STATE OF OHIO
BOARD OF PHARMACY

IN THE MATTER OF:

Case No. A-2019-0461
501-0067-A

Mount Carmel Health System
c/o Randal Miles, RPh, Responsible Person

793 West State Street
Columbus, OH 43222

License No. 02-0975550

And

5300 North Meadows Drive
Grove City, Ohio 43123

License No. 02-2359350

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 Mount Carmel Health System ("MCHS"), for the purpose of resolving all issues between the parties relating to the Board investigation of pharmacy policies, including policy deficiencies and policy implementation failures, and related patient deaths at Mount Carmel West ("MCW"). Together, the Board and MCHS are referred to hereinafter as "the parties."

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 Terminal Distributor of Dangerous Drugs (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. On or about January 7, 1997, MCW received its TDDD license number 02-0975550. On or about February 7, 2019, Michael Mabrey signed as the Responsible Person on an application for a TDDD License on behalf of MCW.

3. On or about July 24, 2019, MCW, License number 02-0975550, changed the name and location of its TDDD to Mount Carmel Emergency Room, Franklinton at 120 S. Green Street, Columbus, Ohio 43222, at which time the Board updated the license type from Terminal – Pharmacy – Category 3 with a Hospital classification to Terminal – Clinic – Category 3 with a Free Standing Emergency Dept. classification.

4. On or about April 28, 2019, MCW at 793 West State Street Columbus, Ohio, 43222, License number 02-0975550, transferred its inpatient operations to Mount Carmel Grove City ("MCGC") at 5300 North Meadows Drive, Grove City, Ohio 43123, License Number 02-2359350. On or about December 18, 2019, Randal Miles submitted a change of Responsible Person form, which was approved by the Board on January 6, 2020 and made Miles the Responsible Person for MCGC's License Number 02-2359350. Randal Miles, in his capacity as the Responsible Person for MCGC's License Number 02-2359350, has the authority to sign this Agreement.

FACTS

1. The Board initiated an investigation of MCW, Terminal Distributor of Dangerous Drugs license 02-0975550, pertaining to pharmacy policies, including policy deficiencies and policy implementation failures, and related patient deaths at MCW.

2. On or about October 17, 2019, the Board sent a Notice of Opportunity for Hearing to MCHS, 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 November 12, 2019, MCHS timely submitted a request for a hearing.

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. MCHS neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated October 17, 2019; however, the Board has evidence sufficient to sustain the allegations, finds MCHS to have violated Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. MCHS agrees to pay to the Board a monetary penalty in the amount of $400,000.00. This fine will be attached to licensee's record; to pay this fine licensee must login to www.elicense.ohio.gov and process the items in licensee's cart. Alternatively, MCHS may pay this fine by delivering a check to the Board in the amount of $400,000.00 made payable to "Treasurer, State of Ohio." Any such check must be delivered to the Board (77 South High Street, 17th Floor, Columbus, Ohio 43215) no later than thirty (30) days from the effective date of this Agreement.

4. MCHS agrees to pay the investigative costs of the Board's investigation, $77,492.73. These costs will be attached to licensee's record; to pay these costs the licensee must login to www.elicense.ohio.gov and process the items in licensee's cart. Alternatively, MCHS may pay the investigation costs by delivering a check to the Board in the amount of $77,492.73 made payable to "Treasurer, State of Ohio." Any such check must be delivered to the Board (77 South High Street, 17th Floor, Columbus, Ohio 43215) no later than thirty (30) days from the effective date of this Agreement.

5. The Board hereby places MCW's transferred operational license of MCGC, License No. 02-2359350, on probation for a period of three years from the effective date of this Agreement. During the period of probation MCHS must retain a Board-approved consultant pharmacist or consulting pharmacy organization to review MCGC's compliance with Pharmacy Board rules and regulations. The consultant pharmacist/consulting pharmacy organization must submit to the Board an initial and then biannual reports, for the duration of probation, detailing MCGC's compliance with the Pharmacy Board's standards of practice as set forth in its rules and regulations, including any recommendations for improvement or changes necessary to become compliant. The correspondence or other documentation may be emailed to legal@pharmacy.ohio.gov.

    a. The consultant pharmacist/consulting pharmacy organization's initial report must be submitted to the Board no later than 60 days from the effective date of this Agreement. The report must demonstrate that MCGC meets the Pharmacy Board's standards of practice as set forth in its rules and regulations. At a minimum, the consultant pharmacist/consulting pharmacy organization's report must include the following:

        i. Confirmation additional training has been provided to all MCGC staff on reporting into its electronic incident reporting system;

        ii. Confirmation that MCGC Senior Leadership is conducting a review of all reported level 5 and higher events. This includes any reported events, safety events, and/or pharmacy related events, from the preceding 24 hours which are to be provided via email to Senior Leadership at MCGC (as defined below), as well as the MCHS Regional Chief Clinical Officer and the Regional Chief Nursing Officer;

