Notice of Meeting/Workshop Hearing

DEPARTMENT OF HEALTH
Board of Medicine

The **Board of Medicine – Full Board Meeting** announces a public meeting to which all persons are invited.

DATE AND TIME: Friday, August 5, 2022, beginning at 8:00 AM EST, or soon thereafter.

PLACE: Marriott Fort Lauderdale Airport, 166 North Compass Way, Dania Beach, FL 33004. The hotel's phone number is (954) 802-7543.

GENERAL SUBJECT MATTER TO BE CONSIDERED: General business of the Committee. If held, Committee meetings are conducted prior to each Full Board meeting. Committee meetings may be cancelled or changed prior to the meeting date. Please check the Board website at https://flboardofmedicine.gov/meeting-information/ for cancellations or changes or call the Board of Medicine at (850) 245-4131 for information. The hotel website is https://www.marriott.com/en-us/hotels/fllmp-marriott-fort-lauderdale-airport/ and the public rate is $169 per night.

A copy of the agenda may be obtained seven days prior to the meeting date by contacting: the Board of Medicine athttps://flboardofmedicine.gov/meeting-information/.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 7 days before the workshop/meeting by contacting: the Board of Medicine by email at BOM.MeetingMaterials@flhealth.gov or by calling the Board of Medicine at (850) 245-4131.

If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800) 955-8771 (TDD) or 1(800) 955-8770 (Voice).

If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.

For more information, you may contact: the Board of Medicine by email at BOM.MeetingMaterials@flhealth.gov or by calling the Board of Medicine at (850) 245-4131.

Florida Board of Medicine
Board Meeting

Marriott Fort Lauderdale Airport
166 N. Compass Way
Fort Lauderdale, FL 33004
(954) 802-7543

August 5, 2022

AGENDA

NOTE: Cases shown on the agenda may be heard in a different order but will not be heard prior to 8:00 a.m. Cases are scheduled to be heard beginning at 8:00 a.m.; therefore, it is imperative that you arrive promptly at 8:00 a.m. and be prepared to be at the meeting for several hours until your case is heard.

Lunch will be taken at an appropriate time.

Participants in this public meeting should be aware that these proceedings are being recorded and that an audio file of the meeting will be posted to the board's website.

8:00 a.m. Roll Call

Disciplinary Case Schedule:

Raul D. D. Correa, MD – Recommended Order, Case number 2021-21736 1
.....**Dr. Pages and Ms. Garcia**

Raul D. D. Correa, MD – Recommended Order, Case number 2021-30940 2
.....**Dr. Pages and Ms. Garcia**

Jeffrey D. Morgan, MD – Recommended Order 28
.....**No current members**
.....**Addendum in Version 2**

Jeng Y. Lin, MD – Settlement Agreement 3
.....**No current members**

John A. G. Sampson, MD – Settlement Agreement 4
.....**Mr. Romanello**

Herbert M. Bertram, III, MD – Settlement Agreement 5
.....**Dr. Zachariah and Ms. Garcia**

Jason J. H. Song, MD – Settlement Agreement.....6
.....**Dr. Zachariah and Ms. Garcia**
.....**Addendum in Version 2**

Roger S. Gorman, MD – Settlement Agreement 7
.....**Dr. Chandra**

Tab 22 will be presented as a settlement agreement. After Tab 8, the case will be heard.

UNTIMED ITEMS:

Chair Recognition Award: 40
.....**Addendum in Version 4**

- Daniel R. Bergholz - University of Miami Miller School of Medicine
- Allison Chin – Florida International University Herbert Wertheim College of Medicine
- Zaimary Meneses - Charles E. Schmidt College of Medicine at Florida Atlantic University
- Amr El-Talla - Nova Southeastern University College of Allopathic Medicine

Board Chair's Remarks: .....No tab

Board Counsel's Remarks:.....No tab

Board Director's Remarks: 35

- Boards of Medicine and Osteopathic Medicine's Joint Committee on Medical Marijuana
- State of Florida Deploys Tools to Address Overdose Crisis
  .....**Addendum in Version 3**
- Important Information for Health Care Providers Regarding COVID-19
  .....**Addendum in Version 3**
- Florida Prescription Drug Monitoring Program (PDMP) Monthly Report - June 2022
  .....**Addendum in Version 3**
- Electronic License
- 2024 BOM Proposed Meeting
  .....**Addendum in Version 4**

Department Remarks: 36

- Appellate Report .....**Addendum in Version 3**
- Year-Old Case Report .....**Addendum in Version 3**

Council on Physician Assistants:

July 28, 2022 (Dr. Chandra) .....No tab

Committee Reports:

Credentials Committee.....No tab
August 5, 2022 (Dr. Ackerman)

Boards of Medicine and Osteopathic Medicine's Joint Committee on Surgical Care/Quality Assurance Committee 37
August 5, 2022 (Dr. Cairns)

- Materials Presented at the August 4, 2022, Joint Committee on Surgical Care/Quality Assurance meeting.....**Addendum in Version 3**

Rules/Legislative Committee.....No tab
August 5, 2022 (Dr. Zachariah)

Probation Committee .....No tab
July 28, 2022 (Dr. Pages)

Other Business

New Business

Anticipated Adjournment 5:00 p.m.

Florida Board of Medicine
Board Meeting

Marriott Fort Lauderdale Airport
166 North Compass Way
Fort Lauderdale, FL 33004
(954) 802-7543

August 5, 2022

MEETING MINUTES

I. CALL TO ORDER

The meeting was called to order at 8:01 A.M. EST on Friday August 5, 2022, by Dr. David Diamond, Chair.

Participants in this public meeting were made aware that these proceedings were being recorded and that an audio file of the meeting would be posted to the Board's website.

A. ROLL CALL

Roll call was conducted by Cherise Strickland, Program Operations Administrator. Those present for all, or part of the meeting included the following:

Members Present:
David Diamond, M.D., Chair
Kevin Cairns, M.D., Vice-Chair
Scot Ackerman, M.D.
Ravi Chandra, M.D.
Amy Derick, M.D.
Patrick Hunter, M.D.
Luz Pages, M.D.
Eleonor Pimentel, M.D.
Hector Vila, M.D.
Michael Wasylik, M.D.
Zachariah Zachariah, M.D.
Nicole Justice, ESQ., Consumer Member

Staff Present:
Jenifer Wenhold, Division Director
John Wilson, General Counsel
Paul A. Vazquez, J.D., Executive Director
Edward Tellechea, Board Counsel
Cassandra Fullove, Paralegal
Bettye Cherise Strickland, Program Operations Administrator
Wendy Alls, Program Operations Administrator
Shaila Washington, Regulatory Supervisor
Cyra Williams, Regulatory Specialist III
Brad Dalton, Public Information Officer

Members Absent:
Wael Barsoum, M.D.
Maria Garcia, Esq., Consumer Member
Nicholas Romanello, Esq., Consumer Member

Court Reporter:
Magnolia Court Reporting
Heather Howard
(888) 811-3048

Department of Health Prosecutors Present:
Chad Dunn, Esq.
Kristen Summers, Esq.
Hunter Pattison, Esq.
Kristen Suarez, Esq.
Andrew Pietrylo, Esq.

B. OPENING REMARKS

Mr. Vazquez provided opening remarks. He reminded the audience that this is a publicly noticed meeting and is being recorded for the public record.

II. DISCIPLINARY CASE SCHEDULE

License Number: ME41890
(PCP: No current members)

Allegations of the Administrative Complaint: Violations of §458.331(1)(t)1, §458.331(1)(q), and §458.331(1)(m), F.S.

Action taken: A motion was made to accept the settlement agreement, seconded, and carried unanimously.

Costs: A motion was made to impose costs of $5,000.00, seconded and carried unanimously.

Penalty imposed:

- Letter of concern.
- Fine $5,000.
- Costs $5,000.00
- CME – Laws, Rules, and Ethics (5 hours)
- Drug Course (5 hours)
- Records Course (3 hours)
- Risk Management (5 hours)
- Quality Assurance Consultation/Risk Management Assessment – Engage a certified professional independent risk manager to review Respondent's current practice within 60 days, and to report the quality assurance report to the Board's Probation Committee within six (6) months.

License Number: ME123792
(PCP: Dr. Zachariah and Ms. Garcia)

Allegations of the Administrative Complaint: Violations of §456.072(1)(bb), F.S.

Action taken: A motion was made to accept the settlement agreement, seconded, and carried unanimously.

Costs: A motion was made to impose costs of $1,941.38, seconded and carried unanimously.

Penalty imposed:

- Letter of Concern.
- Fine $2,500.
- Costs $1,919.81.
- CME - Lecture/Seminar on Wrong Site Surgeries to medical staff at an approved medical facility (1 hour).
- CME - Risk Management (5 hours).

License Number: ME130590
(PCP Dr. Vila and Ms. Garcia)

Allegations of the Administrative Complaint: Violations of §458.331(1)(b) and §458.331(1)(kk), F.S.

Action taken: A motion was made to accept the settlement agreement, seconded, and carried unanimously.

Costs: A motion was made to impose cost of $585.00, seconded, and carried unanimously.

Penalty imposed:

- Letter of concern.
- Fine $1,500.
- Costs $585.00.
- CME – Laws, Rules, and Ethics (5 hours).

License Number: ME55602
(PCP: Dr. Vila)

Allegations of the Administrative Complaint: Violations of §458.331(1)(t)1, F.S.

Action taken: A motion was made to accept the settlement agreement, seconded, and carried unanimously.

Costs: A motion was made to impose cost of $4,971.67, seconded, and carried unanimously.

Penalty imposed:

- Letter of concern.
- Fine $4,000.
- Costs $4,971.67.
- CME – Subjects related to Obstetrics and Gynecology, including discussions of hypoxic ischemic encephalopathy; Risk Management (5 hours).

License Number: ME118750
(PCP: Dr. Zachariah and Ms. Garcia)

Allegations of the Administrative Complaint: Violations of §456.072(1)(cc), F.S.

Action taken: A motion was made to accept the settlement agreement, seconded, and carried unanimously.

Costs: A motion was made to impose cost of $3,309.63, seconded, and carried unanimously.

Penalty imposed:

- Letter of concern.
- Fine $2,500.
- Costs $3,309.63.

