

Medical Spas See Increasing Regulation in Maryland

By Ellen B. Flynn

A booming medical spa industry suggests that patients are wooed by the spa-like environment for body transforming surgeries, apparently assuming that health care providers would still comply with basic surgical safety standards in a casual environment. Unfortunately, the medical spas in Maryland were not closely regulated until recently, and not all of them were even set up to provide sterile surgical environments. The ramifications of this failure proved catastrophic for some Maryland residents.

Medical spas, hybrids of medical clinics and day spas, are big business, offering cosmetic procedures, including even liposuction surgeries as long as they can be performed without the use of general anesthesia. Services provided at medical spas vary, but typically include laser treatments, laser hair removal, microdermabrasion, Botox and other filler injections, and various forms of liposuction surgery. By offering to perform procedures without general anesthesia, these facilities have traditionally avoided the same level of state and federal oversight provided to surgicenters and hospitals.

Further exacerbating the problem, since cosmetic procedures performed at these “spas” are not considered medically necessary, they are typically not covered by medical insurance and are not subject to the same scrutiny of other health care centers accepting third party payments. In fact, medical spas providing cosmetic surgical procedures in Maryland were not required to be licensed like an ambulatory surgical facility until November of 2014, and still may not be required to be licensed or accredited for many of the services they perform. Further, while the surgeries at the medical spas are performed by physicians, *any* licensed physician can



claim to be a cosmetic surgeon, and many services can be delegated to non-physicians.

Liposuction, a surgical procedure that removes fat from the body using suction, is often performed with local anesthetic consisting of numerous injections of Lidocaine to numb the area that is then manipulated, dislodged and literally suctioned through a cannula placed into the subcutaneous fat through small incisions in the skin. According to the American Society for Aesthetic Plastic Surgery, it is estimated that over 360,000 liposuction procedures were performed in the United States in 2013.¹

Despite the ability to have liposuction surgery at a medical spa instead of a hospital or surgical center, there are serious risks associated with this surgery. For instance, Lidocaine used to anesthetize the area of the surgery can cause neurological events such as dizziness, tremor, seizure or even cardiac events such as hypotension, arrhythmia's or even cardiac arrest if too much is used. Further, there is a serious risk of infection.

The American Academy of Dermatology Association (AADA) has encouraged increasing oversight for even the lesser invasive procedures performed at these facilities. In a position statement initially issued in May of 2011, the AADA suggested that state and federal regulations should set standards of practice for performance of medical aesthetic services in a medical spa facility in order to protect patient safety and ensure quality care. The position statement suggests that standards should include minimum training and

¹ www.surgery.org/media/statistics: The American Society for Aesthetic Plastic Surgery Reports Americans Spent Largest Amount on Cosmetic Surgery Since The Great Recession of 2008.

educational requirements of both physicians and non-physicians performing services, written treatment plans and procedure protocols and reporting of adverse events, facility licensure, inspection and state enforcement.²

Liposuction procedures performed at the Monarch MedSpa in Timonium, Maryland in August and September 2012, resulted in serious infections causing one death, and catastrophically disfiguring infections in others.³ An outbreak of infections prompted the Maryland Department of Health and Mental Hygiene (DHMH) to begin investigating several severe invasive Group A Streptococcus (GAS) infections in individuals who had liposuction at Monarch MedSpa. As a result of the DHMH investigation, Monarch MedSpa was ordered to close its Maryland facility on September 18, 2012. The facility assessment performed by DHMH together with the Baltimore County Department of Health revealed “a number of deficiencies in infection control procedures based on the CMS Ambulatory Surgical Centers Infection Control Surveyor Worksheet.” The investigation reportedly revealed that there was visibly dirty equipment, no separation of clean and dirty areas for equipment sterilization, a clogged sink in the liposuction procedure room with debris and liquid leaking onto surgical supplies stored underneath, open surgical scrub materials, non-sterile surgical dressings stored open in high-traffic areas, autoclave logs unavailable, expired supplies on shelves, and unlabeled opened multi-use Lidocaine vials. Baltimore County Department of Health and DHMH jointly ordered Facility A to cease operations indefinitely on the morning of September 19, 2012.

The Office of Infectious Disease Epidemiology and Outbreak Response Prevention and Health Promotion Administration, together with DHMH, released its report in September of 2013 identifying numerous problems with the Monarch MedSpa facility.⁴

2 American Academy of Dermatology Association, Protecting Safety & Ensuring Quality Care: State Regulation of Medical Spa Facilities. Position Statement on Medical Spa Standards of Practice (Approved by the Board of Directors: May 7, 2011; Amended by the Board of Directors August 18, 2012). www.aad.org. The position statement suggests that “medical spa facilities should be licensed and inspected on a regular basis to ensure compliance with all applicable federal and state laws. Medical spa facilities must be able to prove they have the necessary personnel, equipment and protocols to safely perform all offered procedures and handle any emergencies or sequelae that may arise. Any incident within the medical spa facility that results in a patient death, transport of the patient to the hospital, or a significant complication or adverse event requiring additional medical treatment, shall be reported to the appropriate state agency, the FDA if applicable, or both.”

