SUMMARY REPORT

OUTBREAK 2012-235

September 2013

Office of Infectious Disease Epidemiology and Outbreak Response
Prevention and Health Promotion Administration
Maryland Department of Health and Mental Hygiene

INTRODUCTION

On September 17, 2012, the Maryland Department of Health and Mental Hygiene (DHMH) received a call from the infection control department at a large acute care hospital in Baltimore City (Hospital A). A trauma physician noted three similar cases of severe invasive Group-A Streptococcus (GAS) infection, one fatal, in patients who had recently received liposuction at the same medical spa facility (Facility A) located in Timonium, Baltimore County, MD. Ultimately, cases associated with related facilities in other states were identified; however, this report summarizes the joint DHMH – Baltimore County Department of Health investigation of cases associated with the facility in Maryland.

BACKGROUND

Facility A was a self-described medical spa where patients received elective, self-pay cosmetic procedures such as laser removal of hair and tattoos, dermal fillers, botulinum toxin injections, and liposuction, a surgical procedure. Unlike other ambulatory surgical centers, which are regulated by the DHMH Office of Healthcare Quality, cosmetic surgical centers, also sometimes called medical spa facilities, were not licensed as healthcare facilities in Maryland if they did not accept payment from an insurer or other third party payor. The total number of such cosmetic surgical centers in Maryland is currently unknown.

Liposuction is the removal of excess subcutaneous fat using a suction-assisted aspiration cannula. In 2012, there were over 200,000 liposuction procedures performed in the United States[1]. A common method of liposuction is the tumescent method, which involves infusing fluid with lidocaine and epinephrine subcutaneously. Lidocaine provides local anesthesia, epinephrine minimizes surgical bleeding, and the use of the fluids causes the targeted area to become swollen and firm. An ultrasound or laser is also used to rupture fat cells prior to suctioning.

Liposuction complications are rare, occurring in 0.1-0.5% of procedures[2]. The complication rate of liposuction using the tumescent method is 0.7%[3]. Fatal outcomes have been reported in 1 out of 5,000 liposuction procedures[4]. Other complications that have been associated with liposuction include

[1] American Society of Plastic Surgeons, 2012 Plastic Surgery Statistics Report. http://www.plasticsurgery.org/Documents/news-resources/statistics/2012-Plastic-Surgery-Statistics/full-plastic-surgery-statistics-report.pdf

[2] Desrosiers A. et al. Don't try this at home: liposuction in the kitchen by an unqualified practitioner leads to disastrous complications. *Plastic and Resonstr Surg*. 2004:113(1):460-461.

[3] Hanke W, Cox SE, Kuznets N, Coleman WP,3rd. Tumescent liposuction report performance measurement initiative: National survey results. Dermatol Surg. 2004;30(7):967-77; discussion 978. doi: 10.1111/j.1524-4725.2004.30300.x.

[4] Grazer FM et al. Fatal outcomes from liposuction: census survey of cosmetic surgeons. *Plast. Reconstr. Surg.* 2000; 105:436.

perforation, pulmonary or arterial embolism, hemorrhage, cardiac arrest, shock, pulmonary edema, infection, and sepsis[5].

Group-A *Streptococcus* (GAS) is a gram-positive bacterium that is most often detected in the throat and on the skin. These bacteria are spread through direct contact with mucus from the nose or throat of persons who are infected or through contact with infected wounds or sores on the skin. The bacteria can also be carried by asymptomatic individuals (called "carriers") for long periods of time, and while carriers are less contagious than those with active infection, they are still capable of transmitting the bacterium that can cause disease. Most GAS infections are relatively mild. The most common GAS infections are "strep throat" and impetigo, a mild skin infection. Occasionally these bacteria can cause severe and even life-threatening diseases when they infect normally sterile body sites, such as blood, muscle, or the lungs, resulting in a condition called "invasive GAS". Examples of forms of invasive GAS are necrotizing fasciitis and streptococcal toxic shock syndrome. Risk factors for invasive GAS include diabetes, drug use, immunosuppression, recent surgery, and traumatic wounds. Mortality rates of invasive GAS are 10-15%. There is approximately a 25% mortality rate associated with invasive infection resulting in necrotizing fasciitis. Antibiotics can be used to treat both mild and invasive infections. For those with invasive disease, treatment in an intensive care unit and surgery to remove damaged tissue may be necessary. About 9,000-11,500 cases of invasive GAS infections occur each year in the United States, resulting in 1,000-1,800 deaths annually.[6]

Invasive GAS is a reportable condition in Maryland. Upon diagnosis of a case of invasive GAS, clinicians and/or laboratories submit a report to their local health department for entry into the Maryland notifiable disease database. Between 2007-2011, there were 946 total cases of invasive GAS in Maryland, and an average of 189 cases of invasive GAS are reported annually.[7]

In the healthcare setting, surgical and obstetric patients are most vulnerable to GAS due to the break in mucosal or cutaneous barriers that occurs during these procedures. Group A Strep infection following surgery and childbirth is still a very rare occurrence, with GAS being the cause of only 1% of all surgical site infections, and 3% of infections after vaginal delivery. Since 1965, there have been at least 15 post-op or post-partum outbreaks of GAS infections attributed to asymptomatic carriage in healthcare workers.[8]

Appropriate infection control measures may help prevent or interrupt transmission from healthcare worker to patient. In addition, per Centers for Disease Control and Prevention (CDC) guidance, once a postsurgical or postobstetrical patient is suspected or identified with GAS, enhanced surveillance and epidemiologic investigation should immediately follow. Screening of all healthcare workers present in the procedure room, as well as those who had some kind of contact with open wounds, should take place. Recommended body sites for screening include the nares, throat, vagina, rectum, and skin.

[5] Lehnhardt M et al. Major and Lethal Complications of Liposuction: A Review of 72 Cases in Germany between 1998 and 2002, Plastic and Reconstructive Surgery, June 2008, 121(6), 396e-403e.
[6] http://www.cdc.gov/ncidod/dbmd/diseaseinfo/groupastreptococcal_g.htm
[7] Unpublished DHMH data
[8] MMWR Weekly Report, Mar 05, 1999, 48(08): 163-166

Potentially infected or colonized healthcare workers should refrain from patient care during the first 24 hours of antibiotic treatment. Molecular typing of the bacterium can be conducted to help identify the strain and can be used to link to any other potentially associated cases.[9]

METHODS

Case Ascertainment/Exposure Assessment

Since all 3 known invasive GAS cases had liposuction at Facility A, records were requested for all patients receiving liposuction at Facility A approximately 6 weeks prior to the first procedure associated with a case—July 1. In addition, although no other infections were identified associated with other procedures performed at that facility, DHMH requested records from Facility A of all 195 patients having received any procedure at Facility A dating back to August 1st. A list of all 2012 invasive GAS cases reported to DHMH was prepared, and patient names were cross-checked against the full list, provided by Facility A, of patients receiving any procedures (including non-liposuction procedures).Facility A was also asked if there were any other infections reported directly to them.

