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

IN THE MATTER OF:
STEPHEN PETTERUTI, DO
License No.: DO 00413
BMLD Case Nos.: 170412, 170978A, 180201, 180286, 180288A, 180319, 180592, 180620, 190480, 190717, 190776

CONSENT ORDER

Stephen Petteruti, DO ("Respondent") is licensed as a physician in Rhode Island and is licensed to prescribe controlled substances under R.I. Gen. Laws Chapter 21-28, having both a state Controlled Substances Registration and a Federal Drug Enforcement Administration Registration to prescribe controlled substances. The Hearing Committee ("Hearing Committee") of the Board of Medical Licensure and Discipline ("Board") makes the following

FINDINGS OF FACT

1. Respondent is a licensed physician in Rhode Island and was issued his license on July 26, 1991. His specialties include family practice and obesity. Respondent's practice, I.M. 120, where he treats patients for various medical conditions, is located at 250 Centerville Road, Bldg. E, Warwick, Rhode Island.

2. The Board has reviewed and investigated the above-referenced complaints pertaining to Respondent through its Investigative Committee.

3. The Board received a complaint in 2019, Complaint No. 190717, from the spouse of Patient A (alias) ("Complainant"), relative to Respondent's care of Patient A. The Complainant stated that Respondent kept increasing doses of opioid medication to treat Patient A's pain, 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.

4. Respondent was Patient A's primary care provider from the early 2000's until November, 2012.

5. 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.

6. 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 also reflects that Respondent referred Patient A to physical therapy and prescribed muscle relaxants, including cyclobenzaprine, as well.

7. 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. The Investigating Committee also concluded Respondent did not conduct an adequate 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. The Investigative Committee concluded that 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.

8. The Investigative Committee found 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.

9. Respondent was prepared to present evidence that history of present illness, initial physical examinations and initial, partial neurologic evaluations were appropriate and within the standard of care, particularly considering the injury to his spine was being treated surgically by his orthopedic surgeon and neurosurgeon, and Respondent was merely managing his pain medication in conjunction with the surgical treatment, epidural steroid injections performed by another physician in December, 2009 and physical therapy.

10. Patient A's medical records also reflects that during the time Respondent was prescribing pain medication for Patient A's serious back and spine injury, the patient was also being contemporaneously treated by an orthopedic surgeon and neurosurgeon, who combined to perform three surgeries on his spine, and a pain medicine specialist. Records of all of those medical providers treating Patient A contemporaneously with Respondent demonstrate that they either knew and approved of the pain medication regimen being prescribed by Respondent or prescribed the same opioids at the same dosages prescribed by Respondent at various points in time. Patient A's neurosurgeon's records of May 14, 2010, August 11, 2010 and March 19, 2012 all reflect that she was aware of the pain medications and dosages being prescribed by

Respondent and agreed with their continuation. Records from the Rhode Island Prescription Drug Management Program in Patient A's orthopedic surgeon's chart and his orthopedic surgeon's own notes confirm that the orthopedic surgeon knew of the opioids and dosages being prescribed by Respondent and in fact prescribed the same opioids and dosages post surgery for Patient A, e.g., in March, 2010 when the orthopedic surgeon prescribed the same opioids in the same dosages as Respondent. Records from Patient A's cardiologist dated August 28, 2013, February 19, 2014 and August 25, 2014 indicated that another physician continued Patient A on OxyContin 60 mg three times per day, an increase from the 40 mg three times per day dosage Respondent was prescribing as of November 20, 2012, the last time he saw the patient. Likewise, the records of pain management specialists Patient A saw show they were aware of and in agreement with the pain medications and dosages being prescribed by Respondent. Moreover, records from those pain management specialists and Prescription Drug Monitoring Program records in the orthopedic surgeon's chart reveal that Patient A was continued at least through 2016 on the same opioids and dosages Inc. prescribed by Respondent when he last saw Patient A in November 2012.

11. In addition, the medical record demonstrates that contrary to Patient A's wife's complaint, his oxycodone dosage was not progressively increased. Instead, dosages were adjusted both up and down in response to Patient A's condition and pain. There were a number of instances when Patient A decreased the dosage: on April 7, 2010, June 22, 2010, May 27, 2011, August 18, 2011, and April 16, 2012. The Investigative Committee felt the medical record does not support the clinical rationale for dosage changes of oxycodone.

12. 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). The Respondent's medical record for Patient A showed a BMI was calculated and recorded on February 15, 2005, August 2, 2006, September 27, 2006, January 16, 2007, July 11, 2007, August 14, 2007, September 18, 2007, December 4, 2007, May 19, 2008, July 7, 2008, August 5, 2008, October 29, 2008, August 4 and 21, 2009, October 22, 2009, April 7, 2010, May 10, 2010, June 22, 2010, July 21, 2010, August 2, 2010, September 1, 16 and 29, 2010, October 13 and 27, 2010, December 1, 2010, January 4, 2011, March 14 and 30, 2011, April 6 and 13, 2011, May 13 and 27, 2011, June 22, 2011, December 22, 2011, January 23, 2012, February 22, 2012, April 3 and 16, 2012, May 6, 2012, June 15, 2012, July 13, 2012, August 8, 2012, September 6, 2012, October 5, 2012, and November 6 and 20, 2012. 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. However, during that appearance and in his written response to Complaint No. 190717, Respondent explained that height and weight had to have been obtained and entered in the medical record on each occasion the BMI was recorded, because BMI is a calculation based upon a patient's height and weight. 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). Upon review of

the medical record, it was not evident that this patient was diagnosed with obesity or morbid obesity, which are important chronic diseases. 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, that brief conversations about weight loss were not effective. Respondent nevertheless stated 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.*"

13. 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, but the Investigating Committee felt that was not done by Respondent.

14. Respondent's medical record for Patient A reveals that he discussed the patient's obesity, need to lose weight and potential methods and treatments to enable that weight loss on numerous occasions. Those records also reveal that Patient A's efforts at weight loss were largely unsuccessful and complicated by his serious back injury and pain and three significant surgeries on his spine. On February 18, 2007, August 5, 2008 and February 4, 2011, the medical record reveals that Respondent discussed with Patient A his need to lose weight and recommended that Patient a engage in medical, weight loss treatment. On June 9, 2011, the medical record reveals Respondent again discussed with Patient A his need for weight loss, and they agreed to further discuss a weight loss plan. On September 15, 2011, the medical record reveals Respondent discussed with patient the benefit weight loss will have on his condition and overall health and noted that the patient planned to start medical weight loss treatment with the Respondent. Respondent's note of January 23, 2012, indicates that the patient did not follow through with that plan but consulted with a nutritionist. Unfortunately, he still had been unsuccessful in reducing his weight, despite that consultation. Respondent's February 22, 2012 note indicates he again

encouraged Patient A to pursue active weight loss, informed him that he was a good candidate for gastric bypass surgery and that treatment should be made a high priority after he recovered from his impending surgery on his spine. On April 3, 2012, the medical record reveals that Respondent saw Patient A in the wake of his third surgery on his spine and again discussed the benefit of medical weight loss treatment with Patient A to address and improve his back pain. Respondent's July 13, 2012 note indicated that in the wake of his last spine surgery, Patient A was feeling pretty good and his pain medication assisted him with controlling his pain and improving his quality of life. With his somewhat improved physical condition, Patient A had finally had some success in reducing his weight. (BMI was 44.69766 on June 15, 2012 but was reduced to 43.81587 on July 13, 2012.) The July 13, 2012 note indicates that Respondent discussed a plan for nutritional counseling, along with appetite suppressant medicine and meal replacement.

15. An expert retained by the Respondent who is board certified in internal medicine, cardiology and obesity medicine, concluded that Respondent's assessment of and attention to Patient A's obesity was appropriate and met the standard of care.

16. 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. The Investigating Committee found Patient A was not evaluated appropriately. The Investigative Committee concluded that this progress note and evaluation did not meet the minimum standard of care.

17. At a May 27, 2011 office visit, Respondent documented that Patient A reported *"some symptoms of unsteadiness, a little queasy stomach."* The Respondent recorded those symptoms had occurred since the patient's last appointment on May 13, 2011 when the patient's dosage of Cymbalta was decreased from 60 mg down to 40 mg. 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. The Investigating Committee felt that according to the medical record, there was really no diagnostic pursuit of the reported problem, and that 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 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. Respondent recorded his conclusion that he suspected the nausea was a side effect of the reduction in the Cymbalta dosage since the last visit two weeks prior. He noted that his plan was to nonetheless continue the decreased dose of 40 mg until the patient is yes next visit and reassess whether his symptoms persisted. He saw the patient two weeks later on June 9, 2011, and the patient no longer had any complaints of nausea and unsteadiness then or at any point thereafter.

