IN THE MATTER OF	*	**BEFORE THE**
DRUG HUT	*	**MARYLAND STATE**
	*	**BOARD OF PHARMACY**
PERMIT NO. P07628	*	
Respondent	*	**Case No. 20-058**

* * * * * * * * * * *

FINAL DECISION AND ORDER

Background

On March 18, 2020, the Maryland Board of Pharmacy (the "Board") issued charges against the pharmacy permit held by Drug Hut, Permit No. P07628 (the "Respondent-Pharmacy"), based on inspections conducted by two units of the Maryland Department of Health – the Board and the Office of Controlled Substances Administration ("OCSA"). The inspections indicated, among other things, that Drug Hut, through its sole staff pharmacist and owner, Pharmacist A, dispensed controlled dangerous substances ("CDS") pursuant to prescriptions that contained numerous red flags without appropriate verification by Pharmacist A that the prescriptions were written for a legitimate medical purpose.

A contested case hearing was held under the Administrative Procedure Act, Md. Code Ann., State Gov't §10-201 *et seq.,* and COMAR 10.34.01, before a quorum of the Board on October 29, 2020, and January 14, 2021, for the purpose of adjudicating the charges. After the conclusion of the hearing, the same quorum of the Board convened to deliberate and voted unanimously to sanction the permit held by Drug Hut for the reasons set forth in this Final Decision and Order.

SUMMARY OF THE EVIDENCE

A. Documents.

The following documents were admitted into evidence:

State's Exhibit No. 1 - Permit/License Information for Drug Hug and Pharmacist A (printed Oct. 2, 2020)

State's Exhibit No. 2 - Maryland Board of Pharmacy Inspection Memoranda (Aug. 19, 2019) re: findings from annual inspection of Drug Hut, with attachments

- A. Inspection Report (July 2, 2019)
- B. Photographs from July 2, 2019
- C. Inspection Report (April 4, 2018)

State's Exhibit No. 3 - Subpoena Duces Tecum to Respondent (Oct. 24, 2019)

State's Exhibit No. 4 - Drug Hut's Response to subpoena (received Nov. 7, 2019)

- A. List of suppliers
- B. CII Dispensing Report from Oct. 2017 – Oct. 2019
- C. CII prescription copies and records subject to audit
- D. CIII-V Dispensing Report from Oct. 2017 – Oct. 2019
- E. CIII-V prescription copies and records subject to audit

State's Exhibit No. 5 - OCSA Investigation Report (Jan. 15, 2020) re: OCSA red flag inspections of Drug Hut, with attachments

- A. Inspection Memorandum (Oct. 3, 2019)
- B. OCSA Red Flag Inspection Report (Oct. 3, 2019)
- C. Utilization Report, Buprenorphine 8mg, Oct. 1, 2017 – Oct. 3, 2019
- D. Drugs by Prescriber Report, Robert Ball, M.D., Oct. 1, 2017 – Oct. 3, 2019
- E. Utilization Report, Oxycodone 30mg, Oct. 1, 2017 – Oct. 3, 2019

State's Exhibit No. 6 - Maryland Board of Pharmacy Investigation Report (Jan. 24, 2020)

State's Exhibit No. 7 - Charges (Mar. 18, 2020)

Respondent's Ex. No. 1	-	List of suppliers and distributors
Respondent's Ex. No. 2	-	Prescription and medical records for audited patients (Bates 62-67, 118-124, 161-189, 210-237 not admitted)
Respondent's Ex. No. 3	-	Photographs – Open area of pharmacy
Respondent's Ex. No. 4	-	Photographs – Pharmacy area (not admitted)
Respondent's Ex. No. 5	-	Photographs – Storage area

B. Witnesses.

State: Heather McLaughlin, M.A. – Investigator, Board of Pharmacy
Kerri Weigley – Inspector, Board of Pharmacy
Lisa Guy, R.Ph. – Division Chief of Enforcement, Office of Controlled Substances Administration

