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

In the Matter of

PHARMACY 4 LESS II
License Nos. 53-01-009691 and 53-15-052950, File No. 53-18-151059

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: 8/16/18

By: Cheryl Wykoff Pezon, Director
Bureau of Professional Licensing

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

In the Matter of

PHARMACY 4 LESS II
License Nos. 53-01-009691 and 53-15-052950, File No. 53-18-151059

Respondent.

ADMINISTRATIVE COMPLAINT

The Michigan Department of Licensing and Regulatory Affairs by Cheryl Wykoff Pezon, Director, Bureau of Professional Licensing, complains against Respondent Pharmacy 4 Less II 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. 53-01-009691 and a controlled substance license no. 53-15-052950. 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 Detroit, Michigan. Respondent's pharmacist-in-charge (PIC) is Belief Aghoghome Emadamerho, R.Ph.[1]

[1]The Department has also filed an Administrative Complaint against Emadamerho for the conduct alleged here. *Belief Aghoghome Emadamerho, R.Ph.,* No. 53-18-151669.

7. Alprazolam is a benzodiazepine schedule 4 controlled substance. Alprazolam is a commonly abused and diverted drug, particularly in its 1 mg and 2 mg dosages.

8. 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.

9. Promethazine with codeine syrup is a schedule 5 controlled substance prescribed for treating cough and related upper respiratory symptoms. Promethazine with codeine syrup is rarely indicated for any other health condition, and is particularly ill-suited for long-term treatment of chronic pain. Promethazine with codeine syrup is a highly sought-after drug of abuse, and is known by the street names "lean," "purple drank," and "sizzurp."

10. Hydrocodone, and combination products including hydrocodone are commonly abused and diverted opioid schedule 2 controlled substances.

11. Oxycodone and oxycodone combination products are opioid schedule 2 controlled substances. These medications are used to treat pain and are commonly abused and diverted.

12. 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.

13. 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."

14. 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.

15. 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.

16. 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 of the following commonly abused and diverted controlled substances among all Michigan dispensers in the following quarters of 2017 and 2018:

Drug	***2017 Q2 Rank***	***2017 Q3 Rank***	***2017 Q4 Rank***	***2018 Q1 Rank***
Oxycodone 30 mg	32	19	3	1
Oxycodone (all strengths)	-	92	-	64
Oxymorphone 40 mg	-	-	43	46
Oxymorphone (all strengths)	-	-	53	58
Promethazine with Codeine	31	30	-	-
Carisoprodol 350 mg	-	-	-	55

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

	Drug	1/1/16 thru 12/31/17	1/1/18 through 3/31/18
(a)	Hydrocodone/apap 10-325 mg	1,825 (18.64%)	193 (14.81%)
(b)	Oxycodone 30 mg	1,512 (15.44%)	338 (25.94%)
(c)	Hydrocodone/apap 7.5-325 mg	966 (9.87%)	110 (8.44%)
(d)	Alprazolam 1 mg	743 (7.59%)	81 (6.22%)
(e)	Total, (a) - (d)	***5,046 (51.54%)***	***722 (55.41%)***
(f)	Total CS prescriptions	9,790	1,303

18. On June 5, 2018, the Department conducted an unannounced inspection of Respondent's business premises and interviewed Respondent's PIC. The investigation produced the following information:

Pharmacy Location and Condition

a. Respondent's PIC stated that Respondent was previously located in a grocery store until the store went out of business around April 20, 2018 and Respondent had to relocate.

b. Respondent's PIC indicated that on or about April 26, 2018, Respondent's relocation license was approved, and the pharmacy moved to its current location.

c. Respondent's PIC stated that Respondent was not "technically" open for business and was currently just delivering prescriptions to patients' homes. Respondent's PIC indicated that since the move to the new location, about 90% of the pharmacy's prescription business was delivery.

d. Respondent did not have an occupancy permit from the City of Detroit due to one or more failed inspections.

e. During the inspection, investigators found no exterior signage or indication that the building housed a pharmacy. The building had no parking lot, only a small dirt-and-gravel driveway.

f. After entering the building, the investigators found the pharmacy and the rest of the interior in various stages of construction.

g. Investigators noted the pharmacy area was extremely cluttered, with paperwork and debris strewn across the pharmacy counter to the point of having no free counter space on which to work.

h. Despite the pharmacy's physical condition, MAPS data indicates that prescriptions had been dispensed from late April until the inspection date. Respondent's PIC acknowledged the pharmacy was dirty and disorganized.

Storage of Medications

i. Bags of filled prescriptions were stored in various areas within Respondent, even though an empty area designated for "will call" existed within the main pharmacy area.

j. Respondent's PIC indicated that Respondent's controlled substance stock was stored in a safe.

k. Investigators found that non-controlled medications were not being stored on shelving in the main pharmacy area. Investigators were directed to an adjoining room, where the majority of medications were being stored out of sight in drawers and cabinets.

l. Respondent's PIC admitted these drugs were being hidden from the view of City of Detroit inspectors.

