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TO: All Office-Based Surgery Practitioners

RE: **Update:** New York State Department of Health (NYSDOH) Guidance for Performing Liposuction with and without Fat Grafting in the Office-Based Surgery Setting.

From: Office of Health Services Quality and Analytics, Clinical Center, Office-Based Surgery Program

Purpose of the Guidance

This guidance for performing liposuction with and without fat grafting in the Office-Based Surgery (OBS) setting was developed by the New York State Department of Health (NYSDOH) OBS Program based on recommendations of a Plastic Surgery Expert Workgroup and the OBS Advisory Committee. This guidance document aims to achieve the following goals:

- Improve safety in the performance of liposuction with and without fat grafting procedures in the OBS setting.
- Reduce adverse events and deaths related to OBS procedures of liposuction with and without fat grafting.

The NYSDOH OBS Program is publishing this guidance in relation to the following:

- In recent years, liposuction and gluteal fat grafting/augmentation procedures have become some of the most frequently performed plastic surgery procedures in the United States.[1,2]
- The NYSDOH Office-Based Surgery Program has recently experienced an increase in reported deaths related to liposuction and liposuction with fat grafting.
- Recommendations to improve safety in the performance of liposuction and liposuction with fat grafting procedures include that subfascial or intramuscular injection should not be performed.[1,3] All injections should be performed exclusively into the subcutaneous tissue.
- Anatomical studies have found that the injection of fat subjacent to the fascia of the gluteus maximus muscle can migrate deep through the muscle into the submuscular space, possibly causing tears in the gluteal veins, leading to fat embolisms to the heart and lungs.[3]

The purpose of this guidance is to provide recommendations as a supplement to other standards or guidelines for the OBS procedures of liposuction with or without fat grafting.

Office-Based Surgery (OBS) in New York State:

- New York State Public Health Law (PHL) Section 230-d defines OBS, requires private physician practices in which OBS is performed to maintain accreditation from an accrediting agency designated by NYSDOH, and mandates reporting of specific adverse events that occur subsequent to OBS.

- Practices seeking to perform OBS must comply with PHL Section 230-d as well as all other applicable statutes and regulations.

- PHL Section 230-d defines OBS as any surgical or other invasive procedure accompanied by general anesthesia, deep sedation, or moderate sedation; any liposuction procedure with removal of 500 cc or more of fat regardless of level of sedation; or any liposuction procedure with removal of less than 500 cc of fat under supplemented local, minimal or moderate sedation, or inhalational nitrous oxide in any concentration; where the procedure is performed by a physician, physician assistant (PA), specialist assistant (SA), or podiatrist privileged to perform ankle surgery by the State Education Department in a location other than an Article 28 hospital or Article 28 ambulatory surgery center.

- In accordance with PHL Section 230-d, all physicians, PAs, SAs, and podiatrists must report specific adverse events occurring in relation to the performance of OBS to the Office of Health Services Quality and Analytics (OHSQA) of the NYSDOH. Such reportable adverse events shall be reported to OHSQA within three business days of the occurrence of the event; suspected transmission of bloodborne pathogens must be reported within three business days of becoming aware of a suspected transmission.

- Any violation of PHL Section 230-d is professional misconduct under Education Law Section 6530(48).

Adverse Events that must be reported according to PHL Section 230-d:

1. Patient death within thirty (30) days of the procedure;
2. Unplanned transfer to a hospital for reasons related to the OBS encounter;
3. An emergency department visit within seventy-two (72) hours of OBS for reasons related to the OBS encounter;
4. Unscheduled hospital admission or assignment to observation services within seventy-two (72) hours of the OBS, for longer than twenty-four (24) hours;
5. Any other serious or life-threatening events: The NYSDOH has adopted those events identified and defined as Serious Reportable Events by the **National Quality Forum** as meeting the definition of "other serious or life-threatening events" involving OBS patients.
   In addition to the National Quality Forum Serious Reportable Events, the NYSDOH has identified the following events as meeting the OBS law definition of an "other serious or life-threatening event":
   - Unplanned return to the Operating Room after discharge from an OBS practice for a procedure related to the OBS procedure;
   - Delayed admission to the hospital for actual or potential OBS-related complications occurring between seventy-three (73) hours and thirty (30) days after an OBS procedure.

