STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the Matter of

SEAWAY PHARMACY
License Nos. 53-01-008838 and 53-15-034932, File No. 53-17-148557

Respondent.

ORDER OF SUMMARY SUSPENSION AND FOR SEIZURE OF CONTROLLED SUBSTANCES

The Department filed an *Administrative Complaint* against Respondent as provided by the Public Health Code, MCL 333.1101 *et seq.*, the rules promulgated under the Code, and the Administrative Procedures Act, MCL 24.201 *et seq.*

After careful consideration and after consultation with the Chairperson of the Board of Pharmacy pursuant to MCL 333.7314(2), the Department finds that there is an imminent danger to the public health or safety that requires emergency action.

Therefore, IT IS ORDERED that Respondent's controlled substance license is SUMMARILY SUSPENDED, commencing the date this *Order* is served.

IT IS FURTHER ORDERED that, pursuant to Article 7 of the Code, MCL 333.7101 *et seq.,* all controlled substances owned or possessed by Respondent at the time the *Administrative Complaint* was filed before the Disciplinary Subcommittee shall be seized by the Department pending completion of proceedings.

Under Mich Admin Code, R 792.10702, Respondent may petition for the dissolution of this *Order* by filing a document clearly titled **Petition for Dissolution of Summary Suspension** with the Department of Licensing and Regulatory Affairs, Bureau of Professional Licensing, P.O. Box 30670, Lansing, MI 48909.

MICHIGAN DEPARTMENT OF
LICENSING AND REGULATORY AFFAIRS

Dated: 5-9, 2018

By: for
Cheryl Wykoff Pezon, Acting Director
Bureau of Professional Licensing

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Respondent.

ADMINISTRATIVE COMPLAINT

The Michigan Department of Licensing and Regulatory Affairs by Cheryl Wykoff Pezon, Acting Director, Bureau of Professional Licensing, complains against Respondent Seaway Pharmacy as follows:

1. The Michigan Board of Pharmacy is an administrative agency established by the Public Health Code, MCL 333.1101 *et seq.* The Board's Disciplinary Subcommittee is empowered to discipline licensees for Code violations.

2. The Board administers the controlled substance provisions in Article 7 of the Code, MCL 333.7101 - .7545, and is empowered to discipline licensees for Article 7 violations under MCL 333.7311.

3. MCL 333.7333(1) provides, in pertinent part:

> "[G]ood faith" means the prescribing or dispensing of a controlled substance by a practitioner . . . to or for an individual . . . . Application of good faith to a pharmacist means the dispensing of a controlled substance pursuant to a prescriber's order which, in the professional judgment of the pharmacist, is lawful. The pharmacist shall be guided by nationally accepted professional standards including, but not limited to, all of the following, in making the judgment:
>
> (a) Lack of consistency in the doctor-patient relationship.

(b) Frequency of prescriptions for the same drug by 1 prescriber for larger numbers of patients.

(c) Quantities beyond those normally prescribed for the same drug.

(d) Unusual dosages.

(e) Unusual geographic distances between patient, pharmacist, and prescriber.

4. Mich Admin Code, R 338.490(2) provides:

A pharmacist shall not fill a prescription order if, in the pharmacist's professional judgment, any of the following provisions apply:

(a) The prescription appears to be improperly written.

(b) The prescription is susceptible to more than 1 interpretation.

(c) The pharmacist has reason to believe that the prescription could cause harm to the patient.

(d) The pharmacist has reason to believe that the prescription will be used for other than legitimate medical purposes.

5. Respondent holds a pharmacy license no. 53-01-008838 and a controlled substance license no. 53-15-034932. After consultation with the Board Chairperson, the Department found that there is an imminent danger to the public health or safety that warrants suspension of Respondent's controlled substance license. Therefore, pursuant to MCL 333.7314(2), the Department summarily suspended Respondent's State of Michigan controlled substance license, effective on the date the accompanying Order of Summary Suspension was served.

