

FLORIDA | Board of Osteopathic Medicine

June 10, 2022



DRAFT MEETING MINUTES
Board of Osteopathic Medicine
GoTo Meeting
Meet-Me-Number 1(866) 899-4679
Participation Code 755-082-469
June 10, 2022
4 p.m.

The meeting was called to order by Dr. Sandra Schwemmer, Chair, at approximately 4:02 p.m.

Roll Call was conducted by Paul Vazquez, JD, Executive Director for the Board of Medicine. Those present for all, or part of the meeting included the following:

MEMBERS PRESENT:

Sandra Schwemmer, DO, Chair
Michelle R. Mendez, DO, Vice-Chair
Tiffany Sizemore Di Pietro, DO
Jorge Gadea, DO
William Kirsh, DO

MEMBERS ABSENT

Valerie Jackson, Consumer Member

COURT REPORTER:

For the Record Reporting
(850) 222-5491
Ray Convery

BOARD STAFF PRESENT:

Paul Vazquez, JD, Executive Director
of the Board of Medicine
Carol Taylor, Program Administrator
Derek Nieves, RSIII
Christa Peace, Regulatory Supervisor

BOARD COUNSEL

Donna McNulty, Board Counsel
Ed Tellechea, Board Counsel
Cassandra Fullove, Paralegal

Please note that the meeting minutes reflect the actual order that agenda items were discussed during the meeting and may differ from the agenda outline

OPENING REMARKS:

Dr. Schwemmer informed the board that the purpose of the meeting was to present a proposed emergency rule. The rule was adopted by the Board of Medicine at their last meeting, having been recommended by the Joint Surgical Care/Quality Assurance Committee, related to the number of deaths associated with Gluteal Fat Transfer Surgeries.

RULE AMENDMENTS:

Donna McNulty, board counsel identified the proposed emergency rule as Rule 64B15-ER22, Florida Administrative Code.

Mr. Tellechea again noted that at the June 3, 2022, board meeting the Board of Medicine passed the proposed emergency rule. He then provided background information; including, that on June 27, 1919, the Board of Medicine and shortly thereafter the Board of Osteopathic Medicine, passed a previous emergency rule to avoid complications and deaths related to gluteal fat grafting procedures. The board continues to see an unacceptable number of deaths related to gluteal fat grafting procedures. Data was obtained to assist the boards in determining the deaths prior to the previous rule and following the previous rule. It was noted that the Board of Medicine didn't believe enough has been done and that an emergency rule is needed regarding standards of care for Gluteal Fat Grafting procedures. Mr. Tellechea then summarized the changes that appear in the proposed emergency rule before the board.

Dr. Schwemmer noted that the deaths are concerning.

Dr. Schwemmer noted that the emergency rule, if adopted, will be the same language as the Board of Medicine. The rule will be good for ninety days and will become effective June 13th.

Dr. Schwemmer requested the board members look at the emergency rule language being proposed with the changes that Mr. Tellechea went through. Dr. Schwemmer then read the changes into the record.

Amended changes:

1. Fat may only be injected into the subcutaneous space and must never cross the fascia overlying the gluteal muscle. 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 of the procedure in the patient's medical record including time and date stamps of the ultrasound recording.
3. A surgeon must not perform more than three (3) gluteal fat grafting procedures in one calendar day.

Dr. Schwemmer noted these are the three changes to the existing rule that are before the board.

Dr. Schwemmer allowed comments from each board member regarding their concerns prior to general discussion.

TAB-3 – GENERAL DISCUSSION

Mr. Allen Grossman was recognized by the Board to speak. He asked that his comments at the Board of Medicine be incorporated into the current record.

Mr. Grossman provided statements in opposition to the rule being an emergency rule.

Mr. Christopher Nuland, on behalf Florida Society of Plastic Surgeons, spoke in support of the emergency rule with suggestions provided by his client.

Board members participated in the discussion.

It was noted that if passed, the emergency rule would be followed by rulemaking where further discussions will take place.

The goal is to put a measure in place to further protect the public.

After discussion, the following action was taken:

Motion: by Dr. Mendez, to approve the emergency rule language as presented in the materials, seconded by Dr. Kirsh. Motion carried unanimously.

Motion: by Dr. Mendez, to proceed with the rulemaking process for Rule 64B15-14.007, Florida Administrative Code, seconded by Dr. Kirsh. Motion carried unanimously.

The Emergency Rule was approved.

TAB-4 - OLD BUSINESS

There was no old business.

TAB-5 - NEW BUSINESS

There was no new business.

ADJOURN:

Motion: by Dr. Gadea, to adjourn, seconded by Dr. Mendez.

Meeting adjourned at 5:01 p.m.

Next Meeting: June 23, 2022

Following Meeting: August 12, 2022