- CME - Risk Management (5 hours).
- Presentation of a one (1) hour lecture on Retained Foreign Bodies to medical staff at an approved medical facility within six (6) months of the date of the Final Order.

License Number: ME79321
(PCP: Dr. Pages and Ms. Garcia)

Allegations of the Administrative Complaint: Violations of §458.331(1)(nn), by violating §456.072(1)(ss), by committing an act that constitutes a violation of §794.011; §456.072(1)(v) through a violation of §456.063(1); §458.331(1)(j) as defined and/or prohibited in §458.329 through Rule 64B8-9.008. The same allegations were applied to both administrative complaint cases.

Dr. Diamond provided opening statements and instructions on how the proceedings would be conducted.

Dr. Correa was not present and was represented by Bruce Lamb, Esq.

Ms. Summers represented the Department.

Following opening remarks, Mr. Lamb proceeded summarizing their 35 exceptions to the proposed recommended order.

Action taken: Each exception was heard individually with respondent's counsel and Department's counsel given testimony. All 35 exceptions were denied by the Board by individual vote.

Ms. Summers requested a motion to adopt the allegations of fact in the Administrative Complaint as the findings of fact to the Board.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Ms. Summers requested a motion to adopt the Administrative Law Judge's Conclusions of Law as the Board Conclusions of Law.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Ms. Summers requested a motion that the Board enter a final order complying with the Administrative Law Judge's recommendation of revocation of license, imposing a fine of $10,000, and imposing cost for the investigation and prosecution of this case.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Ms. Summers request a motion to bifurcate the cost of the case and come back at later date for a cost motion.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Respondent's counsel requested a stay pending a potential appeal. The Department requested the Board deny the request as the physician constitutes a danger to the public.

Action taken: A motion was made to deny the Respondent's counsel's request, seconded, and carried unanimously.

Penalty imposed:

- Revocation of license.

License Number: ME103348
(PCP: No current members)

Dr. Diamond provided opening statements and instructions on how the proceedings would be conducted.

Dr. Morgan was not present and was not represented by counsel.

Mr. Dunn and Ms. Suarez represented the Department.

Following opening remarks, Ms. Suarez proceeded with summarizing the proposed recommended order and case details.

Ms. Suarez requested a motion to deny all of respondent's exceptions due to §120, F.S., for failing to notate page number or paragraph of the exceptions.

Action taken: A motion was made to reject respondent's exceptions in total, seconded, and carried unanimously.

Ms. Suarez requested a motion to adopt the allegations of fact in the Administrative Complaint as the findings of fact to the Board.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Ms. Suarez requested a motion to adopt the Administrative Law Judge's Conclusions of Law as the Board Conclusions of Law.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Ms. Suarez requested a motion that the Board enter a final order complying with the Administrative Law Judge's recommendation of revocation of license and impose cost for the investigation and prosecution of this case.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Mr. Dunn requested a motion to impose costs of $54,939.39.

Action taken: A motion was made to impose costs, seconded, and carried unanimously.

Penalty imposed:

- Revocation of license.
- Costs $54,939.39.

License Number: ME121890
(PCP: Mr. Romanello)

Allegations of the Administrative Complaint: Violations of §458.331(1)(t), F.S., §458.331(1)(nn), F.S. by violating Rule 64B88-9.009(2)(f), F.A.C., and §458.331(1)(k), F.S., and §458.331(1)(nn) and/or 458.328(1)(g) by violating Rule 64B8-9.001, F.A.C.

Dr. Sampson was present and was represented by Monica Felder, Esq.

Ms. Summers represented the Department.

After opening remarks and discussion, the following action was taken:

Action taken: A motion was made to reject the settlement agreement as presented, seconded, and carried unanimously.

Action taken: A motion was made to accept amended settlement agreement, seconded, and carried unanimously.

Respondent chose to respond to the agreement within 7 days of filing.

Penalty imposed:

- Fine $20,000.
- Costs $4,626.65.
- CME - Laws, Rules, and Ethics (5 hours).
- CME - Medical Records (5 hours).
- CME - Lecture/Seminar on complications related to liposuction and gluteal fat grafting at an approved medical facility (1 hour).
- Restriction on Practice – Permanently restricted from performing gluteal fat grafting.
- Restriction on Practice – Permanently restricted from serving as the Designed Physician of an office surgery center.
- Quality Assurance Consultation/Risk Management Assessment – Engage a certified professional independent risk manager to review Respondent's current practice within 60 days, and to report the quality assurance report to the Board's Probation Committee within six (6) months.

License Number: ME78271
(PCP: Dr. Zachariah and Ms. Garcia)

Allegations of the Administrative Complaint: Violations of §456.072(1)(bb), F.S.

Dr. Bertram was present and represented by Mandy Smith, Esq.

Ms. Suarez represented the Department.

After opening remarks and discussion, the following action was taken:

Action taken: A motion was made to accept the settlement agreement, seconded, and carried unanimously.

Penalty imposed:

- Letter of Concern.
- Fine $7,500.

- Costs $4,146.01.
- CME - Lecture/Seminar on Wrong Site Surgeries (1 hour).
- CME - Risk Management (5 hours).

License Number: ME50540
(PCP: Dr. Chandra)

Allegations of the Administrative Complaint: Violations of §458.331(1)(t), F.S. and §458.331(1)(m), F.S.

Dr. Gorman was present and represented by Matthew M. Fischer, Esq.

Mr. Pietrylo represented the Department.

After opening remarks and discussion, the following action was taken:

Action taken: A motion was made to reject the proposed settlement agreement and amend the terms, seconded, and carried unanimously.

Action taken: A motion was made to accept the amended settlement agreement, seconded, and carried unanimously.

Respondent chose to respond to the agreement within 7 days of filing.

Penalty imposed:

- Letter of Reprimand.
- Fine $10,000.
- Costs $6,836.68.
- CME - Medical Records (3 hours).
- CME - Managing Hypotension During Surgical Procedures (10 hours).
- CME - Anesthesiology During Surgical Procedures (10 hours).
- CME - Risk Management (5 hours).
- Evaluation by Florida CARES, Center for Personalized Education for Professional (CPEP), the UC San Diego PACE program, or another equivalent program preapproved by the Board (within 9 months).
- Probation with direct supervision (until evaluation).

License Number: ME64482
(PCP: Dr. Barsoum and Mr. Romanello)

Allegations of the Administrative Complaint: Violations of §458.331(1)(c), F.S.

Dr. Villaman-Bencosme was not present and not represented by counsel.

Mr. Dunn represented the Department.

Mr. Dunn requested a motion from the Board that no Election of Rights had been received and finding that Respondent waived his right to elect his avenue of resolution by failing to timely reply to the properly noticed Administrative Complaint.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Mr. Dunn requested a motion to adopt the allegations of fact in the Administrative Complaint as the findings of fact to the Board.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Ms. Dunn requested a motion to adopt the Conclusions of Law.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Mr. Dunn requested a motion for imposition of penalty.

After discussion, the following action was taken:

Action taken: A motion was made to impose penalty, seconded, and carried unanimously.

Mr. Dunn requestion a motion for imposition of costs total $554.97.

Action taken: A motion was made to impose costs, seconded, and carried unanimously.

Penalty imposed:

- Revocation of license.
- Costs $554.97.

License Number: ME70549
(PCP: Dr. Wasylik and Mr. Romanello)

Allegations of the Administrative Complaint: Violations of §458.331(1)(b), F.S.

Dr. Cullen was not present and not represented by counsel.

Mr. Pietrylo represented the Department.

Mr. Pietrylo requested a motion from the Board that no Election of Rights had been received and finding that Respondent waived his right to elect his avenue of resolution by failing to timely reply to the properly noticed Administrative Complaint.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Mr. Pietrylo requested a motion to adopt the allegations of fact in the Administrative Complaint as the findings of fact to the Board.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Mr. Pietrylo requested a motion to adopt the Conclusions of Law.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Mr. Pietrylo requested a motion for imposition of penalty.

After discussion, the following action was taken:

Action taken: A motion was made to reject the Departments recommended penalty, seconded, and carried unanimously.

Action taken: A motion was made to amend the penalty imposed, seconded, and carried unanimously.

Mr. Pietrylo requestion a motion for imposition of costs.

Action taken: A motion was made to waive costs, seconded, and carried unanimously.

Penalty imposed:

- Revocation of license.

License Number: ME124462
(PCP: Dr. Zachariah)

Allegations of the Administrative Complaint: Violations of §458.331(1)(b), F.S. and §456.072(1)(w), F.S.

Dr. Nielson was not present and not represented by counsel.

Ms. Summers represented the Department.

Ms. Summers requested a motion from the Board that no Election of Rights had been received and finding that Respondent waived his right to elect his avenue of resolution by failing to timely reply to the properly noticed Administrative Complaint.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Ms. Summers requested a motion to adopt the allegations of fact in the Administrative Complaint as the findings of fact to the Board.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Ms. Summers requested a motion to adopt the Conclusions of Law.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Ms. Summers requested a motion for imposition of penalty.

After discussion, the following action was taken:

Action taken: A motion was made to impose penalty, seconded, and carried unanimously.

Ms. Summers requestion a motion for imposition of costs.

Action taken: A motion was made to waive costs, seconded, and carried unanimously.

Penalty imposed:

- Revocation of license.

License Number: ME30183
(PCP: Dr. Wasylik and Mr. Romanello)

Allegations of the Administrative Complaint: Violations of §458.331(1)(b), F.S. and §456.072(1)(w), F.S.

Dr. Barnes was not present and not represented by counsel.

Mr. Dunn represented the Department.

Mr. Dunn requested a motion to accept the exhibits of the case into evidence.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Mr. Dunn requested a motion to adopt the allegations of fact in the Administrative Complaint as the findings of fact of the Board.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Mr. Dunn requested a motion finding the respondent in violation of Florida Statutes as charged in the Administrative Complaint.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Mr. Dunn requested a motion for the imposition of penalty.

After discussion, the following action was taken:

Action taken: A motion was made to impose penalty, seconded, and carried unanimously.

Mr. Dunn requested a motion to impose costs of $109.85.

Action taken: A motion was made to waive costs, seconded, and carried unanimously.

Penalty imposed:

- Letter of Concern.

Joan C. McTigue, P.A. – Hearing Not Involving Disputed Issues of Material Fact……..14
License Number: PA1763
(PCP: Dr. Vila)

Allegations of the Administrative Complaint: Violations of §458.331(1)(s), F.S. and §456.072(1)(hh), F.S.

