BEFORE THE KANSAS STATE BOARD OF PHARMACY

In the Matter of	)	
	)	Case No. 23-222
Philip Rellihan, Jr.	)	
	)	
Pharmacist License No. 1-11294	)	

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 Philip Rellihan, Jr. ("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 License No. 1-11294 which entitles Respondent to function as a pharmacist 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 79th Street in Lenexa, registration number 2-13167 (the "Pharmacy").

3. Respondent is the pharmacist-in-charge ("PIC") of the Pharmacy.

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 the Pharmacy's Manager, Jason McLain.

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 McLain 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. Upon request, Respondent provided no documentation of any cleaning of the segregated compounding area or any equipment.

k. There was cardboard in the room and a piece of cardboard partially taped over a vent in the ceiling.

l. There were no sterile gloves in the Pharmacy and none available to be donned in the CAI.

m. Used garbing attire was wadded up and stuffed onto a shelf.

n. A sink was available with hot and cold running water, but the sink was insanitary.

o. No in-date hand washing product was available in the sink or surrounding area.

p. The segregated compounding area was noticeably warm compared to the rest of the Pharmacy.

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 Pharamcy 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. An inappropriate beyond use date ("BUD") was documented on the compounding worksheets as follows:

    i. The Pharmacy's Ceftriaxone, after compounding, had a BUD longer than the manufacturer's drug information for 41 compounded IV products. The Pharmacy noted "14 days refrigerated" as the BUD. The drug manufacturer indicates the "drug should be administered within 72 hours when stored under refrigeration." Respondent provided no evidence of testing to allow a longer BUD.

    ii. The Pharmacy's Cefazolin, after compounding, had a BUD longer than the manufacturer's drug information for 15 compounded IV products. The Pharmacy noted 60 days as the BUD. The drug manufacturer indicates the reconstituted/diluted drug is stable for "10 days if stored under refrigeration." Respondent provided no evidence of testing to allow a longer BUD.

    iii. The Pharmacy's Lacosamide, after compounding, had a BUD longer

than the manufacturer's recommendation. The Pharmacy noted 24 hours as the BUD. The manufacturer's drug information indicates "the diluted solution should not be stored for more than 4 hours at room temperature." The manufacturer does not indicate the product's BUD may be extended by refrigeration.

iv. The Pharmacy's Daptomycin was placed in the "bulb," an elastomeric system. The manufacturer's literature indicates the drug is incompatible with this system. The impurity leached from the "bulb" is 2-mercaptobenzothiazole. This impacted 19 doses of medication and one patient.

i. Most of the compounding worksheets indicate a "bulb" was used to compound the sterile preparation. Respondent provided no media fill documentation showing the pharmacy staff performing sterile compounding could aseptically manipulate the elastomeric system without contamination. Respondent did not provide a lot number or expiration date for the "bulb" on 43 compounding worksheets and could not provide a commercial name or manufacturer associated with the term "bulb."

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

a. There were many expired products available for use in compounding.

b. Many items had no expiration date and were not dated as to when the product was opened.

c. Several items available for use in compounding did not have Certificates of

Analysis ("CoA"), including a bottle of Jim Beam whiskey, a bottle labeled "Everclear," and a squeeze bottle of blue food coloring.

d. One plastic lid was corroded to the point that the sides of the lid fell off the top.

e. The segregated area was noticeably warm compared to the rest of the Pharmacy and, while cleaner than the sterile compounding area, was still insanitary.

