BEFORE THE KANSAS BOARD OF PHARMACY

In the Matter of

Case No. 21-134

Hallandale Pharmacy
Kansas Registration No. 22-102800

FINAL ORDER

Decision

The Kansas Board of Pharmacy (Board) has carefully considered the evidence presented and reviewed the applicable statutes, regulations and policies, and hereby affirms the November 9, 2021 Summary Order of Denial denying the application of Hallandale Pharmacy (Hallandale) for renewal of its registration as a non-resident pharmacy.

Statement of Case

This matter comes on for hearing on February 2, 2022 before the Board upon the request by Hallandale for a hearing to review the Summary Order of Denial denying Hallendale's application for renewal of its registration as a non-resident pharmacy.

Appearing for the Board were: Jonathan Brunswig, PharmD, President; and members, Bill Walden, R.Ph; Terica Gatewood, PharmD; Tiffany Strohmeyer, PharmD; Erick Axcell, PharmD ; Andrew Truong, PharmD; and, Lucinda Noches Talbert, Public Member

Hallandale was represented by Edwin A. Bayó, counsel for Hallandale; David Rabbani, President of Hallandale; and Stephanie Bellieni (Bellieni), licensing and compliance for Hallandale.[1] Representatives of Hallandale appeared via video conference.

Brenda Head appeared as the Board's disciplinary counsel.

Alexandra Blasi (Blasi), Executive Secretary for the Board, and Shelly Rosebrook (Rosebrook), Pharmacy Inspector, appeared and provided testimony for the Board.

Loren F. Snell, Jr., Administrative Law Judge, was appointed and served as the Presiding Officer over the evidentiary hearing.

[1] Bayó is licensed to practice law in the State of Florida, FL Bar No. 327727. Nothing was offered to indicate that Bayó was licensed to practice in the State of Kansas, nor did Bayó have local counsel present with him during the hearing.

Evidentiary Rulings

The Board offered Exhibits 1 through 6 for admission as evidence. Hallandale had no objection to admission of Exhibits 1 through 6. The Board's Exhibits 1 through 6 were admitted.

Hallandale offered Hallandale Exhibits 1 through 8 for admission as evidence. The Board's disciplinary counsel had no objection to admission of Hallandale Exhibits 1 through 8. Hallandale Exhibits 1 through 8 were admitted.

Findings of Fact

1. The Board previously issued Hallandale Kansas non-resident pharmacy registration number 22-102800. (Board Ex. 3).

2. On September 26, 2018, Applicant entered into an Agreed Order, Case No. 18-0358, with the Kentucky Board of Pharmacy (Kentucky Board), which Agreed Order provided for the discipline of Hallandale's Kentucky pharmacy permit (Kentucky Agreed Order). The Kentucky Agreed Order was adopted as a final order of the Kentucky Board on October 10, 2018. Hallandale failed to advise the Kansas Board of the Kentucky Agreed Order making their application false and in violation of K.S.A. 65-1627(a)(1) and Hallandale failed to report the discipline to the Board within 30 days of its issuance as required by K.A.R. 68-2-23.

3. On June 11, 2019, the Kansas Board entered a Stipulation and Consent Order disciplining Hallandale for various reasons including: failing to timely notify the Board of an address change; failing to report Oklahoma discipline; lack of adequate pharmacy personnel training documentation; and incomplete policies and procedures in violation of K.S.A. 65-1627(e)(1) and K.S.A. 65-1627(e)(4). Among other things, the Stipulation and Consent Order required Hallandale to comply fully with the Kansas Pharmacy Act, the Board's rules and regulations and all state and federal laws relating to Kansas pharmacies.

4. On December 19, 2019, Hallandale entered into an Agreed Settlement 190957 Mail Service Pharmacy with the State of Nebraska Department of Health and Human Services (Nebraska Department), which Agreed Settlement provided for a final disciplinary order of Hallandale's Nebraska pharmacy permit (Nebraska Agreed Order). The Nebraska Agreed Order was adopted as a final order by the Nebraska Department on February 10, 2020. Hallandale failed to advise the Kansas Board of the Nebraska Agreed Order making their Application false in violation of K.S.A. 65-1627(a)(1) and Hallandale failed to report the discipline to the Board within 30 days of its issuance as required by K.A.R. 68-2-23.

