STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF HEALTH CARE SERVICES
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the Matter of

Theodore L. Roumell, M.D.
License No. 43-01-024386
_____/ Complaint No. 43-13-127718

ADMINISTRATIVE COMPLAINT

Attorney General Bill Schuette, through Assistant Attorney General Kelly K. Elizondo, on behalf of the Department of Licensing and Regulatory Affairs, Bureau of Health Care Services (Complainant), files this complaint against Theodore L. Roumell, M.D. (Respondent), alleging upon information and belief as follows:

JURISDICTIONAL ALLEGATIONS

1. The Board of Pharmacy (Board), an administrative agency established by the Public Health Code (Code),1978 PA 368, as amended, MCL 333.1101 *et seq*, is empowered to discipline licensees under the Code through its Disciplinary Subcommittee.

2. The Board of Pharmacy has been designated the administrator of the controlled substance provisions in Article 7 of the Code and is empowered to discipline licensees under the controlled substance provisions of the Code through its DSC.

3. At all times relevant to this complaint Respondent held a controlled substance 3 license issued by the administrator.

4. Section 7311(1) of the Code provides that a license under section 7306 to manufacture, distribute, prescribe, or dispense a controlled substance may be denied, suspended, or revoked or a licensee may be fined, reprimanded, ordered to perform community service or make restitution, or placed on probation by the disciplinary subcommittee upon a finding that an applicant for licensure or a licensee is subject to any of the following:

> (f) The applicant or licensee is not in compliance with applicable federal, state, and local laws.
> (h) Violating or attempting to violate, directly or indirectly, assisting in or abetting the violation of or conspiring to violate article 7 or rules promulgated under article 7.

5. Section 7303(1) of the Code provides: "a person who manufactures, distributes, prescribes, or dispenses a controlled substance in this state or who proposes to engage in the manufacture, distribution, prescribing, or dispensing of a controlled substance in this state shall obtain a license issued by the administrator in accordance with the rules. A person who has been issued a controlled substance license by the administrator under this article and a license under article 15 shall renew the controlled substances license concurrently with the renewal of the license issued under article 15, and for an equal number of years."

6. Section 7303(5) of the Code provides: "a separate license is required at each principal place of business or professional practice where the applicant manufactures, distributes, prescribes, or dispenses controlled substances."

7. 2007 AACS, R 338.3132(3) provides: "if a principal place of business or professional practice consists of multiple locations, then each location shall obtain a separate controlled substance license if controlled substances are received, stored, administered, or dispensed at that location."

8. 2002 AACS, R 338.3153(1) provides: "a licensee shall keep and make available for inspection all records for controlled substances, including invoices and other acquisition records, but excluding sales receipts, however a copy of each receipt shall be retained for 90 days. Acquisition records, except for executed DEA 222 order forms, may be kept at a central location, subject to the approval of the administrator. The approval shall specify the nature of the acquisition records to be kept and the exact location where the acquisition records will be kept. All records shall be readily retrievable within 48 hours."

9. 2002 AACS, R 338.3153(2) provides: "a licensee shall maintain acquisition records as follows:

(a) Invoices and other acquisition records of all controlled substances listed in schedules 1 and 2 of R 338.3111 to R 338.3119a shall be maintained in a separate file.

(b) Invoices and other acquisition records of all controlled substances listed in schedules 3, 4, and 5 of R 338.3120 to R 338.3125 shall be maintained in a separate file or in such form so that the information

required is readily retrievable from the ordinary acquisition records maintained by the dispenser."

10. 2002 AACS, R 338.3153(3) provides: "a licensee shall initial the invoice and indicate the date that the controlled substances are received."

11. 2002 AACS, R 338.3153(7) provides: "records of controlled substances distributed to another licensee, shall include all of the following information and be maintained in the appropriate file described in subrule (2) of this rule or in a separate record that is available for inspection:

a) Name, address, and DEA number of receiver.
b) Name, address, and DEA number of supplier.
c) Name and quantity of controlled substances distributed.
d) Date distributed.

A DEA 222 order form shall be used for schedule 2 drugs."

12. 1992 AACS, R 338.3186 provides: "an order form shall be used to distribute schedule 2 substances and an invoice shall be used to distribute schedules 3 to 5 substances. The order form may be executed only by a practitioner who is licensed to prescribe or dispense controlled substances."