Ms. McTigue was not present and not represented by counsel.

Ms. Summers represented the Department.

Ms. Summers requested a motion to accept the exhibits of the case into evidence.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Ms. Summers requested a motion to adopt the allegations of fact in the Administrative Complaint as the findings of fact of the Board.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Ms. Summers requested a motion finding the respondent in violation of Florida Statutes as charged in the Administrative Complaint.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Ms. Summers requested a motion for the imposition of penalty.

After discussion, the following action was taken:

Action taken: A motion was made to impose penalty, seconded, and carried unanimously.

Ms. Summers requested a motion to impose costs of $3,696.63.

Action taken: A motion was made to impose costs, seconded, and carried unanimously.

Penalty imposed:

- Fine $5,000.
- Costs $3,696.63.
- Respondent's license to practice medicine in the State of Florida is hereby SUSPENDED until such time as she demonstrates the ability to practice medicine with reasonable skill and safety.

License Number: ME52118
(PCP: Dr. Wasylik and Mr. Romanello)

Allegations of the Administrative Complaint: Violations of §458.331(1)(t), F.S.

Dr. Ong was not present and represented by William D. Bonezzi, Esq.

Mr. Dunn represented the Department.

Mr. Dunn requested a motion to accept the exhibits of the case into evidence.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Mr. Dunn requested a motion to adopt the allegations of fact in the Administrative Complaint as the findings of fact of the Board.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Mr. Bonezzi was recognized by Dr. Diamond and presented to testimony on behalf of Dr. Ong.

Mr. Dunn requested a motion finding the respondent in violation of Florida Statutes as charged in the Administrative Complaint.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Mr. Dunn requested a motion for the imposition of penalty.

After discussion, the following action was taken:

Action taken: A motion was made to impose penalty, seconded, and carried unanimously.

Mr. Dunn requested a motion to impose costs of $6,242.84

Action taken: A motion was made to impose costs upon reinstatement of license, seconded, and carried unanimously.

Penalty imposed:

- Letter of concern.
- Fine $5,000.
- Costs $6,242.84 to be paid after the license is reinstated.
- CME - Risk Management (5 hours).
- CME - Pathological Interpretation & Diagnosis (3 hours).

License Number: ME147296
(PCP: Dr. Zachariah and Ms. Garcia)

Allegations of the Administrative Complaint: Violations of §458.331(1)(b), F.S. and §456.072(1)(w), F.S.

Dr. Matarasso was not present and not represented by counsel.

Ms. Suarez represented the Department.

Ms. Suarez requested, on behalf of the Department, a motion to accept the exhibits of the case into evidence.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Ms. Suarez requested a motion to adopt the allegations of fact in the Administrative Complaint as the findings of fact of the Board.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Ms. Suarez requested a motion finding the respondent in violation of Florida Statutes as charged in the Administrative Complaint.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Ms. Suarez requested a motion for the imposition of penalty.

Following discussion, the following action was taken:

Action taken: A motion was made to impose penalty, seconded, and carried unanimously.

Ms. Suarez requested a motion to impose costs of $91.54.

Action taken: A motion was made to impose costs, seconded, and carried unanimously.

Penalty imposed:

- Letter of concern.
- Fine $1,000.
- Costs $91.54.
- CME - Laws, Rules, and Ethics (5 hours).

License Number: PA9110400
(PCP: Dr. Zachariah and Ms. Garcia)

Allegations of the Administrative Complaint: Violations of §458.331(1)(b), F.S.

Mr. Hammonds was present and not represented by counsel.

Ms. Suarez represented the Department.

Ms. Suarez requested a motion to accept the exhibits of the case into evidence.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Ms. Suarez requested a motion to adopt the allegations of fact in the Administrative Complaint as the findings of fact of the Board.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Mr. Hammonds presented his case before the Board.

Ms. Suarez requested a motion finding the respondent in violation of Florida Statutes as charged in the Administrative Complaint.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Ms. Suarez requested a motion for the imposition of penalty.

After discussion, the following action was taken:

Action taken: A motion was made to impose penalty, seconded, and carried unanimously.

Ms. Suarez requested a motion to impose costs of $307.24.

Action taken: A motion was made to impose costs, seconded, and carried unanimously.

Penalty imposed:

- Letter of reprimand
- Fine $1,000
- Costs $307.24
- CME – Laws, Rules, and Ethics (5 hours).

License Number: ME64467
(PCP: No current members)

Allegations of the Administrative Complaint: Violations of §456.072(1)(ll), F.S.

Dr. Cabrera was present and represented by Allen R. Grossman, Esq.

Mr. Dunn represented the Department.

Mr. Dunn requested a motion to accept the exhibits of the case into evidence.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Mr. Dunn requested a motion to adopt the allegations of fact in the Administrative Complaint as the findings of fact of the Board.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Mr. Grossman was recognized by Dr. Diamond and presented testimony on behalf of Dr. Cabrera.

Mr. Dunn requested a motion finding the respondent in violation of Florida Statutes as charged in the Administrative Complaint.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Mr. Dunn requested a motion for the imposition of penalty.

After discussion, the following action was taken:

Action taken: A motion was made to impose penalty, seconded, and carried unanimously.

Mr. Dunn requested a motion to impose costs of $61.03.

Action taken: A motion was made to waive cost, seconded, and carried unanimously.

Penalty imposed:

- Revocation of license.

License Number: ME78844
(PCP: Mr. Romanello)

Allegations of the Administrative Complaint: Violations of §458.331(1)(c), F.S.

Dr. Morariu was present and not represented by counsel.

Mr. Pattison represented the Department.

Mr. Pattison requested a motion to accept the exhibits of the case into evidence.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Mr. Pattison requested a motion to adopt the allegations of fact in the Administrative Complaint as the findings of fact of the Board.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Dr. Morariu provided his testimony about his case.

Mr. Pattison requested a motion finding the respondent in violation of Florida Statutes as charged in the Administrative Complaint.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Mr. Pattison requested a motion for the imposition of penalty.

After discussion, the following action was taken:

Action taken: A motion was made to impose penalty, seconded, and carried unanimously.

Mr. Pattison requested a motion to impose costs of $4,052.90.

Action taken: A motion was made to waive cost, seconded, and carried unanimously.

Penalty imposed:

- Revocation of license.

License Number: ME36950
(PCP: Dr. Zachariah and Ms. Garcia)

Allegations of the Administrative Complaint: Violations of §458.331(1)(b), F.S. and §458.331(1)(kk), F.S.

Dr. Wolff was not present and not represented by counsel.

Ms. Suarez represented the Department.

Ms. Suarez requested a motion to accept the exhibits of the case into evidence.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Ms. Suarez requested a motion to adopt the allegations of fact in the Administrative Complaint as the findings of fact of the Board.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Ms. Suarez requested a motion finding the respondent in violation of Florida Statutes as charged in the Administrative Complaint.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Ms. Suarez requested a motion for the imposition of penalty.

After discussion, the following action was taken:

Action taken: A motion was made to impose penalty, seconded, and carried unanimously.

Ms. Suarez requested a motion to impose costs of $61.03.

Action taken: A motion was made to impose cost, seconded, and carried unanimously.

Penalty imposed:

- Letter of concern.
- Fine $2,000.
- Costs $61.03.
- CME – Laws, Rules, and Ethics (5 hours).

License Number: ME72540
(PCP: Dr. Pimentel and Ms. Garcia)

Allegations of the Administrative Complaint: Violations of §458.331(1)(b), F.S. and §456.072(1)(w), F.S.

Dr. Yeh was not present and not represented by counsel.

Ms. Summers represented the Department.

Ms. Summers requested a motion to accept the exhibits of the case into evidence.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Ms. Summers requested a motion to adopt the allegations of fact in the Administrative Complaint as the findings of fact of the Board.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Ms. Summers requested a motion finding the respondent in violation of Florida Statutes as charged in the Administrative Complaint.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Ms. Summers requested a motion for the imposition of penalty.

After discussion, the following action was taken:

Action taken: A motion was made to impose penalty, seconded, and carried unanimously.

Ms. Summers requested a motion to impose costs of $73.24.

Action taken: A motion was made to impose cost, seconded, and carried unanimously.

Penalty imposed:

- Letter of concern
- Fine $2,000
- Costs $73.24
- CME – Laws, Rules, and Ethics (5 hours)
- Respondent's license to practice medicine in the State of Florida is hereby SUSPENDED until such time as he demonstrates to the Board that his license is unencumbered and free from any restrictions or conditions in any and all jurisdictions where he is licensed.

Jorge I. Gaviria, M.D. – Hearing Not Involving Disputed Issues of Material Fact.....23
License Number: ME94318
(PCP: Dr. Ackerman and Mr. Romanello)

CONTINUED TO THE OCTOBER MEETING

Ted D. Friehling, M.D. – Hearing Not Involving Disputed Issues of Material Fact.....24
License Number: ME150732
(PCP: Dr. Pages)

Allegations of the Administrative Complaint: Violations of §458.331(1)(b), F.S. and §456.072(1)(w), F.S.

Dr. Friehling was not present and not represented by counsel.

Mr. Pietrylo represented the Department.

Mr. Pietrylo requested a motion to accept the exhibits of the case into evidence.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Mr. Pietrylo requested a motion to adopt the allegations of fact in the Administrative Complaint as the findings of fact of the Board.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Mr. Pietrylo requested a motion finding the respondent in violation of Florida Statutes as charged in the Administrative Complaint.

Action taken: A motion was made in the affirmative, seconded, and carried unanimously.

Mr. Pietrylo requested a motion for the imposition of penalty.

After discussion, the following action was taken:

Action taken: A motion was made to impose penalty, seconded, and carried unanimously.

Mr. Pietrylo requested a motion to impose costs of $21.80.

Action taken: A motion was made to impose cost, seconded, and carried unanimously.

Penalty imposed:

- Costs $21.80.
- CME – Laws, Rules, and Ethics (5 hours).
- Respondent's license to practice medicine in the State of Florida is hereby SUSPENDED until such time as he demonstrates to the Board that his license is unencumbered and free from any restrictions or conditions in any and all jurisdictions where he is licensed.

License Number: ME110682
(PCP: Dr. Pimentel)

Action taken: A motion was made to accept the voluntary relinquishment, seconded, and carried unanimously.