On September 19, 2012, DHMH issued a press release (APPENDIX A—Press Release) to increase public awareness and reporting and a memorandum to local health officers to identify additional associated cases. Two other state health departments were also contacted given that similar facilities operating under the same ownership were located in their jurisdictions, and healthcare professionals were known to practice at more than one facility, including the facility in Maryland.

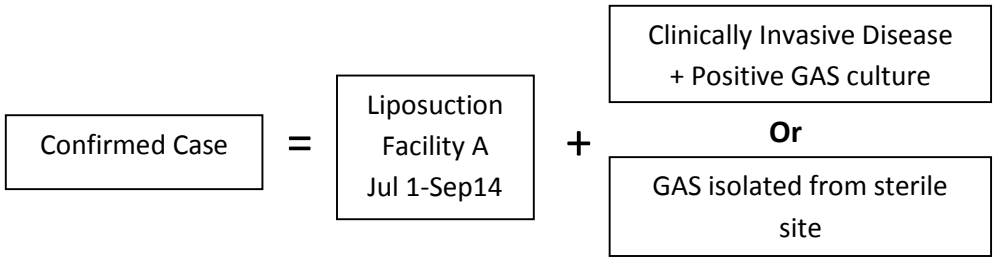
All patients that received liposuction by any doctor at Facility A since July 1st were contacted by health department staff, and asked for information about their procedure (including the use of Personal Protective Equipment (PPE) by facility staff during liposuction), their recovery, any follow-up with the treating facility, and medical complications or additional medical care sought (APPENDIX B—Survey Questions). Patients having received procedures other than liposuction were not contacted for follow-up because all known cases had undergone liposuction and no cases had been identified among people who had undergone other procedures at Facility A.

Outbreak Case Definitions

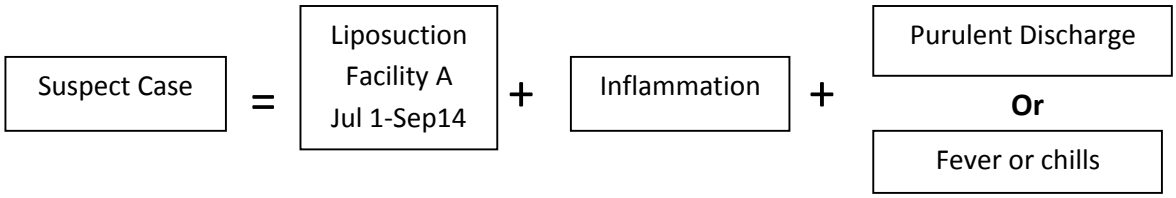
Since no invasive GAS infections were identified in patients who had undergone procedures other than liposuction at Facility A, the following case definitions were developed.

Confirmed case – patient with history of liposuction at Facility A between July 1, 2012 and September 14, 2012 presenting with clinically invasive disease and a positive GAS culture, OR a patient with GAS isolated from a normally sterile site.

[9] MMWR Weekly Report, Mar 05, 1999, 48(08): 163-166; and CID, 2002: 35 (15 October), 950-959.



Suspect case – patient with history of liposuction at Facility A between July 1, 2012 and September 14, 2012 self-reporting signs of inflammation (redness, swelling, pain) AND purulent discharge from the surgical site OR fever or chills.



Facility Assessment

DHMH and the Baltimore County Department of Health visited Facility A on September 18, 2012 to perform a facility environmental assessment. DHMH Office of Health Care Quality surveyors provided technical assistance during the assessment. Health department staff also referenced the Centers for Medicare & Medicaid Services (CMS) Ambulatory Surgical Center Infection Control Surveyor Worksheet[10] while performing the facility assessment.

Laboratory Testing

GAS isolates from wound cultures of the three Maryland case-patients during their hospitalizations were forwarded from hospital laboratories to the DHMH Laboratories Administration where they were confirmed to be GAS, then prepared on slants to be shipped to CDC for further characterization. CDC's Streptococcus Laboratory performed T-agglutination characterization (T-typing) and M protein gene (*emm*) typing.

Nose, throat, vaginal, and rectal specimens were collected for culture from all staff members who worked with patients at Facility A. DHMH and Baltimore County Department of Health coordinated testing of most staff members. Five staff members who worked during the case ascertainment period were tested by another state health department. Any positive specimens were also forwarded to the CDC for T-typing and *emm* typing.

RESULTS

Case Ascertainment/Exposure Assessment

The review of statewide infectious disease surveillance systems in Maryland revealed no further cases associated with this outbreak. There were 3 other cases of invasive GAS with *emm* type 28, the *emm* type identified in this outbreak, in Maryland in 2012. However, there were no common factors identified

[10] http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107_exhibit_351.pdf

between these and the outbreak cases; these cases occurred in May and October, and there was no record of liposuction procedures and none had procedures done at facility A.

10 people were identified as having liposuction at Facility A by one of two doctors identified as performing liposuction at Facility A, Doctor A and Doctor B. Doctor A performed liposuction procedures on 7 patients, Doctor B performed liposuction procedures on 3 patients. Contacting patients who received liposuction at Facility A since July 1st revealed one additional Maryland case, a suspect case. The suspect case-patient self-reported presenting to multiple community hospital emergency departments and healthcare providers with redness and "pus" drainage, and was provided antibiotics for possible infection. Review of available medical records documented redness and pain at the surgical site, but did not confirm purulent drainage. No cultures were collected from this suspect case.

The facility reported one additional infection in a patient subsequent to receiving buttocks augmentation. The procedure was done by Doctor B at another facility in Maryland, not owned by the medical spa corporation. After reviewing the hospital admission and discharge reports for this patient, it was determined to not be related to this outbreak because the organism isolated was *Staphylococcus epidermis*, not GAS.

Therefore, in Maryland, there were 3 confirmed GAS cases and 1 suspect case identified among the people who had liposuction procedures at Facility A during the period of July through September 2012. Illness onsets ranged from August 16 to September 13, 2012. All 4 case-patients lived in Maryland, and all were women. Ages for the case-patients ranged from 28 to 60 years old. The 3 confirmed case-patients were hospitalized and diagnosed with necrotizing fasciitis, requiring multiple surgeries. Hospitalizations ranged from 4 – 77 days. One case-patient died.

