State of Rhode Island
Department of Health
Board of Medical Licensure and Discipline

IN THE MATTER OF:
Stephen Petteruti, DO
License No.: DO 00413
Complaint No.: C19-0717 and C19-0776

SUMMARY SUSPENSION

The Rhode Island Board of Medical Licensure and Discipline ("Board") has reviewed and investigated the above-referenced complaints pertaining to Dr. Stephen Petteruti ("Respondent") through its Investigative Committee and the Office of the Director ("Director") of the Rhode Island Department of Health ("RIDOH"). Respondent has been a licensed physician in the State of Rhode Island since July 26, 1991. His primary specialty is Family Practice. His practice is located at 250 Centerville Road, Building E, Warwick, RI 02886.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. The Board received a complaint, C19-0717, from the spouse of Patient A (alias) ("Complainant"), relative to Respondent's care of Patient A. The Complainant stated that treated Patient A's pain with excessive and increasing doses of opioid medication, but that, after transferring care to a new physician, Patient A was successfully able to wean down these medications. Complainant had other concerns about Respondent's care of Patient A, as well.

2. Respondent was the attending physician and primary care provider for Patient A.

3. The Board reviewed the medical record for Patient A, supplied by Respondent. At his

last visit with Respondent, Patient A was 51 years old and was treated for several medical problems.

4. According to his medical record, Patient A reported having back pain, first noted in 2009. The record reflects that, to facilitate the management of Patient A's pain, Respondent prescribed various opioid medications, including oxycodone of varying strengths, multiple times over the course of Respondent's care of Patient A. The record reflects that Respondent referred Patient A to physical therapy and prescribed muscle relaxants, including cyclobenzaprine, as well.

5. The Investigative Committee, pursuant to its review of Patient A's medical record, noted that, although Patient A reported back pain, and Respondent made the above-stated efforts to manage such pain, Respondent never adequately examined Patient A's back over the course of his care. Nor did Respondent conduct a neurological exam. The Investigative Committee could not find a single progress note in Patient A's medical record that met the standard of care relative to documentation of the care and management of a patient with chronic or acute back pain. At several visits, including those of January 22, 2009, November 4 and 12, 2009, February 12, 2010, March 24, 2010, May 10, 2010, June 22, 2010, and July 21, 2010, and visits throughout 2011, Patient A's back was never adequately examined, yet opioid medications, including OxyContin, were prescribed or increased. The medical record does not reflect that a neurological exam was ever performed.

6. It was not evident from the medical record how Patient A had come to have back pain, as the History of Present Illness was often brief and lacked sufficient detail. The medical records consistently lacked justification for the course of treatment and there was no evidence of medical decision making by Respondent in the care given to Patient A.

7. The Investigative Committee noted that Patient A's weight was not recorded at any point

in the medical record, but that, periodically, there was a measurement of Body Mass Index (BMI). At his August 28, 2019 appearance before the Investigative Committee, Respondent explained that his medical record vendor had changed and that the patient's weight had not carried over in the conversion of his medical records. In Respondent's written response to the complaint C19-0717, Respondent noted that Patient A had an elevated BMI and that it increased over time to the point that it became the dominant medical issue by January 2011. Despite this representation, it was noted by the Investigative Committee that the medical record does not reflect Respondent has having ever diagnosed Patient A with obesity.

8. Even though the medical record reflects that back pain was described as the dominant issue in the History of Present Illness at Patient A's January 24, 2011 office visit, Respondent did not examine Patient A's back or conduct a neurological exam. On the other hand, Respondent refilled Patient A's prescription for OxyContin, 40 mg three times a day, at that visit. In his written response to the Board Respondent stated, *"Patient A's BMI has increased to 42.5 [from 37-38 prior to that injury]. His smoking has also increased to one pack per day. Our discussion focused on smoking cessation and weight loss."* Based on its review of the medical record, the Investigative Committee determined that, although Patient A was morbidly obese, having a BMI greater than 40 (and as high as 46 at one point), there was no documentation in the medical record of Patient A being obese. Contrary to Respondent's representation in his written response, there was also no documentation of Patient A's weight being a health concern or that it needed to be addressed. There was no documentation that Respondent had ever discussed Patient A's nutritional intake or exercise. At his August 28, 2019 appearance before the Investigative Committee, Respondent claimed that his practice was one of the leading weight loss centers in the country and, separately, stated that brief conversations about weight loss were

not effective. Respondent nevertheless stated that he provides the "*highest level of what we do nationwide and if we can't help them, we refer them to bariatric surgery, which is unusual.*"

