

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

In the Matter of

PEOPLE PHARMACY LLC
License Nos. 53-01-008586 and 53-15-030017,

File No. 53-18-152031

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: 11/16/18


By: Cheryl Wykoff Pezon, Director
Bureau of Professional Licensing

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Respondent.

ADMINISTRATIVE COMPLAINT

The Michigan Department of Licensing and Regulatory Affairs by Cheryl Wykoff Pezon, Director, Bureau of Professional Licensing, complains against Respondent People Pharmacy LLC 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. 53-01-008586 and a controlled substance license no. 53-15-030017. 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) and owner is Anthony Olusegun Akande, R.Ph.¹

¹The Department has also filed an Administrative Complaint against Akande for the conduct alleged here. *Anthony Olusegun Akande, R.Ph.*, No. 53-18-152030.

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. Hydrocodone is an opioid. Hydrocodone combination products (e.g., Norco), are Schedule 2 controlled substances due to their high potential for abuse.

10. Oxycodone and oxycodone combination products are opioid schedule 2 controlled substances. These medications are used to treat pain and are commonly abused and diverted. Oxycodone 30 mg is the most commonly abused and diverted strength of oxycodone. The approximate street price for immediate release oxycodone is \$1.00 per milligram.

11. Oxymorphone, a schedule 2 controlled substance, is an opioid used to treat pain, and is a commonly abused and diverted drug. Oxymorphone ER 40 mg is the most commonly abused and diverted strength of oxymorphone. Street prices for oxymorphone range from \$10.00 to \$40.00 per pill.

12. 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."

13. When used in combination, opioids, carisoprodol, 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 during the following quarters of 2017 and 2018:

<i>Drug</i>	<i>2017 Rank Q1</i>	<i>2017 Rank Q2</i>	<i>2017 Rank Q3</i>	<i>2017 Rank Q4</i>	<i>2018 Rank Q1</i>	<i>2018 Rank Q2</i>
Oxycodone 30 mg	34	63	95	22	32	54
Oxymorphone ER 40 mg	3	13	12	10	13	23

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

Drug	2016	2017	1/1/2018 thru 8/15/2018
(a) Oxycodone 30 mg	306 (16.33%)	469 (22.37%)	242 (21.76%)
(b) Oxymorphone ER 40 mg	192 (10.25%)	326 (15.55%)	142 (12.77%)
(c) Hydrocodone-apap 10-325 mg	148 (7.90%)	138 (6.58%)	68 (6.12%)
(d) Total, (a) - (c)	646 (34.47%)	933 (44.49%)	452 (40.64%)
(e) Total CS prescriptions	1,874	2,097	1,112

Pharmacy Inspection and Operations

18. On September 11, 2018, the Department inspected Respondent's place of business and discovered the following violations of rules governing the practice of pharmacy:

- a. Not all controlled substance prescriptions indicated the quantity in both written and numeric terms;
- b. Respondent was unable to produce a daily log of controlled substances dispensed, as required by federal law; and
- c. Respondent failed to produce annual controlled substance inventories for 2016, 2017, and 2018 upon request.

19. During the inspection, the investigator requested copies of several prescriptions. The investigator noted that while Respondent's PIC was in the process of finding several of the requested prescriptions, he was adding documentation to them. The investigator then stood by Respondent's PIC while he searched for the remaining prescriptions; the PIC could not produce all of the requested prescriptions.

20. The Department's investigator completed an audit for five controlled substances dispensed at Respondent: promethazine with codeine syrup, carisoprodol

350 mg, oxycodone 30 mg, hydrocodone-apap 10-325 mg, and alprazolam 1 mg. The audit used both Respondent's dispensing data, confirmed by Respondent's PIC, and Respondent's MAPS data. The audit revealed significant shortages of oxycodone 30 mg, hydrocodone-apap 10-325 mg, alprazolam 1 mg, and carisoprodol 350 mg; it also revealed a notable overage for promethazine with codeine syrup.