Prescriptions and Prescription Labels

m. During the inspection, investigators opened a cabinet in the main pharmacy area and came across several stacks of prescription labels rubber-banded together. Labels without medications raise a red flag of fraud, both in billing and moderating the percent of controlled substances dispensed compared to all prescriptions dispensed.

n. Respondent's PIC indicated these were duplicate labels of prescriptions that had already been filled and delivered to customers and were awaiting shredding. Respondent's PIC could not adequately explain why duplicate labels were being printed.

o. Investigators reviewed the stacks of labels and discovered nearly all of them were for non-controlled medications known to have high insurance reimbursement, such as asthma inhalers, lidocaine cream, non-steroidal anti-inflammatories, stool softeners, and vitamins. These medications were prescribed by the same physicians who also issued high numbers of controlled substances, especially oxycodone 30 mg, on Respondent's MAPS report.

p. Investigators subsequently requested copies of prescriptions and documentation to substantiate that patients received the prescriptions, as indicated. Respondent's PIC provided the patient profiles for these individuals, after redacting the prices charged by the pharmacy. Some prescriptions and documentation were provided at the inspection; more were provided via fax after the inspection. Investigators noted the patient signatures on the faxed documentation were in the same handwriting and appeared to be fraudulent.

q. Investigators also reviewed numerous controlled substance prescriptions during the inspection and noted multiple instances of prescriptions from the same physician but for different patients in sequential order. This suggests that patients were coming to Respondent in groups or one person was handling prescriptions for multiple patients.

Red Flags for Abuse and Diversion

r. Respondent's PIC indicated he was familiar with several red flags for abuse and diversion of controlled substances, including patients traveling far distances to obtain prescriptions, pattern prescribing to patients, patients willing to pay cash for prescriptions, and prescriptions for excessive quantities.

s. Respondent's PIC is conscious of Respondent's rate of controlled substance medications as a percentage of total medications dispensed and acknowledged that higher percentages could attract unwanted attention from the State and the Drug Enforcement Administration (DEA). Respondent's PIC indicated he refuses to fill just controlled substance prescriptions for customers and demands they bring in maintenance/non-controlled medications as well.

t. Investigators asked Respondent's PIC about the significant increase in oxycodone 30 mg dispensing from 2016-2017 to the first quarter of 2018. Respondent's PIC admitted somehow losing control over Respondent's oxycodone 30 mg dispensing percentages and could not explain the increase.

Inspection-Related Violations

19. The Department's inspection revealed several violations of rules governing the practice of pharmacy, including:

a. Schedule 2 invoices were not kept in a separate file.

b. Investigators found no signed controlled substance logs since April 17, 2018, in violation of the Code of Federal Regulations.

c. Not all controlled substance prescriptions indicated the quantity in both written and numeric terms.

d. Expired drugs were found within Respondent's active inventory.

e. A blister pack of medication had an incorrect expiration date

f. Respondent's building did not have hot water.

g. Pharmacy technician licenses were not posted.

h. The consumer information notice was not displayed.

i. One unlicensed pharmacy technician was working at Respondent. Bureau inspectors previously notified Respondent's PIC that the unlicensed person in question should not be working in a technician capacity.

Dispensing for Pattern Prescribers

20. The Department analyzed Respondent's dispensing data between January 1, 2016 and March 31, 2018 and noticed that Respondent was dispensing for providers who tended to prescribe the same medications to a number of patients. Several of the providers have been recently disciplined by the State of Michigan, federally indicted, or are under investigation for over prescribing and/or healthcare fraud. Pattern prescribing is suggestive of prescriptions being written for illegitimate purposes. Examples include:

a. Respondent filled 423 controlled substance prescriptions authorized by Reese James, D.O., who has been disciplined by the State of Michigan for prescribing controlled substances for other than lawful or diagnostic purposes. Of these prescriptions, 314 (74.23%) were for oxycodone 30 mg and 89 (21.04%) were for carisoprodol 350 mg.

b. Respondent filled 124 controlled substance prescriptions authorized by Alex Kafi, M.D., who has been federally indicted for conspiracy to distribute controlled substances, including oxycodone. Of these prescriptions, 96

(77.42%) were for oxycodone 30 mg and 21 (16.94%) were for promethazine with codeine syrup.

c. Respondent filled 102 controlled substance prescriptions authorized by James Beale, M.D., who has been disciplined by the State of Michigan for prescribing controlled substances for other than lawful or diagnostic purposes. Of these prescriptions, 74 (72.55%) were for oxycodone 30 mg and 24 (23.53%) were for alprazolam 2 mg.

