GERMANTOWN PROFESSIONAL PHARMACY AND COMPOUNDING

October 11, 2019

Date

Kevin M. Morgan, Pharm.D.
President
State Board of Pharmacy
4201 Patterson Avenue
Baltimore, Maryland 21215

RE: **Surrender of Permit**
Permit Number: P06662
Case Numbers: PI 16-223; 18-243

Dear Mr. Morgan and Members of the Board:

Please be advised that Germantown Professional Pharmacy and Compounding ("Germantown Pharmacy") has decided to voluntarily surrender its permit to operate as a pharmacy in the State of Maryland, Permit Number: P06662 effective immediately. It is understood that upon surrender of its permit, Germantown Pharmacy may not operate as a pharmacy in the State of Maryland as it is defined in the Maryland Pharmacy Act (the "Act"), Md. Code Ann., Health Occ. ("Health Occ.") §§ 12-101 *et seq.*, (2014 Repl. Vol. & 2018 Supp.) and other applicable laws.

Germantown Pharmacy understands that this **Letter of Surrender** is a **PUBLIC DOCUMENT**, and, on the Board's, acceptance becomes a **FINAL ORDER** of the Board.

Germantown Pharmacy's decision to voluntarily surrender its permit to operate as a pharmacy in the State of Maryland has been prompted by investigations conducted by the Maryland State Board of Pharmacy (the "Board"). The results of the investigations led the Board to issue disciplinary charges against Germantown Pharmacy on or about May 15, 2019, under Case Numbers: PI 16-223; 18-243 (See attachment A Charging Document dated Mary 15, 2019).

Germantown Pharmacy has decided to voluntarily surrender its permit to operate as a pharmacy in the State of Maryland. Germantown Pharmacy acknowledges that the Board could have revoked Germantown Pharmacy's permit following an evidentiary hearing.

Germantown Pharmacy acknowledges that the Board initiated an investigation of this matter and issued disciplinary charges against Germantown Pharmacy. After its investigation, the Board charged Germantown Pharmacy with violating the following provisions of the Act:

Health Occ. §12-403:

(c) *In general.* - Except as otherwise provided in this section, a pharmacy for which a pharmacy permit has been issued under this title:

(1) Shall be operated in compliance with the law and with the rules and regulations of the Board;

(5) Shall provide complete pharmaceutical service by preparing and dispensing all prescriptions that reasonably may be expected of a pharmacist;

(9) May not participate in any activity that is a ground for Board action against a licensed pharmacist under § 12–313 of this title, a registered pharmacy technician under § 12–6B–09 of this title, or a registered pharmacy intern under § 12–6D–11 of this title;

(11) (i) Shall maintain at all times the minimum professional and technical equipment and sanitary appliances that are necessary in a pharmacy:

1. To prepare and dispense prescriptions properly; and

2. To otherwise operate a pharmacy; and

(ii) Shall:

1. Be equipped with the minimum equipment and appliances specified by the Board under this section;

2. Be kept in a clean and orderly manner;

(12) Shall store all prescription or nonprescription drugs or devices properly and safely subject to the rules and regulations adopted by the Board;

(13) Shall:

(i) Make and keep on file for at least 5 years a record of each prescription prepared or dispensed in the pharmacy;
(ii) Disclose the records and files maintained of prescriptions for drugs or devices that identify or may be readily associated with the identity of a patient only in accordance with the provisions of Title 4, Subtitle 3 of the Health – General Article; and
(iii) Keep additional records as required by the rules and regulations adopted by the Board;

(21) Shall dispense or dispose of prescription drugs or medical supplies in accordance with Title 15, Subtitle 6 of the Health – General Article[.]

Health Occ. §12-313

(1) Fraudulently or deceptively obtains or attempts to obtain a license for the applicant or licensee or for another;

(15) Dispenses any drug, device, or diagnostic for which a prescription is required without a written, oral, or electronically transmitted prescription from an authorized prescriber;

(21) Is professionally, physically, or mentally incompetent;

(24) Is disciplined by a licensing or disciplinary authority of any state or country or convicted or disciplined by a court of any state or country for an act that would be grounds for disciplinary action under the Board's disciplinary statutes;

(25) Violates any rule or regulation adopted by the Board[.]

