Public

STATE OF NEW YORK DEPARTMENT OF HEALTH BPMC No. 14-145
STATE BOARD FOR PROFESSIONAL MEDICAL CONDUCT

IN THE MATTER

OF

SHELDON RANDALL, M.D.
CO-13-09-4776A

COMMISSIONER'S SUMMARY ORDER

TO: Sheldon Randall, M.D.
101 Main St., Ste. 107
Medford, MA 02155

Sheldon Randall, M.D.
REDACTED

Sheldon Randall, M.D.
REDACTED

The undersigned, Howard A. Zucker, M.D., J.D., Acting Commissioner of Health, pursuant to New York Public Health Law §230, upon the recommendation of a Committee on Professional Medical Conduct of the State Board for Professional Medical Conduct, has determined that the duly authorized professional disciplinary agency of another jurisdiction, the Commonwealth of Massachusetts, has made a finding substantially equivalent to a finding that the practice of medicine by **SHELDON RANDALL, M.D.**, Respondent, New York license number 141764, in that jurisdiction, constitutes an imminent danger to the health of its people, as is more fully set forth in the Order of Temporary Suspension of the Commonwealth of Massachusetts Board of Registration in Medicine, dated August 16, 2013 (henceforth: "predicate action"), attached, hereto, as Appendix "A," and made a part, hereof.

It is, therefore:

ORDERED, pursuant to New York Public Health Law §230(12)(b), that effective immediately, **SHELDON RANDALL, M.D.**, shall not practice medicine in the State of

New York or in any other jurisdiction where that practice is predicated on a valid New York State license to practice medicine.

ANY PRACTICE OF MEDICINE IN THE STATE OF NEW YORK IN VIOLATION OF THIS ORDER SHALL CONSTITUTE PROFESSIONAL MISCONDUCT WITHIN THE MEANING OF NEW YORK EDUCATION LAW §6530(29) AND MAY CONSTITUTE UNAUTHORIZED MEDICAL PRACTICE, A FELONY DEFINED BY NEW YORK EDUCATION LAW §6512.

This Order shall remain in effect until the final conclusion of a hearing which shall commence within thirty (30) days after the final conclusion of the disciplinary proceeding in Massachusetts.

The hearing will be held pursuant to the provisions of New York Public Health Law §230, and New York State Administrative Procedure Act §§301-307 and 401. The hearing will be conducted before a committee on professional conduct of the State Board for Professional Medical Conduct on a date and at a location to be set forth in a written Notice of Referral Proceeding to be provided to the Respondent after the final conclusion of the Massachusetts proceeding. Said written Notice may be provided in person, by mail, or by other means. If Respondent wishes to be provided said written notice at an address other than that set forth above, Respondent shall so notify, in writing, both the attorney whose name is set forth in this Order, and the Director of the Office of Professional Medical Conduct, at the addresses set forth below.

RESPONDENT SHALL NOTIFY THE DIRECTOR OF THE OFFICE OF PROFESSIONAL MEDICAL CONDUCT, NEW YORK STATE DEPARTMENT OF HEALTH, RIVERVIEW CENTER, SUITE 355, 150 BROADWAY, ALBANY,

NY 12204, VIA CERTIFIED MAIL, RETURN RECEIPT REQUESTED, OF THE FINAL CONCLUSION OF THE PROCEEDING IMMEDIATELY UPON SUCH CONCLUSION.

THESE PROCEEDINGS MAY RESULT IN A DETERMINATION THAT YOUR LICENSE TO PRACTICE MEDICINE IN NEW YORK STATE BE REVOKED OR SUSPENDED AND/OR THAT YOU BE FINED OR SUBJECT TO OTHER SANCTIONS SET FORTH IN NEW YORK PUBLIC HEALTH LAW §230-a. YOU ARE URGED TO OBTAIN AN ATTORNEY TO REPRESENT YOU IN THIS MATTER.

DATE: Albany, New York
June 3rd, 2014

REDACTED

Howard A. Zucker, M.D., J.D.
Acting Commissioner of Health
New York State Department of Health

Inquires should be directed to:

David W. Quist
Associate Attorney
Bureau of Professional Medical Conduct
Corning Tower – Room 2512
Empire State Plaza
Albany, New York 12237
(518) 473-4282

COMMONWEALTH OF MASSACHUSETTS

Middlesex, SS.

Board of Registration in Medicine

Adjudicatory Case No. 2013-039

In the Matter of

SHELDON RANDALL, M.D.

ORDER OF TEMPORARY SUSPENSION

In accordance with the Rules of Procedure Governing Disciplinary Proceedings of the Board of Registration in Medicine, 243 CMR 1.03(11)(a), the Board of Registration in Medicine ("the Board") **ORDERS** that

> The certificate of registration to practice medicine in the Commonwealth of Massachusetts of Sheldon Randall, M.D., Registration No. 54846, is **SUSPENDED** effective immediately. Sheldon Randall, M.D. must cease the practice of medicine immediately, and he is directed to surrender his wallet card and wall certificate to the Board forthwith.

The Board has determined that, based upon the information set forth in the Motion for Summary Suspension, the health, safety, and welfare of the public necessitates said suspension.