            1) Level 5 harm is harm, even temporary, to a patient;

            2) Reported events may include, but are not limited to, quality assurance concerns, administration errors, order set concerns, formulary concerns, misuse of the electronic health record;

            3) Safety events may include, but are not limited to, high dose of medications, dosages outside MCHS' established policies, medication errors, misuse of medication, pharmacy delays, tampering, unapproved or misuse of the over-rides of the automated drug storage system (i.e. pyxis, etc.), inadequate charting;

            4) Pharmacy-related events may include, but are not limited to, patient harm or death as it relates to dangerous drugs;

            5) Senior Leadership of MCGC includes the MCGC President, the MCGC Chief Nursing Officer, the MCGC Chief Medical Officer, the MCGC Patient Safety Risk Officer, and the MCGC Responsible Person (hereinafter, "MCGC Senior Leadership").

        iii. Confirmation that MCGC Senior Leadership is participating in a daily (Monday through Friday) safety call regarding potential safety events, pharmacy-related events, or other patient safety issues; Monday safety calls will include a review of the preceding 72 hours;

iv. Confirmation that MCGC's Responsible Person is notified, at a minimum, of all safety and/or pharmacy-related events pertaining to the pharmacy or use of dangerous drugs;

v. Confirmation that the MCGC Responsible Person and/or MCGC pharmacy leadership team are performing a daily (Monday through Friday) safety huddle in person with employees, consisting of a review of, at a minimum, safety and/or pharmacy-related events pertaining to the pharmacy or use of dangerous drugs; Monday safety huddles will include a review of the preceding 72 hours;

vi. Confirmation that MCGC is following its pharmacy related policies and procedures;

vii. Confirmation that MCGC is conducting a review of all mortalities of at least the following categories of cases:

1) Surgical Inpatient mortality for patient with serious treatable condition;
2) Electrophysiology – mortality in hospital or 30-day readmission with mortality following EP procedure;
3) Surgery – mortality during index admission or mortality during 30-day readmission;
4) Cardiothoracic Surgery operative mortality;
5) Endovascular mortality – mortality during index admission or mortality during 30-day readmission;
6) Orthopedic mortality during hip and/or knee procedure;
7) Emergency Department mortalities;
8) Structural Heart – in-hospital mortality during TAVR, MitraClip, or mitral valve related surgery, or mortality during 30-day readmission;
9) Cardiovascular – in hospital mortality following a catheterization or catheterization percutaneous coronary intervention procedure;
10) All trauma-related mortality;
11) Obstetrics/Gynecology – All maternal, fetal, and infant mortality;
12) Stroke – unanticipated mortality;
13) Anesthesia – all mortalities within 48 hours;
14) Any mortality referred for review by the Chief Clinical Officer and/or Chief Medical Officer; and
15) Any patient whose cause of death is determined to be respiratory failure or respiratory depression, or adverse sequelae related to respiratory failure or respiratory depression, who concomitantly was administered a benzodiazepine or opioid.

b. After submission of the initial report, MCGC must employ the consultant pharmacist/consulting pharmacy organization to submit a biannual report to the Board demonstrating compliance with Pharmacy Board rules and regulations during the entirety of the probationary period. The second report will be due to the Board six months from the date the initial report is submitted, and every six months thereafter.

c. MCGC agrees to comply with and implement all recommendations identified in the consultant pharmacist/consultant pharmacy organization's report.

d. Failure to comply with and/or implement the recommendations in the consultant pharmacist/consultant pharmacy organization's report will be reviewed by the Board and may result in unannounced inspections to ensure compliance with Pharmacy Board rules and regulations.

i. An inspection may result in immediate corrective action requiring a written response and/or potential additional administrative disciplinary action, up to and including additional discipline, suspension, or revocation of MCGC's license;

ii. A consultant pharmacist/consulting pharmacy organization report and/or Board inspection may result in a summary suspension of MCGC's License if the Board determines that there is clear and convincing evidence of danger of immediate and serious harm to others due to the method used by MCGC to possess or distribute dangerous drugs or the method of prescribing dangerous drugs used by a licensed health professional authorized to prescribe who practices in the employ of or under contract with MCGC.

6. MCHS agrees that its MCGC Responsible Person will:

a. Be issued and comply with a position description consistent with Board of Pharmacy Institutional Rules as set forth in agency 4729 of the Ohio Administrative Code as they exist as of the effective date of this Agreement;

b. Be provided an updated position description and training on the expectations of that position within 30 days of the effective date of any changes in the Board of Pharmacy's Institutional Rules, including amendments or updates thereto;

c. Have immediate, direct access to and communication with MCHS' Chief Clinical Officer for reporting, at a minimum, safety events and/or pharmacy-related events.

d. Be informed immediately by MCGC's Pharmacy Clinical Coordinator upon discovery of incidents of medical error involving high risk central nervous system ("CNS") medications.