License Number: ME27163

Mr. Pietrylo represented the Department and provided an overview of the reasoning to vacate the final order.

Action taken: A motion was made to vacate the final order, seconded, and carried unanimously.

License Number: ME58146
(PCP: Dr. Vila)

Dr. Gallo was not present and represented by William Carcioppolo, Esq.

Mr. Pietrylo represented the Department.

After discussion, the following action was taken:

Action taken: A motion was made to deny the petition to amend the final order, seconded, and carried unanimously.

III. REPORTS & REMARKS (Part I)

Mr. Dunn presented an update to the Department's staffing.

Mr. Pietrylo presented the Appellate Report and Year-Old Case Report to the Board members.

Action taken: A motion was made to continue the prosecution of one year old or older cases, seconded, and carried unanimously.

- Daniel R. Bergholz – University of Miami Miller School of Medicine
- Allison Chin – Florida International University Herbert Wertheim College of Medicine
- Zaimary Meneses – Charles E. Schmidt College of Medicine at Florida Atlantic University
- Amr El-Talla – Nova Southeastern University College of Allopathic Medicine

IV. EXEMPTIONS

Mr. Davis' counsel provided statements on behalf of Mr. Davis for the AHCA exemptions.

Action taken: A motion was made to accept the AHCA exemption, seconded, and carried unanimously.

Dr. Vega provided statements for the AHCA exemptions.

Action taken: A motion was made to accept the AHCA exemption, seconded, and carried unanimously.

V. PETITION FOR DECLARATORY STATEMENT

Mr. Beregovich provided statements for clarification for a declaratory statement on the referenced rule.

Action taken: A motion was made to deny the declaratory statement on grounds of lack of standing, seconded, and carried unanimously.

VI. DISCUSSION

Mr. Vazquez provided statements on the conduct of the discussion and reminded everyone that this is a publicly noticed meeting and is being recorded.

Dr. Diamond provided opening statements on the purpose of the discussion.

Dr. Ladapo begin the discussion by thanking the Board for the work that has been done and that continues to be done. Dr. Ladapo provided the Board and public with statements regarding gender dysphoria.

Mr. Wilson was recognized to present the petition to initiate rulemaking setting the standard of care for the treatment of gender dysphoria. Mr. Wilson wanted to remind all in attendance that this is the start of the rulemaking process, and nothing will be set in rules based on this vote.

Dr. Diamond recognized Dr. Michael Haller, M.D., Pediatric Endocrinologist, to provided statements and present his research on gender dysphoria.

Dr. Diamond recognized Dr. Quentin Van Meter, M.D., Pediatric Endocrinologist, to provided statement and present his research on gender dysphoria.

After a robust discussion between the Board and the invited physicians, Dr. Diamond invited the public to make statements. Individuals were called randomly from the speaker cards completed prior to the discussion. There were multiple individuals who spoke for and against the petition.

After public comments, the following action was taken:

Action taken: A motion was made to accept the petition, seconded, and carried with one vote in opposition.

VII. REMARKS & REPORTS (Part II)

No comments.

No comments.

No comments.

Dr. Chandra provided the report from the July 28, 2022, Council of Physician Assistants meeting.

Action taken: A motion was made to approve the minutes, seconded, and carried unanimously.

Dr. Ackerman provided the report from the August 4, 2022, Credentials Committee meeting.

Action taken: A motion was made to approve the minutes, seconded, and carried unanimously.

Boards of Medicine and Osteopathic Medicine's Joint Committee on Surgical Care/Quality Assurance Committee Report.....37

Dr. Cairns provided the report from the August 4, 2022, Joint Committee on Surgical Care/Quality Assurance meeting.

Action taken: A motion was made to approve the minutes, seconded, and carried unanimously.

Rules/Legislative Committee Report.....No tab

Dr. Zachariah was not present at the time of the report discussion.

Action taken: A motion was made to table the report, seconded, and carried unanimously.

Probation Committee Report.....No tab

Dr. Pages provided the report from the July 28, 2022, Probation Committee meeting.

Action taken: A motion was made to approve the minutes, seconded, and carried unanimously.

Finance & Process Accountability Meeting Report.....No tab

Ms. Justice provided the report from the July 28, 2022, Finance & Process Accountability meeting.

Action taken: A motion was made to approve the minutes, seconded, and carried unanimously.

Approval of Meeting Minutes.....27

Action taken: A motion was made to approve the minutes, seconded, and carried unanimously.

Ratification of Applicants Pursuant to Chapter 458, F.S.....38

Action taken: A motion was made to approve the ratification list of applicants, seconded, and carried unanimously.

VIII. OTHER BUSINESS

IX. NEW BUSINESS

Adjournment at 4:02 P.M. EST.

Notice of Meeting/Workshop Hearing

DEPARTMENT OF HEALTH
Board of Osteopathic Medicine

The Department of Health, Board of Osteopathic Medicine announces a public meeting to which all persons are invited.
DATE AND TIME: August 12, 2022, at 9:00 a.m., EST
PLACE: Marriott Ft. Lauderdale Airport, 166 N. Compass Way, Dania Beach, Florida 33004 (954)802-7543.
GENERAL SUBJECT MATTER TO BE CONSIDERED: General business of the board.
A copy of the agenda may be obtained by contacting: Board website at www.floridasosteopathicmedicine.gov/meeting-information.
Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 7 days before the workshop/meeting by contacting: Christa Peace, Regulatory Specialist III, at (850) 245-4161 or MQA.Osteopath@flhealth.gov or 4052 Bald Cypress Way, #C-06, Tallahassee, FL 32399.
If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).
If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.
For more information, you may contact: Christa Peace, Regulatory Specialist III, at (850) 245-4161 or MQA.Osteopath@flhealth.gov or 4052 Bald Cypress Way, #C-06, Tallahassee, FL 32399.

FLORIDA | Board *of* Osteopathic Medicine

UPDATED AGENDA
August 12, 2022
9:00 a.m., EST

Marriott Fort Lauderdale Airport
166 North Compass Way
Dania Beach, FL 33004
(954)-802-7543

Friday, August 12, 2022

TURN OFF OR PLACE YOUR CELL PHONE ON VIBRATE DURING THE MEETING.

Participants in this public meeting should be aware that these proceedings are being recorded and that an audio file of the meeting will be posted to the Board's website.

CALL TO ORDER (9 a.m.) Sandra Schwemmer, DO, *Chair*

ROLL CALL Danielle Terrell, *Executive Director*

PLEDGE OF ALLEGIANCE

PLEDGE OF OSTEOPATHIC COMMITMENT

I pledge to: Provide compassionate, quality care to my patients; Partner with them to promote health; Display integrity and professionalism throughout my career; Advance the philosophy, practice, and science of osteopathic medicine; Continue life-long learning; Support my profession with loyalty in action, word, and deed; and live each day as an example of what an osteopathic physician should be.

AGENDA

INTRODUCTION AND VOTE ON NEW EXECUTIVE DIRECTOR

DISCIPLINARY ACTIONS

Settlement Agreement
TAB 1: James S. McAdoo, D.O. **(Case 2016-14652)**
PCP: Andriole & Jackson

Informal Hearing
TAB 2: Shannon P. Calhoun, D.O. **(Case 2021-31377)**
PCP: Rose & Kirsh

Voluntary Relinquishment
TAB 3: Virgil W. McMillion, D.O. **(Case 2022-08797)**
PCP: None

TAB 4: PROSECUTION SERVICES REPORT - *Sarah Corrigan, Esq.*

TAB 5: REVIEW AND APPROVAL OF MINUTES - May 20, 2022, *General Business Meeting*

PROBATION AND COMPLIANCE

Petition to Modify Final Order
TAB 6: David Glickman, D.O. (Case 2010-08124)

Petition for Formal Approval of Monitor
TAB 7: Jennifer Louise Graybill, D.O. (Case 2019-47341)

APPLICATIONS

Applications for Osteopathic Physician Licensure
TAB 8: Christopher Scott Blaisdell, D.O. (File 17081)
TAB 9: Lanna Cheuck, D.O. (File 18063)
TAB 10: Bradley Kurgis, D.O. (File 18517)
TAB 11: Bobby Nourani, D.O. (File 18940)
TAB 12: Thomas Ryan, D.O. (File 19031)

Applications for Osteopathic Physician in Training Registration
TAB 13: Carson Creamer, D.O. (File 9088)

RATIFICATION OF LICENSURE

TAB 14: Osteopathic Physician Licenses (4/18/2022 - 7/28/2022)
TAB 15: Osteopathic Physician in Training Initial Registrations (4/18/2022 - 7/28/2022)

GENERAL DISCUSSION

TAB 16: Osteopathic Physician Expert Witness Certificates (4/18/2022 - 7/28/2022)
TAB 17: PDMP Monthly Report (June 2022)

BOARD COUNSEL REPORT - *Donna McNulty, Esq.*

TAB 18: RULES REPORTS
Rules Report - August 2022
Rules Report - July 2022
Rules Report - June 2022
Rules Report - May 2022

RULES DISCUSSION

TAB 19: Rule 64B15-18.001, Florida Administrative Code
Prescriptions of Certain Medicinal Drugs by Pharmacists; Purpose and Effect

TAB 20: Rules 64B15.14.0076 and 64B15-14.0077, Florida Administrative Code
Requirement for Osteopathic Physician Office Surgery Registration; Inspection or Accreditation

Approval of Osteopathic Physician Office Accrediting Organizations

TAB 21: Rules 64B15-15.002 and 64B15-15.004, Florida Administrative Code
Handling of Patient Records Upon Termination of Practice

Written Records; Minimum Content; Retention

TAB 22: Rule 64B15-7.012, Florida Administrative Code
Fees Regarding Anesthesiologist Assistants
(Board of Medicine Rule 64B8-31.012, Florida Administrative Code included for reference)

TAB 23: Rule 64B15-6.013 &
Physician Assistant Fees
(Board of Medicine Rule 64B8-30.019, Florida Administrative Code included for reference)

TAB 24: Annual Regulatory Plan

TAB 25: HB 1209 Implementation

TAB 26: Discussion on Letter from State Surgeon General Joseph A. Ladapo, MD, PhD, Related to Gender Dysphoria in Children and Adolescents

TAB 26a: Petition to Initiate Rulemaking Setting the Standard of Care for Treatment of Gender Dysphoria

TAB 27: EXECUTIVE DIRECTOR REPORT – Danielle Terrell, *Executive Director*

TAB 28: BOARD CHAIR REPORT – Sandra Schwemmer, D.O.