3 See, *Snow v. Daniel Francis, D.O. et al.*, Case No. 24-C-14-005694; *Rachel Machlinski v. Daniel Francis, D.O., et al.*, Case No. 24-C-14-005718; *Michelle Thompson, Personal Representative of the Estate of Eula Witherspoon v. Daniel Francis, D.O., et al.*, Case No. 24-C-14-006080; *Eaton v. Monarch MedSpa, Inc. et al.*, Case No. 24-C-14-005831. These cases are all pending against Monarch MedSpa and its agents and employees and allege numerous deficiencies in infection control procedures and failures to provide a proper surgical environment leading to the spread of infection to the Plaintiffs.

4 Summary Report, Outbreak 2012-235, September 2013; dhmh.maryland.gov/docs/

This outbreak was examined by a team of physicians, who concluded, as did the DHMH, that the severe GAS infections were likely caused by transmission from colonized health care workers to patients during liposuction procedures.⁵ The authors of this peer-reviewed article concluded that additional oversight of outpatient cosmetic surgery facilities is needed to assure that they maintain appropriate infection control practices and other patient protections.

It is alleged in the numerous civil actions now pending in the Circuit Court for Baltimore City, that the Monarch MedSpa did not comply with basic infection prevention techniques, including failing to use gloves, masks, and sterilizing equipment and techniques during surgical procedures that one would expect to be used by any competent facility performing surgical procedures.⁶

After the tragic experiences of several Maryland patients, the Maryland Legislature was called to action. Joshua Sharfstein, Maryland’s Secretary of Health, responded to a groundswell of concern over medical spas, proposing that the legislature clearly require that these facilities in Maryland be licensed and accredited. Sharfstein told the Baltimore Sun that “The goal is to make sure the riskier procedures are happening in the safer places.”⁷

Prior to these new regulations, the DHMH already regulated ambulatory surgical centers, facilities that operate primarily for the purpose of providing surgical services to patients requiring a period of postoperative observation but not requiring overnight hospitalization and receive payment from health insurance carriers and Medical Assistance programs. Since many cosmetic surgery centers bill patients directly and don’t take insurance at all, these facilities took advantage of a loophole, operating without a license from DHMH despite performing surgical procedures. Some medical-spa facilities still voluntarily sought accreditation as an ambulatory surgery center.

New Regulations in Maryland

Maryland Department of Health and Mental Hygiene responded to increasing concerns over

5 JAMA Intern Med. 2014 Jul;174(7):1136-42. doi: 10.1001/jamainternmed.2014.1875. Invasive group A Streptococcus infections associated with liposuction surgery at outpatient facilities not subject to state or federal regulation. Beaudoin AL, Torso L, Richards K, Said M, Van Beneden C, Longenberger A, Ostroff S, Wendt J, Dooling K, Wise M, Blythe D, Wilson L, Moll M, Perz

6 See supra fn. 2

7 After death, Maryland to limit where cosmetic surgeries are performed, April 27, 2013, by Scott Dance, The Baltimore Sun.

unregulated Medical Spas. New regulations that went into effect on November 19, 2014, require mandatory accreditation and licensing for cosmetic surgery facilities. Under the new regulations, offices or facilities (“spa” or otherwise) in which cosmetic surgical procedures are performed must be licensed and accredited as a cosmetic surgical facility with the State.⁸

Cosmetic surgical procedures are defined under the new regulations as surgical services to reshape the structure of a human body to change the appearance of an individual, but does not include a procedure done under local anesthesia or mild sedation; or liposuction that removes less than 1,000 cubic centimeters (1 Liter!) of aspirate.⁹ In order to be licensed, a cosmetic surgical facility must be accredited by the American Association for Accreditation of Ambulatory Surgical Facilities (AAASF); the Accreditation Association for Ambulatory Health Care (AAAHC); The Joint Commission; or an accreditation organization approved by the Secretary of Health and Mental Hygiene.¹⁰ These accreditation requirements increase the likelihood that safe surgical procedures and hygiene will be in place.

The AAASF only permits 500cc’s of aspirate to be removed when a facility is using topical anesthesia or local anesthesia for liposuction, and has extensive requirements for sterile equipment and supplies as well as conditions in the operating room. The AAAHC, however, makes no such distinction but recommends that procedures involving over 5,000 cc’s of aspirate be performed in an acute-care hospital or in a facility that is either accredited or licensed.¹¹

While these new regulations will provide additional oversight, some “medispas” might continue to offer surgeries such as liposuction without meeting the accreditation requirements of state licensing by capping the amount of fat removed during a single procedure. Since these facilities thrive on repeat business, one must consider whether there continues to be a significant loophole in the oversight of these facilities in Maryland. At the end of the day, qualified medical professionals and an appropriate surgical environment, not fancy robes and services, are required to safely perform any surgery – cosmetic or not. ■

⁸ Maryland Register, Volume 41 Issue 19, Friday September 19, 2014, pp. 1086 – 1090; Title 10 Department of Health and Mental Hygiene, Subtitle 12 Adult Health, 10.12.03.

⁹ *Id.* at .01B(2).

¹⁰ *Id.* .03A(1).

¹¹ Practice Advisory on Liposuction: Executive Summary, p. 2, American Society of Plastic Surgeons.



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Biography

Ellen B. Flynn is a partner in the law firm of Dugan, Babij & Tolley, LLC, in Timonium, Maryland. She received a BS in Business Administration from the University of Richmond, and obtained her JD from the Catholic University of America, Columbus School of Law. Ms. Flynn is newly appointed to the MAJ Board of Governors. She is admitted to practice law in Federal and State Courts of Maryland, Connecticut and the District of Columbia. Her primary practice area involves representing those injured by medical negligence. She lives with her husband and two daughters in Ellicott City, Maryland.