FACTUAL ALLEGATIONS

13. Respondent is a medical doctor who at all times relevant to this administrative complaint had three office locations: 111 S. Rochdale, Rochester Hills, Michigan; 1601 E. Grand River Ave, Lansing, Michigan; and 2032 South Saginaw, Flint, Michigan.

14. At all times relevant to this administrative complaint Respondent had a controlled substance 3 license for his office location at 111 S. Rochdale, Rochester Hills, Michigan. Respondent did not have controlled substance 3 licenses for his other two locations referred to above.

15. On April 15, 2013, Respondent was interviewed by Complainant's Pharmacy Inspector at his Rochester office. Respondent advised Complainant's Pharmacy Inspector that he ordered controlled substances for storing and dispensing at his Lansing and Flint office locations.

16. Specifically, Respondent stored and dispensed: Versed (a schedule 4 drug used to produce a "twilight" effect prior to a medical procedure); Fentanyl (a schedule 2 drug used for anesthesia and pain control with a medical procedure); and Nalbuphine (a schedule 2 drug used for pain relief).

17. Respondent ordered the above medications from Smith Medical and the medications were sent to his Rochester Hills office location. Respondent told Complainant's Pharmacy Inspector that at the time of his interview he did not have any controlled substances at his Rochester location nor did he have any records with regard to the acquisition or transfer of controlled substances at his Rochester location.

18. Respondent advised Complainant's Pharmacy Inspector that all controlled substances received by his Rochester office were transferred to, stored and dispensed at his Lansing and Flint locations. Respondent had not generated

any paperwork associated with the acquisition and transfer of the controlled substances including order forms or invoices. Respondent did not recall initialing and dating invoices from Smith Medical for any of the controlled substances he received. Respondent did not use DEA 222 forms for schedule 2 drugs received and distributed to his Lansing and Flint offices.

19. In addition to not having controlled substance licenses for his Lansing and Saginaw locations, Respondent did not have dea registration numbers for his Lansing and Flint locations and therefore did not have transfer records including the dea number of the receiving office.

COUNT I

Respondent's conduct as described above constitutes a violation of section 7303(5) of the Code, contrary to section 7311(1)(f) and (h) of the Code.

COUNT II

Respondent's conduct as described above constitutes a violation of 2007 AACS, R 338.3132(3) contrary to section 7311(1)(f) and (h) of the Code.

COUNT III

Respondent's conduct as described above constitutes a violation of 2002 AACS, R 338.3153(1) in violation of section 7311(1)(f) and (h) of the Code.

COUNT IV

Respondent's conduct as described above constitutes a violation of 2002 AACS, R 338.3153(2) in violation of section 7311(1)(f) and (h) of the Code.

COUNT V

Respondent's conduct as described above constitutes a violation of 2002 AACS, R 338.3153(3) in violation of section 7311(1)(f) and (h) of the Code.

COUNT VI

Respondent's conduct as described above constitutes a violation of 2002 AACS, R 338.3153(7) in violation of section 7311(1)(f) and (h) of the Code.

COUNT VII

Respondent's conduct as described above constitutes a violation of 1992 AACS, R 338.3186 in violation of section 7311(1)(f) and (h) of the Code.

WHEREFORE, Complainant requests that this complaint be served upon Respondent and that Respondent be offered an opportunity to show compliance with all lawful requirements for retention of the aforesaid license. If compliance is not shown, Complainant further requests that formal proceedings be commenced pursuant to the Public Health Code, rules promulgated pursuant to it, and the Administrative Procedures Act of 1969, 1969 PA 306, as amended; MCL 24.201 *et seq*; MSA 3.560(101) *et seq*.

RESPONDENT IS HEREBY NOTIFIED that, pursuant to section 16231(7) of the Public Health Code, Respondent has 30 days from receipt of this Administrative Complaint to submit a written response to the allegations contained in it. The written response shall be submitted to the Bureau of Health Care Services, P.O. Box 30670, Lansing, Michigan, 48909, with a copy to the undersigned assistant attorney general. Further, pursuant to section 16231(8) of the Public Health Code, failure to submit a written response within 30 days shall be treated as an admission of the allegations contained in the Administrative Complaint and shall result in transmittal of the Administrative Complaint directly to the Board's Disciplinary Subcommittee for imposition of an appropriate sanction.

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