

IN THE MATTER OF	*	BEFORE THE MARYLAND
ALLENTOWN DISCOUNT RX	*	STATE BOARD
PHARMACY	*	OF PHARMACY
Respondent	*	Case No. 23-138
Permit No. P07964	*	
AND	*	
HOWARD A. MAJOLAGBE	*	
Respondent	*	
License No. 18796	*	
* * * * *		

FINAL DECISION AND ORDER

Procedural History

On April 17, 2024, the Maryland State Board of Pharmacy (“the Board”) issued charges against Allentown DiscountRx Pharmacy (the “Respondent-Pharmacy”) and its owner and pharmacist, Howard A. Majolagbe, (the “Respondent-Pharmacist) with violating the Maryland Pharmacy Act (“the Act”) based on the result of six (6) inspections conducted by the Office of Controlled Substances Administration (“OCSA”) and the Board between 2019 and 2024. The inspections indicated, among other things, that Respondent-Pharmacist and Respondent-Pharmacy dispensed controlled dangerous substances (“CDS”) pursuant to prescriptions that contained numerous red flags without appropriate efforts by the Respondent-Pharmacist to verify that prescriptions were issued for legitimate medical purposes.

The Board delegated authority to the Office of Administrative Hearings (OAH”) to conduct a contested case hearing and prepare proposed finding of facts, proposed conclusions of law, and a proposed order. Md. Code. Ann., State Gov’t §§10-201 through 10-221; Md. Code. Ann., Health

Occ. §12-315; (Code of Maryland Regulations) COMAR 13.34.01; COMAR 28.02.01. An evidentiary hearing was held at OAH on November 12 and 13, 2024. The Administrative Law Judge (“ALJ”) admitted into evidence 19 documentary exhibits offered by the State and 18 documentary exhibits offered by the Respondents. The evidence also included witness testimony on behalf of the State from Edward Acheampong, Pharm.D., Pharmacist Compliance Officer, Maryland Board of Pharmacy, and Andrew Klinger, R.Ph., Clinical Pharmacist Inspector, OCSA, who was accepted as an expert in pharmacy and dispensing of CDS. The Respondent also testified on his own behalf.

The proposed decision was issued on February 11, 2025, in which the ALJ recommended that the charges issued by the Board be upheld in part and dismissed in part. In terms of sanctions, the ALJ proposed that each of the Respondents be sanctioned by the imposition of a reprimand and at least three years’ probation with certain terms and conditions, and that each of the Respondents be ordered to pay a fine of \$5,000.00. The ALJ’s Proposed Decision of February 11, 2025, is incorporated by reference into this Final Decision and Order.¹

The Proposed Decision was sent to both parties at their address of record. The Respondents filed exceptions with the Board, and an Exceptions Hearing was held before the Board on May 21, 2025. After considering the record, including the evidentiary record made before the ALJ, the Board now issues this Final Decision and Order.

A. Documents

The following documents were admitted into evidence:

State’s Exhibit No. 1 - Respondent-Pharmacy’s Maryland Permit database printout,
undated

¹ The ALJ’s Proposed Decision, dated February 11, 2025, is not attached to this document but has been provided to the Respondents.

- State's Exhibit No. 2 - Respondent-Pharmacist's Maryland License database printout, undated
- State's Exhibit No. 3 - OCSA Red Flag Inspection Report-Pharmacy, dated September 27, 2019
- State's Exhibit No. 4 - OCSA Intra-Office Memorandum, Regulatory and Red Flag Inspection, dated April 28, 2020
- State's Exhibit No. 5 - OCSA Inspection Report – Pharmacy and Red Flag Inspection Report – Pharmacy, dated June 8, 2021.
- State's Exhibit No. 6 - OCSA Intra-Office Memorandum, Regulatory and Red Flag Inspection, dated June 9, 2021
- State's Exhibit No. 7 - Referral from OCSA to the Board, dated August 20, 2022
- State's Exhibit No. 8 - OCSA Intra-Office Memorandum, Regulatory Inspection, dated June 24, 2022
- State's Exhibit No. 9 - Board Inspection report, dated September 14, 2022- October 11, 2022.
- State's Exhibit No. 10 - Prescription Drug Monitoring Program (PDMP) Report, dated July 1, 2022 to July 1, 2023 (on USB drive).
- State's Exhibit No. 11 - OCSA Intra-Office Memorandum, PDMP Analysis, dated August 8, 2023
- State's Exhibit No. 12 - Curriculum Vitae, Andrew Klinger, R. Ph
- State's Exhibit No. 13 - Audit Log Report, dated May 1, 2019, through July 1, 2023 (on USB drive)