d. Respondent filled 124 controlled substance prescriptions authorized by Christina Kimbrough, M.D., who has been federally indicted for conspiracy to commit health care fraud, including fraudulent prescriptions for controlled substances including oxycodone. Of the prescriptions filled at Respondent, 58 (46.77%) were for oxycodone 30 mg and 48 (38.71%) were for promethazine with codeine syrup.

e. Respondent filled 148 controlled substance prescriptions authorized by Zeyn Seabron, M.D., who has recently been summarily suspended by the State of Michigan for prescribing controlled substances for other than lawful or diagnostic purposes. Of these prescriptions, 100% were for oxycodone 30 mg.

f. Respondent filled 245 controlled substance prescriptions for prescriber "P." Of these prescriptions, 174 (71%) were for oxycodone 30 mg and 46 (18.77%) were for oxymorphone 40 mg.

Several of these prescribers' patients who filled prescriptions at Respondent were listed in the State of Michigan's Offender Tracking Information System (OTIS) as having controlled substance-related convictions, among others.

Specific Patient Examples

21. The Department reviewed MAPS data for seven patients to whom Respondent dispensed controlled substance prescriptions between January 1, 2016 and March 31, 2018. All of those patients filled prescriptions for commonly abused and diverted controlled substances at Respondent during that period:

a. Patient D.B. regularly filled prescriptions for promethazine with codeine syrup at Respondent over the period, often alternating prescriptions from

two different providers. Promethazine with codeine syrup is indicated for short-term use. On several of these occasions, patient D.B. also filled an opioid prescription on the same day.

b. Patient J.G. filled numerous prescriptions for carisoprodol 350 mg, hydrocodone-apap 10-325 mg, and promethazine with codeine syrup over the period at Respondent. These medications were often filled together on the same day or within close proximity.

c. Patient J.G.2 repeatedly filled prescriptions for carisoprodol 350 mg and hydrocodone-apap 10-325 mg on the same day at Respondent throughout the review period. In close proximity to filling these two medications at Respondent, patient J.G.2 filled prescriptions for alprazolam 1 mg at other pharmacies, completing the Holy Trinity. On one occasion, patient J.G.2 filled the Holy Trinity at Respondent on the same day.

d. Patient L.P. filled monthly prescriptions for promethazine with codeine syrup throughout a significant portion of the review period at Respondent. Promethazine with codeine syrup is intended for short-term use. Patient L.P. also filled opioids and benzodiazepines on the same day multiple times over the review period at Respondent.

e. Patient D.T. filled several prescriptions for oxycodone 30 mg at Respondent. On two of these occasions, patient D.T. also filled prescriptions for carisoprodol 350 mg. All of these medications were written by Dr. Reese James. After patient D.T. filled his last oxycodone 30 mg prescription at Respondent, patient D.T. did not fill another controlled substance prescription for approximately 5 months.

f. Patient D.C. filled eight prescriptions for oxycodone 30 mg at Respondent. On one of these occasions, patient D.C. filled a prescription for carisoprodol 350 mg on the same day. All of the prescriptions were written by Dr. Reese James. It appears that patient D.C. was opioid naïve before receiving the first oxycodone 30 mg prescription from Dr. James.

g. Patient F.M. filled multiple prescriptions for oxycodone 30 mg, oxymorphone 40 mg, and promethazine with codeine syrup at Respondent over the review period. It appears that patient F.M. was opioid naïve before receiving the first oxycodone 30 mg prescription.

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 for other than legitimate or professionally recognized therapeutic, scientific, or industrial purposes, or outside the Respondent's scope of practice, in violation of MCL 333.7311(1)(g).

COUNT III

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

COUNT IV

Respondent failed to comply with applicable federal, state, or local laws, in violation of MCL 7311(1)(f).

COUNT V

Respondent failed to maintain invoices and other acquisition records of all controlled substances listed in schedules 1 and 2 in a separate file, contrary to Mich Admin Code, R 338.3153(2)(a), in violation of MCL 333.7311(1)(h).

COUNT VI

Respondent failed to keep records and maintain inventories in conformance with the record-keeping and inventory requirements of federal law, contrary to MCL 333.7321(1), in violation of MCL 333.7311(1)(h).

COUNT VII

Respondent's pharmacy department did not have a sink with both hot and cold running water, contrary to Mich Admin Code, R 338.481(1), in violation of MCL 333.17768(1).

COUNT VIII

Respondent's premises lacked clean and sanitary surroundings, contrary to Mich Admin Code, R 338.482(1), in violation of MCL 333.17768(1).

COUNT IX

Respondent failed to display the consumer identification notice, contrary to MCL 333.17761(1), 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: 8/16/18

By: Cheryl Wykoff Pezon, Director
Bureau of Professional Licensing

S:\Drug Monitoring Section\Staff Folders\Prygoski.J\Pharmacy 4 Less II\Pharmacy 4 Less II, 151059 AC + OSS.docx