21. During the inspection, the investigator requested copies of Respondent's controlled substance inventories for 2016, 2017, and 2018. Respondent's PIC stated he was unable to provide copies of these inventories because he had sent the original documents to the Department and had not retained copies.

Interview with Respondent's PIC

22. The Department's investigator interviewed Respondent's PIC, who provided the following information:

Red Flags for Diversion

- a. Respondent's PIC was aware that hydrocodone products were highly diverted and abused medications. Respondent's PIC was unaware that alprazolam 1 and 2 mg, promethazine with codeine syrup, oxycodone 30 mg, oxymorphone ER 40 mg, and carisoprodol were highly diverted and abused medications.
- b. Respondent's PIC indicated he was familiar with the CDC's recommendations regarding MMEs and the concurrent prescribing of opioids and benzodiazepines.
- c. Respondent's PIC stated that he did not consider a patient receiving an opioid and promethazine with codeine syrup concurrently to be a duplication of therapy.
- d. Respondent's PIC stated he was surprised by the high percentages of oxycodone 30 mg and oxymorphone ER 40 mg being dispensed at Respondent.
- e. Respondent's PIC could not explain why many of the prescribers of controlled substances whose prescriptions were being filled at

Respondent had been disciplined by the Department for overprescribing controlled substances.

MAPS Data and Documentation

- f. Respondent's PIC indicated he checks MAPS on new patients and before filling schedule 2 controlled substances. If a patient is filling a schedule 3-5 controlled substance, Respondent's PIC will check MAPS if he is suspicious or if the quantity prescribed is high.
- g. Respondent's PIC stated that if he sees a patient being treated by more than one prescriber on a MAPS report, he will talk to the patient. The PIC also stated he reviews trends on patients' MAPS reports and reviews patients' MME values.
- h. Respondent's PIC further indicated that if he contacts a prescriber, reviews MAPS, or receives information from patients, he documents these findings on the back of prescriptions. The investigator reviewed multiple controlled substance prescriptions from all schedules during the inspection and did not find any documentation of MAPS being reviewed or physicians being contacted on the controlled substance prescriptions.

Specific Patient Examples

23. The Department's investigator questioned Respondent's PIC regarding MAPS data for several patients to whom Respondent dispensed prescriptions during the review period of September 7, 2013 through September 7, 2018. All of those patients filled prescriptions for commonly abused and diverted controlled substances at Respondent during that period:

- a. Patient P.R. filled the first of four prescriptions for oxycodone 30 mg at Respondent starting in February 2018, which carrying daily MMEs of 135 per prescription. Prior to receiving that prescription, patient P.R. had not filled an opioid prescription within the review period. Respondent's PIC did not check MAPS prior to dispensing the February 2018 prescription.
- b. Patients L.N., P.N., and D.N. are three family members living at the same address who filled controlled substance prescriptions at Respondent.

- i. Patient L.N. filled prescriptions for several controlled substances, including oxycodone, oxymorphone, and alprazolam, at various pharmacies and from multiple prescribers throughout the review period. Patient L.N. filled several oxymorphone ER 40 mg prescriptions at Respondent from September 2017 through May 2018. Respondent's PIC did not review MAPS prior to dispensing the first prescription at Respondent.
 - ii. Patient P.N. filled ten prescriptions at Respondent over the review period, between August 2017 and May 2018. The prescriptions were for either oxycodone 30 mg or oxymorphone ER 40 mg. Prior to dispensing patient P.N.'s first prescription at Respondent, oxymorphone ER 40 mg with a daily MME of 240.00, Respondent's PIC did not review MAPS.
 - iii. Patient D.N. filled five prescriptions for oxycodone 30 mg at Respondent between September 2017 and March 2018. Respondent's PIC did not review MAPS prior to dispensing the first prescription at Respondent.
- c. Patient C.M. filled opioid prescriptions carrying daily MMEs between 135.00 and 240.00 at Respondent. Patient C.M. was opioid naïve prior to receiving his first prescriptions for oxycodone 30 mg and oxymorphone ER 40 mg on the same day in January 2017. Respondent's PIC did not request MAPS on the patient until after the January 2017 prescriptions were dispensed.