All 4 case-patients had liposuction procedures done at Facility A. Procedure dates of case-patients ranged from August 14 to September 11, 2012. There were three staff members who had documented patient contact with the three confirmed case-patients—Doctor A and a surgical assistant were present for all liposuction procedures, and a surgical support team member conducted post-operative follow-up for all three patients. No other staff were documented to have had contact with all three confirmed cases.

In addition, case-patients were identified in other states. One case-patient reported directly to Maryland as a result of the press release and subsequent media coverage, and was referred to the state health department where that person lived. Cases whose procedures were performed at facilities outside of Maryland are not described in this report.

Surveys were administered by telephone to the patients who received liposuction dating back to July 1. 8 out of 10 patients were interviewed about PPE use by healthcare workers (of the 2 patients not interviewed, one was deceased and the other was lost to follow-up). Many patients were unsure about PPE use reportedly because of patient positioning and because they were sedated. 25% (2/8) of respondents reported that at least one member of the surgical team was not wearing gloves during their liposuction procedure, and 50% (4/8) reported that at least one member of the surgical team was not wearing either a mask or a gown during their liposuction procedure.

Facility Assessment

The information in this paragraph is based on verbal reports from facility staff and owner. During the facility assessment, facility staff described the general patient flow leading up to liposuction procedures. Staff reported that to schedule a liposuction procedure at Facility A, patients were first seen by a physician for a consultation appointment where health history information was collected, blood work was ordered, and prescriptions for an antibiotic and other medications to be used during/after the procedure were provided. Per staff, patients were awake during procedures, given a sedative and local anesthesia, and were often observed in an exam room that was used as a post-procedure recovery area. Facility A conducted an average of 2 liposuction procedures per week, and most liposuction procedures were performed on-site at Facility A. Non-disposable instruments used during liposuction were reportedly autoclaved on-site after the procedure. In addition, the facility reported that some sterile equipment might have been transported from out-of-state facilities to Facility A. Generally on the day after the procedure, the patient returned to the facility for post-operative assessment of surgical wounds where they may have been seen by a doctor or other office personnel.

There were two physicians practicing at Facility A during the time period of the investigation: Doctor A and Doctor B. Both physicians were individually licensed by the Maryland Board of Physicians. According to the Maryland Board of Physicians website, Doctor A did not report possessing any board-certifications; Doctor B was board-certified in plastic surgery. According to information provided by the owner of Facility A, Doctor A performed liposuctions at both Facility A and Facility B, an out-of-state location with the same owner and company name as Facility A.

During the course of the multistate investigation, Doctor A reportedly described self-treating a cellulitis infection of the hands, coinciding with a five-day absence from work in August.

In addition to Doctor A and Doctor B, at least 3 nurses worked at Facility A during the period July – September 2012. Each of these 3 nurses was licensed by the Maryland Board of Nursing. On at least two occasions, additional nurses from another state and not licensed in Maryland traveled with Doctor A to Facility A to assist with the surgeries. A review of Facility A's records revealed that nursing staff licensed out-of-state, but not in Maryland, appeared to be performing nursing duties in Maryland, such as administering sedative medications to patients.

After case-patients #1 and #2 were hospitalized, and prior to DHMH notification, Facility A hired a specialty cleaning company to clean the facility on August 22, 2012; however, the facility assessment performed by DHMH and the Baltimore County Department of Health on September 18 revealed a number of deficiencies in infection control procedures based on the CMS Ambulatory Surgical Centers Infection Control Surveyor Worksheet (APPENDIX C). No facility-specific infection control policy was available during the site visit at Facility A, but a policy was later submitted to DHMH upon request. 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. In the setting of this outbreak, the conditions at the facility were of such a concern that Baltimore County Department of Health and DHMH jointly ordered Facility A to cease operations indefinitely on the morning of September 19 (APPENDIX D—Order to Cease Operations).

Laboratory Testing

Specific testing at the CDC's Streptococcus Laboratory to determine whether the GAS isolates from the 3 confirmed Maryland cases were genetically related revealed that all three shared the same T-type 28 and *emm* type 28. *Emm* type 28 is uncommon, indicating the three cases likely shared a common source. Based on preliminary Maryland 2012 surveillance data, *emm* type 28 contributed to only 3.9% of all Maryland GAS isolates with an identified *emm* type.[11] Specimens were collected from 15 employees who worked at Facility A. Results from CDC testing reported to Maryland DHMH showed that two employees working at Facility A, Doctor A and a nurse licensed in another state who assisted Doctor A in MD, tested positive for GAS. CDC's Streptococcus Laboratory characterized the same T-type and *emm* type in the healthcare workers as the case-patients. Additionally, all patient and staff isolates shared an identical antimicrobial susceptibility pattern, and were resistant to erythromycin, clindamycin, and tetracycline. These two employees had contact with all three Maryland confirmed case-patients.

CONCLUSIONS

There were 4 total cases in Maryland associated with this outbreak: 3 confirmed and 1 suspect. These cases resulted in 3 hospitalizations with 1 death. Having liposuction at Facility A was determined to be associated with this outbreak based on the common history of liposuction, time of infection onset, lack of other known connections between cases, and matching GAS strains among the primary cases and healthcare workers. Apparent lack of adherence to recommended practices for outpatient infection prevention may have contributed to the acquisition of these infections. Although the effect of facility infection prevention practices cannot be definitively determined in this situation, it is clear that GAS infection has been transmitted in other healthcare settings, such as acute care hospital operating rooms, where more rigorous infection control practices are followed.[12,13,14] Conditions noted at the facility may have allowed potentially contaminated materials to come into contact with the patients' surgical wounds. Lack of PPE use among the healthcare workers, as gleaned from patient surveys, could have allowed for person-to-person transmission, specifically healthcare provider to patient transmission, especially given the matching GAS results from facility staff and case-patient isolates. However, we were not able to determine what role each specific factor played in GAS transmission during this outbreak. Regardless, infection prevention practices at Facility A were noted to be an important problem to be addressed prior to re-opening the facility.

[11] Unpublished 2012 Maryland Active Bacterial Core Surveillance (ABCs) data.
[12] Mastro TD, et al. An outbreak of surgical-wound infections due to group A streptococcus carried on the scalp. N Engl J Med. 1990;323(14):968-972.
[13] Kolmos HJ, et al. The surgical team as a source of postoperative wound infections caused by streptococcus pyogenes. J Hosp Infect. 1997;35(3):207-214
[14] Berkelman RL, et al. Streptococcal wound infections caused by a vaginal carrier.JAMA.1982;247(19):2680-2682.