Respondent: Linh Toung Nguyen, R.Ph. – permit holder for Drug Hut

FINDINGS OF FACT

Based upon the testimony and documentary evidence presented at the evidentiary hearing, the Board finds that the following facts are true:

1. Drug Hut was issued a permit to operate a pharmacy in Maryland on October 13, 2017, under Permit Number P07628 and became operational in January 2018. Drug Hut's permit is currently active. [State's Ex. 1, Bates 001 and State's Ex. 5, Bates 244]
2. At all times relevant herein, Drug Hut was owned and operated by Pharmacist A, the sole dispensing pharmacist. Pharmacist A has been licensed to practice pharmacy in Maryland since July 27, 1990. [State's Ex. 1, Bates 005]

3. Pharmacist A previously owned another pharmacy in Rockville, which Pharmacist A sold in December 2017 prior to opening Drug Hut in January 2018. [State's Ex. 5, Bates 244; T. 82-84]
4. Drug Hut is a community pharmacy located in Glenn Dale, Maryland. [State's Ex. 1, Bates 001]
5. The Board received and reviewed the results of inspections of Drug Hut conducted by the Board's inspectors as well as OCSA's inspectors. [State's Ex. 2A and State's Ex. 5]
6. OCSA inspectors conduct two different kinds of inspections – a regular inspection, and a "red flag" inspection. All of the OCSA inspections received and reviewed by the Board regarding Drug Hut were "red flag" inspections. [T. 78]
7. A "red flag" inspection is a type of OCSA inspection during which it audits prescriptions for controlled dangerous substances for "red flags." Red flags are indications on the prescriptions that warn the pharmacist that the prescription may not be issued for a legitimate medical purpose. [T. 79-81]
8. If a prescription contains red flags, a pharmacist must verify the authenticity and medical legitimacy of a prescription with the prescriber. A pharmacist has a corresponding responsibility (with the prescriber) to ensure that all CDS prescriptions are for a legitimate medical purpose, issued by a prescriber in their normal scope of practice. [T.82, 95]
9. If a pharmacist cannot resolve red flags contained in a prescription to ensure that the prescription is issued for a legitimate medical purpose, the pharmacist may not dispense the prescription. [T. 82, 106-7]

10. OCSA's red flag inspection reviews prescriptions for 14 different red flags such as those listed below: [State's Ex. 5, Bates 260]

- Cocktail prescriptions[1]
- Cash prescriptions
- High strength and/or high quantity
- Out-of-state prescriber
- Out-of-state patient
- In-state prescriber located long distance
- In-state patient located long distance
- Pharmacy-prescriber-patient location triangle
- Prescriptions filled too soon
- Patients under 40 years old
- More than one family member receiving same CDS
- More than one person at same address receiving same CDS

11. OCSA repeatedly found multiple red flags on the majority of prescriptions filled at Drug Hut. [State's Ex. 5, Bates 245-47]

April 4, 2018 Board Inspection

12. The Board conducted an inspection approximately three (3) months after Drug Hut became operational. [State's Ex. 2, Bates 28]
13. The inspector noted tools, boxes, and other clutter in the pharmacy area and suggested general housekeeping. [State's Ex. 2, Bates 30]
14. The inspector conducted a CDS audit and noted that while Drug Hut did not fill a high volume of CDS, a significant amount of filled CDS prescriptions contained red flags such as out-of-state patients travelling long distances for a prescription, patients paying cash even if they had insurance, and multiple patients at the same out-of-state address filling CDS prescriptions. [State's Ex. 2, Bates 34]

[1] Cocktail prescriptions are combinations of: two or more short-acting opioids; two or more long-acting opioids; opioids with a stimulant such as amphetamines; opioids with a benzodiazepine; or opioids with another CDS such as carisoprodol and/or adjunct non-CDS such as clonidine, cyclobenzaprine, promethazine, or gabapentin. [State's Ex. 5, Bates 247]

15. The inspector advised Pharmacist A regarding the need to check for red flags when filling prescriptions. [State's Ex. 2, Bates 34-35]

