Deborah Burgess
License Number 13059

Neil B. Leikach
President, Maryland Board of Pharmacy
4201 Patterson Avenue
Baltimore, Maryland 21215

Re: Surrender of Pharmacist License
License No. 13059
Case No. 20-263

Dear Mr. Leikach and Members of the Board:

Please be advised that I have decided to **SURRENDER** my license to practice pharmacy in the State of Maryland, License Number 13059, effective upon acceptance of this letter by the Board Chair. I understand that I may not give pharmacy advice to any individual (with or without supervision and/or compensation), cannot dispense or administer drugs or assist in the dispensing or administration of drugs, and may not otherwise engage in the practice of pharmacy in Maryland, as it is defined in the Maryland Pharmacy Act (the "Act"), Md. Code Ann., Health Occ. § 12-101 *et seq.* (2014 Repl. Vol. & 2019 Supp.). Moreover, I may not represent myself to the public by title, abbreviation, sign, card, or other representation that I am licensed to practice pharmacy. In other words, as of the effective date of this Letter of Surrender, I understand that I am in the same position as an unlicensed individual.

I understand that this Letter of Surrender is a **PUBLIC DOCUMENT** and that upon the Board's acceptance and execution, this Letter of Surrender becomes a **FINAL ORDER** of the Maryland Board of Pharmacy (the "Board").

My decision to surrender my license to practice pharmacy in Maryland was prompted by a Notice of Charges Under the Maryland Pharmacy Act ("Charging Document") issued by the Board on August 16, 2023. The Charging Document was based on a Board investigation which revealed I violated the Maryland Pharmacy Act and COMAR. In particular, the Charging Document alleged the following:

1. At all times relevant to the Charging Document, I was employed as a pharmacist at a pharmacy in Maryland (the "Respondent-Pharmacy").
2. The Office of Controlled Substances Administration conducted an inspection of the Respondent-Pharmacy on February 3, 2020, which noted several concerns including: Schedule III-V invoices and receipts were not being dated; several patient prescription labels were noted to have an incorrect prescriber's address on them; when Schedule II products were ordered using a controlled substance ordering system ("CSOS") the Respondent-Pharmacy was not creating a record of the quantity of each item received or the date the item was received; no perpetual inventory for Schedule II drugs maintained;

and red flags were noted, such as high strength and high quantity opioids being dispensed, including to patients younger than 40 years old.

3. A review of the 1,463 Schedule II CDS prescriptions from the Respondent-Pharmacy revealed additional red flags, including: 255 prescriptions were for a high quantity and only one of those prescriptions had a notation that CRISP had been accessed for review; 18 prescriptions were paid for with cash, none of which had notated documentation on it; 18 prescriptions had "Fill with Insurance Only" stamped on the front of them by the prescribers but no notation indicating whether insurance had been verified; and 306 prescriptions had long distance by either in state patient prescriber located long distance from the patient and/or from the pharmacy – no notations were documented on any of the prescriptions to indicate verification of a genuine prescriber-patient relationship.
4. Subpoenaed copies of CDS five patients receiving both opioid and benzodiazepine prescriptions revealed no documentation was noted on the prescriptions that PDMP/CRISP was checked or that the prescribing provider was contacted to ensure the medications were prescribed for a legitimate medical purpose.
5. A Prescription Drug Monitoring Program report from January 2, 2019 to December 31, 2019 revealed 2,529 CDS prescriptions were dispensed, of which: 57% were for opioid or opioid containing drugs; 33% were for immediate release oxycodone strengths 10mg, 15 mg, 20mg, or 30mg dispensed in quantities of ninety or greater as a thirty day supply; 30% were benzodiazepines, mostly high strengths and frequently dispensed to patients who were also receiving high dose immediate release oxycodone prescriptions; several of the prescribers are located in Prince George's County, Maryland "which is a significant distance" from Baltimore City, Maryland where the Respondent-Pharmacy is located; and the Clinical Pharmacist Inspector noted that the Respondent-Pharmacy "routinely dispenses CDS prescriptions with red flags of potential abuse or diversion. . . . Most pharmacists and pharmacies will not fill the kinds of red flag prescriptions that are being dispensed from [the Respondent-Pharmacy]."
6. A comparison of the 1,463 Schedule II hard copy red flag prescriptions against audit logs for myself and the Pharmacist-Owner, revealed only the following CDS prescriptions on the audit logs: 2% of high quantity CDS prescriptions; 11% of prescriptions paid for in cash; none of the insurance only prescriptions; and 6% of the long distance patients.
7. Additionally, the audit logs and the hard copy prescriptions revealed myself and the Pharmacist-Owner were sharing PDMP login credentials and/or entered incorrect data on the prescription labels.