9. The Investigative Committee noted Patient A had morbid obesity, which is an important and serious chronic disease. The minimum standard of care is to diagnose and treat this chronic disease, about which Respondent claimed to be an expert in his August 28, 2019 appearance, but that was not done by Respondent.

10. According to the medical record, at a November 4, 2010 office visit, Patient A presented with a concern noted by Respondent as follows: "*right leg swollen? clot. Nurse came few days ago and did us on his leg and that really hurt him.*" The physical exam documented at that visit included only Patient A's height. No other vital signs were recorded. The exam, in its entirety, was documented as follows: "*right lower extremity has diffuse interstitial edema. Pulses are excellent.*" The assessment was "*edema and the plan was swollen right leg- Lasix 40 mg daily. Obtain femoral renal ultrasound.*" The Investigative Committee concluded that Patient A's concerns that day could have represented a serious health concern; Patient A was on anticoagulants and at risk for a blood clot or pulmonary embolus. Patient A was not evaluated appropriately. The Investigative Committee concluded that this progress note and evaluation did not meet the minimum standard of care.

11. At May 27, 2011 office visit, Respondent documented that Patient A reported "*some symptoms of unsteadiness.*" The medical record includes no evidence of a physical exam of any type that day. Documented vital signs do not include orthostatic blood pressure measurements. According to the medical record, there was really no diagnostic pursuit of the reported problem. The Assessment and Plan did not address unsteadiness. The Investigative Committee noted Patient A had an important health concern that day, i.e., "unsteadiness," which condition could

have many different causes. The minimum standard of care includes a history to understand why the patient is unsteady, and assess his risk of falling, and an appropriate physical exam and a plan to address the patient's problem. The Investigative Committee concluded Respondent did not meet the minimum standard of care regarding evaluation and management of Patient A's reported condition at that visit.

12. Patient A presented to Respondent on June 9, 2011, the note for which visit states, *"[C]ontinues to have significant pain in his back and down her(sic) right leg."* The only documentation of a physical exam at that visit includes the phrase "cardiovascular-regular rate and rhythm." The medical record includes no evidence of an exam of Patient A's back, spine, or musculoskeletal system, or of a neurological exam. The progress note did not include a diagnosis of back pain or an explanation of Patient A's back pain. The Plan stated only, *"[C]hronic pain – continue Oxycontin 4mg (sic) 3 times a day, hydromorphone 4 mg as needed for breakthrough."*

13. Patient A visited Respondent in his office June 22, 2011, at which visit Respondent noted of Patient A: *"[A]lso has a very bad burn on his leg from his lap top. He states he has no feeling in his leg. It looks like it has gotten red around the wound....He has a diminished sense of pain in his right lower extremity."* The documented vital signs at that visit include only height and BMI. There is no temperature. The physical exam, in its entirety, includes only: "*cardiovascular-regular rate and rhythm, erythematous wound on the right lower extremity with a 1 cm eschar in the middle-ye (sic)."* The Assessment for this visit included: *"DVT/EMB lower extremity, Coumadin drug monitoring, CAD, Cellulitis of leg."* Respondent prescribed three separate antibiotics: clindamycin, Cipro, and Bactroban. The Investigative Committee concluded that the evaluation of Patient A did not meet the minimum standard of care at that

visit. Patient A may have had a burn—even a third degree burn—yet the History, physical and diagnostic pursuit was lacking. Patient A returned on June 11, 2011, two days later, at which visit it is still not evident which leg is affected. There are no vital signs other than height. The exam, in its entirety, includes only: *"[T]he wound appears improved. Sequential photographs have been taken in order to track its progress."* At that visit, Respondent prescribed Patient A a fourth antibiotic, Augmentin, with no justification or explanation. The medical record did not contain even the most basic elements of competent care for these two visits. At Patient A's subsequent July 21, 2011 office visit, the first reference is made to the burn being better.

