FLORIDA DEPARTMENT of STATE

RON DESANTIS
Governor

CORD BYRD
Secretary of State

June 15, 2022

Cassandra Fullove
Paralegal Specialist
Office of the Attorney General
PL 01, The Capitol
Tallahassee, FL 32399

Dear Cassandra Fullove:

Your adoption package for Emergency Rule 64B8ER22-3, F.A.C. was received, electronically, by the Florida Department of State, Administrative Code and Register at 4:48 p.m. on June 14, 2022. After review, it appears that the package meets statutory requirements and those of Rule 1-1.010, F.A.C. and is deemed filed for adoption at the time received, as indicated above. The effective date is June 14, 2022.

Sincerely,

Anya C. Owens
Program Administrator

ACO/mas

CERTIFICATION OF

BOARD OF MEDICINE EMERGENCY RULE

FILED WITH THE DEPARTMENT OF STATE

I hereby certify that an immediate danger to the public health, safety or welfare requires emergency action and that the attached rule is necessitated by the immediate danger. I further certify that the procedures used in the promulgation of this emergency rule were fair under the circumstances and that the rule otherwise complies with subsection 120.54(4), Florida Statutes. The adoption of this rule was authorized by the head of the agency and this rule is hereby adopted upon its filing with the Department of State.

Rule No.

64B8ER22-3

Under the provision of subparagraph 120.54(4)(d), F.S., this rule takes effect upon filing unless a later time and date less than 20 days from filing is set out below:

Effective: _____
(Month) (Day) (Year)

_____
Signature, Person Authorized
To Certify Rules

Executive Director for David A. Diamond, M.D., Chair
Title

_____
Number of Pages Certified

CERTIFICATION OF DEPARTMENT OF STATE
DESIGNATION OF RULE THE VIOLATION OF WHICH IS A MINOR VIOLATION

Pursuant to Section 120.695(2)(c)3, Florida Statutes, I certify as agency head, as defined by section 20.05(1)(b), Florida Statutes, that:

[X] All rules covered by this certification are not rules the violation of which would be minor violation pursuant to Section 120.695, F.S.

[ ] The following parts of the rules covered by this certification have been designated as rules the violation of which would be a minor violation pursuant to Section 120.695, F.S.:

Rule No(s).

Rules covered by this certification:

Rule No(s).

64B8ER22-3

Signature of Agency Head

Executive Director for David A. Diamond, M.D., Chair
Title

Form: DS-FCR-6
Rule 1-1.010(3)(f), F.A.C.; effective 10-17

NOTICE OF EMERGENCY RULE

DEPARTMENT OF HEALTH

Board of Medicine

RULE TITLE: RULE NO.:

Standard of Care for Office Surgery 64B8ER22-3

SPECIFIC REASONS FOR FINDING AN IMMEDIATE DANGER TO THE PUBLIC HEALTH, SAFETY OR WELFARE: The Board of Medicine (hereinafter the "Board") has statutory authority to set standards of practice and care for various practice settings. Pursuant to this authority, the Board has promulgated rules setting forth standards of practice and care for office surgery settings where cosmetic surgeries are commonly performed.

During recent years gluteal fat grafting, commonly referred to in marketing literature and the media as the "Brazilian Butt Lift," has become a popular cosmetic procedure in Florida and around the world. It is a procedure, commonly performed in office surgery facilities, where a surgeon removes fat from an unwanted area such as the abdomen or thighs and inserts the fat into the patient's buttocks to enlarge and recontour the buttocks. Unfortunately, this procedure has been connected to numerous patient deaths.

This issue first came to the Board's attention through multiple disciplinary actions taken against physicians who performed gluteal fat transfers in office surgery facilities that resulted in multiple adverse incidents including patient deaths. The Board has also reviewed medical journal articles and practice advisories that found a higher mortality rate associated with gluteal fat grafting than with any other aesthetic surgical procedure. The first such journal entry titled *Report on Mortality from Gluteal Fate Grafting: Recommendations from the ASERF Task Force* was published online in the *Aesthetic Surgery Journal* on March 21, 2017. It reported the result of a survey conducted of 692 surgeons who performed 198,857 gluteal fat grafting procedures throughout their careers. The surgeons reported 32 fatalities from pulmonary fat emboli and 103 nonfatal pulmonary fat emboli. They further reported that the practice of injecting fat into the deep muscle resulted in a significantly increased rate of fatal and nonfatal pulmonary fat emboli.