18. 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."* Respondent would present evidence that the care and treatment he rendered Patient A on June 9, 2011 was appropriate and met the standard of care. He believed the extent of the evaluation and examination on that day was appropriate. The patient was known to have a long-standing and painful back condition, for which he was being seen and treated by an orthopedic surgeon and pain management specialist, in conjunction with Respondent. Thus, further examination and workup of his pain at that point was not required.

19. 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 entirely, 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.

20. 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. The Investigating Committee did not find any documentation that Patient A was advised about the potential for dependence or side effects or the additional risk of adding benzodiazepines. Respondent did note in the medical record on October 5, 2012 that the patient had not experienced any neurocognitive impairment from his pain medication regimen and that "he has always been reliable, consistent in his use of medications. He has never manifested symptoms of addiction or diversion."

21. The Board received Complaint No. 190776 from the Board of Pharmacy, which complaint was based on a review of the Prescription Drug Monitoring Program (PDMP), prompted by the allegations contained in Complaint No. 190717. 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 three 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, *"Respondent 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."*

22. 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 three months or longer. None of those 34 patients have made any complaint concerning the Respondent's care, and there is no allegation that they have suffered any harm or injury.

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

24. 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."

25. 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."

26. Respondent and an expert retained by him who is board certified in internal medicine, cardiology and obesity medicine pointed out that the warnings and contraindications with respect to the combination of phentermine and other anorectic agents are based upon labeling approved by the FDA when both medications were first approved for weight loss treatment approximately 50 years ago and were not based upon studies that actually evaluated the combined use of those medications. Those warning and contraindications, as noted in paragraph 24 above, referred to a case-controlled epidemiologic study in which the use of anorectic agents was associated with an increased risk of developing pulmonary hypertension, with a 23 fold increase in that risk for the use of anorectic agents for longer than three months. That referenced study appears to be Abenhaim, L., et al. Appetite-Suppressant Drugs and the Risk of Primary Pulmonary Hypertension. The New England Journal of Medicine. 1996 August; 335 (9): 609-616. That 1996 study reported on the increased risk of primary pulmonary hypertension with the use of certain anorexic drugs and specifically referenced an odds ratio of 23.1 when the anorexic drugs at issue were used for a total of more than three months. Abenhaim, L., et al. Appetite-Suppressant Drugs and the Risk of Primary Pulmonary Hypertension. The New England Journal of Medicine. 1996 August; 335 (9): at 609. However, the medications evaluated in that study did not include phentermine or phendimetrazine. Abenhaim, L., et al. Appetite-Suppressant Drugs and the Risk of Primary Pulmonary Hypertension. The New England Journal of Medicine. 1996 August; 335 (9): Table 3 at 612. Instead, like the dangerous Fen/Phen combination, all but one of the medications referenced in that 1996 study were removed from the market in the late 1990's for similar reasons. Thus, Respondent and his expert did not believe that the study referenced in the Drugs.com information and the FDA approved labelling and

package inserts does not support the warnings and contraindications contained in those documents.

27. In addition, Respondent and the expert he retained pointed out that no studies of phentermine subsequent to its initial approval by the FDA some 50 years ago bore out the label warnings and contraindications over length of use or use with other anorectic agents. This is exemplified by the FDA's 2012 approval of the package insert and labelling for Qysimia, a component of which is phentermine. The above warnings and contraindications for phentermine and its use with phendimetrazine are not contained in the FDA approved package insert and labeling for Qysimia, evidencing that the clinical trials upon which the FDA approved Qysimia in 2012 did not support those warnings and contributions. Thus, Respondent and his expert did not believe the most recent studies and literature do not support the warnings and contraindications referenced above in the Drugs.com information and the FDA approved labeling and package inserts for phentermine and phendimetrazine.

28. 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.

29. 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. Specifically, for a small portion of his patients who find that the effects of phentermine taken in the morning wear off late

in the day, Respondent would prescribe and instruct patients to take phendimetrazine in the late afternoon or evening. The half-life of phentermine is such that its effect is no longer present when the phendimetrazine is taken late in the day. Respondent indicated that for those patients he suggests phendimetrazine, which does not inhibit sleep, rather than a repeat dose of phentermine, which can inhibit sleep. 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. However, there were numerous notes in the records indicating the patients were instructed to take phentermine in the morning and phendimetrazine in the late afternoon. 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.

30. 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.

31. 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."

32. The Investigative Committee reviewed the consent form and concluded it was significantly inaccurate 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 for the patients with outdated warnings and contraindications and thereby, preclude them from using them to effectively lose weight. 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. The consent form also inaccurately describes Primary Pulmonary Hypertension, which is not a stiffening of the lung tissue, but is an irreversible, fatal condition. Respondent explained that he was attempting to use more simplified language that might be more easily understood by his patients. 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. As is explained above, Respondent indicated he did not include these additional warnings and contraindications in the consent form, because he did not believe the most current studies and medical literature support them.

33. 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 concluded, 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.

34. 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. Respondent explained at his August 28, 2018 appearance before the Investigative Committee that Patients vital signs were checked during clinical visits at varying intervals and patients' conditions were discussed at weekly group meetings.

35. 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.

36. 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 weekly group sessions, but the medical record contained inadequate documentation about these group sessions and did not include a detailed description of what was discussed with the patients.

37. 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.

38. 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 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.

39. 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 30.

40. 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.

41. Relative to complaint 190776, 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.

42. 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 part 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. Respondent pointed out that the record indicates the patient received medical care and sutures for the dog bite before Respondent ever saw him. Thus, Respondent believed that provider would have assessed for rabies and reported the dog bite to the RIDOH. Rabies is a viral infection that is not curable and rabies vaccine, given less than ten 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 wound 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.

43. 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.

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

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

46. 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."

47. 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.

48. 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.

49. Respondent operates a "Drip Bar" at his practice, which utilizes compounded sterile products to treat patients.

50. On May 9, 2012, the Board accepted a "position paper" which indicated the Board was adopting USP General Chapter <797> *Pharmaceutical Compounding – Sterile Preparations* ("USP 797"), as the standard governing "sterile compounding performed by practitioners." Respondent was unaware the Board had accepted that "position paper," adopting USP 797 until apprised of that fact on October 3, 2019. Additionally, the Board recognizes the *Rules and Regulations for Pharmacists, Pharmacies, and Manufacturers, Wholesalers, and Distributors* (216-RICR-40-15-1) as the applicable standard of care for the compounding sterile products by physicians. However, those regulations do provide

> In accordance with R.I. Gen. Laws sec. 5-19.1-22, nothing in the Act [defined

> elsewhere as R.I. Gen. Laws Chapter 5-19.1, the statutory scheme enabling and empowering the Board of Pharmacy] or this Part [the Rhode Island Regulations promulgated by and governing the Board of Pharmacy] shall apply to any practitioner with authority to prescribe who does not maintain an open shop for the retailing, dispensing of medicines and poisons, nor prevent him or her from administering or supplying his patients such articles as he or she may deem fit and proper.

2016-RICR-40-15-1.4.2A.

51. According to USP 797, preparation of compounded sterile products ("CSPs") must be done in an aseptic manner in order to prevent serious infections in patients receiving any intravenous (I.V.) fluids.

52. The Board asked the Investigator to inspect Respondent's practice following Respondent's July 25, 2018 appearance before the Investigative Committee when Respondent acknowledged that he was compounding pharmaceuticals.

53. The Investigator noted the following deficiencies:

> "*#1) Failure to use sterile gloves in the ISO 5 direct compounding area*
>
> *#2) Failure to use sterile 70% Isopropyl alcohol*
>
> *#3) Failure to clean daily with a 1-step EPA registered disinfectant/cleaner*
>
> *#4) Failure to perform gloved fingertip tests and media fill test*
>
> *#5) Failure to perform monthly surface and air environmental monitoring*
>
> *#6) Failure to keep cleaning tolls for ISO 5 area inside the ISO 5 compounding area.*"

54. Respondent submitted an acceptable plan of correction within 10 day to remedy the deficiencies.

55. The Investigator conducted a routine follow-up sterile compounding inspection at Respondent's practice on April 10, 2019. During the inspection, the Investigator noted that

Respondent was not following USP 797 standards when preparing CSPs, in violation of the Rules and Regulations for Pharmacists, Pharmacies, and Manufacturers, Wholesalers, and Distributors (216-RICR-40-15-1.7.10(B)), which sets forth the general requirements for all risk levels of sterile compounding, and provides that "*[a]ll CSPs shall be prepared in a manner that maintains sterility and minimizes the introduction of particulate matter*," which is to be accomplished "*as outlined in current USP standards*," and in violation of the standard of care adopted by the Board. Additionally, the Investigator noted that Respondent was not using a Compounding Aseptic Isolator (CAI) to maintain sterility or minimize introduction of particles. The Investigator determined that Respondent's failure to meet these standards represented an immediate threat to the patients receiving the compounded products, stating "*I feel he should be ordered to stop immediately until he can prepare these products according to USP standards.*"

56. The Investigator conducted an unscheduled inspection on May 14, 2019, in accordance with an agreement entered into by and between Respondent and RIDOH.