The Department's investigator reviewed the January 2017 prescriptions for oxycodone 30 mg and oxymorphone ER 40 mg, which contained documentation that the prescriptions had been verified with the prescriber despite the prescriptions having an incorrect telephone number for the prescriber.

- d. Patient T.R. filled prescriptions for hydrocodone-apap 10-325, alprazolam 1 mg, and promethazine with codeine syrup at Respondent. Respondent's PIC did not check MAPS prior to dispensing these medications to patient T.R.
- e. Patient K.F. filled a prescription for oxymorphone ER 40 mg and oxycodone 30 mg on February 8, 2018 at Respondent. Patient K.F. had not received an opioid for at least four months prior to receiving these two medications, which carried a combined daily MME of 330.00. Copies of the prescriptions were obtained at the inspection; neither contained any documentation and the attached MAPS reports

were dated February 9, 2018, a day after the medications were dispensed.

- f. Patient C.D. filled multiple prescriptions for oxycodone and oxymorphone at Respondent over the review period while filling controlled substance prescriptions at several other pharmacies intermittently. Patient C.D. also used several different prescribers to obtain controlled substances. Respondent's PIC acknowledged concern about the combination of opioids patient C.D. was receiving because the patient was using multiple pharmacies and had a high MAPS overdose risk score.
- g. Patient R.D. filled multiple prescriptions for oxycodone 30 mg and oxymorphone ER 40 mg at Respondent during the review period. When patient R.D. filled these medications on the same day, the medications carried combined daily MMEs over 300.00.
- h. Patient C.D.2 filled prescriptions for oxycodone 30 mg and oxymorphone ER 40 mg at Respondent on the same day, on two occasions. These medications together carry a daily MME of 375.00. Respondent's PIC did not check MAPS prior to dispensing this medication combination the first time.
- i. Patient E.B. filled prescriptions for oxycodone 30 mg and oxymorphone ER 40 mg at Respondent, carrying a combined daily MME of 330.00 or 375.00. Patient E.B. also filled this combination at another pharmacy in between filling it at Respondent. Respondent's PIC only ran a MAPS report on the patient once, only after dispensing the medications several times.

24. The Department reviewed MAPS data for several other patients filling prescriptions for commonly abused and diverted controlled substances at Respondent over the review period. Examples include, but are not limited to:

- a. Patient Z.B. regularly filled prescriptions for an opioid, a benzodiazepine, and promethazine with codeine syrup at Respondent. Patient Z.B. filled controlled substance prescriptions at other pharmacies on several occasions after she first filled controlled substances at Respondent and frequented multiple prescribers. Patient Z.B. filled prescriptions for promethazine with codeine syrup on a long-term basis; promethazine with codeine syrup is not indicated for long-term use.

- b. Patient L.B. filled controlled substance prescriptions, mainly oxycodone and oxymorphone, at Respondent throughout the review period. Patient L.B. frequented several other pharmacies in between filling prescriptions at Respondent and received controlled substance medications from 17 pharmacies over the review period. Some of the providers who authorized controlled substance medications for patient L.B. have been disciplined by the State of Michigan or are under investigation.
- c. Patient B.B. regularly filled prescriptions for hydrocodone-apap and promethazine with codeine syrup throughout the review period. Promethazine with codeine syrup is not intended for long-term use.
- d. Patient C.B. regularly filled prescriptions for hydrocodone-apap, alprazolam, and promethazine with codeine syrup throughout the review period. Promethazine with codeine syrup is not intended for long-term use. Patient C.B. has the same address as patient B.B., above.
- e. Patient B.B.2 repeatedly filled prescriptions for hydrocodone-apap, alprazolam, and carisoprodol at Respondent on the same day throughout the review period. The combination of these medications is known as the Holy Trinity and is highly sought after.