This investigation did have limitations. First, there is no causal temporality established by the laboratory results; that is, the GAS positive healthcare workers were not known to be GAS positive or negative prior to the patients' infections, and all cultures of healthcare workers were performed after patient cultures. Results indicate that both the patients and staff likely shared the same organism, and staff testing occurred shortly after outbreak recognition, however it is impossible, based on these results alone, to know if the GAS originated from a patient or a healthcare worker. Lastly, Maryland investigators were unable to directly observe Doctor A and the surgical team performing liposuction either during or after the outbreak. Therefore, details of the procedure and post-procedure care could only be obtained from records and interviews with the healthcare providers, staff, and patients, rather than from direct observation.

As a result of the outbreak, Facility A operations were suspended by DHMH and the Baltimore County Department of Health. Facility A has not resumed operations. The Maryland Board of Nursing was notified that out-of-state nurses not licensed in Maryland were potentially performing nursing duties in Maryland. The Maryland Board of Physicians was also notified about Doctor A's association with the Maryland GAS cases.

In response to this outbreak, and to prevent other outbreaks, HB1009 entitled Cosmetic Surgical Facilities—Regulation, was introduced and passed in 2013. As of October 1, 2013, Annotated Code of Maryland Health-General Articles §19-3C-01 and §19-3C-02 will permit the Maryland Secretary of Health to regulate facilities performing certain cosmetic surgical procedures that were not previously regulated, such as liposuction, if those procedures raise substantial health and safety concerns. The information presented in this report suggests that liposuction can pose substantial health and safety concerns, and therefore facilities that perform liposuction should be regulated by the Maryland Department of Health and Mental Hygiene.

RECOMMENDATIONS

Should Facility A wish to re-open, the following requirements must be met:

- Facility A must satisfactorily address at least all relevant infection control elements listed in the CDC "Infection Prevention Checklist for Outpatient Settings: Minimum Expectations for Safe Care"[15] prior to resuming operations, as well as any other guidelines required by Maryland law.
- Facility A must undergo another inspection prior to reopening to patients.
- Facility A should ensure that any invasive GAS infections and any other potential clusters of infections among facility patients are reported immediately to the Baltimore County Department of Health.
- Facility A and all associated providers should follow the CDC guidance detailed in the March 5, 1999 MMWR for any potentially associated invasive GAS infections.

In addition, the following recommendations apply as good practice for any cosmetic surgical centers in Maryland:

[15] http://www.cdc.gov/hai/settings/outpatient/checklist/outpatient-care-checklist.html

- Cosmetic surgical centers should immediately report all reportable infections and infectious disease outbreaks of any type to the local health department.
- Cosmetic surgical centers should adhere to any guidelines required by Maryland law, including upcoming regulations (Annotated Code of Maryland Health-General Articles §19-3C-01 and §19-3C-02).
- Prior to implementation of legislation and accompanying regulations, cosmetic surgical centers should institute facility-specific infection control procedures, and it is recommended centers implement at least all related elements of infection control policies, procedures, and practices of the CDC's "Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care".[16]
- It is recommended that cosmetic surgical centers employ an infection control consultant to review and/or update facility infection control policies and procedures, including completing the checklist criteria outlined above. This consultant may also provide infection control training to facility staff.

Consumer guidance: Consumers should be aware of the risks and benefits of any elective cosmetic procedure. Consumers can verify licensing and qualifications of physicians through the Board of Physicians website.[17] Consumers should also check with their provider and the facility where the procedure will be performed about any licensing, accreditation, or credentials they maintain, and by asking about infection prevention practices.

Other recommendations: New Maryland legislation (Annotated Code of Maryland Health-General Articles §19-3C-01 and §19-3C-02) ensures the legal framework is in place for increased oversight of patient safety and infection control in cosmetic surgical facilities through regulation and accreditation. This outbreak investigation report clearly provides the documentation required by the statute of substantial health and safety risks associated with any liposuction procedure, regardless of volume of liposuction aspirate. This information should be used by the Secretary of Health and Mental Hygiene to justify the inclusion of liposuction as a cosmetic surgical procedure in the regulations pertaining to cosmetic surgery centers, which will ensure that facilities performing liposuction as well as other cosmetic surgical procedures receive the patient safety oversight directed by this law.

[16] http://www.cdc.gov/HAI/pdfs/guidelines/standatds-of-ambulatory-care-7-2011.pdf
[17] http://www.mbp.state.md.us/

STATE OF MARYLAND

DHMH PRESS RELEASE

Maryland Department of Health and Mental Hygiene
201 W. Preston Street • Baltimore, Maryland 21201
Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – Joshua M. Sharfstein, M.D., Secretary

Office of Communications

Dori Henry
410-767-3536
Karen Black
410-767-6491

FOR IMMEDIATE RELEASE:

DHMH and Baltimore County Department of Health Investigating Cluster of Invasive Group A Streptococcus Associated with Cosmetic Surgery Center

BALTIMORE (September 19, 2012) – The Maryland Department of Health and Mental Hygiene (DHMH) and the Baltimore County Department of Health are investigating a cluster of three severe invasive Group A *Streptococcus* (GAS) infections in persons who recently had liposuction at a cosmetic surgery center, Monarch Med Spa, in Timonium, Maryland. The procedures occurred in mid-August to mid-September. All three patients were hospitalized; one subsequently died.

DHMH and Baltimore County have ordered the facility closed while the investigation proceeds to determine possible sources of the infections and to limit further spread (the order is attached). The facility has been cooperative in the course of the investigation.

Any individual who has had any procedure at this facility recently and has concerns about a subsequent infection should consult with his/her primary care provider and notify his/her local health department. Symptoms may include:

- Fever or influenza-like syndrome
- Redness at a wound site
- Abrupt onset of generalized or localized severe pain and swelling, often rapidly increasing
- Progressive dizziness, weakness and confusion

Group A *Streptococci* are often found in the throat and on the skin. These bacteria are spread through direct contact with mucus from the nose or throat of persons who are infected or through contact with infected wounds or sores on the skin or by contact with contaminated surfaces. Sick individuals, such as those who have strep throat or skin infections (impetigo), are most likely to spread the infection. Persons (also called "carriers") who carry the bacteria but have no symptoms are much less contagious.

Most GAS infections are relatively mild; however, occasionally these bacteria can cause severe and even life-threatening diseases when they infect parts of the body where bacteria usually are not found, such as the blood, muscle, or the lungs. These infections are termed "invasive GAS disease."

Persons with skin lesions (such as cuts, surgical wounds, chickenpox), the elderly, and adults with a history of alcohol abuse or injection drug use have a higher risk for developing invasive GAS disease. Also, people with chronic illnesses like cancer, diabetes, and chronic heart or lung disease, and those who use medications such as steroids, have a higher risk.

Over the last five years, an average of 189 cases of invasive GAS were reported annually in Maryland. About 9,000 to 11,500 cases of invasive GAS disease occur each year in the United States, resulting in 1,000 to 1,800 deaths annually. For more information, visit http://www.cdc.gov/ncidod/dbmd/diseaseinfo/groupastreptococcal_g.htm.

