

May 17, 2023

Jason McLain  
806 Courtland Ct  
Belton MO 64012

RE: Case No. 23-221

Dear Mr. McLain:

Enclosed you will find a Summary Order issued by the Kansas Board of Pharmacy (Board) in the above-referenced matter. Please read the order in its entirety.

If you disagree with the findings of fact, you have the right to request a hearing. Instructions for filing a written request are included under the "Notices" section of the order. Hearings are held before the full Board during their regularly scheduled quarterly meetings.

According to KSA 65-1627h, the Board is required to recoup the costs of administrative hearings when the decision is adverse to the licensee. These costs may include charges for services rendered by the Board's disciplinary counsel, an administrative law judge, and, if applicable, a court reporter.

If you have any questions, feel free to contact the Board at [Pharmacy.Compliance@ks.gov](mailto:Pharmacy.Compliance@ks.gov).

Sincerely,

Kansas Board of Pharmacy

Enclosure

BEFORE THE KANSAS STATE BOARD OF PHARMACY

In the Matter of	)	
	)	Case No. 23-221
Jason McLain	)	
	)	
<u>Registration No. 14-04871</u>	)	

**SUMMARY ORDER**

NOW, on this 17th day of May 2023, comes before the Kansas Board of Pharmacy (the “Board”), through its Executive Secretary, the matter of Jason McLain ("Respondent").

Pursuant to the authority granted to the Board by the Kansas Pharmacy Act, K.S.A. 65-1625, *et seq.*, and in accordance with the provisions of the Kansas Administrative Procedure Act, K.S.A. 77-501, *et seq.*, the Board enters this Summary Order in the above-captioned matter. After reviewing the application materials and being otherwise duly advised in the premises, the Board makes the following findings, conclusions, and order:

FINDINGS OF FACT

1. The Board has previously issued Respondent Registration No. 14-04871 which entitles Respondent to function as a pharmacy technician in the State of Kansas (“Respondent’s Registration”).
2. On February 1, 2023, the Board’s inspectors conducted an in-person inspection of HealthDirect Institutional Pharmacy Services, Inc. at 11131 W 79<sup>th</sup> Street in Lenexa, registration number 2-13167 (the “Pharmacy”).
3. Respondent is the Pharmacy Manager of the Pharmacy and a pharmacy technician employee. In a statement to the Board’s inspectors, Respondent indicated he was responsible for the CAI and the BSC not being certified because, as the Pharmacy Manager, he had not called the

certification organization to schedule the inspection/certification.

4. During the inspection, the Board's inspectors observed and noted the following in the segregated area for compounding sterile preparations:

- a. There were clumps of dust on the floor and other debris.
- b. The walls were dusty, leaving a sleeve of a blue jacket white after brushing across the wall.
- c. Upon request, no current certifications were provided for the primary engineering controls ("PECs"), including the Compounding Aseptic Isolator ("CAI") and Biological Safety Cabinet ("BSC"). The CAI certification expired on December 14, 2022. The BSC certification expired in September 2022.
- d. Upon request, no documentation was provided for any viable or nonviable environmental sampling. There was no evidence or documentation to suggest any viable or nonviable environmental sampling had been completed. This was confirmed in a written statement by Respondent.
- e. The back wall of the CAI had visible strands of unknown material blowing in the air.
- f. The CAI showed residue from prior compounding.
- g. The BSC had visible rust, mildew, or mold as well as drug residue in the front grill area.
- h. There were no appropriate cleaning products for the CAI or BSC that were in date. The written statement from Respondent indicated that the units were cleaned but the Pharmacy had no log or record documenting completion of cleaning.

- i. The alcohol bottles were outdated, showing a 2015 expiration date. Staff indicated to the Board's inspectors that required Sterile Isopropyl Alcohol (sIPA) bottles were refilled with 70% IPA instead of sIPA.
- j. There were no sterile gloves in the Pharmacy and none available to be donned in the CAI.
- k. Used garbing attire was wadded up and stuffed onto a shelf.
- l. A sink was available with hot and cold running water, but the sink was insanitary.
- m. No in-date hand washing product was available in the sink or surrounding area.

