, sterile non-hazardous drugs involved the transfer of more than three commercially available manufactured packages.

    i. The Olympia kits stored by the R&R Wellness involve the addition of three or more vial contents into one IV bag. This exceeds Ohio rule.

5. On or about March 17, 2025, the Board received confirmation from Abbvie, the drug distributor of the Botox seized during the inspection, that the Botox is counterfeit.

    a. Note: In addition to confirming the Botox was counterfeit, the drug distributor provided records confirming R&R Wellness made one purchase of Botox manufactured by Allergan and sold by Abbvie on January 31, 2024. No other purchases of Botox have been made under R&R Wellness' TDDD number.

6. On or about March 17, 2025, the Board confirmed that the seven vials of Liporase are not FDA-approved and are, therefore, adulterated and illegal to distribute into/within the United States.

7. On or about March 20, 2025, a Board Specialist spoke with Nicole Walker, Physician Assistant (PA). PA Walker stated the following about a February 8, 2025 meeting with RN Cantrell:

    a. On or about February 8, 2025, Nicole Walker, PA, who is employed by another medical spa looking for additional space for its services, visited R&R Wellness. PA Walker was given a tour of R&R Wellness by Patty Cantrell. During the tour, RN Cantrell showed PA Walker the contents of the medication storage cabinet and refrigerator where medication is stored.

    b. PA Walker saw approximately 8-10 boxes of Botox in the medication refrigerator, as well as a partial vial of Botox that was in use.

c. PA Walker was in a room with RN Cantrell where a patient was being treated, so she only had a brief glance at the drug stock, but during that time she noted the Botox vial looked "weird." A patient was present, so she quietly asked RN Cantrell where the product came from.

d. PA Walker stated that once she expressed her concern to RN Cantrell regarding the appearance of the vial, RN Cantrell asked how or why PA Walker was concerned.

e. PA Walker told RN Cantrell that, in her experience, Botox vials look different (than the vial(s) she saw at R&R Wellness).

f. PA Walker asked RN Cantrell who R&R Wellness' Allergan drug representative was. RN Cantrell stated they didn't have one.

g. Note: when PA Walker was speaking to the Board Specialist, she stated that the Botox vial did not look like vials she was used to seeing.

8. During the March 20, 2025 conversation with the Board Specialist, PA Walker stated the following about Botox she observed at Choosi Aesthetics, a Board licensed medical spa:

a. On March 10, 2025, staff at Choosi Aesthetics realized Botox had not been ordered and the clinic did not have enough Botox to treat the patients for the day. Choosi staff asked to borrow two vials of Botox from R&R Wellness and let R&R Wellness know they would replace the Botox vials on March 11, 2025.

b. A staff member from Choosi Aesthetics picked up the two vials of Botox from R&R Wellness and brought them back to Choosi Aesthetics.

c. PA Walker was present at Choosi Aesthetics that day. She observed the two vials of Botox at Choosi Aesthetics and believed they were not real Botox.

d. One of the vials of Botox had writing on the label which was later determined to be Turkish, and the other label was in English.

e. PA Walker reached out to Allergan (the manufacturer of the Botox) and asked Allergan to confirm whether the vials were real.

f. Within approximately 30 minutes Allergan confirmed the Botox vials were counterfeit.

g. The Responsible Person and Medical Director of Choosi Aesthetics, Dr. Tiffany Hall, was notified of the counterfeit Botox vials from R&R Wellness. (Note: Dr. Hall, also the Acting Responsible Person of R&R Wellness, resigned from her position at R&R Wellness later that day).

9. On or about March 20, 2025, Board inspectors conducted a follow-up inspection at R&R Wellness to evaluate drug stock that was supposed to be transferred from the unlicensed location in

Franklin, Ohio to R&R Wellness (Maineville). Board inspectors spoke with RN Cantrell, during the inspection. The following was discovered:

a. A Board inspector observed a counterfeit vial of unopened Botox. RN Cantrell stated she brought the vial from the Franklin location, as she was instructed to do on March 14, 2025.

b. RN Cantrell estimated she began ordering Botox from the California dentist's buying group in approximately September or October 2024.

c. When she began purchasing from California, she ceased purchasing from Allergan (the legitimate Botox).

d. She repeatedly stated she had no knowledge the drugs were counterfeit.

e. RN Cantrell stated the dentist's name and explained he was part of a buying group called "CARE." The group buys in bulk to decrease cost per vial.

f. She stated Botox normally costs $600-700 per vial if purchased through Allergan, but through the dentist, she paid $275-350 per vial.

g. RN Cantrell said now that she knows the drugs are counterfeit, the significant cost savings is suspicious.

h. She paid for the counterfeit Botox through Venmo.

i. She estimated 20 vials were purchased from the dentist.

j. She destroyed the counterfeit Botox once notified by Dr. Hall, the former Responsible Person, it was counterfeit.

k. She estimated she destroyed approximately 12 vials at her house; her husband who is not a licensed healthcare professional, witnessed the destruction.

10. On March 20, 2025, the two counterfeit vials of Botox, one label written in Turkish and one label written in English, were seized from Choosi Aesthetics. These were the vials transferred to Choosi Aesthetics from R&R Wellness on or about March 10, 2025.

CONCLUSIONS OF LAW

The practice violations discovered by Board inspectors during the March 14, 2025 inspection and the repeated denial of knowledge or awareness of the rules and laws that medical spas must follow are alarming. The medical spa operated on a daily basis without guidance or oversight from a Responsible Person or an understanding of the basic TDDD rules, despite ownership by a licensed medical professional. R&R Wellness failed to follow rules for ordering, receiving, storing, processing, filling, compounding, verifying, and dispensing dangerous drugs. The compounding and administration of IV hydration using dangerous drugs was facilitated without any prescriber oversight.

The inspection and testimony revealed there were no records of prescriber orders in nearly all administrations and when an order did exist, it was a pre-printed order that was copied (instead of wet ink). Records of purchasing, compounding, and administration of dangerous drugs were either non-existent or incomplete, which is particularly concerning given the fact counterfeit and non-FDA approved drugs were being injected. These daily practice violations- taken collectively or individually- demonstrate either a reckless disregard for the rules and laws or a willingness to ignore them until confronted by the Board.

Ms. Cantrell's purchase and possession of counterfeit drugs, both from an unlicensed person in California and from an unlicensed medical spa found on Facebook was egregious and reckless, and each injection of these drugs put patients' safety at risk.

1. Such conduct as set forth in the Findings of Fact, each constitutes a violation of section 3715.52 of the ORC, prohibited acts, each, a misdemeanor of the fourth degree. The following acts and causing them are prohibited:

    a. The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated[1] or misbranded,[2] ORC Section 3715.52(A)(1); and

[1] ORC Section 3715.63 states: A drug or device is adulterated within the meaning of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, if any of the following apply:
1. It consists, in whole or in part, of any filthy, putrid, or decomposed substance, ORC Section 3715.63(A)(1); and/or
2. It has been produced, processed, prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health, ORC Section 3715.63(A)(2); and/or
3. It is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health, ORC Section 3715.63(A)(3); and/or
4. It purports to be or is represented as a drug the name of which is recognized in the United States pharmacopoeia and national formulary, or any supplement to them, and its strength differs from or its quality or purity falls below the standard set forth in those compendiums. A determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in the compendiums, or in the absence or inadequacy of such tests or methods of assay, those prescribed under the authority of the "Federal Food, Drug, and Cosmetic Act." A drug recognized in the compendiums is not adulterated under this division because it differs from the standard of strength, quality, or purity set forth for that drug in the compendiums, if the difference in strength, quality, or purity is plainly stated on its label. Whenever a drug is recognized in both the homoeopathic pharmacopoeia of the United States and in the United States pharmacopoeia and national formulary, including their supplements, it shall be subject to the requirements of the United States pharmacopoeia and national formulary unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the homoeopathic pharmacopoeia of the United States and not to those of the United States pharmacopoeia and national formulary, ORC Section 3715.63(A)(5); and/or
5. It is not subject to the provisions of division (A)(5) of this section, and its strength differs from or its purity or quality falls below that which it purports or is represented to possess, ORC Section 3715.63(A)(6).

[2] ORC Section 3715.64 states: A drug or device is misbranded within the meaning of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, if:
1. Its labeling is false or misleading in any particular, ORC Section 3715.64(A)(1); and/or
2. It is in package form and does not bear a label containing both of the following:
a. In clearly legible form, the name and place of business of the manufacturer, packer, or distributor, ORC Section 3715.64(A)(2)(a); and/or

b. The adulteration or misbranding of any food, drug, device, or cosmetic, ORC Section 3715.52(A)(2); and

c. The receipt in commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise, ORC Section 3715.52(A)(3); and

d. The sale, delivery for sale, holding for sale, or offering for sale of any article in violation of section 3715.61 or 3715.65 of the Revised Code, ORC Section 3715.52(A)(4); and

e. The dissemination of any false advertisement, ORC Section 3715.52(A)(5).

2. Such conduct as set forth in the Findings of Fact, constitutes a violation of section 3715.68(A) of the ORC, An advertisement of food, drug, device, or cosmetic is false if it is false or misleading in any particular.

3. Such conduct as set forth in the Findings of Fact, each constitutes a violation of Section 4729.51(F) of the ORC, effective September 29, 2017 and April 6, 2017, No licensed terminal distributor of dangerous drugs or person that is exempt from licensure under section 4729.541 of the Revised Code shall purchase dangerous drugs or investigational drugs or products from any person other than a licensed manufacturer, outsourcing facility, third-party logistics provider, repackager, or wholesale distributor, each violation is a misdemeanor of the first degree.