The Respondent shall provide a copy of this Order of Suspension within twenty-four (24) hours to the following designated entities: any in- or out-of-state hospital, nursing home, clinic, other licensed facility, or municipal, state, or federal facility at which he practices medicine; any in- or out-of-state health maintenance organization with whom he has privileges or any other kind of association; any state agency, in- or out-of-state, with which he has a provider contract; any in- or out-of-state medical employer, whether or not he practices medicine there; and the state licensing boards of all states in which he has any kind of license to practice medicine; Drug Enforcement Administration Boston Diversion Group; and the Massachusetts Department of Public Health Drug Control Program. The Respondent is further directed to certify to the Board within forty-eight (48) hours that he has complied with this directive.

REDACTED

Gerald B. Healy, M.D.
Vice Chair

Dated: August 16, 2013

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SENT CERTIFIED MAIL 8/16/13 (mg)

Exhibit 14

COMMONWEALTH OF MASSACHUSETTS

Middlesex, SS. Board of Registration in Medicine

Adjudicatory Case Nos. 2013-039

In the Matter of

SHELDON RANDALL, M.D.

STATEMENT OF ALLEGATIONS

The Board of Registration in Medicine (Board) has determined that good cause exists to believe the following acts occurred and constitute a violation for which a licensee may be sanctioned by the Board. The Board therefore alleges that Sheldon Randall, M.D. (Respondent) has practiced medicine in violation of law, regulations, or good and accepted medical practice as set forth herein. The investigative docket numbers associated with this order to show cause are Docket Nos. 12-238, 12-446 and 13-252.

Biographical Information

1. The Respondent was born on February 6, 1952. He graduated from the Centro de Estudios Universitarios Xochicalco, Mexico in 1978. He is certified by the American Board of Medical Specialties in General Surgery. He has been licensed to practice medicine in Massachusetts under certificate number 54846 since 1985. He is also licensed to practice medicine in New York.

2. The Respondent has had full privileges at Metro West Medical Center/Leonard Morse Hospital Campus (MetroWest) since 2007.

Factual Allegations

3. The Respondent held privileges at Hallmark from 1999 until March 18, 2012, at which time Hallmark imposed a precautionary suspension of the Respondent's privileges pending an investigation into the death of Patient A.

4. The Respondent was credentialed to perform open Roux-En-Y gastric bypass procedures, and laparoscopic gastric banding procedures at Hallmark.

5. The Respondent was not credentialed to perform laparoscopic Roux-en-Y bypass procedures at Hallmark.

6. On or about April 11, 2012, Hallmark notified the Respondent that his Medical Staff membership was terminated and all of his clinical privileges were revoked.

7. Hallmark informed the Respondent that the reason for the termination was concerns related to the case of Patient A and to other areas of broad concern that called into serious question the Respondent's ability to abide by the principles and display the integrity required to be a member of the Hallmark Health Medical Staff.

8. The Respondent appealed this decision and the appeal was scheduled for a hearing on November 16, 2012.

9. On November 16, 2012, the Respondent withdrew his request for a hearing and resigned from Hallmark's Medical Staff, effective that day.

10. The Respondent has had privileges at MetroWest since 2007.

11. The Respondent was not approved to perform laparoscopic gastric bypass operations at MetroWest until April 23, 2013.

12. In or around early 2013, MetroWest conducted an investigation into the Respondent's performance, including his care of Patients C and D.

13. On May 14, 2013, MetroWest restricted the Respondent's privileges as follows: (1) All primary open high gastric bypass surgery cases must be prospectively reviewed with the Chair of Surgery prior to the procedure and the Chair must approve the procedure; (2) all laparoscopic high gastric bypass surgery cases must be performed with a second laparoscopic/ bariatric surgeon in attendance.

Patient A

14. In March 2012, Patient A was a 45-year-old male who had a Body Mass Index (BMI) of 41. He had a history of insulin-dependent diabetes mellitus, hyperlipidemia, hypertension, metabolic syndrome, reflux and sleep apnea.

15. Patient A had poorly controlled diabetes preoperatively; he wasn't taking his insulin and had a hemoglobin A1c of 12.6 in or about January 2012.

16. There is no record that Patient A's hemoglobin A1c was re-checked following the A1c result of 12.6.

17. Poorly controlled diabetes can represent a sign of poor patient compliance with medical treatment.

18. On March 2, 2012, Patient A's pre-operative fasting blood sugar was 214.

19. On March 14, 2012, the Respondent performed an open Roux-en-Y gastric bypass, liver biopsy, gastrostomy tube (G-tube) placement, TAP nerve block, and percutaneous catheter placement on Patient A at Hallmark.

20. In May 2006, the Respondent co-authored a study that concluded that open gastric bypass led to higher complication rates compared to laparoscopic gastric bypass.

21. The procedure that was performed on Patient A was an undivided (aka non-divided) gastric bypass.

22. Undivided gastric bypass has a high incidence of the undivided gastric staple line breaking down over time and causing fistula formation.

23. Patient A underwent a difficult operation, described by the Respondent in his Operative Report as deep.

24. During the procedure, the stapler did not fire properly, causing the Respondent to remove staples and restaple Patient A's stomach.

25. On March 16, 2012, Patient A's temperature fluctuated between approximately 98° and 101° with elevated blood sugar and creatinine levels.