5. During the inspection, staff reported to the Board's inspectors that the Pharmacy conducted very little compounding of sterile preparations. Compounding records obtained by the Board during the inspection indicated that from January 11 through January 30, 2023, there were 102 items compounded and dispensed by the Pharmacy that were purported to be sterile preparations. The 44 compounding worksheets indicate the following:

- a. 102 items were prepared for six patients and five different drugs.
- b. Two compounding worksheets (three compounded intravenous ("IV") drug products) had no pharmacist verification (Rx #8046750 on dates 1/16/2023 and 1/11/2023)
- c. All 44 compounding worksheets had missing lot numbers and expiration dates of components (commonly the diluent, normal saline, and "bulb"). The "bulb" is not identified as to actual name on any of the worksheets.
- d. Incorrect directions appeared on labeling for nine compounded IV drugs compounded over five days. Rx # 8050389 stated that the product was

Ceftriaxone 2gm/100ml NS IV. The directions on the label read: “Infuse Ceftriaxone 2mg/100ml NS IV in the morning for skin and soft tissue infection.”

- e. 89 compounded IV drug product labels had no flow rates.
- f. Labeling on all compounded preparations did not include the initials of the individuals compounding the medication.
- g. Directions for compounding the sterile drug compounds were missing from or incomplete on nearly all compounding worksheets.
- h. Inappropriate beyond use dates (“BUD”) were documented on the compounding worksheets.

6. During the inspection, the Board’s inspectors observed and noted the following in the

Pharmacy:

- a. Upon request, the Pharmacy provided no records of prepackaging and no records for drug, lot number, expiration date, or other information required by the Board. Staff reported that the Pharmacy only “removes from bulk inventory.”
- b. Upon request, Respondent did not know if packaging material used by the Pharmacy could have an expiration date of six months or 12 months, demonstrating a lack of knowledge regarding the dating allowed for particular packaging products used by the Pharmacy.
- c. Names of the individuals responsible for the Pharmacy’s packaging were not documented on the medication label or in a suitable pharmacy record system.
- d. Upon request, Respondent confirmed that the Pharmacy had no policies and procedures for sterile compounding.
- e. Upon request, the Pharmacy provided no records of training for Respondent or

regarding Respondent's ability to perform aseptic techniques, and no documentation of annual review. One of Respondent's pharmacy technicians provided a certificate from PCCA for compounding training in 2004 but provided no documentation of what training occurred to obtain the certificate. Upon request, the Pharmacy provided no records of gloved fingertip testing or media fills for staff performing sterile compounding. This was confirmed in a statement to the Board from pharmacist Jamie Kuss, indicating the Pharmacy had no documentation of annual compounding training, media challenge, or fingertip sampling.

7. At the conclusion of the inspection, the Board's inspectors explained to Kuss and Respondent that each sterile preparation compounded after expiration of the PECs was considered adulterated.

8. On February 22, 2023, the Board's inspectors conducted a follow-up, in-person inspection of the Pharmacy, and observed and noted the following:

- a. Respondent's staff indicated the Pharmacy had ceased compounding sterile preparations.
- b. Walls in the sterile compounding area were still dusty, leaving a black cloth with a white streak after wiping.
- c. Sterile gloves had been obtained.
- d. No current certifications were provided for the primary engineering controls ("PECs"), including the Compounding Aseptic Isolator ("CAI") and Biological Safety Cabinet ("BSC").

## CONCLUSIONS OF LAW

1. That pursuant to K.S.A. 65-1663, the Board may take action on an application for issuance or renewal of any registration as a pharmacy technician on any ground which would authorize the board to take action against the license of a pharmacist under K.S.A. 65-1627, and amendments thereto.

2. Pursuant to K.S.A. 65-1627(a)(3), the Board may take action against the license of a pharmacist upon a finding that the licensee is guilty of unprofessional conduct or professional incompetency.

3. Pursuant to K.S.A. 65-1626(III), professional incompetency means one or more instances involving failure to adhere to the applicable standard of pharmaceutical care to a degree that constitutes gross negligence or a pattern of pharmacy practice or other behavior that demonstrates a manifest incapacity or incompetence to practice pharmacy.

4. Pursuant to K.A.R. 68-5-15(b)(7), the pharmacist-in-charge of any pharmacy in which one or more pharmacy technicians perform any tasks authorized by the pharmacy act shall insure that there exists for the pharmacy a current pharmacy technician training course, designed for the functioning of that pharmacy and addressing knowledge of and the ability to perform procedures and techniques, including aseptic techniques, relating to the compounding, packaging, and labeling of drugs.