6. Respondent is a licensed pharmacy located in Taylor, Michigan. Respondent's part-owner and pharmacist-in-charge (PIC) is Hani Mohamad Zaher, R.Ph.[1]

[1]The Department has also filed an Administrative Complaint against Zaher for the conduct alleged here. *Hani Mohamad Zaher, R.Ph.,* No. 53-17-148558.

7. For historical purposes, the following events occurred:

a. On June 13, 2001, the Department executed a Complaint and Notice of Intended Action against Respondent's PIC based on a dispensing error. In resolution, the Board's Disciplinary Subcommittee (DSC) executed a Consent Order and Stipulation that reprimanded Respondent's PIC on June 29, 2001.

b. On February 15, 2002, the Department executed an Administrative Complaint against Respondent's PIC based on information that he diverted large quantities of prescription medications from his workplace.

c. On November 20, 2003, in resolution of the Administrative Complaint, the Board's DSC suspended the pharmacist license of Respondent's PIC for six months and one day, requiring him to apply for reinstatement of his license.

d. On June 24, 2005, the Board's DSC executed a Final Order Granting Reinstatement. The order granted Respondent's PIC a limited license to practice as a pharmacist for a minimum period of one year, requiring him to practice under direct supervision for six months and abstain from owning or having a financial interest in a pharmacy. The Order also placed Respondent's PIC on probation for two years.

e. On November 20, 2006, the Board's Disciplinary Subcommittee executed an Order Granting Reclassification, which granted Respondent's PIC a full and unlimited license to practice as a pharmacist.

8. Alprazolam (e.g. Xanax) is a benzodiazepine schedule 4 controlled substance. Alprazolam is a commonly abused and diverted drug, particularly in its 1 mg and 2 mg dosages.

9. Buprenorphine and buprenorphine combination products, including Suboxone, are schedule 3 controlled substances used to treat opioid dependency and/or pain and are commonly diverted.

10. Carisoprodol is a muscle relaxant and a schedule 4 controlled substance. Carisoprodol has significant potential for abuse, dependence, overdose, and withdrawal, particularly when used in conjunction with opioids and benzodiazepines.

11. Codeine preparations (e.g., codeine/promethazine syrup) are schedule 5 controlled substances prescribed for treating cough and related upper respiratory symptoms. Codeine/promethazine syrup is rarely indicated for any other health condition, and is particularly ill-suited for long-term treatment of chronic pain. Codeine/promethazine syrup is a highly sought-after drug of abuse, and is known by the street names "lean," "purple drank," and "sizzurp."

12. Hydrocodone, and combination products including hydrocodone (e.g., Norco) are commonly abused and diverted opioid schedule 2 controlled substances.

13. Lisdexamfetamine (e.g., Vyvanse), a schedule 2 controlled substance, is a central nervous system stimulant commonly used to treat attention deficit hyperactivity disorder.

14. Oxycodone, and combination products including oxycodone (e.g., Percocet) are commonly abused and diverted opioid schedule 2 controlled substances.

15. Oxymorphone, a schedule 2 controlled substance, is an opioid used to treat pain, and is a commonly abused and diverted drug. Oxymorphone 40 mg is the most commonly abused and diverted strength of oxymorphone.

16. Pregabalin (e.g., Lyrica) is a schedule 5 controlled substance used to control seizures and pain.

17. When used in combination, opioids, muscle relaxants, and benzodiazepines can produce a feeling of euphoria. These combinations are highly desired for diversion and abuse and have the street name "Holy Trinity."

18. The Centers for Disease Control and Prevention (CDC) guidelines for opioid prescribing direct providers to avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.

19. The CDC's guidelines for opioid prescribing direct providers to use "extra precautions" when prescribing opioids with a daily morphine milligram equivalent (MME) of 50 or more. Those guidelines also direct providers to "avoid or carefully justify" increasing dosage to a daily MME of 90 or more.