4. Such conduct as set forth in the Findings of Fact, each constitutes a violation of Section 4729.51(A) of the ORC, effective October 3, 2023, No person other than a licensed manufacturer of dangerous drugs, outsourcing facility, third-party logistics provider, repackager of dangerous drugs, or wholesale distributor of dangerous drugs shall possess for sale, sell, distribute, or deliver, at wholesale, dangerous drugs or investigational drugs or products, each violation is a misdemeanor of the first degree.

5. Such conduct as set forth in the Findings of Fact, each constitutes a violation of Section 4729.51(G) of the ORC, effective October 3, 2023, No licensed terminal distributor of dangerous drugs shall engage in the retail sale or other distribution of dangerous drugs or investigational drugs or products or maintain possession, custody, or control of dangerous drugs or investigational drugs or products for any purpose other than the distributor's personal use or consumption, at any establishment or place other than that or those described in the license

3. Any word, statement, or other information that is required by or under authority of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code to appear on the label or labeling is not prominently placed on the label or labeling in a conspicuous manner, as compared with other words, statements, designs, or devices on the label or labeling, and in terms that render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use, ORC Section 3715.64(A)(5); and/or
4. It is an imitation of another drug, ORC Section 3715.64(A)(10)(b); and/or
5. It is offered for sale under the name of another drug, ORC Section 3715.64(A)(10)(c).

issued by the state board of pharmacy to such terminal distributor, each violation is a misdemeanor of the first degree.

6. Such conduct as set forth in the Findings of Fact, each constitutes a violation of the following sections of Rule 4729:5-3-09 of the OAC, as effective May 27, 2023:

    a. The term "occasional sale" as used in section 4729.51 of the Revised Code means a wholesale sale of a commercially manufactured dangerous drug to a person licensed in accordance with section 4729.52 of the Revised Code, terminal distributor of dangerous drugs or any entity or person exempted from licensure as a terminal distributor of dangerous drugs by any of the following: A licensed terminal distributor of dangerous drugs that is not a pharmacy, but only as authorized in section 4729.51 of the Revised Code, OAC Rule 4729:5-3-09(A)(2); and

    b. A licensed terminal distributor of dangerous drugs having more than one licensed location may transfer or deliver dangerous drugs from one licensed location to another licensed location owned by that terminal distributor if the license issued for each location is in effect at the time of the transfer or delivery. Such transfer or delivery includes either of the following: Intracompany sales, which includes any transaction or transfer between any division, subsidiary, parent or affiliated or related company under the common ownership and control, OAC Rule 4729:5-3-09(E)(1).

7. Such conduct as set forth in the Findings of Fact, each constitutes a violation of Section 4729.60(B) of the ORC, Before a licensed terminal distributor of dangerous drugs may purchase dangerous drugs at wholesale, the terminal distributor shall query the roster established pursuant to section 4729.59 of the Revised Code to confirm the seller is licensed to engage in the sale or distribution of dangerous drugs at wholesale.

8. Such conduct as set forth in the Findings of Fact, each constitutes a violation of the following sections of Rule 4729:5-3-04 of the OAC, as effective March 1, 2019:

    a. Before a terminal distributor of dangerous drugs may purchase dangerous drugs at wholesale, the terminal distributor shall query the board's online roster (available on the board's website: www.pharmacy.ohio.gov) to confirm any of the following:

        i. The seller is licensed to engage in the sale of dangerous drugs in accordance with section 4729.52 of the Revised Code, OAC Rule 4729:5-3-04(A)(1); and/or

        ii. The seller is licensed to engage in the occasional sale or distribution of dangerous drugs at wholesale in accordance with rule 4729:5-3-09 of the Administrative Code, OAC Rule 4729:5-3-04(A)(2); and

    b. If no documented query is conducted before a purchase is made, it shall be presumed that the purchase of dangerous drugs by the terminal distributor is in violation of section 4729.51 of the Revised Code, OAC Rule 4729:5-3-04(B).

9. Such conduct as set forth in the Findings of Fact, each constitutes a violation of the following sections of Rule 4729:5-2-01 of the OAC, as effective April 25, 2022:

    a. A location licensed as a terminal distributor of dangerous drugs must have a responsible person at all times, OAC Rule 4729:5-2-01(E)(1); and

    b. When there is a change of responsible person, the state board of pharmacy shall be notified within ten days of the effective date of the appointment of the new responsible person in a manner determined by the board. For a limited terminal distributor of dangerous drugs license, the notification shall include a drug list required in accordance with agency 4729 of the Administrative Code, OAC Rule 4729:5-2-01(E)(2); and

    c. A complete inventory, pursuant to 21 CFR 1304.11 of the Code of Federal Regulations (9/9/2014) and rule 4729:5-3-07 of the Administrative Code, shall be taken of the controlled substances on hand by the new responsible person on the effective date of the change of responsible person. The new responsible person shall be responsible for completing and maintaining this inventory record at the location licensed as a terminal distributor of dangerous drugs, OAC Rule 4729:5-2-01(E)(3); and

    d. 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

    e. A responsible person must be physically present at the location for a sufficient amount of time to provide supervision and control of dangerous drugs on-site, OAC Rule 4729:5-2-01(E)(5); and

    f. 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).

10. Such conduct as set forth in Findings of Fact, constitutes a violation of each of the following divisions of Section 4729.55 of the ORC, as effective October 3, 2023, TDDD license requirements:

    a. A… licensed health professional authorized to prescribe drugs… 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); and

    b. Adequate safeguards are assured to prevent the sale or other distribution of dangerous drugs by any person other than a pharmacist or licensed health professional authorized to prescribe drugs, ORC 4729.55(C).

11. Such conduct as set forth in Findings of Fact, constitutes a violation of each of the following divisions of Section 4729.57(B) of the ORC, as effective April 4, 2023:

    a. Violating any rule of the board, ORC Section 4729.57(B)(2); and

    b. Violating any provision of this chapter, ORC Section 4729.57(B)(3); and

    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

    d. Falsely or fraudulently promoting to the public a dangerous drug, except that nothing in this division prohibits a terminal distributor of dangerous drugs from furnishing information concerning a dangerous drug to a health care provider or another licensed terminal distributor; ORC Section 4729.57(B)(6); and

    e. 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

    f. 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).

12. Such conduct as set forth in Findings of Fact, each constitutes a violation of the following sections of Rule 4729:5-4-01 of the OAC, as effective April 25, 2022:

    a. Violating any rule of the board, OAC Rule 4729:5-4-01(B)(2); and

    b. Violating any provision of Chapter 4729. of the Revised Code, OAC Rule 4729:5-4-01(B)(3); and

    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

    d. Falsely or fraudulently promoting to the public a dangerous drug, except that nothing in this rule prohibits a terminal distributor of dangerous drugs from furnishing information concerning a dangerous drug to a health care provider or another licensed terminal distributor, OAC Rule 4729:5-4-01(B)(6); and

    e. 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

    f. Commission of an act that constitutes a misdemeanor that is related to, or committed in, the person's professional practice, OAC Rule 4729:5-4-01(B)(18); and

g. 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).

13. Such conduct as set forth in the Findings of Fact, each constitutes a violation of the following sections of Rule 4729:5-5-24 of the OAC, as effective August 19, 2022:

    a. Records of receipt shall contain the name, strength, dosage form, and quantity of the dangerous drugs received, the name and address of the seller, the name and address of the recipient, and the date of receipt, OAC Rule 4729:5-5-24(A); and

    b. Records of dangerous drugs disposed from inventory, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug disposed, the date of disposal, the method of disposal, and the positive identification of the licensed or registered health care professional that performed the disposal, OAC Rule 4729:5-5-24(C); and

    c. All records maintained in accordance with this chapter shall be readily retrievable and uniformly maintained for a period of three years, OAC Rule 4729:5-5-24(G).

14. Such conduct as set forth in the Findings of Fact, each constitutes a violation of the following sections of Rule 4729:7-3-03 of the OAC, as effective March 31, 2021:

    a. Except as provided in paragraph (L) of this rule, all non-hazardous, non-sterile compounded drug preparations shall be prepared in accordance with United States pharmacopeia chapter <795>, OAC Rule 4729:7-3-03(A); and

    b. Except as provided in paragraph (C) of this rule, all non-hazardous, sterile compounded drug preparations, shall be prepared in accordance with United States pharmacopeia chapter <797>, OAC Rule 4729:7-3-03(B); and

    c. For all immediate-use, non-hazardous sterile compounded drug preparations, a prescriber shall comply with either:

        i. Rule 4729:7-3-04 of the Administrative Code, OAC Rule 4729:7-3-03(C)(1); or

        ii. United States pharmacopeia chapter <797>, OAC Rule 4729:7-3-03(C)(2); and

    d. For all hazardous non-sterile and sterile compounded drug preparations, a prescriber shall comply with rule 4729:7-3-05 of the Administrative Code, OAC Rule 4729:7-3-03(D); and

    e. The responsible person of a facility where a prescriber is engaged in the compounding of dangerous drugs shall be responsible for all of the following:

        i. Developing and implementing appropriate compounding procedures, OAC Rule 4729:7-3-03(E)(1); and

ii. Overseeing facility compliance with this rule, OAC Rule 4729:7-3-03(E)(2); and

iii. Compliance with Title 21 U.S. Code section 353a (November 27, 2013) and all other applicable federal and state laws, regulations and rules, OAC Rule 4729:7-3-03(E)(3); and

