

**STATE OF FLORIDA
DEPARTMENT OF HEALTH**

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK: *Sandra Soto*
DATE: 11-1-11

BOARD: Medicine
CASE NUMBER: 2010-05671
COMPLAINT MADE BY: DOH
COMPLAINT MADE AGAINST: Mohamed O. Saleh, M.D.
1408 San Marco Blvd.
Jacksonville, Florida, 32207-8536
DATE OF COMPLAINT: March 25, 2010
INVESTIGATED BY: Richard C. Walchle
REVIEWED BY: Gavin D. Burgess
Assistant General Counsel
RECOMMENDATION: Dismissal (4099)

NOTICE OF RECONSIDERATION/CLOSING ORDER

THE COMPLAINT: Complainant alleges Subject violated Section 458.331(1)(g), Florida Statutes, by failing to perform any statutory or legal obligation placed upon a licensed physician.

THE FACTS: On or about March 25, 2010, the Department of Health Investigative Services Unit initiated a complaint against Subject.

The Subject operates an opioid detoxification clinic in Jacksonville, where he routinely dispenses Suboxone and Subutex (both Schedule V opioid withdrawal medications) to his patients as needed. In addition, Subject contracted with Physician's Choice Dispensing Services (PCDS) to manage an onsite pharmacy as a service to his patients.

An Administrative Complaint was filed on September 10, 2010, alleging that Subject violated Rule 64B16-28.140(3), Florida Administrative Code (2006-2009), which requires pharmacies to maintain records each time a prescription drug order is filled, including but not limited to, the date, patient name, practitioner's name, and the name and strength of the drug; Section 893.07, Florida Statutes (2006-2009), which requires each person who dispenses a controlled substance to maintain "a complete and accurate record of each substance ... received, sold, delivered, or otherwise disposed of by him"; and Rule 64F-12.012(3), Florida Administrative Code (FAC), which requires each person who receives a prescription drug from a wholesale distributor to maintain "pedigree papers," which include information such as the name of the drug, dosage form, strength, quantity, and the name and address of each owner of the prescription drug.

The panel should dismiss the allegations that Subject violated Section 893.07, Florida Statutes, and Rule 64B16-28.140(3), FAC. Subsequent to the filing of the Administrative Complaint, Subject provided the Department with dispensing logs detailing the Suboxone and Subutex that he provided to patients. The records contain identification of the lot number of the medications, the patient to whom the medications were dispensed, the date, and amount dispensed.

In addition, the panel should dismiss the allegations alleging Subject's failure to maintain pedigree papers under Rule 64F-12.012(3), FAC. As noted above, Subject contracted PCDS to manage the onsite pharmacy. However, a dispute arose between Subject and PCDS, at which time PCDS "removed all software from the pharmacy computer, and therefore, no information is available on the computer and no pedigree records are able to be retrieved." As a result of PCDS removing the pedigree papers, Subject does not have any of the pedigree papers and is unable to resell the medications.

Based on the foregoing facts and circumstances, it would be proper and in the public's best interest for the Panel to dismiss the complaint.

THE LAW: Based on the foregoing, and pursuant to Section 456.073(4), Florida Statutes, the complaint should be dismissed.

It is, therefore, ORDERED that this matter should be and the same is hereby DISMISSED.

DONE AND ORDERED this 9 day of September, 2011.

Leon Orr

Chair, Probable Cause Panel
Board of Medicine

PCP Date: September 9, 2011
PCP Members: Leon, Orr

A-02

**STATE OF FLORIDA
DEPARTMENT OF HEALTH**

DEPARTMENT OF HEALTH,

PETITIONER,

v.

CASE NO.: 2010-05671

MOHAMED O. SALEH, M.D.,

RESPONDENT.

_____ /

ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health, by and through its undersigned counsel, and files this Administrative Complaint before the Board of Medicine against the Respondent, Mohamed O. Saleh, M.D., and in support thereof alleges:

1. Petitioner is the state department charged with regulating the practice of medicine pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 458, Florida Statutes.

2. At all times material to this Complaint, Respondent was a licensed physician within the State of Florida, having been issued license number ME 43827.

3. Respondent's address of record is 1408 San Marco Boulevard, Jacksonville, Florida, 32207.

4. Respondent describes himself as a physician who assists in the detoxification and rehabilitation of patients who have opiate dependencies.

5. Between February 26, 2007, and October 28, 2009, Respondent purchased a total of 47 bottles (1410 tablets) of controlled substances Subutex and Suboxone from The Apothecary at Memorial, a retail pharmacy wholesaler.