20. The Department reviewed data from the Michigan Automated Prescription System (MAPS), the State of Michigan's prescription monitoring program, which gathers data regarding controlled substances dispensed in Michigan. The Department discovered that Respondent was among the highest-ranked dispensers for several commonly abused and diverted controlled substances among all Michigan dispensers in 2017, including:

Drug	***2017 Q1 Rank***	***2017 Q2 Rank***	***2017 Q3 Rank***	***2017 Q4 Rank***
Oxycodone 30 mg	2	2	3	5
Oxycodone (all strengths)	20	29	22	45
Alprazolam 1 mg	28	21	20	21
Alprazolam 2 mg	10	17	13	17

21. During the following periods, Respondent filled prescriptions for the following commonly abused and diverted controlled substances in the following quantities:

Drug	***2016***	***2017***
(a) Suboxone 8 mg- 2 mg	1,079 (7.31%)	930 (6.24%)
(b) Hydrocodone.apap 7.5/325 mg	1,275 (8.64%)	1,121 (7.53%)
(c) Alprazolam 2 mg	411 (2.79%)	366 (2.46%)
(d) Carisoprodol 350 mg	352 (2.39%)	274 (1.84%)
(e) Alprazolam 1 mg	1,165 (7.89%)	1,078 (7.24%)
(f) Hydrocodone apap 10/325 mg	2,049 (13.88%)	2,056 (13.81%)
(g) Oxycodone 30 mg	715 (4.85%)	1,238 (8.31%)
(h) Oxycodone apap 10/325 mg	608 (4.12%)	535 (3.59%)
(i) Total, (a) - (h)	***7,654 51.86%***	***7,598 51.02%***
(j) Total CS prescriptions	14,757	14,892

22. The Department compared Respondent's dispensing of alprazolam 2 mg and oxycodone 30 mg to the dispensing of two pharmacies within a mile from Respondent's location for the year 2017. Respondent dispensed both medications at higher rates than the other two pharmacies:

Respondent		
Medication	Number of scripts	Percent of Total CS
Oxycodone 30mg	1,238	8.31%
Alprazolam 2mg	366	2.458%
Total CS	**14,892**	-

Pharmacy A		
Medication	Number of scripts	Percent of Total CS
Oxycodone 30mg	2	0.0189%
Alprazolam 2mg	115	1.0899%
Total CS	**10,551**	-

Pharmacy B		
Medication	Number of scripts	Percent of Total CS
Oxycodone 30mg	12	0.1638%
Alprazolam 2mg	63	0.86%
Total CS	**7,325**	-

23. On January 25, 2018, the Department inspected Respondent's business premises. The Department's investigators noted violations of regulations governing the practice of pharmacy, including out of date reference materials, expired medication, no policy and procedures for delegated tasks presented upon inspection, a pharmacist's license not properly posted, and two unlicensed individuals working as pharmacy technicians.

24. During the inspection, the Department's investigators interviewed Respondent's PIC, who provided the following information:

a. Respondent's PIC works at Respondent three to four hours per day.

b. Respondent's PIC reviewed controlled substance prescriptions dispensed from Respondent daily, after he completed his shift. Respondent's PIC reviewed and confirmed that prescriptions were dispensed from Respondent prior to signing the controlled substance

logs, but did not necessarily review the controlled substance logs for unusual activities or patterns.

c. Dispensing pharmacists did not always document verification with a physician's office on the prescription blank.

d. Respondent's PIC was familiar with the "red flags" associated with diversion but was unfamiliar with the current CDC recommendations regarding MMEs.

e. Respondent's schedule 2 controlled substance policy requires its pharmacists to run MAPS reports on all schedule 2 controlled substances dispensed at Respondent.

f. Respondent's PIC periodically reviews patients' MAPS data and looks for unusual activities such as patients frequenting multiple prescribers or pharmacies and the combination or quantity of controlled substances prescribed. If something is unusual, Respondent's PIC will not fill the prescription without consulting the physician.

g. When informed that over 50% of the controlled substance prescriptions dispensed at Respondent were for the most commonly abused and diverted controlled substances, Respondent's PIC reiterated that he verified controlled substance prescriptions and ran MAPS reports on patients.

