

Filed By
FEB 18 2022
KANSAS STATE
BOARD OF PHARMACY

BEFORE THE KANSAS BOARD OF PHARMACY

In the Matter of)
) Case No. 21-057
ALMAC CLINICAL SERVICES, LLC)
Registration No. 5-110642)

STIPULATION AND CONSENT ORDER

IT IS HEREBY STIPULATED AND AGREED by and between the Kansas Board of Pharmacy (the "Board") and Almac Clinical Services, LLC located in Souderton, Pennsylvania ("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, Emma McAllister, VP Corporate & Legal, Almac Group, Almac House, 20 Seagoe Industrial Estate, Craigavon, BT63 5QD, Northern Ireland.

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 as a non-resident wholesale distributor.

3. Respondent has made application to be registered by the Board as a non-resident wholesale distributor and was issued the conditional registration number 5-110642.

4. The Board's Investigation Member has received certain information, investigated and determined that there are reasonable grounds to believe that Respondent has committed one or more actions in violation of the Act which would justify the revocation or imposition of other disciplinary action against its Kansas Registration under the provisions of K.S.A. 65-1627(f) and

the assessment of an appropriate fine against Respondent under the provisions of K.S.A. 65-1658.

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 that:

A. On August 29, 2019, respondent submitted a Non-Resident Facility application to the Board. On October 4, and 7, 2019, the Board lawfully requested a satisfactory inspection dated within the last three (3) years which was required for registration by the Board.

B. Respondent failed to provide the Board with the requested satisfactory inspection and withdrew their application on November 22, 2019.

C. On September 17, 2020, Respondent submitted a Non-Resident Facility application to the Board which included a July 13, 2020 satisfactory inspection report from the Commonwealth of Pennsylvania Department of Health.

D. K.S.A 65-1643(c) provides that it is unlawful for any entity to distribute at wholesale any drugs in Kansas without a registration issued by the Board.

E. On Respondent's Supplemental Application Form S-350 dated August 5, 2020, Respondent self-reported shipping drugs and/or devices into Kansas eighty-eight (88) times in the previous 12 months when Respondent did not have a registration to do so in violation of K.S.A. 65-1643(c).

6. Upon motion duly made, seconded and passed, the Board finds and concludes that the conduct and violations found in the preceding paragraphs constitute violates the Act and the Regulations of the Board and are therefore grounds for disciplinary action against the

Respondent's Kansas Registration provided for herein, pursuant to K.S.A. 65-1643(c), 65-1655 and 65-1627(f)(6).

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

A. ADMINISTRATIVE FINE. Within ten (10) days of the Board entering the Consent Order provided for herein, Respondent shall pay to the Kansas Pharmacy Board an administrative fine in the total amount of Ten Thousand Dollars (\$10,000.00) [\$5,000.00 fine for unlawful shipping without a registration and \$5,000.00 fine for failing to respond to the Board's lawful request].

B. PROBATION. Respondent's Kansas Registration shall be placed on probationary status for a period of 5 years from the effective date of the Stipulation and Consent Order contemplated hereby ("Probation Period"). During the Probationary Period, the Respondent shall:

- i. Provide the Board with un-redacted copies of any disciplinary action taken by a federal or state regulatory agency within ten (10) days of receipt;
- ii. Provide the Board with un-redacted copies of Respondent's Kansas shipping manifest prior to entry into this Stipulation and Consent Order and every six (6) months thereafter during the probationary period; and
- iii. Respondent shall obtain a satisfactory NABP inspection within eighteen (18) months of entry of this Stipulation and Consent Order and provide the Board with proof of the same.

C. CONDITIONAL REGISTRATION. It is agreed that upon Respondent's execution of this Stipulation, Respondent will be issued a conditional registration as a Non-Resident Kansas Wholesale Distributor Registration ("Respondent's Registration"), subject to

the Probation Period requirements provided for herein, which will expire on the date of the next meeting of the Board at which approval of this Stipulation and Consent Order is considered. If the Board approves and adopts this Stipulation and Consent Order anticipated hereby, Respondent's Registration shall become unconditional, subject to the Probation Period requirements provided for herein .

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. Comply fully with the Kansas Pharmacy Act, the Board's rules and regulations and all state and federal laws relating to Kansas 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 this Final Order by the Board, this Stipulation and Consent Order shall be a public record in the custody of the Board.

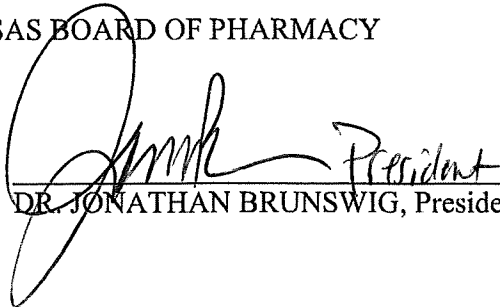
17. This Stipulation and Consent Order shall become effective on the day it is approved, accepted, and made an order of the Board by way of signature of the Board's authorized representative.

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 18 day of February, 2022.

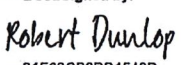
KANSAS BOARD OF PHARMACY

By:


DR. JONATHAN BRUNSWIG, President


AGREED AND APPROVED BY:

Almac Clinical Services, LLC
25 Fretz Road, 3rd Floor
Souderton, PA 18964

DocuSigned by:

By: 31F83CB2DD1548D...
Robert Dunlop
President Almac Clinical Services

15-Feb-2022

Date


Dr. Terica Gatewood
Investigation Member

2/18/22

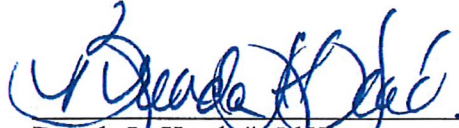
Date

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Attorney for Respondent

15-Feb-2022

Date


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1414 SW Ashworth Place, Suite 201
Topeka, KS 66604
(785) 354-1100
bhead@fflawllp.com
Attorney for Kansas Board of Pharmacy

2-15-22

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 21st day of February, 2022 addressed to:

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

Almac Clinical Services, LLC
25 Fretz Road, 3rd Floor
Souderton, PA 18964

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Representative of the
KANSAS BOARD OF PHARMACY