April 27, 2018 OCSA Red Flag Inspection

16. OCSA performed a red flag inspection of Drug Hut on April 27, 2018. [State's Ex. 5, Bates 245]

17. Twenty (20) Schedule II[2] CDS prescriptions were reviewed, all of which contained multiple red flags such as cash pay, high strength/high quantity, dangerous cocktail combination, long-distance or out-of-state patients. In addition, all of the Oxycodone prescriptions dispensed at Drug Hut were for daily morphine milligram equivalents ("MME") of 180-225.[3] [State's Ex. 5, Bates 245]

18. All of the Schedule III prescriptions reviewed also contained red flags, such as patients from West Virginia paying cash for Buprenorphine 8mg. [State's Ex. 5, Bates 245; T. 92]

19. The OCSA inspector testified that Drug Hut did not dispense Suboxone, which is a partial opioid agonist typically prescribed as medication-assisted therapy ("MAT") for patients with a substance use disorder. Suboxone contains naloxone, which prevents patients from abusing the drug. Buprenorphine is the active ingredient in Suboxone, but Buprenorphine on its own, as dispensed by Drug Hut, does not contain naloxone to prevent abuse. Buprenorphine is not commonly prescribed and is typically only prescribed as MAT if the patient has documented allergies that warrant its use in lieu of Suboxone. [T. 116-117, 135]

---

[2] Schedule II controlled dangerous substances have a high potential for abuse which may lead to severe psychological or physical dependence. *See* DEA Pharmacist's Manual, Sec. II.

[3] The Centers for Disease Control (CDC) recommends daily MME not to exceed 90 to reduce the risk of overdose. [State's Ex. 5, Bates 245]

20. Drug Hut only stocks Oxycodone 30mg, the highest strength available, and does not stock the lesser strengths (5mg, 10mg, 15mg, 20mg). Oxycodone 30mg is rarely prescribed, and is typically only used for palliative care or cancer patients. [T. 90, 289]

21. The OCSA inspector educated Pharmacist A again about the existence of red flags on prescriptions filled at his pharmacy, and reiterated the importance of ensuring that prescriptions are issued for a legitimate medical purpose before dispensing. [State's Ex. 5, Bates 245]

22. Pharmacist A indicated that he fingerprints his patients (directly onto the paper prescription) although the fingerprints are not sent for analysis. [State's Ex. 5, Bates 245] There is no evidence suggesting that Pharmacist A has any expertise or training in fingerprint identification. [T. 114, 172-73]

23. Pharmacist A indicated that he has some patients submit to a saliva-based drug test. [State's Ex. 5, Bates 245]

24. Drug Hut's saliva drug kits do not measure potency, thus they do not indicate whether the patient is taking the medication as prescribed or diverting the medication – although they may indicate if other substances are present in the patient's system at the time of testing. However, Pharmacist A testified that the cutoff for metabolites of the drug screen is probably 1-2 days prior which would allow for a patient to self-abstain ahead of a drug test. [T. 141-42, 204]

25. The OCSA inspector noted that Drug Hut was cluttered and had a "mattress with a pillow and a blanket in the middle of a large open area of the pharmacy in view of patients." [State's Ex. 5, Bates 245]

February 1, 2019 OCSA Red Flag Inspection

26. OCSA returned to perform another red flag inspection on February 1, 2019, to determine if the red flags had been addressed by the Respondent-Pharmacy. [T. 92]
27. All Schedule II prescriptions filled after the April 27, 2018 inspection (35 in total) were reviewed. All 35 prescriptions contained multiple red flags: 33 of 35 were for Oxycodone 30mg; 29 of 35 were paid by cash or discount card; and 35 of 35 were for high strength/high quantity opioids. [State's Ex. 5, Bates 245]
28. The OCSA inspector also reviewed 37 prescriptions for Buprenorphine 8mg, a Schedule III drug. All of the Buprenorphine prescriptions were self-pay (cash or discount card), and 36 of the 37 were patients who had travelled from West Virginia. [State's Ex. 5, Bates 245]
29. Drug Hut continued to be cluttered, with items including tools and wires, and an additional mattress was found in the back area. [State's Ex. 5, Bates 245-46, T. 94]