Cosmetic surgery centers in Maryland are not currently subject to state licensure. In the near future, DHMH will seek public comment on potential approaches to oversight of these facilities.

Media inquiries regarding this infection cluster will be handled by the Baltimore County Department of Health Public Information Office. Call Monique Lyle at 410-887-6092 or 443-463-3757.

###

Case Finding Questionnaire for Monarch Med Spa GAS Outbreak

1. Date of call _____
2. Time of call _____

Client Demographic Information:
3. Name _____
4. DOB _____
5. Phone Number _____
6. What is your home address?
7. Which county do you live in?
8. State of Residence _____

GAS Outbreak Questions:
9. At which Monarch Med Spa location did you seek care (*Locations: Greenville, DE; Harrisburg, PA; King of Prussia, PA; Philadelphia, PA; Timonium, MD*), ?

10. What procedure did you have at Monarch Med Spa?

11. What was the date of your procedure?

12. Who is your physician at Monarch Med Spa?

13. Did you take antibiotics before, during, or after your procedure?

14. Did you have any symptoms or problems after your procedure? Please explain.

15. (If yes) Did you seek medical attention for these symptoms or problems after the procedure?

16. (If yes) Where did you seek medical attention? (*Prompts as necessary: Monarch Med Spa facility, primary care provider, or ER.)*

17. What was the result of the medical care you received? (*Prompts as necessary: no treatment, medications (such as antibiotics) prescribed, admission to hospital, etc.)*

18. Do you have any other information about your visit to Monarch MedSpa that might be useful in our investigation?

GAS Follow-Up Questionnaire for Patients undergoing liposuction since July 1

Patient Name: _____

Who was in the room at any time during your procedure(s)? (If you don't remember names, please provide gender and a brief description.)

1. 4.
2. 5.
3. 6.

Now, thinking about just Person #1:

- Was he/she wearing gloves? Yes/No/DK
- Was he/she wearing a mask? Yes/No/DK
- Was he/she wearing a surgical gown? Yes/No/DK
- Did he/she leave the room during your procedure? Yes/No/DK

Now, thinking about just Person #2:

- Was he/she wearing gloves? Yes/No/DK
- Was he/she wearing a mask? Yes/No/DK
- Was he/she wearing a surgical gown? Yes/No/DK
- Did he/she leave the room during your procedure? Yes/No/DK

Now, thinking about just Person #3:

- Was he/she wearing gloves? Yes/No/DK
- Was he/she wearing a mask? Yes/No/DK
- Was he/she wearing a surgical gown? Yes/No/DK
- Did he/she leave the room during your procedure? Yes/No/DK

Do you have any other information about your visit to Monarch MedSpa that might be useful in our investigation?

Exhibit 351

ASC INFECTION CONTROL SURVEYOR WORKSHEET

(Rev. 84, Issued: 06-07-13, Effective: 06-07-13, Implementation: 06-07-13)

Name of State Agency or AO (please *specify*) _____

Instructions: The following is a list of items that must be assessed during the on-site survey, in order to determine compliance with the infection control Condition for Coverage. Items are to be assessed primarily by surveyor observation, with interviews used to provide additional confirming evidence of observations. In some cases information gained from interviews may provide sufficient evidence to support a deficiency citation.

The interviews and observations should be performed with the most appropriate staff person(s) for the items of interest (*e.g.*, the staff person responsible for sterilization should answer the sterilization questions).

A minimum of one surgical procedure must be observed during the site visit, unless the ASC is a low volume ASC with no procedures scheduled during the site visit. The surveyor(s) must identify at least one patient and follow that case from registration to discharge to observe pertinent practices. For facilities that perform brief procedures, e.g., colonoscopies, it is preferable to follow at least two cases.

When performing interviews and observations, any single instance of a breach in infection control would constitute a breach for that practice.

Citation instructions are provided throughout this instrument, indicating the applicable regulatory provision to be cited on the Form CMS-2567 when deficient practices are observed.

PART 1 – ASC CHARACTERISTICS

1. ASC Name _____

2. Address, State and Zip Code

_____
Address

_____
City State Zip

3. 10-digit CMS Certification Number | | | | | | | | | | |

4. What year did the ASC open for operation? | | | | |
y y y y

5. Please list date(s) of site visit: | | / | | / | | to | | / | | / | |
m m / d d / y y y Y to m m / d d / y y y y

6. What was the date of the most recent previous federal (CMS) survey: | | / | | / | | |
m m / d d / y y y y

7. Does the ASC participate in Medicare via accredited "deemed" status?
- ○ YES
- ○ NO

7a. If YES, by which CMS-recognized accreditation organization*(s)*?
- ○ Accreditation Association for Ambulatory Health Care (AAAHC)
- ○ American Associate for Accred. of Ambulatory Surgery Facilities (AAAASF)
- ○ American Osteopathic Association (AOA)
- ○ The Joint Commission (TJC)

7b. If YES, according to the ASC, what was the date of the most recent accreditation *survey?* | | / | | / | | |
m m / d d / y y y y

8. What is the ownership of the facility? ***(SELECT only ONE bubble)***

- ○ Physician-owned
- ○ Hospital-owned
- ○ National corporation (including joint ventures with physicians)
- ○ Other (please *specify*): _____

9. What is the primary procedure performed at the ASC (i.e., what procedure type reflects the majority of procedures performed at the ASC)?
(*Select* only ONE bubble)

- ○ Dental
- ○ Endoscopy
- ○ Ear/Nose/Throat
- ○ OB/Gyn
- ○ Ophthalmologic
- ○ Orthopedic
- ○ Pain
- ○ Plastic/reconstructive
- ○ Podiatry
- ○ Other (**please *specify***): _____

10. What additional procedures are performed at the ASC? (***Select* all that apply)**
Do not include the procedure type indicated in question 9.

- ○ Dental
- ○ Endoscopy
- ○ Ear/Nose/Throat
- ○ OB/Gyn
- ○ Ophthalmologic
- ○ Orthopedic
- ○ Pain
- ○ Plastic/reconstructive
- ○ Podiatry
- ○ Other (**please specify**): _____
- ○ *N/A*

11. Who does the ASC perform procedures on?
(*Select* only ONE bubble)

- ○ Pediatric patients only
- ○ Adult patients only
- ○ Both pediatric and adult patients

12. What is the average number of procedures performed at the ASC **per month**?

						per month

13. How many Operating Rooms (including procedure rooms) does the ASC have?

○ 1	○ 2	○ 3	○ 4	○ 5	○ 6	○ 7	○ 8	○ 9+

Number actively maintained:

○ 1	○ 2	○ 3	○ 4	○ 5	○ 6	○ 7	○ 8	○ 9+

14. Please indicate how the following services are provided: **(*select* all that apply)**

	Contract	Employee	Other	**If Other, *please specify*:**
Anesthesia*/Analgesia*	○	○	○	
Environmental Cleaning	○	○	○	
Linen	○	○	○	
Nursing	○	○	○	
Pharmacy	○	○	○	
Sterilization/Reprocessing	○	○	○	

Waste Management	○	○	○	

INFECTION CONTROL PROGRAM

15. Does the ASC have an explicit infection control program?

○ YES
○ NO

NOTE! If the ASC does not have an explicit infection control program, a condition-level deficiency related to 42 CFR 416.51 **must** be cited.

