STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

RHODE ISLAND DEPARTMENT OF HEALTH,
MICHAEL FINE, M.D., IN HIS CAPACITY
AS DIRECTOR OF THE RHODE ISLAND
DEPARTMENT OF HEALTH

In the matter of:
Frank Paletta, M.D., D.M.D.
Physician License Number MD10576
Dentist License Number DEN02741
Controlled Substances Registration
Number CDEN02741
Anesthesia Permit DAGD02741

Complaint Numbers C13-DEN018
and C13-234

AMENDED IMMEDIATE COMPLIANCE ORDER

Frank Paletta, M.D., D.M.D. (hereinafter "Respondent") is licensed as a physician and as a dentist in Rhode Island and is licensed to prescribe controlled substances under Rhode Island General Laws chapter 21-28, having both a state Controlled Substances Registration and a Federal Drug Enforcement Administration Registration to prescribe controlled substances. After a review of the complaint, records, and information obtained from inspectors, the Director of the Department of Health makes the following:

FINDINGS OF FACT

1. Frank Paletta, M.D., D.M.D. (herineafter "Respondent") has been a licensed physician in Rhode Island since May 9, 2001, and has been licensed as a dentist in this state since May 6, 2001. His practice is located at 243 Jefferson Boulevard,

Warwick, Rhode Island. He is a graduate of the University of Connecticut School of Medicine, and the University of Pittsburgh School of Dental Medicine. He has privileges at Miriam, Rhode Island and Kent County Hospitals.

2. On April 5, 2013, in response to a complaint filed with the Department of Health, inspectors for the Rhode Island Board of Dental Examiners visited Respondent's office; and the office was revisited on April 9, 2013.

3. Respondent is the dentist and physician in his practice who is licensed with the United States Drug Enforcement Agency to order and receive controlled substances. During the April 5, 2013, inspection, Respondent was unable to produce all of the United States Drug Enforcement Agency forms for a two year period that document the ordering of controlled substances. The forms that were observed were filled out incorrectly.

4. Respondent purchases medications from three companies that are not licensed in Rhode Island to distribute pharmaceuticals: Drug Valet and Medical Purchasing Solutions, both based in Arizona, and Oral Surgery Supplies, based in Georgia.

5. During the April 5, 2013, inspection, the controlled substances log listed 74 vials of Midazolam in the office inventory as of April 2, 2013, but only 45 vials were counted by inspectors on April 5. During the April 9, 2013, inspection, Midazolam was located in second area of the office.

6. During the April 5, 2013, visit, Department dental inspectors learned that Respondent directs an assistant to pour medications from ten milliliter vials into

separate syringes for use in surgery with different patients either that day or within "a couple of days," and the vials are then labeled with the name of the medication but not the name of the patient to whom it shall be administered. As such, the medications are misbranded. The assistant told Department inspectors that the medications in the syringes are not always checked by Respondent. The assistant stated that he administers drugs intravenously.

7. During the April 5, 2013, inspection, the cabinet in Respondent's office that contains controlled substances was observed to have a lock on the door, but the unlocked side of the cabinet allows any person to have access to the medications, and the back door to the office was left ajar, allowing access by any person to those medications. Inside the cabinet, inspectors found vials of personal medication, and multiple filled syringes for use in later surgery. A lock box in the cabinet contained Schedule II substances, but the lock box could have been removed from the cabinet by unauthorized individuals and taken from the office.

8. During the April 5, 2013, inspection, the refrigerator contained non-controlled medications along with food and beverages, and the refrigerator did not contain a thermometer. During the April 9, 2013, inspection, inspectors observed that ice had built up in the small refrigerator that contained medication, and one package of sterile irrigation fluid had frozen solid. An indoor/outdoor thermometer was observed at that time, but no alarm was seen that would indicate when stored medication had been exposed to excursions.