JOINT COMMITTEE MEETING UPDATES
TAB 29: Council on Physician Assistants Committee
TAB 30: Boards of Medicine and Osteopathic Medicine Joint Surgical Care/ Quality Assurance Committee

TAB 31: LIAISON REPORTS
Budget Liaison Report - William Kirsh, DO
Total Expenditures (Direct and Allocated) by Board for 9 Months Ending March 31, 2022

Expenditures by Function for Period Ending March 31, 2022

Allocations to Boards by Source Organization and Category for 9 Months Ending March 31, 2022

Cash Balance Report for 9 Months Ending March 31, 2022

Legislative Liaison Report - Michelle Mendez, DO
Unlicensed Activity Liaison Report - Sandra Schwemmer, DO

TAB 32: OLD BUSINESS
TAB 33: NEW BUSINESS

ADDENDA
TAB 26b: Additional Materials - Discussion on Letter from State Surgeon General Joseph A. Ladapo, MD, PhD, Related to Gender Dysphoria in Children and Adolescents

INFORMATIONAL MATERIALS
Danielle Terrell, Resume

ADJOURN

Next Meeting: November 4, 2022 (Location TBA)

FLORIDA | Board *of* Osteopathic Medicine

August 12, 2022

DRAFT MEETING MINUTES
Board of Osteopathic Medicine
Marriott Fort Lauderdale Airport
166 North Compass Way
Dania Beach, Fl 33004
April 12, 2022
9 a.m.

The meeting was called to order by Dr. Sandra Schwemmer, Chair, at approximately 9:00 a.m.

INTRODUCTION AND VOTE ON NEW EXECUTIVE DIRECTOR

Dr. Schwemmer took a moment to recognize Danielle Terrell, Executive Director for the Board of Osteopathic Medicine and allowed her to provide the board with her background.

Action Taken: Motion by Ms. Jackson, seconded by Dr. Gadea, to approve Danielle Terrell to serve as Executive Director for the board.

Roll Call was conducted by Danielle Terrell, Executive Director.
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 DiPietro, DO
Jorge Gadea, DO
Valerie Jackson, Consumer Member

BOARD STAFF PRESENT:
Danielle Terrell, Executive Director
Carol Taylor, Program Administrator
Derek Nieves, RSIII
Bettye Strickland, Program Administrator, BOM

MEMBERS ABSENT
William Kirsh, DO

BOARD COUNSEL
David Flynn, Board Counsel

PROSECUTION SERVICES ATTORNEYS:
Sarah Corrigan, Assistant General Counsel
Andrew Pietrylo, Assistant General Counsel

COURT REPORTER:
Magnolia Court Reporting
(407) 896-1813

OTHERS PRESENT:
Matt Knispel, Chief of the Bureau of Investigation for the Department of Health, and several investigators from field offices.

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.

Following roll call, Dr. Schwemmer recognized Jennifer Wenhold, Division Director for the Division of Medical Quality Assurance and John Wilson, General Counsel for the Department of Health. Additionally, she recognized State Surgeon General, Dr. Ladapo.

TAB 26: Discussion on Letter from State Surgeon General Joseph A. Ladapo, MD, PhD, Related to Gender Dysphoria in Children and Adolescents

ADDENDA
TAB 26b: Additional Materials - Discussion on Letter from State Surgeon General Joseph A. Ladapo, MD, PhD, Related to Gender Dysphoria in Children and Adolescents

TAB 26a: Petition to Initiate Rulemaking Setting the Standard of Care for Treatment of Gender Dysphoria

Dr. Schwemmer provided opening statements on the purpose of the discussion. Dr. Ladapo began the discussion by thanking the Board for the work that has been done and that continues to be done. Dr. Ladapo provided the Board and public with statements regarding gender dysphoria noting that this is an issue that has fallen and remains outside of norms of medical care.

Mr. Wilson was recognized to present the petition to initiate rulemaking setting the standard of care for the treatment of gender dysphoria. Mr. Wilson wanted to remind all in attendance that this is the start of the rulemaking process, and nothing will be set in rules based on this vote.

The board was reminded that the responsibility to set standards of care is theirs'. A Request was made for the board to grant the petition.

Instructions were provided regarding public comment.
Dr. Schwemmer invited the public to make statements.

Only one person spoke, Dr. Tom Benton who supports the motion.

After discussion:
Motion: to open rulemaking process on setting the standards for gender dysphoria.
Ms. Jackson opposed.
Motion carried.

DISCIPLINARY CASES:
SETTLEMENT AGREEMENT
TAB 1: James S. McAdoo, D.O., Case 2016-14652
PCP: Andriole & Jackson

Ms. Jackson was recused due to participation on the Probable Cause Panel.

Respondent was present. Respondent was represented by, Ryan Sanders, Esq.

Sarah Corrigan represented the Department and presented the case to the Board. Allegations of Administrative Complaint, violation of Section 459.015(1)(x), Florida Statutes, 2015; by committing medical malpractice as defined in section 456.50; and Section 459.015(1)(o), Florida Statutes, 2015, as defined by Rule 64B15-15.004(1), Florida Administrative Code, by failing to keep legible medical records and violation

of Section 459.015(pp), Florida Statutes, 2015, for violation of rule 64B15-14.001, Florida Administrative Code, which articulates the standard of care for office surgery.

Terms of Settlement Agreement: Reprimand, ten thousand ($10,000.00) fine to be paid within 270 days of the Final Order being filed, costs not to exceed ten thousand four hundred six dollars and seventy-eight cents ($10,406.78) to be paid within 270 days of the Final Order being filed, document completion of five hours of CME in risk management within one year from the date the Final Order is filed, document completion of a board approved medical records course within one year of the date the Final Order is filed, document completion of five hours CME in laws, rules and ethics within one year of the date the Final Order is filed, document completion of three hours CME in plastic surgery procedures involving fat transfer within one year of the date the Final Order is filed, and Respondent's practice is restricted in that Respondent may not perform any fat transfer procedures including, but not limited to: Brazilian Butt Lift (BBL) procedures unless under the immediate supervision of a board-certified physician fully licensed under Chapter 459 or 458 who has been approved by the board. Said restriction shall last until such time as the Respondent undergoes an evaluation by Florida CARES, Center for Personalized Education for Professionals (CPEP), the UC San Diego PACE program or another equivalent program preapproved by the board and Respondent shall personally appear before the board with said evaluation and evaluator's recommendations.

Ms. Corrigan noted a verbal amendment to the proposed settlement agreement which included; correction of typographical error in Paragraph 2 regarding the number of days to pay the fine which should be two hundred and seventy days; Paragraph 5, addresses the medical records course and it should be clear that it is a FMA medical records course or a board approved equivalent; and finally it should be clear that the terms and conditions are to be reasonably set at the time the evaluation is presented and not at the time of reinstatement.

Both Respondent's attorney and Respondent spoke before the board.

Motion: by Dr. Mendez to reject the settlement agreement as currently written, unless Department and Respondent agreed to change board certified physician to board certified plastic surgeon for the supervision. Both parties agreed to the change.

Discussion continued.

Motion: by Dr. Mendez, seconded by Dr. Gadea, to reject the settlement agreement as currently presented.

Motion: by Dr. Mendez, seconded by Dr. Gadea, to propose a counteroffer, which includes all terms and conditions of the current proposed settlement agreement, including verbal amendments identified by Ms. Corrigan, and with the following modifications:
Under stipulated disposition
#2 Increase fine to 25,000. to be paid within 90 days.
#3 Costs are to be paid within 90 days, instead of 270 days.
#4 The five (5) hours CME of risk management is to include a focus on risk management within the realm of out-patient based surgery.
#5 Change language regarding the medical records course to state, "FMA sponsored medical records course or a board equivalent."
#6 The laws, rules and ethics CME requirement is to be changed to two (2) hours from five (5), is required to be taken live in-person, and shall specify it is a Florida laws, rules, and ethics course.
#8 Regarding the Practice Restriction language, change board certified physician to board certified plastic surgeon as previously agreed.
#8 Remove statement that compensation to the monitor will be paid by the Respondent.
#8b Regarding responsibilities of the supervising physician, add an extra responsibility and make it number

one (change numbering)
New number one statement: Prior to procedure Supervisor shall review the pre-operative patient evaluation and consent
#8 Last paragraph, clarification that the terms and conditions will be set as reasonably related to the violation and at the outcome of the evaluation and not at reinstatement.

Motion carried unanimously. Respondent will have seven (7) days following the filing of the Final Order to accept or reject the counteroffer.

VOLUNTARY RELINQUISHMENT
TAB 3: Virgil W. McMillion, D.O., Case 2022-08797
PCP: None

Respondent was not present. Respondent was not represented by counsel.

Motion by Dr. Mendez, seconded by Dr. Gadea, to accept the Voluntary Relinquishment. Motion carried.

INFORMAL HEARING
TAB 2: Shannon P. Calhoun, D.O., Case 2021-31377
PCP: Rose & Kirsh

The Respondent was not present and was not represented by counsel.

Sarah Corrigan represented the Department and presented the case to the Board. Allegations of Administrative Complaint, violation of Section 459.015(1)(b), Florida Statutes, 2021; by having his Colorado osteopathic license acted against.

The Respondent was served an Administrative Complaint. Respondent subsequently filed an election of rights requesting an informal hearing. In accordance with the election of rights and pursuant to Section 120.57(2)(a)(2), Florida Statutes (2020), the Department referred the matter to the Board for an entry of a final order setting forth appropriate action on Respondent's license.

The department offered the investigative file, a copy of which was previously furnished to the Board, into evidence to establish a prima facia case for the violation alleged in the administrative complaint and asked that it be admitted into evidence.

Motion: by Dr. Schwemmer, seconded by Ms. Jackson, to accept the investigative file into evidence. Motion carried.

Motion: by Dr. Schwemmer, to adopt the allegations of fact in the Administrative Complaint as the findings of fact of the board, seconded by Dr. DiPietro. Motion passed unanimously.