7. The Board agrees to reflect this disciplinary action only on the license number at which the violations occurred, 02-0975550, MCW located at 793 West State Street, Columbus, OH 43222 for the duration of probation, unless a violation of this agreement occurs.

a. The MCGC license, located at 5300 North Meadows Drive, Grove City, Ohio 43123, License No. 02-2359350, will remain active, in good standing, unless a violation of probation occurs, at which time a Notice of Opportunity for Hearing will be issued and further administrative disciplinary proceedings will be pending against MCGC.

8. Should MCHS apply for and obtain a TDDD license at 793 West State Street during the pendency of this Agreement, it agrees that both locations, 793 West State Street, Columbus and 5300 North Meadows Drive, Grove City are subject to the entire terms of this Agreement, including probation and discipline.

9. The Board agrees to issue MCHS Emergency Room Franklinton, located at 120 S. Green St., Columbus OH 43222 new license number 02-2889050. The new license number will be issued on the effective date of this agreement. After a period of 45 days from the effective date of this agreement, the Board will sever MCHS Emergency Room Franklinton's affiliation with License No. 02-0975550, which will revert to its original affiliation, MCW.

10. MCHS agrees and acknowledges that this Board disciplinary action must be disclosed to any accrediting bodies and 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.

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

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

13. 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 MCHS will operate.

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

15. 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.

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

17. 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.

18. 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:

Dr. Nicholas Kreatsoulas, DO, FACEP, on behalf of,
Mount Carmel Health System, Respondent

2/11/20
Date of Signature

Randal Miles,
Responsible Person for Mount Carmel Grove City
License Number 02-2359350

2/13/2020
Date of Signature

Sam Endicott, Esq.
Attorney for Respondent

02/14/2020
Date of Signature

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

3/3/2020
Date of Signature

Henry G. Appel, Ohio Assistant Attorney General

3/3/2020
Date of Signature

STATE OF OHIO
BOARD OF PHARMACY

NOTICE OF OPPORTUNITY FOR HEARING
PROPOSAL TO TAKE DISCIPLINARY ACTION
AGAINST TERMINAL DISTRIBUTOR OF DANGEROUS DRUGS LICENSE

IN THE MATTER OF:

Case No. A-2019-0461
501-0067-A

Mount Carmel West Hospital
c/o Michael Mabrey, RPh, Responsible Person
793 West State Street
Columbus, OH 43222

License No. 02-0975550

-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: 17 OCT 2019
-MUST HAVE BOARD SEAL TO BE OFFICIAL-

And

5300 North Meadows Drive
Grove City, Ohio 43123

License No. 02-2359350

October 17, 2019

Dear Mount Carmel West Hospital and Michael Mabrey:

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 against your 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, 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. On or about February 7, 2019, Michael Mabrey signed as the Responsible Person on an application for a TDDD License on behalf of Mount Carmel West Hospital.

3. On or about July 24, 2019, Mount Carmel West, License number 02-0975550, changed the name and location of its TDDD to Mount Carmel Emergency Room, Franklinton at 120 S. Green Street, Columbus, Ohio 43222, at which time the Board updated the license type from Terminal – Pharmacy – Category 3 with a Hospital classification to Terminal – Clinic – Category 3 with a Free Standing Emergency Dept. classification.

4. On or about April 28, 2019, Mount Carmel West at 793 West State Street Columbus, Ohio, 43222, License number 02-0975550, transferred its inpatient operations to Mount Carmel Hospital – Grove City at 5300 North Meadows Drive, Grove City, Ohio 43123, License Number 02-2359350.

ALLEGATION #1

1. On fourteen (14) occasions from on or about 5/28/18 to on or about 11/20/18, Mount Carmel West Hospital and/or its Responsible person failed to ensure that Dr. William Husel co-signed verbal orders within the required time as defined in its policies and procedures. The policy required verbal and telephone orders to be signed by the prescriber responsible for care of the patient within 24 hours. Verbal and telephone orders given on the day of discharge were to be authenticated by the prescriber no later than 30 days post discharge. The fourteen (14) occasions are as follow:

   a. On or about 5/28/18 at 23:20, for patient 1, a verbal order for fentanyl 1000mcg;

   b. On or about 5/28/18 at 23:20, for patient 1, a verbal order for midazolam 6mg;

   c. On or about 7/15/18 at 1:25, for patient 2, a verbal order for fentanyl 1000mcg;

   d. On or about 9/18/18 at 4:04, for patient 3, a verbal order for hydromorphone 4mg;

   e. On or about 9/18/18 at 4:18, for patient 3, a verbal order for hydromorphone 6mg;

   f. On or about 9/30/18 at 23:10, for patient 4, a verbal order for midazolam 6mg;

   g. On or about 9/30/18 at 23:10, for patient 4, a verbal order for fentanyl 600mcg;

   h. On or about 10/24/18 at 3:00, for patient 5, a verbal order for fentanyl 1000mcg;

   i. On or about 10/24/18 at 3:00, for patient 5, a verbal order for midazolam 10mg;

   j. On or about 10/24/18 at 3:05, for patient 5, a verbal order for hydromorphone 10mg;

   k. On or about 11/13/18 at 22:57, for patient 6, a verbal order for fentanyl 1000mcg;

   l. On or about 11/13/18 at 22:58, for patient 6, a verbal order for midazolam 10mg;

   m. On or about 11/20/18 at 22:48, for patient 7, a verbal order for fentanyl 2000mcg;

   n. On or about 11/20/18 at 22:48, for patient 7, a verbal order for midazolam 10mg.