25. Further review of MAPS data indicated that Respondent dispensed 7,507 schedule 2 controlled substance prescriptions in 2017. Pharmacists at Respondent, almost exclusively Respondent's PIC, accessed the MAPS database to run MAPS reports on patients approximately 474 times in 2017, contrary to Respondent's schedule 2 controlled substance policy.

26. On February 1, 2018, additional documents were obtained from Respondent. As the Department's investigator was leaving Respondent, a witness from an adjacent business expressed concerns about customers congregating in Respondent's parking lot and throwing contaminated needles onto the surrounding property.

27. At the inspection, Respondent's PIC provided the Department's investigator an annual controlled substance audit completed on May 15, 2017. Based on this information, the Department's investigator completed an audit which revealed a shortage of hydrocodone-apap 7.5/325 mg (2,451 tablets), an overage of hydrocodone-apap 10/325 mg (1,174 tablets), and an overage oxycodone 30 mg (220 tablets).

28. On February 11, 2018, the Department received a revised annual controlled substance inventory that, when inputted into a revised audit, revealed a greatly reduced shortage of hydrocodone-apap 7.5/325 mg (72 tablets), an overage of hydrocodone-apap 10/325 mg (1,184 tablets), and an overage of oxycodone 30 mg (302 tablets).

29. The Department reviewed MAPS data for 10 patients to whom Respondent dispensed prescriptions during the review period from approximately January 24, 2016 through January 24, 2018. All of those patients filled prescriptions for commonly abused and diverted controlled substances at Respondent during that period:

(a) Patient CC[2] filled multiple prescriptions for alprazolam and hydrocodone-acetaminophen from approximately December 30, 2016 to January 11, 2018, three times filling both on the same day. During the period when patient CC was filling this combination at Respondent, patient CC was also filling prescriptions for Vyvanse at a different pharmacy. Several times, Patient CC obtained refill prescriptions early by a few days. Overall, patient CC filled 18 controlled substance prescriptions at Respondent over the review period.

(b) Patient FF filled prescriptions for carisoprodol and hydrocodone-acetaminophen on the same day or on days within close proximity 25 times at Respondent over the review period. On one of these occasions, patient FF also filled a prescription for promethazine with codeine. On 13 of these occasions, patient FF also filled a prescription for alprazolam, completing the Holy Trinity. Overall,

[2] Patients are identified by their initials or not identified to protect their identities.

patient FF filled 64 controlled substance prescriptions at Respondent over the review period.

(c) Patient TF filled multiple prescriptions for alprazolam and hydrocodone-acetaminophen over the review period at Respondent, filling prescriptions for both on the same day or on days within close proximity 14 times. Overall, patient TF filled 46 controlled substance prescriptions at Respondent over the review period.

(d) Patient MH filled two prescriptions at Respondent, from the same prescriber, carrying high daily MMEs on January 3, 2017. One prescription was for oxycodone 30 mg, carrying a daily MME of 135.00, and the other prescription was for oxymorphone 40 mg, carrying a daily MME of 240.00, for a total daily MME of 375.00.

(e) Patient LW filled prescriptions for oxycodone and Oxycontin at Respondent on the same day 27 times. On one of these occasions, patient LW also filled a prescription for tramadol at Respondent. Daily MMEs for the opioid medication patient LW filled at Respondent trended upwards over the review period, ranging from 210.00 to 360.00. Overall, patient LW filled 55 controlled substance prescriptions at Respondent over the review period. Patient L.W.'s address in MAPS is Toledo, Ohio.