14. The Investigative Committee concluded after reviewing the medical record that the medical records, as a whole, are often missing the most basic elements of a meaningful History, or Review of Systems, or physical exam. There is no evidence of medical decision-making, nor justification of the course of treatment. Significant diagnoses, like morbid obesity, are absent from the medical record. There is no documentation for treatment of weight loss. The pain management is approached very simplistically. There is no pain agreement. There is no evidence the patient ever was advised abut he potential for dependence or side effects or the additional risk of adding benzodiazepines.

15. With respect to complaint C19-0717, the Investigative Committee concluded that Respondent violated R.I. Gen. Laws § 5-37-5.1(19), which defines "unprofessional conduct" as including *"[i]ncompetent, negligent, or willful misconduct in the practice of medicine which includes the rendering of medically unnecessary services, and any departure from, or the failure to conform to, the minimal standards of acceptable and prevailing medical practice in his or her area of expertise as is determined by the board.*

16. Additionally, the Investigative Committee concluded that Respondent violated the Rules

and Regulations for Licensure and Discipline of Physicians, 216-RICR-40-05-1.5.12(D), regarding medical records, which provides: *"Medical records shall be legible and contain the identity of the physician or physician extender and supervising physician by name and professional title who is responsible for rendering, ordering, supervising or billing each diagnostic or treatment procedure. The records must contain sufficient information to justify the course of treatment, including, but not limited to: active problem and medication lists; patient histories; examination results; test results; records of drugs prescribed, dispensed, or administered; and reports of consultations and hospitalizations."*

17. The Board received a second complaint, C19-0776, from the Board of Pharmacy, which complaint was based on a review of the Prescription Drug Monitoring Program (PDMP), prompted by the allegations of excessive prescribing of opioid medications reported in C19-0717. The Board of Pharmacy investigator ("Investigator"), who is a licensed pharmacist, was concerned about the prevalence of Respondent's prescribing both phentermine and phendimetrazine to his patients, identifying 34 patients since June 2017 who were prescribed both for periods of 3 months or longer. The concern of danger to patients is based on the prolonged use of each of these drugs, that these drugs are prescribed in combination, and that the combination is contraindicated. Included in the complaint was information from drugs.com, which is an online pharmaceutical encyclopedia that provides drug information for consumers and health-care professionals, indicating that this combination is contraindicated and considered a "major drug interaction," defined as *"Highly clinically significant. Avoid combinations; the risks of the interaction outweigh the benefit."* The complaint, in its entirety, states, *"Dr. Petteruti has been prescribing a dangerous drug combination for his patients to help with weight loss. He is using a combination of phentermine and phendimetrazine. Both medications carry a*

warning about using the medication with another anorexic agent. This combination has not been approved to be used together for weight loss."

18. The Board issued a subpoena and received from Respondent the most recent two years of medical records for the 34 patients identified as having been prescribed the combination of phentermine and phendimetrazine for 3 months or longer.

19. Respondent was the attending physician for Patients 1-34.

20. The Board reviewed the package insert for phentermine approved by the Food and Drug Administration (FDA). The package insert lists several contraindications for the prescribing of phentermine: "1. *History of cardiovascular disease (e.g., coronary artery disease, stroke, arrythmias, congestive heart failure, uncontrolled hypertension. 2. Coadministration with other drugs for weight loss is not recommended (safety and efficacy of combination not established. 3. Rare cases of primary pulmonary hypertension have been reported. Phentermine should be discontinued in case of new, unexplained symptoms of dyspnea, angina pectoris, syncope or lower extremity edema."*