26. In the morning of March 16, 2012 and continuing throughout the day, Patient A complained of pain at a level of 8 or 9 on a scale of 10, and of feeling bloated.

27. In the morning of March 16, 2012 and continuing throughout the day, Patient A's heart rate was tachycardic.

28. At approximately 1400 on March 16, 2012, the Respondent noted that Patient A felt bloated, but his abdomen was soft, and his wound was clear. The Respondent noted that Patient A's progress was slow but satisfactory, and that Patient A might be possibly home the following day.

29. At 2250 on March 16, 2012, Patient A complained of 10 out of 10 pain, with little response to pain medication. The nurse documented that Patient A's abdomen was distended and tender.

30. Around that time, the Respondent saw Patient A and ordered Ativan.

31. The Respondent did not evaluate Patient A for a leak, bleeding or a pulmonary embolism on March 16, 2012.

32. On March 17, 2012, between midnight and approximately 0230, Patient A became agitated. He twice vomited a reddish brown emesis. He had a fever, and his heart rate was 120 bpm.

33. The Respondent was called and ordered blood tests, a chest x-ray, and a CT scan.

34. A CT performed between approximately 0200 and 0230 on March 17, 2012, was suspicious for a small bowel obstruction at the level of the jejunojejunostomy.

35. By 0230 on March 17, 2012, Patient A was confused, his abdomen was distended and his temperature was 102.2°.

36. The nurse called the Respondent about 0230 on March 17, 2012. She told the Respondent about Patient A's condition, the results of the CT scan, and the results of the blood tests.

37. The Respondent examined Patient A at approximately 0400 on March 17, 2012. The Respondent noted that Patient A had a probable small bowel obstruction at the jejunojejunostomy. The Respondent's impression was that it was postoperative ileus or postoperative edema at the site. The Respondent wrote that he planned to treat Patient A conservatively and to perform exploratory surgery if there was no improvement over the subsequent 12 to 24 to 36 hours.

38. The Respondent's impression of a post-operative ileus was not supported by Patient A's clinical signs and symptoms.

39. At approximately 0530 on March 17, 2012, Patient A's temperature was 105.3°. The nurse was unable to reach the Respondent and she paged the Critical Care physician to evaluate Patient A.

40. At approximately 0600, the Critical Care physician noted that Patient A's temperature was 106°.

41. At 0645 on March 17, 2012, the Respondent noted that Patient A's temperature was down to 103°. The Respondent planned a surgical exploration. He noted questionable small bowel obstruction secondary to intraluminal bleed.

42. On March 17, 2012, at approximately 0800, the Respondent performed an exploratory laparotomy, small bowel enterotomy, and evacuation of the intraluminal bleed of approximately 1300 ml of old clotted blood, with an oversew of the anterior anastomosis.

43. The Respondent described a bleed at the distal anastomosis [the jejuno-jejunostomy] causing a backup of fluid and [a leak] bubbles at the proximal anastomosis [the gastro-jejunostomy].

44. The Respondent interpreted his findings as "no leak" after he repaired the site of the bubbles.

45. The Respondent did not address the bleeding site, which was the staple line of the jejuno-jejunostomy.

46. Following surgery, Patient A was on antirrhymics to maintain his heart rate and rhythm and pressors to maintain his blood pressure.

47. At approximately 1700 on March 18, 2012, Patient A's temperature was 106.5°.

48. At approximately 1930 on March 18, 2012, Patient A had developed atrial fibrillation with a rapid ventricular response of 120-130 bpm and a mean arterial pressure (MAP) of 50-60 Hg.

49. At approximately 2328 on March 18, 2012, Patient A's blood pressure was 50-60 systolic on Levophed at 20 mcg/min and his temperature was 106.1°.

50. At approximately 2333 on March 18, 2012. Dr. Randall signed the Authorization for Transfer. He checked the box that stated. "This individual has been stabilized such that, within reasonable medical probability, no material deterioration of this individual's condition is likely to result from transfer."

51. At approximately 2338 on March 18, 2012. Patient A had a sudden episode of a supraventricular tachycardia (SVT) at greater than 170 bpm.

52. At approximately 0300 on March 18, 2012. Patient A's care was transferred to the MedFlight paramedics.

53. The MedFlight team arrived at Massachusetts General Hospital (MGH) with Patient A at 0337. As the paramedics were backing the ambulance into place, Patient A went into cardiac arrest.

54. Cardiopulmonary resuscitation (CPR) was continued as the paramedics brought Patient A into the MGH ER. The MGH ER staff continued with CPR and Advanced Cardiovascular Life Support (ACLS) protocol, but they were never able to regain a rhythm or pulse.

55. Patient A was pronounced dead at 0352 on March 18, 2012; the cause of death was sepsis.

56. The Respondent failed to meet the standard of care in his treatment of Patient A. in that he:

a) Performed an open gastric bypass which has been shown to lead to higher complication rates compared to laparoscopic gastric bypass;

b) Failed to investigate whether Patient A had a leak or bleeding, when Patient A became tachycardic following surgery;

c) Failed to address Patient A's leak and bleeding in a timely manner;

d) Failed to recognize that Patient A's clinical presentation was inconsistent with an ileus;

e) Failed to evaluate the bleeding site during Patient A's second surgery;

f) Ordered the transfer of Patient A to another hospital, when Patient A was medically unstable; and

g) Failed to resuscitate and stabilize Patient A prior to transfer to another hospital.