July 2, 2019 Board Inspection

30. The Board inspector performed a Schedule II audit and noted multiple red flags: patients travelling long distances to the prescriber and Drug Hut; a majority of prescriptions written for Oxycodone 30mg; and prescribers writing for only one drug. [State's Ex. 2, Bates 18]
31. The Board inspector performed an audit of the Schedule III-V prescriptions and noted multiple red flags: patients from out-of-state; prescriptions paid by cash or discount card; and a majority of prescriptions written for Buprenorphine 8mg. [State's Ex. 2, Bates 18]

32. The inspector noted that Drug Hut was not neat and organized; it had dusty shelves, clutter, papers on the floor, and mattresses and a bunk bed in the back room storage area. [State's Ex. 2, Bates 18 & 27]

October 3, 2019 OCSA Inspection

33. OCSA conducted another red flag inspection to determine if "any reduction in red flags or increase in verification of legitimate medical needs for the prescriptions with multiple red flags" had occurred since their last inspection. [State's Ex. 5, Bates 246]

34. The OCSA inspector reviewed 26 Schedule II prescriptions. All 26 prescriptions were written for Oxycodone 30mg in quantities over 100 tablets; 21 were paid by cash or discount card. [State's Ex. 5, Bates 246] These prescriptions also included patients from the same family or same address presenting prescriptions from the same prescriber for the same red flag drug (Oxycodone 30mg) on the same date. [State's Ex. 5, Bates 301-302, 335-36; T. 104-111]

35. The inspector reviewed 32 Schedule III-V prescriptions. All 32 prescriptions were for Buprenorphine for patients from West Virginia, and all were paid for with cash. [State's Ex. 5, Bates 246]

36. The inspector noted that numerous prescriptions for Buprenorphine also had handwritten prescriptions by Pharmacist A for Ibuprofen 400mg. Pharmacist A testified that he dispensed Ibuprofen 400mg with the Buprenorphine, without consulting the physician or obtaining a prescription, as a measure to prevent the patient from seeking opioids. [State's Ex. 5, Bates 250, T. 114-15, 161]

37. The inspector noted that Drug Hut continued to be cluttered, with a mattress or blanket on the floor. The back room contained piles of boxes, tools, and a bunk bed. [State's 5, Bates 249]

Prescription Review – Below are examples of Schedule II prescriptions dispensed by Drug Hut containing various red flags that Drug Hut failed to satisfactorily address in determining whether the prescriptions were issued for a legitimate medical purpose:

38. Patient 1 (State Ex. 4, Bates 48-59; T. 193-97)

- Oxycodone 30mg, 114 quantity – high dose/high quantity of immediate-release ("IR") opioid; 270 MME/day
- Written for "low back pain" – Oxycodone 30mg is not typically prescribed for treatment of chronic pain
- Age 29, male – young patient (under 40), unusual to experience chronic pain
- Prescriber specialty is OB/GYN – prescriber not a pain management specialist[4]
- Medical records obtained 9 months after dispensing indicate only "mild to moderate" lumbar issues

39. Patient 2 (State Ex. 4, Bates 60-72)

- Oxycodone 30mg, 120 quantity – dated 11/27/18; high dose/high quantity of IR opioid
- Methadone 10mg, 60 quantity – dated 11/27/18; duplicate IR opioid, resulting in cocktail of 2 IR opioids
- Patient resides 55 miles from Respondent-Pharmacy
- Written for "chronic back pain" – Oxycodone 30mg is not typically prescribed for treatment of chronic pain
- Prescriber is a family nurse practitioner at a "medical spa," not a pain management specialist

40. Patient 3 (State Ex. 4, Bates 73-91)

- Oxycodone 30mg, 120 quantity – high dose/high quantity of IR opioid
- Patient affidavit indicates prescription for "broke pelvis"
- Prescriber diagnosis letter indicates "chronic pain" - received after Oxycodone was dispensed; Oxycodone 30mg is not typically prescribed for treatment of chronic pain

