STATE OF OHIO
BOARD OF PHARMACY

**IN THE MATTER OF:**

**CASE No. A-2019-0260**

**The Nord Center Pharmacy**
c/o Jesse M. McDonald, R.Ph.
6140 S. Broadway
Lorain, OH 44053

**License No. 02-2397550**

June 9, 2021

**SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY**

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and The Nord Center Pharmacy, for the purpose of resolving all issues between the parties relating to the Board investigation of the illegal transfer of dangerous drugs. Together, the Board and The Nord Center Pharmacy are referred to hereinafter as "the parties."

**JURISDICTION**

1. Pursuant to Section 4729.57 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, or refuse to grant or renew any license issued pursuant to Section 4729.54 of the Ohio Revised Code.

2. The Nord Center Pharmacy is a licensed Terminal Distributor of Dangerous Drugs under license number 02-2397550.

**FACTS**

1. On or about December 19, 2018, the Board initiated an investigation of The Nord Center Pharmacy, Terminal Distributor of Dangerous Drugs license number 02-2397550.

2. On or about April 12, 2021, the Board sent a Notice of Opportunity for Hearing to The Nord Center Pharmacy, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

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

## TERMS

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

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. The Nord Center Pharmacy neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated April 12, 2021; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. The Nord Center Pharmacy agrees to pay to the Board a monetary penalty in the amount of $4,000.00. This fine will be attached to your license record and must be paid no later than 30 days from the effective date of this Settlement Agreement. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.

4. The Nord Center Pharmacy agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

5. The Nord Center Pharmacy agrees to comply with all federal and state requirements related to Terminal Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by The Nord Center Pharmacy of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to The Nord Center Pharmacy by the Board and will NOT discharge The Nord Center Pharmacy from any obligation under the terms of this Agreement.

6. The Nord Center Pharmacy agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

7. The Nord Center Pharmacy understands that it has the right to be represented by counsel for review and execution of this agreement.

8. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom The Nord Center Pharmacy will operate.

9. The Nord Center Pharmacy waives its opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and waives any right to appeal.

10. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

11. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

12. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

13. This Agreement shall become effective upon the date of the Board President's signature below.

*[SIGNATURE PAGE FOLLOWS]*

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:

Don Schiffbauer, CEO
The Nord Center Pharmacy

6/23/21
Date of Signature

David Schweighofer per/jw
Attorney for Respondent (if applicable)

6-23-21
Date of Signature

DRMiller

Donald R. Miller
~~Jennifer M. Rudell~~, R.Ph., President
State of Ohio Board of Pharmacy

07.09.2021
Date of Signature

Henry Appel, Ohio Assistant Attorney General

07.09.2021
Date of Signature

STATE OF OHIO BOARD OF PHARMACY

-THIS IS A RED INK STAMP-
I certify this to be a true and exact copy of the original document on file with the Ohio State Board of Pharmacy.
Steven W. Schierholt, Esq., Executive Dir.
Date: 04/12/2021
-MUST HAVE BOARD SEAL TO BE OFFICIAL-

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

**IN THE MATTER OF:** **CASE No. A-2019-0260**

**Nord Center Pharmacy** **License No. 02-2397550**
c/o Jesse M. McDonald, R.Ph.
6140 S. Broadway
Lorain, OH 45417

April 12, 2021

Dear Nord Center Pharmacy and Jesse M. McDonald, R.Ph.:

**You are hereby notified, in accordance with the provisions of Section 119.07 of the Ohio Revised Code the State of Ohio Board of Pharmacy (Board) proposes to take action against your license as a Terminal Distributor of Dangerous Drugs (TDDD) under authority of Section 4729.57 of the Revised Code.**

**JURISDICTION**

1. Pursuant to section 4729.57 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, or refuse to grant or renew any license issued pursuant to section 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. Nord Center Pharmacy has an active TDDD license with the Board under license number 02-2397550, which lists Jesse M. McDonald, R.Ph. as the Responsible Person.

**ALLEGATIONS**

1. On or about December 19, 2018, an inspection was conducted by the Board at Nord Center Pharmacy. During the inspection, a shelving unit of samples of dangerous drugs was discovered in the pharmacy. Samples of dangerous drugs were also discovered in the "Will Call" area of the pharmacy labeled to be dispensed. Two bottles of medications were found labeled "SAMPLE". There were also cards of samples missing tablets and sample bottles were found to be opened with pills missing. The samples included the following:

    a. Abilify Maintena 400mg and 10mg tablets.

b. Aristada Initio 675mg syringe.

c. Aristada 441mg, 662mg, and 882mg syringes.

d. Trinellex 5mg and 10 mg tablets.

e. Invega Sustenna 156mg and 234 mg syringes.

f. Invega 3mg and 6 mg tablets.

g. Ingrezza 40mg and 80mg tablets.

h. Latuda 20mg, 40mg, 60mg, 80mg, and 120 mg tablets.

i. Rexulti 2mg, 3mg, and 4mg tablets.

j. Rexulti 0.5mg/1mg and 1mg/2mg tablets.

k. Vrayler 1.5mg and 3mg tablets.

l. Viibryd 20mg and 40mg tablets.