Patient B

57. The Respondent initially consulted with Patient B on November 20, 2009, when he evaluated her for weight-loss surgery.

58. At that time, Patient B was a 25-year-old female, who weighed 319 pounds and had a BMI of 46.

59. On March 25, 2010, the Respondent performed an open gastric bypass and cholecystectomy surgery on Patient B at MetroWest.

60. In November 2011 and January 2012, Patient B presented to the ER at MetroWest with abdominal pain. CT scans and other diagnostic tests were negative for pathology.

61. In December 2011, Patient B met with the Respondent on two occasions concerning the abdominal pain she was experiencing.

62. On or about February 2, 2012, Patient B met with the Respondent. He noted a fascial defect and spoke to her concerning an incisional hernia repair.

63. By February 2012, Patient B had lost approximately 100 pounds following her 2010 gastric bypass surgery.

64. The Respondent noted that Patient B had a history of yeast infections from excessive abdominal adiposity.

65. At that visit, the Respondent also noted that Patient B needed a panniculectomy.

66. On February 2, 2012, Patient B signed an operative consent for repair of incisional hernia, possible use of mesh, and panniculectomy.

67. The Respondent told Patient B that he would not perform a panniculectomy without also performing a full abdominoplasty.

68. The Respondent told Patient B that an abdominoplasty was a cosmetic procedure that would not be covered by insurance.

69. Patient B agreed to pay the Respondent $1,000 for an abdominoplasty.

70. The Respondent told Patient B not to discuss the abdominoplasty with MetroWest staff.

71. On February 10, 2012, Patient B was admitted to MetroWest for surgery to be performed by the Respondent.

72. The Respondent's Operative Report of February 10, 2012 noted that he performed the following procedures on Patient B: incisional hernia repair, TAP nerve block and panniculectomy.

73. The Respondent also performed an abdominoplasty on Patient B.

74. The term "abdominoplasty" did not appear in the Respondent's Operative Report.

75. The consent form signed by Patient B did not include consent for an abdominoplasty.

76. The Respondent noted that Patient B's vital signs were stable and her intake and output were good. He wrote that he would transfuse Patient B with two units of packed red blood cells for a preoperative Hct of 28%.

77. Patient B was transfused with two units of blood.

78. The anesthesia record for Patient B's surgery estimated her blood loss at 50cc.

79. At an office visit on February 16, 2012, the Respondent noted that Patient B's wound was clean and dry. He removed the drains that he had placed during her surgery.

80. On February 16, 2012, the Respondent cleared Patient B to return to work half-time beginning on February 20, 2012, and full time beginning one week later. The Respondent noted "no restrictions."

81. Patient B returned to work part-time on Monday, February 20, 2012. By February 22, 2012, she felt sick and had a fever of 104°.

82. On or about February 22, 2012, Patient B contacted a physician who was covering for the Respondent. She told him she had a fever. The physician told her to begin taking Bactrim.

83. Patient B took Bactrim.

84. On February 24, 2012, Patient B sent an email to the Respondent's nurse with a question about healing.

85. The Respondent's nurse emailed Patient B with advice about wound drainage.

86. On Sunday night, February 26, 2012, Patient B spoke to the Respondent on the telephone. She was still experiencing a fever of 103° while on Tylenol.

87. The Respondent told Patient B that it was probably a virus that had nothing to do with the surgery, and to stop taking Bactrim. He suggested that she follow up in a few days if she did not feel better.

88. On the evening of February 27, 2012, Patient B sent another email to the Respondent's nurse.

89. In that email, Patient B noted that her fever had gone up to 103° despite taking Tylenol every 4 to 6 hours, along with Vicodin for pain, vitamins and Bactrim.

90. Patient B stated that she was getting worse and had fluid build up all around where she had surgery.

91. In the early morning of February 28, 2012, Patient B woke up soaked in fluid. Her incision had opened in the front and toward the left side.

92. Patient B's fever broke and she felt a little better.

93. On the morning of February 28, 2012, the Respondent's nurse emailed him that Patient B had reported that her fever had resolved with the drainage of fluid this morning, and that she had woken up soaking wet.

94. The nurse instructed Patient B on wound care, and told her to continue with the Bactrim that the Respondent had prescribed.

95. The nurse reported that Patient B did not feel up to coming to the Respondent's office or to the emergency room (ER) that day, and said she would come to the office at 8:30 a.m. on the following day for a wound evaluation.

96. The Respondent instructed the nurse to perform a wound check and to take a culture and sensitivity of the fluid.

97. The Respondent failed to evaluate Patient B.

98. The Respondent did not image the wound nor did he have the infection drained.

99. On February 29, 2012, Patient B saw the Respondent's nurse. Patient B's heart rate was 107 bpm. The nurse noted that there were small open areas at the midpoint of Patient B's wound and that the wound dressing was saturated with serous drainage. She also noted that the umbilical wound appeared beefy red. The nurse took a culture and sensitivity.

100. On March 1, 2012, the Respondent evaluated Patient B. He diagnosed a post operative seroma, for which he inserted a drain; 100 ml of straw-colored fluid drained out.