21. The Board reviewed the package insert for phendimetrazine, also approved by the FDA. The package insert indicates several contraindications for the prescribing of phendimetrazine, including: "*History of cardiovascular disease (e.g., coronary artery disease, stroke arrythmias, congestive heart failure, uncontrolled hypertension, pulmonary hypertension).*" Additionally: "*Use in combination with other anorectic agents or CNS stimulants*" is also contraindicated. An additional warning in the package insert states, "*Phendimetrazine tartrate should not be used in combination with other anorectic agents, including prescribed drugs, over-the-counter preparations and herbal products. In a case-control epidemiological study, the use of anorectic agents, including phendimetrazine tartrate, was associated with an increased risk of developing*

pulmonary hypertension, a rare, but often fatal disorder. The use of anorectic agents for longer than three months was associated with a 23-fold increase in the risk of developing pulmonary hypertension. Increased risk of pulmonary hypertension with repeated courses of therapy cannot be excluded. The onset or aggravation of exertional dyspnea, or unexplained symptoms of angina pectoris, syncope, or lower extremity edema suggest the possibility of occurrence of pulmonary hypertension. Under these circumstances, phendimetrazine tartrate should be immediately discontinued, and the patient should be evaluated for the possible presence of pulmonary hypertension. Valvular heart disease associated with the use of some anorectic agents such as fenfluramine and dexfenfluramine has been reported. Possible contributing factors include use for extended periods of time, higher than recommended dose, and/or use in combination with other anorectic drugs."

22. Some, but not all, of the medical records supplied by Respondent contained a consent form titled "*Informed consent for the use of Phentermine (Adipex) or Phendimetrazine (Bontril).*" The Investigative Committee noted that the consent form was for **either** drug, but not for both drugs, to be used in the same patient. Those records that did not include this consent form—those for Patients 2,4,6,7,10,11,16,20,22, and 30—did not include any consent form.

23. At his August 28, 2019 appearance before the Investigative Committee, Respondent declared that he does not advocate taking phentermine and phendimetrazine at the same time, stating "*That would be reckless.*" Rather, he stated, because of the short half-life of the drugs, he advises patients to take them separately, at different times of the day. The Investigative Committee noted that there is no documentation in the medical record that Respondent warns patients that taking both medications at the same time would be "reckless" or dangerous. The above-referenced consent form includes no such information. The expert retained by the Board

was advised of Respondent's explanation relative to the timing of the medications and rejected Respondent's claim relative to the safety of prescribing these drugs in combination, albeit split over the day.

24. The above-mentioned consent form includes a section about "Off Label" use, which includes the following language: *"This is a schedule IV-controlled substance. It is so designated due to its structural similarity to amphetamines. In our experience, we have never seen addiction or withdrawal symptoms occur while using this agent."* First, it must be noted that the consent form does not identify which, if not both, of the drugs listed are schedule-IV controlled substances. In fact, phendimetrazine is actually a Schedule III controlled substance. The consent form does contemplate both drugs being used at the same time.

25. An additional phrase in the consent form states, *"There is a rare condition known as 'Primary Pulmonary Hypertension' (PPH) that has been associated with some weight loss medications including Phentermine. This condition is characterized by irreversible stiffening of the lung tissue that leads to permanent shortness of breath. The studies that have shown this association have not proven that the medications cause this condition. We at Intellectual Medicine 120 do not believe that the medication cause PPH and to date no one in our practice has had this diagnosis. However, we want you to be aware of any possible concerns regarding your treatment."*

26. The Investigative Committee reviewed the consent form and concluded it was significantly inaccurate and misleading in multiple areas. The form is for a singular medication, yet these 34 patients were receiving both medications and the consent form does not address or even disclose the risk of both medications taken together. In fact, the form does not fully address the associated risks of taking either drug separately. Respondent, in his August 28, 2019