(f) Patient WP filled two prescriptions for oxycodone 30 mg at Respondent, each carrying an MME of 90.00. In the approximate one-year period prior to filling these prescriptions, patient WP had received opioid prescriptions from four other pharmacies located in Detroit, Wayne, Southfield, and Redford, Michigan.

(g) Patient MH2 filled prescriptions for oxycodone and alprazolam on the same day at Respondent on 24 occasions. Patient MH2 filled one prescription for hydrocodone-acetaminophen and alprazolam on the same day on one occasion at Respondent. Overall, patient MH2 filled 57 controlled substance prescriptions at Respondent over the review period.

(h) Patient DH filled a prescription for oxycodone 30 mg at Respondent that carried a daily MME of 135.00. Patient DH received oxycodone 30 mg prescriptions from three other providers in an approximate 15-month period before receiving it from a fourth provider at Respondent.

(i) Patient CL filled eight prescriptions for oxycodone 30 mg over an eight-month period at Respondent. Each prescription was written by Dr. "V," and carried an MME of 90.00.

(j) John Doe filled a combination of Suboxone, carisoprodol, and alprazolam on the same day or in close proximity 13 times from January 2016 through June 2017 at Respondent.

30. Further review of patient data in MAPS showed that from January 1, 2016 through April 27, 2018, Respondent dispensed 738 prescriptions written by Dr. "V." 629 prescriptions (85.23%) were for oxycodone 30 mg and 104 prescriptions (14.09%) were for oxymorphone 40 mg. Over 99% of Dr. "V"'s prescriptions are for two commonly abused and diverted controlled substances, which is strongly indicative of pattern prescribing.

31. Multiple patients travelled between 15-25 miles to fill Dr. "V"'s prescriptions at Respondent. Additionally, no prescriptions for oxycodone 30 mg written by Dr. "V" were filled at the two pharmacies within a mile of Respondent's location in 2017, as referenced in paragraph 22.

32. A review of epidemiology data in MAPS revealed that patient C.H. filled multiple prescriptions for opioids and benzodiazepine medication at Respondent in 2016. In December 2016, patient C.H. obtained hydrocodone-acetaminophen, alprazolam, and Lyrica at Respondent. Within a month of filling these prescriptions, patient C.H. died from an overdose.

COUNT I

Respondent failed to maintain effective controls against diversion of controlled substances to other than legitimate and professionally recognized therapeutic, scientific, or industrial uses, in violation of MCL 333.7311(1)(e).

COUNT II

Respondent dispensed controlled substances without good faith, contrary to MCL 333.7333(1) and in violation of MCL 333.7311(1)(h).

COUNT III

Respondent's conduct, as described above, constitutes a failure to make an exact count or measure of controlled substances listed as schedule 1 or 2 in the possession or control of the licensee on the date the inventory is taken, contrary to Mich Admin Code, R 338.3151(2)(a) and in violation of MCL 333.7311(1)(h).

COUNT IV

Respondent's conduct, as described above, evidences a failure to maintain not less than two current or revised pharmacy reference texts, contrary to Mich Admin Code, R 338.481(2), in violation of MCL 333.17768(1).

COUNT V

Respondent's conduct, as described above, evidences a failure to ensure that all pharmacy technicians are licensed, contrary to MCL 333.17739(2)(a), in violation of MCL 333.17768(1).

RESPONDENT IS NOTIFIED that, consistent with Mich Admin Code, R 338.1615(3), Respondent has 30 days from the date of receipt of this complaint to answer this complaint in writing and to show compliance with all lawful requirements for retention of the license. Respondent shall submit the response to the Bureau of Professional Licensing, Department of Licensing and Regulatory Affairs, P.O. Box 30670, Lansing, MI 48909.

MICHIGAN DEPARTMENT OF
LICENSING AND REGULATORY AFFAIRS

Dated: 5-9, 2018

By: Cheryl Wykoff Pezon, Acting Director
Bureau of Professional Licensing

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