On January 31, 2018, the American Society of Plastic Surgeons published a Gluteal Fat Grafting Advisory from the Inter-Society Gluteal Fat Grafting Task Force. The Task Force, made up of the American Society of Plastic Surgeons (ASPS), the American Society for Aesthetic Plastic Surgery (ASAPS), the International Society of Aesthetic Plastic Surgeons (ISAPS), the International Society of Plastic & Regenerative Surgeons (ISPRES) and the

International Federation for Adipose Therapeutics and Science (IFATS), analyzed deaths from gluteal fat grafts and found that a death rate of approximately 1/3000 patients is the highest for any aesthetic surgical procedure. The Task Force also found that all the autopsies of deceased gluteal fat grafts patients revealed fat in the gluteal muscles, fat beneath the muscles, damage to the superior or inferior gluteal vein, massive fat emboli in the heart and/or lungs, and two instances of deaths or injuries with fat only in the subcutaneous space.

The January 31, 2018, advisory was followed up by another on July 11, 2018, also from American Society of Plastic Surgeons, wherein the Inter-Society Gluteal Fat Grafting Task Force reported that deaths from gluteal fat grafting procedures continue to be reported wherein the cause of death is uniformly from fatal fat embolism caused by fat entering the venous circulation associated with injury to the gluteal veins. The Task Force further found that in every gluteal fat graft patient who has died, fat was seen within the gluteal muscle at autopsy.

The findings from the aforementioned advisories and journal article were reinforced by the testimony and comments of interested parties that attended the Joint Board of Medicine and Board of Osteopathic Medicine Surgical Care/Quality Assurance Committee meeting on June 6, 2019, where the Board discussed and considered a rule setting forth a standard of care for gluteal fat grafting. Representatives from both the Florida Medical Association and the Florida Society of Plastic Surgeons supported proposed rule language setting forth a standard of care for gluteal fat grafting that prohibits the insertion of fat into a patient's buttocks that crosses the superficial gluteal fascia. Gary M. Brownstein, M.D., F.A.C.S., a plastic surgeon, Chief Executive Officer of the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF) and Chair of AAAASF's board, also supported the proposed rule and clearly stated that inserting fat beneath the gluteal fascia is likely to cause harm and even death to patients.

On June 7, 2019, the full Board of Medicine found that gluteal fat grafts that included intramuscular or submuscular injections of fat presented an immediate danger to the health, safety, and welfare of Florida's patients, and accordingly, on June 27, 2019, filed with the Department of State an emergency rule making it clear that the standard of care for performing gluteal fat grafting procedures required physicians to only inject fat into the subcutaneous space and never below the superficial gluteal fascia. The emergency rule went into effect that same day and a permanent rule containing the same prohibition went into effect on September 3, 2019.

Unfortunately, despite the promulgation of the aforementioned rule, the Board and the Department of Health have continued to see an unacceptable number of fatalities related to gluteal fat grafting procedures performed in

Florida's office surgery facilities. Accordingly, at the request of the Board of Medicine, the Department of Health reviewed its records to ascertain the number of Florida patient deaths associated with gluteal fat graft procedures performed in office surgery facilities since 2015 and produced the following figures:

OFFICE SURGERY GLUTEAL FAT GRAFTING RELATED DEATHS SINCE 2015

2015	2016	2017	2018	2019	2020	2021	2022	Total
1	1	4	4	2	1	5	3	21

Of the two deaths that took place in 2019, one death occurred on May 1, 2019, before the Board's June 17, 2019, gluteal fat graft emergency rule, and the second death occurred on August 20, 2019, after the emergency rule. Hence, there were eleven (11) verified deaths related to gluteal fat grafting during the 54-month period of time prior to the Board's June 17, 2019, emergency rule, and ten (10) verified deaths related to gluteal fat grafting in the 36 months following the emergency rule. It also should be noted that during the 36 months following the initial emergency rule, a 53-day moratorium on elective surgical procedures was enacted by the Governor in response to the COVID pandemic.