101. The Respondent also noted that Patient B's umbilicus was contracted, for which he inserted another drain and sutures.

102. The closed suction drains that the Respondent inserted were inappropriate to drain open wounds like Patient B had.

103. On that visit, the Respondent told Patient B that it was likely that she had done something to cause her wound to open, and that she had gone back to work too soon.

104. On the evening of March 6, 2012, Patient B sent an e-mail to the Respondent's nurse to tell her that she had just spoken to the Respondent because the front of her incision had broken open, as well as the right side of the incision. She said she could see the drainage tube being fed into the incision.

105. The Respondent's nurse agreed to see Patient B the following morning.

106. On March 7, 2012, Patient B saw the Respondent's nurse in the office. The nurse sent a culture of the umbilical wound and noted that Patient B's wounds were reddened. Suction was not being maintained on the Jackson-Pratt drains. The nurse called the Respondent who stated he would see Patient B the following day.

107. The Respondent saw Patient B on March 8, 2012 and noted a skin dehiscence on her right flank. The cultures grew *staph aureus* for which he started antibiotics. The Respondent removed a drain and packed Patient B's wounds.

108. The Respondent again saw Patient B in his office on March 9, 2012, and documented that hospitalization was a possibility if the drainage did not decrease.

109. On March 11, 2012, Patient B was admitted to MetroWest with the diagnosis of non-healing abdominal wounds. Patient B was being admitted for IV antibiotics and Wound VAC placement.

110. Patient B was discharged from MetroWest on March 13, 2012.

111. Patient B was followed by a Visiting Nurses' Association nurse upon discharge from MetroWest.

112. Patient B's last visit with the Respondent was on April 12, 2012. At that time, the Respondent documented that Patient B's wound was greater than 90% healed. He cauterized some skin on her flank wound.

113. At that visit, the Respondent cleared Patient B to return to work on April 17, 2012.

114. The Respondent failed to meet the standard of care in his treatment of Patient B, in that he:

a) Performed an abdominoplasty without obtaining Patient B's written consent;

b) Performed an abdominoplasty without including the term in Patient B's medical records;

c) Performed a transfusion that was medically unnecessary;

d) Failed to recognize clear symptoms of a wound infection in Patient B;

e) Failed to address Patient B's complications in a timely manner; and.

f) Attempted to drain Patient A's open wounds with closed suction drains.

Patient C

115. In August 2012, Patient C was a 46-year-old female who had a BMI of 40. She had a medical history of hypertension, hypothyroidism, status post cholecystectomy, status post rotator cuff surgery, and breast reduction surgery with unspecified complications.

116. On August 3, 2012, the Respondent performed an open Roux-en-Y gastric bypass, liver biopsy, TAP nerve block, and percutaneous bilateral catheters for pain control on Patient C.

117. The procedure that was performed on Patient C was an undivided (aka non-divided) gastric bypass.

118. On August 4, 2012, Patient C's vital signs were stable. However, her WBC was 16,700, and her Hbg/Hct were low.

119. Patient C began to have signs and symptoms of postoperative bleeding between postoperative day one and two. These signs were dropping hemoglobin, hemodynamic instability with heart rate at 130 bpm and systolic blood pressure in the 80s.

120. On the morning of August 5, 2012, Patient C's heart rate was 134 bpm, her WBC was 31,000, and her blood pressure was 80/40.

121. The Respondent was notified about these results at approximately 0830 on August 5, 2012. He ordered a fluid bolus, a stat abdominal/pelvic CT scan with contrast, antibiotics and transfer to the intensive care unit (ICU).

122. The Respondent saw Patient C at 0940 on August 5, 2012. He documented that she had improved after the bolus. He questioned whether she was having an intraluminal bleed.

123. A CT scan showed partial destruction of the residual gastric pouch and marked dilatation of the excluded portion of the stomach and small bowel. This appearance was suggestive of obstruction by internal hernia or volvulus. Ascites fluid was present.

124. The Respondent documented that the CT scan was consistent with distal gastric dilatation suggesting an intraluminal bleed. He consulted with the Interventional Radiologist (IR) about initiating percutaneous drainage to decompress the distal stomach.

125. At 1227 on August 5, 2012, Patient C's WBC was 40,700.

126. The Critical Care physician who saw Patient C at 1522 on August 5, 2012, recorded that Patient C's WBC of 40,700 was "far and away above what would be expected just for a gastric outlet obstruction." She also noted that Patient C's abnormal electrolytes, platelets, and bicarbonate levels spoke to sepsis.

127. At 1610 on August 5, 2012, the IR performed a CT-guided percutaneous gastrostomy procedure to decompress the gastric component and to place a pigtail catheter into Patient C's gastric remnant. Coffee ground-type material freely flowed through the catheter. The IR also noted a moderate amount of free fluid in the upper abdomen.

128. At 1700 on August 5, 2012, the Respondent documented that Patient C was feeling better. The Respondent felt that there was no evidence for septicemia.

129. Patient C had imaging which documented the likely cause of blood loss as being into the excluded stomach, causing ascites and gastric remnant distention. The imaging documented likely bleeding into the excluded stomach, which warranted surgical exploration to prevent staple line disruption, stomach perforation, and to stop the bleeding.