- State's Exhibit No. 14 - Hard copy prescriptions, May 1, 2019, through July 1, 2023 (on USB drive)
- State's Exhibit No. 15 - Board Investigative Information and Summary, dated June 7, 2023
- State's Exhibit No. 16 - Board Annual Inspection report and attachments, dated January 2, 2024, through February 9, 2024.
- State's Exhibit No. 17 - OCSA Inspection Report-Pharmacy, dated January 29, 2024
- State's Exhibit No. 18 - OCSA Intra-Memorandum, Regulatory Inspection, dated January 30, 2024
- State's Exhibit No. 19 - Charges Under the Maryland Pharmacy Act against the Respondents
- Resp.'s Exhibit No. 1 - Letter from OCSA, dated August 20, 2019, and the Respondents' documents sent in response, undated
- Resp.'s Exhibit No. 2 - Documents related to the Board of Physicians' Investigation, August – November 2022
- Resp.'s Exhibit No. 3 - Pharmacy finance documents, various dates
- Resp.'s Exhibit No. 4 - Inspection report, dated September 14, 2022, and related documents, various dates
- Resp.'s Exhibit No. 5 - Registration/ Certificate (Respondent-Pharmacist), expires October 31, 2027; Washington D.C. License (Respondent-Pharmacist), issued May 11, 2009; U.S. Department of Justice Drug Enforcement Administration Controlled Substance Registration Certificate, expires June 30, 2027; Pharmacy Registration, expires May 31, 2026; Non-

Resident Pharmacy certificate, issued June 26, 2024 and expired May 31, 2025; Pharmacist Registration, expires June 30, 2026; State of West Virginia Board of Pharmacy Mail Order Pharmacy Permit & Controlled Substance Permit, issued December 1, 2023 and expired June 30, 2025.

- Resp.'s Exhibit No. 6 - Emails related to the North Carolina Board of Pharmacy, dated January 12, 2024
- Resp.'s Exhibit No. 7 - Emails related to the Board, dated August 22, 2023 and February 6, 2024
- Resp.'s Exhibit No. 8 - Respondent-Pharmacy Policies, various dates
- Resp.'s Exhibit No. 9 - Excerpt from the Federal Register Vol. 89, No. 23, Medications for the Treatment of Opioid Use Disorder, February 2, 2024, and Letters of Concerns, various dates.
- Resp.'s Exhibit No. 10 - Training materials and studies, various dates
- Resp.'s Exhibit No. 11 - Documents related to establishing a pharmacy, dated April 24, 2018
- Resp.'s Exhibit No. 12 - American Redwood Consulting report, dated September 23, 2024, and related documents, various dates
- Resp.'s Exhibit No. 13 - Excerpt from the Federal Register, Vol. 89, No. 23, Medications for the Treatment of Opioid Use Disorder, published February 2, 2024
- Resp.'s Exhibit No. 14 - Claim records, various dates
- Resp.'s Exhibit No. 15 - Patient records, various dates

- Resp.'s Exhibit No. 16 - The Pharmacy Access to Resources and Medication for Opioid Use Disorder (PhARM-OUD) Guideline, undated
- Resp.'s Exhibit No. 17 - Maryland Schools Record of Examination form (blank), undated
- Resp.'s Exhibit No. 18 - Screenshots of text messages, undated

A. Witnesses

State: Edward Acheampong, Pharm.D. - Pharmacist Compliance Officer, Maryland Board of Pharmacy; and

Andrew Klingler, R. Ph. - Clinical Pharmacist Inspector, OCSA, accepted as an expert in pharmacy and dispensing of CDS.

Respondents: Howard A. Majolagbe, R. Ph., Pharm.D. – Respondent-Pharmacist and owner of the Respondent-Pharmacy

FINDINGS OF FACT

The Board finds the following facts which incorporate the ALJ's proposed findings of fact in substance and which are supported by substantial evidence in the record.

1. At all times relevant, the Respondent-Pharmacist was licensed as a pharmacist in the State of Maryland under License Number 18796. The Respondent-Pharmacist's license expires on June 30, 2026.
2. At all times relevant, the Respondent-Pharmacy held a permit to operate as a pharmacy in the State of Maryland under Permit Number P07964.

3. The Respondent-Pharmacist co-owns and manages the Respondent-Pharmacy, which opened in April 2019 and has dispensed CDS since its opening. The Respondent-Pharmacy is located in Temple Hills, which is in Prince George's County, Maryland.
4. OCSA oversees CDS registration requirements, conducts pharmacy inspections, and educates pharmacists who dispense prescriptions for CDS.
5. Controlled dangerous substances (CDS) are organized into five Schedules (I through V) based on their acceptable medical use and the risk for abuse and/or dependency. Schedule I drugs have the highest risk for abuse/dependency, and Schedule V drugs have the lowest risk.
6. Buprenorphine is a partial opioid agonist generally prescribed to treat opioid use disorder. It is classified as a Schedule III CDS.
7. Buprenorphine is usually prescribed in a combination product with Naloxone, which is an opioid antagonist, or blocker, to prevent misuse of buprenorphine. The combination product prevents abuse through injection; in other words, if the patient attempts to inject the buprenorphine, the naloxone will cause withdrawal. Buprenorphine is typically prescribed alone, also known as monoprodut buprenorphine, only when there is a clinical contraindication to the combination buprenorphine/naloxone product, such as pregnancy or an allergy to the combination product.
8. In the context of CDS prescriptions, red flags are characteristics that raise concern regarding the misuse, abuse, or diversion of the CDS prescribed. Red flags include high strength and/or high quantity, payments in cash, dangerous combinations of drugs,²

² Concerning cocktails include combinations of two or more short acting opioids; two or more long acting opioids; opioid with a stimulant; opioid with benzodiazepine; opioid with another CDS and/or adjunct non-CDS. (State Ex. 3, p. S018).

patients who reside a long distance from the pharmacy or out of state, prescribers located a long distance from the pharmacy or out of state, multiple CDS prescriptions for individuals residing at the same address, multiple CDS prescriptions for family members, signs of forgery, prescriptions filled too soon, and patients under age forty receiving opioids.