Motion: by Dr. Schwemmer, that the Respondent violated Florida Statutes as charged in the Administrative Complaint, seconded by Dr. DiPietro. Motion passed unanimously.

The Department provided a proposed penalty recommendation to the Board consisting of: a letter of concern; an administrative fine in the amount of one thousand five hundred ($1500.00) dollars to be paid within thirty (30) days from the date of the Final Order; and Suspension until such time that the Respondent appears before the board and shows he is safe to practice with reasonable skill and safety by means of a PRN evaluation with the board reserving jurisdiction to impose additional terms if necessary following the PRN evaluation.

Motion: by Dr. Schwemmer, seconded by Dr. DiPietro, to impose the Department's recommended penalty.

After discussion, the motion was amended to impose the Department's recommended penalty with the exception of lowering the fine to one thousand ($1000.00) dollars. Motion carried with Dr. Gadea opposing.

Motion: by Dr. Schwemmer, seconded by Dr. DiPietro to approve Petitioner's Motion for Costs and to impose costs in the amount of eighty-nine dollars and fifty-five cents ($89.55). Motion carried.

TAB 4: PROSECUTION SERVICES REPORT- Sarah Corrigan, Esq.

Sarah Corrigan presented the prosecution services report (PSU). Ms. Corrigan requested the board consider allowing PSU to continue to prosecute cases that are a year and older. The report reflects a reduction of 25 cases, three of which are over a year old. PSU is moving forward with their goal of reducing the cases over one year.

Motion: by Dr. Mendez, seconded by Dr. Gadea, to allow PSU to continue prosecuting cases one year and older. Motion passed.

REVIEW AND APPROVAL OF MINUTES

TAB 5: May 20, 2022, Board of Osteopathic Medicine Meeting Minutes

Motion: by Dr. Gadea, seconded by Ms. Jackson, to accept the May 20, 2022, meeting minutes.
Motion carried.

PROBATION AND COMPLIANCE

Petition to Modify Final Order

TAB 6: David Glickman, D.O., Case 2010-08124

Licensee was present. Licensee was not represented by counsel.

Respondent made a statement.

Motion: by Dr. Gadea, seconded by Ms. Jackson, to deny the petition to lift the permanent practice restrictions. Motion carried.

Petition for Formal Approval of Monitor

TAB 7: Jennifer Louise Graybill, Case No. 2019-47341

This matter was continued to the November 4, 2022, board meeting.

APPLICANTS

APPLICANTS FOR FULL LICENSURE

TAB 8: Christopher Scott Blaisdell, D.O., File 17081

Applicant was present. Applicant was not represented by counsel.
Dr. Polles provided a statement on Dr. Blaisdell's behalf.

After discussion,
Motion: by Dr. Gadea, to deny the application, seconded by Dr. DiPietro.
Dr. Blaisdell requested to withdraw his application.
Dr. Gadea and Dr. DiPietro withdrew their motions.
Motion: by Dr. DiPietro, seconded by Dr. Gadea, to allow Dr. Blaisdell to withdraw his application.
Motion carried.

TAB 9: Lanna Cheuck, D.O., File 18063

This item was continued to the November 4, 2022, board meeting. No action taken.

TAB 10: Bradley Kurgis, D.O., File 18517
Applicant was present. Applicant was not represented by counsel.

After discussion,
Motion: by Dr. DiPietro to approve the application, seconded by Dr. Gadea. Motion carried.

TAB 11: (CONTINUED) Bobby Nourani, D.O., File 18940
This matter was continued to the November 4, 2022, board meeting. No action taken.

TAB 12: Thomas Ryan, D.O., File 19031
Applicant was present. Applicant was not represented by counsel.

After discussion,
Motion: by Dr. DiPietro to approve the application, seconded by Dr. Gadea. Motion carried.

APPLICANTS FOR OSTEOPATHIC PHYSICIAN IN TRAINING REGISTRATIONS

TAB 13: Carson Creamer, D.O., File 9088
Applicant was present. Applicant was not represented by counsel.
Dr. Polles from PRN spoke on the applicant's behalf. The final report has not been submitted at this time.

After discussion,
Motion: by Dr. DiPietro, to approve the application, seconded by Dr. Mendez. Motion carried. Dr. Schwemmer opposed.

RATIFICATION OF LICENSURE

TAB 14: Osteopathic Physician Licenses - 4/18/2022 - 7/28/2022
Motion: by Dr. Schwemmer, seconded by Dr. DiPietro, to ratify the full licenses issued 4/18/2022 - 7/28/2022; license numbers 18766-19123 inclusive totaling 358 licenses.

TAB 15: Osteopathic Physician in Training Initial Registrations - 4/18/2022 - 7/28/2022
Motion: by Dr. Schwemmer, to ratify the resident registrations issued 4/18/2022 - 7/28/2022; numbers 8136 through 8805 inclusive totaling 670 registrations. Motion carried.

GENERAL DISCUSSION

TAB 16: Osteopathic Physician Expert Witness Certificates, 4/18/2022 - 7/28/2022
This information was provided for informational purposes only.

TAB 17: PDMP Monthly Report (June 2022)
This information was provided for informational purposes only.

BOARD COUNSEL REPORT – David Flynn, Esq.

TAB 18: RULES REPORTS

Rules Report - August 2022
Rules Report - July 2022
Rules Report - June 2022
Rules Report - May 2022

Board counsel informed the board that the information was included in the board materials for informational purposes only. No action taken.

RULES DISCUSSION

TAB 19: Rule 64B15-18.001, Florida Administrative Code

Prescriptions of Certain Medicinal Drugs by Pharmacists; Purpose and Effect

Board counsel noted that the purpose and effect in the rule does not meet the requirements of a rule per JAPC. The rule is on the agenda to consider repeal.

Following discussion,
Motion: by Dr. Schwemmer, seconded by Dr. DiPietro, to repeal Rule 64B15-18.001, Florida Administrative Code. Motion carried.

Motion: by Dr. Schwemmer, seconded by Dr. Mendez, that the proposed changes will not make an adverse impact on small business and proposed changes would not directly or indirectly increase regulatory costs to any entity including the government in excess of $200,000.00 in aggregate in Florida within one year after the implementation of the rule. No SERC is needed. Motion carried.

TAB 20: Rules 64B15.14.0076 and 64B15-14.0077, Florida Administrative Code

Rule 64B15-14.0076, Florida Administrative Code- *Requirement for Osteopathic Physician Office Surgery Registration; Inspection or Accreditation*

Rule 64B15-14.0077, Florida Administrative Code- *Approval of Osteopathic Physician Office Accrediting Organizations*

The board was reminded that they voted to include sunset language on both rules at the May board meeting. Subsequently JAPC provided a letter taking issue with the language used. Both items are on the agenda for consideration of revising the sunset language to the proposed language.

Following discussion,
Motion: by Ms. Jackson, seconded by Dr. Gadea, to approve the proposed sunset language for Rules 64B15-14.0076 and 64B15-14.0077, Florida Administrative Code, as presented by board counsel. Motion carried.

Motion: by Dr. Mendez, seconded by Dr. Schwemmer, that the proposed changes will not make an adverse impact on small business and proposed changes would not directly or indirectly increase regulatory costs to any entity including the government in excess of $200,000.00 in aggregate in Florida within one year after the implementation of Rules 64B15-14.0076 and 64B15-14.0077, Florida Administrative Code. Motion carried.

Motion: by Dr. Mendez, seconded by Dr. Schwemmer, to find that a violation of Rule 64B15-14.0076, Florida Administrative Code, or Rule 64B15-14.0077, Florida Administrative Code, or any part of Rule 64B15-14.0076, Florida Administrative Code, or Rule 64B15-14.0077, Florida Administrative Code, would not be considered a minor violation. Motion carried.

TAB 21: Rules 64B15-15.002 and 64B15-15.004, Florida Administrative Code

Rule 64B15-15.002, Florida Administrative Code - *Handling of Patient Records Upon Termination of Practice*

Rule 64B15-15.004, Florida Administrative Code - *Written Records; Minimum Content; Retention*

Board counsel informed the board that the two rules were on the agenda as a result of a letter received from JAPC. The purpose of reviewing the rules is to eliminate ambiguity of which rule is controlling regarding osteopathic retention of records.
Following discussion,

Motion: by Dr. Schwemmer, seconded by Dr. Mendez, to approve the draft rule language for Rule 64B15-15.004, Florida Administrative Code, as presented by board counsel,. Motion carried.

Motion: by Dr. Schwemmer, seconded by Dr. Mendez, that the proposed changes will not make an adverse impact on small business and proposed changes would not directly or indirectly increase regulatory costs to any entity including the government in excess of $200,000.00 in aggregate in Florida within one year after the implementation of the rule. No SERC is needed. Motion carried.

Motion: by Dr. Mendez, seconded by Dr. DiPietro, to find that a violation of Rule 64B15-15.004, Florida Administrative Code, or any part of Rule 64B15-15.004, Florida Administrative Code, would not be considered a minor violation. Motion carried.

Motion: by Dr. Schwemmer, seconded by Dr. Mendez, to not add a sunset provision to this rule as the rule is required by statute to protect the health, safety, and welfare of the citizens of Florida and it eliminates ambiguity. Motion carried.

TAB 22: Rule 64B15-7.012, Florida Administrative Code
Fees Regarding Anesthesiologist Assistants
(Board of Medicine Rule 64B8-31.012, Florida Administrative Code included for reference)
This item extends fee reductions previously approved through February 1, 2027.

Following discussion,
Motion: by Dr. Schwemmer, seconded by Dr. Gadea, to approve the draft rule language as presented by board counsel. Motion carried.

Motion: by Dr. DiPietro, seconded by Dr. Gadea, that the proposed changes will not make an adverse impact on small business and proposed changes would not directly or indirectly increase regulatory costs to any entity including the government in excess of $200,000.00 in aggregate in Florida within one year after the implementation of the rule. Motion carried.

Motion: by Dr. Mendez, seconded by Dr. DiPietro, to find that a violation of this rule or any part of this rule would not be considered a minor violation. Motion carried.

Motion: by Dr. Gadea, seconded by Dr. DiPietro, to not add a sunset provision to this rule as the rule is required by statute to protect the health, safety, and welfare of the citizens of Florida and it is required by law to set fees. Motion carried.