16. Does the ASC's infection control program follow nationally recognized infection control guidelines?

○ YES
○ NO

NOTE! If the ASC does not follow nationally recognized infection control guidelines, a deficiency related to 42 CFR 416.51(b) **must** be cited. Depending on the scope of the lack of compliance with national guidelines, a condition-level citation may also be appropriate.

16a. Is there documentation that the ASC considered and selected nationally-recognized infection control guidelines for its program?

○ YES
○ NO

*NOTE! If the ASC cannot document that it considered and selected specific guidelines for use in its infection control program, a deficiency related to 42 CFR 416.51(b) **must** be cited. This is the case even if the ASC's infection control practices comply with generally accepted standards of practice/national guidelines. If the ASC neither selected any nationally recognized guidelines nor complies with generally accepted infection control standards of practice, then the ASC should be cited for a condition-level deficiency related to 42 CFR 416.51.*

16b. *If YES to (a), w*hich nationally-recognized infection control guidelines has the ASC selected for its program? **(*Select* all that apply)**

○ CDC/HICPAC Guidelines:
- ○ Guideline for Isolation Precautions (CDC/HICPAC)
- ○ Hand hygiene (CDC/HICPAC)
- ○ Disinfection and Sterilization in Healthcare Facilities (CDC/HICPAC)
- ○ Environmental Infection Control in Healthcare Facilities (CDC/HICPAC)

○ Perioperative Standards and Recommended Practices (AORN)

○ Guidelines issued by a specialty surgical society / organization (List)

Please specify (please limit to the space provided):

○ Others

Please specify (please limit to the space provided):

17. Does the ASC have a licensed health care professional qualified through training in infection control and designated to direct the ASC's infection control program?

○ YES
○ NO

NOTE! If the ASC cannot document that it has designated a qualified professional with training (not necessarily certification) in infection control to direct its infection control program, a deficiency related to 42 CFR 416.51(b)(1) **must** be cited. Lack of a designated professional responsible for infection control should be considered for citation of a condition-level deficiency related to 42 CFR 416.51.

17a. If YES, Is this person an:
(***Select*** **only ONE bubble**)

○ ASC employee
○ ASC contractor

17b. Is this person certified in infection control (i.e., CIC) (Note: §416.50(b)(1) does **not** require that the individual be certified in infection control.)

○ YES
○ NO

17c. If this person is **NOT** certified in infection control, what type of infection control training has this person received?

17d. On average, how many hours per week does this person spend in the ASC directing the infection control program?

[ ][ ] hours per week

(Note: §416.51(b)(1) does **not** specify the amount of time the person must spend in the ASC directing the infection control program, but it is expected that the designated individual spends sufficient time on-site directing the program, taking into consideration the size of the ASC and the volume of its surgical activity.)

18. Does the ASC have a system to actively identify infections that may have been related to procedures performed at the ASC?
NOTE! If the ASC does not have a documented identification system, a deficiency related to 42 CFR 416.51(b)(3) must be cited.

○ YES
○ NO

18a. If YES, how does the ASC obtain this information?
(*Select* all that apply)

○ The ASC sends e-mails to patients after discharge
○ The ASC follows-up with their patients' primary care providers after discharge
○ The ASC relies on the physician performing the procedure to obtain this information at a follow-up visit after discharge, and report it to the ASC
○ Other (**please *specify***):

18b. Is there supporting documentation confirming this tracking activity?

○ YES
○ NO

NOTE! If the ASC does not *have supporting documentation*, a deficiency related *to* 42 CFR 416.51(b)(3) **must** be cited.

18c. Does the ASC have a policy/procedure in place to comply with State notifiable disease reporting requirements?

○ YES
○ NO

NOTE! If the ASC does not have a reporting system, a deficiency **must** be cited related to *42 CFR 416.51(b)(3)*. CMS does not specify the means for reporting; generally this would be done by the State health agency.

19. Do staff members receive infection control training?
If training is completely absent, then consideration should be given to condition-level citation in relation to 42 CFR 416.51, particularly when the ASC's practices fail to comply with infection control standards of practice.

- ○ YES
- ○ NO

19a. If YES, how do they receive infection control training? (***Select*** **all that apply**)

- ○ In-service
- ○ Computer-based training
- ○ Other (**please *specify***):

19b. Which staff members receive infection control training? **(*Select* all that apply)**

- ○ Medical staff
- ○ Nursing staff
- ○ Other staff providing direct patient care
- ○ Staff responsible for on-site sterilization/high-level disinfection
- ○ Cleaning staff
- ○ Other (**please *specify***):

19c. Is training:

- ○ the same for all categories of staff
- ○ different for different categories of staff

19d. Indicate frequency of staff infection control training **(*Select* all that apply)**

- ○ Upon hire
- ○ Annually
- ○ Periodically / as needed
- ○ Other (**please *specify***):

19e. Is there documentation confirming that training is provided to all categories of staff listed above?

- ○ YES
- ○ NO

NOTE! If training is not provided to appropriate staff upon hire/granting of privileges, with some refresher training thereafter, a deficiency **must** by cited in relation to 42 CFR 416.51(b) and (b)(3).

20. How many procedures were observed during the site visit?

○ 1 ○ 2 ○ 3 ○ 4 ○ Other

If other, **please *specify* the number**: [ ][ ] procedures

PART 2 – INFECTION CONTROL & RELATED PRACTICES

INSTRUCTIONS:

- Please ***select*** **ONE bubble** for each "Was Practice Performed?" and "Manner of Confirmation" question, unless otherwise noted.
- If N/A is ***selected***, please explain why there is no associated observation, or why the question is not applicable, in the COMMENTS box at the end of each section.

I. Hand Hygiene

Observations are to focus on staff directly involved in patient *c*are (e.g., physicians, nurses, CRNAs, etc.). Hand hygiene should be observed not only during the case being followed, but also while making other observations in the ASC throughout the survey. Interviews are used primarily to provide additional evidence for what the surveyor has observed, but may in some cases substitute for direct observation to support a citation of deficient practice.