The Board also charged Germantown Pharmacy with violating the following provisions of COMAR:

COMAR 10.34.05

.04 Records.

A. A pharmacy permit holder shall:

(3) Maintain current computerized records in a manner which permits reconstruction within 48 hours, except:

(a) In an emergency as defined in Regulation .01 of this chapter, or

(b) With the prior approval of the Board.

COMAR10.34.08.

.01 Information Required on All Original and Refill Prescriptions or Patient Drug Profiles or Computerized Patient Drug Records.

In addition to the information required by law on every prescription, patient drug profile, or computerized patient drug record, the following information shall be legibly entered on all original and refill prescriptions or patient drug profiles or computerized patient drug records:

A. The date of filling or refilling;

B. The initials of, or other identifying symbol for:

(1) The pharmacist responsible for filling or refilling the prescription; and

(2) The data-entry pharmacy technician involved in the dispensing process.

COMAR 10.34.19

.04 Pharmacy Environment.

The compounding, preparation, and dispensing of compounded sterile preparations shall be accomplished in a pharmacy environment subject to State and federal laws, regulations, and standards.

COMAR 10.34.19

.07 Record-Keeping Requirements.

A. Patient Prescription Records.

(1) The pharmacy shall maintain records of patient prescriptions.

(2) Patient prescription records shall contain:

(a) Available medical information consistent with prevailing pharmacy standards; and

(b) The complete record of the formulations of the solutions that were compounded.

(3) The pharmacy shall keep completed patient prescription records in a retrievable manner for at least 5 years, either:

Germantown Pharmacy wishes to make clear that it has voluntarily, knowingly, and freely chosen to submit this Letter of Surrender to avoid the uncertainties which could arise from the prosecution of the charges and violation of probation determination under the Act. Germantown Pharmacy acknowledges that for all purposes relevant to operating a pharmacy, those investigative findings will be treated as if proven by the preponderance of the evidence.

Germantown Pharmacy acknowledges that the State would provide the following evidence if this matter had proceeded to a full evidentiary hearing:

On December 7, 2017, Germantown Pharmacy entered into a Consent Order with the Board. The Board concluded in the 2017 Consent Order the following: Germantown Pharmacy violated Health. Occ. § 12-403(c)(1), (5), (9), (11), (12), (13), (19), and (21); § 12-409 (a) (1), (2), and (3); § 12-313(b) (3), (15), and (25); and COMAR 10.34.22.03A (1)(a) and (b), and (2). The Board's findings in the 2017 Consent Order were based upon

Germantown Pharmacy's engagement in the inappropriate compounding of the Federal Food and Drug Administration ("FDA") approved, commercially available Enstilar Foam, and dispensing it in a smaller, clear plastic container that was not the FDA approved 60-gram pressurized aluminum spray can.[1] The Board's findings in the 2017 Consent Order were also based upon deficiencies found during inspections of Germantown Pharmacy that occurred on July 22, 2016 and August 11, 2016.The following deficiencies were found during the inspections:

July 22, 2016 inspection

A. An unregistered pharmacy technician entering orders and pulling medications;

B. No technician registrations posted in the pharmacy;

C. Pharmacists were not vaccination certified, but vaccines were found stored in the pharmacy's refrigerator;

D. A prescription for Zostavax filled for a patient on March 15, 2016 was stored in the pharmacy's refrigerator instead of the freezer;

E. The refrigerator used for storage of vaccines and medication pick-ups did not have a thermometer;

F. Multiple expired compounded medications that were incorrectly labeled were stored in non-sterile compounding room;

G. Expired bulk drug products;

H. Excessive stock of compounded medications (including ointments and capsules) that were not being used as anticipatory compounding, including ointments and capsules compounded for patients' prescriptions. The labels on the prescription had the patient name crossed out. Several ointments did not have sufficient closures;

I. Unlabeled and illegibly labeled compounded medication;

J. Germantown Pharmacy was acting as repository and was accepting

[1] Enstilar Foam was not approved by the FDA until October 2015. Enstilar Foam did not become commercially available in Maryland until January 18, 2016. This medication is a topical solution used to treat certain types of psoriasis.

