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Kansas
Board of Pharmacy

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Alexandra Blasi, Executive Secretary

Laura Kelly, Governor

September 20, 2024

Milka Goodlett
2715 Hickory St
Hays KS 67601

RE: Case No. 23-415

Dear Ms. Goodlett:

Enclosed you will find a copy of the final Stipulation and Consent Order approved by the Kansas Board of Pharmacy in the above-referenced matter. Please read the order in its entirety. In addition, a civil fine has been assessed totaling $8,250.00. The first monthly installment is due by October 1, 2024. Please make all checks payable to the Kansas Board of Pharmacy and include your case number in the memo.

If you have any questions, feel free to contact the Board at Pharmacy.Compliance@ks.gov.

Sincerely,

Kansas Board of Pharmacy

Enclosure

cc:
Diane Bellquist
Joseph Hollander & Craft
1508 SW Topeka Blvd
Topeka KS 66612-1887

BEFORE THE KANSAS BOARD OF PHARMACY

In the Matter of	)	
	)	Case No. 23-415
MILKA GOODLETT, R.PH.	)	
Kansas License No. 1-15036	)	

STIPULATION AND CONSENT ORDER

IT IS HEREBY STIPULATED AND AGREED by and between the Kansas Pharmacy Board (the "Board") and Milka Goodlett, R.Ph. ("Respondent") as follows:

1. The Board is represented herein by its attorney, Brenda L. Head of Frieden & Forbes, 1414 SW Ashworth Place, Suite 201, Topeka, Kansas 66604. The Respondent is represented herein by her attorney, Diane L. Bellquist of Joseph Hollander & Craft LLC, 1508 SW Topeka Blvd., Topeka, Kansas 66612-1887.

2. The Board is the Kansas agency vested with the authority to carry out and enforce the provisions of the Kansas Pharmacy Law, K.S.A. 65-1626 *et seq.*, (the "Act") including conducting hearings and proceedings to revoke, suspend or otherwise discipline a Kansas license to practice pharmacy.

3. The Respondent is presently entitled to engage in the practice of pharmacy in the State of Kansas by reason of the Board having issued her Kansas license number 1-15036 ("Kansas License"). At all times relevant hereto, the Respondent has held a current license to engage in the practice of pharmacy in the State of Kansas and is the owner and Pharmacist-in-Charge ("PIC") of Kellstrom Pharmacy (the "Pharmacy") located at 1860 Claflin Rd., Manhattan, Kansas.

4. The Board's Investigation Member has received certain information, investigated and determined that there are reasonable grounds and probable cause to believe that Respondent has operated in a manner that violates the Kansas pharmacy act, K.S.A. 65-1626, *et. seq.* and the Board's regulations which would justify the revocation or imposition of other disciplinary action

against her Kansas License under the provisions of K.S.A. 65-1627(a) and the assessment of an appropriate fine against Respondent under the provisions of K.S.A. 65-1658.

5. Respondent hereby admits and waives any further proof in this or any other proceeding before or initiated by the Board, and upon motion duly made, seconded and passed, the Board finds the following:

A. On July 8, 2020, the Board entered into a Stipulation and Consent Agreement (Case No. 19-341) with Respondent, placing Respondent's Kansas Pharmacist License on a 5-year probationary status subject to multiple terms and conditions, including the following:

a. Respondent was required to hire a pharmacy consultant within 60 days to do the following:

i. Conduct a full audit and review of the Pharmacy's recordkeeping methods, policies and procedures, and assist in the implementation of improvements of those procedures when necessary;

ii. Prepare a written review of the Pharmacy's compliance with Kansas statutes and regulations to be submitted to the Board;

iii. Submit to Respondent and the Board an evaluation of the Pharmacy's policies and procedures within six months;

iv. Additional periodic evaluations and reviews of the Pharmacy's policies and procedures, recordkeeping, etc.; and

v. In conjunction with Respondent, file quarterly reports with the Board regarding the Pharmacy's ongoing compliance with the pharmacy act and regulations adopted thereunder; and

b. Respondent was required to comply with the Pharmacy act, the Board rules and regulations, and all state and federal laws relating to pharmacy practice.