Unless otherwise indicated, a "No" response to any question below ***must*** *be cited as a deficient practice in relation to 42 CFR 416.51(a).*

Practices to be Assessed	Was Practice Performed?	Manner of Confirmation
A. All patient care areas have: Note: 42 CFR 416.51(a) should be cited only if the answer to both a and b is "No."		
a. Soap and water available	○ Yes ○ No	○ Observation ○ Interview ○ Both
b. Alcohol-based hand rubs available	○ Yes ○ No	○ Observation ○ Interview ○ Both
I. If alcohol-based hand rub is available in patient care areas, it is installed as required. **(There are LSC requirements at 42 CFR 416.44(b)(5) for installation of alcohol-based hand rubs)**	○ Yes ○ No	
B. Staff perform hand hygiene:		
a. After removing gloves	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
b. Before direct patient contact	○ *Yes* ○ *No* ○ *N/A*	○ *Observation* ○ *Interview* ○ *Both*
*c. A*fter direct patient contact	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both

Practices to be Assessed	Was Practice Performed?	Manner of Confirmation
d. Before *performing invasive procedures (e.g. placing an IV)*	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
e. After contact with blood, body fluids, or contaminated surfaces (even if gloves are worn)	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
C. Regarding gloves, staff:		
a. Wear gloves for procedures that might involve contact with blood or body fluids	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
b. Wear gloves when handling potentially contaminated patient equipment	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
c. Remove gloves before moving to the next tasks and/or patient	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
D. Additional breaches in hand hygiene, not captured by the questions above, were identified (If YES, **please specify** further in comments)	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both

Comments: **(please *specify*)**	

II. Injection Practices (injectable medications, saline, other infusates)
Observations are to be made of staff *preparing* and *administering* medications and *performing* injections (e.g., anesthesiologists, certified registered nurse anesthetists, nurses).
*Unless otherwise indicated, a "No" response to any question below **must** be cited as a deficient practice in relation to 42 CFR 416.51(a).*

Practices to be Assessed	Was Practice Performed?	Manner of Confirmation
A. Needles are used for only one patient	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both

Practices to be Assessed	Was Practice Performed?	Manner of Confirmation
B. Syringes are used for only one patient	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
C. The rubber septum on a medication vial is disinfected with alcohol prior to piercing.	○ *Yes* ○ *No* ○ *N/A*	○ *Observation* ○ *Interview* ○ *Both*
D. Medication vials are always entered with a new needle	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
E. Medication vials are always entered with a new syringe	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
F. Medications that are pre-drawn are labeled with the *date and* time of draw, initials of the person drawing, medication name, strength and *discard* date *and* time	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
Note: A "No" answer should result in citation as a deficient practice in relation to 42 CFR 416.48(a), Administration of Drugs		
G. a. Single dose (single-use) medication vials are used for only one patient	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
b. Manufactured prefilled syringes are used for only one patient	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
c. Bags of IV solutions are used for only one patient	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
d. Medication administration tubing and connectors are used for only one patient	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both

Practices to be Assessed	Was Practice Performed?	Manner of Confirmation
H. Multi-dose injectable medications are used for only one patient	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both

(Note: a "No" answer here is not necessarily a breach in infection control and does not result in a citation. However, a "No" response to *either or both of* the related questions *I and J* should be cited).

(Fill in N/A if no multi-dose medications/infusates are used).

If YES, please skip to "*K*"

If NO, please answer "*I and J*":

I. Multi-dose vials are dated 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 for the vial. The multi-dose vial can be dated with either the date opened or the discard date as per ASC policies and procedures, so long as it is clear what the date represents and the same policy is used consistently throughout the ASC.	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
J. Multi-dose medications **used for more than one patient** are *stored and accessed away from* the immediate areas where direct patient contact occurs	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
K. All sharps are disposed of in a puncture-resistant sharps container	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
L. Sharps containers are replaced when the fill line is reached	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
M. Additional breaches in injection practices, not captured by the questions above were identified (If YES, **please specify** further in comments)	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both

Comments: **(please *specify*)**	

III. Single Use Devices, Sterilization, and High Level Disinfection

Pre-cleaning must always be performed prior to sterilization and high-level disinfection

Sterilization must be performed for critical equipment (i.e., instruments and equipment that enter normally sterile tissue or the vascular system, such as surgical instruments)

High-level disinfection must be performed for semi-critical equipment (i.e., items that come into contact with non-intact skin or mucous membranes such as reusable flexible endoscopes, laryngoscope blades)

Observations are to be made of staff *performing* equipment reprocessing (e.g., surgical techs), unless these activities are performed under contract or arrangement off-site from the ASC.

*Unless otherwise indicated, a "No" response to any question below **must** be cited as a deficient practice in relation to 42 CFR 416.51(a).*

SINGLE-USE DEVICES

(Choose N/A if single-use devices are never reprocessed and used again) (Surveyor to confirm there is a contract or other documentation of an arrangement with a reprocessing facility by viewing it)

Practices to be Assessed		Was Practice Performed?	Manner of Confirmation
A.	a. If single-use devices are reprocessed, they are devices that are approved by the FDA for reprocessing	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
	b. If single-use devices are reprocessed, they are reprocessed by an FDA-approved reprocessor.	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both

STERILIZATION

A. Critical equipment is sterilized	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
B. Are sterilization procedures performed on-site? **(If NO, skip to "F")** (A "No" answer does not result in a citation, since ASCs are permitted to provide for sterilization off-site, under a contractual arrangement.) (Surveyor to confirm there is a contract or other documentation of an arrangement for off-site sterilization by viewing it)	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both

a. **If YES to B**, please indicate method of sterilization:

- ○ Steam autoclave
- ○ Peracetic acid
- ○ Other (**please *specify***):

Practices to be Assessed	Was Practice Performed?	Manner of Confirmation
C. Items are pre-cleaned according to manufacturer's instructions or evidence-based guidelines prior to sterilization	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
D. a. Medical devices and instruments are visually inspected for residual soil and re-cleaned as needed before packaging and sterilization	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
b. A chemical indicator is placed in each load	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
c. A biologic indicator is performed at least weekly and with all implantable loads	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
d. Each load is monitored with mechanical indicators (e.g. time, temperature, pressure)	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
e. Documentation for each piece of sterilization equipment is maintained and up to date and includes results from each load	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
E. Items are appropriately contained and handled during the sterilization process to assure that sterility is not compromised prior to use	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
F. After sterilization, medical devices and instruments are stored in a designated clean area so that sterility is not compromised	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
G. Sterile packages are inspected for integrity and compromised packages are reprocessed	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
H. Additional breaches in sterilization practices not captured by the questions above were identified (If YES, **please specify** further in comments)	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both