Other sources, such as the Miami-Dade Medical Examiner's office, report that there were eight (8) deaths related to gluteal fat graft procedures in South Florida in 2021 alone. The authors of the April 11, 2022, "Practice Advisory on Gluteal Fat Grafting," published on the Aesthetic Society's *Aesthetic Surgery Journal*, also report that there were 12 deaths related to gluteal fat grafting procedures in Florida over the 24 months preceding the publication of the advisory. While neither of the preceding claims are verified, and it is unclear whether the reported deaths arise from gluteal fat grafting procedures performed in office surgery settings, the Board believes that they nonetheless support its belief that there continues to be an unacceptable number of deaths related to gluteal fat grafting procedures performed in Florida's office surgery facilities.

The ten (10) verified deaths over a 36-month period reported by the Department that occurred since the enactment of the Board's initial gluteal fat grafting emergency rule justify the immediate enactment of additional measures to protect those patients who elect to undergo gluteal fat grafting procedures in Florida's office surgery facilities. Accordingly, the Board has decided to mandate the following additional safeguards:

1. The surgeon performing the procedure must use ultrasound guidance when placing and navigating the canula and injecting fat into the subcutaneous space to ensure that the fat is placed above the

fascia overlying the gluteal muscle. The surgeon must also maintain the ultrasound video recordings in the patient's medical record including the time and the date stamp of the ultrasound video recording.

2. A surgeon must not perform more than three (3) gluteal fat grafting procedures in one calendar day.

The preceding safeguards come from the Aesthetic Society's *Practice Advisory on Gluteal Fat Grafting,* published on April 11, 2022. In their recommendations, the authors of the advisory characterize ultrasound assisted fat grafting as a promising technique that assures the subcutaneous deposition of fat in the area intended by the physician. The Board concurs with the authors' assertions that the use of ultrasound guidance to guide the canula while injecting fat during gluteal fat grafting procedures will assist the surgeon in avoiding crossing the fascia overlying the gluteal muscle and will minimize fatal intramuscular or submuscular fat injections. The use of ultrasound will also create an ultrasonic record of the procedure that will serve to memorialize its safe execution and the identity of the operating physician.

The advisory authors also recommend that a surgeon perform not more than three (3) gluteal fat grafting procedures in any given day. Given a three (3) hour gluteal fat transfer procedure and a one (1) hour turnaround time for the operating room, it is not unreasonable for a surgeon to perform no more than three (3) gluteal fat transfer procedures in an eleven-hour workday. The authors believe, and the Board concurs, that such a limitation will decrease surgeon fatigue and distractions and in turn will likely minimize surgical errors resulting in fatalities.

The Board continues to believe that an outright ban on gluteal fat grafting procedures is not necessary, but the fact that there has been at best a de minimis reduction in the number of deaths related to gluteal fat grafting during the 36 months following the Board's June 17, 2019, emergency rule, leads the Board of Medicine to conclude that the status quo is unacceptable and that it continues to present an immediate danger to the health, safety, and welfare of Florida's patients. Hence, the Board calls for further action to protect those Floridians who choose to undergo gluteal fat grafting procedures in office surgery facilities and therefore, via emergency rule, establishes a standard of care that calls for the use of ultrasound guidance to guide the canula while injecting fat during gluteal fat grafting procedures and a limit of three (3) gluteal fat grafting procedures per surgeon in one calendar day. The Board is of the opinion that its actions are a measured regulatory approach that protects Florida's patients while maintaining the availability of this popular aesthetic surgical procedure.

REASONS FOR CONCLUDING THAT THE PROCEDURE USED IS FAIR UNDER THE CIRCUMSTANCES:

The procedure used for the promulgation of this emergency rule is fair under the circumstances. The Board of Medicine began addressing deaths associated with gluteal fat grafting procedures at its April, 2019, board meeting when it began discussing its first gluteal fat grafting emergency order, but even before that it had been disciplining Florida physicians who performed gluteal fat transfers in office surgery facilities that resulted in multiple adverse incidents including patient deaths. It is safe to say that "Brazilian Butt Lifts" have been on the Board's regulatory radar for a long time.