appearance before the Investigative Committee, explained his not addressing even those risks as his substituting his experienced judgment so as not to "stigmatize the drugs." The form inaccurately describes "this" drug as a schedule-IV controlled substance, when one of the drugs is actually schedule-III, and, moreover, the form inaccurately explains why the drugs are scheduled controlled substances. drug. The consent form also inaccurately describes Primary Pulmonary Hypertension, which is not a stiffening of the lung tissue, but is an irreversible, fatal condition. The consent form also does not disclose that Primary Pulmonary Hypertension is a fatal complication, nor does the consent form indicate that the combination of these medications is, at all, contraindicated. The consent form does not explain that the risk of these life threatening complications increases the longer the patient is on the medications. The consent form also does not disclose that there are other contraindications, such as history of cardiovascular disease (e.g., coronary artery disease, stroke, arrythmias, congestive heart failure, or uncontrolled hypertension.) The consent form goes further and mistakenly presents the risk to the patient as minimal or non-existent, yet the actual risks to the patient are potentially fatal.

27. The Board retained an expert in weight management to review the medical records and offer his expert medical opinion on this matter. The expert reported that he never prescribes this combination of medications and it is not the standard of care to prescribe this combination of medications for weight loss or for any reason because of the well-known risks. He also opined that this combination of drugs is dangerous and sets patients up for a rare yet avoidable life-threatening complication. The expert based his clinical experience, his knowledge of and review of the package inserts, and his clinical determination that the danger to the patients posed by this combination, for any duration, is not worth the risk.

28. Pursuant to his review of the records, the expert also noted that patients' doses are often

increased based on phone visits and that, despite contraindications and known risks, there is no assessment of blood pressure at those visits. The expert noted that, overall, even for patients seen by Respondent for visits, blood pressures are not checked at every visit.

29. Based on the foregoing, on C19-0776, the Investigative Committee concluded that Respondent violated R.I. Gen. Laws § 5-37-5.1(19).

30. The Investigative Committee reviewed the medical records and noted that there was a templated section in each medical record for *Patient Goals*, but that no patient had weight loss goals documented in the medical records, nor was there documentation of any patients who had dietary histories or evaluation of their exercise habits at initial intake or in an ongoing manner.

31. At his August 28, 2019 appearance before the Investigative Committee, Respondent stated that his practice was "one of the leading weight loss centers in the country" and that "brief conversations about weight loss were not effective." He stated that he did hold group sessions, but the medical record contained no documentation about these group sessions and did not include a description of what was discussed with the patients.

32. The Investigative Committee noted that there were several patients who gained weight even though they were prescribed both drugs for long periods, even years. Patients 6, 8, 11, 13, 14, 17, and 18 are examples of patients who gained weight while taking both drugs. Notwithstanding this weight gain, there was no documentation about whether this was a concern or consideration of whether a change in plan or continued usage of this combination of drugs was in the patient's best interest. Respondent did not exhibit a pattern of discontinuing the medication when there was weight gain, nor review with the patient alternative treatments or discuss the ongoing risks to the patients.

33. Various patients had pre-existing issues with hypertension, heart disease or other vascular

issues, yet were still prescribed this combination of medications. Patients 1, 3, 13, 14 and 20 are examples of patients with such issues to whom the record reveals the additional risk and contraindication were not disclosed. Patient 1 had syncope, yet had no ECG was performed and there was no discussion of stopping the medications for weight loss. Patient 3 was on losartan and, although his blood pressure was elevated at several visits, the losartan dosage was not adjusted, nor was phentermine or phendimetrazine discontinued. Additionally, the medical record reveals Patient 3 was rarely examined. Patient 13 had a prior myocardial infarction and cardiac stents, hyperlipidemia, atherosclerotic heart disease and erectile dysfunction. Patient 13 gained weight despite weight loss treatment. Nevertheless, phentermine and phendimetrazine were not discontinued. It was noted that, on July 30, 2019, Patient 13 weighed 177.6 lbs., with a BMI of 28.6 (overweight). Patient 13 was not even clinically obese, contrary to the medical record, making this dangerous combination of medications all the more inappropriate. Patient 14 had a pre-existing diagnosis of hypertension and had elevated blood pressure at each visit. On December 5, 2018, after a year of elevated blood pressures, and a final record blood pressure of 156/108, Patient 14 was started on lisinopril 10 mg. It was only at that time that Patient 14 was actually diagnosed by Respondent as having hypertension, although it was a known pre-existing condition. There was no mention in the medical record of the warning from the phentermine package insert *"use in caution in patients with even mild hypertension (risk of increase blood pressure)."* Patient 20 is an example of a patient who had elevated blood pressure—158/84 on September 6, 2018—but this elevated blood pressure is not addressed in the medical record.