57. Pursuant to that inspection, the Investigator identified a deficiency. Specifically, the Investigator found in the refrigerator, co-mingled with non-expired medications, an old labeled prescription vial containing Human Chorionic Gonadotropin (HCG), a schedule III controlled substance, which had been compounded by Bayview Pharmacy. The Investigator noted in his report, "*The bottle of HCG clearly stated discard after 7/28/2017. This is a violation of RI Pharmacy regulation 1.5.5.A.6 (d) Ensure that . . . the expiration dates of the pharmaceutical stock are periodically checked to ensure that no expired medications are dispensed.*"

58. Respondent failed to appropriately discard a schedule III injectable controlled substance and stored it in the same area as current medications.

59. Pursuant to that same inspection, the Investigator found another deficiency. Specifically,

the Investigator found a vial of HCG for an individual patient of HCG that had been compounded by Wells Pharmacy Network of Ocala, Florida. The prescription had been dispensed on January 4, 2019. The vial of HCG was a multi-dose vial with a concentration of 1,000 units/ml. There was neither a date of opening nor a beyond use date ("BUD") indicated on the vial.

60. The Investigator reported, "*According to USP 797 once a multi-dose vial has been punctured, the beyond use date becomes 28 days maximum from date of opening.*" Citing to USP 797, the Investigator continued, "*Multiple-dose containers (e.g., vials) are formulated for removal of portions on multiple occasions because they usually contain antimicrobial preservatives. The BUD after initially entering or opening (e.g., needle-punctured) multiple-dose containers is 28 days (see Antimicrobial Effectiveness Testing 51) unless otherwise specified by the manufacturer.*" He concluded, "*These Compounded Sterile Products need to have a 28 beyond use date placed onto the vial after puncturing.*"

61. Additionally, RIDOH cites the CDC published *Guide to Infection Prevention For Outpatient Settings: Minimum Expectations for Safe Care* (version 2.3 September 2016), which provides in relevant part, "*Multi-dose vials are dated by [healthcare personnel] when they are first opened and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial. Note: This is different from the expiration date printed on the vial.*"

62. Respondent did not date the vial upon opening and did not indicate a BUD on the vial.

63. The Director of RIDOH ("Director") issued a compliance order May 16, 2019 regarding the facts and circumstances set forth in paragraphs 49-55, which ordered that "*1. Respondent shall appropriately discard all expired and/or out of date medications, following applicable state and*

federal law for appropriate disposal. 2. Respondent shall date every multi-dose vial as soon as it is opened and prior to giving any medication in that vial to a patient. 3. Respondent shall discard every multi-dose vial appropriately, following applicable state and federal law for disposal of any multi-dose vial, that is beyond 28 days. 4. Respondent shall adhere to the Guide to Infection Prevention For Outpatient Settings: Minimum Expectations for Safe Care (version 2.3 September 2016), for all matters pertaining to infection prevention, which is a recognized standard, as determined by the Board."

64. The Investigator conducted an unscheduled inspection on July 11, 2019 pursuant the above-referenced agreement between Respondent and RIDOH.

65. Pursuant to that inspection, the Investigator found a deficiency. The Investigator stated, "*While performing the inspection I discovered multiple IV bags had been compounded for the day. There were approximately 10 bags made and only 1 patient in the IV lounge receiving an IV. I was told the IV bags were prepared for all the customers coming in that day. There was a label on the bag with a general description such as chelation, or superman. The problem is this violates RI Pharmacy regulation 1.7.A.6 a&b. The compounded sterile product must be labeled with the patient name, and exact list of ingredients and their concentrations and the appropriate beyond use date. These products had none of the above.*"

66. Pharmacy products need to be labeled to ensure the right product is given to the correct patient. It is also important for the product to be appropriately labeled so that the ingredients can be verified before being given to the patient. It is the standard of care to administer the correct medication to the correct patient and do so in a manner that is safe for the patient. Respondent explained that each intravenous vitamin infusion mixed, other than high dose Vitamin C, was labeled with the name assigned to the standardized recipes for each mixture and that patients

received intravenous vitamin infusions by recipe day, so that could not be no confusion which would result in a patient receiving the wrong intravenous vitamin infusion. All other intravenous infusions were labeled with the patient's name.

67. The Director issued a Notice of Compliance Order on July 25, 2019 regarding the facts and circumstances set forth in paragraphs 63-64, which alleged Respondent had committed unprofessional conduct as defined by R.I. Gen. Laws § 5-37-5.1(19) by violating the Rules and Regulations for Pharmacists, Pharmacies, and manufacturers, wholesalers and distributors (216-RICR-40-15-1.7(a)(6)) and stated that "upon determinations" of those alleged violations, "Respondent shall appropriately label all pharmaceutical products prior to them being given to a patient in accordance with applicable pharmacy regulations." On August 5, 2019, Respondent formally requested a hearing relative to the July 25, 2019 Notice of Compliance Order, stating that he "disputes that his I.V. drip bar utilizes compounded sterile products governed by or that his practice is otherwise subject to the statues and regulations cited in that Notice of Violation and Compliance Order."

68. Respondent appeared before the Investigative Committee on July 31, 2019 relative to the facts and circumstances set forth in paragraphs 50-66, at which time Respondent stated that he was then aware of the Board's position relative to the standard of care for physicians compounding sterile products However, Respondent indicated that he had previously learned through a number of continuing medical education seminars and consulting with colleagues throughout the country that it was not standard for IV drip bars in physicians' offices to follow USP 797 or local pharmacy laws and regulations. Instead, the standard was to aseptically draw up the relevant ingredients with a sterile syringe and introduce those ingredients into the sterile intravenous bag by the sterile syringe for mixing. He explained further that he had initially

bought and utilized the sterile hood in his office for mixing IV infusions, because his initial, long-range business plan was to mix IV infusions at his Warwick office for distribution to other offices. However, that plan changed, and Respondent was only mixing for infusion in his office. Utilizing the sterile hood to mix IV infusions became time-consuming and inefficient for the numerous walk-in patients seeking IV vitamin infusions. Thus, since his office was only mixing ingredients to be infused within hours at his Warwick office and he had learned that it was not standard for IV drip bars to follow USP 797 or local pharmacy regulations, Respondent's office returned to its former practice of aseptic mixing of IV infusions outside of hood.

69. Respondent was asked, "Are you compounding?" He replied that he was "*mixing multiple ingredients to deliver product for patient use.*"

70. The Investigative Committee concluded that Respondent failed to meet the minimum standard of care. The Investigative Committee concluded that Respondent is a physician who chooses to compound sterile ingredients but does not meet the applicable standard, as evinced by his violating the above referenced pharmacy regulations and USP 797. In addition, Respondent is not adhering to routine safeguards, such as labeling medication with patient names and ingredients. It is important to label medications appropriately to ensure that the right medication gets to the right patient. Respondent also does not indicate the date a sterile vial is opened or the BUD, which is important to prevent expired or contaminated medication from being given to and potentially harming a patient. Respondent has stored expired medications with current medications, increasing the likelihood of giving a patient an expired medication that could be ineffective or dangerous for the patient. Respondent also compounded sterile products without using an appropriate sterile hood, which creates the potential for serious and potentially life-threatening harm to patients from bacterial or fungal contamination.

71. Complaint 170412 was submitted by a physician alleging deceptive advertising. The complainant heard an infomercial hosted and sponsored by Respondent on WPRO, which is a radio station that broadcasts in Rhode Island as well as over the internet at www.630wpro.com.

72. The Investigative Committee obtained an audio file of the broadcast in question, which had aired on March 4, 2017. This audio file was subsequently transcribed into a document by a stenographer, which transcript was reviewed by the Investigative Committee.