TAB 23: Rule 64B15-6.013, Florida Administrative Code
Physician Assistant Fees
(Board of Medicine Rule 64B8-30.019, Florida Administrative Code included for reference)
Motion: by Dr. Schwemmer, seconded by Dr. Mendez, to table this item until the next scheduled meeting. Motion carried.

TAB 24: Annual Regulatory Plan
The board was reminded that the Annual Regulatory Plan (ARP) is required to be filed by October 1st every year. Board counsel requested delegation authority be granted to complete this task.

Motion: by Dr. Gadea, seconded by Dr. Mendez, to delegate authority to the board chair and board counsel to finalize the Annual Regulatory Plan and bring back to the board for ratification. Motion carried.

There was brief conversation about the long range planning survey.

TAB 25: HB 1209 Implementation

Motion: by Dr. DiPietro, seconded by Dr. Gadea, to support House Bill 1209 implementation by the Board of Pharmacy. Motion carried.

TAB 27: EXECUTIVE DIRECTOR REPORT – Danielle Terrell, Executive Director

Ms. Terrell updated the board regarding recent staff changes in the board office.

TAB 28: BOARD CHAIR REPORT – Sandra Schwemmer, D.O.

Board chair, Sandra Schwemmer informed the board that she continues to review non-routine applications, monitoring reports and quarterly reports. She also informed board members to provide any questions they have or need addressed to board staff for her response.

JOINT COMMITTEE MEETING UPDATES

TAB 29: Council on Physician Assistants

Dr. Mendez noted three applicants appeared before the committee and were approved. She further provided background on requirements for physician assistants certification and a recent change regarding same. The report ended with restatement that the council is adamant about the fee issue.

TAB 30: Boards of Medicine and Osteopathic Medicine Joint Surgical Care/Quality Assurance Committee

Dr. DiPietro reminded the board of the June approval of the ninety-day emergency rule. She stated that after hearing the public comment during the recent rule workshop the committee agreed to make the following changes to the rule: change the number of procedures that can be performed in a day from 3 to 5, the use of ultrasound, and that the procedure in its entirety must be performed by the consenting physician. The rule is currently open for rulemaking. Board members were also informed that the emergency rule was upheld during appeal. The liaisons agreed it was a good collaboration.

TAB 31: LIAISON REPORTS

BUDGET LIAISON REPORT – William Kirsh, D.O.

Dr. Kirsh was not present; however, the reports were included on the agenda for the board's information.

LEGISLATIVE REPORT – Michelle Mendez, D.O.

There was no report.

UNLICENSED ACTIVITY LIAISON REPORT – Sandra Schwemmer, D.O.

There was no report.

TAB 32: OLD BUSINESS

TAB 33: NEW BUSINESS

ADJOURN: Motion by Dr. Schwemmer, seconded by Dr. Gadea, to adjourn. Motion carried.
Meeting adjourned at 2:05 p.m.
Next Meeting: November 4, 2022
Holiday Inn Disney Springs

Notice of Meeting/Workshop Hearing

DEPARTMENT OF HEALTH
BOARD OF MEDICINE

RULE NO.:	RULE TITLE:
64B8-9.019	Practice Standards for the Treatment of Gender Dysphoria

The **Florida Boards of Medicine and Osteopathic Medicine Joint Rules/Legislative Committee** announce a workshop to which all persons are invited.

DATE AND TIME: Friday, October 28, 2022, 8:00 a.m. EDT and ending no later than 1:00 p.m. EDT

PLACE: Hyatt Regency Orlando International Airport, 9300 Jeff Fuqua Boulevard, Orlando, Florida 32827

GENERAL SUBJECT MATTER TO BE CONSIDERED: The Florida Boards of Medicine and Osteopathic Medicine Joint Rules/Legislative Committee will conduct a rule workshop and meeting to receive and consider presentations from subject matter experts and comments from the public, and to discuss and develop draft rule language related to practice standards for the treatment of gender dysphoria. A copy of the agenda may be obtained by contacting: Board of Medicine by email at BOM.MeetingMaterials@flhealth.gov or by calling the Board of Medicine at (850)245-4131. Written public comments should not be sent to this email address. Information regarding written public comment submissions is provided below.

Public comments presented at the workshop will be limited to no more than two hours in total. Any person who wants to make public comments must notify board staff in writing. Speaker cards will be available at the workshop for this purpose. Public comments will be limited to three minutes per person. This time will not include time spent by the public commenter responding to questions imposed by Committee members, staff, or board counsel. If a group or faction of persons consisting of five or more persons wishes to address the Committee, please identify one individual who will speak on behalf of the group. Public commenters may use pseudonyms if they do not wish to identify themselves on the record. All public comments received at the workshop will become part of the rulemaking record.

Written public comments may be submitted to the Committee between the publication of this notice until 24 hours following the conclusion of the workshop. The email address for such submissions is BOMPublicComment@flhealth.gov. All comments received at this email address, including the sender's email address, will become part of the rulemaking record and will be a public record.

Public participation is solicited without regard to race, color, national origin, age, sex, gender, religion, disability, or family status.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop is asked to advise the Committee at least seven days before the workshop by contacting the Board of Medicine by email at BOM.MeetingMaterials@flhealth.gov or by calling the Board of Medicine at (850)245-4131.

If you are hearing or speech impaired, please contact the Committee using the Florida Relay Service at 1(800)955-8771 (TDD) or (800) 955-8770 (Voice).

If any person decides to appeal any decision made by the Boards with respect to any matter considered at this meeting or hearing, they will need to ensure that a verbatim record of the proceeding is made, including the testimony and evidence from which the appeal is to be issued.

For more information, you may contact: Florida Board of Medicine by email at BOM.MeetingMaterials@flhealth.gov or by calling the Board at (850)245-4131.

Notice of Meeting/Workshop Hearing

DEPARTMENT OF HEALTH
BOARD OF OSTEOPATHIC MEDICINE

RULE NO.: RULE TITLE:
64B15-14.014 Practice Standards for the Treatment of Gender Dysphoria

The Florida Boards of Medicine and Osteopathic Medicine Joint Rules/Legislative Committee announce a workshop to which all persons are invited.

DATE AND TIME: Friday, October 28, 2022, 8:00 a.m. EDT and ending no later than 1:00 p.m. EDT

PLACE: Hyatt Regency Orlando International Airport, 9300 Jeff Fuqua Boulevard, Orlando, Florida 32827

GENERAL SUBJECT MATTER TO BE CONSIDERED: The Florida Boards of Medicine and Osteopathic Medicine Joint Rules/Legislative Committee will conduct a rule workshop and meeting to receive and consider presentations from subject matter experts and comments from the public, and to discuss and develop draft rule language related to practice standards for the treatment of gender dysphoria. A copy of the agenda may be obtained by contacting: Board of Medicine by email at BOM.MeetingMaterials@flhealth.gov or by calling the Board of Medicine at (850)245-4131. Written public comments should not be sent to this email address. Information regarding written public comment submissions is provided below.

Public comments presented at the workshop will be limited to no more than two hours in total. Any person who wants to make public comments must notify board staff in writing. Speaker cards will be available at the workshop for this purpose. Public comments will be limited to three minutes per person. This time will not include time spent by the public commenter responding to questions imposed by Committee members, staff, or board counsel. If a group or faction of persons consisting of five or more persons wishes to address the Committee, please identify one individual who will speak on behalf of the group. Public commenters may use pseudonyms if they do not wish to identify themselves on the record. All public comments received at the workshop will become part of the rulemaking record.

Written public comments may be submitted to the Committee between the publication of this notice until 24 hours following the conclusion of the workshop. The email address for such submissions is BOMPublicComment@flhealth.gov. All comments received at this email address, including the sender's email address, will become part of the rulemaking record and will be a public record.

Public participation is solicited without regard to race, color, national origin, age, sex, gender, religion, disability, or family status.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop is asked to advise the Committee at least seven days before the workshop by contacting the Board of Medicine by email at BOM.MeetingMaterials@flhealth.gov or by calling the Board of Medicine at (850)245-4131.

If you are hearing or speech impaired, please contact the Committee using the Florida Relay Service at 1(800)955-8771 (TDD) or (800) 955-8770 (Voice).

If any person decides to appeal any decision made by the Boards with respect to any matter considered at this meeting or hearing, they will need to ensure that a verbatim record of the proceeding is made, including the testimony and evidence from which the appeal is to be issued.

For more information, you may contact: Florida Board of Medicine by email at BOM.MeetingMaterials@flhealth.gov or by calling the Board at (850)245-4131.

Florida Boards of Medicine and Osteopathic Medicine
Joint Rules/Legislative Committee Rule Workshop

Hyatt Regency Orlando International Airport
9300 Jeff Fuqua Boulevard
Orlando, FL 32827
407-825-1234

October 28, 2022

AGENDA

Participants in this public meeting should be aware that the proceedings are being recorded and that an audio file of the meeting will be posted to the Boards' websites.

Roll call will be at 8:00 a.m. or soon thereafter. The meeting will end no later than 1:00 p.m.

Rule Workshop:

Rules 64B8-9.019 & 64B15-14.014, F.A.C. – Practice Standards for the Treatment of Gender Dysphoria

- **Roll call**
- **Opening Remarks and Administrative Matters**
- **Subject Matter Experts – Questions and Answers**
  - **Michael Biggs, PhD**
  - **Kristin Dayton, M.D.**
  - **Aron Janssen, M.D.**
  - **Riittakerttu Kaltiala, M.D.**
  - **Michael Laidlaw, M.D.**
  - **Meredithe McNamara, M.D.**
- **Discussion and Development of Rule Language**
- **Public Comments**
- **Closing Remarks and Administrative Matters**
- **Meeting Adjourns**

Florida Boards of Medicine and Osteopathic Medicine
Joint Rules/Legislative Committee Rule Workshop

Hyatt Regency Orlando International Airport
9300 Jeff Fuqua Boulevard
Orlando, FL 32827
407-825-1234

October 28, 2022

MEETING MINUTES

Dr. Zachariah, Chair, called the meeting to order at 8:09 A.M. EDT on Friday, October 28, 2022.