130. Patient C should have been emergently returned to the operating room (OR) by August 5, 2012.

131. On August 6, 2012, Patient C underwent a CT scan that showed a moderate amount of free fluid or blood in the peritoneal cavity. There was a density posterior to the transverse colon from edema, or perhaps hemorrhage, that had increased since the previous CT scan.

132. On August 7, 2012, Patient C's hematocrit was essentially unchanged, despite having received six units of blood.

133. On August 8, 2012, Patient C underwent an endoscopic evaluation of her esophagus, stomach, and duodenum/jejunum. The endoscopy showed evidence of recent bleeding, but no vessels were currently bleeding.

134. On August 9, 2012, Patient C's WBC increased again to 18,100 with 32% bands, and Patient C had spiked a fever of 102° with shaking chills.

135. The Respondent noted that there was no evidence for sepsis and ordered a CT scan.

136. A CT scan was performed on August 10, 2012. The CT showed that the excluded portion of the stomach and duodenum were distended with fluid; the drainage catheter was seen within the stomach. Oral contrast had not extended beyond the anastomosis. There was ascites.

137. From August 4, 2012 through August 11, 2012, Patient C continued to spike fevers and have on-going transfusion requirements.

138. On August 11, 2012, Patient C developed atrial flutter at a rate of 170 bpm.

139. The Respondent performed an exploratory laparotomy on August 11, 2012 at approximately 1520. He found diffuse ileus, without points of obstruction. There was staining on the omentum from Patient C's previous G-tube site that might have leaked. There was less

than 1L of ascites and no purulent fluid. The Respondent aspirated about 1500 ml from the gastric remnant and replaced the G-tube.

140. During the surgery, the Respondent failed to expose the source of bleeding, the gastric remnant, and failed to examine the source for leak or on-going bleeding.

141. Over the next several days, Patient C continued to spike fevers, have an elevated WBC, tachycardia and require blood transfusions.

142. On August 16, 2012, a CT scan was performed. There was increased induration of the mesentery with increased ascites. There was also a new oval area along the hepatic margin that had soft tissue and air density. The radiologist discussed this finding with the Respondent who said that he had placed Surgicel in this area.

143. The Respondent wrote that there were no major findings in the CT results and attributed the increase in ascites to the peritoneal irrigation fluid he used during surgery.

144. Irrigation fluid is absorbed within hours after surgery.

145. The Respondent failed to tap, culture and drain the fluid that he described as irrigation fluid.

146. At 1800 on August 16, 2012, the Infectious Disease consultant noted that Patient C's wound had opened slightly and was draining serous fluid. He thought that Patient C's abdominal fluids were infected.

147. On August 19, 2012, Patient C was again febrile with an elevated WBC. Her wound had opened more and was draining purulent drainage.

148. Patient C passed approximately 200 ml of mahogany blood per rectum.

149. On August 20, 2012, Patient C underwent an endoscopy. Although the findings were negative for a GI bleed, the gastroenterologist found esophagitis and possible candida.

150. The type of endoscopies performed on August 8, 2012 and August 20, 2012 were not able to access the source of Patient C's bleeding, which was the gastric remnant.

151. Multiple endoscopies increased Patient C's risk of disruption to her anastomoses.

152. During the course of Patient C's prolonged hospital stay, the Respondent failed to evaluate Patient C's nutritional parameters or provide supplemental nutrition to improve her chances of healing.

153. On August 22, 2012, Patient C was discharged from MetroWest.

154. On September 4, 2012, Patient C saw the Respondent in his office. He removed her G-tube.

155. On September 6, 2012 at 0900, Patient C arrived in the ER at Holy Family Hospital in Methuen complaining of 10/10 abdominal pain. Patient C said that she passed a large red blood clot after a bowel movement that morning.

156. Patient C was tachypneic (40), hypotensive (46/32), tachycardic (160), with weak peripheral pulses, and cool diaphoretic skin. Her temperature was 104.3° rectally. She had mental status changes. Her blood work was consistent with sepsis and GI bleeding.

157. The ER physician arranged for direct admission of Patient C to MetroWest's ICU.

158. At 1232, Patient C was admitted to MetroWest's ICU with a diagnosis of intra-abdominal abscess and infected hematoma.

159. The Respondent saw Patient C at approximately 1240.

160. Patient C underwent CT scanning at 1611. The CT findings were consistent with a staple line dehiscence in the diverted stomach. An abscess had developed in the mid-abdominal region where a fluid collection was present two weeks earlier. There were additional areas of fluid density and air bubbles with thickening of the ascending colon.

161. The radiologist discussed the CT findings with the Respondent that afternoon.

162. At 1730, the Critical Care physician noted that she was waiting to learn from the Respondent whether surgery would be performed that day or the next day.

163. At approximately 2030 on September 6, 2012, the Respondent documented that he felt that Patient C was stable enough to wait twenty-four hours for surgery, to be performed during the daylight hours.

164. At approximately 1500 on September 7, 2012, the Respondent performed an exploratory laparotomy, evacuation of infected hematoma, placement of a G-tube, and took cultures and irrigated the abdomen.

165. Intraoperatively, the Respondent found an infected, foul-smelling hematoma that he evacuated that included approximately 500 ml of fluid and necrotic tissue. He found no signs of purulence in the small bowel or pelvis, but noted that the upper abdomen was somewhat frozen. He also noted that he was able to identify the stomach.