73. The Investigative Committee took notice of several statements made during the broadcast. On page 2 of the transcript, *"the smartest hour on your morning radio."* On pages 8 and 9 of the transcript, referring to alpha-lipoic acid, *"feels great, liver functions are getting better, **measurements of liver elasticity are improving,** so I took this hopeful information and discussed with another patient, who's interested in receiving the same care."* In his July 25, 2018 appearance before the Investigative Committee, Respondent acknowledged that there was no measure of liver elasticity. However, Respondent explained at that appearance and in his written submission to the Board that he maintained regular communication with that patient's hepatologist who confirmed that the patient' as liver functions had improved. On pages 16 and 17 of the transcript, referencing television personality Bob Harper, *"so he is doing a few things that are misleading to the public. One is propagating the notion that diet and exercise will help you with significant weight loss. **We know it doesn't**, that you need treatment beyond that. And that's why Intellectual Medicine exists, one of the reasons. The other is it will insulate you from heart disease."* On page 26 of the transcript, *"in the face of cancer, one of the changes we advocate for is regular intermittent doses of intravenous vitamin C that has the potential to be toxic toward cancer cells, with **the probability of diminishing the risk of relapse,** at a time when it's easier to do that, at a time when the intensity of treatment required is very low."* Respondent

retained an expert who will is board certified in internal medicine, with a palliative care certification, and board certified in integrative medicine. He is the Medical Director for the Center for Integrative Medicine at a major teaching hospital and an Assistant Professor of Medicine at the medical school affiliated with that hospital. In a lengthy written submission to the Board, that expert in integrative medicine stated that Respondent's "description of what is known about intravenous vitamin C's potential toxicity toward cancer cells and probability of diminishing the risk of leave relapse is accurate and absolutely consistent with the current state of medical knowledge about that treatment, as reflected and reported by the National Cancer Institute."

74. The Board retained an expert in pharmacology to opine on the role of Vitamin C in treatment of cancer. The Board approved expert opined, "*Administration of high-dose intravenous vitamin C has been studied for cancer based on its antioxidant properties. However, published studies are of poor quality and small sample sizes, with none being randomized, controlled, clinical trials. Further, most studies were quasi-experiments that did not contain a comparator arm. The lack of well-designed clinical trials is evident when looking at the standard of care for cancer treatment; high-dose intravenous vitamin C is not included in any treatment guideline from the National Comprehensive Cancer Network. Additionally, the association of high-dose vitamin C with a risk of oxalosis and kidney injury is concerning as case reports of fatality and one case of renal graft loss resulting from acute kidney injury are published. The patient did not appear to be screened for G6PD deficiency, which should be considered for all patients receiving high-dose vitamin C. In my expert opinion, , intravenous vitamin C, at any dose for any indication, has NEVER been evaluated for safety and efficacy by the FDA . . .*" However, Respondent's integrative medicine expert explained in his detailed written submission

to the Board, with citations to numerous peer reviewed studies, that "it is beyond dispute that intravenous vitamin C is offered and provided as a treatment for patients presently suffering from various forms of cancer and those in remission by physicians throughout the country, in both academic and purely clinical settings. This treatment has been provided to thousands of patients at my own academically based clinic. Even a simple online search will demonstrate similar treatments being offered and studied by physicians and institutions throughout the country, including the Department of Integrative Medicine at the Kansas University Medical Center, the Marcus Institute of Integrative Health at the Jefferson University Hospitals, and The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, will to name a few. The provision and study of this treatment by so many providers and institutions indicates that . . . this treatment is within the standard of care for integrated medicine. This is no doubt due to the fact that . . . there are accepted, data-based studies which support the administration of this treatment." That expert also stated with citations to numerous peer reviewed studies that "[t]he safety and efficacy of intravenous vitamin C with respect to cancer has been studied since the 1970s. An the excellent overview with citations to relevant studies can be found at the National Institutes of Health's National Cancer Institute's "Physician Data Query" ("PDQ") website. Laboratory studies have shown that high doses of the vitamin C slow the growth and spread of various types of cancer cells, including prostate, pancreatic, liver and colon. Animal studies have demonstrated tumor growth inhibition in connection with intravenous vitamin C treatment for pancreatic cancer, liver cancer, prostate cancer, sarcoma, mesothelioma and ovarian cancer. Clinical studies in humans have indicated that intravenous vitamin C may actually increase the efficacy of several chemotherapeutic drugs and radiation, while decreasing symptoms and side effects of those treatments. Just as important, the safety of intravenous vitamin C has been well established."

75. The Board also retained an expert who is an oncologist for his expert opinion. The expert opined, "*After a complete investigation of intravenous Vitamin C, it appears that there are many studies that have examined the efficacy of Vitamin C as an antioxidant for the treatment and prevention of cancer which it enhances the body's ability to free itself of toxic free radicals. However, there is very little evidence to support the role of vitamin C in cancer prevention. There have been many double blinded trials of at least oral vitamin C which have failed to make a significant difference in terms of cancer outcomes. It has been noted that high dose vitamin C has been used as an alternative and complementary therapy and it is widely used by doctors who advocate alternative treatments. At this time, there are no clinical trials which have adequately addressed the efficacy in using high dose vitamin C. Large randomized trials have found no reduction of cancer in patients who have received high dose vitamin C. Vitamin C has shown moderate to severe impairment of kidney function and there has been no dosage adjustment in the manufacturers labeling. However, vitamin C should be used in caution in patients with renal impairment or with patients who are prone to kidney stones because of the risk of developing acute nephrolithiasis. Adverse reactions with Vitamin C include dizziness, diarrhea, fatigue, flank pain, flushing, nausea and vomiting.*"

76. The Investigative Committee determined, based on these expert opinions, that there was no basis for the claim *"In the face of cancer, one of the changes we advocate for is regular intermittent doses of intravenous vitamin C that has the potential to be toxic toward cancer cells, with* ***the probability of diminishing the risk of relapse,*** *at a time when it's easier to do that, at a time when the intensity of treatment required is very low.*" The Investigative Committee also determined that statements relative to measuring liver elasticity were misleading, as were the statements regarding Bob Harper and weight loss.

77. The Board received complaint 180620 from a physician who was given Respondent's Curriculum Vitae (CV) by a colleague. The complainant alleged that claims in Respondent's CV are misleading. Specifically, the complainant noted that Respondent claimed to have held the academic rank of Associate Clinical Professor at Brown University School of Medicine ("Brown") from 1995-1997. The complainant questioned the credibility of this claim based on the duration of the position. The complainant also noted his lack of familiarity with any the board "ACLS," listed under "Board Certifications" on Respondent's CV, but noted his familiarity with that term in reference to a common American Heart Association certification for Advanced Cardiac Life Support, which is not a Board Certification. In his written submission to the Board during his appearance before the Investigative Committee, Respondent explained that, from 1995 through 1997, students from the Brown University Medical School rotated with him as part of their primary care academic experience. He provided clinical instruction to those students and understood his resulting title to be Associate Clinical Professor. He explained that it was conceivable that he mis-stated the title that was given, since he was operating out of memory when he subsequently added it to his CV and was not knowledgeable regarding the hierarchy of academic titles. However, he believed he had accurately stated the title on his CV and certainly, was not intending to misstate it or mislead anyone in any way. The Respondent also acknowledged that there is no Board Certification for a ACLS and explained that that credential was simply, mistakenly listed in the wrong section of his CV.

78. On May 24, 2018, the Investigative Committee verified with Brown that Respondent had held the academic appointment of Assistant Clinical Professor from February 1, 1997 to June 30, 2000. The Investigative Committee obtained from Brown a chart of academic appointments, which revealed that the title of Assistant Clinical Professor is a junior faculty position below the

position of Associate Clinical Professor reflected in Respondent's CV.

79. The Investigative Committee determined Respondent inflated his academic rank and that the inclusion of ACLS as a board certification on his CV was misleading.

80. The Investigative Committee received complaint 180592 from a Board member who heard a radio advertisement on WPRO from Respondent relative obesity, which the complainant thought was misleading. The Investigative Committee obtained an audio file of this advertisement.

81. The Investigative Committee took notice of several statements made in the advertisement, including, "*A silent epidemic sweeping the nation that affects more people than any other known disease leading to premature death and disability for its victims . . . . Obesity and excess body weight is ignored by orthodox medicine . . . . Over 100 years we have been lied too . . . . Nothing in medicine is harder to treat . . . . Over the last 30 years Dr Petteruti has developed the solution to the problem of obesity . . . . When you enroll in our program the weight comes off and stays off. You will lose fat not muscle. At Intellectual medicine, we have the cure.*" In his written submission to the Board, the respondent pointed out that in its 2013 Resolution 420, declaring obesity a disease, the American Medical Association noted that "[o[besity rates have doubled among adults in the last 20 years and tripled among children in a single generation . . . ." Also, the United States Centers for Disease Control and Prevention (the "CDC") report that the "prevalence of obesity was 39.8% and affected about 93.3 million of U.S. adults in 2015-16." Respondent also suggested that obesity -related conditions are some of the leading causes of mortality and morbidity. He pointed out that as the AMA noted in its resolution, the "physical increase in fat mass associated with obesity is directly related to comorbidities including type 2 diabetes, cardiovascular disease, some cancers, osteoporosis [and]

polycystic ovary syndrome . . . ." The AMA also concluded that reversal of obesity for weight loss "can dramatically reduce early mortality" and the risk and/or progression of those comorbidities. Similarly, the CDC states that "[o]besity-related conditions including heart disease, stroke, type 2 diabetes and certain types of cancer [that are] some of the leading causes of preventable death." The Respondent also cited to authorities stating that" many clinicians "do not routinely provide weight management services for obese patients" and that the most prevalent barriers to obesity care work or education during medical school and residency lack of information provided . . . to both clinicians and patients;" and "recent studies confirm that obese patients encounter prejudice, ambivalence and oftentimes unsatisfactory treatment in healthcare;" lastly, Respondent submitted data generated from patients in his own medical weight loss treatment program demonstrating average weight loss significantly greater the amount designated by the FDA as an effective weight-loss treatment.