B. On December 5, 2020, the consultant conducted the initial and only in-person audit of the Pharmacy. All other reports attest to accuracy based on this visit. Respondent's controlled substance inventory dates were listed as 3/3/2019 and 12/12/2020 (seven days after the consultant's visit) and marked as compliant.

C. Around March 2021, the first quarterly report was submitted marking the continuous quality improvement program compliant for newsletter review of ISMP, but there was no mention of review of the Board's newsletters. The report also indicated Respondent was implementing the PRS operations manual for pharmacy technician training.

D. Around June 2021, the second quarterly report was submitted indicating Respondent was implementing TECHTrack for pharmacy technician training. All prepackaging activities were marked as compliant.

E. Around September 2021, the third quarterly report was submitted. Respondent's controlled substance inventory dates were noted as 3/3/2019, 12/12/2020, and 7/27/2021 with next due 7/27/2022. Later in the report there is a conflicting statement that the next controlled substance inventory is due 10/27/2022. All prepackaging activities were marked as compliant.

F. Around December 2021, the fourth quarterly report was submitted. The next controlled substance inventory date listed was 7/27/2022. No deficiencies were noted.

G. On April 6, 2021, the Board's inspector received information from Kansas Prescription Monitoring Program ("K-TRACS") staff that Respondent was submitting odd patient names to K-TRACS.

H. On May 6, 2021, the Board's inspector conducted an in-person inspection of the Pharmacy and discovered that the prescriptions were for wholesale distribution transactions that were also being submitted as prescription dispensations. The inspector educated Respondent about not submitting these transactions to K-TRACS.

I. On March 28, 2023, the Board's inspector received information from Kansas Prescription Monitoring Program ("K-TRACS") staff that Respondent was submitting wholesale transactions to K-TRACS.

J. On April 25, 2023, the Board's inspectors conducted an in-person inspection of the Pharmacy. Respondent was educated on not submitting wholesale distribution transactions to K-TRACS.

K. During the inspection, the Board's inspectors observed and noted the following:

a. Outdated blister packs in the prepackage area with the active packs.

b. Drugs prepackaged into blister cards had been given beyond-use-dates ("BUD") ranging up to three years.

c. Name of manufacturer was missing on some prepacked blister cards.

d. No BUD on some of the items compounded in advance of need.

e. Controlled substance invoices not properly separated for CII and CIII-V. PSE products were not included in the CV inventory.

f. FDA side effect statement only provided with new dispensations.

g. Good Shepherd Hospice House (GSH) notification of e-kit use form found when flipping through hard copy prescriptions. This form was filled out to include the name of the patient that received the drug.

h. Compounding records (CR) not complete. No uniform formulation records (UFR). Examples of some of the items missing from some of the reviewed records include the following:

i. B – missing component expiration date, exceeded BUD without stability documentation, no mixing instructions, multiple preparation dates listed, no storage instructions, no container instructions, no final product description.

ii. G – 2 BUDs indicated on form (30-days and 5/30/23), no mixing instructions, actual amount weighed out not listed, no storage instructions, no container instructions, no final product description, no pharmacist check documented, cites PCCA formula but no formulation record available.

iii. Ma – extended 90-day BUD without documentation, no pharmacist check, no final product description, 3.2 written next to one of the checker lines without description or meaning, no container closure information, no mixing instructions, no storage instructions, no formula citation.