5. Pursuant to K.A.R. 68-5-15(d)(1), the pharmacist-in-charge of any pharmacy in which one or more pharmacy technicians perform any tasks authorized by the pharmacy act shall also ensure that there is an annual review of the pharmacy technician training course developed for the pharmacy.

6. Pursuant to K.A.R. 68-7-10(c), each unit-dose system shall meet the following

requirements:

- a. All medication shall be packaged in unit-dose containers as far as practicable and the packaging shall meet the requirements of K.A.R. 68-7-15 and 68-7-16, unless the manufacturer specifies a different type of packaging to be used to prevent adulteration as defined by K.S.A. 65-668, and amendments thereto.
- b. The pharmacist shall be responsible for filling and refilling prescriptions or prescriber's orders, or both, according to the directions of the prescriber by relying on the original prescription or prescriber's order or a copy thereof.
- c. The pharmacist shall comply with all requirements for prescription orders, including inventory and recordkeeping requirements, under the following:
  - i. The Kansas uniform controlled substances act, K.S.A. 65-4101 et seq. and amendments thereto;
  - ii. the Kansas pharmacy act, K.S.A. 65-1625 et seq. and amendments thereto;
  - iii. the board's applicable regulations in articles 1 and 20; and
  - iv. all federal laws and regulations applicable to prescriptions or medication orders.
- d. Packaging for the unit-dose system shall take place at the address of the pharmacy providing the unit-dose system.
- e. Container requirements for unit-dose systems may include trays, bins, carts, and locked cabinets if the requirements of K.A.R. 68-7-14 are met. If these options are used, all patient medication trays or drawers shall be sufficiently labeled to identify each patient.

- f. Each unit-dose system shall provide a verification check at the point of patient administration in order to ensure proper drug utilization.
- g. The delivery time-cycle or hours of exchange shall not be limited to a specific time, but shall depend upon the pharmacist's discretion, the needs of the long-term care facility, the stability of the drug, and the type of container used.

7. Pursuant to K.A.R. 68-7-15(c), all containers used for packaging and the storage conditions shall be maintained according to the manufacturer's recommendations to preserve the stability of the drug. The expiration date shall be the manufacturer's expiration date, the expiration date for the type of packaging material used, or not more than 12 months from the date of packaging, whichever is earlier.

8. Pursuant to K.A.R. 68-7-15(d), an electronic or a written record shall be established for lot numbers for recall purposes.

9. Pursuant to K.A.R. 68-7-16, labels for prepackaged and repackaged drugs shall contain the generic name with manufacturer and distributor's name or the brand name; strength and quantity; lot number and date repackaged and the person responsible for packaging; the expiration date, if applicable; and auxiliary labels necessary. Manufacturer, lot numbers, date repackaged, and the person responsible may be deleted from the label if a suitable record system is maintained to indicate them.

10. Pursuant to K.A.R. 68-13-4:

- h. (q)(1): Each pharmacist or pharmacy compounding sterile preparations shall have a primary engineering control that is currently certified by an inspector certified by the controlled environmental testing association to ensure aseptic conditions within the working area and that has the required documentation. The

certification shall be deemed current if the certification occurred within the previous six months or on the date the device was last moved to another location, whichever is more recent. The required documentation shall include the following:

- i. Inspection certificates for the past five years or since the date of installation, whichever is more recent;
  - ii. records of all filter maintenance for the past five years or since the date of installation, whichever is more recent;
  - iii. records of all HEPA filter maintenance for the past five years or since the date of installation, whichever is more recent; and
  - iv. records of all disinfecting and cleaning for the past year or since the date of installation, whichever is more recent.
- i. (s): Each pharmacist-in-charge shall maintain on the original order or on a separate, uniform record a compounding record for each sterile preparation, documenting the following:
- i. The name and strength of the sterile preparation;
  - ii. the formulation record reference for the sterile preparation;
  - iii. the name of the manufacturer or repackager and, if applicable, the lot number and the expiration date of each component;
  - iv. the total number of dosage units or total quantity compounded;
  - v. the name of the person or persons who compounded the sterile preparation;
  - vi. the name of the pharmacist, or the pharmacy student or intern working

under the direct supervision and control of the pharmacist, who verified the accuracy of the sterile preparation;