9. The standard of care when a pharmacist encounters prescriptions with red flags is to contact the prescriber to determine the basis for the prescription. The call to the prescriber should be documented in the pharmacist's electronic or hard-copy records. If the pharmacist is not able to agree with the prescriber that, in his or her professional judgment, the prescription is for a legitimate medical purpose, the pharmacist must decline to dispense the prescribed medication.

10. The Prescription Drug Monitoring Program (PDMP) is a state program that monitors the prescribing and dispensing of all Schedule II, Schedule III, Schedule IV, Schedule V CDS and the dispensing of naloxone medication by all Maryland prescribers and dispensers.

11. The Chesapeake Regional Information Systems for our Patients (CRISP) administers the PDMP by a database through which pharmacists can search for PDMP data pertaining to a specific patient who is presenting a CDS prescription to be filled. Each search that returns results (including searches that result in a "no data" finding) creates a record of a "successful query."

12. An Audit Log is a report that shows all PDMP data access by a clinical user, such as a pharmacist, through their CRISP account.

September 27, 2019 OCSA Inspection

13. On September 27, 2019, OCSA Clinical Pharmacist Inspectors (“Inspector A” and “Inspector B”) conducted an annual regulatory inspection of the Respondent-Pharmacy. The Respondent-Pharmacist was present for the inspection.

14. The inspection revealed that from June 2019 to September 2019, the Respondent-Pharmacy ordered high quantities of high-strength CDS medications (oxycodone³ 15 mg, 20 mg, and 30 mg and methadone⁴ 10 mg) and unusually few lower-strength CDS medications and non-opioid medications. Additionally, the Respondent-Pharmacy ordered large amounts of buprenorphine 8 mg.⁵

15. The CDS medications the Respondent-Pharmacy stocked upon opening, and the large amounts ordered, were so unusual for a new pharmacy that the OCSA inspectors opted to conduct a red flag inspection instead of a regulatory inspection. In a red flag inspection, the OCSA examines the practices of a pharmacy by reviewing the pharmacy records for red flags.

16. The red flag inspection conducted on September 27, 2019, revealed an inventory discrepancy (corrected during inspection), a failure to separate CII and CIII inventory in the biennial inventory, and a CII prescription missing a prescriber’s signature. Additionally, of the 243 CII prescriptions the inspector reviewed, approximately 86% had red flags, including dangerous drug combinations, cash payments, high strength/high quantity, out-of-state patients, in-state patients traveling long distances, in-state long distance prescribers, problematic prescribers, and patients under age 40 receiving opioids.

³ Oxycodone is a Schedule II CDS.

⁴ Methadone is Schedule II CDS.

⁵ For purposes of this order, references to buprenorphine mean monoproduct buprenorphine unless otherwise stated.

17. The inspection also revealed multiple prescriptions for buprenorphine 8 mg for patients with addresses in West Virginia.

18. The OCSA inspectors verbally counseled the Respondent-Pharmacist on adherence to the standard of care and his regulatory corresponding responsibility to ensure that the prescriptions he filled were issued for a legitimate medical purpose; they documented the conversation in their report. The Respondent-Pharmacist was also advised to separate CII and CIII medications in the biennial inventory, ensure that all hardcopy CDS prescriptions have prescriber signatures, and verify with prescribers that all CDS prescriptions have a legitimate medical purpose.

June 8, 2021 OCSA Inspection

19. On June 8, 2021, Inspector A and Inspector B conducted regulatory and red flag inspections of the Respondent-Pharmacy. The Respondent-Pharmacist was present for the inspection.

20. The inspection revealed that between March 3, 2021, and June 2, 2021, the Respondent-Pharmacy ordered large quantities of buprenorphine 8 mg, oxycodone (10 mg, 15 mg, and 30 mg) and methadone 10 mg.

21. The inspection reviewed 341 CII prescriptions and identified 81.2% as containing red flags, such as: high strength/quantity, in-state patients traveling long distances, patients under forty years old receiving opioids, dangerous drug combinations, and cash payments.

22. The June 8, 2021 inspection also revealed that the Respondent-Pharmacy had mailed medications to patients in West Virginia, Virginia, and Pennsylvania even though it was not licensed to do so.⁶

⁶ Although the Board adopts this finding, it has elected not to associate any corresponding violation.

23. The inspection also revealed that the Respondent-Pharmacist filled a high number of monoprodut buprenorphine prescriptions for West Virginia residents located long distances from the Respondent-Pharmacy. These were frequently prescribed by the same few prescribers and often paid for by the patients themselves, rather than covered by insurance.

24. The inspection found one CII prescription that was filled with a photocopied prescription, and one hard-copy CIII prescription filled without a pen-to-paper signature but rather an e-signature with no documentation of an oral confirmation with the prescriber.