iv. Mo – missing a component expiration date, "prepared date 6/27/22" typed at top but "prepared 3/7/23" handwritten on page, no mixing instructions, no final product description, no

container closure information, no verification of final weights of capsules and no capsule variation, no pharmacist verification, hazardous drug with no CVE or negative pressure, lists green food color by weight but only food grade liquid on shelf (Note: Goodlett verbally stated to the Board's inspector they actually used purple powder food color they have on shelf.), lactose powder expiration date 5/19/23 but final product expiration date was 6/5/23.

i. Pre-prepared aliquots and APIs on shelf without expiration dates.

j. An uncovered, unsealed compliance package loaded with patient pills was left sitting open on a front counter that was accessible to customers during the entirety of the inspection despite Board staff commenting to the Pharmacy staff that it was open and accessible to customers but the card was never moved or covered.

k. Pharmacy was selling controlled substances to the GSH institutional drug room registration. The GSH DEA registration expired on 11/30/2021.

L. On May 29, 2023, the Pharmacy submitted a wholesale distribution transaction to K-TRACS.

M. On June 14, 2023, the Pharmacy submitted a wholesale distribution transaction to K-TRACS.

N. On June 29, 2023, the Board's inspectors conducted an in-person inspection at GSH to determine if an e-kit was being maintained there by the Pharmacy. Board staff were

able to meet with administrative GSH staff who thought the stocked drugs that were not patient specific belonged to the Pharmacy. GSH had an identical blank template as that observed in the Pharmacy hanging in the institutional drug room to be filled out after use of stocked drugs and sent to the Pharmacy. The template indicated the drugs belonged to the Pharmacy.

O. On June 29, 2023, the Board's inspectors conducted an in-person inspection of the Pharmacy. Respondent was, again, educated on not submitting wholesale distribution transactions to K-TRACS.

P. Board staff asked Respondent about the GSH e-kit. Respondent indicated the Pharmacy did not have an e-kit at GSH and the templates notified her when GSH had used something and needed more, which was replaced as a wholesale transaction between the Pharmacy and GSH. She indicated the forms were leftover from the Pharmacy's previous owner. However, the completed templates were being filled out by GSH to the patient-specific level and stored at the Pharmacy with the dispensed prescriptions.

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

a. Unable to produce UFR, Respondent stated she had a membership with PCCA and would log into their library for UFR's. No facility UFR library was established, approved, or maintained. Respondent was unable to log in to PCCA during the inspection to demonstrate any UFRs for any compounded products. Respondent had one printed UFR in a stack of papers on the pharmacy counter she was able to provide, which was missing the dispensing container to be used, the pharmacist verifying the UFR within the pharmacy's UFR

library, the date approved for the pharmacy's UFR library, and quality control procedures. The UFR was not cited in CR.

b. There was no documentation in the continuous quality improvement records of any review of Board newsletters.

c. Respondent uses PRS COMPLIANCE Track for pharmacy technician training. However, not all required topics are covered and there is only one shared login to the system so there is no record of when each pharmacy technician completed training modules.

d. The prepackaged blister cards with extended BUDs noted in April were still in stock and being used.

e. There were prepackaged blister cards that had no labeling at all, including no drug name.

f. Invoices for office-use compounds were deficient and noncompliant, missing lot number, BUD, and quantity.

g. No documentation of training for pharmacy technicians for the dosage forms they were compounding, or the equipment being used.

h. CR missing information on all components being used. Example: lot number, expiration date, and manufacturer of capsules not documented in CR.

i. Nonsterile compounding counter covered in unidentified, fine white powder.

R. K.S.A. 65-1658 provides that 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, which the Respondent violated.

S. K.S.A. 65-1627(a)(3) provides that the Board may take action against the license of a pharmacist if the licensee is found by the board to be guilty of professional incompetency, as defined by K.S.A. 65-1626(lll), which 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, which Respondent violated.

T. K.S.A. 65-1627(a)(5) provides that the Board may take action against the license of a pharmacist upon a finding that the licensee has violated a provision of the federal or state food, drug and cosmetic act, the federal or state uniform controlled substances act, or any rule and regulation adopted under any such act, which Respondent violated.