5. On March 11, 2020, the U.S. Food and Drug Administration (FDA) issued a Warning Letter to Hallandale from a facility inspection conducted July 2, 2018 to July 13, 2018. The FDA was not able to evaluate the corrective actions based on Hallandale's response to FDA 483. Samples of the violations listed in the FDA Warning Letter are:

- Failure to receive valid prescriptions for individually identified patients for some drug products making them ineligible products and putting them under the requirements of cGMP
  - These drugs were deemed adulterated due to Hallandale not meeting the requirements of cGMP
  - Hallandale holds no FDA-approved applications making these drugs unapproved new drug products
  - These drugs were deemed to be misbranded
- Turning off power to sterile suites for cleaning without a way to verify ISO classification afterwards
- 3 holes in the wall between the ISO7 suite and an unclassified area
- Unsealed hole in the ISO5 BSC
- Inadequate smoke studies
- Visible debris and stains in the ISO5 BSC
- Rust on the exterior surface of the ISO5 BSC and the prep table in the ISO7 sterile suite
- Dirt on the HEPA filter covers in the ISO7 sterile suite
- Mop head constructed of particle-generating material
- Media fills not performed under most challenging conditions

6. On September 21, 2020, the Kansas Board entered a Stipulation and Consent Order disciplining Hallandale for failure to report discipline in Alaska, Minnesota, Louisiana, Texas, Colorado and Maryland within 30 days as required by K.A.R. 68-2-23. Hallandale was also disciplined for failing to disclose the Alaska and Louisiana discipline on its Application, all in violation of K.S.A. 65-1627(e)(1). Among other things, the Stipulation and Consent Order imposed a three (3) year term of Probation on Hallandale's Kansas non-resident pharmacy registration and required Hallandale to comply fully with the Kansas Pharmacy Act, the Board's rules and regulations and all state and federal laws relating to Kansas pharmacies.

7. Hallandale's facility received a VPP inspection from NABP on February 17, 2021 to February 18, 2021. (Board Ex. 4). Samples of some of the highlights of the findings are:

- Licenses and permits not posted in view of customers.
- Hallandale operating outside of allowed FL technician to pharmacist ratios.
- Biennial inventory records did not specify the date of the inventory.
- Controlled substance invoices not kept separately.
- Inadequate processes to assure that medications are not prescribed and dispensed based on online consultations without prescriber-patient relationship. Pharmacy sends the prescriber a "set-up package" where the prescriber states all prescriptions are "medically necessary."
- Inspector identified a prescription with incorrect day supply calculations that resulted in the patient using the mediation past the beyond-use date.
- Patient package inserts not provided for required medications.
- Pharmacists does not check measurement of each ingredient of non-sterile compounds.

- No records for personnel training for each nonsterile dosage form they compound.
- Nonsterile training documents did not indicate performance of the procedure under supervision before independent compounding.
- Troche mold filled from a syringe without measuring.
- Inadequate processes for ensuring uniformity and integrity of capsules (checked 10 out of a batch of 1500 capsules).
- Pharmacist checking labeled compounded prescriptions did not record review for signs of instability and final appearance.
- Hallandale continues to compound lyophilized hCG products after FDA guidance to the contrary.
- Only one pharmacist is trained for sterile compounding. There were no personnel qualified to supervise sterile compounding when this person was out of the pharmacy.
- The certification report did not contain any information about the equipment used.
- Certification reports did not indicate if equipment in the rooms and PEC's were in operational condition during certification.
- Incubation times and temperatures not indicated on certification reports.
- Questionable implementation of sterile compounding processes when only 1 pharmacist is trained in sterile compounding.

8. On June 2, 2021 the Board received an application from Hallandale seeking to renew its Kansas non-resident pharmacy registration number. (Board Ex. 1). Included with the application were multiple documents that had been uploaded, including a letter detailing adverse actions taken against Hallandale since the previous renewal in June of 2020.

9. An investigation was opened by the Board and assigned to Rosebrook. Rosebrook performs inspections and investigations for compliance. Rosebrook completed a Compliance Assessment/Recommendation report on July 7, 2021. (Board Ex. 2).

10. Having reviewed the documentation related to Hallandale's registration number and application, Rosebrook concluded Hallandale had failed to report adverse actions that had been taken against Hallandale in violation of the Kansas Pharmacy Act, as required by Kansas Administrative Regulations (K.A.R.) 68-2-3, and in violation of the Stipulation and Consent Orders entered into with the Board on June 10, 2019 and September 21, 2020.

11. Having reviewed the Compliance Assessment/Recommendation report and considered the matter, the Board issued a Summary Order of Denial on November 9, 2021 advising that Hallandale's application for renewal of its registration as a non-resident pharmacy was denied. (Board Ex. 3).

12. On November 29, 2021 the board received a letter from Hallandale. (Board Ex. 4). The letter requested a hearing on the Summary Order of Denial. The letter acknowledged and confirmed Hallandale's failure to report adverse actions by the states of Nebraska and Ohio, and the Commonwealth of Kentucky.