25. The Respondent-Pharmacist was again counseled about the red flags found in the prescriptions reviewed and his corresponding responsibility and the importance of confirming with patients and/or prescribers that a prescription has a legitimate medical purpose.

June 24, 2022 OCSA Inspection

26. On June 24, 2022, Inspector B conducted a regulatory inspection of the Respondent-Pharmacy.

27. The inspection again revealed orders of unusually large quantities of buprenorphine 8mg.

28. A review of the dispensing report (for the period of June 23, 2021, to June 23, 2022) and hardcopy prescriptions (for August 23, 2021, to April 7, 2022) for CII medications revealed red flags including long distance travel by in-state patients, cash payments, dangerous drug combinations, high strength/quantity, prescriptions for the same medication for multiple individuals at the same address, in-state prescribers located a long distance from the Respondent-Pharmacy, and prescribers of note.

29. On site review of the dispensing report (for the period of May 23, 2022, to June 23, 2022) and hard copy prescriptions (for the period of April 25, 2022, to May 21, 2022) for CIII medications revealed red flags including multiple buprenorphine 8mg prescriptions written by prescribers of note (many from the same treatment center, Treatment Center A) and West Virginia patients traveling long distances (up to 400 miles roundtrip). Some hardcopy prescriptions from Treatment Center A were marked “Verified with [Staff A].”

30. Two (2) CDS prescriptions were missing patient addresses.

31. A subsequent analysis of the dispensing reports for CII medication and CIII medications revealed numerous prescriptions for very high dose opioid and opioid combination medications, many of which were prescribed by prescribers of note. Of the 1,158 CII prescriptions, 85.2% were for opioid or opioid combination medications. Most were for 90 morphine milligram equivalents (MME) or greater, which is considered high and would warrant additional review and verification by a pharmacist.

32. Additionally, 65.5% of the 1,636 CIII-CV prescriptions dispensed were for buprenorphine 8 mg, while only a small percentage were for buprenorphine/naloxone combination product. Ninety-six percent (96%) of the buprenorphine prescriptions were written by providers of note.

33. On or about August 20, 2022, OCSA referred the Respondent-Pharmacy to the Board because the same red flags had persisted through multiple inspections despite repeated counseling and education.

September 14, 2022 Board Inspection

34. On September 14, 2022, a pharmacy inspector for the Board (“Board Inspector A”), conducted an annual inspection of the Respondent-Pharmacy. The Board Inspector A noted the following violations:

- a. Two (2) CDS prescriptions missing the patient’s address
- b. Two (2) CDS II inventory discrepancies of one tablet each (oxycodone 5 mg and methadone 5 mg);
- c. Missing prescriber address on two (2) hard copy CII prescriptions;
- d. Some red flag CII and CIII prescriptions based on out-of-state prescribers and/or patients, and seven (7) buprenorphine-only prescriptions paid for in cash;
- e. Deliveries of prescription medications to address in Washington D.C., despite not holding a non-resident pharmacy license in D.C.⁷

35. The Board Inspector advised the Respondent-Pharmacist that “[c]ontrolled prescriptions without pen to paper signature should be verified and noted.” (State Ex. 9, p. S067.)

Board Review and Investigation

36. The Board requested and obtained a report from the PDMP. This report included dispensing information for all CDS dispensed by the Respondent-Pharmacy from July 1, 2022, through July 1, 2023.

37. Based on the PDMP report, during the period of July 1, 2022, through July 1, 2023, the Respondent Pharmacy dispensed 2,427 CDS prescriptions. These prescriptions had the following characteristics:

⁷ Although the Board adopts this finding, it has elected not to associate any corresponding violation.

- a. 45% were for buprenorphine products;
 - b. Buprenorphine 8 mg tablets were dispensed in large quantities (60 to 120 tablets);
 - c. 28% were for CII opioids;
 - d. 9% were for CII stimulants;
 - e. 4% were for benzodiazepines;
 - f. Of the CDS medications, 41% of the prescriptions were for buprenorphine 8 mg tablets, and nearly all of these were dispensed to patients with out-of-state addresses a long distance (over 100 miles) from the Respondent-Pharmacy;
 - g. Of those buprenorphine prescriptions, most were likely self-pay and based on prescriptions from providers with a history of prescribing buprenorphine-only tablets to patients residing in West Virginia;
 - h. An allergy to the buprenorphine/naloxone combination was documented for only two (2) of the 995 buprenorphine prescriptions;
 - i. Eleven percent (11%) of the CDS prescriptions were high dose/high quantity and prescribed by prescribers with histories of prescribing red flag prescriptions;
 - j. Of the 268 immediate-release opioid prescriptions, the Respondent-Pharmacist checked patient data via CRISP for only 2%.
38. Based on the hardcopy prescriptions for buprenorphine dispensed by the Respondent-Pharmacist from July 1, 2022, through July 1, 2023, nearly all were self-pay; dispensed in large quantities (60 to 120 tablets); dispensed to out-of-state patients

in West Virginia, Georgia, North Carolina, and Virginia; and, for out-of-state patients, written by the same two (2) prescribers.

January 2, 2024 Board Inspection

39. On January 2, 2024, another Board inspector (“Board Inspector B”) conducted an annual inspection. The Respondent-Pharmacist was present for the inspection.