POTENTIAL VIOLATIONS OF LAW PERTAINING TO ALLEGATION #1

1. Such conduct as set forth in Allegation #1, paragraphs (1)(a) through (1)(n), if proven, each constitutes a violation of Rule 4729-17-09 of the OAC, as effective September 1, 2016, Drug orders for patients of an institutional facility, each violation punishable by a maximum penalty of $1,000:

a. Drugs shall be dispensed by a pharmacist for inpatients pursuant to an original patient specific order issued by a prescriber. Oral orders issued by a prescriber for inpatients of an institutional facility may be transmitted to a pharmacist by personnel authorized by, and in accordance with, written policies and procedures of the facility. Such orders shall be recorded by the pharmacist, noting the full name(s) of the authorized personnel transmitting the order. Oral orders issued by a prescriber and transmitted by authorized personnel shall be verified by the prescriber using positive identification within a reasonable time and as required by the written policies and procedures of the facility, OAC Rule 4729-17-09(A)(2).

2. Such conduct as set forth in Allegation #1, paragraphs (1)(a) through (1)(n), if proven, each instance of conduct constitutes a violation of Section 4729.55 of the ORC, as effective April 6, 2017, Terminal Distributor License Requirements, each violation punishable by a maximum penalty of $1,000:

   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 Section 4729.55(D).

ALLEGATION #2

1. From on or about 09/26/2014 to on or about 11/20/2018 Mount Carmel West Hospital and/or its Responsible person failed to develop written policies and procedures that provided for the safe and efficient distribution of drugs in all areas of the institution and failed to ensure adherence to policies and procedures that provided for the safe and efficient distribution of drugs in all areas of the institution. In relevant part, the policy "Subject: Automated Dispensing System: Medication Overrides" in the Special Comment provided:

> Override medications are medications that can be accessed by nursing staff before review of an order by the pharmacist. The purpose of the override function is to allow for quick administration of medications in emergency situations to prevent patient harm. However, best practice includes prospective pharmacist review of all medication orders prior to administration of the drug. The override function can only be used in emergency situations when time does not permit the pharmacist review, such as circumstances when patient harm could result from delay in administration of a medication, including situations in which the patient experiences a sudden clinical decline.
>
> There are two allowable exceptions: 1. A LIP controls the ordering, dispensing, and administration of the drug, such as (but not limited to) in the operating room, endoscopy suite, emergency room, and cath lab suite. 2. Emergency situations when time does not permit the pharmacist review, such as STAT orders or circumstances when patient harm could result from delay in administration of a medication, including situations in which the patient experiences a sudden clinical decline.

Mount Carmel West and/or its Responsible person failed to provide appropriate supervision and control of the automated dispensing units which allowed nurses to override controlled substances for non-emergent purposes when carrying out orders from Dr. William Husel. Mount Carmel West's patient

records demonstrate nurses performed overrides on withdrawals of medication for the following twenty-eight (28) patients, beyond the parameters of the policy, contributing to patient deaths (note: all times are as documented in Mount Carmel West's records):

a. On or about September 26, 2014, for patient 9, Dr. Husel gave an order for fentanyl 100mcg at 2:38, verified at 2:42, withdrawn from Pyxis using the override function at 1:56, administered at 2:39, time of death 2:58.

   On or about September 26, 2014, for patient 9, Dr. Husel gave an order for fentanyl 100mcg at 2:53, verified at 2:56, withdrawn from Pyxis using the override function at 2:49, administered at 2:55, time of death 2:58.

b. On or about March 1, 2015, for patient 10, Dr. Husel gave an order for fentanyl 800mcg at 1:11, verified at 1:19, withdrawn from Pyxis using the override function on February 28, 2015 at 23:51, administered on March 1, 2015 at 00:11, time of death March 1, 2015 at 00:42.

c. On or about May 3, 2015, for patient 11, Dr. Husel gave an order for fentanyl 500mcg at 23:57, verified at 23:59, withdrawn from Pyxis using the override function at 23:54, administered at 23:57, time of death May 4, 2015 at 00:30.