9. During the April 9, 2013, inspection, inspectors observed an IV bag containing clear liquid that was marked as containing Brevital, a controlled substance used for anesthesia. The mixture was not labeled properly and listed no expiration date. It was compounded in the office without sterile hood by a person who was not licensed to do so. The manufacturer of Brevital requires immediate use of the drug upon opening, and then destruction of the drug within 24 hours. This plastic bag was dated April 8, 2013, indicating either a failure to destroy in a timely manner or intent to reuse.
10. During the April 5 and April 9, 2013, visits, inspectors observed that Respondent did not maintain a biennial controlled-substances inventory, consistent administrative logs or waste logs.
11. Respondent's records indicated that he transferred Schedule II, III, and IV controlled substances to and from another facility operated by Respondent in Massachusetts without keeping the required documentation.
12. Respondent is in civil violation of Rhode Island General Laws §§ 21-28-3.04 and 21-31-3, and § 5-37-5.1(19) and (26), and § 5-31.1-10(19) and (26) for failure to adhere to minimum standards of acceptable practice and for violation of state laws concerning standards of practice and administration of controlled substances.
13. Nothing herein shall be construed as an admission by Respondent as to the facts contained herein.

ORDER

1. The Immediate Compliance Order issued to Respondent on April 12, 2013, is hereby vacated.

2. Because the Department of Health has re-inspected Respondent's office since April 12, 2013, and has determined that the violations hereinbefore mentioned have been corrected in accordance with controlled substances statutes and regulations, Respondent's office may re-open and continue to remain open.

3. Respondent may continue to practice medicine and dentistry, and to prescribe and administer controlled substances.

4. Respondent has instituted and shall continue to maintain improved security and recordkeeping protocols with regard to his maintenance of controlled substances in his practice; and Respondent has created a single inventory log for each controlled substance that describes the precise quantity of each drug obtained by the practice and administered to any patient, which is also contained in each patient's individual medical or dental record.

5. Respondent has developed and shall follow a new policy and procedure for the direct administration of medication that does not involve pre-pouring or pre-filling syringes from another source until further order.

6. Respondent has obtained a temperature-sensitive alarm that reveals any excursions in the office refrigerator used to store medication, and shall ensure its continued operation.

7. Respondent shall not, and shall not allow anyone in his practice to:

   a. prescribe or administer any drug that is purchased from any distributor not registered with the State of Rhode Island;

   b. administer any medication intravenously unless the person is licensed to do so;

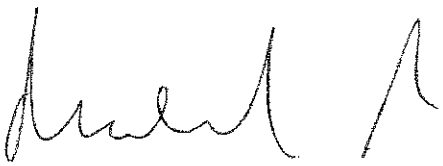
   c. compound any drug unless approved beforehand in writing by the Department of Health. The term "compound" shall not include sterile reconstitution of any drug for immediate single use for one patient, the remainder of which is discarded according to manufacturer guidelines.

   d. use on more than one patient any drug that is listed by its manufacturer as "single use."

   e. keep food or beverages in the same refrigerator as any medications stored for office use; or

   f. use any drug that is expired or that is not labeled with an expiration date.

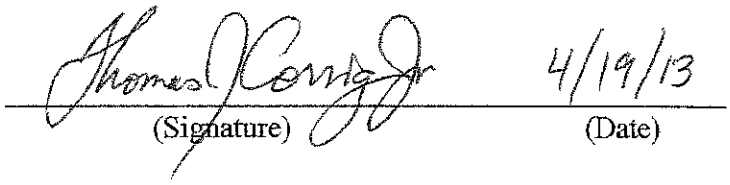
Signed this 19 day of April, 2013.



Michael Fine, MD
Director of the
Department of Health

CERTIFICATION OF SERVICE

A copy of this Amended Immediate Compliance Order was delivered to Frank Paletta, M.D., D.M.D., 243 Jefferson Boulevard, Warwick, Rhode Island, and to his attorney, Jennifer Cervenka, Esquire, Partridge Snow & Hahn, LLP, 180 South Main Street, Providence, Rhode Island, by the undersigned on April 19, 2013, who herein documents delivery and receipt of this order.