40. The inspection revealed inventory discrepancies (lisdexamfetamine⁸ 40 mg and methylphenidate⁹ 36 mg); the Respondent Pharmacist submitted an explanation for the discrepancy on February 7, 2024, well after the January 9, 2024, deadline set by Board Inspector B.

41. The Respondent-Pharmacist had blister packs of medications which he delivered to Washington D.C., addresses, despite not yet having the Respondent-Pharmacy licensed to dispense in Washington, D.C.¹⁰

42. Additionally, similar red flags were documented, including numerous monoprodukt buprenorphine prescriptions for patients residing in West Virginia and prescribed by prescribers of note.

January 29, 2024 OCSA Inspection

43. On January 29, 2024, Inspector A and another OCSA Inspector (“Inspector C”) conducted a red flag inspection. Findings included several hardcopy CDS prescriptions with patient and/or prescriber address deficiencies and an inventory discrepancy (oxycodone 20 mg); and large orders for buprenorphine 8 mg.

⁸ Lisdexamfetamine is a Schedule II CDS.

⁹ Methylphenidate is a Schedule II CDS.

¹⁰ Although the Board has adopted this finding, it elects not to associate any corresponding violation.

44. Of the 201 CDS prescriptions dispensed from December 30, 2023, through January 29, 2024, 100 (or 50%) were for monoprodut buprenorphine, and nearly all of these were dispensed as self-pay to patients who traveled long distances from West Virginia, and other patients from hundreds of miles away. The same three prescribers were responsible for the majority of these 100 prescriptions.

45. The inspectors also noted 18 high-dose oxycodone prescriptions, most of which were self-pay and prescribed by prescribers of note.

DISCUSSION

Pharmacists and pharmacies play an integral role in the provision of safe and effective pharmaceutical care to patients. Because of pharmacists' advanced professional education and training in pharmaceutical care, and because they are the last healthcare provider to have an opportunity to clinically review medications before they are dispensed to the patient, they have the responsibility to apply professional scrutiny to every prescription before a patient receives a medication. With respect to controlled dangerous substances (CDS), this standard is codified in federal and state regulations and states that a pharmacist has a "corresponding responsibility" to that of a prescriber to ensure that a prescription is written by a prescriber acting in the usual course of the prescriber's professional practice and issued for a legitimate medical purpose. COMAR 10.19.03.07; 21 C.F.R. § 1306.04. The Respondent-Pharmacist, through the Respondent-Pharmacy, dispensed thousands of CDS prescriptions containing red flags with little to no effort to engage in any verification to ensure that the prescriptions were legitimate and clinically appropriate.

In the ALJ's Proposed Decision, she ably and objectively assessed the expert testimony presented at the evidentiary hearing and set forth a well-reasoned analysis of the evidence in the record. Excerpts from the relevant sections of the ALJ's discussion are adopted in substance and set forth below.

Testimony

...

Mr. Klinger also testified, explaining that most OCSA inspections are regulatory, though he has participated in fifteen to twenty red flag inspections, which can be triggered by concerns uncovered in a regulatory inspection. He was one of two inspectors who conducted both the September 27, 2019 inspection and the June 8, 2021 inspection. He emphasized that the mission of OCSA is educational, rather than enforcement oriented, and explained that data pertaining to a list of specific red flags is gathered and reviewed for patterns and for changes over multiple inspections.

Mr. Klinger explained that the standard of care requires a pharmacist to contact a provider when a prescription has a red flag to determine the basis for the prescription and then make an independent professional judgment as to whether the prescription is for a legitimate medical purpose. The contact with the prescriber should be documented, either in a pharmacy's own patient records or on the hard-copy prescription. Mr. Klinger offered the example of a prescriber explanation that a CDS prescription was issued because a patient requested it, as a circumstance where a pharmacist's professional judgment should result in a declining to fill the prescription, even though the prescriber provided an explanation.

Regarding the specific red flags at issue, Mr. Klinger addressed the many monoproduct buprenorphine prescriptions at length. He emphasized that these prescriptions are not typical because there is significant concern for drug abuse when buprenorphine is not combined with naloxone. Generally, buprenorphine would only appropriately be prescribed on its own when a patient is pregnant or has a documented allergy to naloxone. Mr. Klinger also pointed to the large number of prescriptions written by "prescribers of note", meaning prescribers whose practices have been flagged as potentially problematic with regard to CDS abuse, misuse, or distribution by OCSA. Mr. Klinger acknowledged there is no list of such prescribers given to pharmacies, and that the identities of prescribers who are being investigated but who have not been barred from issuing prescriptions would not be available to pharmacies or pharmacists. However, he explained that pharmacists dispensing CDS have a professional responsibility to pay attention to patterns in the CDS prescriptions they fill, including the prescribers. He also noted that when this issue was called to the Respondent-Pharmacist's attention during inspections, he was defensive, rather than receptive to reconsidering his practices.

Regarding the large number of cash payments, Mr. Klinger similarly explained that while cash payments are permissible, a pharmacist has an obligation to pay attention to a pattern of such payments, since cash payments tend to be made when insurers have declined coverage due to a CDS prescription being high-dosage or because of other concerns about the prescription.