U. K.S.A. 65-1627(a)(8) provides that 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, which Respondent violated.

V. K.S.A. 65-1627(a)(16) provides that the Board may take action against the license of a pharmacist upon a finding that the licensee has violated or failed to comply with any lawful order or directive of the board, which Respondent violated.

W. K.S.A. 65-1627(a)(17) provides that 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 prescription monitoring program act of the state of Kansas or any rule and regulation of the board pursuant to the provisions of the prescription monitoring program act, which Respondent violated.

X. K.S.A. 65-1627(a)(18) provides that the Board may take action against the license of a pharmacist upon a finding that the licensee has failed to keep records required to be kept or filed by the provisions of the Pharmacy act of the state of Kansas, the federal or state uniform controlled substances act or rules and regulations adopted by the board, which Respondent violated.

Y. K.S.A. 65-1683(b) requires each pharmacy shall submit to the Board by electronic means information required by the Board regarding each prescription dispensed for scheduled substances and drugs of concern, which Respondent violated.

Z. K.S.A. 65-4122 requires that controlled substances in schedules I and II shall be distributed by a registrant to another registrant only pursuant to an order form, which Respondent violated.

AA. K.S.A. 65-657 provides the following acts and the causing thereof within the state of Kansas are hereby prohibited, which Respondent violated:

a. The processing, storage or distribution of any food, drug, device or cosmetic that is adulterated or misbranded.

b. The adulteration or misbranding of any food, drug, device or cosmetic.

BB. K.S.A. 65-668(a) states 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; or

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; or

d. if it is a drug and it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of K.S.A. 65-667, or it is a color additive, the intended use of which in or on drugs is for purposes of coloring only, and is unsafe within the meaning of K.S.A. 65-667. Respondent violated K.S.A. 65-668(a).

CC. K.A.R. 68-5-15(b)(7) provides 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, which Respondent violated.

DD. K.A.R. 68-5-15(d)(1) provides 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, which Respondent violated.

EE. K.A.R. 68-7-12(b) provides 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, which Respondent violated.

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

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.

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.

GG. K.A.R. 68-7-12(d) provides 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, which Respondent violated.

HH. K.A.R. 68-7-16 provides each label for a drug or device packaged in advance of immediate need shall contain the following, which Respondent violated:

a. The generic name of the drug or device and the manufacturer's name. If the packaged drug or device bears a brand name, the brand name may be substituted for the generic name of the drug or device;

b. the strength and quantity of the drug or device;

c. the lot number, date of packaging, and the name of the individual responsible for packaging;

d. the beyond-use date; and

e. necessary auxiliary labels.

II. K.A.R. 68-13-3 provides:

a. (d)(2): A pharmacist shall not compound a nonsterile preparation by any of the following methods: receiving, storing, or using any drug component that is not guaranteed or otherwise determined to meet the requirements of an official compendium, which Respondent violated.

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.

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

(2) 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.

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

(4) Each compounding area shall include a sink that is equipped with hot and cold running water for hand and equipment washing. Respondent violated K.A.R. 68-13-3(j).

c. (l) Each pharmacist-in-charge shall maintain a uniform formulation record for each nonsterile preparation, documenting the following, which Respondent violated:

i. The ingredients, quantities, strength, and dosage form of the nonsterile preparation;

ii. the equipment used to compound the nonsterile preparation and the mixing instructions;

iii. the container used in dispensing;

iv. the storage requirements;

v. the beyond-use date to be assigned;

vi. quality control procedures, which shall include identification of each person performing or either directly supervising or

checking each step in the compounding process and which may include monitoring the following:

1. Capsule weight variation;
2. adequacy of mixing to ensure uniformity and homogeneity; and
3. the clarity, completeness, or pH of solutions;

vii. the source of the formulation, including the name of the person, entity, or publication; and

viii. the name or initials of the person creating the formulation record and the date on which the formulation record was established at the pharmacy.