25. The Department further reviewed Respondent's MAPS data and found that patients were filling prescriptions from several prescribers who appeared to be engaging in pattern prescribing, which is a red flag for diversion. Among those prescribers were:

- a. Timothy Barth, M.D., who prior to having his license revoked on a separate matter, was being investigated by the Department for overprescribing controlled substances. Of the 171 total controlled substance prescriptions filled at Respondent in 2017, 94 (54.97%) were for oxymorphone ER 40 mg and 77 (45.03%) were for oxycodone 30 mg.
- b. Zeyn Seabron, M.D, whose license was summarily suspended by the Department based on evidence of overprescribing controlled substances. Of the 109 total controlled substance prescriptions filled at Respondent in 2017, 55 (50.46%) were for oxymorphone ER 40 mg and 54 (49.54%) were for oxycodone 30 mg.

- c. Vasan Deshikachar, M.D., who has been federally indicted for participating in a \$9.6 million opioid distribution conspiracy. Of the 93 total controlled substance prescriptions filled at Respondent in 2017, all were for oxycodone 30 mg.
- d. Practitioner "H," who is known to the Department prescribe large quantities of opioid medication. Of the 54 total controlled substance prescriptions filled at Respondent in 2017, 31 (57.41%) were for oxycodone 30 mg and 23 (42.59%) were for oxymorphone ER 40 mg. Of the 154 total controlled substance prescriptions filled at Respondent from January 1, 2018 to November 7, 2018, 86 (55.84%) were for oxycodone 30 mg and 68 (44.16%) were for oxymorphone ER 40 mg.
- e. Practitioner "P," who is currently being investigated by the Department for overprescribing controlled substances. Of the 61 total controlled substance prescriptions filled at Respondent from January 1, 2018 to November 7, 2018, 38 (62.30%) were for oxymorphone ER 40 mg and 23 (37.70%) were for oxycodone 30 mg.
- f. Dr. "G," who is currently being investigated by the Department for overprescribing controlled substances. Of the 56 total controlled substance prescriptions filled at Respondent from January 1, 2018 to November 7, 2018, 28 (50.00%) were for oxycodone 30 mg and 28 (50.00%) were for oxymorphone ER 40 mg.

26. Notably, an independent pharmacy in close proximity to Respondent filled a drastically fewer number of controlled substance prescriptions authorized by the above-mentioned prescribers in 2017 and from January 1, 2018 through November 7, 2018. The independent pharmacy filled only two controlled substance prescriptions authorized by Dr. Barth in 2017.² The independent pharmacy did not fill any controlled substance prescriptions authorized by practitioner "H" in 2017 and filled only six controlled substance prescriptions authorized by practitioner "H" from January 1, 2018 through November 7, 2018.

² Dr. Barth's medicine license was summarily suspended in September 2017 and was revoked in February 2018.

27. Similarly, a chain pharmacy in close proximity to Respondent did not fill any controlled substance prescriptions authorized by the above-mentioned prescribers in 2017 and from January 1, 2018 through November 7, 2018.

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 ensure that all controlled substance prescriptions received in writing contain the quantity in both written and numerical terms, contrary to Mich Admin Code, R 338.3161(1)(d), in violation of MCL 333.7311(1)(h).

COUNT V

Respondent failed to keep records and maintain inventories in conformance with the record-keeping and inventory requirements of federal law, contrary to C.F.R. 1306.22(f)(3), contrary to MCL 333.7321(1), and in violation of MCL 333.7311(1)(h).

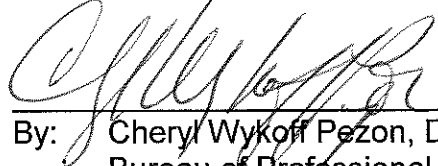
COUNT VI

Respondent failed produce controlled substance inventories at the request of the Department, contrary to MCL 333.7321(2), in violation of MCL 333.7311(1)(h).

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: 11/16/18


By: Cheryl Wykoff Pezon, Director
Bureau of Professional Licensing

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