COMMONWEALTH OF MASSACHUSETTS

Middlesex, SS.

Board of Registration in Medicine
Adjudicatory Case No. 2013-046

In the Matter of)
KIMBERLEY L. O'SULLIVAN, 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 Kimberley L. O'Sullivan, 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. 11-349 and 11-451.

Biographical Information

- 1. The Respondent was born on December 31, 1964. She graduated from the University of Vermont College of Medicine in 1991. She is certified by the American Board of Plastic Surgery. She has been licensed to practice medicine in Massachusetts under certificate number 157703 since 1998. The Respondent maintains a private practice, O'Sullivan Plastic Surgery, located in Wellesley, Massachusetts. She does not have any privileges at any Massachusetts hospital or clinic.
- 2. On November 20, 2012, the Board indefinitely suspended the Respondent's license to practice medicine, but stayed the suspension for a period of sixty (60) days to permit

the Respondent to enter into a Board-approved five-year Probation Agreement that included certain terms and conditions. *See* In the Matter of Kimberley L. O'Sullivan, M.D., Board of Registration in Medicine, Adjudicatory Case No. 2010-029 (Final Decision & Order, November 20, 2012).

3. On January 20, 2013, the stay expired and the Respondent's license was indefinitely suspended by the terms of the November 20, 2012 Final Decision & Order.

Factual Allegations

- 4. The Respondent performed a procedure on Patient A in the Respondent's Wellesley office on February 28, 2011.
- 5. Beginning on June 20, 2011, and on divers dates and times thereafter through August 16, 2011, Patient A requested, initially orally and subsequently in writing, a complete copy of her medical records from the Respondent.
- 6. By September 2011, Patient A received a copy of her medical records, but those records did not include the consent form that Patient A signed immediately prior to the February 28, 2011 procedure, nor any photographs of Patient A that were taken by the Respondent.
- 7. The Respondent wrote a letter to Patient A in September 2011, stating that she was compiling the remainder of Patient A's medical records.
- 8. In October 2011, the Respondent mailed copies of additional records and photographs that were located; the above-referenced consent form could not be located.
- 9. On December 15, 2011, the Respondent sent to Patient A additional documents and copies of photographs that the Respondent had taken of Patient A; the above-referenced consent form remained missing.

- 10. In January 2012, the Respondent located additional photographs and mailed them to Patient A.
 - 11. The medical records that were provided to Patient A were not complete.
- 12. The Respondent violated her statutory and regulatory duty to provide a complete copy of a patient's medical records upon request, or within a timely matter following such request.
- 13. The Respondent's notes and medical record concerning Patient A were below the standard of care in that the Respondent only documented a focused, and not a complete, physical exam, and that the records do not consistently document the medications prescribed by the Respondent to Patient A by dose, quantity or frequency.

Docket No. 11-451

- 14. On or about February 27, 2009, Patient A, the same patient as in Docket No. 11-349, consulted with the Respondent for a Smart Liposuction® procedure to her knees and inner and outer thighs, and agreed to undergo the procedure in the Respondent's Wellesley office on March 13, 2009.
- 15. A few months after the liposuction procedure, Patient A noticed wrinkling of the skin above both knees, and visible indentation marks in the inner aspects of both knees.
- 16. The Respondent provided treatments to these areas during several subsequent office visits between May 29, 2009 and December 14, 2010.
- 17. The Respondent tried a number of different procedures between May 29, 2009 and December 14, 2010, including fat injections, laser treatments, Radiesse® injections and silicone gel sheets applied directly to the scars, in attempts to alleviate the appearance and to ameliorate Patient A's concerns.

- 18. On October 21, 2009, during a follow-up appointment concerning the March 13, 2009 procedure, Patient A asked the Respondent to evaluate several moles on Patient A's back.
- 19. The Respondent advised Patient A that the moles could be removed and biopsied under general anesthesia in a hospital setting, and that while the Respondent performed that procedure, she would attempt to repair the indentations in Patient A's knees.
- 20. The biopsy and removal procedure occurred at the Beth Israel Hospital in Needham, Massachusetts on November 19, 2009; the Respondent also made repairs to Patient A's knee scars at that time.
- 21. Patient A continued to complain thereafter that the knee indentations remained visible, and that the skin above her knees remained excessively wrinkly in appearance.
- 22. During an office visit on December 14, 2010, at which the Respondent performed laser treatments to Patient A's knees, the Respondent considered Patient A for dermal implants made from animal bladder, to allow regeneration of the normal soft tissue surrounding Patient A's knees.
- 23. At the December 14, 2010 office visit, the Respondent told Patient A that a product representative for a porcine-based regeneration product would be available to speak with Patient A about the use of this product for Patient A's complaints on February 28, 2011.
- 24. On February 28, 2011, Patient A met with an ACell® representative at the Respondent's Wellesley office.
- 25. The Respondent told Patient A that ACell® studies claim to promote healing and improve the scarring, leaving essentially no visible scar.
 - 26. The Respondent had not previously used the ACell® product in any patient.

- 27. This particular use of the ACell® products for Patient A's presentations was not a use explicitly listed on the product label.
- 28. The off-label use of the ACell® product in Patient A's case, in the manner herein described, is below the standard of care.
- 29. Patient A signed a consent form prior to the Respondent performing the procedure in her office; the consent form cannot be located.
- 30. The Respondent performed the procedure by making incisions across each of Patient A's kneecaps, inserting an ACell® patch into each knee, and then closing the incisions using sutures.
- 31. The ACell® representative was present during the procedure, but was not gowned; he wore street clothing.
- 32. The ACell® representative advised the Respondent as to the use of the product including the shape, size and placement of the patch to be inserted into Patient A's knees.
- 33. The incisions made to Patient A's knees spanned from the inner aspect of each knee cap to the outer aspect.
- 34. Patient A drove herself to the Respondent's office on February 28, 2011, and she drove herself home post-procedure; her knees were bandaged.
- 35. Patient A's knees began to swell over the next several days, and Patient A observed red marks beginning to appear at the edges of the bandages on both knees.
- 36. By March 4, 2011, the swelling and redness had expanded to above and below Patient A's knees, and beyond the bandages on Patient A's knees.
 - 37. Patient A was admitted to the Mount Auburn Hospital for bilateral cellulitis.

- 38. Patient A received a course of intravenous antibiotics over the next several days at Mount Auburn Hospital.
- 39. On March 10, 2011, a board certified plastic surgeon removed the ACell® patches from Patient A's knees.
 - 40. On March 11, 2011, Patient A was discharged from Mount Auburn Hospital.

 <u>Legal Basis for Proposed Relief</u>
- A. Pursuant to G.L. c. 112, §5, ninth par. (b) and 243 CMR 1.03(5)(a)2, the Board may discipline a physician upon proof satisfactory to a majority of the Board, that said physician committed offenses against a provision of the laws of the Commonwealth relating to the practice of medicine, or a rule or regulation adopted thereunder. More specifically:
 - 1. G.L. c. 112, § 12CC, which requires that physicians provide patients with a copy of such patient's record upon request upon payment of a reasonable fee;
 - 2. 243 CMR 2.07(13)(b), which requires that, upon a patient request, a physician provide a copy of the patient's medical record to a patient, other licensee or other specifically authorized person, in a timely manner.
- B. 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 she 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.
- 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

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,

Condace lapidus Sloane, MD

Candace Lapidus Sloane, M.D.

Board Chair

Date: September 25,2013

SENT CERTIFIED MAIL 9/26/13 (m)