82. The Investigative Committee determined that the statements from Respondent's radio ad referenced above constituted absolutes and guarantees and, as such, were misleading.

83. The Board received several complaints against Respondent that raised concerns relative to advertising on Respondent's website and other media: 170412, 170978A, 180201, and 180319. One complaint referenced a mailed flyer highlighting the "I.M. Drip Bar." The advertisement stated that the "I.M. Drip Bar" offers I.V. infusions, claiming, "*I.V. Infusions: The safe and painless way to deliver more of the nutrients you need to stay healthy and vital, all while you relax . . . . A DRIP for All Occasions: Choose from a variety of IV Infusion cocktails to help with the energy levels, travel woes, weight loss and more. Our favorites include The Power Pack: Recharge after a trip or before your workweek. The Jet Setter: Boost your immune system and have a great trip!*"

84. The Investigative Committee took notice of various treatments advertised as offered at the "I.M. Drip Bar." These treatments included various I.V. solutions, some of which were compounded and some of which were reconstituted with various fluids and medications. These I.V. treatments involved inserting an I.V. catheter into a patient and infusing over various durations specifically offered I.V. solutions targeted to address a health condition or disease or to prevent a problem.

85. Respondent's website offered various I.V. products, including one titled "Pre-op," with the claim, "*Any operation, major or minor, requires careful preparation and a plan. Add this drip to that plan and go into any operation worry-free. With a high-dose of red blood cell-creating B12 and other vitamins, you'll head into the O.R. with a recipe that helps make for a smooth procedure. The first step in the road to recovery is here!*" In his written response submission to the Board, Respondent noted that surgery is known to be a stress inducing, free radical generating trauma to the body. Excess of free radicals can have pro-inflammatory consequences that can harm general health. He cited to numerous peer-reviewed studies demonstrating reduction in postoperative complications and improved postoperative outcomes with various vitamin and mineral supplements. His intent and offering vitamin and mineral IV infusions was to potentiate those improved outcomes and hopefully, permit patients to worry less when facing surgery.

86. The Investigative Committee determined that the claim was misleading and that, specifically, the word choice "*worry free*" was an unrealistic guarantee.

87. Respondent's website offered another I.V. product titled "Post-op," with the claim, "*The second stage of that smooth operation is recovery! With a steady dose this drip, you'll be prepared to snap back faster than normal. The high-dose vitamin C and B12 work to enhance*

your body's natural healing process up and get back to your normal life." In his written submission to the Board, Respondent explained that nutritional health is an important part of the post-operative recovery. Most patients have altered eating habits postoperatively. Some have altered gastrointestinal function that can interfere with absorption of micro nutrients. In addition, their body is in a catabolic state with increased free radicals that can interfere with recovery. All of the properties described above in the supplements that have value in the pre-operative state also have merit post operatively. The post-operative infusion has increased amounts of vitamin C to support collagen recovery, and higher doses of glutathione for its antioxidant benefit.

88. The Investigative Committee determined that the claim was misleading and that, specifically, the claim "*snap back faster than normal*" was an unrealistic guarantee unsupported by evidence.

89. Respondent's website offered another I.V. product titled "Time-Machine," with the claim, "*There's more to your body's aging than you think. Free radicals and toxic metals take a toll on you. This drip addresses it all! With a combination of calcium EDTA (removes heavy metals), antioxidants (neutralizes free radicals), l-arginine, B vitamins, L-carnitine, and Biotin, it may even decrease your risk of dementia, cancer, and heart disease. Give your brain, hair, skin, nails, and sexual vitality the boost they need. Turn back the clock today!*" In his written submission to the Board, responded explained that she did not believe patients would literally interpret commonly used phrase "turn back the clock" to mean that they literally were going to reverse their age. Instead, he thought patients would understand that elements of this infusion can impede some of the physical consequences of aging.

90. The Investigative Committee determined that the claim was misleading and that, specifically, the claim "*Turn back the clock today*" was an unrealistic guarantee unsupported by

evidence. There was no evidence that this infusion caused patients to become younger.

91. Respondent's website offered another I.V. product titled "Flu-Fighter," with the claim, "*Beating the flu is all about fast action! As soon as you feel something coming on, stop it in its tracks with this immune boosting cocktail full of supplements that will send knock that nasty virus right out.*" In his written submission to the Board, Respondent explained that this description encouraged people to obtain this vitamin infusion as soon as they felt like symptoms coming on. He stated that the language was intended to inform that receipt of immune system supporting vitamins and minerals at the outset of a viral flu can reduce and shorten symptoms and the time a person is affected by the virus. He went on to cite numerous studies demonstrating how vitamin C and zinc have been shown to effect significant and immediate reduction in flu symptoms and duration.

92. The Investigative Committee determined that the claim was misleading and, specifically, that the claim "*stop it in its tracks*" was an unrealistic guarantee unsupported by evidence. There was no evidence that this infusion killed influenza virus.

93. Respondent's website offered another I.V. product titled "Wing-man," with the claim *"Whether you're going to a full-on party or you're looking at a quieter night of dinner & drinks, this drip is your secret weapon. Stop in to one of our locations before you head out and we'll serve you the pre-game cocktail you need before an exciting night on the town.*"

94. The Investigative Committee determined that the claim was misleading. The Investigative Committee also noted that the expression "*full on party*" suggests drinking to the point of intoxication and that Respondent, in his appearance before the Investigative Committee relative to this complaint, admitted that the intent of this I.V. infusion is to prevent or lessen a hangover from alcohol consumption. In his written submission to the Board, respondent further

explained that this infusion was intended to diminish the toxic effect of alcohol while reversing the dehydration that can result from the body's processing above all. Respondent indicated it was not his intent to support excessive drinking and cited peer-reviewed studies that hangovers do not dissuade excessive drinking. Thus, he did not perceive alleviating the effects of hangovers to promote excessive drinking. Nonetheless, he subsequently unilaterally discontinued offering this infusion. The Investigative Committee noted that there is no known health benefit to excessive alcohol consumption and that excessive alcohol consumption presents known health risks, including intoxication, impaired judgment, and other health adverse outcomes. The Investigative Committee determined that offering a product that claims to reduce the adverse effects of alcohol without acknowledging that the intoxicating and toxic effects of alcohol to the brain and other parts of the body is not keeping with the principle of "Do no harm." The Investigative Committee determined that offering "The Wingman" as therapy is unethical and inconsistent with the basic tenets of the profession.

95. Respondent's website offered another I.V. product titled "Jet Setter," with the claim, "*Whether you have a single flight booked or you're always racking up flyer mileage, this drip is for you. Make sure you have a great trip without getting sick on the plane! Load up on your vitamins to boost your immune system.*"

96. The Investigative Committee determined that the claim was misleading and that, specifically, there was no evidence the "Jet Setter" prevented any disease of a traveler. Respondent admitted during his July 25, 2018 appearance that there were no definitive studies using the I.V. approach for using these supplements.

97. Respondent's website offered another I.V. product titled "Tic-Kick," with the claim, "*Lyme Disease is a serious drain. Fight the fatigue, joint and muscle ache with our mixture of*

pain reducing vitamins, minerals and high-dose vitamin C. Stop by and let us help you get off the long-term antibiotics train."

98. The Investigative Committee determined that the claim was misleading and that, specifically, there was no evidence that "Tic-kick" helps patients recover any faster from Lyme Disease.

99. Respondent's website also features the claim, "*Guiding people towards living the 120 Lifespan while retaining youth.*"

100. The Investigative Committee noted that there was no evidence to suggest Respondent could guide anyone to live to age 120 while retaining youth. In his appearance before the Investigative Committee, the Respondent explained that he did not believe patients would literally believe that this statement meant they would live to the age of 120 while remaining young. In his written submission to the Board, Respondent explained that the goal of anti-aging medicine is to delay the processes and sequelae related to aging. The objective is to maintain youthful physical, mental, emotional and sexual health and vitality throughout the span of life. Controlling percent body fat, sustaining muscle and bone mass, protecting brain health, protecting cardiovascular vitality, supporting youthful hormone levels, and reversing or delaying the progression of the signs of facial aging are all components of the approach.

