IN THE MATTER OF: **CASE NO. A-2020-0398**

Amerimed, LLC **License No. 02-0620050**
c/o Michael Pellek, RPh
9961 Cincinnati-Dayton Rd.
West Chester, OH 45069

SETTLEMENT AGREEMENT WITH THE OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the Ohio Board of Pharmacy (Board) and Amerimed, LLC ("Amerimed") for the purpose of resolving all issues between the parties relating to the Board investigation of Community Mercy Home Care Services Pharmacy ("CMHC")/Amerimed's failure to timely conduct environmental testing and engage in appropriate remedial measures in the sterile compounding suite, following an HVAC outage in September 2019. Together, the Board and Amerimed are referred to hereinafter as "the parties."

JURISDICTION

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

2. Amerimed is a licensed Terminal Distributor of Dangerous Drugs under license number 02-0620050.

FACTS

1. The Board initiated an investigation of Amerimed's Terminal Distributor of Dangerous Drugs license number 02-0620050, related to CMHC/Amerimed's failure to timely conduct environmental testing and engage in appropriate remedial measures in the sterile compounding suite, following an HVAC outage in September 2019.

2. On or about August 25, 2023, the Board sent a Notice of Opportunity for Hearing to Amerimed, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

3. On or about September 22, 2023, Amerimed timely requested an administrative hearing, which was subsequently scheduled for March 4, 2024. Amerimed subsequently requested a continuance, and the administrative hearing was rescheduled for October 9, 2024. WHEREFORE,

the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative 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. Amerimed neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated August 25, 2023; 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. Amerimed agrees to pay to the Board a monetary penalty the amount of $5,000.00. This fine will be attached to your license record and must be paid no later than 180 days from the effective date of this Agreement. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.

4. Amerimed agrees to schedule and pay for its responsible person to attend a Board-approved responsible person continuing education course no later than six months from the effective date of this Agreement.

5. The Board hereby imposes a written reprimand on Amerimed's TDDD license, number 02-0620050.

6. Amerimed 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.

7. Amerimed 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 Amerimed 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 Amerimed by the Board and will NOT discharge Amerimed from any obligation under the terms of this Agreement.

8. Amerimed agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

9. Amerimed understands that it has the right to be represented by counsel for review and execution of this agreement.

10. 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 Amerimed will operate.

11. Amerimed explicitly withdraws its request for a hearing, waives its right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code, and waives any right to an appeal.

12. 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.

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

14. 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.

15. If any of the provisions, terms, or clauses of this Agreement are declared illegal, unenforceable, or ineffective by an authority of competent jurisdiction, those provisions, terms, and clauses shall be deemed severable, such that all other provisions, terms, and clauses of this Agreement shall remain valid and binding upon both Parties.

16. 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:

Michael Pellek, RPh, on behalf of,
Amerimed, LLC, Respondent

8/5/2024
Date of Signature

Attorney for Respondent

8/7/24
Date of Signature

Mindy Ferris, RPh, President,
Ohio Board of Pharmacy

08.12.2024
Date of Signature

-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: Aug 25, 2023
-MUST HAVE BOARD SEAL TO BE OFFICIAL-

STATE OF OHIO BOARD OF PHARMACY

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

IN THE MATTER OF: **CASE NO. A-2020-0398**
I-2019-1130

Amerimed, LLC **License No. 02-0620050**
c/o Tim D. Smith, RPh
9961 Cincinnati-Dayton Rd.
West Chester, OH 45069

August 25, 2023

Dear Amerimed, LLC and Tim D. Smith, RPh:

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 (effective April 4, 2023) and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, or refuse to grant or renew any license issued pursuant to section 4729.55 of the ORC to practice as a TDDD in the state of Ohio. Additionally, Section 4729.57 of the Ohio 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. Amerimed, LLC (formerly Amerimed Infusion Pharmacy), located at 9961 Cincinnati-Dayton Rd., West Chester, OH 45069, has an active TDDD license with the Board under license number 02-0620050, which lists Tim D. Smith, RPh (license no. 03-132385), as the Responsible Person.

ALLEGATIONS

1. On or about September 2019, Amerimed Infusion Pharmacy (TDDD 02-0620050), located at 9961 Cincinnati-Dayton Road, West Chester, Ohio was co-located and co-operated with Community Mercy Home Care Services Pharmacy (CMHC) (TDDD 02-1252950), located at 9963 Cincinnati-Dayton Rd., West Chester, Ohio.