7. During the inspection, the Board's inspectors observed and noted the following in the Pharmacy:

a. Upon request, Respondent 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 Pharamcy only "removes from bulk inventory."

b. Upon request, Respondent's staff 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 provided no policies and procedures for the Pharmacy's compounding of sterile preparations. McLain's statement confirmed that Respondent had no policies and procedures for sterile compounding.

e. Upon request, Respondent provided no training records for any staff performing sterile compounding or nonsterile compounding, no records of training of Respondent's pharmacy technicians in the ability to perform aseptic techniques,

and no documentation of annual review. One of Respondent's pharmacists stated he "had taken sterile products in pharmacy school." Another one of Respondent's pharmacists reported attending UMKC School of Pharmacy. 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, Respondent provided no records of gloved fingertip testing or media fills for Respondent's 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.

f. Upon request, Respondent provided no incident reports or quarterly continuous quality improvement ("CQI") reports.

g. The Pharmacy's controlled substances were located in a room that was able to be accessed from a surrounding hallway and office area outside the Pharmacy. Walls did not go to the height of the roof deck, which could allow unauthorized personnel to crawl over the wall to access controlled substances from outside the Pharmacy. Additionally, the window in the door to the room was open to the extent that unauthorized personnel could reach into the room, access, and remove controlled substances without entering the locked room.

h. The Pharmacy was storing a box of controlled substances that had been returned from automation in other facilities, but was unable to provide, upon request, copies of DEA 222 transfer forms, invoices, or inventories for any controlled substances in the box.

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

9. 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. Pursuant to K.S.A. 65-1658, the Board may assess a civil fine not to exceed $5,000, after notice and an opportunity to be heard, to any registrant for violation of the pharmacy act of the state of Kansas or any other rules or regulations of the state board of pharmacy.

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(lll), 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.S.A. 65-1627(a)(8), the Board may take action against the license of a pharmacist upon a finding that the licensee has violated any of the provisions of the pharmacy act of the state of Kansas or any rule and regulation adopted by the board pursuant to the provisions of such pharmacy act.

5. Pursuant to K.S.A. 65-1642(a), each pharmacy shall be equipped with proper pharmaceutical utensils, in order that prescriptions can be properly filled and United States pharmacopeia and national formulary preparations properly compounded, and with proper sanitary appliances that shall be kept in a clean and orderly manner.

6. Pursuant to K.S.A. 65-1695, each pharmacy shall establish a CQI program. The purpose of the CQI program shall be to assess errors that occur in the pharmacy in dispensing or furnishing prescription medications so that the pharmacy may take appropriate action to prevent a recurrence. All reports and records generated as part of a pharmacy's CQI program shall be available for inspection by the board of pharmacy within a time period established by the Board.

7. Pursuant to K.S.A. 65-668(a), a drug or device shall be deemed to be adulterated:

   a. If it consists in whole or in part of any filthy, putrid, or decomposed substance;

   b. if it has been produced, prepared, packed or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health, or if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this act as to safety and has the identity and strength, and meets the quality and

purity characteristics, which it purports or is represented to possess; or

c. if it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

8. 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.

9. 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.

10. 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.

11. Pursuant to K.A.R. 68-7-12(b), each pharmacist-in-charge shall be personally available to the extent required to ensure comprehensive pharmaceutical services within the pharmacy and to develop a staff of additional licensed pharmacists and supportive personnel as necessary to serve the needs of the pharmacy. Each pharmacist-in-charge shall maintain records in

the pharmacy describing the training and education regarding work functions performed by all pharmacy personnel. Each pharmacist-in-charge shall maintain in the pharmacy written procedures that address the following areas:

a. Designate the person or persons functioning as pharmacy technicians and supportive personnel;

b. describe the functions of all personnel; and

c. document the procedural steps taken by the pharmacist-in-charge to limit the functions of all personnel to their respective pharmacy work functions.

12. Pursuant to K.A.R. 68-7-12(c), each pharmacist-in-charge shall develop or approve written policies and procedures for the pharmacy that meet all of the following conditions:

a. Adequate accountability and control of drugs in compliance with the Kansas pharmacy act, the Kansas uniform controlled substances act, federal drug laws, and all applicable regulations are provided for.

b. Any incident that occurs as a result of an alleged or real error in filling or dispensing a prescription or medication order is brought to the attention of the pharmacist-in-charge and completely documented in accordance with the requirements of K.A.R. 68-7-12b.

c. Adequate records of the pharmacy's dispensing, prepackaging, and bulk compounding actions are maintained, and all prepackaging of drugs is done in suitable containers, properly labeled in accordance with K.A.R. 68-7-16.