   On or about May 4, 2015, for patient 11, Dr. Husel gave an order for fentanyl 400mcg at 00:20, verified at 00:22, withdrawn from Pyxis using the override function at 00:11, administered at 00:10, time of death 00:30.

d. On or about May 10, 2015, for patient 12, Dr. Husel gave an order for fentanyl 1000mcg at 23:23, verified at 23:24, withdrawn from Pyxis using the override function at 23:24, administered at 23:32, time of death 23:40.

e. On or about July 25, 2016, for patient 13, Dr. Husel gave an order for fentanyl 400mcg at 21:46, was not verified, was withdrawn from Pyxis using the override function at 21:48, administered at 21:46, time of death 22:06.

f. On or about April 3, 2017, for patient 14, Dr. Husel gave an order for fentanyl 1000mcg at 22:53, verified at 22:58, withdrawn from Pyxis using the override function at 22:45, administered at 22:57, time of death 23:30.

   On or about April 3, 2017, for patient 14, Dr. Husel gave an order for midazolam 10mg at 22:53, verified at 22:58, withdrawn from Pyxis using the override function at 22:45, administered at 22:57, time of death 23:30.

   On or about April 3, 2017, for patient 14, Dr. Husel gave an order for hydromorphone 10mg at 22:53, verified at 22:57, withdrawn from Pyxis using the override function at 22:45, administered at 22:57, time of death 23:30.

   On or about April 3, 2017, for patient 14, Dr. Husel gave an order for fentanyl 1000mcg at 23:15, verified at 23:17, withdrawn from Pyxis using the override function at 23:02 and 23:03, administered at 23:16, time of death 23:30.

On or about April 3, 2017, for patient 14, Dr. Husel gave an order for midazolam 10mg at 23:15, verified at 23:17, withdrawn from Pyxis using the override function at 23:02, administered at 23:16, time of death 23:30.

On or about April 3, 2017, for patient 14, Dr. Husel gave an order for hydromorphone 10mg at 23:15, verified at 23:17, withdrawn from Pyxis using the override function at 23:02, administered at 23:16, time of death 23:30.

g. On or about May 7, 2017, for patient 15, Dr. Husel gave an order for fentanyl 200mcg at 1:39, verified at 1:41, withdrawn from Pyxis using the override function at 1:29, administered at 1:39, time of death 1:48.

h. On or about May 29, 2017, for patient 16, Dr. Husel gave an order for fentanyl 200mcg at 19:45, verified at 20:09, withdrawn from Pyxis using the override function at 19:46, administered at 19:50, time of death 20:25.

i. On or about September 17, 2017, for patient 17, Dr. Husel gave an order for hydromorphone 4mg at 21:05, verified at 21:12, withdrawn from Pyxis using the override function at 21:04 and 22:07, administered at 22:00 and 22:05, time of death 22:15.

On or about September 17, 2017, for patient 17, Dr. Husel gave an order for midazolam 4mg at 21:05, verified at 21:12, withdrawn from Pyxis using the override function at 21:04, administered at 22:00 and 22:05, time of death 22:15.

On or about September 17, 2017, for patient 17, Dr. Husel gave an order for lorazepam 2mg at 21:43, was not verified, withdrawn from Pyxis using the override function at 21:40, administered at 21:43, time of death 22:15.

j. On or about October 9, 2017, for patient 18, Dr. Husel gave an order for fentanyl 200mcg at 20:21, verified at 20:31, withdrawn from Pyxis using the override function at 20:22, administered at 20:28, time of death 21:05.

k. On or about October 9, 2017, for patient 19, Dr. Husel gave an order for fentanyl 500mcg at 20:24, verified at 20:32, withdrawn from Pyxis using the override function at 20:50, administered at 21:03, time of death 21:10.

l. On or about October 9, 2017, for patient 20, Dr. Husel gave an order for fentanyl 500mcg at 23:22, verified at 23:25, withdrawn from Pyxis using the override function at 22:59, administered at 23:24, time of death 23:34.

On or about October 9, 2017, for patient 20, Dr. Husel gave an order for midazolam 4mg at 23:22, verified at 23:25, withdrawn from Pyxis using the override function at 22:59, administered at 23:24, time of death 23:34.

m. On or about October 11, 2017, for patient 21, Dr. Husel gave an order for midazolam 6mg at 4:02, verified at 4:03, withdrawn from Pyxis using the override function at 4:05, administered at 4:11, time of death 4:19.

On or about October 11, 2017, for patient 21, Dr. Husel gave an order for fentanyl 500mcg at 4:01, verified at 4:02, withdrawn from Pyxis using the override function at 4:02, administered at 4:12, time of death 4:19.

n. On or about December 5, 2017, for patient 22, Dr. Husel gave an order for fentanyl 1000mcg at 21:23, verified at 21:41, withdrawn from Pyxis using the override function at 21:27, administered at 21:37, time of death 21:41.

On or about December 5, 2017, for patient 22, Dr. Husel gave an order for hydromorphone 2mg at 21:40, was not verified, withdrawn from Pyxis using the override function at 21:35, administered at 21:40, time of death 21:41.