iv. Ensuring documented training and competency of compounding personnel, OAC Rule 4729:7-3-03(E)(4); and

v. Ensuring environmental control of the compounding areas, OAC Rule 4729:7-3-03(E)(5); and

vi. Ensuring compounded drug preparations maintain quality and sterility until administered or personally furnished, OAC Rule 4729:7-3-03(E)(6); and

vii. Maintaining drug compounding records pursuant to rule 4729:7-3-06 of the Administrative Code, OAC Rule 4729:7-3-03(E)(7); and

viii. The proper maintenance, cleanliness, and use of all equipment used in compounding, OAC Rule 4729:7-3-03(E)(8); and

ix. Ensuring aseptic technique for the preparation of all sterile compounded drugs, OAC Rule 4729:7-3-03(E)(9); and

f. A prescriber may designate an appropriately trained agent to prepare compounded drug preparations, OAC Rule 4729:7-3-03(F); and

g. For all compounded drugs prepared pursuant to this rule, a prescriber shall:

i. Inspect and approve the compounding process, OAC Rule 4729:7-3-03(G)(1); and

ii. Except as provided in paragraph (H) of this rule, perform medication validation ("final check") prior to the medication being administered, OAC Rule 4729:7-3-03(G)(2); and

h. All the following are required to administer a compounded drug preparation in accordance with paragraphs (H)(1) and (H)(2) of this rule:

i. Verify the accuracy of:

1. Drug name, OAC Rule 4729:7-3-03(I)(3)(a); and

2. Drug strength and dosage form, OAC Rule 4729:7-3-03(I)(3)(b); and

3. Drug volume, OAC Rule 4729:7-3-03(I)(3)(c); and

4. Rate of administration, OAC Rule 4729:7-3-03(I)(3)(d); and

5. Route of administration, OAC Rule 4729:7-3-03(I)(3)(e); and

6. Expiration dates/times, OAC Rule 4729:7-3-03(I)(3)(f); and

7. Appearance and physical integrity of the drugs, OAC Rule 4729:7-3-03(I)(3)(g); and

ii. Indicate in the compounding record verification was completed, OAC Rule 4729:7-3-03(I)(4); and

iii. A licensed prescriber is on-site and immediately available, OAC Rule 4729:7-3-03(I)(5).

15. Such conduct as set forth in the Findings of Fact, each constitutes a violation of the following sections of Rule 4729:7-3-04 of the OAC, as effective April 2, 2021:

a. The responsible person of a facility where a prescriber is engaged in the compounding of immediate-use, sterile non-hazardous dangerous drug preparations in accordance with paragraph (B) of this rule shall be responsible for all the following:

i. Developing and implementing appropriate compounding procedures, OAC Rule 4729:7-3-04(A)(1); and

ii. Overseeing facility compliance with this rule, OAC Rule 4729:7-3-04(A)(2); and

iii. Compliance with Title 21 U.S.C. section 353a (11/27/2013) and all other applicable federal and state laws, regulations and rules, OAC Rule 4729:7-3-04(A)(3); and

iv. Ensuring training and competency of compounding personnel, OAC Rule 4729:7-3-04(A)(4); and

v. Ensuring that compounded drug preparations maintain quality and sterility until administered, OAC Rule 4729:7-3-04(A)(5); and

vi. Maintaining drug compounding records pursuant to rule 4729:7-3-06 of the Administrative Code, OAC Rule 4729:7-3-04(A)(6); and

vii. The proper maintenance, cleanliness, and use of all equipment used in compounding, OAC Rule 4729:7-3-04(A)(7); and

viii. Ensuring aseptic technique for the preparation of all sterile compounded drugs, OAC Rule 4729:7-3-04(A)(8); and

b. Immediate-use, sterile compounded drug preparations are exempt from the requirements in rule 4729:7-3-03 of the Administrative Code if all the following criteria are met:

i. The compounding process involves the simple transfer of not more than three commercially manufactured packages of sterile, non-hazardous drugs from the

manufacturers' original containers and not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device, OAC Rule 4729:7-3-04(B)(1); and

c. Preparations that do not meet all the requirements listed in paragraph (B) of this rule shall comply with the requirements in rule 4729:7-3-03 of the Administrative Code, OAC Rule 4729:7-3-04(E); and

d. Immediate-use compounded drug preparations shall be prepared in accordance with this rule except in an emergency, as documented in the medical record, when the product is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, OAC Rule 4729:7-3-04(F); and

e. For all compounded drugs prepared pursuant to this rule, a prescriber shall:

   i. Inspect and approve the compounding process, OAC Rule 4729:7-3-04(L)(1); and

   ii. Except as provided in paragraph (M) of this rule, perform medication validation ("final check") prior to the medication being administered, OAC Rule 4729:7-3-04(L)(2); and

f. The requirements of paragraph (M)(2) of this rule do not apply to either of the following:

   i. A compounded drug preparation is being administered to a patient in the facility by a nurse licensed under Chapter 4723. of the Revised Code pursuant to a prescriber's order and, prior to administration, at least two nurses that are approved by the responsible person to prepare or administer compounded drugs comply with the requirements in paragraph (N) of this rule, OAC Rule 4729:7-3-04(M)(1); or

   ii. A compounded drug preparation is prepared and administered to a patient in the facility by a nurse licensed under Chapter 4723. of the Revised Code pursuant to a prescriber's order and, prior to administration, the same nurse complies with paragraph (N) of this rule, OAC Rule 4729:7-3-04(M)(2); and

g. All the following are required to administer a compounded drug preparation in accordance with paragraphs (M)(1) and (M)(2) of this rule:

   i. Verify the accuracy of:

      1. Drug strength and dosage form, OAC Rule 4729:7-3-04(N)(3)(b); and

      2. Expiration dates/times, OAC Rule 4729:7-3-04(N)(3)(f); and

      3. Appearance and physical integrity of the drugs, OAC Rule 4729:7-3-04(N)(3)(g); and

   ii. Indicate in the compounding record verification was completed, OAC Rule 4729:7-3-04(N)(4); and

iii. A licensed prescriber is on-site and immediately available, OAC Rule 4729:7-3-04(N)(5).

16. Such conduct as set forth in the Findings of Fact, each constitutes a violation of the following sections of Rule 4729:5-3-07 of the OAC, as effective March 1, 2019:

    a. Unless otherwise stated in this division of the Administrative Code, all category III terminal distributor licensees shall complete a controlled substances inventory in accordance with 21 CFR 1304.11 (9/9/2014), OAC Rule 4729:5-3-07(A); and

    b. All controlled substance inventories performed in accordance with this rule shall be conducted on an annual basis. The annual inventory may be taken on any date which is within thirteen months of the previous inventory date, OAC Rule 4729:5-3-07(B); and

    c. The terminal distributor's responsible person shall be responsible for completing and maintaining this inventory record at the location licensed as a terminal distributor of dangerous drugs, OAC Rule 4729:5-3-07(C); and

    d. All inventory records shall be maintained for a period of three years from the completion date of the inventory and made readily retrievable, OAC Rule 4729:5-3-07(D); and

    e. When a drug or compound is added to the schedule of controlled substances by state or federal law, rule or regulation, a terminal distributor shall complete an inventory pursuant to this rule of all stocks of such drug or compound no later than ten days of the drug or compound being added to the schedule, OAC Rule 4729:5-3-07(E); and

    f. In the event a terminal distributor of dangerous drugs commences business with no controlled substances on hand, this fact shall be recorded as the initial inventory, OAC Rule 4729:5-3-07(F).

17. Such conduct as set forth in the Findings of Fact, each constitutes a violation of the following sections of Rule 4729:5-3-06 of the OAC, as effective July 1, 2024:

    a. 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.

        i. Adulterated drugs shall be stored no longer than one year from the date of adulteration or expiration by those holding a terminal distributor of dangerous drugs license. Adulterated drugs shall be stored in a manner that prohibits access by unauthorized persons, OAC Rule 4729:5-3-06(A); and

        ii. Dangerous drugs, other than controlled substances, may be destroyed utilizing proper methods of disposal and following the record keeping requirements noted in agency 4729 of the Administrative Code, or may be donated to a pharmacy school pursuant to sections 3715.88 to 3715.92 of the Revised Code. Methods of disposal of

non-controlled dangerous drugs shall prevent the possession or use of the drugs by unauthorized persons, OAC Rule 4729:5-3-06(B).

18. Such conduct as set forth in Findings of Fact, each constitutes a violation of the following sections of Rule 4729:5-3-14(A) of the OAC, as effective March 1, 2020: terminal distributors of dangerous drugs shall provide effective controls and procedures to:

    a. Deter and detect the theft and diversion of dangerous drugs, OAC Rule 4729:5-3-14(A)(1); and

    b. Ensure supervision and control of dangerous drugs, as required in division (B) of section 4729.55 of the Revised Code, and adequate safeguards to ensure that dangerous drugs are being distributed in accordance with all state and federal laws, as required in section 4729.55 of the Revised Code, OAC Rule 4729:5-3-14(A)(2).