2. On or about December 19, 2018, Jesse McDonald was interviewed by employees of the Board, instructed that the samples needed to be removed from the pharmacy by the end of the day, and requested to provide records of their return to the prescriber or destruction. You made the following statements:

    a. The samples maintained in the pharmacy were property of the doctors and nurse practitioners of the Nord Center.

    b. The perpetual inventory did not include the sample medications.

    c. The samples are labeled and dispensed like regular prescriptions, but the label says, “FREE Sample”.

    d. If a medication is not available in the pharmacy’s regular stock (pharmacy purchased) for a patient, but is available in sample stock, they will dispense the sample to the patient. The sample being dispensed is run through insurance like a regular (paid) prescription.

    e. When the regular stock medication (pharmacy purchased) comes into the pharmacy, it is placed on the sample shelving units to replace the sample.

    f. Bottles that were purchased to replace used sample medications are marked “SAMPLE”.

3. On or about January 31, 2019, employees of the Board went to Nord Center Pharmacy for a follow-up visit and to review records. The following was found:

    a. There were no records of samples found in the pharmacy except for the time-period from March 18, 2018 to December 18, 2018.

b. An employee stated that she had worked at Nord Center Pharmacy for two and a half years and the samples had been in the pharmacy the entire time she has been employed there.

c. Jesse McDonald stated there were times when a pharmaceutical sales representative would bring samples directly to the pharmacy and there is no record of these samples in the pharmacy.

d. There were discrepancies in the records provided for the samples returned to providers or destroyed. Jesse McDonald admitted there were inaccuracies, and that they were due to the records not being maintained properly. The discrepancies included the following:

    i. Abilify Maintena 400mg syringes, three additional syringes.

    ii. Abilify Maintena 10mg tablets, 14 additional tablets.

    iii. Aristada 882mg syringes, one additional syringe.

    iv. Invega Sustenna 234mg syringes, one syringe is unaccounted.

    v. Invega 3mg tablets, seven tablets unaccounted.

    vi. Invega 6mg tablets, two additional tablets.

    vii. Invega 9mg tablets, seven additional tablets.

    viii. Ingrezza 80mg tablets, seven tablets are unaccounted.

    ix. Ingrezza 40mg tablets, 48 additional tablets.

    x. Latuda 20mg tablets, 27 additional tablets.

    xi. Latuda 60mg tablets, 35 additional tablets.

    xii. Latuda 80mg tablets, 101 additional tablets.

    xiii. Latuda 120mg tablets, 28 additional tablets.

    xiv. Rexulti 0.5mg/1mg tablets, two tablets unaccounted.

    xv. Rexulti 1mg/2mg tablets, seven additional tablets.

    xvi. Vrayler 1.5mg tablets, 111 tablets unaccounted.

**POTENTIAL VIOLATIONS OF LAW**

1. Such conduct as set forth in paragraphs (1)(a), (1)(b), (1)(c), (1)(d), (1)(e), (1)(f), (1)(g), (1)(h), (1)(i), (1)(j), (1)(k), and (1)(l) of the Allegations Section, if proven, each constitutes a violation of Section 3719.81(B)(1) of the ORC, A person may furnish another a sample drug if the sample drug is furnished free of charge by a manufacturer, manufacturer's representative, or wholesale dealer in pharmaceuticals to a licensed health professional authorized to prescribe drugs, or is furnished free of charge by such a professional to a patient for use as medication, each violation is punishable by a maximum penalty of $1,000 if committed by an organization.

2. Such conduct as set forth in paragraphs (1)(a), (1)(b), (1)(c), (1)(d), (1)(e), (1)(f), (1)(g), (1)(h), (1)(i), (1)(j), (1)(k), and (1)(l) of the Allegations Section, if proven, each constitutes a violation of Section 3719.81(B)(2) of the ORC, A person may furnish another a sample drug if the sample drug is in the original container in which it was placed by the manufacturer, and the container is clearly marked as a sample, each violation is punishable by a maximum penalty of $1,000 if committed by an organization.

3. Such conduct as set forth in Allegations Section, if proven, constitutes a violation of each of the following divisions of Section 4729.57(B) of the ORC, as effective September 29, 2017, each violation punishable by a maximum penalty of $1,000 if committed by an organization:

    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. Violating any provision of the federal drug abuse control laws or Chapter 2925. Or 3719. Of the Revised Code, ORC Section 4729.57(B)(5).