On or about December 5, 2017, for patient 22, Dr. Husel gave an order for midazolam 4mg at 21:40, was not verified, withdrawn from Pyxis using the override function at 21:34, administered at 21:40, time of death 21:41.

o. On or about December 10, 2017, for patient 23, Dr. Husel gave an order for fentanyl 500mcg at 22:34, verified at 22:35, withdrawn from Pyxis using the override function at 22:12, administered at 22:35, time of death 22:41.

On or about December 10, 2017, for patient 23, Dr. Husel gave an order for midazolam 4mg at 22:34, verified at 22:37, withdrawn from Pyxis using the override function at 22:12, administered at 22:36, time of death 22:41.

p. On or about January 14, 2018, for patient 8, Dr. Husel gave an order for midazolam 6mg at 21:30, verified at 22:00, withdrawn from Pyxis using the override function at 21:34, administered at 21:51, time of death 22:06.

On or about January 14, 2018, for patient 8, Dr. Husel gave an order for fentanyl 1000mcg at 21:31, verified at 22:00, withdrawn from Pyxis using the override function at 21:33, administered at 21:51, time of death 22:06.

q. On or about January 14, 2018, for patient 24, Dr. Husel gave an order for fentanyl 1000mcg at 00:02, verified at 00:08, withdrawn from Pyxis using the override function on January 13, 2018 at 23:47, administered on January 14, 2018 at 00:02, time of death January 14, 2018 at 00:19.

r. On or about March 25, 2018, for patient 25, Dr. Husel gave an order for fentanyl 500mcg at 21:20, verified at 21:24, withdrawn from Pyxis using the override function at 21:24, administered at 21:30, time of death 21:45.

s. On or about April 1, 2018, for patient 26, Dr. Husel gave an order for midazolam 6mg at 21:36, was not verified, withdrawn from Pyxis using the override function at 21:29, administered at 21:36, time of death 21:41.

On or about April 1, 2018, for patient 26, Dr. Husel gave an order for fentanyl 800mcg at 21:35, was not verified, was withdrawn from Pyxis using the override function at 21:30, administered at 21:35, time of death 21:41.

t. On or about May 28, 2018, for patient 1, Dr. Husel gave an order for fentanyl 1000mcg at 23:20, was not verified, was withdrawn from Pyxis using the override function at 22:59, administered at 23:20, time of death 23:40.

On or about May 28, 2018, for patient 1, Dr. Husel gave an order for midazolam 6mg at 23:20, was not verified, was withdrawn from Pyxis using the override function at 22:59, administered at 23:20, time of death 23:40.

u. On or about July 15, 2018, for patient 2, Dr. Husel gave an order for fentanyl 1000mcg at 1:25, was not verified, was withdrawn from Pyxis using the override function at 1:17, administered at 1:25, time of death 1:28.

v. On or about September 18, 2018, for patient 3, Dr. Husel gave an order for hydromorphone 4mg at 4:04, was not verified, was withdrawn from Pyxis using the override function at 4:28, administered at 4:04, time of death 5:00.

On or about September 18, 2018, for patient 3, Dr. Husel gave an order for hydromorphone 6mg at 4:18, verified at 4:20, withdrawn from Pyxis using the override function at 3:35, administered at 4:33, time of death 5:00.

w. On or about September 25, 2018, for patient 27, Dr. Husel gave an order for fentanyl 500mcg at 20:00, verified at 20:10, withdrawn from Pyxis using the override function at 20:02, administered at 20:25, time of death 21:25.

On or about September 25, 2018, for patient 27, Dr. Husel gave an order for midazolam 6mg at 20:00, verified at 20:10, withdrawn from Pyxis using the override function at 20:02, administered at 20:25, time of death 21:25.

x. On or about September 30, 2018, for patient 4, Dr. Husel gave an order for midazolam 6mg at 23:10, verified at 23:15, withdrawn from Pyxis using the override function at 23:12, administered at 23:22, time of death 23:53.

On or about September 30, 2018, for patient 4, Dr. Husel gave an order for fentanyl 600mcg at 23:10, verified at 23:15, withdrawn from Pyxis using the override function at 23:12, administered at 23:22, time of death 23:53.

y. On or about October 24, 2018, for patient 5, Dr. Husel gave an order for midazolam 10mg at 3:00, was not verified, was withdrawn from Pyxis using the override function at 2:33, administered at 3:00, time of death 3:13.

On or about October 24, 2018, for patient 5, Dr. Husel gave an order for fentanyl 1000mcg at 3:00, was not verified, was withdrawn from Pyxis using the override function 800 mcg at 2:34 and 200 mcg at 2:35, administered at 3:00, time of death 3:13.

On or about October 24, 2018, for patient 5, Dr. Husel gave an order for hydromorphone 10mg at 3:05, was not verified, was withdrawn from Pyxis using the override function at 2:54, administered at 3:05, time of death 3:13.