d. (m) Each pharmacist-in-charge shall maintain on the original order or on a separate, uniform record a compounding record for each nonsterile preparation, documenting the following, which Respondent violated:

i. The name and strength of the nonsterile preparation;

ii. the identifier used to distinguish the nonsterile preparation's formulation record from other formulation records;

iii. the name of the manufacturer or repackager and, if applicable, the lot number and expiration date of each component;

iv. the total number of dosage units or total quantity compounded;

v. the name of each person who compounded the nonsterile 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 nonsterile preparation;

vii. the date of compounding;

viii. the assigned internal identification number, if used;

ix. the prescription number, if assigned;

x. the results of quality control procedures; and

xi. the assigned beyond-use date. In the absence of valid scientific stability information that is applicable to a specific drug or nonsterile preparation, the beyond-use date shall not be later than the expiration date of any component of the formulation and shall be established in accordance with the following criteria:

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

    a. If a 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 a 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 water-containing oral formulations, not more than 14 days when stored under refrigeration; and
3. for water-containing non-oral formulations, not longer than the intended duration of therapy or 30 days, whichever is earlier.

e. (n) The compounding record and the corresponding formulation record specified in subsections (m) and (l), respectively, 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, which Respondent violated.

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

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

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

JJ. K.A.R. 68-19-1(c)(3) and (4) provide each pharmacy's CQI program shall review each Board newsletter published since the last quarterly meeting, and shall create a report of the meeting including a list of the Board newsletters reviewed, which Respondent violated.

KK. K.A.R. 68-20-16(a) provides each registrant shall keep records and maintain inventories in conformance with the recordkeeping and inventory requirements of 21 C.F.R. 1304.04(a)(2), (a)(3), (f), (g), (h)(1), (h)(2), (h)(3), and (h)(4), as in effect on February 1, 2022, which are hereby adopted by reference, which Respondent violated. Except as otherwise provided in this regulation, the registrant shall maintain executed order forms and controlled substance inventories at the registered facility and keep the records on file for at least five years, which Respondent violated.

LL. K.A.R. 68-20-16(b) provides after the initial inventory is taken, the registrant shall take a subsequent inventory of all controlled substances and drugs of concern on hand at least every year but no later than 375 days after the date of the previous inventory, which Respondent violated. All controlled substances and drugs of concern shall be inventoried on the same calendar date, which Respondent violated.

MM. K.A.R. 68-20-16(d) provides each registrant handling schedule V controlled substances and drugs of concern shall be subjected to the same inventory and recordkeeping requirements specified in subsections (a) and (b), which Respondent violated.

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

a. Insanitary conditions in the principal nonsterile compounding area, including white powder on counter, in violation of K.A.R. 68-13-

3(j), thus rendering all products compounded in that environment adulterated, which Respondent violated.

b. Maintaining pre-prepared aliquots and APIs on the shelf without expiration dates, in violation of K.A.R. 68-13-3(d)(2), which Respondent violated.

c. Failure to review Board newsletters at quarterly CQI meetings, including failure to document review of Board newsletters in the quarterly report, in violation of K.A.R. 68-19-1, which Respondent violated.

d. Failure to properly label prepackaged drug, including drugs prepackaged into blister cards with BUDs ranging up to three years, missing manufacturer names, and prepackaged blister cards with no labels or drug name, in violation of K.A.R. 68-7-16, which Respondent violated.

e. 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), which Respondent violated.

f. Failure to require, document, and readminister at appropriate intervals the requisite training for all pharmacy staff involved in compounding nonsterile preparations, in violation of K.A.R. 68-5-15(b)(7) and (d)(1), 68-7-12(b), and 68-13-3(p), which Respondent violated.

g. Incomplete compounding records, including missing expiration dates, exceeding BUD with no stability documentation, no mixing instructions, multiple preparation dates listed, no storage instructions, no container instructions, no final product description, actual amount weighed out not listed, no pharmacist check documented, no formulation record available, no container closure information, no formula citation, no verification of final weight of capsules and no capsule variation, no pharmacist verification, and a final product expiration date exceeding a component expiration date by 17 days, all of which were in violation of K.A.R. 68-13-3.

