

BEFORE THE KANSAS BOARD OF PHARMACY

In the Matter of)	
)	
PRECISION COMPOUNDING)	Case No. 21-112
PHARMACY, INC.)	
)	
<u>Registration No. 22-16424</u>)	

STIPULATION AND CONSENT ORDER

IT IS HEREBY STIPULATED AND AGREED by and between the Kansas Board of Pharmacy (“Board”) and Precision Compounding Pharmacy, Inc., a licensed non-resident pharmacy located in Omaha, Nebraska (“Respondent”) as follows:

1. The Board is represented herein by its attorney, Brenda L. Head of Frieden & Forbes, LLP, 1414 SW Ashworth Place, Suite 201, Topeka, Kansas 66604. The Respondent is represented herein by its attorney, Kathleen M. Foster, Peterson & Foster Law, 14747 California Street, Suite 2, Omaha, Nebraska 68154.

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.*, (“Act”) including conducting hearings and proceedings to revoke, suspend or otherwise discipline a Kansas registration to operate a pharmacy.

3. On August 13, 2018, the Board issued Respondent a Summary Order in Case No. 18-586, holding Registration number 22-16424, which denied renewal of its registration for failing to designate a Kansas-licensed Pharmacist-in-Charge (“PIC”) as required by the Act and Respondent’s registration was canceled in November of 2018. Thereafter, Respondent submitted a new application to the Board which was received January 28, 2021 (“Respondent’s Application”).

4. The Board's Investigation Member has determined that there is probable cause to believe that Respondent's Registration could be disciplined pursuant to K.S.A. 65-1627(e)(1).

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

A. From and since November of 2018 until approximately January 28, 2021, Respondent did not hold a valid Kansas registration.

B. On Respondent's Non-Resident Supplemental S-350 form, Respondent answered "yes" to the following question: "Has the facility listed on the application shipped drugs and/or devices into Kansas in the previous 12 months." The form directs that if the applicant answered "yes," the applicant should provide the specific drugs and/or devices sent in, the dates of shipment and the locations they were sent to in Kansas. Respondent estimated the number of Kansas customer or patients the facility planned to serve annually or has served during the preceding 12 months at 22.

C. In conjunction with Respondent's Application, Respondent provided requested copies of shipping records for products shipped into Kansas via email. Respondent reported shipping into Kansas 300 times during the previous 12 month period.

D. Respondent's February 1, 2021 NABP VPP Inspection Form indicates Respondent dispensed 28 prescription products per month in Kansas.

E. On May 17, 2021, Respondent's Vice President Jodi Peterson represented on Respondent's letterhead that "No prescriptions have been sent to Kansas" which is not consistent with the information in Respondent's Application or the February 1, 2021 NABP VPP Inspection Form and was subsequently corrected.

F. In 2017, Respondent was fined \$1,000.00 for shipping into Iowa without a license.

G. Pursuant to K.S.A. 65-1657(a), no non-resident pharmacy shall ship, mail or deliver, in any manner, prescription drugs to a patient in Kansas unless registered as a non-resident pharmacy.

H. Respondent's actions of providing prescription drugs to patients in Kansas when it was not registered violates K.S.A. 65-1657(a).

I. Pursuant to K.S.A. 65-1657(f), the Board may limit, condition, revoke, suspend or place in probationary status a registration on any ground that would authorize the Board to take action against the registration of a pharmacy under K.S.A. 65-1627, and amendments thereto.

J. Pursuant to K.S.A. 65-1627(e)(1), the Board may revoke, suspend or place in probationary status the registration of a pharmacy upon a finding that such pharmacy has been operated in such a manner that violations of the provisions of the Pharmacy Act of the State of Kansas or the rules and regulations of the Board have occurred in connection therewith.

K. Pursuant to K.S.A. 65-1658, the Board may assess a civil fine for violation of the Kansas Pharmacy Act, K.S.A. 65-1626 *et seq.*

6. Upon motion duly made, seconded, and passed, the Board finds and concludes that the events described in paragraph 5 above constitute the operation of a nonresident pharmacy in a manner that violates the Act and the Regulations of the Board and misrepresentations made in Respondent's Application are therefore grounds for disciplinary action against the Respondent's Kansas Registration pursuant to K.S.A. 65-1627(e)(1).