101. In his appearance before the Investigative Committee and through written communications with the Board, Respondent offered to revise the statements on his website and advertisements with the Board's input. Without any direct guidance from the Board, he unilaterally revised those statements to try to address the Investigative Committee's concerns.

102. On June 21, 2017, the Board received a complaint from the spouse of Patient B (alias), who died from esophageal cancer. Patient B was diagnosed with esophageal cancer on

November 6, 2013, at age 80.

103. Respondent was the attending physician for Patient B.

104. The complainant reported that she and her husband specifically sought care from Respondent for high dose Vitamin C I.V. infusions. The complainant reported that Patient B was in remission. The complainant reported that Patient B had completed chemotherapy and radiation and was doing well, his only side effect being fatigue. The complainant said "*that it was safe to do, according to Respondent,*" and she and Patient B wanted "*to give it a try.*" As Respondent explained in his written submission to the Board, his medical record for Patient B reflects that he, Patient B and his wife discussed the incurable profile of his cancer and the likely poor prognosis. They also discussed the potential role for IV vitamin C therapy to optimize his health and immunologic function. Respondent clearly explained to Patient B that intravenous vitamin C could not be counted on as the singular treatment for or a cure of his cancer. Further, As Patient B's wife confirmed in her complaint, Respondent B made no promises about successfully treating his cancer. We agreed that Patient B would proceed with weekly infusions, commencing initially with 50,000 mg of vitamin C. Respondent, Patient B and his wife also discussed that patient suffering from weakness and wasting in late stage cancer can benefit from the use of hormonal treatments, including testosterone therapy, to support their energy and lean body mass. They planned to address that potential treatment in the future.

105. Patient B received his first consultation regarding Vitamin C infusion on May 7, 2014. The complainant reported that Respondent discussed switching Patient B's supplements to another brand even though Patient B only wanted Vitamin C.

106. Patient B received an I.V. dose of I.V. Vitamin C, 50,000 mg, through his Port-A-Cath (central line) on May 14, 2014 without complication. Patient B received another dose of

Vitamin C on May 22, 2014, this time of 50,000 mg without complication. The complainant voiced concerns about how rapidly the infusion occurred and asked that it be given more slowly. Respondent explained that while infusion times can vary, it is common for an infusion of that dosage to take approximately one hour. Patient B received another dose of Vitamin C on May 28, 2014, this time of 50,000 mg without complication. The complainant reported that when Respondent came into the room, Patient B was very thirsty and was experiencing stomach pain. The first note of any complaint of thirst was during the infusion on June 4, 2014. There is no note of any stomach complaints on any date. The complainant alleged that Respondent never responded to the complaints of thirst and stomach ache on May 28,2014 and showed no concern. Respondent, on the contrary, wanted Patient B to have a blood test to evaluate his testosterone level. The complainant reported that they were not interested, but that Respondent offered treatment with testosterone pellets if the level was low. Respondents spouse, an advanced practice registered nurse, also suggested this was a good idea.

107. The complainant reported that on June 4, 2014, Patient B was at the office for another I.V. infusion of Vitamin C when respondent came into the room and asked whether Respondent had decided on the testosterone pellets. According to the complainant, Respondent stated, "*Testosterone pellets would make him feel like a young stud and would be good for him. Respondent then turned to me with a smirk on his face. My husband was so embarrassed and humiliated.*" The complainant reaffirmed that Patient B was there for the Vitamin C only. In his written submission to the Board, Respondent explained that consistent with their prior discussion about potential testosterone treatment for Patient B's weakness and wasting from the cancer, he did revisit that potential treatment with him on May 28, 2014. They again discussed obtaining various labs, including testosterone levels to assess the issue. Patient B agreed to obtain those

labs, and they were performed on May 31, 2014. At his next visit on June 4, 2014, they revisited the issue. At that time, Patient B indicated that he did not wish to pursue it, and that was the end of the discussion. Respondent explained that contrary to the complainant's suggestions, the treatment was not pushed upon Patient B, nor were there any inappropriate comments made about the effects of the treatment. Patient B was an 81-year-old cancer patient, and Respondent was merely offering him the testosterone treatment to support his energy and lean body mass in the wake of his reported loss of 40 pounds of muscle weight and decreased energy.

108. Patient B received another infusion of vitamin C on June 4, 2014. The infusion was noted to commence at 12:30 PM. At 12;40, Patient B was noted to be feeling well. At 12:55, he was noted to be thirsty, but felt well after having a drink of water. The complainant alleged Patient B became thirsty and had chills and a stomach ache. At 1:15 PM., the medical record indicates that Patient B developed bilateral tremors of the upper extremities. The complainant reported that Patient B became worse and repeatedly asked to see Respondent. The complainant alleged that Patient B became dizzy, very thirsty, and suffered excruciating stomach pains, chills, chest pains and headache as well as shortness of breath. With the exception of headache, none of the multiple medical providers who saw Patient B on June 4, 2014 noted any of these other symptoms. The complainant reported that she was told that Respondent was busy with another patient. When Respondent finally came to evaluate Patient B, he called 911 for an ambulance to take Patient B to the Rhode Island Hospital Emergency Department ("RIH ED") for evaluation and treatment. In his written submission to the Board, respondent explained that upon Patient B's development of tremors, he was immediately called and evaluated the patient. He immediately discontinued the infusion. While Respondent was evaluating Patient B, his tremors subsided. The medical record indicates that by 1:20 PM, Patient B's breathing was unlabored

and stable and his vital signs were normal, with a pulse of 95, blood pressure 130/82 and a slightly elevated temperature of 99.7. Although Patient B stabilized and had no respiratory distress, Respondent thought it prudent to call 911 and have him evaluated in an Emergency Department, giving the underlying frailty of his condition.

109. The EMS report indicated that Patient B reported that he had awoken that morning with uncharacteristic lethargy and weariness. It indicated he developed some dizziness, weakness and was near syncope during his infusion and that his color was pale/jaundice. He received 300 mL of normal saline en route to the hospital, and his dizziness and headache had dissipated by the time he arrived at the hospital. The RIH ED record indicated Patient B was no longer experiencing tremors or any other symptoms upon his arrival to the emergency department. Patient B reported to the RIH ED nurse that he had earlier become dizzy and weak and nearly fainted. However, to the RIH ED nurse, he complained of headache but no other symptoms. His vital signs were normal throughout his time in the RIH ED, except that his diastolic pressure was slightly low. Patient B reported to the RIH ED physician that he had had an approximate 20-minute, single episode of near syncope, tremors and weakness. The RIH ED physician's note indicates that Patient B denied chest pain, stomach pain, nausea, chills, weakness, dizziness and continued tremors. Patient B reported to the RIH ED physician that he was not experiencing any symptoms and felt he was back to baseline. Aside from noting his tremors and near syncope earlier in the afternoon, the RIH ED physician's review of symptoms and examination of Patient B were all negative. In particular, the RIH ED physician noted normal cardiovascular, neurologic and respiratory exams. He noted Patient B's abdomen to be soft, nontender, with normal bowel sounds and no guarding, rebound or evidence of tenderness throughout. Patient B's creatinine and BUN were elevated and his eGFR was below normal. However, because he

was otherwise stable, his condition was good and he was requesting to go home. The RIH ED physician discharged him home with instructions to follow up with his primary care physician on his acute renal failure. The discharge diagnosis was near syncope of unknown etiology and renal insufficiency.

110. Respondent called RIH ED and spoke to the attending physician caring for Patient B. The medical record indicates he told the RIH ED that he had given Patient B 75,000 grams of Vitamin C. This dose of Vitamin C is recorded in Patient A's medical record at Respondent's office and RIH ED. Respondent explained that this was a typographical error on his part and that he miscommunicated the dose to the RIH ED physician. Respondent suggested to the RIH ED physician that Patient B's presentation was a consequence of the Vitamin C infusion, idiopathic tremulousness, and that calcium gluconate I.V. would reverse this effect. There as an elevated creatinine of 2.05 in the RIH ED record and diagnosis of acute renal failure on discharge.

111. Patient B was seen in his oncologist's office the following day on June 5, 2014. The medical records from that visit indicates that complainant reported the symptoms Patient B experienced the prior day. She explained that Patient B was evaluated at the RIH ED where labs revealed a creatinine of 2 which was unusual for him. She expressed concern that Patient B did not receive appropriate care at Rhode Island Hospital, and therefore brought him to the oncologist's office for evaluation. Labs taken that day showed a resolution of the acute renal insufficiency Patient B experienced the prior day. His creatinine was actually slightly low at 0.6 and his BUN was mildly elevated at 21.