[4] Drug Hut filled many prescriptions issued by this prescriber (including for Patients 1and 4), who ultimately had restrictions placed on his registration that prohibited him from prescribing any opioids. [T. 138-39]

- Prescriber specialty is immunology and dermatology, not pain management specialist[5]

41. Patient 4 (State Ex. 4, Bates 92-97)

    - Oxycodone 30mg, 120 quantity – high dose/high quantity of IR opioid
    - Patient affidavit indicates prescription is to treat "toe gangrene"
    - Patient resides 105 miles from Respondent-Pharmacy
    - Prescriber diagnosis letter obtained 2 months after dispensing indicates "chronic pain" – Oxycodone 30mg is not typically prescribed to treat chronic pain

42. Patient 5 (State Ex. 5, Bates 111-120)

    - Oxycodone 30mg, 120 quantity – high dose/high quantity of IR opioid, dated 12/20/18
    - Patient affidavit indicates "low back pain" – Oxycodone 30mg is not typically prescribed to treat chronic pain
    - Medical records indicate "minor abnormality" – highest dose of Oxycodone is not appropriate
    - Prescriber is a family nurse practitioner at a "medical spa," not a pain management specialist

Prescription Review - Buprenorphine Prescription Unresolved Red Flags:

43. Of the 743 Buprenorphine prescriptions dispensed by Drug Hut between October 2017 and October 2019:

    a. There were 740 for out-of-state patients, primarily located in West Virginia, who lived approximately 4-6 hours from Drug Hut. [State's Ex. 5, Bates 246, T. 118]

    b. All paper Buprenorphine prescriptions reviewed were accompanied by an affidavit that included a notation from the patient or Pharmacist A that the patient had allergies or other adverse reaction to Suboxone to purportedly justify the prescription for Buprenorphine. [State's Ex. 4, Bates 149-243]

    c. The patients' noted adverse reactions to Suboxone were generally based on patient narratives rather than consultations with the prescribers. [T. 210]

[5] Drug Hut filled many prescriptions issued by this prescriber (including Patient 3), who ultimately was prohibited from prescribing CDS for two years by the Board of Physicians. [T. 215-16]

d. None of the Buprenorphine prescriptions reviewed contained a notation that Pharmacist A consulted with the prescriber.[6], [7]

e. Several patients were dispensed Buprenorphine and Alprazolam at the same time, which is a red flag due to the dangerous cocktail of an opioid and a depressant. [State's Ex. 4, Bates 121-148]

f. Several patients with the same last name and residing at the same address presented the same prescriptions at the same time written by the same prescriber, which constitutes another red flag. [State's Ex. 4, Bates 121-148; State's Ex. 5, Bates 263-322]

g. Drug Hut's dispensing reports indicate that several patients were dispensed two Buprenorphine prescriptions on the same day. [State's Ex. 4, Bates 127, 139]

OPINION

This case illustrates the importance of a pharmacist's duty to utilize his clinical expertise in reviewing and dispensing prescriptions, especially prescriptions for controlled dangerous substances. As the State and nation grapple with the ongoing opioid epidemic, pharmacists play an integral role (and are arguably the ultimate healthcare professional, the final line of defense) in ensuring that prescriptions for controlled dangerous substances are dispensed in a manner that not only is clinically appropriate for the patient, but, more importantly, does not cause the patient harm. Thus, it is crucial that a pharmacist and pharmacy permit holder exercise due diligence when reviewing CDS prescriptions that contain red flags. While Pharmacist A, as the sole

[6] Copies of prescriptions provided by Drug Hut to the Board contained different notations than the copies of the same prescriptions provided by Drug Hut at the hearing. [T. 246-248]

[7] Indeed, one of the Buprenorphine prescribers testified that her communications with Drug Hut were limited to whether Drug Hut had Buprenorphine 8mg in stock and did not include discussions regarding the medical necessity for Buprenorphine 8mg. [T. 287, 296]

pharmacist and owner of Drug Hut, engaged in acts ostensibly meant to ensure the legitimacy of CDS prescriptions, these acts were meaningless, superficial procedures intended to justify the dispensing of CDS prescriptions that were blatantly questionable due to their multiple red flags. Indeed, many of Drug Hut's own records substantiate the red flags such that the prescriptions should not have been dispensed.