Comments: **(please *specify*)**	

HIGH-LEVEL DISINFECTION		
Practices to be Assessed	**Was Practice Performed?**	**Manner of Confirmation**
A. Semi-critical equipment is high-level disinfected or sterilized	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
B. Is high-level disinfection performed on site? **(If NO, Skip to "F")**	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
(A "No" answer does not result in a citation, since ASCs are permitted to provide for high-level disinfection off-site, under a contractual arrangement.) (Surveyor to confirm there is a contract or other documentation of an arrangement for off-site sterilization by viewing it)		
a. **If answer to B was YES**, please indicate method of high-level disinfection:	○ Manual ○ Automated ○ Other (**please *specify***):	
C. Items are pre-cleaned according to manufacturer's instructions or evidence-based guidelines prior to high-level disinfection	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
D. a. Medical devices and instruments are visually inspected for residual soil and re-cleaned as needed before high-level disinfection	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
b. High-level disinfection equipment is maintained according to manufacturer instructions	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
c. Chemicals used for high-level disinfection are:		
I. Prepared according to manufacturer instructions	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both

Practices to be Assessed	Was Practice Performed?	Manner of Confirmation
II. Tested for appropriate concentration according to manufacturer's instructions	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
III. Replaced according to manufacturer's instructions	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
IV. Documented to have been prepared and replaced according to manufacturer's instructions	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
d. Instruments requiring high-level disinfection are:		
I. Disinfected for the appropriate length of time as specified by manufacturer's instructions or evidence-based guidelines	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
II. Disinfected at the appropriate temperature as specified by manufacturer's instructions *or* evidence-based guidelines	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
E. Items that undergo high-level disinfection are allowed to dry before use	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
F. Following high-level disinfection, items are stored in a designated clean area in a manner to prevent contamination	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
G. Additional breaches in high-level disinfection practices, not captured by the questions above were identified (If YES, **please specify** further in comments)	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both

Comments: **(please *specify*)**	

IV. Environmental Infection Control

Observations are to be made of staff *performing* environmental cleaning (e.g., surgical technicians, cleaning staff, etc.)

*Unless otherwise indicated, a "No" response to any question below **must** be cited as a deficient practice in relation to 42 CFR 416.51(a).*

Practices to be Assessed	Was Practice Performed?	Manner of Confirmation
A. Operating rooms are cleaned and disinfected after each surgical or invasive procedure with an EPA-registered disinfectant	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
B. Operating rooms are terminally cleaned daily	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
C. High-touch surfaces in patient care areas are cleaned and disinfected with an EPA-registered disinfectant	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
D. The ASC has a procedure in place to decontaminate gross spills of blood	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
E. Additional breaches in environmental cleaning not captured by the questions above were identified (If YES, **please specify** further in comments)	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both

Comments: **(please *specify*)**	

V. Point of Care Devices (e.g., blood glucose meter)

Observations are to be made of staff *performing* fingerstick testing (e.g., nurses)

If N/A is *selected*, please clarify in the comments box below why it was not applicable or not observed.

*Unless otherwise indicated, a "No" response to any question below **must** be cited as a deficient practice in relation to 42 CFR 416.51(a).*

Practices to be Assessed	**Was Practice Performed?**	**Manner of Confirmation**
1. Does the ASC have a *point of care device, such as a* blood glucose meter? **If NO, STOP HERE.**	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
A. A new single-use, auto-disabling lancing device is used for each patient	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
B. *If used for more than one patient, the point of care device is cleaned and disinfected after every use according to manufacturer's instructions.* *Note: If the manufacturer does not provide instructions for cleaning and disinfection, then the device must not be used for more than one patient.*	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
C. Additional breaches in appropriate use of point of care devices (like glucose meters) not captured by the questions above were identified (If YES, **please specify** further in comments)	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both

Comments: **(please *specify*)**	

STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene
201 W. Preston Street • Baltimore, Maryland 21201
Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – Joshua M. Sharfstein, M.D., Secretary

September 19, 2012

By express mail and facsimile
Mr. Kevin Campbell
President & CEO
Monarch Med Spa, Inc.
200 North Warner Road
Suite 121
King of Prussia, Pennsylvania 19406

By hand delivery
Mr. Abraham Fadley, President
Baltimore Laser Solutions, Inc.
d/b/a Monarch Med Spa
9608 Deereco Road
Timonium, Maryland 21093

By express mail
Baltimore Laser Solutions, Inc.
c/o Maryland Agent Service, Inc.
8005 Baileys Lane
Pasadena, Maryland 21122

ORDER TO CEASE OPERATIONS

Dear Mr. Campbell and Mr. Fadley:

On September 17, 2012, the University of Maryland Medical System's infection control unit reported to the Department of Health and Mental Hygiene that three patients who had been seen for procedures in the last six weeks at Monarch Med Spa, 9608 Deereco Road, Timonium, Maryland, had contracted invasive streptococcal infections, and that one of the three patients had died as a result of the infection. On September 18, 2012, investigators from the Department of Health and Mental Hygiene and the Baltimore County Department of Health inspected the facility at 9608 Deereco Road and observed probable deviations from standard infection control practices, among other potential deficiencies. Because of the severity of invasive streptococcal disease, all health care providers, among others, are required to report its occurrence to the Department of Health and Mental Hygiene. *See* COMAR 10.06.01.03 & .04. According to the Centers for Disease Control and Prevention, 10 to 15 percent of patients with Invasive group A streptococcal disease die from the infection.

Based on this information, we have determined that conditions at the Monarch Med Spa facility at 9608 Deereco Road endanger the public health and that all operations at the facility should cease until the cause of the infections is investigated and the threat to the public health has abated.

Therefore, pursuant to § 18-102(b) of the Health-General Article of the Maryland Code and COMAR 10.06.01.06(C), it is hereby **ORDERED** that Monarch Med Spa, Inc. and Baltimore Laser Solutions, Inc. shall immediately cease operating their facility at 9608 Deereco Road in Timonium, Maryland; and it is further **ORDERED** that Monarch Med Spa and Baltimore Laser Solutions shall not resume operations at 9608 Deereco Road until a determination has been made pursuant to COMAR 10.06.01.06(C) that the threat to the public health has abated.

This Order is effective immediately. Monarch Med Spa and Baltimore Laser Solutions may request a hearing concerning this Order by submitting a written request, by October 1, 2012, to Frances B. Phillips, Deputy Secretary for Public Health Services, Department of Health and Mental Hygiene, 201 West Preston Street, Baltimore, Maryland 21201.

Sincerely,

Joshua M. Sharfstein, MD
Secretary

Gregory Wm. Branch, MD, MBA, CPE
Baltimore County Health Officer