several patient medications for disposal but was not registered to act as a repository;

K. The compounding area of the Germantown Pharmacy was unorganized with poor segregation of different compounded preparations. For example, two baskets filled with unlabeled tubes next to one another contained different strengths of Tretinoin;

L. An expired box of Oral Transmucosal Fentanyl Citrate was stored outside the controlled substance cabinet in an unlocked cabinet alongside miscellaneous storage;

M. A bottle of simple syrup without an expiration date or other information was stored in a Deer Park water bottle, beside compounding ingredients;

N. No compounding logs;

O. Expired eye drops products in the over the counter area;

P. A bottle labeled with prescription information found on shelf with compounded medication contained the kidney stones of the managing pharmacist;

Q. A bottle containing an unknown powder with a patient prescription labeled for Viagra tablets was stored with the compounding stock;

R. A bottle of an herbal sleep aid contained an assortment of unknown partially broken tablets.

August 11, 2016 inspection

A. An unregistered pharmacy technician was entering orders and pulling medications;

B. The Zostavax that was found in the refrigerator during the July 22, 2016 inspection was not disposed. It was observed in the freezer.

Germantown Pharmacy also acknowledges that the State can prove that pursuant to the 2017 Consent Order, Board inspectors conducted four inspections at the Germantown Pharmacy February 2018 and September 2018 and found numerous

deficiencies. The following deficiencies were found during the inspections:

February 15, 2018 inspection

A. A technician with an inactive registration was working at the pharmacy as a clerk;

B. The pharmacy did not maintain a minimum of two continuous years of records clearly demonstrating the content of annual educational training provided to each member of the pharmacy staff involved in the medication delivery system regarding the roles and responsibilities of pharmacy staff in preventing medication errors; and

C. Biennial inventory of Schedule II - V controlled substances could not be located.

February 23, 2018 inspection

A. There was no documentation explaining the reason(s) why commercially available medications were being compounded; and

B. Compounded medications were not marked on the prescription label to indicate it had been compounded.

April 20, 2018 inspection

A. Numerous examples of the Germantown-Pharmacy's compounding of FDA-approved, commercially available products that were not documented properly for doctor authorization;

B. Prescriptions for lidocaine 4% nasal spray which were compounded and had two prescription labels attached to the prescriptions. One of the labels for both prescriptions had an NDC which matched olopatadine hydrochloride, but the drug name listed on the label was Lidocaine 4% NS;

C. Sterile procedures were not being used when compounding formula for the product required it to be sterilely compounded;

D. Naltrexone was compounded without documentation of the formula or proof of bioavailability;

E. Compounding logs were incomplete, and several prescriptions lacked completed worksheets;

F. There were many CDS Schedule II prescriptions that were filled for patients whose addresses or addresses for the prescriber were over 20 miles away;

G. Rx 60967 was written for hydrocodone/APAP 7.5/300mg solution to be taken 7.5/300mg po q6h for 10 days but dispensed as hydrocodone/APAP tab 7.5-300mg #120 "Compound liquid 7.5/300g/5ml" was handwritten in a different pen/hand;

H. There were large gaps in prescription files. These gaps coincided with prescriptions that were billed for costly brand-name medications;

I. At least six prescription bags waiting in a bin had copays that were crossed off and replaced with a lower, handwritten price. One prescription bag waiting in the same bin had a UHC code and a zero copay that was crossed out and replace with a handwritten price of $15.00;

J. The Respondent-Pharmacy has an agreement with a hospital ("Hospital A") to fill prenatal prescriptions for its patients. The preprinted Pharmacy Referral Form states that: Hospital A "will pay $3.00 per prescription" to the Respondent-Pharmacy. Many of these prescriptions had a back tag with a higher cash price;

K. Prenatal prescriptions had only a back tag on a blank prescription pad with no other information;

L. Expired medication was observed on windowsills and in file cabinets, including a container with a prescription label identifying it as Epiduo with no other identifying labels or markings from the manufacturer;

M. Expired medications were observed in the CII safe and in the prescription refrigerator;

N. Return to stock vials were on the prescription shelves with no NDC,

lot, or expiration date;

O. A prescription vial was found in a bag in the will-call bin that had at least two desiccant packs in with the tablets;

P. CII prescriptions were dispensed under a nurse practitioner instead of the prescribing physician.

Germantown Pharmacy denies the allegations set forth in paragraphs B, C, F, G, H, I, and J.