One example of Drug Hut's dubious verification procedure is the requirement that certain patients filling CDS prescriptions be fingerprinted. The patient's fingerprint was typically placed on the paper prescription. There was no testimony or other evidence as to the relevance or purpose of these fingerprints, except to state that it was part of Drug Hut's policies to ensure CDS prescriptions were legitimate. Another example is that Drug Hut would have certain patients submit to a saliva drug test. The test results did not measure potency and thus, were unable to indicate if the patient was taking the medication as prescribed or diverting the medication. Lastly, Pharmacist A would have the patient complete, or Pharmacist A would complete, "affidavits" which would be signed by the patients attesting to various statements, many of which were incomplete or inapplicable. Indeed, many of the affidavits contained statements that conflicted with medical records obtained by Respondent-Pharmacy after dispensing the CDS prescriptions. Either Drug Hut is purposefully engaged in these efforts as subterfuge, or it believes these actions legitimize the dispensing of suspect prescriptions; both scenarios are equally concerning.[8]

Drug Hut also frequently obtained medical records purportedly to substantiate patients' medical conditions and, more importantly, to substantiate the medical necessity for dispensing

[8] While Pharmacist A frequently noted that he checked "CRISP" (the Prescription Drug Monitoring Database) on certain prescriptions, the Board places little weight on this measure as it is abundantly clear from his testimony as a whole that he did not scrutinize any medical information provided by the prescribers if such information indicated that the prescription at issue should not be dispensed.

Oxycodone 30mg, typically only prescribed for cancer or palliative care patients. These records often conflicted with the information patients provided regarding their medical condition, which often indicated a medical condition that would not be appropriately treated with Oxycodone 30mg. Nonetheless, Pharmacist A testified that these medical records were not reliable, and that information from the patient was more appropriate to substantiate legitimate medical need. Furthermore, Drug Hut's records demonstrate that it sometimes did not receive the medical records prior to dispensing the opioids; indeed, sometimes they were received months afterwards. Pharmacist A's explanation was "you take whatever they let you have." [T. 199] The Board does not believe this is an acceptable standard when dispensing opioids, or any prescription drugs. Again, if Pharmacist A was not able to verify the legitimate medical necessity for dispensing high quantities of a powerful opioid, he should not have dispensed the drug.

Drug Hut also argues that Pharmacist A confirmed the issuance of the Schedule II prescriptions with the prescribers. A pharmacist's review of CDS prescriptions, however, is not limited to confirming their authenticity by checking that a physician did in fact write them. While confirming the issuance of a suspect prescription with the prescriber is commendable, a pharmacist must also address any clinical issues or concerns with the prescriber.[9] Pharmacist A failed to address any standard clinical concerns with prescribers and ignored information in medical records that contradicted information from patients. In fact, Pharmacist A shockingly stated that any contraindicating information in medical records or his own pharmacy records was not reliable. Pharmacist A appeared to rest his corresponding responsibility entirely on

[9] As noted above, at least two of the prescribers who wrote the prescriptions dispensed at Drug Hut were later censured for their prescription-writing practices.

assertions made by the patients, patients who traveled up to 100 miles to obtain these dangerous narcotics.