OO. K.S.A. 65-1627(a)(18) states the Board may take action against Respondent's License for Respondent's failure as PIC to keep or file the following records required by the provisions of the Pharmacy act of the state of Kansas, the federal or state uniform controlled substances act or rules and regulations adopted by the Board, which Respondent violated:

a. Records for nonsterile compounding required by K.A.R. 68-13-3.

b. Uniform formulation records required by K.A.R. 68-13-3.

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

d. CQI reports required by K.A.R. 68-19-1.

PP. K.S.A. 65-1627(a)(5) states the Board may take action against Respondent's License for Respondent's operation of the Pharmacy as PIC in such a manner that violations the following provisions of the federal or state food, drug and cosmetic act, the federal

or state uniform controlled substances act, or any rule and regulation adopted thereunder. Respondent's violations include:

a. The Pharmacy took controlled substance inventories on 3/3/2019 and 12/12/2020. The 12/12/2020 inventory was nine months overdue. The Pharmacy took additional controlled substance inventories on 7/27/2021 and 7/27/2022. However, any inventory taken after 12/12/2020 required eight months to elapse before another inventory, which means the 7/27/2021 inventory was a month early and no valid 2021 inventory was taken. In the consultant's report, there is a conflicting statement that a controlled substance inventory was taken on 10/27/2022 instead of 7/27/2022, which would have been late. To ensure compliance, the Pharmacy should have taken inventories in March of each year from 2019 to 2023. Respondent failed to take inventories at the required intervals, in violation of K.A.R. 68-20-16.

b. The Pharmacy's controlled substance inventories for their C-II, C-III, and C-IV drugs were not filed separately, in violation of K.A.R. 68-20-16(a).

c. The Pharmacy's C-V controlled substance inventories did not include PSE products in the report, in violation of K.A.R. 68-20-16(d).

d. The Pharmacy sold controlled substances to a facility with an expired DEA registration which, therefore, did not meet the requirements of being a "registrant" pursuant to K.S.A. 65-4122.

e. The Pharmacy left an unsealed compliance package with patient pills left open and accessible to customers even after being notified by Board staff, in violation of K.S.A. 65-657(a) and 65-668, and which render the product adulterated.

QQ. K.S.A. 65-1627(a)(17) states the Board may take action against Respondent's License for Respondent's operation of the Pharmacy as PIC in such manner that the violations of the provisions of the prescription monitoring program act of the state of Kansas or any rule and regulation of the Board have occurred in connection therewith: Respondent's repeated and knowing submissions of wholesale distribution transactions to K-TRACS, after multiple on-site visits for education, is a violation of K.S.A. 65-1683 which requires only reporting of controlled substances and drugs of concern dispensed.

RR. K.S.A. 65-1627(a)(16) states the Board may take action against Respondent's License for Respondent's violation of the previous Stipulation and Consent Agreement, which required Respondent to comply with all requirements of the pharmacy act of the state of Kansas, the federal and state uniform controlled substances act, the federal and state food, drug, and cosmetic act, and all regulations thereunder. Based on the above conclusions, Respondent has clearly failed to comply with this lawful Order of the Board, in violation of K.S.A. 65-1627(a)(16).