6. Any Suspected Health Care Transmission of a Bloodborne Pathogen (BBP): a suspected transmission of a bloodborne pathogen (BBP) from a healthcare practitioner to a patient or between patients originating in an OBS practice as a result of improper infection control practices. BBP include but are not limited to Hepatitis B virus, Hepatitis C virus, and Human Immunodeficiency Virus.

Who Must Report Adverse Events:

- It is the personal responsibility of each mandated reporter to ensure that an adverse event has been reported.

- A mandated reporter includes ANY physician, PA, SA, and/or podiatrist in an OBS practice, hospital, or other setting who believes or becomes aware of a patient complaint, complication, condition, emergency department visit, hospital admission, or death that occurred related to an OBS procedure.

The Adverse Event Report can be found at: https://obsaer.health.ny.gov.

Guidance for Proceduralist Performing Liposuction with and without Fat Grafting in the Office-Based Surgery (OBS) Setting

I. Proceduralist

a. Proceduralist must be a NYS-Licensed physician (MD or DO) with appropriate training, experience and competence to perform these procedures and practice in compliance with New York State Education Law Article 131-A § 6530 https://www.op.nysed.gov/title8/education-law/article-131a
b. Physicians planning to perform procedures of liposuction with removal of 500 cc or more of fat with or without fat grafting in the OBS setting should have privileges in their specialty for the same procedure at a licensed Article 28 acute care hospital and/or Article 28 ambulatory surgery center or should have a written transfer agreement with a physician having privileges in their specialty for the same procedure at a licensed Article 28 acute care hospital who agrees to provide care for the OBS provider's patient(s) in need of care in an acute care hospital setting.

II. Patient selection for OBS setting vs. hospital recommendations

a. Patients should be under the care of a licensed practitioner (physician performing procedure and/or patient's primary care provider), who should evaluate the condition of the patient, including specific comorbidities that may complicate performance of the procedure and/or anesthetic management, and identify and discuss with the patient the potential risks associated with treatment options.
b. A patient who, due to pre-existing medical or other conditions, is at undue risk for complications, should be referred to an appropriate specialist for a preoperative consultation, and to another treatment setting/facility for performance of the surgery and administration of the anesthesia as deemed necessary by the evaluation.
c. Preoperative evaluation should include, but may not be limited to:
    i. Review of patient's medical status to include medical history, surgical history, anesthetic history, social history, allergies, height, weight, current medications, hematological or bleeding disorders, and psychological status.

ii. Review of previous medical records and interview of the patient or family to identify:
    1. Abnormalities of the major organ systems (e.g., cardiac, renal, pulmonary, neurologic, sleep apnea, metabolic, endocrine).
    2. Adverse experience with sedation/analgesia, as well as regional and general anesthesia.
    3. History of a difficult airway.
    4. History of previous surgical procedures with potential of scar tissue or herniations within the planned surgical site locations.
    5. Current medications (e.g., prescription, over the counter, herbals, supplements, or other), potential drug interactions, drug allergies, and nutraceuticals.
    6. Prior experience with post-operative pain, current and previous use of pain medications, and expectation of post-operative pain management plan.
    7. History of tobacco, alcohol, or substance use or abuse.
    8. History of hematological disorders and/or use of medications such as antithrombotics (anticoagulants/antiplatelet) or herbal supplements which may increase risk of bleeding or thrombosis.

iii. Performance of a physical examination of the patient should include vital signs, auscultation of the heart and lungs, evaluation of the airway, and evaluation of other organ systems where abnormalities have been identified.

d. Documentation of preprocedural evaluation, including the review of findings and decision to perform procedure should be included in the medical record.

III. Preprocedural testing recommendations

a. Perform pertinent preprocedural testing based upon findings of the preprocedural evaluation.
    i. Review available laboratory test results; order additional laboratory tests guided by the patient's medical condition, physical examination, and the potential that results will affect the management of moderate sedation/analgesia.
    ii. Document review of preprocedural testing in the medical record.