"Brazilian Butt Lifts" have also been extensively covered by the media since as early as May, 2016. Extensive coverage has been provided by local and national media of instances where patients suffered injuries, both fatal and non-fatal, when undergoing gluteal fat grafts. It is safe to say that this issue has been on the public radar for some time as well of that of the medical profession.

Persons and entities interested in this issue were aware of the Board's intention to readdress the standard of care for gluteal fat grafts at the meeting of the Board's Surgical Care/Quality Assurance Committee meeting of May 26, 2022. The meeting was properly noticed on May 3, 2022, pursuant to Section 120.525(1), Florida Statutes. Tab 3 on the agenda containing three (3) medical review/journal articles on the safety of gluteal fat transfer procedures was published on the agenda on May 18, 2022, as was Tab 4 that was titled "Possible OSR Rule Amendments." The matter first appeared on the full Board's agenda on May 26, 2022.

The public was put on notice through board action and through the extensive media coverage of the issue. The public and interested parties were given opportunity to participate in the rulemaking process and did so at the properly noticed Surgical Care/Quality Assurance Committee meeting and the Board meeting a week later. Legal counsel representing the Florida Society of Plastic Surgeons, a medical society made up of approximately 300 board certified physicians, attended and participated in the both the committee and the Board meeting as did legal counsel for Surgeons for Safety, an organization of Florida licensed osteopathic and allopathic board-certified and board-eligible plastic surgeons who perform gluteal fat grafting procedures in their medical practices. Legal counsel for the Florida Medical Association, a medical society with over 25,000 allopathic and osteopathic physician members, also attended both the Committee and the Board meetings. Given such, it is clear that the procedure employed by the Board to promulgate this emergency rule was fully transparent and fair under the circumstances.

SUMMARY: The proposed emergency rule amendment further clarifies the standard of care for gluteal fat grafting.

THE PERSON TO BE CONTACTED REGARDING THE EMERGENCY RULE IS: Paul Vazquez, J.D., Executive Director, Board of Medicine/MQA, 4052 Bald Cypress Way, Bin # C03, Tallahassee, Florida 32399-3253.

THE FULL TEXT OF THE EMERGENCY RULE IS:

64B8ER22-3 (64B8-9.009) Standard of Care for Office Surgery.

Nothing in this rule relieves the surgeon of the responsibility for making the medical determination that the office is an appropriate forum for the particular procedure(s) to be performed on the particular patient.

(1) No change.

(2) General Requirements for Office Surgery.

(a) through (e) No change.

(f) Standard of Care for Gluteal Fat Grafting. When performing gluteal fat grafting procedures, the surgeon must comply with the following standards:

1. F~~f~~at may only be injected into the subcutaneous space and must never cross the fascia overlying the gluteal muscle ~~fascia~~. Intramuscular or submuscular fat injections are prohibited.

2. The surgeon performing the procedure must use ultrasound guidance when placing and navigating the canula and injecting fat into the subcutaneous space to ensure that the fat is placed above the fascia overlying the gluteal muscle. The surgeon must also maintain the ultrasound video recordings in the patient's medical record including the time and the date stamp of the ultrasound video recording.

3. A surgeon must not perform more than three (3) gluteal fat grafting procedures in one calendar day.

(g) through (p) No change.

(3) through (6) No change.

Rulemaking Authority 458.309(1), 458.328(2), 458.331(1)(v) FS. Law Implemented 458.328, 458.331(1)(v), 458.351 FS. History–New 2-1-94, Amended 5-17-94, Formerly 61F6-27.009, Amended 9-8-94, 11-15-94, Formerly 59R-9.009, Amended 2-17-00, 12-7-00, 2-27-01, 8-1-01, 8-12-01, 3-25-02, 3-22-05, 4-19-05, 10-23-05, 10-10-06, 4-18-07, 9-3-07, 3-25-10, 8-6-12, 11-22-12, 1-9-13, 3-3-13, 7-22-14, 4-6-15, 9-4-16, 5-22-17, 6-23-17, 9-4-17, 5-7-18, 7-2-18, 9-3-19, 3-2-20, 3-10-22.

THIS RULE TAKES EFFECT IMMEDIATELY UPON BEING FILED WITH THE DEPARTMENT OF STATE UNLESS A LATER TIME AND DATE IS SPECIFIED IN THE RULE.