Mr. Klinger further testified that the same red flags noted at the 2019 inspection persisted in 2021, including large wholesale purchases of buprenorphine 8mg tablets and prescriptions that were high strength/high quantity, written by prescribers of note, self-paid, dispensed to in-state patients who traveled a long distance, cocktail combinations, and for patients under forty years of age. (State's Exs. 5 & 6) And the same concerns were present once again in the 2022 and 2024 inspections that followed the OCSA referral to the Board, such as patients traveling long distances and large quantities of buprenorphine 8mg tablets ordered.

Mr. Klinger also explained his analysis of the dispensing report, which included CII and CIII-CV medications dispensed from June 23, 2021 to June 23, 2022. Of particular concern were the "exceptionally high" dosages of the opioid medications dispensed, most of which exceeded ninety MME (morphine milligram equivalent)¹¹ or greater and were prescribed by prescribers of note, as well as the high percentage of monoprodut buprenorphine prescriptions. Mr. Klinger characterized such a large number of monoprodut buprenorphine prescriptions as an "extreme outlier" for a pharmacy.

Finally, Mr. Klinger addressed the most recent inspection, conducted on January 29, 2024. Again, the inspection and the dispensing report revealed large orders for buprenorphine, high dosage oxycodone prescriptions frequently written by providers of note, patients traveling from "hundreds of miles" away, and a high number of self-pay prescriptions. (State's Exs. 17 & 18) Mr. Klinger noted that the Respondent-Pharmacist continued to be defensive of his practices.

Analysis

That the Respondents dispensed prescriptions with red flags is not in dispute. The Respondent-Pharmacist acknowledged that he did so and maintained that it was appropriate; the State averred that in filling these prescriptions, the Respondent-Pharmacist failed to (1) "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 thus (2) did not meet his "corresponding responsibility" to ensure that the CDS prescriptions were for a legitimate medical purpose. Md. Code Ann., Health Gen. § 21-2A-04.2(e). Based on the evidence

¹¹ Morphine milligram equivalent (MME) is a calculation used to standardize the potency of opioid medications to assist clinicians in determining risk assessment for patient safety. [T. 128] The Center for Disease Control (CDC) found that patients receiving 50MME to 100MME daily have a significantly greater risk of fatal overdose compared to those taking less than 50MME. (State's Ex. 11, Bates 99)

presented, I am persuaded that the Respondent-Pharmacist failed to request the prescription monitoring data with a frequency even remotely appropriate to the extraordinary breadth of the red flags present in the prescriptions he filled. Accordingly, he did not meet his “corresponding responsibility” as a pharmacist.

In so concluding, I give significant weight to the expertise of Mr. Klinger, who has been a registered pharmacist in Maryland since 1993 and has five years of experience as a Clinical Pharmacist Inspector for OCSA – including over a thousand inspections of pharmacist dispensing CDS. His role in educating CDS registrants on Maryland and federal laws governing the dispensing of CDS requires him to be highly familiar with these provisions and knowledgeable about both the typical and atypical practices in Maryland pharmacies. Mr. Klinger’s background thus equips him to have not only extensive regulatory knowledge, but also a perspective informed by both pragmatism and an awareness of the challenges pharmacies encounter in ensuring their compliance with the law. Additionally, Mr. Klinger’s testimony made clear his familiarity with PDMP reports, pharmacy dispensing reports, pharmacy records, and written prescriptions, and I found his explanations and opinions regarding each of these to be illuminating, cogent, and clearly stated.

It is true that the Respondent-Pharmacist also has extensive experience as a pharmacist. Additionally, I accept his testimony that he holds a doctorate degree in pharmacy. His opinions regarding the treatment of addiction were both thoughtful and provocative. However, the Respondent-Pharmacist is not a lawmaker, policymaker or academic; he is a pharmacist and pharmacy owner/manager. The laws and regulations cited by the State make clear his obligations to dispense CDS medications within the confines of the law and consistent with the standard of care – which includes his corresponding responsibility as a pharmacist. Additionally, the Respondent-Pharmacist’s testimony is inherently self-serving, while Mr. Klinger’s is objective. Notably, nothing in this record remotely corroborates the Respondent-Pharmacist’s claim of inappropriate, unethical, or biased treatment by the inspectors.

The State presented uncontradicted evidence, including Mr. Acheampong’s investigative report and testimony, Mr. Klinger’s testimony, the PDMP report for July 1, 2022 through July 1, 2023 and the Audit Log entries for that same period, that of the 268 immediate-release opioid prescriptions the Respondent-Pharmacist reported dispensing during that period, he checked the monitoring data for only 2% of them. The State also presented uncontradicted evidence, including Mr. Klinger’s expert opinion and first-hand familiarity with the Respondents, that the Respondents filled CDS prescriptions over a period of several years despite numerous readily apparent red flags. While the Respondent-Pharmacist compellingly testified that prescriptions with red flags are appropriate to fill when those flags are effectively “cleared”, he failed to present persuasive evidence that he in fact cleared them. Instead, in dispensing the prescription, he apparently relied on his ideological belief that many red flags are more accurately characterized as “barriers” to effective treatment that merit little to no scrutiny and on his insistence that he had professional relationships with prescribers sufficient to simply trust their prescriptions, despite the red flags.

