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.	)

CONSENT ORDER

Pursuant to G.L. c. 30A, § 10, Kimberley L. O'Sullivan, M.D. (Respondent) and the Board of Registration in Medicine (Board) (hereinafter referred to jointly as the "Parties") agree that the Board may issue this Consent Order to resolve the above-captioned adjudicatory proceeding. The Parties further agree that this Consent Order will have all the force and effect of a Final Decision within the meaning of 801 CMR 1.01(11)(d). The Respondent admits to the findings of fact specified below and agrees that the Board may make the conclusions of law and impose the sanction set forth below in resolution of investigative Docket Nos. 11-349 and 11-451.

Findings of Fact

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.

Docket No. 11-349

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.

Conclusion of Law

A. The Respondent has violated G.L. c. 112, § 5, ninth par. (b) and 243 CMR 1.03(5)(a)2 by committing offenses against a provision of the laws of the Commonwealth relating to the practice of medicine, or a rule or regulation adopted thereunder—to wit:

1. G.L. c. 112, § 12CC, which requires that physicians provide patients with a copy of such patient's record upon request;

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. The Respondent has violated G.L. c. 112, § 5, ninth par. (c) and 243 CMR 1.03(5)(a)3 by engaging in conduct that places into question the Respondent's competence to practice medicine.

C. The Respondent has engaged in conduct that undermines the public confidence in the integrity of the medical profession. *See Levy v. Board of Registration in Medicine*, 378 Mass. 519 (1979); *Raymond v. Board of Registration in Medicine*, 387 Mass. 708 (1982).

Sanction and Order

The Respondent's license is hereby indefinitely suspended, with leave to petition the Board for a stay of said suspension.

Prior to petitioning for a stay of suspension the Respondent must participate in an audit of the Respondent's practice by a Board-approved entity to assess her level of compliance with standards for clinical record keeping and office management; and an assessment of the Respondent's clinical skills and patient interactions at all stages of care (i.e., initial consultation, surgeries, and post-operative visits) by the same Board-approved entity that performs the practice audit. The Respondent shall be responsible for all costs of evaluation and testing, and the granting of any stay remains in the discretion of the Board.

Any stay of suspension is conditioned upon the Respondent's entry into a five (5) year probation agreement. The Probation Agreement shall include, but not be limited to, the following terms and conditions:

1. The Respondent must comply with the recommendations identified in the audit of the Respondent's practice performed by the Board-approved entity.

2. The Respondent must comply with the recommendations identified in the assessment of the Respondent's clinical skills and patient interactions at all stages of care by the Board-approved entity.

3. The Respondent must execute any and all mutual releases necessary to allow Board staff to discuss and provide reports, results and recommendations with all persons and entities providing auditing, assessing and/or monitoring services pursuant to the Probation Agreement.

4. There must be a Board-approved worksite monitor to meet with the Respondent weekly to assess her initial consultations, disclosures of risks and complications, review random patient charts, and to discuss patient and practice issues and to provide any other monitoring functions recommended by the monitor, office audit and/or clinical skills assessment entity. The Respondent may petition the Board to decrease the frequency of monitoring to once per month after six months of documented compliance with all terms and conditions of the Probation Agreement and upon the recommendation of said monitor.

5. The Respondent must undergo any Continuing Professional Development and/or other course of education recommended by the monitor, office audit and/or clinical skills assessment entity.

Execution of this Consent Order

The Respondent shall provide a complete copy of this Consent Order and Probation Agreement with all exhibits and attachments within ten (10) days by certified mail, return receipt requested, or by hand delivery 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 s/he practices medicine; any in- or out-of-state health maintenance organization with whom the Respondent has privileges or any other kind of association; any state agency, in- or out-of-state, with which the Respondent has a provider contract; any in- or out-of-state medical

employer, whether or not the Respondent practices medicine there; the state licensing boards of all states in which the Respondent has any kind of license to practice medicine; the Drug Enforcement Administration Boston Diversion Group; and the Massachusetts Department of Public Health Drug Control Program. The Respondent shall also provide this notification to any such designated entities with which the Respondent becomes associated for the duration of this stayed suspension and probation. The Respondent is further directed to certify to the Board within ten (10) days that the Respondent has complied with this directive.

The Board expressly reserves the authority to independently notify, at any time, any of the entities designated above, or any other affected entity, of any action it has taken.

Kimberley L. O'Sullivan — Date: 6/18/13
Licensee

Brooks L. Glahn, Esq. — Date: 7/19/13
Attorney for the Licensee

~~John Costello~~ Interim Director of Enforcement — Date: 7/24/13
~~Complaint Counsel~~

So ORDERED by the Board of Registration in Medicine this 25th day of September, 2013.

Candace Lapidus Sloane, MD
Candace Lapidus Sloane, M.D.
Board Chair

SENT CERTIFIED MAIL 9/26/13 (mg)