STATE OF OHIO
BOARD OF PHARMACY

September 15, 2023

PharMerica
c/o Steven Grove
720 Lakeview Plaza Blvd, Suite H
Worthington, Ohio 43085

Re: License Number: 02-1508850

Dear PharMerica:

This letter is to confirm that the probationary period outlined in the Settlement Agreement dated May 5, 2020, is now concluded as of May 5, 2022, as PharMerica has satisfied all the terms of their probation. PharMerica's license number 02-1508850 is now deemed in good standing. The Board would like to acknowledge your diligence in meeting this goal.

If you have any questions or concerns, please contact the Board of Pharmacy at 614-466-4143.

Respectfully,

Kathryn Lewis
State of Ohio Board of Pharmacy
Legal Administrator

CMRRR: 9414 7118 9956 2047 3740 47

STATE OF OHIO
BOARD OF PHARMACY

IN THE MATTER OF:

CASE Nos. A-2020-0238; I-2020-0326
A-2020-0485; I-2020-0764

PharMerica
c/o Steven Grove, RPh
720 Lakeview Plaza Blvd., Suite H
Worthington, Ohio 43085

License No. 02-1508850

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 PharMerica for the purpose of resolving all issues between the parties relating to the Board investigation of illegal sales of dangerous drugs to an unlicensed entity. Together, the Board and PharMerica 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. PharMerica is a licensed Terminal Distributor of Dangerous Drugs under license number 02-1508850.

FACTS

1. The Board initiated an investigation of PharMerica, Terminal Distributor of Dangerous Drugs license number 02-1508850, related to PharMerica's illegal sales of dangerous drugs to an unlicensed entity.

2. On or about May 5, 2021 the Board sent a Notice of Opportunity for Hearing to PharMerica, 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. PharMerica neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated May 5, 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. PharMerica agrees to pay to the Board a monetary penalty the amount of $1,700.00. 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.elicense.ohio.gov and process the items in your cart.

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

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

7. PharMerica 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 PharMerica will operate.

9. PharMerica 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:

Steven Grove, RPh, on behalf of,
PharMerica, Respondent

5-18-2021
Date of Signature

Attorney for Respondent (if applicable)

Date of Signature

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

06.10.2021
Date of Signature

Henry Appel, Ohio Assistant Attorney General

06.10.2021
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: 05/05/2021
-MUST HAVE BOARD SEAL TO BE OFFICIAL-

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

IN THE MATTER OF:

CASE Nos. A-2020-0238; I-2020-0326
A-2020-0485; I-2020-0764

PharMerica
c/o Steven Grove, RPh
720 Lakeview Plaza Blvd., Suite H
Worthington, Ohio 43085

License No. 02-1508850

May 5, 2021

Dear PharMerica and Steven Grove, 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 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. PharMerica has an active TDDD license with the Board under license number 02-1508850, which lists Steven Grove, RPh as the Responsible Person.

ALLEGATIONS

1. From on or about April 16, 2019 through on or about September 19, 2019, PharMerica, located at 720 Lakeview Plaza Blvd., Suite H, Worthington, Ohio, sold dangerous drugs to National Church Residences Medical Home (National Church) as set forth in Attachment A, attached hereto and incorporated as though fully set forth herein. National Church, located at 1280 Norton Avenue, Columbus, Ohio, was operating without a Board-issued Terminal Distributer of Dangerous Drugs license during this time.

2. From on or about March 31, 2019 to on or about April 26, 2020, PharMerica, sold APLISOL injections, a dangerous drug, to Harrison Pavilion, located at 2171 Harrison Ave., Cincinnati, Ohio, as set forth in

Attachment B, attached hereto and incorporated as though fully set forth herein. Harrison Pavilion, was operating without a Board-issued Terminal Distributor of Dangerous Drugs license at this time.