13. Rabbani is a pharmacist and president of Hallandale.

14. Hallandale is currently located in Fort Lauderdale, Florida, having moved in August of 2018.

15. Rabbani testified that the actions taken against Hallandale were administrative and not related to quality, pointing out there were no issues of patient safety or quality concerns. Rabbani testified that Hallandale had not been disciplined for compounding issues.

16. Rabbani testified regarding the fact that the facility had moved and the improvements that had been made. Rabbani further testified that he had hired new staff and has a licensing department that is responsible for making sure everything is done timely.

17. Bellieni is responsible for licensing and compliance at Hallandale.

18. Bellieni testified as to FedEx receipts documenting deliveries from Fort Lauderdale, Florida to Topeka, Kansas. (Hallandale Exs. 1-5). Bellieni testified that the deliveries consisted of documentation reporting adverse actions taken against Hallandale by the states of Colorado and Maine.

19. No documentation was offered to establish what was delivered from Fort Lauderdale, Florida to Topeka, Kansas by FedEx

Applicable Statutes, Regulations and Policies

"The board may deny an application or renewal, limit, condition, revoke, suspend or place in a probationary status the registration of any pharmacy upon a finding that: (1) Such pharmacy has been operated in such manner that violations of the provisions of the pharmacy act of the state of Kansas or of the rules and regulations of the board have occurred in connection therewith."[2]

"The board may deny an application or renewal, limit, condition, revoke, suspend or place in a probationary status the registration of any pharmacy upon a finding that: (4) the registrant has had a registration revoked, suspended or limited, has been censured or has had other disciplinary action taken, or an application for registration denied, by the proper registering authority of another state, territory, District of Columbia or other country, a certified copy of the record of the action of the other jurisdiction being conclusive evidence thereof."[3]

"Each pharmacy owner shall notify the board in writing within 30 days of any denial, limitation, suspension, revocation, voluntary surrender, or other disciplinary action taken by the

[2] K.S.A. 65-1627(e).

[3] K.S.A. 65-1627(e).

state of Kansas or another jurisdiction against the pharmacy or the pharmacy owner or any application, license, registration, or permit held by the pharmacy owner.[4]

Decision

The Board considered the information provided and concluded Hallandale Pharmacy has violated the terms and conditions of the Stipulation and Consent Order by failing to notify the Board of adverse actions taken against Hallandale Pharmacy within the time required by the Kansas Administrative Regulation. Failure to comply with the regulation constitutes a violation of the Kansas Pharmacy Act. While Hallandale Pharmacy referenced the adverse actions and what they were for, the Board notes that the basis for denial is not because Hallandale Pharmacy was disciplined in other states or what Hallandale Pharmacy was disciplined for, but because Hallandale Pharmacy failed to report those adverse actions to the State of Kansas in a timely fashion, as required by statute and regulation.

The Board voted 6-0 to affirm the Summary Order of Denial and deny Hallandale Pharmacy's application to renew its registration as a non-resident pharmacy.

Because Hallandale Pharmacy did not prevail, it is also ordered to pay the costs of the hearing in the amount of $2,440.35.

_____ _____

Date Jonathan Brunswig, PharmD, President
Kansas Board of Pharmacy

[4] K.A.R. 68-2-23.

Notices

1. This is a Final Order and becomes effective upon service.

2. **Within fifteen (15) days** after service of the Final Agency Order, any party may file a Petition for Reconsideration.[5]

3. Either party to this agency proceeding may seek judicial review of the Final Order by filing a timely petition in the District Court.[6] Reconsideration of the Final Order is not a prerequisite to judicial review. A petition for judicial review is not timely unless filed **within thirty (30) days** following service of the Final Order.

4. A copy of any petition for judicial review must be served upon the Kansas Board of Pharmacy. The agency officer designated to receive service of a petition for judicial review is:

Alexandra Blasi, Executive Secretary
Kansas State Board of Pharmacy
800 SW Jackson #1414
Topeka, KS 66612-1244

[5] K.S.A. 77-529.

[6] K.S.A. 77-613.

Certificate of Service

On _____, 2022, I certify that a copy of the foregoing was deposited in business mail to be placed in the United States first class mail, postage prepaid, addressed to:

Hallandale Pharmacy
2666 SW 36th St.
Ft. Lauderdale, FL 33312

Brenda Head
Frieden & Forbes, LLP
1414 SW Ashworth Place, Ste 201
Topeka, KS 66604

and, I further certify that I caused a copy of the foregoing to be hand-delivered to:

Alexandra Blasi
Executive Secretary
Kansas State Board of Pharmacy
800 SW Jackson #1414
Topeka, KS 66612-1244

_____
Staff Person
Kansas Board of Pharmacy