(Signature) (Date)

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IMMEDIATE COMPLIANCE ORDER

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8. During the April 9, 2013, inspection, inspectors observed in a refrigerator a package of single-use Botox (not a controlled substance) that was opened and had several punctures in the cover. Storage of the drug with other unopened products is indicative of intent to reuse the product. The manufacturer labeled the product with instructions to discard after 24 hours of reconstitution.
9. During the April 9, 2013, inspection, inspectors observed an IV bag containing clear liquid that was marked as containing Brevital, a controlled substance used for anesthesia. The mixture was not labeled properly and listed no expiration date. It was compounded in the office without sterile hood by a person who was not licensed to do so. The manufacturer of Brevital requires immediate use of the drug upon opening, and then destruction of the drug within 24 hours. This plastic bag was dated April 8, 2013, indicating either a failure to destroy in a timely manner or intent to reuse.
10. During the April 5 and April 9, 2013, visits, inspectors observed that Respondent did not maintain a biennial controlled-substances inventory, consistent administrative logs or waste logs.
11. Respondent's records indicated that he transferred Schedule II, III, and IV controlled substances to and from another facility operated by Respondent in Massachusetts without keeping the required documentation.
12. Respondent is in civil violation of Rhode Island General Laws §§ 21-28-3.04 and

21-31-3, and § 5-37-5.1(19) and (26), and § 5-31.1-10(19) and (26) for failure to adhere to minimum standards of acceptable practice and for violation of state laws concerning standards of practice and administration of controlled substances.

13. The public health, safety, or welfare imperatively requires emergency action, and the continuation of the Respondent's practice without remediation and re-inspection would constitute an immediate danger to the public, pursuant to R.I. Gen. Laws § 42-35-14(c), §§ 5-37-8 and 5-31.1-19, and §§ 21-28-3.04 and 21-31-3.

ORDER

1. Based on the foregoing, the Director of the Department of Health has determined that the continuation of the practice of Frank Paletta, M.D., D.M.D., without remediation and re-inspection constitutes an immediate threat to the health, welfare and safety of the public.

2. Accordingly, Respondent shall close his office in Rhode Island until such time that the Department of Health re-inspects the office to ensure compliance with controlled substances laws, and then approves the re-opening of Respondent's office.

3. Respondent may continue to practice medicine and dentistry, and to prescribe controlled substances, but prior to and upon the Department of Health allowing the

re-opening of his Rhode Island office, Respondent shall institute and maintain improved security and recordkeeping protocols with regard to his maintenance of controlled substances in his practice.

4. Respondent shall develop new policies and procedures for the direct administration of medication that do not involve pre-pouring or pre-filling syringes.

5. Respondent shall ensure continued operation of a temperature-sensitive alarm that reveals any excursions in the office refrigerator used to store medication.

6. Respondent shall not, and shall not allow anyone in his practice to:

    a. prescribe or administer any drug that is purchased from an unlicensed distributor;

    b. administer any medication intravenously unless the person is licensed to do so, which thus excludes any dental hygienist, dental assistant or emergency medical technician from administering medications intravenously;

    c. purchase any drug from an unlicensed distributor;

    d. compound any drugs unless approved in writing by the Department of Health;

    e. use any misbranded drug;

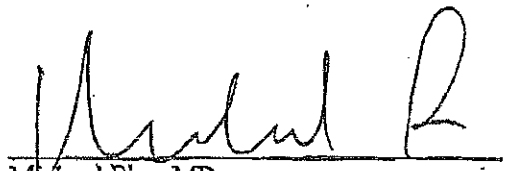
f. keep food or beverages in the same refrigerator as any medications stored for office use;

g. use any drug that is expired or that is not labeled with an expiration date;

h. pre-pour or prefill any syringes;

i. reuse any drug that is listed by its manufacturer as "single use."

Signed this 12 day of April, 2013.



Michael Fine, MD
Director of the
Department of Health

CERTIFICATION OF SERVICE

A copy of this Immediate Compliance Order was hand-delivered to Frank Patella, M.D., D.M.D., 243 Jefferson Boulevard, Warwick, Rhode Island, by the undersigned on April 12, 2013, who herein documents delivery and receipt of this order.

(Signature) (Date)

f. keep food or beverages in the same refrigerator as any medications stored for office use;

g. use any drug that is expired or that is not labeled with an expiration date;

h. pre-pour or prefill any syringes;

i. reuse any drug that is listed by its manufacturer as "single use."

Signed this 12 day of April, 2013.

Michael Fine, MD
Director of the
Department of Health

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A copy of this Immediate Compliance Order was hand-delivered to Frank Patella, M.D., D.M.D., 243 Jefferson Boulevard, Warwick, Rhode Island, by the undersigned on April 12, 2013, who herein documents delivery and receipt of this order.

Paul Spera 4/12/13
(Signature) (Date)
Deputy Sheriff