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: 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/TSB/alg/kll

Encl: Attachments A & B

CMRRR: 7021 0350 0000 3918 0296

Attachment A

Sales made by PharMerica to National Church

Order Date	Invoice Number	Medication	Quantity
04/16/19	# 0000900441	Ketorolac 60mg/2ml vial	40.0 ml
04/12/19	# 0000903208	Bupivacaine 0.5%	10.0 ml
04/25/19	# 0000907743	Boostrix TDAP Vaccine	5.0 ml
05/09/19	# 0000914875	Ketoralac 60mg/2ml	40.0 ml
05/31/19	# 0000923803	Cyanocobalamin 1.00 mcg/ml	5.0 ml
06/28/19	# 0000923803	Boostrix TDAP Vaccine	5.0 ml
06/28/19	# 0000923803	Solu-Medrol 125 mg	2.0 ml
06/28/19	# 0000923803	Nitroglycerin TB 0.4mg (4x25)	25.0 ml
06/28/19	# 0000923803	Epinephrine 0.3mg auto-inject	2.0 ml
06/28/19	# 0000923803	Bupivacaine 0.5%	10.0 ml
06/28/19	# 0000923803	Ketorolac 60mg/2ml	10.0 ml
06/28/19	# 0000923803	Albuterol sul 2.5mg/3ml	90.0 ml
06/28/19	# 0000923803	Aplisol 10 test 1ml	1.0 ml
06/28/19	# 0000923803	Kenalog-40 40mg/ml	1.0 ml
07/15/19	# 0000928833	Triamcinolone acet 400mg/10m	10.0 ml
09/05/19	# 0000944159	Flucelavax quad 2019-2020 syr	75.0 ml
09/05/19	# 0000944159	Fluad 2019-2020 syr	5.0 ml
09/19/19	# 0000948358	Mupirocin 2% ointment	66.0 gm
09/19/19	# 0000948358	Ketorolac 60mg/2ml	40.0 ml
09/19/19	# 0000948358	Cyanocobalamin 1.000mcg/ml	20.0 ml

Attachment B

Purchases made by Harrison Pavilion

Wholesaler	Date	Invoice Number	Medication
Pharmerica	4/24/2019	3948634	APLISOL
Pharmerica	6/18/2019	3948634	APLISOL
Pharmerica	8/6/2019	3948634	APLISOL
Pharmerica	9/5/2019	3948634	APLISOL
Pharmerica	11/11/2019	3948634	APLISOL
Pharmerica	1/13/2020	5377270	APLISOL
Pharmerica	2/6/2020	5377270	APLISOL
Pharmerica	2/27/2020	5377270	APLISOL

Package Size	Quantity
INJ 5/0.1ML	4
INJ 5/0.1ML	5
INJ 5/0.1ML	5
INJ 5/0.1ML	5
INJ 5/0.1ML	3
INJ 5/0.1ML	3
INJ 5/0.1ML	2
INJ 5/0.1ML	2

.

IN THE MATTER OF: **CASE No. A-2019-0088**

PharMerica **License No. 02-1508850**
c/o Steven Grove
720 Lakeview Plaza Blvd., Suite H
Worthington, OH 43085

April 27, 2020

Dear Steven Grove and PharMerica:

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 PharMerica, for the purpose of resolving all issues between the parties relating to the Board investigation of PharMerica's compounding practices in violation of USP 797, Chapter 4729 of the Ohio Revised Code (ORC), and Chapter 4729-16 of the Ohio Administrative Code (OAC). Together, the Board and PharMerica are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to ORC 4729.57 and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, refuse to grant or renew, reprimand, place on probation any license issued pursuant to ORC 4729.54.

2. Pursuant to ORC 4729.57 and the rules adopted thereunder, the Board has 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 one thousand dollars if the acts committed have not been classified as an offense by the Revised Code on any license issued pursuant to ORC 4729.54.