On or about October 24, 2018, for patient 5, Dr. Husel gave an order for midazolam 20mg at 3:05, was not verified, 10 mg was withdrawn from Pyxis using the override function at 2:52, administered at 3:05, time of death 3:13.

z. On or about November 13, 2018, for patient 6, Dr. Husel gave an order for fentanyl 1000mcg at 22:57, was not verified, was withdrawn from Pyxis using the override function at 22:39, administered at 22:57, time of death 23:20.

On or about November 13, 2018, for patient 6, Dr. Husel gave an order for midazolam 10mg at 22:58, was not verified, was withdrawn from Pyxis using the override function at 22:40, administered at 22:58, time of death 23.20.

aa. On or about November 19, 2018, for patient 28, Dr. Husel gave an order for fentanyl 1000mcg at 00:54, verified at 1:31, withdrawn from Pyxis using the override function at 00:55, administered at 1:26, time of death 1:32.

On or about November 19, 2018, for patient 28, Dr. Husel gave an order for midazolam 10mg at 00:54, verified at 1:31, was withdrawn from Pyxis using the override function at 00:56, administered at 1:27, time of death 1:32.

bb. On or about November 20, 2018, for patient 7, Dr. Husel gave an order for fentanyl 2000mcg at 22:48, verified at 22:50, withdrawn from Pyxis using the override function at 22:30 and 22:28, administered at 22:48 time of death 22:53.

On or about November 20, 2018, for patient 7, Dr. Husel gave an order for midazolam 10mg at 22:48, verified at 22:50, withdrawn from Pyxis using the override function at 22:29, administered at 22:49, time of death 22:53.

POTENTIAL VIOLATIONS OF LAW PERTAINING TO ALLEGATION #2

1. Such conduct as set forth in Allegation #2, paragraphs (1)(a) through (1)(e), if proven, each constitutes a violation of the following provisions of Rule 4729-17-02(D) of the OAC, as effective January 1, 2011, Responsible person for an institutional pharmacy, each violation punishable by a maximum penalty of $1,000, the responsible person shall:

a. Be responsible for the practice of pharmacy performed within the institution, OAC Rule 4729-17-02(D)(1); and/or

b. Develop, implement, supervise, and coordinate all services provided by the pharmacy, OAC Rule 4729-17-02(D)(2); and/or

c. In conjunction with the appropriate interdisciplinary committees, be responsible for the development of written policies and procedures which are consistent with this chapter of the Administrative Code and other applicable federal and state laws and rules governing the legal distribution of drugs, ensure adherence to these policies and procedures in order to provide for the safe and efficient distribution of drugs in all areas of the institution, and make available a current copy of these written policies and procedures for inspection and/or copying by an employee of the state board of pharmacy, OAC Rule 4729-17-02(D)(3); and/or

d. Be responsible for the security and control of all drugs within the institution, OAC Rule 4729-17-02(D)(4); and/or

e. Be responsible for the maintenance of all records, required by state or federal law to be kept at the licensed location, of the acquisition, use, distribution, and disposition of all drugs, OAC Rule 4729-17-02(D)(5).

2. Such conduct as set forth in Allegation #2, paragraphs (1)(f) through (1)(bb), inclusive, if proven, each constitutes a violation of Rule 4729-17-02(C) of the OAC, as effective September 1, 2016, Responsible person for an institutional pharmacy, each violation punishable by a maximum penalty of $1,000, the responsible person shall:

a. Be responsible for the practice of pharmacy performed within the institution, OAC Rule 4729-17-02(C)(1); and/or

b. Develop, implement, supervise, and coordinate all services provided by the pharmacy, OAC Rule 4729-17-02(C)(2); and/or

c. In conjunction with the appropriate interdisciplinary committees, be responsible for the development of written policies and procedures which are consistent with this chapter of the Administrative Code and other applicable federal and state laws and rules governing the legal distribution of drugs, ensure adherence to these policies and procedures in order to provide for the safe and efficient distribution of drugs in all areas of the institution, and make available a current copy of these written policies and procedures for inspection and/or copying by an employee of the state board of pharmacy, OAC Rule 4729-17-02(C)(3); and/or

d. Be responsible for the security and control of all drugs within the institution, OAC Rule 4729-17-02(C)(4); and/or

e. Be responsible for the maintenance of all records, required by state or federal law to be kept at the licensed location, of the acquisition, use, distribution, and disposition of all drugs, OAC Rule 4729-17-02(C)(5).

3. Such conduct as set forth in Allegation #2, paragraphs (1)(a) through (1)(bb), inclusive, if proven, each constitutes a violation of Section 4729.55 of the ORC, as effective May 20, 2001 and April 6, 2017, Terminal Distributor License Requirements, each violation punishable by a maximum penalty of $1,000:

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 Section 4729.55(D).