The Respondent-Pharmacist appears to have eschewed his corresponding responsibility to ensure the appropriateness of CDS prescriptions in favor of his own personal ideologies regarding opioid use disorder (OUD) treatment. The Board is not insensitive to issues regarding access to OUD treatment. And while the Respondents argue that he was merely “lowering barriers to treatment”, this is not permissible if it means lowering the standard of care required to ensure the safety of vulnerable patients.

It is undisputed that the Respondents dispensed large volumes of monoprodut buprenorphine prescriptions with little to no verification or documentation of an allergy or other rationale as to why the preferred combination buprenorphine product was not prescribed. The State’s expert testified that the monoprodut buprenorphine does not contain naloxone (the opioid reversal drug), and thus, is susceptible to abuse through injection. Therefore, this is a treatment decision that should be carefully considered particularly since this medication is primarily prescribed to treat patients suffering from opioid use disorder. The Respondents argue that any refusal to fill would deny much needed access to medication-assisted treatment for these patients. The Board fully supports the use of medication-assisted treatment, including buprenorphine, for treatment of opioid use disorder. However, the Board finds that providing monoprodut buprenorphine without even a minimum effort to verify that it is best treatment option for vulnerable patients, some who were travelling 400 miles roundtrip and paying hundreds cash (even though they may have prescription coverage), is not helping these patients nor providing quality pharmaceutical care. Rather, it may be harming them by contributing to their opioid use disorder and addictive behaviors.

It is important to note that the Respondents' dispensing records also indicate myriad other red flag issues in addition to the outlier practice involving monoprodut buprenorphine prescriptions. The inspections revealed the Respondents' continued dispensing of high dose/high quantity opioids, or dangerous drug combinations/cocktails, without documented consultation with the prescriber and querying PDMP/CRISP regarding clinical necessity and appropriateness, evidencing a clear breach of a pharmacist's corresponding responsibility.¹² Indeed, the Respondents' extensive pattern of dispensing dangerous and addictive Schedule II opioids with multiple red flags, and without any documented attempt to resolve them, undermines the Respondents' purported benevolent rationale.

The Respondents admitted documents containing literature regarding treatment of opioid use disorder. While some of these documents discussed the various barriers and opined on the appropriate weight that should be afforded certain red flags, the documents acknowledge the national standard preference for combination buprenorphine as a first-line of treatment for opioid use disorder. (Resp.'s Ex. 16, Bates 446) In addition, the documents recommend querying the PDMP "to make informed buprenorphine decisions." (Resp.'s Ex. 16, Bates 434) Furthermore, the Respondents submitted a document entitled "Dispensing of Highly Abused Controlled Substances", dated February 1, 2021, in which it acknowledges the very red flags that were ignored in this case (e.g., distances, cash payments, drug cocktails, young age of patient, high dosage/high quantity). (Resp.'s Ex. 8, Bates 75-77). Lastly, the Respondents' own policies and procedures include: proper verifications (PDMP);

¹² Although OCSA includes "prescribers of note" in the red flag analysis, the Board relies on the myriad other red flags contained in the CDS prescriptions filled at the pharmacy. Mr. Klinger testified that the Respondent was not educated on the prescribers of note, although he maintains, and the Board agrees, that a pharmacist should recognize concerning prescribing patterns of a prescriber. It's also notable that several of the prevalent prescribers who issued the prescriptions the Respondents filled without any verification were also subsequently disciplined by the Board of Physicians for inappropriate prescribing.

follow strict CDC guidelines on MME threshold; (c) encourage the resolution of red flags. (Resp.'s Ex. 12, Bates 236). Unfortunately, the record does not reflect the implementation of these policies and procedures.

The record is replete with evidence demonstrating that the Respondents failed to engage in and document substantive attempts to verify the appropriateness of thousands of CDS prescriptions that contained multiple red flags over a five-year period despite numerous attempts by OCSA and the Board's inspectors to educate him, and thus, failed to exercise the corresponding responsibility required of all pharmacists.

CONCLUSIONS OF LAW

Based on the findings of facts and discussion, as set forth above, the Board concludes that the Respondent-Pharmacy is subject to discipline in accordance with Md. Code Ann., Health Occ. §§ 12-403(c)(1) and (9), and COMAR 10.34.20.02A; 10.34.20.03A; 10.34.20.04. The Board also concludes that the Respondent-Pharmacist is subject to discipline in accordance with Md. Code Ann., Health Occ. §§12-313(b)(21) and (25) and Health Gen. § 21-2A-04.2(e) and COMAR 10.34.10.01A and B(1); 10.34.20.02A; 10.34.20.03A; 10.34.20.04; 10.19.03.07C-D; and 10.19.03.08A(1).

SANCTION

The Board is responsible for ensuring the safe and competent delivery of pharmacy services to Maryland citizens. In this case, the Respondents were repeatedly counseled by OCSA and Board inspectors in an effort to provide education that would bring the Respondents into compliance with the corresponding responsibility requirements to review and resolve pervasive red flag issues in prescriptions presented at the pharmacy. The overriding purpose of identifying and resolving red

flag issues prior to dispensing a CDS prescription is to ensure that the patient receives medication that will provide effective treatment, and not harm the patient. However, instead of receiving the education and taking advantage of the numerous opportunities to review his dispensing practices for the betterment of the health and safety of his patients, the Respondent-Pharmacist continued on the same course.