It is clear from the evidence that Drug Hut engaged in a pattern of dispensing CDS prescriptions that contained multiple red flags such as: (1) highest dosage and high quantity of Oxycodone; (2) Oxycodone and Methadone (both immediate-release opioids) prescriptions at one time; (3) patients from West Virginia or other long distance from Drug Hut; (4) patients from the same address in West Virginia presenting prescriptions for Buprenorphine at the same time; (5) all patients allegedly experiencing allergic or adverse reactions to Suboxone; (6) patients with prescription coverage paying cash; (7) prescriptions for immediate-release opioids to treat chronic pain; and (8) prescribers with specialties in immunology, family practice, or gynecology treating chronic pain. This pattern apparently started at Pharmacist A's prior pharmacy and carried over to Drug Hut despite numerous inspections advising Drug Hut about the red flag issues. Pharmacist A failed to engage in any meaningful review or verification of these CDS prescriptions and ignored information contraindicating medical necessity, which resulted in the provision of highly addictive and dangerous drugs to patients.

Drug Hut argues that since there is no evidence that any of the prescriptions at issue were false or fraudulent, or that any of the prescriptions dispensed resulted in actual harm to the patients, there is no violation of the law. The Board vehemently disagrees. A pharmacist's corresponding responsibility requires that a pharmacist engage in measures to verify that a CDS prescription has been written for a legitimate medical purpose. Therefore, when presented with a CDS prescription that contains multiple red flags, it is incumbent upon the pharmacist to verify that such prescription is appropriate for the stated medical purpose. If a pharmacist cannot verify the prescription in a manner that reconciles the red flags, then the pharmacist may not dispense

the prescription. The Board finds that, despite the saliva drugs tests, patient fingerprints, and template affidavits, Drug Hut, through Pharmacist A, did not exercise its corresponding responsibility in verifying that the CDS prescriptions containing multiple red flags were issued for a legitimate medical purpose.

Furthermore, there is no requirement that a patient first be harmed or overdose from a dispensed prescription in order for the Board to find that a pharmacist did not meet his corresponding responsibility to ensure that a prescription was issued for a legitimate medical purpose. Such an interpretation would result in perverse enforcement actions requiring the Board to confront patients regarding substance abuse issues or to simply monitor and wait for a patient to overdose. Rather, the Board utilizes its statutory authority and expertise to perform inspections of pharmacies to ensure that pharmacists are engaged in properly scrutinizing CDS prescriptions for red flags and reconciling clinical concerns before dispensing for the safety of the patient. In this case, Pharmacist A failed to reconcile numerous and repeated red flags, accepting cash in exchange for controlled dangerous substances without any legitimate assurance that such drugs would help and not harm his patients.

Both State and federal regulations provide that a pharmacist bears corresponding liability for ensuring that prescriptions for controlled substances are valid. Specifically, the regulations state:

> 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. COMAR 10.19.03.07C; 21 CFR § 13.06.04.

The ever-increasing health crisis involving prescription drug abuse renders this legal obligation integral to community pharmacy practice. If a pharmacist willingly turns a blind eye to clinically inappropriate and potentially dangerous opioid prescriptions for his financial gain, there is little that differentiates that pharmacist from a common drug dealer. The Board finds that Drug Hut, through Pharmacist A, failed to exercise reasonable professional judgment with respect to appropriate dispensing of controlled dangerous substances. Pharmacist A was educated myriad times regarding the existence of multiple red flags during inspections of his pharmacy. Rather than engage in meaningful clinical review prior to dispensing highly dangerous, addictive drugs with significant street value, Pharmacist A chose to rely on meaningless measures that supported his dispensing of suspect controlled dangerous drug prescriptions for cash. Even more concerning is that Pharmacist A apparently relied on these measures despite glaring red flags, and even after receiving medical records to the contrary. In other words, Pharmacist A failed to engage in substantive efforts to resolve multiple red flags that existed on virtually every prescription he dispensed. There is substantial evidence in the record that Drug Hut, through Pharmacist A, did not meet its corresponding responsibility to ensure that the CDS prescriptions dispensed were issued for a legitimate medical purpose.

An additional factor is that Drug Hug, through Pharmacist A, still has no appreciation for the serious issues that have resulted in this disciplinary action. Pharmacist A remained defensive and argumentative during his testimony and maintains that he met his corresponding responsibility in dispensing the CDS prescriptions. It is concerning to the Board that Pharmacist A does not appear to appreciate the risk of harm posed to these patients in dispensing controlled dangerous substances that are not clinically appropriate.

