HILL TOP PHARMACY LLC

12 05 2024 Date

Kristopher Rusinko, Pharm.D. President State Board of Pharmacy 4201 Patterson Avenue Baltimore, Mary land 21215

RE: Surrender of Permit

Permit Number: P08600 Case Number: 23-414

Dear Mr. Rusinko and Members of the Board:

Please be advised that HILL TOP PHARMACY LLC ("Hill Top Pharmacy") has decided to voluntarily surrender its permit to operate as a pharmacy in the State of Maryland, Permit Number: P08600 effective immediately. It is understood that upon surrender of its permit, Hill Top 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., (2021 Repl. Vol. & 2023 Supp.) and other applicable laws.

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

Hill Top 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 Hill Top Pharmacy on or about June 26, 2024, under Case Number: 23-414 (See Attachment A – Charging Document dated June 26, 2024).

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

. . . .

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

Health Occ. § 12-403. Required standards.

- (c) 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;
 - (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[.]

Health Occ. § 12-313. Denials, reprimands, suspensions, and revocations—Grounds

- (b) Subject to the hearing provisions of § 12-315 of this subtitle, the Board, on the affirmative vote of a majority of its members then serving, may . . . reprimand any licensee, place any licensee on probation, or suspend or revoke a license of a pharmacist if the licensee:
 - (2) Fraudulently or deceptively uses a license;

. . . .

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

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

The Board also charged Hill Top Pharmacy with violating the following provisions of Md. Code Ann., Health-General ("Health-Gen."):

Health-Gen. § 21-2A-03. Powers and duties of Secretary.

. . . .

. . . .

(c) Except as provided in subsection (d) of this section, each dispenser shall submit prescription monitoring data and naloxone medication data to the Program by electronic means, in accordance with regulations adopted by the Secretary.

Health-Gen. § 21-2A-04.2. Prescriber to request prescription monitoring data.

. . . .

- (e) If a pharmacist or pharmacist delegate has a reasonable belief that a patient may be seeking a monitored prescription drug for any purpose other than the treatment of an existing medical condition:
 - (1) Before dispensing a monitored prescription drug to the patient, the pharmacist or pharmacist delegate shall request prescription monitoring data to determine if the patient has received other prescriptions that indicate misuse, abuse, or diversion of a monitored prescription drug; and
 - (2) The pharmacist shall have the responsibility described in 21 C.F.R. 1306.04.

The Board also charged Hill Top Pharmacy with violating the following provisions of the Code of Maryland Regulations ("COMAR"):

COMAR 10.34.10.01. Patient Safety and Welfare.

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A. A pharmacist shall:

- (1) Abide by all federal and State laws relating to the practice of pharmacy and the dispensing, distribution, storage, and labeling of drugs and devices, including but not limited to:
 - (a) United States Code, Title 21,
 - (b) Health-General Article, Titles 21 and 22, Annotated Code of Maryland,
 - (c) Health Occupations Article, Title 12, Annotated Code of Maryland,
 - (d) Criminal Law Article, Title 5, Annotated Code of Maryland, and
 - (e) COMAR 10.19.03;
- (2) Verify the accuracy of the prescription before dispensing the drug or device if the pharmacist has reason to believe that the prescription contains an error[.]

B. A pharmacist may not:

- (1) Engage in conduct which departs from the standard of care ordinarily exercised by pharmacist;
- (2) Practice pharmacy under circumstances or conditions which prevent the proper exercise of professional judgment; or
- (3) Engage in unprofessional conduct.

COMAR 10.34.20.02. Requirements for Prescription Validity.

A. A valid prescription shall be:

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(1) Valid in the professional judgment of the pharmacist responsible for filling the prescription

COMAR 10.34.20.04. Controlled Dangerous Substances.

Transmission and dispensing of controlled dangerous substances shall be in accordance with applicable State and federal statutes and regulations.

COMAR 10.19.03.07. Prescriptions.

. . .

- C. Purpose of Issue of Prescription (21 CFR §1306.04)
 - A prescription for a controlled dangerous substance to be (1) effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of the individual practitioner's professional practice. responsibility for the proper prescribing and dispensing of controlled dangerous substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of the Maryland Controlled Dangerous Substances Act Criminal Law Article, §§5-501-5-505, Annotated Code of Maryland, and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled dangerous substances.

Hill Top 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. Hill Top 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.

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

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Hill Top Pharmacy has a single employee who is a pharmacist (the "Pharmacist"). On September 20, 2022, the Board conducted an inspection of Hill Top Pharmacy, during which the Pharmacist stated that he has procedures in place to verify CDS prescriptions, including calling the physician, using CRISP, checking fill history, checking for red flags, and reporting to PDMP. On December 8, 2022, an inspector from the Maryland Office of Controlled Substances Administration ("OCSA") conducted an inspection, during which the inspector educated the Pharmacist on red flag issues and the responsibility to ensure all CDS prescriptions are written for a legitimate purpose.

Following notice from OCSA, the Board began an investigation.

An audit trail request for the period from January 1, 2023, through September 1, 2023, revealed that the Pharmacist did not query the PDMP database for this period.