- vii. the date of compounding;
- viii. the assigned internal identification number, if applicable;
- ix. the prescription number, if assigned;
- x. the results of quality control procedures;
- xi. the results of the sterility testing and, if applicable, pyrogen testing for the batch; and
- xii. the assigned beyond-use-date. In the absence of valid scientific stability information that is applicable to a component or the sterile preparation, the beyond-use date shall be established in accordance with the following criteria:

1. For nonaqueous and solid formulations, one of the following:

- a. If the manufactured drug product is the source of the active ingredient, six months from the date of compounding or the time remaining until the manufactured drug product's expiration date, whichever is earlier; or
- b. if the substance listed in an official compendium is the source of an active ingredient, six months from the date of compounding or the time remaining until the expiration date of any component of the formulation, whichever is earlier;

2. for formulations containing water and made from ingredients in solid form, not more than 14 days when stored under refrigeration; and
  3. for all other formulations, not longer than the intended duration of therapy or 30 days, whichever is earlier.
- j. (y): Each pharmacist engaged in the dispensing of sterile preparations shall meet all labeling requirements under state and federal law. In addition, the label of each sterile preparation shall contain the following information:
- i. The name and quantity of each component;
  - ii. the beyond-use date;
  - iii. the prescribed flow rate;
  - iv. the name or initials of each person who compounded the sterile preparation; and
  - v. any special storage instructions.
- k. (z):
- i. The pharmacist-in-charge and all personnel involved in compounding sterile preparations shall have practical or academic training in sterile compounding, clean room technology, laminar flow technology, and quality assurance techniques. The training shall include the following:
    1. At least one successful media fill test; and
    2. a successful glove fingertip test.
  - ii. The pharmacist-in-charge shall ensure that all supportive personnel are trained and successfully demonstrate the following before performing

any delegated sterile admixture services:

1. Comprehensive knowledge of the pharmacy's standard operating procedures with regard to sterile admixture services, as specified in the policy and procedure manual;
  2. familiarity with the compounding techniques; and
  3. aseptic technique, which shall be proven by means of a media fill test and a glove fingertip test.
- iii. The pharmacist-in-charge shall be responsible for testing the aseptic technique of all personnel involved in compounding sterile preparations annually by means of a media fill test. All personnel involved in compounding high-risk sterile preparations shall undergo this testing twice each year. Each individual who fails to demonstrate acceptable aseptic technique shall be prohibited from compounding sterile preparations until the individual demonstrates acceptable technique by means of a media fill test.
- l. (aa): The pharmacist-in-charge shall document all training and test results for each person before that person begins compounding sterile preparations. This documentation shall be maintained by the pharmacy for at least five years and shall be made available to the board upon request.
- m. (bb): The pharmacist-in-charge shall be responsible maintaining records documenting the frequency of cleaning and disinfection of all compounding areas, according to the following minimum requirements:
- i. Each ISO class five environment shall be cleaned and disinfected as

follows:

1. At the beginning of each shift;
  2. every 30 minutes during continuous periods of compounding individual sterile preparations;
  3. before each batch; and
  4. after a spill or known contamination.
- ii. All counters, work surfaces, and floors shall be cleaned and disinfected daily.
  - iii. All walls, ceilings, and storage shelves shall be cleaned and disinfected monthly.
- n. (dd): The pharmacist-in-charge shall be responsible for maintaining records documenting the monitoring of the cleanliness and sterility of the sterile compounding environment. Environmental sampling shall be performed in each new facility before any sterile preparation in that facility is provided to a patient and, at a minimum, every six months thereafter. The environmental sampling shall include the primary engineering control, anteroom and buffer area, and equipment and shall be performed following any repair or service performed at the facility and in response to any identified problem or concern. Environmental sampling shall consist of the following, at a minimum:
- i. Environmental nonviable particle counts;
  - ii. environmental viable airborne particle testing by volumetric collection;
  - iii. environmental viable surface sampling; and
  - iv. certification of operational efficiency of the primary engineering control

by an independent contractor according to the international organization of standardization classification of particulate matter in room air, at least once every six months.

- o. (ee): The environmental sampling records shall be retained at the pharmacy for at least five years and shall be made readily available to the pharmacist-in-charge, the Board, and the Board's designee.