6. Subutex is a brand of buprenorphine, which is a Schedule V controlled substance commonly prescribed to treat opioid dependence. According to Section 893.03(5), Florida Statutes, buprenorphine is a Schedule V controlled substance that has a low potential for abuse relative to the substances in Schedule IV and has a currently accepted medical use in treatment in the United States. Abuse of buprenorphine may lead to limited physical or psychological dependence relative to the substances in Schedule IV.

7. Suboxone is a brand of buprenorphine, which is a Schedule V controlled substance commonly prescribed to treat opioid dependence. According to Section 893.03(5), Florida Statutes, buprenorphine is a

Schedule V controlled substance that has a low potential for abuse relative to the substances in Schedule IV and has a currently accepted medical use in treatment in the United States. Abuse of buprenorphine may lead to limited physical or psychological dependence relative to the substances in Schedule IV.

8. Respondent stated that he prescribed and dispensed Subutex and Suboxone to his patients as part of his "detox' routine" but that "[n]o patients were charged for the medications." Additionally, Respondent stated that he "[o]ccasionally" will "fill a prescription at no charge to indigent patients."

9. Respondent failed to maintain records documenting the purchase 47 bottles of Subutex and Suboxone, and failed to maintain records documenting the dispensing of any of the Subutex and Suboxone tablets.

10. In his response to the Uniform Complaint, Respondent stated that he had previously contracted with Physician's Choice Dispensing Services (PCDS) to manage and onsite pharmacy as a service to his patients. However, after a dispute arose between Respondent and PCDS, and PCDS "removed all software from the pharmacy computer, and

therefore, no information is available on the computer and no pedigree records are able to be retrieved.”

11. Section 458.331(1)(g), Florida Statutes (2006-2009), allows the Board of Medicine to impose discipline against a licensee for failing to perform any statutory or legal obligation placed upon a licensed physician.

12. Section 465.0276(2)(b), Florida Statutes (2006-2009), requires all practitioners who dispense medications for a fee or remuneration of any kind, whether direct or indirect, to comply with all rules and laws applicable to pharmacies, including Chapters 499 and 893, Florida Statutes.

13. Rule 64B16-28.140(3), Florida Administrative Code (2006-2009), requires the maintenance of records each time a prescription drug order is filled. Such records require specific information including, but not limited to, the date, patient name, practitioner’s name, and the name and strength of the drug.

14. Similarly, Section 893.07, Florida Statutes (2006-2009), requires each person who dispenses a controlled substance to maintain “a complete and accurate record of each substance ... received, sold, delivered, or otherwise disposed of by him. ...”

15. Finally, Rule 64F-12.012(3), Florida Administrative Code (2006-2009), requires each person who receives a prescription drug from a wholesale distributor to maintain "pedigree papers," which include information such as the name of the drug, dosage form, strength, quantity, and the name and address of each owner of the prescription drug.

16. Respondent is a dispensing practitioner who administered Subutex and Suboxone to patients as part of the "'detox' routine" in the course of his medical practice and realized indirect remuneration from the dispensing of Subutex and Suboxone.

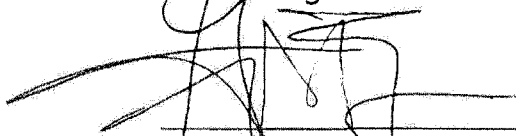
17. Respondent failed to maintain adequate records of the 47 Subutex and Suboxone bottles he purchased and failed to maintain adequate records of the Subutex and Suboxone tablets he dispensed between February 26, 2007, and October 28, 2009, in violation of Sections 465.0276(2)(b) and 893.07, Florida Statutes (2006-2009), and Rules 64B16-28.140(3) and 64F-12.012(3), Florida Administrative Code (2006-2009).

18. Based on the foregoing, Respondent has violated Section 458.331(1)(g), Florida Statutes (2006-2009), by failing to perform any statutory or legal obligation placed upon a licensed physician.

WHEREFORE, the Petitioner respectfully requests that the Board of Medicine enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of the Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 10th day of September, 2010.

Ana M. Viamonte Ros, M.D., M.P.H.
State Surgeon General



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DATE 9-10-10

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PCP Date: September 10. 2010
PCP Members: Leon, Thomas

DOH vs. MOHAMED O. SALEH, M.D. Case No.: 2010-05671

DOH vs. MOHAMED O. SALEH, M.D.

Case No.: 2010-05671

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition any other discipline imposed.