19. Such conduct as set forth in Findings of Fact, each constitutes a violation of the following sections of Rule 4729:5-19-03 of the OAC, as effective February 4, 2021:

    a. All areas where dangerous drugs and devices are stored shall be dry, well-lit, well-ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures and conditions which will ensure the integrity of the drugs prior to use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling. Refrigerators and freezers used for the storage of drugs and devices shall comply with the following:

        i. Maintain either of the following to ensure proper refrigeration and/or freezer temperatures are maintained:

            1. Temperature logs with, at a minimum, daily observations, OAC Rule 4729:5-19-03(K)(1)(a); or

            2. A temperature monitoring system capable of detecting and alerting staff of a temperature excursion, OAC Rule 4729:5-19-03(K)(1)(b); and

        ii. 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, OAC Rule 4729:5-19-03(K)(2); and

        iii. The terminal distributor shall develop and implement a policy that no food or beverage products are permitted to be stored in refrigerators or freezers used to store drugs, OAC Rule 4729:5-19-03(K)(3); and

    b. Upon the initial puncture of a multiple-dose vial containing a drug, the vial shall be labeled with a beyond-use date or date opened. The beyond-use date for an opened or entered (e.g., needle punctured) multiple-dose container with antimicrobial preservatives is twenty-eight days, unless otherwise specified by the manufacturer. A multiple-dose vial that exceeds its beyond-use date shall be deemed adulterated, OAC Rule 4729:5-19-03(L); and

c. 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); and

d. Disposal of non-controlled dangerous drugs shall be conducted in accordance with rule 4729:5-3-06 of the Administrative Code, OAC Rule 4729:5-19-03(O).

20. Such conduct as set forth in Findings of Fact, each constitutes a violation of the following sections of Rule 4729:5-19-04 of the OAC, as effective February 4, 2021:

a. A clinic or prescriber office shall keep a record of all dangerous drugs received, administered, personally furnished, disposed, sold or transferred, OAC Rule 4729:5-19-04(A); and

b. Records of receipt shall contain the name, strength, dosage form, and quantity of the dangerous drugs received, the name and address of the seller, the name and address of the recipient, and the date of receipt. An invoice from a drug distributor licensed in accordance with division 4729:6 of the Administrative Code containing the required information may be used to meet this requirement, OAC Rule 4729:5-19-04(B); and

c. Records of temperature control monitoring described in paragraph (K)(1) of rule 4729:5-19-03 of the Administrative Code shall include any of the following:

i. For temperature logs, either:

1. The date and time of observation, the full name or the initials of the individual performing the check, and the temperature recorded, OAC Rule 4729:5-19-04(C)(1)(a); or

2. For systems that provide automated temperature monitoring, maintain a report that provides, at a minimum, the date and time of observation and the temperature recorded, OAC Rule 4729:5-19-04(C)(1)(b); and

ii. For temperature monitoring systems capable of detecting and alerting staff of a temperature excursion, maintain reports that provide information on any temperature excursion that includes the date, time, temperature recorded, and length of each excursion, OAC Rule 4729:5-19-04(C)(2); and

d. Records of disposal of dangerous drugs from inventory, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug disposed, the date of disposal, the method of disposal, and the identification of the licensed health care professional that performed the disposal, OAC Rule 4729:5-19-04(F); and

e. Records of transfer or sale conducted in accordance with rule 4729:5-3-09 of the Administrative Code shall contain the name, strength, dosage form, national drug code, expiration date and quantity of the dangerous drug transferred or sold, the address of the

location where the drugs were transferred or sold, and the date of transfer or sale, OAC Rule 4729:5-19-04(H); and

f. All records maintained in accordance with this rule and rule 4729:5-19-03 of the Administrative Code shall be readily retrievable and shall be kept on-site for a period of three years.

   i. A terminal distributor intending to maintain records at a location other than the location licensed by the state board of pharmacy must notify the board in a manner determined by the board, OAC Rule 4729:5-19-04(J)(1); and

   ii. Any such alternate location shall be secured and accessible only to authorized representatives or contractors of the terminal distributor of dangerous drugs, OAC Rule 4729:5-19-04(J)(2).

DECISION OF THE BOARD

Pursuant to Section 4729.57 of the Ohio Revised Code and Ohio Administrative Code Rule 4729:5-1-01(U), and after consideration of the record as a whole, the nature and egregiousness of the findings of fact and violations of law, the willingness to repeatedly ignore- or refuse to learn- basic principles meant to ensure patient safety, and an avoidance of responsibility, Rejuv and Renew Wellness Spa DBA R&R Wellness demonstrates a compromised ability to competently operate an entity that can continuously ensures patient safety. The Ohio Board of Pharmacy adjudicates the matter of Rejuv and Renew Wellness Spa DBA R&R Wellness as follows:

On the basis of the Findings of Fact and Section (1) through (20) of the Conclusions of Law, taken collectively or as individual violations, the Ohio Board of Pharmacy hereby revokes permanently the Terminal Distributor of Dangerous Drugs (TDDD) license, No. 02-62001568, held by Rejuv and Renew Wellness DBA R&R Wellness, effective the date of this Order.

The Board finds Rejuv and Renew Wellness Spa DBA R&R Wellness and/or its owner Patty Cantrell may not reapply for a Terminal Distributor of Dangerous Drugs License over which the Board has jurisdiction.

Pursuant to 4729.57 of the Ohio Revised Code, the State of Ohio Board of Pharmacy imposes a monetary penalty in the amount of $60,000.00. This fine will be attached to the license record for Rejuv and Renew Wellness Spa DBA R&R Wellness and must be paid no later than 180 days from the effective date of this Order. To pay this fine a representative of R&R Wellness must log in to www.elicense.ohio.gov and process the items in the cart.

Further, the Board hereby grants the State's Motion to Seal portions of the record in that include confidential patient health information including, but not limited to, State's Exhibit 14 and 15.

Mr. Grimm moved for Findings of Fact; Mr. Hubert seconded the motion. Motion passed (Yes-6/No-0).

Mr. Grimm moved for Conclusions of Law; Mr. Hubert seconded the motion. Motion passed (Yes-6/No-0).

Mr. Grimm moved for Action of the Board; Mr. Hubert seconded the motion. Motion passed (Yes-6/No-0).

SO ORDERED.

It is hereby certified by this Board that the above language is a copy of the Order entered upon its journal in this case.

TIME AND METHOD TO PERFECT AN APPEAL

Any party desiring to appeal shall file a Notice of Appeal with the Ohio Board of Pharmacy, 77 South High Street, 17th Floor, Columbus, OH 43215, setting forth the order appealed from and stating that the agency's order is not supported by reliable, probative, and substantial evidence and is not in accordance with law. The notice of appeal may, but need not, set forth the specific grounds of the party's appeal beyond the statement that the agency's order is not supported by reliable, probative, and substantial evidence and is not in accordance with law. The Notice of Appeal shall also be filed by the appellant in the court of common pleas of the county in which the place of business of the licensee is located or the county in which the licensee is a resident. If the appellant is not a resident of and has no place of business in this state, the party may appeal to the court of common pleas of Franklin County. Such notices of appeal shall be filed within fifteen (15) days after the service of the notice of the Ohio Board of Pharmacy's Order as provided in Section 119.12 of the Ohio Revised Code.

BY ORDER OF THE OHIO BOARD OF PHARMACY

ORDER MAILED & EFFECTIVE: **June 6, 2025**

By: Steven W. Schierholt

Steven W. Schierholt, Esq., Executive Director

SWS/alg/jrn

-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, Esq., Executive Dir.
Date: 3/25/2025
-MUST HAVE BOARD SEAL TO BE OFFICIAL-

SUMMARY SUSPENSION/NOTICE OF OPPORTUNITY FOR HEARING
TERMINAL DISTRIBUTOR OF DANGEROUS DRUGS LICENSE

IN THE MATTER OF: **CASE NO. A-2025-0082**

Rejuv and Renew Wellness Spa DBA R&R Wellness **License No. 02-62001568**
f.k.a. Rejuvenation and Relaxation Wellness Spa
DBA Rejuv & Renew Wellness Spa
c/o Patricia Cantrell and Lindsey Midkiff
2906 W US Highway 22 And 3 Unit 2
Mainville, Ohio 45039

March 25, 2025

Dear Rejuv and Renew Wellness Spa DBA R&R Wellness:

You are notified, in accordance with Section 119.07 of the Revised Code, the Ohio Board of Pharmacy (Board) hereby SUMMARILY SUSPENDS Rejuv and Renew Wellness Spa DBA R&R Wellness' license as a Terminal Distributor of Dangerous Drugs (TDDD), under authority of Sections 4729.57 and 4729.571 of the Ohio Revised Code.

Furthermore, the Board finds that based upon the facts set forth in the Allegations Section, there is clear and convincing evidence of a danger of immediate and serious harm to others due to Rejuv and Renew Wellness Spa DBA R&R Wellness' method used to possess or distribute dangerous drugs. As such, the Board summarily suspends Rejuv and Renew Wellness Spa DBA R&R Wellness' license as a Terminal Distributor of Dangerous Drugs. Pursuant to Division (D)(1) of Section 4729.57 of the ORC, Rejuv and Renew Wellness Spa DBA R&R Wellness must immediately surrender license number 02-62001568 to the Board.

JURISDICTION

1. Pursuant to Section 4729.57 of the Ohio Revised Code (ORC) 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 Sections 4729.54 and 4729.55 of the ORC 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 ORC.

2. Pursuant to Section 4729.571(A)(1) of the ORC and the rules adopted thereunder, the Board has the authority to suspend a terminal distributor's license without a hearing if it determines that there is clear and convincing evidence of a danger of immediate and serious harm to others due to the method used by the terminal distributor to possess or distribute dangerous drugs.