11. Pursuant to K.S.A. 65-1627(a)(3), the Board may take action against Respondent's Registration for professional incompetency as a pharmacy technician and Pharmacy Manager, indicated by a pattern of incompetent practice as a pharmacy technician in the Pharmacy, exemplified by the following violations of the pharmacy act of the state of Kansas or rules and regulations thereunder:

- a. Insanity conditions, including dust and debris in the Pharmacy and segregated sterile compounding area and segregated nonsterile compounding area; residue and other foreign materials on the CAI, BSC, ceiling vent, walls, and other surfaces; and a dirty sink in the sterile compounding area, all in violation of K.S.A. 65-1642(a), thus rendering all products compounded in that environment adulterated.
- b. Failure to provide current certifications for the PECs, including both the CAI and BSC, and failure to provide records of all disinfecting or cleaning of the PECs in violation of K.A.R. 68-13-4(q)(1).
- c. Failure to maintain records documenting the monitoring of the cleanliness and sterility of the sterile compounding environment by failing to provide documentation of viable or nonviable environmental sampling, in violation of

K.A.R. 68-13-4(dd) and (ee).

- d. Failure to maintain records documenting the frequency of cleaning and disinfection of all compounding areas, in violation of K.A.R. 68-13-4(bb).
- e. Failure to identify the lot number and the expiration date of each component on 44 compounding worksheets, and compounding with use of a “bulb” without providing a manufacturer name, lot number, or expiration date for the “bulb,” in violation of K.A.R. 68-13-4-(s)(3).
- f. Failure to include the prescribed flow rate on the label of 89 compounded IV drug products, in violation of K.A.R. 68-13-4(y)(3).
- g. Failure to include the initials of the individuals compounding the medication on all compounded preparations, in violation of K.A.R. 68-13-4(y)(4).
- h. Failure to properly label prepackaged drugs with the person responsible for packaging or record the same information in a suitable pharmacy record system, in violation of K.A.R. 68-7-16(c).
- i. Failure to receive and have documented in the Pharmacy appropriate intervals the requisite training for all pharmacy staff involved in compounding sterile and nonsterile preparations including, at a minimum, a media fill test, glove fingertip test, procedures for sterile admixture services, compounding techniques, and aseptic technique, in violation of K.A.R. 68-5-15(b)(7) and (d)(1), 68-7-12(b), 68-13-3(p), 68-13-4(z) and (aa).

### **ORDER**

Based upon the foregoing findings of fact and conclusions of law, Respondent is hereby restricted from performing any sterile or nonsterile compounding until Respondent has completed

10 hours of additional ACPE-approved or APhA-approved continuing education on the topics of sterile and nonsterile compounding, and provided proof of completion to the Board within 30 days of the date of this Order. Completion of penalty hours shall not count toward Respondent's next continuing education renewal requirement.

### NOTICES

Respondent is hereby notified as follows:

1. Respondent may request a hearing pursuant to the Kansas Administrative Procedure Act by filing a written request with the Kansas Board of Pharmacy, 800 SW Jackson, Suite 1414, Topeka, KS 66612-1231, within 15 days after service of this Order. If the outcome of the hearing is adverse to Respondent, costs of the proceedings shall be charged to Respondent.

2. If a hearing is not requested as described above, the Order shall become a final order of the Board, effective upon the expiration of the time to request a hearing.

3. Within 15 days after entry of a final agency order, either party may file a petition for reconsideration pursuant to K.S.A. 77-529.

4. Within the time limits established in K.S.A. 77-613, either party may seek judicial review of a final agency order, pursuant to K.S.A. 77-613. The agency officer designated to receive service of a petition for judicial review is:

Alexandra Blasi  
Executive Secretary  
Kansas Board of Pharmacy  
800 SW Jackson, Suite 1414  
Topeka, KS 66612

IT IS SO ORDERED.

5/17/2023  
Date

  
\_\_\_\_\_  
Alexandra Blasi, JD, MBA  
Executive Secretary  
Kansas Board of Pharmacy

CERTIFICATE OF SERVICE

I hereby certify that I did, on the 17th day of May 2023, deposit in business mail a copy of the foregoing Summary Order, which is then placed in the United States Mail, postage prepaid, properly addressed to the following:

Jason McLain  
806 Courtland Ct  
Belton MO 64012

  
\_\_\_\_\_  
Kansas Board of Pharmacy Staff