112. The complainant alleged that the dose of 75,000 grams was given on June 4, 2014, which is a lethal dose, and contributed to the cause of death of Patient B. In his written submission to the Board and during his appearance before the Investigative Committee, Respondent explained

that Patient B was not and could not have been infused with 75,000 g of vitamin C. That would literally be impossible. It would require the administration of 3000 bottles of vitamin C, rather than the three bottles of vitamin C that were utilized to infuse 75,000 mg. He explained that there was merely a notation error on the June 4, 2014 infusion record which indicated 75,000 g, rather than the actual dose of 75,000 mg. It is not evident from the medical record what dose of Vitamin C was actually given to this patient.

113. The Board retained an expert pharmacologist to review this matter. The expert opined, "*If a dose of 75,000 g was truly administered, it would represent an approximate 1000X overdose compared to doses used for high-dose intravenous vitamin C therapy. Because doses so high have never been documented, assessment of causality cannot be made; however, because the renal excretion of vitamin C and oxalic appear dose-dependent, the risk of acute kidney injury is entirely possible. If the dose administered was 75 g (75,000 mg), significant toxicity is still possible based on reports published in the biomedical literature.*"

114. The Board retained an oncologist for an expert opinion who agreed that it was unlikely Patient B received 75,000 g of vitamin C on June 4, 2014. He stated "I find it difficult to grasp that this amount was given at one time. To give over 15 pounds of vitamin C or any substance seems extremely excessive." He also stated, "*I do not feel that nephropathy developed in this patient because of his normal glomerular filtration rate. I do feel Patient A died of recurrent esophageal cancer. I do feel Respondent's office should have explained the side effects of intravenous vitamin C and reviewed all side effects as well as potential for renal failure. I would have discussed all potential side effects with the patient and his family in detail, including G6PD deficiency.*" However, the expert also agreed that "[t]here is no evidence that the patient suffered from a G6PD deficiency."

115. The Investigative Committee could not determine what dose of Vitamin C Respondent actually gave to Patient B. The medical record documents 75,000 grams, which is a very high amount and perhaps an impossible amount to give. Since there is a documentation error in the medical record, the Investigative Committee concluded the dose actually given remains in doubt. It was apparent Respondent was not prepared to treat a known complication of Vitamin C infusion and did not appropriately counsel Patient B and family on relevant side effects. Additionally, Respondent did not attend to Patient B's concern promptly.

116. The Board opened complaint 180286 regarding to the review of medical records of 16 patients treated by Respondent. None of those patients submitted any complaint to the Board

117. Four medical records were reviewed in particular of Patient C, D, E and F.

118. The medical records were consistently found by the Investigating Committee to be deficient in the basic elements of a progress note, including, a history suitable to justify medical decision making and sufficient information to justify course of treatment. The Investigating Committee found patients were frequently not examined. Review of Systems was not obtained. And, the medical record lacked detail for another physician to take over the care of the patient if needed. In his written submission to the Board, Respondent explained in detail that the purported documentation deficiencies all related to: medical weight loss program group discussion sessions, which were not clinical visits warranting a typical medical note; aesthetic procedures that did not require a typical full workup and medical note; or procedure notes after a full and detailed workup had been performed and documented at a prior visit.

119. The Investigative Committee found Respondent violated the *Rules and Regulations for the Licensure and Discipline of Physicians* (216-RICR-40-05-1.5.12), 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 mediation lists; patient histories; examination results; test results; records of drugs prescribed, dispensed, or administered; and reports of consultations and hospitalizations."

120. The Investigative Committee found Respondent violated 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)), relative to "Documentation of Treatment Plan," which provides,

"*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."

121. The Investigative Committee found Respondent violated 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."

122. The Investigative Committee found Respondent violated 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."

123. The Investigative Committee found Respondent violated 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."

124. The Investigative Committee found 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 practice in his or her area of expertise as is determined by the board.*" Specifically, Respondent violated the standard of care for sterile compounding by physicians. The Board has adopted USP <797> as the applicable standard of care. Additionally, the Board recognizes the *Rules and Regulations for Pharmacists, Pharmacies, and Manufacturers, Wholesalers, and Distributors* (216-RICR-40-15-1) as the applicable standard of care for the practice of pharmacy by physicians. Respondent violated the standard of care as set forth in 216-RICR-40-15-1.7.10(B), which sets forth the general requirements for all risk levels of sterile compounding, and provides that "*[a]ll CSPs shall be prepared in a manner that maintains sterility and minimizes the introduction of particulate matter*," which is to be accomplished "*as outlined in current USP standards*." Respondent violated the standard of care as set forth in 216-RICR-40-15-1.5.5(A)(6)(d), which requires that the "*the pharmacy dispensing area and equipment [be] in clean and orderly condition . . . and that expiration dates of the pharmaceutical stock are periodically checked to ensure that no expired medications are dispensed.*" Respondent violated the standard of care as set forth in 216-RICR-40-15-1.7(A)(6), which requires that "*all compounded products . . . be labeled with the following information: a. Complete list of active ingredients (components) (Abbreviations may be included); b. The assigned beyond-use date.*"

125. The Investigative Committee found Respondent violated R.I. Gen. Laws § 5-37-5.1(2), which defines "unprofessional conduct" as including "*[a]ll advertising of medical business,*

which is intended or has a tendency to deceive the public."

The parties agree as follows:

1. Respondent admits to and agrees to remain under the jurisdiction of the Board.

2. Respondent has agreed to this Consent Order and understands that it is subject to final approval of the Hearing Committee and is not binding on Respondent until final ratification by the Hearing Committee.

3. If ratified by the Hearing Committee, Respondent hereby acknowledges and waives:

a. The right to appear personally or by counsel or both before the Board;

b. The right to produce witnesses and evidence on his behalf at a hearing;

c. The right to cross examine witnesses;

d. The right to have subpoenas issued by the Board;

e. The right to further procedural steps except for those specifically contained herein;

f. Any and all rights of appeal of this Consent Order;

g. Any objection to the fact that this Consent Order will be presented to the Hearing Committee for consideration and review; and

h. Any objection to the fact that this Consent Order will be reported to the National Practitioner Data Bank and Federation of State Medical Boards and posted to the RIDOH public website.

4. On September 3, 2019, the Director summarily suspended Respondent's license to practice medicine and controlled substance registration to prescribe controlled substances pursuant to R.I. Gen. Laws §§ 5-37-8, 21-28-3.04(a)(2), and 42-35-14(C), upon her

determination that Respondent's continuation in practice would constitute an immediate danger to the public.

5. To resolve the September 3, 2019 Summary Suspension, as well as all of Respondent's open cases with the Board, Respondent agrees to the following:

6. Respondent's license to practice medicine is suspended for five years, 120 days to serve, minus the number of days Respondent has already been summarily suspended, as of the Ratification of this Order. The remaining 56 months of Respondent's suspension shall be stayed throughout the Probationary Period on the condition that Respondent fully comply with this Consent Order and abide by all applicable laws and regulations relative to the practice of medicine in Rhode Island.

7. Respondent shall adhere, at all times, to USP 797 as the standard of care for the preparation of compounded sterile products.

8. Respondent shall retain, at his own expense, a Board-approved monitor who shall conduct quarterly inspections of his compounding practices. Respondent shall follow the advice of the monitor. Reports of this monitoring shall be sent to the Board at DOH.PRCompliance@health.ri.gov on or before the 15th of the month immediately following the end of each quarter or immediately if the monitor reasonably determines an issue requires the Board's immediate attention.

9. Respondent shall successfully complete the Case Western Intensive Course on Medical Documentation prior to resuming clinical practice or within 180 days of ratification of this Consent Order, whichever is sooner. Respondent shall send evidence of compliance with this requirement to DOH.PRCompliance@health.ri.gov.

10. Respondent shall complete a Board-approved course on controlled substance prescribing such as the Vanderbilt curriculum, the Case Western Intensive Course in Controlled Substance Prescribing, or the CPEP controlled substance prescribing course, prior to resuming clinical practice or within 180 days of ratification of this Consent Order, whichever is sooner. Respondent shall send evidence of compliance with this requirement to DOH.PRCompliance@health.ri.gov.

11. Respondent shall engage at his own expense a Board-approved monitor for a period of five years from Respondent's return to clinical practice. The monitor shall monthly review and approve all electronic, print and pre-recorded advertisements involving medical claims for five years to ensure that there are no guarantees, promises, or claims without evidence base. Respondent is subject to existing laws regarding advertising that is conducted "live" and or in "real time." The monitor shall be engaged before Respondent resumes clinical practice. The monitor shall report to the Board monthly, at DOH.PRCompliance@health.ri.gov, by the 15th of each month, or immediately if the monitor reasonably determines an issue requires the Board's immediate attention.

