



IN THE MATTER OF:

CASE No. A-2020-0193
I-2019-1418

Genoa Healthcare, LLC
c/o Krystina Hepler, RPh
726 Wick Avenue
Youngstown, Ohio 44505

License No. 02-2212100

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 Genoa Healthcare, LLC for the purpose of resolving all issues between the parties relating to the Board investigation of illegal sales of dangerous drugs, including controlled substances, to an unlicensed entity. Together, the Board and Genoa Healthcare, LLC 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. Genoa Healthcare, LLC is a licensed Terminal Distributor of Dangerous Drugs under license number 02-2212100.

FACTS

1. The Board initiated an investigation of Genoa Healthcare, LLC, Terminal Distributor of Dangerous Drugs license number 02-2212100, related to Genoa Healthcare, LLC's illegal sales of dangerous drugs, including controlled substances, to an unlicensed entity.
2. On or about February 23, 2021 the Board sent a Notice of Opportunity for Hearing to Genoa Healthcare, LLC, 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.

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

T: (614) 466.4143 | F: (614) 752.4836 | contact@pharmacy.ohio.gov | www.pharmacy.ohio.gov



TERMS

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

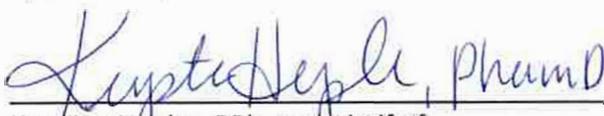
1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.
2. Genoa Healthcare, LLC neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated February 23, 2021; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.
3. Genoa Healthcare, LLC agrees to pay to the Board a monetary penalty the amount of \$250.00. This fine will be attached to your license record and must be paid no later than 30 days from the effective date of this Order. To pay this fine you must login to www.license.ohio.gov and process the items in your cart.
4. Genoa Healthcare, LLC 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. Genoa Healthcare, LLC 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 Genoa Healthcare, LLC 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 Genoa Healthcare, LLC by the Board and will NOT discharge Genoa Healthcare, LLC from any obligation under the terms of this Agreement.
6. Genoa Healthcare, LLC agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.
7. Genoa Healthcare, LLC 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 Genoa Healthcare, LLC will operate.

9. Genoa Healthcare, LLC waives its right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and waives any right to an appeal.
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.

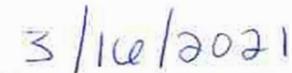
(SIGNATURE PAGE FOLLOWS)

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:



Krystina Hepler, RPh, on behalf of,
Genoa Healthcare, LLC, Respondent



Date of Signature

Attorney for Respondent (if applicable)



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



Date of Signature

03.23.2021

Date of Signature

03.23.2021

Henry Appel, Ohio Assistant Attorney General

Date of Signature



**STATE OF
OHIO**
BOARD OF PHARMACY

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

IN THE MATTER OF:

**CASE No. A-2020-0193
I-2019-1418**

Genoa Healthcare, LLC
c/o Krystina Hepler, RPh
726 Wick Avenue
Youngstown, Ohio 44505

License No. 02-2212100

February 23, 2021

Dear Genoa Healthcare, LLC and Krystina Hepler, RPh:

-THIS IS A RED INK STAMP-
I certify this to be a true and exact copy of
the original document on file with the
Ohio State Board of Pharmacy.

Steven W. Schierholt
Steven W. Schierholt, Esq., Executive Dir.
Date: 02/23/2021

MUST HAVE BOARD SEAL TO BE OFFICIAL

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 disciplinary action against your Terminal Distributor of Dangerous Drugs (TDDD) license(s) under authority of Section 4729.57 of the Revised Code.

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, 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. Genoa Healthcare, LLC has an active TDDD license with the Board under license number 02-2212100, which lists Krystina Hepler, RPh as the Responsible Person.

ALLEGATIONS

1. From on or about August 9, 2019 through on or about September 6, 2019, Genoa Healthcare, LLC, located at 726 Wick Avenue, Youngstown, Ohio, sold dangerous drugs, including controlled substances, to Neil Kennedy Recovery Center (NKRC), as set forth in Attachment A, attached hereto and incorporated as though fully set forth herein. NKRC, located at 1044 Belmont Avenue, Youngstown, Ohio, was operating without a Board-issued Terminal Distributer of Dangerous Drugs license during this time.

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

T: (614) 466.4143 | F: (614) 752.4836 | contact@pharmacy.ohio.gov | www.pharmacy.ohio.gov



POTENTIAL VIOLATIONS OF LAW

1. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.51(A)(1) of the ORC, 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, except as follows: A licensed terminal distributor of dangerous drugs that is a pharmacy may make occasional sales of dangerous drugs or investigational drugs or products at wholesale, a misdemeanor of the first degree, each punishable by a maximum fine of \$5,000, if committed by an organization.
2. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Rule 4729:5-3-09(E) of the OAC, as effective March 1, 2019, failing to query the Board's online roster to determine active licensure prior to distributing dangerous drugs, each violation 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 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).
4. 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 March 1, 2019, each violation punishable by a maximum penalty of \$1,000 if committed by an organization:
 - a. Violating any rule of the board, 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).

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

SWS/alg/kll

Encl: Attachment A

CMRRR: 7020 1290 0001 7926 1043