7. The Board finds, concludes, and orders that the following disposition is just and appropriate under the circumstances:

A. PROBATION. Pursuant to K.S.A. 65-1627(e)(1), Respondent's Kansas Registration will be placed on Probation for a period of five (5) years. As a condition of Probation, Respondent must submit a new NABP VPP or Kansas inspection report every eighteen (18) months showing no deficiencies that could result in patient harm exist. Respondent shall be responsible for the cost of a Kansas inspection. Respondent shall be responsible for and billed probation fees based on actual costs to the Board. Further, violation of Respondent's conditions of Probation will result in revocation of Respondent's Kansas registration.

B. ADMINISTRATIVE FINES. Respondent shall pay to the Board an administrative fine in the amount of Five Thousand Dollars (\$5,000.00) for their violation of the Kansas Pharmacy Act by providing prescription drugs in Kansas without a registration. The administrative fine is due within ten (10) days of the Board approving this Stipulation and Consent Order.

C. NABP INSPECTION. Respondent shall report to the Board the results of any NABP inspection within ten (10) days of receipt of the inspection report. If the FDA performs an inspection during the term of Respondent's Probationary period, Respondent shall provide an unredacted copy of the FDA inspection report to the Board within ten (10) days of receipt.

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

- i. Comply fully with this Stipulation and Consent Order; and

- ii. In all applicable respects, comply fully with the Kansas Pharmacy Act, the Board's rules and regulations and all state and federal laws relating to pharmacies.

8. Respondent agrees that all information in the possession of the Board's Investigation Member, 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 and the Final Order provided for herein, with or without the presence of the Respondent or its attorney. In the event that this Stipulation and Consent Order and the Final Order provided for herein are 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.

9. The stipulations contained herein shall not become binding until this Stipulation and Consent Order is approved by the Board and the Consent Order provided for herein is entered by the Board. If the Board fails to approve this Stipulation and Consent Order, it shall be of no force or effect to either the Board or the Respondent. 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.

10. 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 and enter the Final

Order provided for herein. 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.

11. 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.

12. The Respondent acknowledges that it has the following rights:

A. To have formal notice of charges served upon it;

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 it 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.

13. The Respondent acknowledges that it enters into this Stipulation and Consent Order freely and voluntarily after consultation with counsel of its choosing. The Respondent further acknowledges that it has read this Stipulation and Consent Agency order in its entirety,

that it understands its legal consequences and that it agrees that none of its terms are unconscionable, arbitrary or capricious.

14. 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 it. 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.

15. 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.

16. 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.

17. 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.

18. The Respondent acknowledges that it has been advised by the Board that it 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.

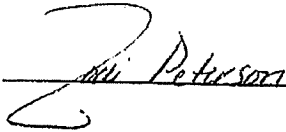
ENTERED AND EFFECTIVE this 15th day of April, 2022.

KANSAS BOARD OF PHARMACY

By: Dr. Jonathan W. Brunswig, PharmD
Dr. Jonathan W. Brunswig, PharmD (Apr 12, 2022 11:03 CDT)
DR. JONATHAN BRUNSWIG, President

AGREED AND APPROVED BY:

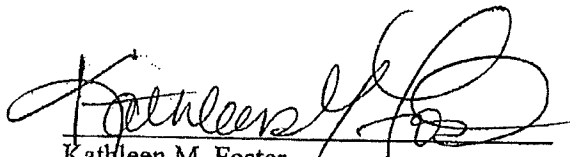
Precision Compound Pharmacy, Inc.
15722 W. Center Road
Omaha, NE 68130

By: 

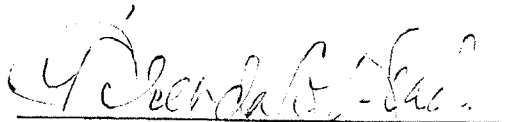
2/15/22
Date

Terica Gatewood
Terica Gatewood (Apr 14, 2022 09:40 CDT)
Dr. Terica Gatewood
Investigation Member

Apr 14, 2022
Date


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Attorney for Precision Compounding
Pharmacy, Inc.

2-15-2022
Date


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Topeka, KS 66604
(785) 354-1100
bhead@fflawllp.com
Attorney for Kansas Board of Pharmacy

2-24-22
Date

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 15th day of April, 2022 addressed to:

Brenda L. Head
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Topeka, KS 66604

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Representative of the
KANSAS BOARD OF PHARMACY