3. Rejuv and Renew Wellness Spa DBA R&R Wellness located at 2906 W US Highway 22 And 3, Unit 2, Mainville, Ohio, is a licensed TDDD under license number 02-62001568. A change of Responsible Person form was submitted to the Board on or about March 17, 2025, listing Rebecca Jones, DO, [State Medical Board of Ohio license number 34.017218] as the Responsible Person. During the time of the conduct outlined below, Dr. Tiffany Hall was the Acting Responsible Person [State Medical Board of Ohio license number 35.073597], due to the TDDD failing to submit a Change of Responsible Person form as required, in October 2024. Adedoyin Adetoro, MD, was the Responsible Person on the license; however, Dr. Adetoro resigned in October 2024. Dr. Hall resigned from her position at Rejuv and Renew Wellness Spa DBA R&R Wellness on March 11, 2025.

   Note: On or about March 24, 2025, Rejuvenation and Relaxation Wellness Spa DBA Rejuv & Renew Wellness Spa submitted a "change of business name" request to the Board. The request was approved. The business name associated with the TDDD license is Rejuv and Renew Wellness Spa DBA R&R Wellness (R&R Wellness).

ALLEGATIONS

1. On or about March 14, 2025, a Board Agent and a Board Specialist (Board inspectors) conducted an inspection at R&R Wellness (fka Rejuvenation and Relaxation Wellness Spa DBA Rejuv & Renew Wellness Spa), located at 2906 W US Highway 22 And 3, Unit 2, Mainville, Ohio. Upon arrival, Board inspectors met with Patty Cantrell, Registered Nurse (RN), license no. RN.397952. RN Cantrell stated she is a co-owner of R&R Wellness, along with her business partner Lindsey Midkiff.

2. The inspection revealed R&R Wellness was in possession of the following dangerous drugs which were suspected to be counterfeit:

   a. A partial vial of Botox. The vial was opened and had been used.

      i. The vial did not have a National Drug Code (NDC), nor did it have the manufacturer's hologram on the front.

   b. Seven vials of Liporase (Hyaluronidase).

      i. Each vial had characters of an unknown language on the label.

   c. Four vials of Xeomin.

3. During the inspection, Patty Cantrell, RN stated the following to the Board inspectors when asked about the suspected counterfeit drugs:

a. RN Cantrell explained she purchased the Botox from a dentist in the Bay area of California who was part of a buying group called "CARE."

    i. RN Cantrell was not willing to share the name of the dentist or the specific location from which she ordered/he shipped from. She said she knew him from high school and considered him a friend.

b. RN Cantrell explained she purchased the Liporase (lip filler dissolver) from a salon in Dayton, Ohio that had abruptly closed sometime in the Fall of 2024 or January 2025.

    i. She described the purchases as "cash purchases."

    ii. She ordered these drugs off of Facebook.

    iii. She did not have invoices or documentation of the purchases.

c. She asked that "if" the Xeomin was found to be real, could she get the money back. She stated the product taken was worth $1,000.00 and she did not want to lose the money. She was able to produce invoices for the Xeomin.

d. R&R Wellness has a second location in Franklin, Ohio which was not licensed by the Board.

    i. RN Cantrell stated she and other nurses employed by the clinic injected Botox at R&R Wellness and the business' second location in Franklin, Ohio.

    ii. RN Cantrell stated the Franklin location stores Botox and derma fillers (Botox is a dangerous drug and requires a TDDD license to order/possess).

    iii. Note: as of the date of issuance of this Summary Suspension, "Rejuv and Renew Wellness Spa – Franklin" has a website advertising the following services, all of which require a Board-issued TDDD license:

        1. Botox Allergan, Semaglutide, Trizepatide, Xeomin, injection shots (Lipolean, B12, Vitamin C, Vitamin D), Hylaronidase (filler dissolver), etc.

4. The inspection of R&R Wellness conducted by Board inspectors on March 14, 2025, resulted in 8 warnings requiring a written response and multiple warnings, including:

    a. The TDDD license does not have a Responsible Person.

        i. Dr. Adetoro was the Responsible Person listed on the TDDD license; however, RN Cantrell stated Dr. Adetoro had not been the Responsible Person since October 2024.

        ii. Dr. Tiffany Hall assumed the role of Responsible Person in October 2024 but vacated the position on March 11, 2025.

iii. Dr. Rebecca Jones became the Responsible Person on March 11, 2025; the application was submitted to the Board on March 17, 2025.

b. The TDDD failed to submit a Change of Responsible Person form for Dr. Hall and failed to complete an inventory of controlled substances on the effective date of the new Responsible Person.

c. The Responsible Person was not physically present at the medical spa for a sufficient amount of time.

i. RN Cantrell reported Dr. Adetoro was never physically on-site and Dr. Jones had yet to visit the location.

d. The TDDD failed to verify licensure prior to purchasing dangerous drugs at wholesale.

i. There were no records indicating licensure of drug distributors were queried prior to purchase.

ii. RN Cantrell stated the following were drug distributors R&R Wellness purchased drugs from: Allergan, Abbvie, Olympia, Revance, Merz, SKNV and "the CARE Group."

e. The facility stored expired and adulterated drugs on site.

i. Board inspectors observed multiple expired products comingled with the active drug stock. The drugs were not segregated as required.

1. Expiration dates included: September 2023, July 2024, May 2024, February 2024 and November 2023.

f. Drugs were stored longer than one year from the date of adulteration or expiration.

i. Drugs from 2023 and February 2024 were observed.

g. The TDDD accepted occasional drug transfers from entities that are not permitted to conduct occasional sales or transfers. These "medical spas" are not licensed drug distributors in Ohio.

i. R&R Wellness purchased Olympia products from a med spa located in Indiana.

ii. RN Cantrell stated R&R Wellness purchased "Liporase" from a med spa in Ohio that ceased their dangerous drugs services.

h. The refrigerators where drugs are stored does not comply with the Ohio Administrative Code.

i. Board inspectors observed temperature logs for January 2025 to present. Several dates did not have the temperature documented.

ii. The weight loss drugs were stored in a refrigerator containing food and beverages.

i. Multi-dose vials are not properly labeled with a beyond-use-date (BUD) or date of puncture.

i. Board inspectors observed 13 multi-dose vials that had been opened but did not include a date of puncture or BUD. These vials must be destroyed.

j. Records of drug receipt did not contain required information.

i. Records from the drug distributors did not contain the date of receipt.

k. R&R Wellness did not have records of drug receipt for dangerous drugs for the following drugs, as described by RN Cantrell:

i. Ketorolac, a dangerous drug, purchased from "STAT DDS," not a drug wholesaler (or entity) licensed with the Board.

ii. Dangerous drugs purchased from "She's So Pretty," which RN Cantrell stated discontinued services for dangerous drugs and sold to R&R Wellness. "She's So Pretty" is not a drug wholesaler (or entity) licensed with the Board and was not able to be found upon investigation by Board inspectors.

iii. Botox, a dangerous drug, purchased from "a dentist associated with 'CARE Group' in the Bay Area in California."

l. All records are not readily retrievable and kept on-site for at least three years.

i. RN Cantrell stated temperature logs are maintained at her personal residence.

m. Compounding of non-hazardous drugs is performed and administered without prescriber oversight.

i. R&R Wellness compounds and administers IV hydration, including Olympia products Reboot and B-Lean. Both products are compounded by an RN, but the compounding/administration is not overseen by a prescriber.

n. The required documentation of non-hazardous compounding (by a prescriber) was not observed; the Responsible Person was not overseeing the requirements.

o. A Registered Nurse compounds and administers the compounded preparations, but there is no final or visual check of the drugs by a prescriber prior to the drug being administered.

p. The compounding of immediate-use, sterile non-hazardous drugs involved the transfer of more than three commercially available manufactured packages.

i. The Olympia kits stored by the R&R Wellness involve the addition of three or more vial contents into one IV bag. This exceeds Ohio rule.

5. On or about March 17, 2025, the Board received confirmation from Abbvie, the drug distributor of the Botox seized during the inspection, that the Botox is counterfeit.

    a. Note: In addition to confirming the Botox was counterfeit, the drug distributor provided records confirming R&R Wellness made one purchase of Botox manufactured by Allergan and sold by Abbvie on January 31, 2024. No other purchases of Botox have been made under R&R Wellness' TDDD number.

6. On or about March 17, 2025, the Board confirmed that the seven vials of Liporase are not FDA-approved and are, therefore, adulterated and illegal to distribute into/within the United States.

7. On or about March 20, 2025, a Board Specialist spoke with Nicole Walker, Physician Assistant (PA). PA Walker stated the following about a February 8, 2025 meeting with RN Cantrell:

    a. On or about February 8, 2025, Nicole Walker, PA, who is employed by another medical spa looking for additional space for its services, visited R&R Wellness. PA Walker was given a tour of R&R Wellness by Patty Cantrell. During the tour, RN Cantrell showed PA Walker the contents of the medication storage cabinet and refrigerator where medication is stored.

    b. PA Walker saw approximately 8-10 boxes of Botox in the medication refrigerator, as well as a partial vial of Botox that was in use.

    c. PA Walker was in a room with RN Cantrell where a patient was being treated, so she only had a brief glance at the drug stock, but during that time she noted the Botox vial looked "weird." A patient was present, so she quietly asked RN Cantrell where the product came from.

    d. PA Walker stated that once she expressed her concern to RN Cantrell regarding the appearance of the vial, RN Cantrell asked how or why PA Walker was concerned.

    e. PA Walker told RN Cantrell that, in her experience, Botox vials look different (than the vial(s) she saw at R&R Wellness).

    f. PA Walker asked RN Cantrell who R&R Wellness' Allergan drug representative was. RN Cantrell stated they didn't have one.

    g. Note: when PA Walker was speaking to the Board Specialist, she stated that the Botox vial did not look like vials she was used to seeing.