166. The Respondent placed the G-tube into the colon, rather than where he intended to place it, into the remnant stomach.

167. On September 8, 2012, Patient C had an x-ray that was suggestive of a misplaced G-tube and ongoing bowel leakage.

168. The Respondent decided to continue with the current treatment plan, rather than to replace the G-tube.

169. On September 11, 2012, a CT scan showed that the G-tube did not appear to be within Patient C's stomach, but instead appeared to be in the transverse colon.

170. The CT scan confirmed the diagnosis of colonic injury and malpositioned G-tube.

171. The Respondent failed to perform an immediate diversion and washout to treat the bacteremia as soon as the diagnosis of a malpositioned G-tube and colonic leakage was made.

172. On September 13, 2012, Patient C began draining fecal material through her Jackson-Pratt drains.

173. On September 15, 2012, Patient C was transferred to MGH.

174. The Respondent failed to meet the standard of care in his treatment of Patient C. in that he:

a) Performed an open gastric bypass which has been shown to lead to higher complication rates compared to laparoscopic gastric bypass;

b) Failed to emergently return Patient C to the operating room when she developed signs and symptoms of significant postoperative bleeding between postoperative day one and two;

c) Failed to surgically explore Patient C in a timely manner to prevent staple line disruption, stomach perforation and stop her bleeding between postoperative day one and two;

d) Failed to explore Patient C until eight days after surgery, despite her continued fevers and on-going transfusion requirements;

e) Failed to expose Patient C's gastric remnant as the source of bleeding and to examine it for leaks during Patient C's second surgery;

f) Failed to tap, culture and drain Patient C's abdominal fluid, during her surgery on August 11, 2012;

g) Failed to operate on Patient C on September 6, 2012, when she showed signs of sepsis;

h) Mistakenly placed a G-tube into Patient C's colon;

i) Failed to diagnose Patient C's colonic injury and the malpositioned G-tube in a timely manner; and,

j) Failed to treat the ongoing fecal contamination in Patient C's peritoneum for four days.

Patient D

175. In December 2012, Patient D was a 67-year-old female with a BMI of approximately 51. She had a history of type II diabetes, hypertension, sleep apnea, restrictive lung disease, and decreased cardiac ejection fraction.

176. Patient D was a high risk patient for gastric bypass surgery.

177. High risk patients typically have a limited reserve to deal with surgical complications, and as a result require more urgent treatment for complications.

178. Laparoscopic gastric bypass, laparoscopic sleeve gastrectomy and laparoscopic adjustable gastric band surgeries carry lower risk profiles than undivided open Roux-en-Y gastric bypass procedures.

179. Patient D should have had a type of bariatric surgery that carried a lower risk profile than undivided open Roux-en-Y gastric bypass.

180. On December 19, 2012, the Respondent performed an undivided open Roux-en-Y gastric bypass, liver biopsy, TAP block, and percutaneous placement of bilateral catheters for postoperative pain control on Patient D at MetroWest.

181. Patient D was clinically stable on December 20, 2012 and December 21, 2012.

182. On December 22, 2012, Patient D had several episodes of vomiting.

183. The Respondent was notified about this on at least two occasions on December 22, 2012.

184. The Respondent did not obtain imaging on that day.

185. The endocrine consult on December 22, 2012, noted that Patient D was vomiting, not tolerating anything by mouth, and she no longer was receiving IV fluids. The consultant ordered anti-nausea medication and continuous IV fluids.

186. A CT scan on December 23, 2012, showed marked distention of the gastric pouch and fluid and air in the gastric remnant. The findings were consistent with obstruction of the excluded stomach and the proximal jejunojejunostomy.

187. On December 23, 2012, the radiologist discussed the CT results with the Respoondent.

188. The Respondent noted that Patient D had intermittent nausea and was now vomiting blood.

189. On or about December 23, 2012, Patient D had a CT guided G-tube placement. There was a large amount of yellow drainage.

190. The Respondent noted that Patient D's G-tube drained more than two liters of bloody fluid from the distal stomach and biliopancreatic limb.

191. A percutaneous G-tube placement would not address vomiting.

192. The Respondent should have returned Patient D to the OR for relief of an early postoperative bowel obstruction in order to prevent ongoing vomiting, reduce the risk of aspiration, and reduce the risk to the anastomoses.

193. In the early morning of December 24, 2012, Patient D's G-tube fell out, allowing the stomach hole to leak gastric contents into Patient D's peritoneum.

194. The Respondent failed to return Patient D to the operating room when the G-tube fell out.

195. On December 24, 2012, the Respondent ordered a Gastrografin upper GI study for Patient D, which showed a bowel obstruction.

196. Following the upper GI study results, on December 24, 2012, the Respondent performed an exploratory laparotomy, revision of the jejunojejunostomy, and redoing of the jejunojejunostomy/enteroenterostomy by 2 on Patient D.

197. During the operation on December 24, 2012, the Respondent noted that he visually inspected the anastomoses for signs of a leak.

198. Gastrografin contrast is clear and its presence in the peritoneal cavity is not obvious.

199. During the operation of Patient D, the Respondent failed to perform a standard leak test, which was needed to determine whether there was an anastomotic leak.