34. The Investigative Committee noted that there were some patients who were actually obese, as evidenced by a BMI greater than 30, yet were not diagnosed with obesity, such as Patient 10.

35. The Investigative Committee noted that some patients taking phentermine and phendimetrazine were not clinically obese, including one who was not even overweight; Patient 12 had a BMI that varied from 20.9 (normal) to a peak of 29.7 (overweight), but was diagnosed as obese. Patient 13 was also just overweight (25<BMI<30), not obese. Patient 30 had a BMI of 23.4 (normal). At his August 28, 2019 appearance before the Investigative Committee, Respondent claimed that Patient 30 was obese in the past, but the medical record does not support this assertion, and there was never a diagnosis of this patient being overweight or obese.

36. Relative to C19-0776, the Investigative Committee noted that, overall, the medical records were difficult to follow, there was no evidence of medical decision making, nor justification for course of treatment, nor adequate differential diagnoses, nor adequate examinations of patients, nor adequate assessments of patient health-care concerns.

37. Additionally, the Investigative Committee concluded that Respondent violated R.I. Gen. Laws § 5-37-5.1(19).

38. Additionally, the Investigative Committee concluded Respondent violated the Rules and Regulations for Licensure and Discipline of Physicians, 216-RICR-40-05-1.5.12(D).

39. The Investigative Committee took note of the medical record of Patient 17, an adult male who was treated for other medical problems unrelated to his obesity. On February 11, 2019, Patient 17 was treated for a dog bite. The medical record does not record what party of his body suffered from the dog bite, nor does the physical exam, yet he was prescribed oxycodone/acetaminophen (an opioid) on February 6, 2019. It is not clear why Patient 17 was prescribed an opioid. The medical record does not reveal whether Patient 17 was assessed for risk of acquiring rabies from this dog bite, nor is there evidence that this dog bite was reported to RIDOH, as is required. Rabies is a viral infection that is not curable and Rabies vaccine, given

less than 10 days after exposure, is generally life saving. There is also a visit on November 15, 2018, also for a dog bite, which presumably represents a separate dog bite. The exam from that visit notes a submental puncture would of the lower mandible. Still, the record reveals no assessment or diagnosis of dog bite at that visit. There is no evidence to suggest that this patient was assessed for his risk of rabies, either, or that this dog bite was reported to RIDOH.

40. Additionally, Patient 17 was evaluated via a phone visit, only, on August 16, 2018, pursuant to which Respondent noted *"[H]aving hesitancy with urination. Some terminal dysuria."* There is no diagnosis associated with that phone visit, but Patient 17 was nevertheless prescribed azithromycin (an antibiotic) and Percocet (an opioid). It is not clear why either medication was prescribed.

41. The Investigative Committee determined that the minimum standard of care was not met in the care of Patient 17.

42. The Investigative Committee was concerned about the dangerous overlapping combinations of controlled substance prescribing, including opioids and benzodiazepines, of Patients 8 and 18.

43. Patient 8 was being treated for low back pain and pain in knee with Percocet (opioid), tramadol (opioid), alprazolam (benzodiazepine), cyclobenzaprine (muscle relaxant) and oral naltrexone (opioid antagonist). It is not clear from the medical record why this patient was prescribed this combination of medications. There is a notation in the medical record that "*patient is on opioid dosages that do not put him or her at high risk for overdose, there are no dangerous combinations.*" The Investigative Committee disagrees with this assessment since it is known in Rhode Island that there have been accidental overdose deaths from patients taking prescription opioids and benzodiazepines. Additionally, on August 31, 2016, the FDA

announced the requirement of a "Black Box" warning on the package insert of these medications, specifically regarding co-prescribing opioids and benzodiazepines due to the known risk of accidental overdose and death. It should be noted that, when asked by the Investigative Committee what the clinical indications are for prescribing a combination of opioid and benzodiazepine medications, Respondent stated, simply, "When you have a patient who is anxious and in pain."