SS. K.S.A. 65-1627(a)(3) provides the Board may take action against Respondent's License 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, the lack labeling, prepackaging, and nonsterile compounding violations in the Pharmacy, the demonstrated inability of Respondent to make corrections to K-TRACS reporting after repeated warnings and education, Respondent's inability to provide adequate training records for Pharmacy staff, Respondent's inability to provide any nonsterile compounding UFR or formulary citation, failure to take required controlled substance inventories at required intervals, failure to separate controlled substance inventories, and failure to include inventories for PSE products, all of which failed to meet the requirements of the pharmacy act, the uniform controlled substance act, the food, drug and cosmetic act, and the Prescription Monitoring Program Act, and potentially jeopardized consumer safety. As PIC, Respondent has responsibility and accountability for each of these failures.

Upon motion duly made, seconded and passed, the Board finds and concludes that Respondent's conduct, as described above, violates the Act and such conduct warrants the imposition of appropriate disciplinary action against Respondent's Kansas License pursuant to K.S.A. 65-1627(a)(8), (a)(3), (a)(5), (a)(16), (a)(17) and (a)(18) and an administrative fine pursuant to K.S.A. 65-1658.

6. The Respondent agrees and consents and the Board finds, concludes and orders that the following disposition is just and appropriate under the circumstances:

A. ADMINISTRATIVE FINE. Respondent shall pay to the Board an administrative fine in the amount of Eight Thousand Two Hundred Fifty Dollars ($8,250.00) payable in sixty (60) equal consecutive monthly installments of $137.50 with the first payment due within ten (10) days of the Board approving this Stipulation and Consent Order.

B. CONTINUING EDUCATION. Respondent shall successfully complete fifteen (15) hours of additional ACPE-approved or APhA-approved continuing education on non-sterile compounding within ninety (90) days of the entry of this Stipulation and Consent Order. These penalty hours may have been completed before the entry of this Order, but these penalty hours cannot be counted toward license renewal.

C. OTHER REQUIREMENTS. Respondent acknowledges and agrees that as a condition of this Stipulation and Consent Order she must, and the Board further orders the Respondent to:

1. Comply fully with this Stipulation and Consent Order;

2. Comply fully with the Kansas pharmacy act, the Board's rules and regulations and all state and federal laws relating to Kansas pharmacies;

7. Respondent agrees that all information in the possession of the Board's Investigation Member or Investigation Committee, its staff, its investigators and/or its attorney regarding the investigation which lead to this disciplinary action and all information discovered during the pendency of the disciplinary action may be disclosed to and considered by the Board as part of the presentation and consideration of the proposal of settlement in the form of this Stipulation and Consent Order, with or without the presence of the Respondent or her attorney. In the event that this Stipulation and Consent Order is not accepted and approved by the Board, the Respondent further waives any objection to the Board members' consideration of this Stipulation and Consent Order or the information mentioned in the preceding sentence and further agrees to waive any claim of due process violation or the right to seek the disqualification of any Board member as a result of the Board member's consideration of said document and information.

8. The stipulations contained herein shall not become binding until this Stipulation and Consent Order is approved and entered as a Final Order by the Board. The Respondent acknowledges that the approval of the Board's Investigation Member or its attorney shall not constitute the approval of the Board or bind the Board to approve this Stipulation and Consent Order.

9. The Respondent agrees that this Stipulation and Consent Order is in conformance with Kansas and federal law and the Board has jurisdiction to enter into it as a final order of the Board. The Respondent further agrees, for purposes of this matter, that the Kansas pharmacy act, K.S.A. 65-1626 *et seq.* is constitutional on its face and as applied in this case.

10. This Stipulation constitutes the entire agreement of the parties and may only be modified by a subsequent writing signed by them. The agreement shall be interpreted in accordance with the laws of the State of Kansas.

11. The Respondent acknowledges that she has the following rights:

(a) To have formal notice of charges served upon her;

(b) To file a response to the charges;

(c) To have notice of and participate in a formal adjudicative hearing with the Board or its designee making specific findings of facts and conclusions of law based only upon evidence admitted at such hearing; and

(d) To take advantage of all applicable provisions of the Kansas Administrative Procedure Act, K.S.A. 77-501 *et seq.* and the Kansas Judicial Review Act, K.S.A. 77-601 *et seq.*

The Respondent freely waives these rights and acknowledges that said waiver is made voluntarily and in consideration of the Board's limiting the disciplinary action taken against her to

those provided for herein. The Respondent further waives the right to seek reconsideration or appeal or otherwise contest this Stipulation and Consent Order provided for herein.