I have decided to surrender my pharmacy license to avoid further investigation and prosecution for violations of the Act, and to focus on my current health. I acknowledge that if the case were to proceed to an evidentiary hearing, the Board would submit evidence to support the investigative findings that I violated the following provisions under the Act:

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

. . . .

(b) *In general* — 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;

. . . .

(7) Willfully makes or files a false report or record as part of practicing pharmacy;

. . . .

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

The pertinent provisions of Md. Code Ann., Health-General provide as follows:

Health-General § 21-221. Prescription drug labeling.[1]

(a) A drug that is dispensed under a prescription shall bear a label that states:

(1) The name and address of the dispenser[.]

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

[1] Effective October 1, 2022, Health-General § 21-221(c) was revised to add "and naloxone medication data" as listed here.

(2) The pharmacist shall have the responsibility described in 21 C.F.R. § 1306.04.

The pertinent provisions of Code Md. Regs ("COMAR"), 10.34.08, COMAR 10.34.10, COMAR 10.19.03, and COMAR 10.47.07 provide as follows:

COMAR 10.34.08.01. 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 10.34.10.01. Patient Safety and Welfare.

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 a 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:

(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).

(1) A prescription for a controlled dangerous substance to be 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. The 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.

. . . .

E. Persons Entitled to Fill Prescriptions. A prescription for controlled dangerous substances may only be filled by a pharmacist acting in the usual course of the pharmacist's professional practice and either registered individually or employed in a registered pharmacy or registered institutional practitioner.

COMAR 10.19.03.08. Controlled Substances Listed in Schedule II.

A. Requirement of Prescription-Schedule II (21 CFR §1306.11).

(1) A pharmacist may dispense directly a controlled dangerous substance listed in Schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, only pursuant to a written prescription signed by the prescribing individual practitioner, except as provided in §A(4) of this regulation. Except as noted in §A(5)-(7) of this regulation, a prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy by facsimile equipment, if the original written, signed prescription is presented to the pharmacist for review before the actual dispensing of a controlled substance.

COMAR 10.47.07.03. Dispenser Reporting.

A. For each monitored prescription drug dispensed, the dispenser shall report the following prescription monitoring data to the Department:

. . . .

(4) Identifying information for the dispenser, including a valid Drug Enforcement Administration registration number.

The pertinent provisions of Code of Federal Regulations, 21 C.F.R. § 1304.21 and 21 C.F.R. § 1305.22 provide as follows:

21 C.F.R. § 1304.21. General requirements for continuing records.

(a) Every registrant[2] required to keep records pursuant to § 1304.03 shall

[2] Pursuant to 21 C.F.R. § 1301.11(a), "Every person who manufactures, distributes, dispenses, imports, or exports any controlled substance or who proposes to engage in the manufacture, distribution, dispensing, importation or exportation of any controlled substance shall obtain a registration unless exempted by law or pursuant to §§ 1301.22 through 1301.26. Except as provided in paragraph (b) of this section, only persons actually engaged in such activities are required to obtain a registration; related or affiliated persons who are not engaged in such activities are not required to be registered. (For example, a stockholder or parent corporation of a corporation manufacturing controlled substances is not required to obtain a registration.)"

maintain, on a current basis, a complete and accurate record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by him/her, and each inner liner, sealed inner liner, and unused and returned mail-back package, except that no registrant shall be required to maintain a perpetual inventory.

(b) Separate records shall be maintained by a registrant for each registered location except as provided in § 1304.04 (a). In the event controlled substances are in the possession or under the control of a registrant at a location for which he is not registered, the substances shall be included in the records of the registered location to which they are subject to control or to which the person possessing the substance is responsible.

(c) Separate records shall be maintained by a registrant for each independent activity and collection activity for which he/she is registered or authorized, except as provided in § 1304.22(d).

(d) In recording dates of receipt, distribution, other transfers, or destruction, the date on which the controlled substances are actually received, distributed, otherwise transferred, or destroyed will be used as the date of receipt, distribution, transfer, or destruction (e.g., invoices or packing slips, or DEA Form 41). In maintaining records concerning imports and exports, the registrant must record the anticipated date of release by a customs official for permit applications and declarations and the date on which the controlled substances are released by a customs officer at the port of entry or port of export for return information.