Given the seriousness of the Respondents' actions, the Respondent's lack of accountability and failure to substantively respond to repeated attempts at education, the ALJ's recommended sanctions are generally appropriate and commensurate with the Board's extensive precedent. *See In the Matter of Extracare Pharmacy (Case 20-263); In the Matter of Walker Pharmacy (Case 20-265); In the Matter of Accokeek Pharmacy (Case 20-172/20-207); In the Matter of Drug Hut (Case 20-058); In the Matter of Beckman's Greene Street Pharmacy (Case 24-002)*. However, as stated in the Proposed Order, the Act provides that the Board may suspend, revoke, and/or fine a pharmacy for violations of the Act; the Board may not unilaterally impose probation on a pharmacy permit. Therefore, although the ALJ's recommended sanction was that the Respondent-Pharmacy be reprimanded, fined \$5,000 and placed on probation, with terms and conditions, the Board is statutorily limited to the imposition of a suspension, revocation and/or a fine in this matter. Thus, the Board will impose a period of stayed suspension in lieu of the recommended probationary period. The Board further modified the sanction from the proposed three (3) years of probation to two (2) years of probation for the Respondent-Pharmacist and two (2) years of stayed suspension for the Respondent-Pharmacy.

ORDER

It is, by an affirmative vote of a quorum of the Board, hereby:

Respondent-Pharmacy:

ORDERED that the Respondent-Pharmacy's permit be SUSPENDED for a period of TWO (2) YEARS, ALL STAYED; and be it further,

ORDERED that within 60 days of the date of this Order, Respondent-Pharmacy shall submit to the Board the name and curriculum vitae of a pharmacist for approval to serve as a consultant to the Respondent-Pharmacy to address the issues set forth herein who shall have the following minimum qualifications:

- a. Licensed to practice in Maryland in good standing;
- b. No disciplinary actions regarding standard of care;
- c. Minimum of five (5) years of community pharmacy experience;
- d. Minimum of one (1) continuing education credit in opioid use disorder, and one (1) continuing education credit in medication assisted treatment;
- e. Demonstrated knowledge and experience in the corresponding responsibility of pharmacists;
- f. No personal or existing professional relationship with the Respondents; and be it further; and be it further,

ORDERED that the Respondent-Pharmacy shall ensure that the pharmacist consultant submits quarterly reports to the Board for at least two (2) years utilizing a Board-approved form; and be it further,

ORDERED that the Respondent-Pharmacy pay a fine in the amount of FIVE THOUSAND DOLLARS (\$5,000.00) within ONE YEAR, and payable to the Maryland State Board of Pharmacy and sent to:

Santander Bank
Attn: State of Maryland – Board of Pharmacy
Lockbox 2051
101 Woodcrest Road, Suite 201

Cherryhill, New Jersey 08003
(Reference Case No. 23-138)

and be it further,

ORDERED that the Board, or its agents, may perform random inspections of Respondent-Pharmacy to ensure compliance with all laws governing the dispensing of controlled dangerous substances; and be it further,

Respondent-Pharmacist:

ORDERED that the Respondent-Pharmacist's license is REPRIMANDED; and be it further,

ORDERED that the Respondent-Pharmacist's license be placed on PROBATION for a period of TWO (2) YEARS, during which time the Respondent-Pharmacist shall successfully complete six (6) continuing education credits focusing on a pharmacist's corresponding responsibility; and be it further,

ORDERED that the Respondent-Pharmacist shall pay a fine in the amount of FIVE THOUSAND DOLLARS (\$5,000.00) within ONE YEAR, and payable to the Maryland State Board of Pharmacy and sent to:

Santander Bank
Attn: State of Maryland – Board of Pharmacy
Lockbox 2051
101 Woodcrest Road, Suite 201
Cherryhill, New Jersey 08003
(Reference Case No. 23-138)

and be it further,

ORDERED that in the event Respondents fail to fully comply with any of the conditions of this Order, the Board may lift the stay of the suspension of Respondent-Pharmacy and/or pursue

NOTICE OF RIGHT TO PETITION FOR JUDICIAL REVIEW

Pursuant to Md. Code Ann., Health Occ. §§ 12-316 and 12-412, the Respondents have the right to seek judicial review of this Order. Any petition for judicial review shall be filed within thirty (30) days from the date of mailing of this Order. The cover letter accompanying this Order indicates the date the decision is mailed. Any petition for judicial review shall be made as provided for in the Administrative Procedure Act, Md. Code Ann., State Gov't § 10-222 and Title 7, Chapter 200 of the Maryland Rules of Procedure.

If the Respondents file a petition for judicial review, the Board is a party and should be served with the court's process at the following address:

**Maryland Board of Pharmacy
Deena Speights-Napata, M.A., Executive Director
4201 Patterson Avenue, 5th Floor
Baltimore, Maryland 21215**

Notice of any petition should also be sent to the Board's counsel at the following address:

**Linda M. Bethman
Assistant Attorney General
Maryland Department of Health
300 West Preston Street, Suite 302
Baltimore, Maryland 21201**