13. Pursuant to K.A.R. 68-7-12(d), each pharmacist-in-charge shall develop written procedures for maintaining records of the pharmacy's dispensing, prepackaging, and bulk compounding actions and shall ensure that prepackaged medication is packaged in suitable

containers and properly labeled.

14. Pursuant to K.A.R. 68-7-12b, the pharmacist-in-charge shall ensure that procedures exist requiring each pharmacist who becomes aware of a reportable incident to report the incident to the pharmacist-in-charge as soon as practical. As soon as possible after discovery of the incident, the pharmacist shall prepare a report containing the date of the incident and the date of the report, and a pharmacist's description of the incident. The maintenance of incident reports as required by this regulation shall be the responsibility of the pharmacist-in-charge.

15. 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.

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

17. 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.

18. Pursuant to K.A.R. 68-13-3:

a. (d): A pharmacist shall not compound a nonsterile preparation by any of the following methods:

i. Using any component withdrawn from the market by the FDA for safety reasons;

ii. receiving, storing, or using any drug component that is not guaranteed or otherwise determined to meet the requirements of an official compendium;

iii. compounding finished drugs from bulk active ingredients that do not meet the requirements of a monograph listed in the official compendium; or

iv. compounding finished drugs from bulk active ingredients that are not components of FDA-approved drugs.

b. (j): Within each pharmacy in which compounding occurs, one area shall be designated as the principal compounding area, where all nonsterile compounding shall take place.

i. Each compounding area shall be well-lighted and well-ventilated, with clean and sanitary surroundings, and shall be free of food and beverages.

ii. Each compounding area shall provide the drugs, chemicals, and devices with necessary protection from deterioration due to light, heat, and evaporation and shall be arranged to protect all prescription drugs and devices from theft and any other unauthorized removal.

iii. All components used in compounding nonsterile preparations shall be stored in labeled containers in a clean, dry area and, if required, under proper refrigeration.

iv. Each compounding area shall include a sink that is equipped with hot

and cold running water for hand and equipment washing.

c. (p): The pharmacist-in-charge shall ensure that all support personnel are trained and successfully demonstrate the following before performing delegated compounding:

    i. Comprehensive knowledge of the pharmacy's standard operating procedures with regard to compounding as specified in the policy and procedure manual; and

    ii. familiarity with the compounding techniques used at the pharmacy.

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

a. (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.

b. (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.

c. (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.

d. (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.

e. (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.

f. (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.

g. (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, antearea 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.

h. (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.

20. Pursuant to K.A.R. 68-19-1, each pharmacy's CQI program shall meet the following minimum requirements:

a. Meet at least once each quarter of each calendar year; and

b. create a report of the meeting, including at least the following information:

i. A list of the persons in attendance;

ii. a list of the incident reports and newsletters reviewed; and

iii. a description of the steps taken or to be taken to prevent recurrence of each incident reviewed.

21. Pursuant to K.A.R. 68-20-15a, each pharmacy shall provide effective controls and procedures to guard against theft and diversion of controlled substances in conformance with the security requirements of federal law, including the requirements of 21 CFR 1301.71 as in effect on April 1, 1999, which are hereby adopted by reference.

22. Pursuant to K.S.A. 65-1627(a)(8), the Board may take action against Respondent's Registration for Respondent's operation of the Pharmacy as PIC in such a manner that violates the following statutes and regulations:

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 name of the pharmacist who verified the accuracy of the sterile preparation on two compounding worksheets (Rx #8046750 on dates 1/16/2023 and 1/11/2023), in violation of K.A.R. 68-13-4(s)(6).

f. 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).

g. 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).

h. 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).

i. Failure to maintain on the original order or on a separate, uniform record a compounding record for each sterile preparation, an assigned BUD that conforms to the requirements of K.A.R. 68-13-4(s)(12) for 41 compounded IV Ceftriaxone products, 15 compounded IV Cefazolin products, Lacosamide, and 19 doses of Daptomycin.

