

**IN THE MATTER OF**

\*

**BEFORE THE**

**HALLANDALE PHARMACY**

\*

**MARYLAND STATE**

**PERMIT NO. P07560**

\*

**BOARD OF PHARMACY**

\*

**Case No. 19-266**

\* \* \* \* \*

**CONSENT ORDER**

**Background**

The Maryland Board of Pharmacy (the "Board") received notice that Hallandale Pharmacy (the "Pharmacy") was issued an FDA 483 list of observations on July 13, 2018, regarding its sterile compounding operations for its location at 1109 E. Hallandale Beach Blvd. The Pharmacy failed to report the FDA 483 to the Board as required. The Board then opened an investigation into the matter which revealed that the Pharmacy subsequently moved its operations to its current location in August 2018, but failed to submit a change of location application with the Board until January 21, 2019, and dispensed drugs into Maryland in the interim. In addition, the Pharmacy was formally disciplined by the Oklahoma and Kentucky Boards of Pharmacy, neither of which was reported to the Board as required.

In lieu of instituting formal proceedings against Hallandale Pharmacy, in accordance with the Maryland Pharmacy Act, Md. Code Ann., Health Occ. § 12-101 *et seq.*, the Board and Hallandale Pharmacy, have agreed to resolve this matter as set forth in this Consent Order.

**FINDINGS OF FACT**

1. The Pharmacy is currently located at 2666 SW 36<sup>th</sup> Street Fort Lauderdale,

Florida, and obtained a non-resident pharmacy permit to operate in Maryland under Permit Number P07560 on or about June 21, 2017. The Pharmacy's permit is active and will expire on May 31, 2020.

2. The Pharmacy dispenses compounded sterile products pursuant to patient-specific prescriptions.
3. On or about July 13, 2018, the Food and Drug Administration ("FDA") issued a Form 483 list of observations based on an inspection of the Pharmacy's location at 1109 E. Hallandale Beach Blvd. that indicated various issues in the Pharmacy's sterile compounding environment.
4. The Pharmacy failed to report the FDA 483 to the Board as required by the Board's sterile compounding regulations.
5. The Pharmacy subsequently moved its operations to its current location at 2666 SW 36<sup>th</sup> Street in August 2018. The Pharmacy failed to submit a change of location application to the Board until January 21, 2019.
6. The Pharmacy dispensed approximately 296 drugs into Maryland from its 2666 SW 36<sup>th</sup> Street location without a Maryland non-resident permit for that location.
7. The Pharmacy was disciplined by the Oklahoma Board of Pharmacy on November 29, 2017, for shipping on an expired license and failing to report data to the Oklahoma PDMP. The Pharmacy failed to report the Oklahoma disciplinary action to the Board within five (5) calendar days as required.
8. On October 10, 2018, the Kentucky Board of Pharmacy sanctioned the Pharmacy for dispensing without a license. The Pharmacy failed to report the Kentucky disciplinary action to the Board within five (5) calendar days as required.
9. The Pharmacy has since engaged in remedial efforts to enhance its licensing software to prohibit the shipment of drugs into any state in which it does not hold an active permit.
10. The Pharmacy's current location at 2666 SW 36<sup>th</sup> Street has been satisfactorily

inspected by the Florida and Texas Boards of Pharmacy, and has received PCAP and VIPPS certifications.

### CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes that Hallandale Pharmacy, Permit Number P07560, is subject to discipline in accordance with Md. Code Ann., Health Occ. §§ 12-403(e)(1), (g)(1) and (10), 12-313(b)(24) and COMAR 10.34.19.18.

### ORDER

Based upon an affirmative vote of the Board under the authority of Md. Code Ann., Health Occ. Art. § 12-409, it this 11<sup>th</sup> day of December, 2019, hereby,

ORDERED that Hallandale Pharmacy, Permit No. P07560, shall pay a FINE in the amount of FIVE THOUSAND DOLLARS (\$5,000.00) within sixty (60) days, in the form of a check made payable to the Maryland Board of Pharmacy, and sent to:

Wells Fargo Bank  
c/o State of Maryland – Board of Pharmacy  
Lockbox 2051  
7175 Columbia Gateway Drive  
Columbia, Maryland 21046  
*(Please include the Case No. 19-266 to ensure proper assignment.)*

and be it further;

ORDERED that Hallandale Pharmacy shall submit to the Board within sixty (60) days policies and procedures for reporting adverse events and other required information to the Board, in accordance with COMAR 10.34.19.18; and be it further,

ORDERED that Hallandale Pharmacy shall comply with all laws and regulations governing the operation of a non-resident pharmacy in the State of Maryland, to include

Maryland laws governing sterile compounding and the reporting of adverse events and disciplinary actions; and be it further,

ORDERED that this is a formal order and as such is a public document pursuant to the Maryland Public Information Act, Md. Code Ann., General Provisions Article § 4-101, *et seq.*

12/11/19

Date



Deena Speights-Napata,  
Executive Director for:

Kevin Morgan, Pharm.D.  
Board President

### CONSENT

1. By signing this Consent, Hallandale Pharmacy makes no admission of wrongdoing but submits to the foregoing Consent Order as a resolution of this matter and agrees to be bound by its terms and conditions.

2. Hallandale Pharmacy acknowledges the validity of this Consent Order as if it were made after a hearing in which it would have had the right to counsel, to confront witnesses, and to all other substantial procedural protections provided by law.

3. Hallandale Pharmacy acknowledges that, by entering into this Consent Order, it is waiving its right to appeal any adverse ruling of the Board that might have followed such an evidentiary hearing.

4. Hallandale Pharmacy acknowledges the legal authority and the jurisdiction of the Board to enter and enforce this Consent Order.

5. Hallandale Pharmacy signs this Consent Order freely and voluntarily, after having had the opportunity to consult with counsel. Hallandale Pharmacy fully understands the language, meaning, and effect of this Consent Order.


12/19/19  
Date

  
Name: Jessica Naman  
Title: Secretary

STATE OF Florida  
COUNTY/CITY OF Broward:

I hereby certify that on this 9 day of December 2019, before me, a Notary Public of the State of Florida and County/City aforesaid, personally appeared Jessica Naman, and made an oath in due form that the foregoing Consent was ~~his~~ her voluntary act and deed on behalf of Hallandale Pharmacy.



  
Notary Public  
commission expires: Aug 11, 2020