3. PharMerica is a licensed Terminal Distributor of Dangerous Drugs under license number 02-1508850.

FACTS

1. On or about September 5, 2018, the Board initiated an investigation of PharMerica, Terminal Distributor of Dangerous Drugs (TDDD) license number 02-1508850, related to PharMerica's compounding practices in violation of USP 797, ORC 4729, and OAC 4729-16.

2. On or about April 27, 2020, the Board sent a Notice of Opportunity for Hearing to PharMerica, 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. PharMerica neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated April 27, 2020; 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. PharMerica agrees to pay to the Board a monetary penalty in the amount of $5,000.00. 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. PharMerica TDDD License No. 02-1508850 will be placed on probation for two-years from the effective date of this Agreement. As a condition of its probation, PharMerica must submit the results of testing required by USP 797 to the Board for review every six months. The test results should include, at a minimum:

    a. Records of certification or recertification of all classified areas including the primary engineering control(s)(PECs) and secondary engineering controls (SECs).
    b. Total airborne particle counts in each classified area including the primary engineering control(s)(PECs).
    c. Viable air sampling to evaluate airborne microorganisms for all classified areas.
    d. Surface sampling for viable particles of all classified areas including the primary engineering control(s)(PECs).
    e. Applicable data collected and corrective actions for any out-of-level occurrences, including media-fill test, endotoxin, sterility, etc.

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

6. PharMerica agrees to comply with all federal and state requirements related to Terminal Distributors of Dangerous Drugs, including but not limited to, ORC Chapter 4729. and the rules adopted thereunder, ORC Chapter 3719. and the rules adopted thereunder, ORC 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 PharMerica 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 PharMerica by the Board and will NOT discharge PharMerica from any obligation under the terms of this Agreement.

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

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

9. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom PharMerica will operate.

10. PharMerica waives its opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and waives any right to appeal.

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

12. All parties to this Agreement understand that this document is a public record pursuant to ORC 149.43.

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

14. 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:

Steven Grove, *on behalf of,*
PharMerica

4-30-2020
Date of Signature

Attorney for Respondent (if applicable)

Date of Signature

Shawn C. Wilt, R.Ph., President
State of Ohio Board of Pharmacy

05.05.2020
Date of Signature

Henry Appel, Ohio Assistant Attorney General

05.05.2020
Date of Signature

STATE OF OHIO
BOARD OF PHARMACY

NOTICE OF OPPORTUNITY FOR HEARING
FOR TERMINAL DISTRIBUTOR OF DANGEROUS DRUGS LICENSE

IN THE MATTER OF: **CASE No. A-2019-0088**

PharMerica **License No. 02-1508850**
c/o Steven S. Grove
720 Lakeview Plaza Blvd., Suite H
Worthington, OH 43085

-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: 04/27/2020
-MUST HAVE BOARD SEAL TO BE OFFICIAL-

April 27, 2020

Dear Steven Grove and PharMerica:

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 deny your application(s) for license as a Terminal Distributor of Dangerous Drugs (TDDD) under authority of Section 4729.57.

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 Section 4729.54 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.

1. PharMerica is licensed by the Board as a TDDD, License No. 02-1508850, which lists Steven Grove as the Responsible Person.

ALLEGATIONS

1. On or about September 5, 2018, a Board inspection revealed significant sterile compounding violations, which resulted in PharMerica entering into an agreement with the Board to dispense all sterile compounded products with a beyond-use date (BUD) of only one-hour, until the hospital was found by the Board to be compliant with United States Pharmacopeia Chapter 797 (USP 797), ORC 4729, and chapter 4729-16 of the Ohio Administrative Code (OAC). The violations consisted of the following:

    a. Environmental testing did not include the ISO rooms and such testing was not performed under dynamic conditions.

    b. The ISO rooms were not inspected to determine if the air exchange is compliant with USP 797.

c. Smoke studies were not being performed to demonstrate unidirectional airflow under dynamic conditions.

d. Testing of HEPA filters was not being conducted.

e. Viable air sampling of ISO rooms was not being conducted.