j. Failure to properly store and label (including expiration date) all containers in the nonsterile compounding area, including maintaining products beyond the expiration date, in violation of K.A.R. 68-13-3(j)(3).

k. Receiving and/or storing in the nonsterile compounding area several items (i.e.,

Jim Beam, Everclear, and blue food coloring) not guaranteed or otherwise determined to meet the requirements of an official compendium, and without any CoA, in violation of K.A.R. 68-13-3(d)(2).

l. Failure to provide the drugs, chemicals, and devices in the nonsterile compounding area with necessary protection from deterioration, demonstrated by a corroded and ill-fitting plastic lid, in violation of K.A.R. 68-13-3(j)(2).

m. Insanity conditions, including dust and debris in the segregated nonsterile compounding area and failure to provide adequate ventilation (warmer than the rest of the Pharmacy) to the nonsterile compounding area, in violation of K.A.R. 68-13-3(j)(1), thus rendering all products compounded in that environment adulterated.

n. Failure to properly understand and meet the requirements of prepackaging (i.e., unit-dose packaging), including: failure to maintain and provide adequate records; failure to record the drug, lot number, expiration date, and other required information for all prepackaging; failure to maintain, store, and label (specifically, expiration date) packaging in accordance with the manufacturer's recommendations; and failure to generate an electronic or written record, in violation of K.A.R. 68-7-10(c) and K.A.R. 68-7-15(c) and (d).

o. 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).

p. Failure to maintain or conduct necessary review of a policy and procedure manual for compounding sterile preparations, in violation of K.A.R. 68-13-

4(q)(5).

q. Failure to require, document, and readminister at 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).

r. Failure to generate quarterly CQI reports for any period, including failure to document review of Board newsletters, in violation of K.A.R. 68-19-1.

s. Failure to maintain records in the Pharmacy and failing to furnish such records to the Board's inspectors upon request, including:

    i. Current certifications for PECs, including CAI and BSC, required by K.A.R. 68-13-4.

    ii. Environmental sampling required by K.A.R. 68-13-4.

    iii. Documentation of cleaning compounding areas required by K.A.R. 68-13-3 and 68-13-4.

    iv. Certificates of Analysis for items used in nonsterile compounding required by K.A.R. 68-13-3.

    v. Records of prepackaging required by K.A.R. 68-7-10 and 68-7-15.

    vi. Policies and procedures required by K.A.R. 68-7-12 and 68-13-4.

    vii. Documentation of training or training records required by K.A.R. 68-5-15, 68-7-12, 68-13-3, and 68-13-4.

    viii. Incident reports required by K.A.R. 68-7-12b.

ix. CQI reports required by K.S.A. 65-1695(d) and K.A.R. 68-19-1.

23. Pursuant to K.S.A. 65-1627(a)(3), the Board may take action against Respondent's Registration for the professional incompetency demonstrated by a pattern of incompetent practice as PIC and a pharmacist in the Pharmacy, which is exemplified by the insanitary conditions in the Pharmacy and segregated compounding areas, the lack of certification (or expired certification) of the CAI, and the volume of compounding worksheets (102 items on 44 compounding worksheets for 6 different drugs and 5 different patients over 19 days in a limited Board review) that failed to meet the requirements of the Pharmacy Act and potentially jeopardized consumer safety. As PIC, Respondent has responsibility and accountability for each of these failures.

ORDER

Based upon the foregoing findings of fact and conclusions of law, Respondent is ordered to pay a fine to the Board in the amount of $12,000. Respondent has 30 days from the date of this order to pay the fine by check or money order.

Furthermore, Respondent shall complete 20 hours of additional ACPE-approved or APhA-approved continuing education on the topics of sterile and nonsterile compounding, and provide 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

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:

Philip Rellihan, Jr.
18605 E 25th Terr, Crt S
Independence MO 64057

[redacted]rmacy Staff