2. On or about September 1, 2019, Amerimed/CMCH's sterile suite experienced a heating ventilation and air conditioning (HVAC) malfunction and an HVAC outage occurred until on or about September 6, 2019:

a. Due to the HVAC outage, the sterile compounding suite's ante room failed to maintain appropriate positive pressure for three days and the conditions were outside of USP <797> guidelines.

b. From on or about September 1, 2019, to September 6, 2019, during the HVAC outage, the temperature of the clean room was approximately 87-89 degrees Fahrenheit (F) and the ante room was between 85-90 degrees F.

c. Portable air conditioning units without high efficiency air purification (HEPA) filters were brought in but did not cool the rooms adequately.

d. The elevated temperatures caused compounding personnel to perspire and fail to appropriately change gloves while compounding due to discomfort.

e. Sterile compounding continued during the time of the outage with no changes.

3. Following an HVAC failure on September 1, 2019, no appropriate environmental testing of Amerimed Pharmacy's sterile compounding suite was conducted until September 24, 2019. As a result, 41 days passed between the time of the HVAC failure and the pharmacy receiving viable sampling results, which indicated mold was present in the sterile compounding area. Numerous out of range results were observed and viable sampling results demonstrated highly pathogenic microorganisms (mold) and CFU quantities that exceeded USP <797> action levels within the sterile compounding suite's hazardous and non-hazardous buffer areas.

4. On or about October 17, 2019, as a result of the findings on September 24, 2019, Amerimed/CMHC signed a beyond-use date (BUD) reduction letter with the Board. The agreement prevented pharmacies from dispensing any sterile products other than low-risk, non-hazardous compounds with a BUD less than 12 hours. On or about October 17 to November 25, 2019, all sterile compounding operations were transferred to another location. After a follow-up inspection conducted by agents of the Board, Amerimed/CMHC was released from the requirements set forth in the BUD letter.

5. On or about September 11, 2019, an agent of the Board spoke with Amerimed's responsible person Tim Smith, RPh, who made the following statements:

   a. Sterile operations were maintained during the HVAC outage.

   b. During the HVAC outage, mobile air conditioning units were utilized in an attempt to keep the sterile suite as cool as possible.

   c. No follow-up environmental testing of the sterile suite was planned or performed after the HVAC system was brought back online.

6. On or about September 11, 2019, an agent of the Board spoke with CMCH's responsible person, Marinna Chalk, who acknowledged the sterile suite HVAC system failure.

POTENTIAL VIOLATIONS OF LAW

1. Such conduct as set forth in paragraphs (2)(a), (2)(b), (2)(c), (2)(d), (2)(e), (3), (5)(b) and (5)(c) of the Allegations Section, if proven, constitutes a violation of the following divisions of Rule 4729-16-03(B) of the OAC, as effective February 15, 2016, for all sterile compounded drug products, the pharmacy shall comply with the United States pharmacopeia chapter <797>, USP 38 - NF 33, or any official supplement thereto (9/10/2015), each violation punishable by a maximum penalty of $1,000:

    a. "Environmental sampling shall occur as part of a comprehensive quality management program and shall occur minimally under any of the following conditions: …following any servicing of facilities and equipment…" (797> Pharmaceutical Compounding – Sterile; official from May 1, 2018, p 6568); and/or

    b. "The CSP work environment is designed to have the cleanest work surfaces (PEC) located in a buffer area. The buffer area shall maintain at least ISO Class 7 (see Table 1) conditions for 0.5-mm and larger particles under dynamic operating conditions. The room shall be segregated from surrounding, unclassified spaces to reduce the risk of contaminants being blown, dragged, or otherwise introduced into the filtered unidirectional airflow environment, and this segregation shall be continuously monitored. For rooms providing a physical separation through the use of walls, doors, and pass-throughs, a minimum differential positive pressure of 0.02- to 0.05- inch water column is required." (<797> Pharmaceutical Compounding – Sterile; official from May 1, 2018, p 6567); and/or

    c. "A pressure gauge or velocity meter shall be installed to monitor the pressure differential or airflow between the buffer area and the ante-area and between the ante-area and the general environment outside the compounding area. The results shall be reviewed and documented on a log at least every work shift (minimum frequency shall be at least daily) or by a continuous recording device. The pressure between the ISO Class 7 (see Table 1) and the general pharmacy area shall not be less than 5 Pa (0.02 inch water column)". (<797> Pharmaceutical Compounding – Sterile; official from May 1, 2018, p 6569).