12. The Respondent acknowledges that she enters into this Stipulation and Consent Order freely and voluntarily after consultation with or an opportunity to consult with counsel of her choosing. The Respondent further acknowledges that she has read this Stipulation and Consent Order in its entirety, that she understands its legal consequences and that she agrees that none of its terms are unconscionable, arbitrary or capricious.

13. Time is of the essence to this Stipulation and Consent Order. Respondent acknowledges and agrees that any violation of this Stipulation and Consent Order shall constitute a willful violation of a lawful Board order and grounds for further disciplinary action against her. The pendency of any disciplinary action arising out of an alleged violation of this Stipulation and Consent Order shall not affect the obligation of Respondent to comply with all terms and conditions of this Stipulation and Consent Order.

14. This Stipulation and Consent Order constitutes the entire and final agreement of the parties. In the event any provision of this Stipulation and Consent Order is deemed invalid or unenforceable by a court of competent jurisdiction, it shall be severed and the remaining provisions of this Stipulation and Consent Order shall be given full force and effect.

15. Upon approval and entry of the Final Order by the Board, this Stipulation and Consent Order shall be a public record in the custody of the Board.

16. This Stipulation and Consent Order shall become effective on the day it is approved, accepted and made an order of the Board by way of signature of the Board's authorized representative.

17. The Respondent acknowledges that she has been advised by the Board that she would have the right within 15 days after service of the Final Order provided for herein to file a petition for reconsideration with the Board and the right within 30 days after service of the Final Order provided for herein to file a petition for judicial review in the District Court of Shawnee County, Kansas in accordance with the Kansas Judicial Review Act, K.S.A. 77-601 *et seq.* and to serve such a petition for judicial review on the Kansas Board of Pharmacy by serving Alexandra Blasi, JD, MBA, its Executive Secretary at 800 SW Jackson St., Suite 1414, Topeka, KS 66612. The Respondent hereby waives those rights.

ENTERED AND EFFECTIVE this 19th day of September, 2024.

KANSAS BOARD OF PHARMACY

By: _____

ERICK AXCELL, PHARMD
Vice-President

AGREED AND APPROVED BY:

DocuSigned by:
Milka Goodlett
51997025C6624EA...

Milka Goodlett, R.Ph. — 9/10/2024 Date

Signed by:
Diane Bellquist
3D9F2DFC26B042D...

Diane L. Bellquist — 9/11/2024 Date

JOSEPH HOLLANDER & CRAFT LLC
1508 SW Topeka Blvd.
Topeka, KS 66612-1887
Counsel for the Respondent

Andrew Truong, PharmD — 9-19-2024 Date
Investigation Member

Brenda L. Head — 9-11-2024. Date
FRIEDEN & FORBES, LLP
1414 SW Ashworth Place, Suite 201
Topeka, KS 66604
(785) 354-1100
bhead@fflawllp.com
Counsel for the Kansas Board of Pharmacy

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing STIPULATION AND CONSENT ORDER was served by depositing same in the United States mail, postage prepaid, this 20th day of September, 2024 addressed to:

Brenda L. Head
FRIEDEN & FORBES, LLP
1414 SW Ashworth Place, Suite 201
Topeka, KS 66604

Milka Goodlett, R.Ph.
2715 Hickory St.
Hays, KS 67601

Diane L. Bellquist
JOSEPH HOLLANDER & CRAFT LLC
1508 SW Topeka Blvd.
Topeka, KS 66612-1887

Representative of the
KANSAS BOARD OF PHARMACY