12. Respondent shall attend and be assessed by the Center for Personalized Education for Physicians (CPEP) and follow its recommendations, which recommendations shall be incorporated by reference within this Consent Order. All results from CPEP shall be forwarded by CPEP directly to the Board and Respondent. The results of that assessment shall be within the "Independently address education needs" or "Structured Education Intervention" categories, as defined and described in the CPEP Educational Recommendations: Explanations and Implications attached hereto.

13. Respondent has ceased offering the product "Wingman" and Respondent shall not offer it or any other product that promotes excessive alcohol consumption.

14. Respondent shall not prescribe or cause to be prescribed by others the combination of phentermine and phendimetrazine to the same patient.

15. Respondent shall attend and successfully pass CPEP Probe prior to returning to practice or within 180 days of ratification of this Consent Order, whichever is sooner, which course will address all ethical concerns identified in this Consent Order, including: how offering the contraindicated combination of phentermine and phendimetrazine comports with the medical principle "First Do no Harm;" the ethical implications of the consent form used for prescribing phentermine or phendimetrazine contained misleading statements; the ethical implications of concealing or minimizing associated risks in the informed consent form to prevent "stigmatizing the drugs" for patients; the ethical implications of starting patients on this combination of medications who had hypertension and/or a history of cardiovascular disease; and the ethical implications of offering products that promote excessive alcohol consumption. All results from CPEP shall be forwarded by CPEP directly to the Board and Respondent.

16. Copies of all materials or information submitted to CPEP and CPEP Probe will be contemporaneously provided to Respondent.

17. Respondent will notify the Board (DOH.PRCompliance@health.ri.gov) if he applies for licensure to practice medicine in any jurisdiction anywhere in the world.

18. Respondent shall ensure continuity of care for any patient affected by his suspension and shall ensure medical records are made available to patients in a timely manner.

19. Respondent agrees to pay, within 180 days of the ratification of this Consent Order , an administrative fee to the Board of $36,810.63 for costs associated with investigating the above-

referenced complaints. Such payment shall be made by certified check, made payable to "Rhode Island General Treasurer," which payment shall be sent to Rhode Island Department of Health, 3 Capitol Hill, Room 205, Providence, RI 02908, Attn: Lauren Lasso. Respondent will send notice of compliance with this condition to DOH.PRCompliance@health.ri.gov within 30 days of submitting the above-referenced payment.

20. Respondent agrees to this reprimand on his physician license.

21. In the event that any term of this Consent Order in paragraphs 5-20 above is violated, after ratified and approved, the Director of the Department of Health shall have the discretion to impose further disciplinary action pursuant to R.I. Gen. Laws §§ 5-37-5.1 through 5-37-6.3, including immediate suspension of his medical license pursuant to and as permitted by R.I.Gen.Laws §§ 5-37-8 and 42-35-14(c). If the Director imposes further disciplinary action, Respondent shall be given notice and shall have the right to request an administrative hearing within twenty (20) days of the suspension and/or further discipline. The Director of the Department of Health shall also have the discretion to request an administrative hearing after notice to Respondent of a violation of any term of this Consent Order. The Board may suspend Respondent's license or impose further discipline as described above if any alleged violation is proven by a preponderance of evidence. Any administrative hearings, whether initiated by the Director or the Respondent, shall be conducted in accordance with R.I.Gen.Laws §§ 5-37-5.1 through5-37-6.3 or R.I.Gen.Laws §§ 5-37-8 and 42-35-14(c) , the Rules and Regulations for the Licensure and Discipline of Physicians (216-RICR-40-05-1), the Rules and Regulations for Practices and Procedures Before the Rhode Island Department of Health (216-RICR-10-05-4), and applicable provisions of R.I. Gen. Laws Chapter 42-35 and § 42-35-9 through 42-35-13.

Any discipline ultimately imposed pursuant to this paragraph is appealable pursuant to Rhode Island Gen. Laws §§ 5-37-37 et seq. and 42-35-15 et seq. *

Signed this 9 day of October 2019.

Stephen Petteruti DO
Stephen Petteruti, DO

Ratified by the Hearing Panel as appointed by the Director, Dr. Nicole Alexander-Scott on the 9th day of October, 2019.

10/9/19
James Monti, MD — Date

9 Oct 2019
Patricia Delaney — Date

10/9/2019
Catherine DeGood, DO — Date

Ratified and approved by the Director of the Department of Health:

Nicole Alexander-Scott, MD, MPH
Director of Health
3 Capitol Hill, Room 401
Providence, RI 02908

* As modified on the record at the Hearing Committee hearing on October 9, 2019, which portion of the record will be transcribed and attached hereto.

Appendix III

CPEP Educational Recommendations: Explanations and Implications

Note: Although this document refers to physicians, CPEP conducts Assessments and Educational Interventions for physician assistants, advanced practice nurses, and podiatrists, and the following is applicable to all healthcare providers that are evaluated by CPEP.

Physician performance on a CPEP Assessment falls along a broad spectrum. Often, for both the physician involved and the referring organization, the critical questions are, "What does this mean?" and "How do I/we move forward from here?" CPEP provides direction through the Educational Recommendations that are provided in the Assessment Report.

While the educational activities that would benefit a physician are very specific to that individual, CPEP Educational Recommendations fall into three broad categories.

- *Independently address educational needs*

No physician is expected to perform perfectly during an Assessment, and no physician knows everything. Some physicians who participate in an Assessment demonstrate minimal or limited educational needs, which we believe they should be able to address independently through self-study, CME, and other resources. We recommend that these physicians incorporate these topics into their ongoing professional education activities. Although CPEP does not use the terms "pass" or "fail," if thinking along those terms, it is reasonable to consider that an individual receiving this recommendation has "passed" the Assessment.

The wording used to convey this in an Assessment Report is typically similar to the following: "CPEP believes that Dr. Smith should have the resources to address these educational needs independently, without the benefit of an Educational Intervention. All professionals have a responsibility for self-directed, ongoing learning and Dr. Smith should continue to make this a part of his work."

- *Residency or residency-like setting*

On the other end of the spectrum, some physicians demonstrate educational needs that are of a quantity or quality such that CPEP believes that they are not equipped with the resources to address their educational needs while they continue to practice. CPEP recommends that these physicians address their educational needs in a residency or residency-like setting. Our opinion is that it would not be safe for this physician to practice independently; they are in need of the structure and rigor of an academic setting to provide an intensive and highly supervised educational experience. As stated previously, CPEP does not use the terms "pass" or "fail." However, it is reasonable to consider that an individual receiving this recommendation has "failed" the Assessment.

CPEP acknowledges that residency positions may be difficult for practicing physicians to secure; therefore, the wording residency-like setting is intended to suggest that other situations may be acceptable, such as a voluntary position in a training setting, a fellowship, or other such situation

in which the physician can benefit from learning in a formal training or educational setting. To further clarify, a recommendation that an individual address their educational needs in a training setting does not necessarily indicate that the equivalent of a full residency be completed; the specific needs of the physician will vary and the training might range from one year or longer.

The wording used in an Assessment Report to convey such a recommendation will be similar to the following: "Because of the extent of the deficiencies identified, CPEP believes that Dr. Smith should retrain in a residency or residency-like setting. CPEP does not believe that Dr. Smith demonstrated the ability to remain in independent practice while attempting to remediate his clinical skills."

- *Structured Educational Intervention*

In the middle of the spectrum are those participants who demonstrate educational needs that CPEP believes should be addressed with external structure, oversight, and/or some level of supervision. These physicians should be able to address their educational needs while they continue or return to practice.

The Educational Recommendations in the Assessment Report will read something comparable to: "CPEP recommends that Dr. Smith participate in structured, individualized education to address the identified areas of need." Physician-participants and referring organizations have found value in CPEP Education Services, through which we provide expertise in developing specific and clear educational objectives, structure in the educational process, and a means by which integration and implementation of new learning and approaches can be demonstrated. CPEP Education Services are available, if desired and requested by the physician-participant or referring organization, and would include development of an Educational Intervention Plan (a detailed learning contract) and ongoing support, monitoring, and oversight during the course of the physician's educational process. Please contact CPEP Education Services for additional information.

DR. McDONALD: In the event CPEP does not require medical record review, Respondent agrees to a Board-approved monitor, at his own expense, to conduct a medical record review of 10 percent of charts of each of three services lines, Drip Bar/cancer, weight loss, and primary care, monthly times 12 months. Then, if satisfactory review to the Department, then 10 charts per quarter for each of the three service lines times the remaining four years. Medical record review may terminate sooner upon approval of the Department.