On February 2, 2024, OCSA's Clinical Pharmacist Inspector drafted a memorandum concerning Hill Top Pharmacy and the Pharmacist. Important to the memorandum are the following facts:

- 1. The resident agent for Hill Top Pharmacy is Practice-1.
- 2. Prescriber-1, identified as the director, signed on behalf of Practice-1 in Hill Top Pharmacy LLC's articles of incorporation.
- 3. Prescriber-2 is the resident agent for Practice-1.
- 4. Prescriber-1 signed the articles of incorporation for Practice-1 as an authorized person.
- 5. Prescriber-1 is the resident agent and signed the articles of incorporation as an authorized person for Practice-2.
- 6. Practice-2 shares the same address as Hill Top Pharmacy LLC.
- 7. The Pharmacist and Prescriber-1 are co-owners of a residential property. This is the address the Pharmacist maintains with the board for address of record.
- 8. According to the PDMP report, from January 2, 2023, through August 29, 2023, inclusive:
 - a. 96% of CDS dispensed by the Pharmacy was prescribed by Prescriber-1 and Prescriber-2.
 - b. The Pharmacy dispensed 12 prescriptions for Schedule II medications and 416 prescriptions for Schedule III-IV medications.
 - c. Of the 416 Schedule III-IV medications, 97% were self pay.

¹ For confidentiality and privacy purposes, the names of individuals and facilities involved in this case are not disclosed in this document.

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- d. Of the 404 self-pay prescriptions, 387 were for Buprenorphine 8mg tablets and all of these were for patients with addresses in West Virginia—almost all 100 miles from the Pharmacy but many 200-300 miles from the Pharmacy. Approximately 91% of these Buprenorphine 8mg were prescribed by either Prescriber-1 and Prescriber-2.
- e. The quantities dispensed were usually 90 tablets with prices of \$340, but for a few, the price charged was \$310.
- f. Prescriber-1 and Prescriber-2 electronically prescribed all prescriptions. Prescriber-1 prescribed from the address for Practice-1 and Practice-2. Prescriber-2 dispensed from the address for Practice-

From the above facts, the Clinical Pharmacist Inspector identified the following red flags:

- 1. Dispensing a drug with a high potential for abuse and diversion (buprenorphine 8mg tablets) almost exclusively when equally effective alternative drugs with lesser potential for abuse and diversion (Suboxone, Zubsolv) are widely available.
- 2. Dispensing a drug with a high potential for abuse and diversion (buprenorphine 8mg tablets) almost exclusively as an expensive (\$340 for 90 tablets) self-pay prescription to patients.
- 3. Dispensing a drug with a high potential for abuse and diversion (buprenorphine 8mg tablets) almost exclusively to patients travelling hundreds of miles from out-of-state when equally effective alternative drugs with lesser potential for abuse and diversion (Suboxone, Zubsolv) are available locally to the patients.
- 4. Dispensing the same drug with a high potential for abuse and diversion (buprenorphine 8mg tablets) to multiple members of the same family.
- 5. Dispensing an expensive drug (\$340 for 90 tablets) with a high potential for abuse and diversion (buprenorphine 8mg tablets) that was prescribed 91% of the time by nurse practitioners who have a financial interest in the pharmacy's business.
- 6. Dispensing an expensive drug (\$340 for 90 tablets) with a high potential for abuse and diversion (buprenorphine 8mg tablets) that was prescribed 81% of the time by a nurse practitioner who is a family member of the pharmacy's owner.

On May 14, 2024, OCSA conducted a regulatory inspection of the Pharmacy. The inspector identified a "large amount" of Buprenorphine 8mg tablets ordered totaling 5,670 tablets for the period from March 27, 2024, through May 7, 2024. There were 29

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prescriptions dispensed during this period with 27 of the 29 for Buprenorphine 8mg for self-pay West Virginia residents who lived more than 100 miles from the pharmacy. The charge for 90 tablets was \$360. There were 5 prescribers in addition to Prescriber-1 and Prescriber-2.

Hill Top 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 Hill Top 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.

Hill Top 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 Hill Top Pharmacy has surrendered its permit, in lieu of a hearing on the revocation of its permit license, as further disciplinary action under the Act.

Hill Top 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., (2021 Repl. Vol & 2023 Supp.), and that this Letter of Surrender is considered a disciplinary action by the Board.

Hill Top 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.

Hill Top Pharmacy acknowledges that it may not rescind this Letter of Surrender in part or in its entirety for any reason whatsoever. Finally, Hill Top 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. Hill Top Pharmacy understands both the nature of the Board's actions and this Letter of Surrender fully. Hill Top Pharmacy acknowledges that it understands and comprehends the language, meaning and terms and effect of this Letter of Surrender.

Hill Top Pharmacy voluntarily chooses to surrender its Maryland permit to operate a pharmacy pursuant to the terms and conditions set out herein. Hill Top Pharmacy makes this decision knowingly and voluntarily.

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Date

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Owner

Hill Top Pharmacy LLC

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NOTARY

STATE OF	Manyland	

CITY/COUNTY OF Prince George's County

AS WITNESS, my hand and Notary Seal.



Notary Public

My commission Expires: 02/06/2018

ACCEPTANCE

On behalf of the Maryland Board of Pharmacy, on this **9th** day of **December**, 2024, I accept Hill Top Pharmacy, LLC' PUBLIC SURRENDER the permit in the State of Maryland.

Deena Speights-Napata, M.A.

Executive Director for

Kristopher Rusinko, PharmD President, Maryland Board of Pharmacy