4. Such conduct as set forth in paragraphs (2)(b), (3)(a), (3)(b), (3)(c), and (3)(d) of the Allegations Section, if proven, each constitutes a violation of the following section of Rule 4729-9-22(A) of the OAC, as effective March 1, 2017, each prescriber or terminal distributor of dangerous drugs shall keep a record of all dangerous drugs received, administered, dispensed, personally furnished, distributed, sold, destroyed, or used. The acts of prescribing, administering, dispensing, and destroying of a dangerous drug must be documented with the positive identification of the responsible individual pursuant to paragraph (N) of rule 4729-5-01 of the Administrative Code. These records may be kept electronically if the method is approved by the state board of pharmacy and the records are backed-up each business day, the records of receipt shall contain a description of all dangerous drugs received, the kind and quantity of dangerous drugs received, the name and address of the persons from whom received, and the date of receipt, each violation punishable by a maximum penalty of $1,000 if committed by an organization.

5. Such conduct as set forth in paragraphs (2)(b), (3)(a), (3)(b), (3)(c), and (3)(d) of the Allegations Section, if proven, each constitutes a violation of the following section of Rule 4729-9-22(C) of the OAC, as effective March 1, 2017, each prescriber or terminal distributor of dangerous drugs shall keep a record of all dangerous drugs received, administered, dispensed, personally furnished, distributed, sold, destroyed, or used. The acts of prescribing, administering, dispensing, and destroying of a dangerous drug must be documented with the positive identification of the responsible individual pursuant to paragraph (N) of rule 4729-5-01 of the Administrative Code. These records may be kept electronically if the method is

approved by the state board of pharmacy and the records are backed-up each business day, the records of dangerous drug destructions, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug destroyed, the date destroyed, the method of destruction, the positive identification of the prescriber or responsible person that performed the destruction, and if used the positive identification of the person that witnessed the destruction, each violation punishable by a maximum penalty of $1,000 if committed by an organization.

6. Such conduct as set forth in paragraphs (2)(b), (3)(a), (3)(b), (3)(c), and (3)(d) of the Allegations Section, if proven, each constitutes a violation of the following section of Rule 4729-9-22(E) of the OAC, as effective March 1, 2017, each prescriber or terminal distributor of dangerous drugs shall keep a record of all dangerous drugs received, administered, dispensed, personally furnished, distributed, sold, destroyed, or used. The acts of prescribing, administering, dispensing, and destroying of a dangerous drug must be documented with the positive identification of the responsible individual pursuant to paragraph (N) of rule 4729-5-01 of the Administrative Code. These records may be kept electronically if the method is approved by the state board of pharmacy and the records are backed-up each business day, all records of receipt, distribution, personally furnishing, administering, dispensing, selling, destroying, or using dangerous drugs shall be kept for a period of three years at the place where the dangerous drugs are located and upon request provided to a state board of pharmacy officer, agent, and/or inspector within three working days, excluding weekends and holidays, each violation punishable by a maximum penalty of $1,000 if committed by an organization.

7. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of Rule 4729-5-11(A)(3) of the OAC, as effective February 17, 2017, the person to whom the terminal distributor of dangerous drugs license has been issued and all pharmacists on duty are responsible for compliance with all state and federal laws, regulations, and rules governing the distribution of drugs and the practice of pharmacy, each violation is 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, constitutes a violation of Rule 4729-9-19(A)(4) of the OAC, as effective October 5, 2015, punishable by a maximum penalty of $1,000 if committed by an organization: Is not of good moral character and habits.

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

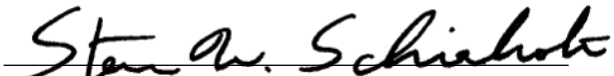
**IF YOU DESIRE A HEARING**, such request shall either be mailed to the State of Ohio Board of Pharmacy, Attn: Legal, 77 South High Street, 17th Floor, Columbus, Ohio 43215-6126 or an e-mail request may be sent to legal@pharmacy.ohio.gov (**please note faxes will not be accepted**). **YOUR REQUEST MUST BE RECEIVED ON OR PRIOR TO THE 30TH DAY FOLLOWING THE MAILING DATE OF THIS NOTICE.** Please note that if you submit a request via email, your request will be acknowledged within one business day of receipt. If you do not receive an acknowledgment, please contact the Board offices at 614-466-4143 and request the legal department. You may appear at such hearing in person, by your attorney, or by such other representative as is permitted to practice before the agency, or you may present your position, arguments or contentions in writing; and, at this hearing,

you may also present evidence and examine any witnesses appearing for and against you. **If you are a corporation, you must be represented at the hearing by an attorney licensed to practice in the state of Ohio.**

**YOU ARE FURTHER ADVISED that if there is no request for such a hearing received by the Board on or prior to the 30th day following the mailing of this notice, the State of Board of Pharmacy, upon consideration of the aforementioned allegations against you, may take action without such a hearing.**

**If you have questions regarding the Chapter 119. Administrative Hearing process, please e-mail your questions to legal@pharmacy.ohio.gov or call the Board office at 614-466-4143 and ask for the legal department.**

BY ORDER OF THE STATE BOARD OF PHARMACY



Steven W. Schierholt, Esq., Executive Director

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