8. During the March 20, 2025 conversation with the Board Specialist, PA Walker stated the following about Botox she observed at Choosi Aesthetics, a Board licensed medical spa:

    a. On March 10, 2025, staff at Choosi Aesthetics realized Botox had not been ordered and the clinic did not have enough Botox to treat the patients for the day. Choosi staff asked to borrow two vials of Botox from R&R Wellness and let R&R Wellness know they would replace the Botox vials on March 11, 2025.

b. A staff member from Choosi Aesthetics picked up the two vials of Botox from R&R Wellness and brought them back to Choosi Aesthetics.

c. PA Walker was present at Choosi Aesthetics that day. She observed the two vials of Botox at Choosi Aesthetics and believed they were not real Botox.

d. One of the vials of Botox had writing on the label which was later determined to be Turkish, and the other label was in English.

e. PA Walker reached out to Allergan (the manufacturer of the Botox) and asked Allergan to confirm whether the vials were real.

f. Within approximately 30 minutes Allergan confirmed the Botox vials were counterfeit.

g. The Responsible Person and Medical Director of Choosi Aesthetics, Dr. Tiffany Hall, was notified of the counterfeit Botox vials from R&R Wellness. (Note: Dr. Hall, also the Acting Responsible Person of R&R Wellness, resigned from her position at R&R Wellness later that day).

9. On or about March 20, 2025, Board inspectors conducted a follow-up inspection at R&R Wellness to evaluate drug stock that was supposed to be transferred from the unlicensed location in Franklin, Ohio to R&R Wellness (Maineville). Board inspectors spoke with RN Cantrell, during the inspection. The following was discovered:

   a. A Board inspector observed a counterfeit vial of unopened Botox. RN Cantrell stated she brought the vial from the Franklin location, as she was instructed to do on March 14, 2025.

   b. RN Cantrell estimated she began ordering Botox from the California dentist's buying group in approximately September or October 2024.

   c. When she began purchasing from California, she ceased purchasing from Allergan (the legitimate Botox).

   d. She repeatedly stated she had no knowledge the drugs were counterfeit.

   e. RN Cantrell stated the dentist's name and explained he was part of a buying group called "CARE." The group buys in bulk to decrease cost per vial.

   f. She stated Botox normally costs $600-700 per vial if purchased through Allergan, but through the dentist, she paid $275-350 per vial.

   g. RN Cantrell said now that she knows the drugs are counterfeit, the significant cost savings is suspicious.

   h. She paid for the counterfeit Botox through Venmo.

   i. She estimated 20 vials were purchased from the dentist.

j. She destroyed the counterfeit Botox once notified by Dr. Hall, the former Responsible Person, it was counterfeit.

k. She estimated she destroyed approximately 12 vials at her house; her husband who is not a licensed healthcare professional, witnessed the destruction.

10. On March 20, 2025, the two counterfeit vials of Botox, one label written in Turkish and one label written in English, were seized from Choosi Aesthetics. These were the vials transferred to Choosi Aesthetics from R&R Wellness on or about March 10, 2025.

POTENTIAL VIOLATIONS OF LAW

1. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of section 3715.52 of the ORC, prohibited acts, each, a misdemeanor of the fourth degree, each punishable by a maximum penalty of $2,000 if committed by an organization: The following acts and causing them are prohibited:

   a. The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated[1] or misbranded,[2] ORC Section 3715.52(A)(1); and/or

[1] ORC Section 3715.63 states: A drug or device is adulterated within the meaning of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, if any of the following apply:
1. It consists, in whole or in part, of any filthy, putrid, or decomposed substance, ORC Section 3715.63(A)(1); and/or
2. It has been produced, processed, prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health, ORC Section 3715.63(A)(2); and/or
3. It is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health, ORC Section 3715.63(A)(3); and/or
4. It purports to be or is represented as a drug the name of which is recognized in the United States pharmacopoeia and national formulary, or any supplement to them, and its strength differs from or its quality or purity falls below the standard set forth in those compendiums. A determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in the compendiums, or in the absence or inadequacy of such tests or methods of assay, those prescribed under the authority of the "Federal Food, Drug, and Cosmetic Act." A drug recognized in the compendiums is not adulterated under this division because it differs from the standard of strength, quality, or purity set forth for that drug in the compendiums, if the difference in strength, quality, or purity is plainly stated on its label. Whenever a drug is recognized in both the homoeopathic pharmacopoeia of the United States and in the United States pharmacopoeia and national formulary, including their supplements, it shall be subject to the requirements of the United States pharmacopoeia and national formulary unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the homoeopathic pharmacopoeia of the United States and not to those of the United States pharmacopoeia and national formulary, ORC Section 3715.63(A)(5); and/or
5. It is not subject to the provisions of division (A)(5) of this section, and its strength differs from or its purity or quality falls below that which it purports or is represented to possess, ORC Section 3715.63(A)(6).

[2] ORC Section 3715.64 states: A drug or device is misbranded within the meaning of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, if:
1. Its labeling is false or misleading in any particular, ORC Section 3715.64(A)(1); and/or
2. It is in package form and does not bear a label containing both of the following:

b. The adulteration or misbranding of any food, drug, device, or cosmetic, ORC Section 3715.52(A)(2); and/or

c. The receipt in commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise, ORC Section 3715.52(A)(3); and/or

d. The sale, delivery for sale, holding for sale, or offering for sale of any article in violation of section 3715.61 or 3715.65 of the Revised Code, ORC Section 3715.52(A)(4); and/or

e. The dissemination of any false advertisement, ORC Section 3715.52(A)(5).

2. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of section 3715.68(A) of the ORC, An advertisement of food, drug, device, or cosmetic is false if it is false or misleading in any particular, each violation punishable by a maximum penalty of $1,000 if committed by an organization.

3. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.51(F) of the ORC, effective September 29, 2017 and April 6, 2017, No licensed terminal distributor of dangerous drugs or person that is exempt from licensure under section 4729.541 of the Revised Code shall purchase dangerous drugs or investigational drugs or products from any person other than a licensed manufacturer, outsourcing facility, third-party logistics provider, repackager, or wholesale distributor, each violation is a misdemeanor of the first degree, each violation punishable by a maximum penalty of $5,000 if committed by an organization.

4. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.51(A) of the ORC, effective October 3, 2023, No person other than a licensed manufacturer of dangerous drugs, outsourcing facility, third-party logistics provider, repackager of dangerous drugs, or wholesale distributor of dangerous drugs shall possess for sale, sell, distribute, or deliver, at wholesale, dangerous drugs or investigational drugs or products, each violation is a misdemeanor of the first degree, each violation punishable by a maximum penalty of $5,000 if committed by an organization.

5. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.51(G) of the ORC, effective October 3, 2023, No licensed terminal distributor of dangerous drugs shall engage in the retail sale or other distribution of dangerous drugs or

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a. In clearly legible form, the name and place of business of the manufacturer, packer, or distributor, ORC Section 3715.64(A)(2)(a); and/or
3. Any word, statement, or other information that is required by or under authority of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code to appear on the label or labeling is not prominently placed on the label or labeling in a conspicuous manner, as compared with other words, statements, designs, or devices on the label or labeling, and in terms that render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use, ORC Section 3715.64(A)(5); and/or
4. It is an imitation of another drug, ORC Section 3715.64(A)(10)(b); and/or
5. It is offered for sale under the name of another drug, ORC Section 3715.64(A)(10)(c).

investigational drugs or products or maintain possession, custody, or control of dangerous drugs or investigational drugs or products for any purpose other than the distributor's personal use or consumption, at any establishment or place other than that or those described in the license issued by the state board of pharmacy to such terminal distributor, each violation is a misdemeanor of the first degree, each violation punishable by a maximum penalty of $5,000 if committed by an organization.

6. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-3-09 of the OAC, as effective May 27, 2023, each violation punishable by a maximum penalty of $1,000:

    a. The term "occasional sale" as used in section 4729.51 of the Revised Code means a wholesale sale of a commercially manufactured dangerous drug to a person licensed in accordance with section 4729.52 of the Revised Code, terminal distributor of dangerous drugs or any entity or person exempted from licensure as a terminal distributor of dangerous drugs by any of the following: A licensed terminal distributor of dangerous drugs that is not a pharmacy, but only as authorized in section 4729.51 of the Revised Code, OAC Rule 4729:5-3-09(A)(2); and/or

    b. A licensed terminal distributor of dangerous drugs having more than one licensed location may transfer or deliver dangerous drugs from one licensed location to another licensed location owned by that terminal distributor if the license issued for each location is in effect at the time of the transfer or delivery. Such transfer or delivery includes either of the following: Intracompany sales, which includes any transaction or transfer between any division, subsidiary, parent or affiliated or related company under the common ownership and control, OAC Rule 4729:5-3-09(E)(1).

7. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.60(B) of the ORC, Before a licensed terminal distributor of dangerous drugs may purchase dangerous drugs at wholesale, the terminal distributor shall query the roster established pursuant to section 4729.59 of the Revised Code to confirm the seller is licensed to engage in the sale or distribution of dangerous drugs at wholesale, each violation punishable by a maximum penalty of $1,000 if committed by an organization.

8. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-3-04 of the OAC, as effective March 1, 2019, each violation punishable by a maximum penalty of $1,000:

    a. Before a terminal distributor of dangerous drugs may purchase dangerous drugs at wholesale, the terminal distributor shall query the board's online roster (available on the board's website: www.pharmacy.ohio.gov) to confirm any of the following:

        i. The seller is licensed to engage in the sale of dangerous drugs in accordance with section 4729.52 of the Revised Code, OAC Rule 4729:5-3-04(A)(1); and/or

ii. The seller is licensed to engage in the occasional sale or distribution of dangerous drugs at wholesale in accordance with rule 4729:5-3-09 of the Administrative Code, OAC Rule 4729:5-3-04(A)(2); and/or

b. If no documented query is conducted before a purchase is made, it shall be presumed that the purchase of dangerous drugs by the terminal distributor is in violation of section 4729.51 of the Revised Code, OAC Rule 4729:5-3-04(B).

9. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-2-01 of the OAC, as effective April 25, 2022, each violation punishable by a maximum penalty of $1,000:

a. A location licensed as a terminal distributor of dangerous drugs must have a responsible person at all times, OAC Rule 4729:5-2-01(E)(1); and/or

b. When there is a change of responsible person, the state board of pharmacy shall be notified within ten days of the effective date of the appointment of the new responsible person in a manner determined by the board. For a limited terminal distributor of dangerous drugs license, the notification shall include a drug list required in accordance with agency 4729 of the Administrative Code, OAC Rule 4729:5-2-01(E)(2); and/or

c. A complete inventory, pursuant to 21 CFR 1304.11 of the Code of Federal Regulations (9/9/2014) and rule 4729:5-3-07 of the Administrative Code, shall be taken of the controlled substances on hand by the new responsible person on the effective date of the change of responsible person. The new responsible person shall be responsible for completing and maintaining this inventory record at the location licensed as a terminal distributor of dangerous drugs, OAC Rule 4729:5-2-01(E)(3); and/or

d. 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

e. A responsible person must be physically present at the location for a sufficient amount of time to provide supervision and control of dangerous drugs on-site, OAC Rule 4729:5-2-01(E)(5); and/or

f. 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).

10. Such conduct as set forth in Allegations Section, if proven, constitutes a violation of each of the following divisions of Section 4729.55 of the ORC, as effective October 3, 2023, TDDD license requirements, each violation punishable by a maximum penalty of $1,000:

a. A… licensed health professional authorized to prescribe drugs… 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); and/or

b. Adequate safeguards are assured to prevent the sale or other distribution of dangerous drugs by any person other than a pharmacist or licensed health professional authorized to prescribe drugs, ORC 4729.55(C).

11. 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 April 4, 2023, 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. Falsely or fraudulently promoting to the public a dangerous drug, except that nothing in this division prohibits a terminal distributor of dangerous drugs from furnishing information concerning a dangerous drug to a health care provider or another licensed terminal distributor; ORC Section 4729.57(B)(6); and/or

    e. 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

    f. 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).

12. 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. Falsely or fraudulently promoting to the public a dangerous drug, except that nothing in this rule prohibits a terminal distributor of dangerous drugs from furnishing information concerning a dangerous drug to a health care provider or another licensed terminal distributor, OAC Rule 4729:5-4-01(B)(6); and/or

e. 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

f. Commission of an act that constitutes a misdemeanor that is related to, or committed in, the person's professional practice, OAC Rule 4729:5-4-01(B)(18); and/or

g. 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).

13. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-5-24 of the OAC, as effective August 19, 2022, each violation punishable by a maximum penalty of $1,000:

    a. Records of receipt shall contain the name, strength, dosage form, and quantity of the dangerous drugs received, the name and address of the seller, the name and address of the recipient, and the date of receipt, OAC Rule 4729:5-5-24(A); and/or

    b. Records of dangerous drugs disposed from inventory, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug disposed, the date of disposal, the method of disposal, and the positive identification of the licensed or registered health care professional that performed the disposal, OAC Rule 4729:5-5-24(C); and/or

    c. All records maintained in accordance with this chapter shall be readily retrievable and uniformly maintained for a period of three years, OAC Rule 4729:5-5-24(G).

14. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:7-3-03 of the OAC, as effective March 31, 2021, each violation punishable by a maximum penalty of $1,000:

    a. Except as provided in paragraph (L) of this rule, all non-hazardous, non-sterile compounded drug preparations shall be prepared in accordance with United States pharmacopeia chapter <795>, OAC Rule 4729:7-3-03(A); and/or

    b. Except as provided in paragraph (C) of this rule, all non-hazardous, sterile compounded drug preparations, shall be prepared in accordance with United States pharmacopeia chapter <797>, OAC Rule 4729:7-3-03(B); and/or

    c. For all immediate-use, non-hazardous sterile compounded drug preparations, a prescriber shall comply with either:

        i. Rule 4729:7-3-04 of the Administrative Code, OAC Rule 4729:7-3-03(C)(1); or

        ii. United States pharmacopeia chapter <797>, OAC Rule 4729:7-3-03(C)(2); and/or

    d. For all hazardous non-sterile and sterile compounded drug preparations, a prescriber shall comply with rule 4729:7-3-05 of the Administrative Code, OAC Rule 4729:7-3-03(D); and/or

e. The responsible person of a facility where a prescriber is engaged in the compounding of dangerous drugs shall be responsible for all of the following:

i. Developing and implementing appropriate compounding procedures, OAC Rule 4729:7-3-03(E)(1); and/or

ii. Overseeing facility compliance with this rule, OAC Rule 4729:7-3-03(E)(2); and/or

iii. Compliance with Title 21 U.S. Code section 353a (November 27, 2013) and all other applicable federal and state laws, regulations and rules, OAC Rule 4729:7-3-03(E)(3); and/or

iv. Ensuring documented training and competency of compounding personnel, OAC Rule 4729:7-3-03(E)(4); and/or

v. Ensuring environmental control of the compounding areas, OAC Rule 4729:7-3-03(E)(5); and/or

vi. Ensuring compounded drug preparations maintain quality and sterility until administered or personally furnished, OAC Rule 4729:7-3-03(E)(6); and/or

vii. Maintaining drug compounding records pursuant to rule 4729:7-3-06 of the Administrative Code, OAC Rule 4729:7-3-03(E)(7); and/or

viii. The proper maintenance, cleanliness, and use of all equipment used in compounding, OAC Rule 4729:7-3-03(E)(8); and/or

ix. Ensuring aseptic technique for the preparation of all sterile compounded drugs, OAC Rule 4729:7-3-03(E)(9); and/or

f. A prescriber may designate an appropriately trained agent to prepare compounded drug preparations, OAC Rule 4729:7-3-03(F); and/or

g. For all compounded drugs prepared pursuant to this rule, a prescriber shall:

i. Inspect and approve the compounding process, OAC Rule 4729:7-3-03(G)(1); and

ii. Except as provided in paragraph (H) of this rule, perform medication validation ("final check") prior to the medication being administered, OAC Rule 4729:7-3-03(G)(2); and/or

h. All the following are required to administer a compounded drug preparation in accordance with paragraphs (H)(1) and (H)(2) of this rule:

i. Verify the accuracy of:

1. Drug name, OAC Rule 4729:7-3-03(I)(3)(a); and/or

2. Drug strength and dosage form, OAC Rule 4729:7-3-03(I)(3)(b); and/or

3. Drug volume, OAC Rule 4729:7-3-03(I)(3)(c); and/or

4. Rate of administration, OAC Rule 4729:7-3-03(I)(3)(d); and/or

5. Route of administration, OAC Rule 4729:7-3-03(I)(3)(e); and/or

6. Expiration dates/times, OAC Rule 4729:7-3-03(I)(3)(f); and/or

7. Appearance and physical integrity of the drugs, OAC Rule 4729:7-3-03(I)(3)(g); and/or

ii. Indicate in the compounding record verification was completed, OAC Rule 4729:7-3-03(I)(4); and/or

iii. A licensed prescriber is on-site and immediately available, OAC Rule 4729:7-3-03(I)(5).

15. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:7-3-04 of the OAC, as effective April 2, 2021, each violation punishable by a maximum penalty of $1,000:

a. The responsible person of a facility where a prescriber is engaged in the compounding of immediate-use, sterile non-hazardous dangerous drug preparations in accordance with paragraph (B) of this rule shall be responsible for all the following:

i. Developing and implementing appropriate compounding procedures, OAC Rule 4729:7-3-04(A)(1); and/or

ii. Overseeing facility compliance with this rule, OAC Rule 4729:7-3-04(A)(2); and/or

iii. Compliance with Title 21 U.S.C. section 353a (11/27/2013) and all other applicable federal and state laws, regulations and rules, OAC Rule 4729:7-3-04(A)(3); and/or

iv. Ensuring training and competency of compounding personnel, OAC Rule 4729:7-3-04(A)(4); and/or

v. Ensuring that compounded drug preparations maintain quality and sterility until administered, OAC Rule 4729:7-3-04(A)(5); and/or

vi. Maintaining drug compounding records pursuant to rule 4729:7-3-06 of the Administrative Code, OAC Rule 4729:7-3-04(A)(6); and/or

vii. The proper maintenance, cleanliness, and use of all equipment used in compounding, OAC Rule 4729:7-3-04(A)(7); and/or

viii. Ensuring aseptic technique for the preparation of all sterile compounded drugs, OAC Rule 4729:7-3-04(A)(8); and/or

b. Immediate-use, sterile compounded drug preparations are exempt from the requirements in rule 4729:7-3-03 of the Administrative Code if all the following criteria are met:

i. The compounding process involves the simple transfer of not more than three commercially manufactured packages of sterile, non-hazardous drugs from the manufacturers' original containers and not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device, OAC Rule 4729:7-3-04(B)(1); and/or

c. Preparations that do not meet all the requirements listed in paragraph (B) of this rule shall comply with the requirements in rule 4729:7-3-03 of the Administrative Code, OAC Rule 4729:7-3-04(E); and/or

d. Immediate-use compounded drug preparations shall be prepared in accordance with this rule except in an emergency, as documented in the medical record, when the product is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, OAC Rule 4729:7-3-04(F); and/or

e. For all compounded drugs prepared pursuant to this rule, a prescriber shall:

i. Inspect and approve the compounding process, OAC Rule 4729:7-3-04(L)(1); and

ii. Except as provided in paragraph (M) of this rule, perform medication validation ("final check") prior to the medication being administered, OAC Rule 4729:7-3-04(L)(2); and/or

f. The requirements of paragraph (M)(2) of this rule do not apply to either of the following:

i. A compounded drug preparation is being administered to a patient in the facility by a nurse licensed under Chapter 4723. of the Revised Code pursuant to a prescriber's order and, prior to administration, at least two nurses that are approved by the responsible person to prepare or administer compounded drugs comply with the requirements in paragraph (N) of this rule, OAC Rule 4729:7-3-04(M)(1); or

ii. A compounded drug preparation is prepared and administered to a patient in the facility by a nurse licensed under Chapter 4723. of the Revised Code pursuant to a prescriber's order and, prior to administration, the same nurse complies with paragraph (N) of this rule, OAC Rule 4729:7-3-04(M)(2); and/or

g. All the following are required to administer a compounded drug preparation in accordance with paragraphs (M)(1) and (M)(2) of this rule:

i. Verify the accuracy of:

1. Drug strength and dosage form, OAC Rule 4729:7-3-04(N)(3)(b); and

2. Expiration dates/times, OAC Rule 4729:7-3-04(N)(3)(f); and/or

3. Appearance and physical integrity of the drugs, OAC Rule 4729:7-3-04(N)(3)(g); and/or

ii. Indicate in the compounding record verification was completed, OAC Rule 4729:7-3-04(N)(4); and/or

iii. A licensed prescriber is on-site and immediately available, OAC Rule 4729:7-3-04(N)(5).

16. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-3-07 of the OAC, as effective March 1, 2019, each violation punishable by a maximum penalty of $1,000:

a. Unless otherwise stated in this division of the Administrative Code, all category III terminal distributor licensees shall complete a controlled substances inventory in accordance with 21 CFR 1304.11 (9/9/2014), OAC Rule 4729:5-3-07(A); and/or

b. All controlled substance inventories performed in accordance with this rule shall be conducted on an annual basis. The annual inventory may be taken on any date which is within thirteen months of the previous inventory date, OAC Rule 4729:5-3-07(B); and/or

c. The terminal distributor's responsible person shall be responsible for completing and maintaining this inventory record at the location licensed as a terminal distributor of dangerous drugs, OAC Rule 4729:5-3-07(C); and/or

d. All inventory records shall be maintained for a period of three years from the completion date of the inventory and made readily retrievable, OAC Rule 4729:5-3-07(D); and/or

e. When a drug or compound is added to the schedule of controlled substances by state or federal law, rule or regulation, a terminal distributor shall complete an inventory pursuant to this rule of all stocks of such drug or compound no later than ten days of the drug or compound being added to the schedule, OAC Rule 4729:5-3-07(E); and/or

f. In the event a terminal distributor of dangerous drugs commences business with no controlled substances on hand, this fact shall be recorded as the initial inventory, OAC Rule 4729:5-3-07(F).

17. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-3-06 of the OAC, as effective July 1, 2024, each violation punishable by a maximum penalty of $1,000:

a. 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.

i. Adulterated drugs shall be stored no longer than one year from the date of adulteration or expiration by those holding a terminal distributor of dangerous drugs license. Adulterated drugs shall be stored in a manner that prohibits access by unauthorized persons, OAC Rule 4729:5-3-06(A); and/or

ii. Dangerous drugs, other than controlled substances, may be destroyed utilizing proper methods of disposal and following the record keeping requirements noted in agency 4729 of the Administrative Code, or may be donated to a pharmacy school pursuant to sections 3715.88 to 3715.92 of the Revised Code. Methods of disposal of non-controlled dangerous drugs shall prevent the possession or use of the drugs by unauthorized persons, OAC Rule 4729:5-3-06(B).

18. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-3-14(A) of the OAC, as effective March 1, 2020, each violation punishable by a maximum penalty of $1,000: All terminal distributors of dangerous drugs shall provide effective controls and procedures to:

    a. Deter and detect the theft and diversion of dangerous drugs, OAC Rule 4729:5-3-14(A)(1); and/or

    b. Ensure supervision and control of dangerous drugs, as required in division (B) of section 4729.55 of the Revised Code, and adequate safeguards to ensure that dangerous drugs are being distributed in accordance with all state and federal laws, as required in section 4729.55 of the Revised Code, OAC Rule 4729:5-3-14(A)(2).

19. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-19-03 of the OAC, as effective February 4, 2021, each violation punishable by a maximum penalty of $1,000:

    a. All areas where dangerous drugs and devices are stored shall be dry, well-lit, well-ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures and conditions which will ensure the integrity of the drugs prior to use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling. Refrigerators and freezers used for the storage of drugs and devices shall comply with the following:

        i. Maintain either of the following to ensure proper refrigeration and/or freezer temperatures are maintained:

            1. Temperature logs with, at a minimum, daily observations, OAC Rule 4729:5-19-03(K)(1)(a); or

            2. A temperature monitoring system capable of detecting and alerting staff of a temperature excursion, OAC Rule 4729:5-19-03(K)(1)(b); and/or

        ii. 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, OAC Rule 4729:5-19-03(K)(2); and/or

iii. The terminal distributor shall develop and implement a policy that no food or beverage products are permitted to be stored in refrigerators or freezers used to store drugs, OAC Rule 4729:5-19-03(K)(3); and/or

b. Upon the initial puncture of a multiple-dose vial containing a drug, the vial shall be labeled with a beyond-use date or date opened. The beyond-use date for an opened or entered (e.g., needle punctured) multiple-dose container with antimicrobial preservatives is twenty-eight days, unless otherwise specified by the manufacturer. A multiple-dose vial that exceeds its beyond-use date shall be deemed adulterated, OAC Rule 4729:5-19-03(L); and/or

c. 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); and/or

d. Disposal of non-controlled dangerous drugs shall be conducted in accordance with rule 4729:5-3-06 of the Administrative Code, OAC Rule 4729:5-19-03(O).

20. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-19-04 of the OAC, as effective February 4, 2021, each violation punishable by a maximum penalty of $1,000:

a. A clinic or prescriber office shall keep a record of all dangerous drugs received, administered, personally furnished, disposed, sold or transferred, OAC Rule 4729:5-19-04(A); and/or

b. Records of receipt shall contain the name, strength, dosage form, and quantity of the dangerous drugs received, the name and address of the seller, the name and address of the recipient, and the date of receipt. An invoice from a drug distributor licensed in accordance with division 4729:6 of the Administrative Code containing the required information may be used to meet this requirement, OAC Rule 4729:5-19-04(B); and/or

c. Records of temperature control monitoring described in paragraph (K)(1) of rule 4729:5-19-03 of the Administrative Code shall include any of the following:

i. For temperature logs, either:

1. The date and time of observation, the full name or the initials of the individual performing the check, and the temperature recorded, OAC Rule 4729:5-19-04(C)(1)(a); and/or

2. For systems that provide automated temperature monitoring, maintain a report that provides, at a minimum, the date and time of observation and the temperature recorded, OAC Rule 4729:5-19-04(C)(1)(b); and/or

ii. For temperature monitoring systems capable of detecting and alerting staff of a temperature excursion, maintain reports that provide information on any temperature excursion that includes the date, time, temperature recorded, and length of each excursion, OAC Rule 4729:5-19-04(C)(2); and/or

d. Records of disposal of dangerous drugs from inventory, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug disposed, the date of disposal, the method of disposal, and the identification of the licensed health care professional that performed the disposal, OAC Rule 4729:5-19-04(F); and/or

e. Records of transfer or sale conducted in accordance with rule 4729:5-3-09 of the Administrative Code shall contain the name, strength, dosage form, national drug code, expiration date and quantity of the dangerous drug transferred or sold, the address of the location where the drugs were transferred or sold, and the date of transfer or sale, OAC Rule 4729:5-19-04(H).

f. All records maintained in accordance with this rule and rule 4729:5-19-03 of the Administrative Code shall be readily retrievable and shall be kept on-site for a period of three years.

   i. A terminal distributor intending to maintain records at a location other than the location licensed by the state board of pharmacy must notify the board in a manner determined by the board, OAC Rule 4729:5-19-04(J)(1); and/or

   ii. Any such alternate location shall be secured and accessible only to authorized representatives or contractors of the terminal distributor of dangerous drugs, OAC Rule 4729:5-19-04(J)(2).

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 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 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 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 OHIO BOARD OF PHARMACY

Steven W. Schierholt, Esq., Executive Director

SWS/alg/kll

cc: Melinda Snyder, State Medical Board of Ohio, at: Melinda.Snyder@med.ohio.gov
David Geiger, Ohio Board of Nursing, at: david.geiger@nursing.ohio.gov