f. Calibration of the Baxter repeater pump was not being documented to determine if calibration and service is occurring.

g. Calibration and gauge testing were not occurring for the ISO areas.

h. It was observed that the walls in both the anteroom and clean room were not painted with epoxy paint. Cracks and chips in the anteroom were observed.

i. The ceiling in the anteroom had a half-inch gap between the tiles.

j. The base of the sink in the ante area pooled water.

k. Records were not in place to document the preparation and maintenance of disinfectant solutions.

l. It was observed that the compounding technician was not properly cleaning the primary engineering control (PEC).

m. It was observed that the compounding technician did not properly wash forearms and did not cover sleeves with the gloves.

n. It was observed that the compounding technician was not cleaning syringes, needles, drug, or IV bags when placing them into the hood to be compounded.

o. Compounding staff was using water-based alcohol to sterilize gloves.

p. It was observed that the compounding technician would leave the hood to pull supplies and did not re-sterilize with sterile isopropyl (IPA) 70% alcohol.

2. As a result of remediation efforts by PharMerica, the Board, on or about October 11, 2018, authorized PharMerica to resume assignment of USP 797 BUD to sterile products compounded by appropriately trained personnel.

POTENTIAL VIOLATIONS OF LAW

1. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of each of the following divisions of Section 4729.57 of the ORC, 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. Ceasing to satisfy the qualifications of a TDDD set forth in section 4729.55 of the Revised Code, ORC Section 4729.57(B)(7).

2. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of each of the following divisions of Section 4729.55 of the ORC, TDDD license requirements:

    a. 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, ORC 4729.55(D); and/or

    b. If the applicant, or any agent or employee of the applicant, has been found guilty of violating section 4729.51 of the Revised Code, the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, the federal drug abuse control laws, Chapter 2925., 3715., 3719., or 4729. of the Revised Code, or any rule of the board, adequate safeguards are assured to prevent the recurrence of the violation, ORC 4729.55(E).

3. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following paragraphs of Rule 4729-17-02 of the OAC, each violation punishable by a maximum penalty of $1,000:

    a. The institutional pharmacy director or designated pharmacist shall be the pharmacist-in-charge pursuant to section 4729.27 of the Revised Code, the responsible person pursuant to rule 4729-5-11 of the Administrative Code, and the pharmacist responsible for maintaining supervision and control over the possession and custody of all dangerous drugs acquired by the institutional facility pursuant to division (B) of section 4729.55 of the Revised Code, OAC 4729-17-02(A); and/or

    b. [The responsible person shall] Be responsible for the practice of pharmacy performed within the institution, OAC 4729-17-02(C)(1).

4. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following paragraphs of Rule 4729-5-11 of the OAC, each violation punishable by a maximum penalty of $1,000:

a. The responsible person shall be responsible for the practice of the profession of pharmacy, 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 as required in rule 4729-9-11 of the Administrative Code and maintaining all drug records otherwise required, OAC 4729-5-11(A)(2); and/or

b. 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, OAC 4729-5-11(A)(3).

5. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following paragraphs of Rule 4729-16-03 of the OAC, each violation punishable by a maximum penalty of $1,000:

   a. For all sterile compounded drug products, the pharmacy shall comply with the United States pharmacopeia chapter, USP 38 - NF 33, or any official supplement thereto (9/10/2015), OAC 4729-16-03(B).

6. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following divisions of Section 3715.52 of the ORC, constituting a misdemeanor of the fourth degree, each punishable by a maximum fine of $2,000 if committed by an organization:

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

   b. The adulteration or misbranding of any food, drug, device, or cosmetic, ORC 3715.52(A)(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 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 MUST BE RECEIVED ON OR PRIOR TO THE 30TH DAY FOLLOWING THE MAILING DATE OF THIS NOTICE.** 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 Ohio 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/jak/kll

CMRRR: 7020 0090 0001 7233 5135