With respect to the disorganization, clutter and overall unprofessional maintenance of the Pharmacy, the Board finds that the Pharmacy was warned repeated times by both the Board and OCSA inspectors that the Pharmacy must be cleaned up. Pharmacies are healthcare establishments and must be maintained in a manner that is conducive to the provision of professional healthcare services. The Pharmacy had strewn boxes, tools, mattresses and a bunk bed throughout the pharmacy. While the Pharmacy submitted evidence that it finally cleaned up the premises, the Board nonetheless finds that the Pharmacy was not maintained in a clean and orderly manner at all times relevant to these charges. [Resp. Exs. 4, 5, 6]

The Board understands that it has imposed a fairly lenient sanction in this matter. Given the limited volume of drugs dispensed from Drug Hut, and the hope that Pharmacist A is able to learn from this experience to become a better practitioner, the Board has determined that Drug Hut should have an opportunity to engage in formal training regarding proper dispensing of controlled dangerous substances. Pharmacist A lacks essential competence required to fulfill his corresponding responsibility to ensure that controlled dangerous substance prescriptions are valid and clinically appropriate. However, based on the sustained pattern and serious nature of the misconduct committed by Drug Hut despite the repeated observations issued by both the Board and OCSA inspectors, the Board finds that a fine against the permit is warranted. The Board feels that this sanction is necessary to address the violations committed by Drug Hut as well as to provide a deterrent to other pharmacy permit holders who may be tempted to engage in similar unethical and illegal acts.

CONCLUSION

Based upon the foregoing summary of evidence, findings of fact, and opinion, the Board concludes that the Respondent-Pharmacy is subject to discipline in accordance with Md. Code Ann., Health Occ. §§ 12-403(c)(1), (9), and (11), and COMAR 10.34.10.01A and B and 10.19.03.07C.

ORDER

Based on the foregoing Findings of Fact, Opinion, and Conclusion, by a unanimous decision of a quorum of the Board it is hereby:

ORDERED that the permit held by Drug Hut is suspended for two (2) years, all of which is STAYED provided Drug Hut comply with the following conditions:

1. Within six (6) months of the date of this Order, Drug Hut shall require all pharmacy staff to successfully complete an ACPE-accredited course in substance use disorders and provide proof of completion to the Board;

2. a. Within 60 days of the date of this Order, Drug Hut shall engage the services of a Board-approved peer consultant focusing on opioid dispensing practices including prescription verification, legitimate medical need, valid patient-prescriber relationships, and clinical documentation.

b. Drug Hut shall submit the following documentation from the peer consultant to the Board for approval *prior to engaging any peer services*: curriculum vitae, outline of proposed consultation including goals/objectives, schedule and timeline, and curriculum content.

c. Drug Hut shall ensure that the peer consultant submit to the Board a final report regarding the Respondent-Pharmacy.

ORDERED that Drug Hut shall pay a FINE of $5,000, payable to the Maryland Board of Pharmacy within the stayed suspension period; and be it further,

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

ORDERED that in the event Drug Hut fails to fully comply with any of the conditions of this Order, the Board may lift the stay of the suspension provided that Drug Hut is first provided notice and an opportunity for a hearing prior to taking such action; and be it further,

ORDERED that Drug Hut is responsible for bearing all costs associated with complying with the terms of this Order; and be it further,

ORDERED that this is a final order of the State Board of Pharmacy and as such is a **PUBLIC DOCUMENT** pursuant to Md. Code Ann., General Provisions §4-301, *et seq.*

6-10-21
Date

Deena Speights-Napata, MA, Executive Director
for
Jennifer Hardesty, Pharm.D.
President, Board of Pharmacy

NOTICE OF RIGHT TO APPEAL

You have the right to appeal this Final Decision and Order. A petition for appeal shall be filed within thirty days of this Final Decision and Order and shall be made pursuant to Md. Code Ann., Health Occ. Art., § 12-412.