IV. Anticoagulation for prevention of thromboembolism (i.e., blood clots) recommendations

a. Patient evaluation for history of, or potential for, venous thromboembolism and performance of risk stratification should be part of preprocedural evaluation.
    i. Utilization of a venous thromboembolism risk assessment tool (e.g., Modified Caprini Scale) is recommended to evaluate patient's risk and guide prophylaxis.
    ii. Documentation in the medical record of risk stratification and venous thromboembolism risk assessment tool used is recommended.

b. Discuss risks of hormone therapy and consider discontinuing. When hormonal therapy is prescribed, consult with the ordering physician prior to discontinuing.

c. Utilization of intermittent pneumatic compression devices for mechanical prophylaxis, early mobilization, chemical prophylaxis based on venous thromboembolism risk assessment findings/score and limiting Operating Room times (recommended Operating Room time limit of 2-3 hours) is recommended.

V. Maximum amount of volume removed by liposuction in OBS setting (Total Aspirate) recommendations

a. Large volume liposuction (greater than 5,000 cc total aspirate) and/or large volume liposuction combined with other procedures should be performed in an Article 28 facility i.e., acute-care hospital or an Ambulatory Surgery Center.

b. No more than 5,000 cc of aspirate should be removed while performing liposuction unless the patient is monitored overnight in an appropriate Article 28 facility with minimum of a registered nurse (RN) with ACLS certification in attendance.

VI. Post-op care/follow-up recommendations

a. Immediate postoperative care considerations:
   - i. Identify length of required patient monitoring/recovery time in facility post procedure (number of hours). If overnight monitoring is needed, transport and stay in an Article 28 facility should be arranged.
   - ii. Assess fluid and electrolyte requirements and plan for administration of replacement fluids to assure fluid and electrolyte balance.
     1. Fluid replacement recommendations:
        - a. Replace preoperative fluid deficit as needed.
        - b. Administer maintenance fluid, adjusting for changes in patients' clinical situation (e.g., vital signs, intake & output) and volume of liposuction.
        - c. Consider total amount of infiltration solution (super wet or tumescent technique) when determining fluid deficit.

b. With longer procedures, 4 to 6 hours in length, patient should not be discharged after less than a 1-2 hour monitored observation in a Post Anesthesia Care Unit (PACU).

c. Post discharge considerations: early ambulation and chemical prophylaxis based on patient venous thromboembolism risk assessment.

VII. Maximum duration of procedures in OBS setting (Length of Procedure) recommendations

a. Recommended Operating Room time of 2-3 hours; not to exceed 6 hours in length. If the Operating Room time is expected to exceed 6 hours, the patient should be referred to an alternative facility (i.e., Article 28 acute-care hospital or an Ambulatory Surgery Center) for performance of the surgery and administration of the anesthesia.

b. If the intended procedure, which under usual circumstances would not exceed 6 hours in the Operating Room, should go beyond 6 hours the following processes should be in place prior to the start of the case:
   - i. a written emergency transfer procedural plan for transferring patients to a hospital and
   - ii. a transfer agreement with a local acute-care hospital within thirty (30) minutes of the OBS facility in which the surgeon has privileges to admit patients or a written transfer agreement with a physician having privileges in their specialty for the same procedure at a licensed Article 28 acute care hospital who agrees to provide care for the OBS provider's patient(s) in need of care in an acute care hospital setting.

VIII. Gluteal fat grafting recommendations

a. There should be no intramuscular/submuscular injection of fat.

i. When performing gluteal fat grafting procedures, fat should be injected into the subcutaneous space only and never cross the gluteal fascia. Intramuscular or submuscular fat injections are contraindicated.
ii. Ultrasound guidance should be used at all times when introducing and navigating the cannula and injecting fat into the subcutaneous space to ensure the fat is placed above the gluteal fascia.[4,5]
iii. If the aesthetic goal requires a greater amount of fat than can be placed in the subcutaneous layer, the surgeon should stage the procedure rather than injecting below the subcutaneous layer.

References:

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5. American Society of Plastic Surgeons. (2022, August 18). *Gluteal Fat Grafting: A joint safety statement.* Retrieved from: https://www.plasticsurgery.org/for-medical-professionals/publications/psn-extra/news/gluteal-fat-grafting-a-joint-safety-statement