September 11, 2018 Inspection

During the inspection, the Board Inspectors obtained computer records and signature logs for a sampling of the prescription numbers which were noted on the April 20, 2018, inspection report as missing from the physical file. Pharmacist A signed the list of prescription numbers attesting that there were no prescriptions or signature logs for patient pick-ups for the prescriptions. For several prescription numbers listed on the request, Pharmacist A indicated that Germantown Pharmacy did not have prescriptions or signature logs for the prescription numbers that appeared on the Germantown Pharmacy's dispensing records.[2]

The State can prove that Pharmacist A did not inform the Board that he had been disciplined by the District of Columbia Board of Pharmacy in March 2012. The State can also prove that Germantown Pharmacy violated the terms of the 2017 Consent Order that it entered into with the Board.

Germantown Pharmacy understands that by executing this Letter of Surrender it is waiving any right to contest the charges in a formal evidentiary hearing at which Germantown Pharmacy would have had the right to counsel, to confront witnesses, to give testimony, to call witnesses on my own behalf and all other substantive and procedural protections provided by law, including the right to appeal.

Germantown Pharmacy understands that the Board will advise the National Practitioners' Data Bank of this Letter of Surrender, and in any response to any inquiry, that Germantown Pharmacy has surrendered its permit, in lieu of a hearing on the revocation of its permit license, as further disciplinary action under the Act.

[2] Pharmacist A is the owner and permitholder of Germantown Pharmacy

Germantown Pharmacy also understands that in the event it would apply for a permit in any form in any other state or jurisdiction, that this Letter of Surrender and the underlying investigative documents may be released or published by the Board to the same extent as a final order that would result from disciplinary action, pursuant to Md. Code Ann., State Govt., § 10-611 *et seq.*, (2014 Repl. Vol & 2018 Supp.), and that this Letter of Surrender is considered a disciplinary action by the Board.

Germantown Pharmacy affirms that on or before the date of Board's acceptance of this Letter of Surrender, it will provide to Board staff all permits issued by the Board.

Germantown Pharmacy acknowledges that it may not rescind this Letter of Surrender in part or in its entirety for any reason whatsoever. Finally, Germantown Pharmacy wishes to make clear that it has been advised of its right to be represented by the attorney of its choice throughout proceedings before the Board, including the right to counsel with an attorney prior to signing this Letter of Surrender. Germantown Pharmacy understands both the nature of the Board's actions and this Letter of Surrender fully. Germantown Pharmacy acknowledges that it understands and comprehends the language, meaning and terms and effect of this Letter of Surrender. Germantown Pharmacy voluntarily chooses to surrender its Maryland permit to operate a pharmacy pursuant to the terms and conditions set out herein. Germantown Pharmacy makes this decision knowingly and voluntarily.

Very truly yours,

Hossein Zamani, R.Ph.
Permit Holder of Germantown Pharmacy

NOTARY

STATE OF MARYLAND

CITY/COUNTY OF Montgomery

I hereby certify that on this 11th day of October 2019, before me, a Notary Public of the State and City/County aforesaid, personally appeared **HOSSEIN ZAMANI, R.Ph., Permit Holder** and declared and affirmed under the penalties of perjury that signing the foregoing Letter of Surrender was his voluntary act and deed.

AS WITNESS my hand and Notarial seal.

Notary Public

My Commission expires: May 31, 2022

JENNY J. CHOI NOTARY PUBLIC MONTGOMERY COUNTY, MD

Jenny J. Choi
NOTARY PUBLIC
Montgomery County
State of Maryland
My Commission Expires
May 31, 2022

ACCEPTANCE

On this 16 day of October, 2019, I, Kevin Morgan, Pharm.D., on behalf of the Maryland State Board of Pharmacy, accept the **SURRENDER** of the permit of **GERMANTOWN PHARMACY** to operate as a pharmacy in the State of Maryland.

Kevin Morgan Pharm.D.
President
Maryland State Board of Pharmacy