44. Patient 8 was also prescribed oral naltrexone, but it was not documented in the medical record that this drug would interfere with the efficacy of this patient's opioids. There was a pain agreement for this patient that addressed oxycodone—the active ingredient in Percocet—but the pain agreement did not include the tramadol, which is also an opioid. Patient 8 was on both opioid medications for greater than 90 days.

45. Patient 18 was seen for various medical problems, in addition to obesity, including: migraine and low back pain. Review of the PDMP reveals that Patient 18 was prescribed Tramadol (opioid), cyclobenzaprine (muscle relaxant), Soma (muscle relaxant), diazepam (benzodiazepine), ketamine (dissociative), oxycodone-acetaminophen (opioid), and butorphanol (opioid), at various times, in an overlapping manner, and for periods greater than 90 days. There was no pain agreement in the medical record for Patient 18. According to the medical record, Patients 8 and 18 were not educated about the risk of opioids including dependence, addiction and possible overdose, nor educated about safe storage, proper disposal and risk of administration with other sedating medications such as benzodiazepines. Patients 8 and 18 also did not have appropriate periodic review noting the functional improvement of their pain.

46. Respondent did not adequately document a treatment plan in the medical record, and is in violation of the Rules and Regulations for Pain Management, Opioid Use and the Registration of

Distributors of Controlled Substances in Rhode Island, 216-RICR-20-20-4.4(B) *Documentation in the medical record for chronic pain shall state the objectives that will be used to determine treatment success and shall include, at a minimum:*

1. Any change in pain relief;

2. Any change in physical and psychosocial function; and

3. Additional diagnostic evaluations or other planned treatments

47. Respondent is in violation the Rules and Regulations for Pain Management, Opioid Use and the Registration of Distributors of Controlled Substances in Rhode Island, 216-RICR-20-20-4.4(D), relative to "*Patient Education/ Informed Consent*," which provides, *"If prescribing opioids, the practitioner will advise patients specifically about adverse risks of taking alcohol or other psychoactive medications (e.g., sedatives and benzodiazepines), tolerance, dependence, addiction overdose or death if acute or long term use. For those patients in recovery from substance dependence, education shall be focused on relapse risk factors. This education will be communicated orally or in writing depending on patient preference and shall include as a minimum:*

1. Acknowledgment that it is the patient's responsibility to safeguard all medications and keep them in a secure location; and

2. Educate patient regarding safe disposal options for unused portion of a controlled substance.

3. Requirement for Conversation: Prior to initiating a prescription for an opioid drug and, upon the second refill and/or upon the third prescription, specifically discuss with the patient who is eighteen (18) years of age or older, or the patient's parent or guardian if the patient is under eighteen (18) years of age:

a. The risks of developing a dependence or addiction to the prescription opioid drug and potential of overdose or death;

b. The adverse risks of concurrent use of alcohol or other psychoactive medications;

c. The risk the medication(s) or underlying medical condition may impair an individual's ability to safely operate any motor vehicle;

d. The responsibility to safeguard all medications;

e. If the prescriber deems it appropriate, discuss such alternative treatments (including non-opioid medications, as well as non-pharmacologic treatments) as may be available;

f. For patients in recovery from substance dependence, education shall be focused on relapse risk factors. This discussion shall be noted in the patient's medical record at each applicable visit.