200. The Respondent resected and re-did the jejunojejunostomy anastomosis even though he described it as being technically adequate.

201. A technically adequate anastomosis would not lead to a bowel obstruction requiring resection and re-do.

202. The peritoneal fluid cultures that the Respondent took intraoperatively were positive for bacteria.

203. Patient D experienced multiple complications from the bowel obstruction and likely anastomotic leak. Patient D suffered rhabdomyolysis, ultimately resulting in dialysis; tracheostomy for ventilator dependence; pressure ulcers; wound infection; heparin induced thrombocytopenia; deep vein thrombosis; urinary tract infection; and encephalopathy.

204. On January 16, 2013, Patient D was transferred from MetroWest to Kindred Rehabilitation Hospital (Kindred).

205. On January 18, 2013, Patient D experienced new onset seizure activity.

206. On January 21, 2013, Patient D was transferred from Kindred to St. Vincent's Hospital for evaluation and treatment.

207. Patient D died on January 30, 2013.

208. The Respondent failed to meet the standard of care in his treatment of Patient D. in that he:

a) Failed to perform bariatric surgery with a lower risk profile, given that Patient D was a high risk patient;

b) Failed to evaluate Patient D when she began vomiting on December 22, 2012;

c) Failed to return Patient D to the operating room on December 23, 2012, when she continued to vomit and when there was evidence of an obstruction;

d) Delayed operating on Patient D when her G-tube fell out in the early morning of December 24, 2012;

e) Failed to adequately investigate for the presence of leaks during Patient D's exploratory laparotomy on December 24, 2012; and

f) Lacked clarity in his intra-operative decision making.

Legal Basis for Proposed Relief

A. Pursuant to G.L. c. 112, §5, ninth par. (c) and 243 CMR 1.03(5)(a)3, the Board may discipline a physician upon proof satisfactory to a majority of the Board, that he engaged in conduct that places into question the Respondent's competence to practice medicine, including but not limited to gross misconduct in the practice of medicine, or practicing medicine fraudulently, or beyond its authorized scope, or with gross incompetence, or with gross negligence on a particular occasion or negligence on repeated occasions.

B. Pursuant to 243 CMR 1.03(5)(a)17, the Board may discipline a physician upon proof satisfactory to a majority of the Board, that said physician has committed malpractice within the meaning of M.G.L. c. 112, § 61.

C. Pursuant to *Levy v. Board of Registration in Medicine*, 378 Mass. 519 (1979); *Raymond v. Board of Registration in Medicine*, 387 Mass. 708 (1982). the Board may discipline a physician upon proof satisfactory to a majority of the Board, that said physician has engaged in conduct that undermines the public confidence in the integrity of the medical profession.

The Board has jurisdiction over this matter pursuant to G.L. c. 112, §§ 5, 61 and 62. This adjudicatory proceeding will be conducted in accordance with the provisions of G.L. c. 30A and 801 CMR 1.01.

Nature of Relief Sought

The Board is authorized and empowered to order appropriate disciplinary action, which may include revocation or suspension of the Respondent's license to practice medicine. The Board may also order, in addition to or instead of revocation or suspension, one or more of the following: admonishment, censure, reprimand, fine, the performance of uncompensated public service, a course of education or training or other restrictions upon the Respondent's practice of

medicine.

Order

Wherefore, it is hereby **ORDERED** that the Respondent show cause why the Board should not discipline the Respondent for the conduct described herein.

By the Board of Registration in Medicine,

REDACTED

Gerald B. Healy, M.D.
Vice Chair

Date: August 16, 2013

SENT CERTIFIED MAIL 8/16/13 mg

COMMONWEALTH OF MASSACHUSETTS

Middlesex, SS.

Board of Registration in Medicine

Adjudicatory Case No. 2013-039

In the Matter of
SHELDON RANDALL, M.D.

MOTION FOR SUMMARY SUSPENSION

Pursuant to 243 CMR 1.03(11), Complaint Counsel hereby moves for the suspension of Sheldon Randall, M.D.'s certificate of registration to practice "pending a hearing on the question of revocation."

As grounds for this Motion, Complaint Counsel states that the attached Affidavit of Nurse Patricia Garrison, which includes documentary evidence, demonstrates that Dr. Sheldon Randall represents a serious threat to the public health, safety or welfare. *See* Attachment A.

Board regulations provide for two options when the Board is presented with evidence that a physician may be a serious threat to the public health, safety or welfare:

1. If the Board determines that Dr. Sheldon Randall poses "an *immediate and serious threat* to the public health, safety, or welfare, the Board may suspend his license, pending a final hearing on the merits of the Statement of Allegations." 243 CMR 1.03(11)(a).

2. In the alternative, if the Board determines that Dr. Sheldon Randall "*may be a serious threat* to the public health, safety or welfare," the Board may order him to file opposing affidavits or other evidence within three business days. 243 CMR 1.03(11)(b). If, after review

of all of the affidavits and evidence before it, the Board still determines that Dr. Sheldon Randall may be a serious threat to the public health, safety or welfare's license, the Board may suspend his license, pending a final hearing on the merits of the Statement of Allegations.

Respectfully submitted,

REDACTED

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Dated: August 6 2013