21 C.F.R. § 1305.22. Procedure for filling electronic orders.

. . . .

(g) When a purchaser receives a shipment, the purchaser must create a record of the quantity of each item received and the date received. The record must be electronically linked to the original order and archived.

I acknowledge that for all purposes relevant to licensure, certification, and/or permit, these allegations and the Allegations of Fact in the Charging Document will be treated as if proven.

I wish to make it clear that I have voluntarily, knowingly, and freely chosen to submit this Letter of Surrender to avoid further prosecution under the Act and to resolve this matter. I understand that by executing this Letter of Surrender, I am waiving any right to contest these findings or the Charging Document in a formal evidentiary hearing at which I would have had the right to counsel, to confront witnesses, to give testimony, to call witnesses on my own behalf,

and to all other substantive and procedural protections provided by law, including the right to appeal.

I understand that the Board will advise the National Practitioner Data Bank of this Letter of Surrender and in response to any inquiry will advise that I have surrendered my license. I understand that this Letter of Surrender will be posted on the Board's website along with all other formal disciplinary actions. I understand that, in the event that I apply for licensure in any form in any other state or jurisdiction, this Letter of Surrender, and all underlying investigative documents, may be released by the Board to the same extent as a Final Order pursuant to Md. Code Ann., Gen. Prov. §§ 4-101 *et seq.* (2014). Finally, I understand that this Letter of Surrender is considered disciplinary action by the Board.

I affirm that enclosed with this Letter of Surrender is my original Maryland pharmacist's license, number 13059, and my recent wallet-sized renewal card.

I further recognize and agree that by submitting this Letter of Surrender my license will remain surrendered unless and until I petition the Board for reinstatement; and I understand that when applying for a new Maryland license or when applying for reinstatement, I will approach the Board in the same posture as an individual whose license has been revoked based on the investigative findings contained herein as well as the Allegations of Fact in the Charging Document, and that the Board has the sole discretion to accept or deny any application that I may submit.

I understand and agree that I must comply with the minimum licensure requirements for reinstatement, which may include fees, continuing education, and reexamination before the Board may act upon any application for reinstatement of my Maryland license to practice pharmacy.

In the event that I apply for reinstatement to practice pharmacy, I fully understand that the Board has full discretion to grant or deny my application for reinstatement, even after my fulfillment of the above conditions. If the Board does grant my petition for reinstatement, I understand that the Board may set terms and conditions that shall apply to my receiving a reinstated Maryland license, including but not limited to a probationary period or limited practice settings. I also understand that if I petition for reinstatement I bear the burden of demonstrating to the Board that I am competent to practice pharmacy and possess good moral character, as specified in Md. Code Ann., Health Occ. §§ 12-302 and 12-310.

I acknowledge that I may not rescind this Letter of Surrender in part or in its entirety for any reason whatsoever. Finally, I wish to make clear that I have been advised I have the right to consult with an attorney before signing this Letter of Surrender and have been given an opportunity to do so. I fully understand the nature of both the Board's actions and this Letter of Surrender. I acknowledge that I understand and comprehend the language, meaning, and terms and effect of this Letter of Surrender. I make the decision to sign this Letter of Surrender knowingly and voluntarily and without duress.

I solemnly affirm under the penalties of perjury and upon personal knowledge that the contents of the foregoing Letter are true:

11-9-2023
Date

Deborah Burgess

NOTARY

STATE OF MARYLAND

COUNTY/CITY OF Howard

I HEREBY CERTIFY that on this 9th day of Nov, 2023, before me, a Notary Public of the State of Maryland and County/City aforesaid, personally appeared Deborah Burgess, and made an oath in due form that the foregoing Letter of Surrender was her voluntary act and deed.

AS WITNESS my hand and Notarial seal.

Mohammad M Ahsan
NOTARY PUBLIC
HOWARD COUNTY
MARYLAND
MY COMMISSION EXPIRES February 08, 2027

M. M. Ahsan
Notary Public

My commission expires: 2/8/2027

ACCEPTANCE

On behalf of the Maryland Board of Pharmacy, on this 20th day of November, 2023, I accept Deborah Burgess' **PUBLIC SURRENDER** of her license to practice pharmacy in the State of Maryland.

Neil B. Leikach
President, Maryland Board of Pharmacy