    d. "The value of viable microbial sampling of the air in the compounding environment is realized when the data are used to identify and correct an unacceptable situation. Sampling data shall be collected and reviewed on a periodic basis as a means of evaluating the overall control of the compounding environment… Any cfu count that exceeds its respective action level [ISO Class 7 – Air Sample > 10 CFU. ISO Class 8 – Air Sample > 100 CFU] should prompt a re-evaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location. An investigation into the source of the contamination shall be conducted. Sources could include HVAC systems, damaged HEPA filters, and changes in personnel garbing or work practices. The source of the problem shall be eliminated, the affected area cleaned, and resampling performed." (<797> Pharmaceutical Compounding – Sterile; official from May 1, 2018, p 6570).

    e. "Regardless of the number of cfu identified in the pharmacy, further corrective actions will be dictated by the identification of microorganisms recovered (at least the genus level) by an appropriate credentialed laboratory of any microbial bioburden captured as a cfu using an

impaction air sampler. Highly pathogenic microorganisms (e.g., Gram-negative rods, coagulase positive staphylococcus, molds and yeasts) can be potentially fatal to patients receiving CSPs and must be immediately remedied, regardless of cfu count, with the assistance of a competent microbiologist, infection control professional, or industrial hygienist." (<797> Pharmaceutical Compounding – Sterile; official from May 1, 2018, p 6570).

f. "Surface sampling is an important component of the maintenance of a suitable microbially controlled environment for compounding CSPs, especially since transfer of microbial contamination from improperly disinfected work surfaces via inadvertent touch contact by compounding personnel can be a potential source of contamination into CSPs." (<797> Pharmaceutical Compounding – Sterile; official from May 1, 2018, p 6575).

g. "Any cfu count that exceeds its respective action level [ISO Class 7 – Surface Sample > 5. ISO Class 8 – Surface Sample > 100] should prompt a re-evaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location." (<797> Pharmaceutical Compounding – Sterile; official from May 1, 2018, p 6575).

h. "Regardless of the number of cfu identified in the compounding facility, further corrective actions will be dictated by the identification of microorganisms recovered (at least the genus level) by an appropriate credentialed laboratory of any microbial bioburden captured as a cfu using an impaction air sampler. Highly pathogenic microorganisms (e.g., Gram-negative rods, coagulase positive staphylococcus, molds and yeasts) can be potentially fatal to patients receiving CSPs and shall be immediately remedied, regardless of cfu count, with the assistance of a competent microbiologist, infection control professional, or industrial hygienist." (<797> Pharmaceutical Compounding – Sterile; official from May 1, 2018, p 6575).

2. Such conduct as set forth in paragraphs (2)(a), (2)(b), (2)(c), (2)(d), (2)(e), (3), (5)(b) and (5)(c) of the Allegations Section, if proven, constitutes a violation of Section 4729.55(D) of the ORC, as effective April 6, 2017, TDDD license requirements – adequate safeguards are assured that the applicant will carry on the business of a terminal distributor of dangerous drugs in a manner that allows pharmacists and pharmacy interns employed by the terminal distributor to practice pharmacy in a safe and effective manner, each violation punishable by a maximum penalty of $1,000.

3. Such conduct as set forth in paragraphs (2)(a), (2)(b), (2)(c), (2)(d), (2)(e), (3), (5)(b) and (5)(c) of the Allegations Section, if proven, constitutes a violation of each of the following divisions of Section 4729.57(B) of the ORC, as effective September 29, 2017, each violation punishable by a maximum penalty of $1,000:

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

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

   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. 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).

4. Such conduct as set forth in paragraphs (2)(a), (2)(b), (2)(c), (2)(d), (2)(e), (3), (5)(b) and (5)(c) of the 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:

   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. The method used by the terminal distributor to store, possess or distribute dangerous drugs poses serious harm to other, OAC Rule 4729:5-4-01(B)(25).

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 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 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, 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 STATE BOARD OF PHARMACY

Steven W. Schierholt

Steven W. Schierholt, Esq., Executive Director

SWS/zas/kll

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