48. Respondent is in violation of violation the Rules and Regulations for Pain Management, Opioid Use and the Registration of Distributors of Controlled Substances in Rhode Island, 216-RICR-20-20-4.4(F), relative to "*Written Patient Treatment Agreement*," which provides:

1. Chronic pain patients who receive opioid medication(s) shall have a written patient treatment agreement which shall become part of their medical record. This written agreement may be started at any point, at the practitioner's discretion, based on individual patient history and risk, however, no later than after ninety (90) days of treatment with an opioid medication. The written agreement shall be signed between, at a minimum, the practitioner and the patient (or their proxy). This written patient agreement for treatment may include, at the practitioner's discretion:

a. The patient's agreement to take medications at the dose and frequency prescribed with a specific protocol for lost prescriptions and early refills;

b. Reasons for which medication therapy may be discontinued, including but not limited to, violation of the written treatment agreement or lack of effectiveness;

c. The requirement that all chronic pain management prescriptions are provided by a single practitioner or a limited agreed upon group of practitioners;

d. The patient's agreement to not abuse alcohol or use other medically unauthorized substances or medications;

e. Acknowledgment that a violation of the agreement may result in action as deemed appropriate by the prescribing practitioner such as a change in the treatment plan or referral to an addiction treatment program; and

f. A request that toxicology screens be performed at random intervals at the practitioner's discretion.

2. At their discretion, practitioners may have a written patient treatment agreement with any patient who receives opioid medication for any duration, based on individual patient history and risk.

49. Respondent did not assess Patients 8 and 18 to determine whether they were making functional improvement using objective evidence. Respondent is in violation of the Rules and Regulations for Pain Management, Opioid Use and the Registration of Distributors of Controlled Substances in Rhode Island, 216-RICR-20-20-4.4(G), relative to "*Periodic Review*," which provides: *"Periodic reviews, including an in-person visit, shall take place at intervals not to exceed six (6) months.*

1. During the periodic review, the practitioner shall determine:

a. Patient's adherence with any medication treatment plan;

b. If pain, function, or quality of life have improved or diminished using objective evidence; and

c. If continuation or modification of medications for pain management treatment is necessary based on the practitioner's evaluation of progress towards treatment objectives.

2. The practitioner shall consider tapering, changing, or discontinuing treatment when:

a. Function or pain does not improve after a trial period; or

b. There is reason to believe there has been misuse, addiction, or diversion.

3. For patients the practitioner is maintaining on continuous opioid therapy for pain for six (6) months or longer, the practitioner shall review information from the prescription drug monitoring program (PDMP) at least every twelve (12) months. Documentation of that review shall be noted in the patient's medical record.

50. Based on the foregoing, the Investigative Committee determined that the continued practice of Respondent presents an immediate danger to the health, welfare and safety of the public.

ORDER

1. The Director has determined that the continuation of the physician license and controlled substance registration of Stephen Petteruti, DO, constitutes an immediate danger to the health, welfare, and safety of the public.

2. The physician license to practice medicine in Rhode Island, and the controlled substance registration to prescribe controlled substances, that have been issued to Respondent are hereby suspended forthwith pursuant to R.I. Gen. Laws §§ 42-35-14(C), 5-37-8, 21-28-3.04(a)(2), and

5-37-5.1(19).

3. Respondent is required to ensure appropriate continuity of care for his patients including appropriate referral to qualified health professionals. Respondent shall make certain medical records are available to patients who need them for continuity of care. Pursuant to the Rules and Regulations for Pain Management, Opioid Use and the Registration of Distributors of Controlled Substances in Rhode Island, 216-RICR-20-20-4.4(J), Respondent is required to facilitate a safe transition of care and have practitioner to practitioner contact regarding appropriate steps to prevent a disruption in the patient's continuity of care for pain management.

4. Respondent is entitled to a hearing in accordance with R.I. Gen. Laws §§ 42-35-14(c), 5-37-8, and 21-28-3.05.

[SIGNATURE PAGE FOLLOWS]

Signed this 3rd day of September 2019

Nicole Alexander-Scott, MD, MPH
Director of Health
Rhode Island Department of Health
Canon Building, Room 401
Three Capitol Hill
Providence, RI 02908

CERTIFICATION

I hereby certify that Summary Suspension was delivered personally served upon Respondent, at his place of business, on the _____ of _____ 2019, and via email to his attorney, Dennis Grieco, Esq., as follows:

DGrieco@grieco-law.com