ALLEGATION #3

1. From on or about 5/03/14 to on or about 11/20/18, Mount Camel West Hospital and/or its Responsible person and the interdisciplinary committees established policies that, inter alia, covered "automated dispensing systems," "procedural sedation," "terminal ventilator withdrawal," and "palliative ventilator

withdrawal." Mount Carmel West's policies required that a drug utilization review be performed before withdrawing controlled substances from automated dispensing systems, except in limited circumstances as described in Allegation #2 of this notice. As detailed in Allegation #2 of this notice, set forth as though fully incorporated herein, nursing staff routinely performed overrides of the automated dispensing system in violation of Mount Carmel West's policies.

Mount Carmel West did not have any policies or procedures requiring investigation of overrides in the automated dispensing system to determine if those overrides were being performed consistent with its policies. Mount Carmel West did not timely perform investigations of overrides of its automated dispensing system.

The failure to perform investigations of overrides of its automated dispensing system contributed to the death of twenty-eight (28) patients for orders written by Dr. William Husel as set forth in more detail in Allegation #2 of this notice.

POTENTIAL VIOLATIONS OF LAW PERTAINING TO ALLEGATION #3

1. Such conduct as set forth in Allegation #3, if proven, each constitutes a violation of Rule 4729-17-03 of the OAC, as effective January 1, 2011 and September 1, 2016, Security and control of drugs in an institutional facility, each violation punishable by a maximum penalty of $1,000:

    a. Contingency drugs shall be used only in the absence of a licensed pharmacist, and shall be stored in a locked cabinet(s) or other enclosure(s) constructed and located outside of the institutional pharmacy. The storage area must be sufficiently secure to deny access, without obvious damage, to unauthorized persons. The responsible person shall provide procedures for the inspection of the contingency drug inventory to ensure proper utilization and replacement of the drug supply, OAC Rule 4729-17-03(A)(2)(e).

2. Such conduct as set forth in Allegation #3, if proven, each constitutes a violation of the following provisions of Rule 4729-17-02(D) of the OAC, as effective January 1, 2011, Responsible person for an institutional pharmacy, each violation punishable by a maximum penalty of $1,000, the responsible person shall:

    a. Be responsible for the practice of pharmacy performed within the institution, OAC Rule 4729-17-02(D)(1); and/or

    b. Develop, implement, supervise, and coordinate all services provided by the pharmacy, OAC Rule 4729-17-02(D)(2); and/or

    c. In conjunction with the appropriate interdisciplinary committees, be responsible for the development of written policies and procedures which are consistent with this chapter of the Administrative Code and other applicable federal and state laws and rules governing the legal distribution of drugs, ensure adherence to these policies and procedures in order to provide for the safe and efficient distribution of drugs in all areas of the institution, and make available a current copy of these written policies and procedures for inspection and/or copying by an employee of the state board of pharmacy, OAC Rule 4729-17-02(D)(3); and/or

d. Be responsible for the security and control of all drugs within the institution, OAC Rule 4729-17-02(D)(4); and/or

e. Be responsible for the maintenance of all records, required by state or federal law to be kept at the licensed location, of the acquisition, use, distribution, and disposition of all drugs, OAC Rule 4729-17-02(D)(5).

3. Such conduct as set forth in Allegation #3, if proven, each constitutes a violation of Rule 4729-17-02 of the OAC, each constitutes a violation of Rule 4729-17-02(C) of the OAC, as effective September 1, 2016, Responsible person for an institutional pharmacy, each violation punishable by a maximum penalty of $1,000, the responsible person shall:

   a. Be responsible for the practice of pharmacy performed within the institution, OAC Rule 4729-17-02(C)(1); and/or

   b. Develop, implement, supervise, and coordinate all services provided by the pharmacy, OAC Rule 4729-17-02(C)(2); and/or

   c. In conjunction with the appropriate interdisciplinary committees, be responsible for the development of written policies and procedures which are consistent with this chapter of the Administrative Code and other applicable federal and state laws and rules governing the legal distribution of drugs, ensure adherence to these policies and procedures in order to provide for the safe and efficient distribution of drugs in all areas of the institution, and make available a current copy of these written policies and procedures for inspection and/or copying by an employee of the state board of pharmacy, OAC Rule 4729-17-02(C)(3); and/or

   d. Be responsible for the security and control of all drugs within the institution, OAC Rule 4729-17-02(C)(4); and/or

   e. Be responsible for the maintenance of all records, required by state or federal law to be kept at the licensed location, of the acquisition, use, distribution, and disposition of all drugs, OAC Rule 4729-17-02(C)(5).

4. Such conduct as set forth in Allegation #3, if proven, each constitutes a violation of Section 4729.55 of the ORC, as effective May 20, 2001 and April 6, 2017, Terminal Distributor License Requirements, each violation punishable by a maximum penalty of $1,000:

   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 Section 4729.55(D).

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. 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/mc

Steven W. Schierholt, Esq., Executive Director

SWS/jak/kll

CMRRR: 9414 7118 9956 1982 6673 68

cc: Sam Endicott, Esq., Baker Hostetler, *via email*: sendicott@bakerlaw.com