Roll call was conducted by Cherise Strickland, Program Operations Administrator. Those present for all, or part of the meeting included the following:

Members Present:
Zachariah Zachariah, M.D., Chair
Sandra Schwemmer, D.O.
David Diamond, M.D.
Scot Ackerman, M.D.
Wael Barsoum, M.D.
Amy Derick, M.D.
Tiffany Di Pietro, D.O.
Patrick Hunter, M.D.
Nicole Justice, Consumer Member
Luz Pages, M.D.
Nicholas Romanello, Esq., Consumer Member

Members Absent:
Maria Garcia, Esq., Consumer Member, Vice-Chair
Wael Barsoum, M.D.
Kevin Cairns, M.D.
Jorge Gadea, D.O.

Board Staff Present:
Janet Hartman, Bureau Chief
John Wilson, General Counsel
Paul Vazquez, J.D., Executive Director, BOM
Danielle Terrell, Executive Director, BOOM
Edward Tellechea, Board Counsel
Donna McNulty, Board Counsel
Cherise Strickland, Program Operations Administrator
Carol Taylor, Program Operations Administrator
Shaila Washington, Regulatory Supervisor
Cyra Williams, Regulatory Specialist III
Derek Nieves, Regulatory Specialist III

Subject Matter Experts Present:
Michael Biggs, M.D.
Kristin Dayton, M.D.
Aron Janssen, M.D.
Riittakerttu Kaltiala, M.D.
Michael Laidlaw, M.D.
Meredithe McNamara, M.D.

Court Reporter:
Cynthia Green
Magnolia Court Reporting
407-896-1813

Mr. Vazquez provided opening remarks and instructions on the conduct of the meeting. Mr. Vazquez reminded everyone that this is a publicly noticed meeting, the proceedings are being recorded, and an audio file of the meeting will be posted to both Boards' websites.

Rule Workshop:
Development of Rule Language 1
Rules 64B8-9.019 & 64B15-14.014, F.A.C. – Practice Standards for the Treatment of Gender Dysphoria

Dr. Zachariah advised the discussion will begin with the testimony from invited Subject Matter Experts, who were each provided with ten minutes to present to the Committee. Dr. Zachariah

recognized subject matter expert, Dr. Michael Biggs. Dr. Biggs, who appeared virtually, provided a statement and research on gender dysphoria. Dr. Biggs answered questions from Dr. Diamond and Dr. Hunter.

Dr. Zachariah recognized Dr. Kristin Dayton, who appeared virtually, and provided a statement and research on gender dysphoria. Dr. Dayton answered questions from Dr. Hunter and Dr. Di Pietro.

Dr. Zachariah recognized Dr. Aron Janssen, who appeared virtually, and provided a statement and research on gender dysphoria. Dr. Janssen answered questions from Dr. Diamond.

Dr. Zachariah recognized Dr. Riittakerttu Kaltiala who appeared virtually, and provided a statement and research on gender dysphoria. Dr. Kaltiala answered questions from Dr. Hunter.

Dr. Zachariah recognized Dr. Michael Laidlaw, who appeared in-person, and provided a PowerPoint Presentation, a statement, and research on gender dysphoria. Dr. Laidlaw answered questions from Dr. Zachariah, Dr. Hunter, and Dr. Derick.

Dr. Zachariah recognized Dr. McNamara, who appeared virtually, and provided a statement and research on gender dysphoria. Dr. McNamara answered questions from Dr. Derick, Dr. Hunter, Dr. Pages, Dr. Diamond, Dr. Ackerman, and Dr. Zachariah.

After the subject matter expert portion of the meeting concluded, a short break was taken at 10:12 A.M. EDT. The meeting reconvened at 10:28 A.M. EDT.

The committee members began discussion. Mr. Romanello proposed a motion based upon the testimony heard and the materials provided that the risks of treatment outweighed the possible benefits. He pointed out the lack of consistent, reliable, scientific peer-reviewed evidence concerning the ethicacy and statements of such treatment. Motion for discussion to draft a rule to prohibit such therapies as puberty blockers, cross hormonal therapies, and surgeries to treat gender affirming care for gender dysphoria to anyone under the chronological age of eighteen. The motion was seconded.

Dr. Zachariah advised everyone the motion on the table is for discussion purposes and will not be voted on until later in the meeting after public comments and further discussion.

Mr. Tellechea advised the members the rule that the Committee writes must be clear, understandable, and defendable.

Dr. Zachariah invited the public to make comments, each public speaker was given three minutes to speak. Individuals were called from the speaker cards completed prior to the meeting. A total of twenty-two individuals spoke for and against rulemaking.

At the conclusion of the public speaker portion of the meeting, a short break was taken at 12:15 P.M. EDT. The meeting reconvened at 12:28 P.M. EDT. The committee members continued discussion.

A Motion was made, seconded, and approved with two votes in opposition to prohibit such therapies as puberty blockers, cross hormonal therapies, and surgeries to treat gender affirming care for gender dysphoria to anyone under the chronological age of eighteen. These are prohibited unless being done within the auspices of an Institutional Review Board (IRB) approved university-affiliated clinical trial. The rule will be a prospective rule. The rule will apply exclusively to minors with gender dysphoria.

Board counsel will prepare draft language for consideration to be presented at the Joint Boards of Medicine and Osteopathic Medicine Meeting scheduled to be held on November 4, 2022.

Action taken: Motion made, seconded, and approved with two votes in opposition to allow Board counsel to draft rule language for approval to set the practice standards for the treatment of gender dysphoria.

Meeting adjourned at 1:03 P.M. EDT.

Notice of Meeting/Workshop Hearing

DEPARTMENT OF HEALTH
BOARD OF MEDICINE

The **Florida Boards of Medicine and Osteopathic Medicine** announce a joint public meeting to which all persons are invited.

DATE AND TIME: Friday, November 4, 2022, 2:00 p.m. EDT or soon thereafter.

PLACE: Holiday Inn, Disney Springs, 1805 Hotel Plaza Boulevard, Lake Buena Vista, FL 32830, 407-827-7060.

GENERAL SUBJECT MATTER TO BE CONSIDERED: General business of the Board. Board meetings may be canceled prior to the meeting date. Please check the Board's website at https://flboardofmedicine.gov/meeting-information for cancellations or changes to the meeting date or time or call the Board at (850) 245-4131 for more information.

A copy of the agenda may be obtained by contacting: https://flboardofmedicine.gov/meeting-information.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 7 days before the workshop/meeting by contacting: the Board by email at BOM.MeetingMaterials@flhealth.gov or by calling the Board at (850) 245-4131.

If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800) 955-8771 (TDD) or 1(800) 955-8770 (Voice).

If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, including the testimony and evidence from which the appeal is to be issued.

For more information, you may contact: the Board at BOM.MeetingMaterials@flhealth.gov or by calling the Board at (850)245-4131.

Notice of Meeting/Workshop Hearing

DEPARTMENT OF HEALTH
Board of Osteopathic Medicine

The Florida Boards of Osteopathic Medicine and Medicine announces a public meeting to which all persons are invited.

DATE AND TIME: November 4, 2022, 2:00 p.m. EDT or soon thereafter

PLACE: Holiday Inn, Disney Springs, 1805 Hotel Plaza Boulevard, Lake Buena Vista, FL 32830, (407)827-7060

GENERAL SUBJECT MATTER TO BE CONSIDERED: General business of the Board. Board meetings may be canceled prior to the meeting date. Please check the Board's website at https://floridasosteopathicmedicine.gov/meeting-information/ for cancellations or changes to the meeting date or time or call the Board at (850)245-4161 for more information.

A copy of the agenda may be obtained by contacting: A copy of the agenda may be obtained by contacting: https://floridasosteopathicmedicine.gov/meeting-information/.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 7 days before the workshop/meeting by contacting: the Board by email at mqa.osteopath@flhealth.gov or by calling the Board at (850)245-4161. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.

For more information, you may contact: the Board at mqa.osteopath@flhealth.gov or by calling the Board at (850)245-4161.

Florida Boards of Medicine and Osteopathic Medicine
Joint Board Meeting

Holiday Inn Orlando – Disney Springs
1805 Hotel Plaza Boulevard
Lake Buena Vista, FL 32830
407-828-8888

November 4, 2022

AGENDA

Participants in this public meeting should be aware that the proceedings are being recorded and that an audio file of the meeting will be posted to the Boards' websites.

Roll call at 2:00 p.m. EDT or soon thereafter.

- **Discussion**

Old Business

New Business

Florida Boards of Medicine and Osteopathic Medicine
Joint Board Meeting

Holiday Inn Orlando – Disney Springs
1805 Hotel Plaza Boulevard
Lake Buena Vista, FL 32830
407-828-8888

November 4, 2022

MEETING MINUTES

I. CALL TO ORDER

The meeting was called to order at 2:00 P.M. EST on Friday, November 4, 2022, by David Diamond, M.D., Chair.

Dr. Diamond introduced Dr. Sandra Schwemmer, Chair, Board of Osteopathic Medicine.

Participants in this public meeting were made aware that these proceedings were being recorded and that an audio file of the meeting would be posted to the Board's website.

A. ROLL CALL

Roll call for the Board of Medicine was conducted by Cherise Strickland, Program Operations Administrator. Danielle Terrell, Executive Director, Board of Osteopathic Medicine conducted the roll call for the Board of Osteopathic Medicine.

Those present for all, or part of the meeting included the following:

Board of Medicine Members Present:

David Diamond, M.D., Chair
Scot Ackerman, M.D., Vice Chair
Patrick Hunter, M.D.
Luz Marina Pages, M.D.
Eleonor Pimentel, M.D.
Hector Vila, M.D.
Michael Wasylik, M.D.
Maria Garcia, Esq., Consumer Member
Nicole Justice, Consumer Member

Board of Medicine Members Absent:

Wael Barsoum, M.D.
Ravi Chandra, M.D.
Amy Derick, M.D.
Zachariah Zachariah, M.D.
Nicholas Romanello, Esq., Consumer Member

Board of Osteopathic Medicine Members Present:

Sandra Schwemmer, D.O., Chair
Michelle Mendez, D.O., Vice Chair
Tiffany Di Pietro, D.O.
William Kirsh, D.O.
Jorge Gadea, D.O.

Board of Osteopathic Medicine Members Absent:

Valerie Jackson, Consumer Member

Department Staff Present:

Paul Vazquez, J.D., Executive Director, BOM
Danielle Terrell, Executive Director, BOOM
Edward Tellechea, Board Counsel
Donna McNulty, Board Counsel
Cherise Strickland, Program Operations Administrator
Carol Taylor, Program Operations Administrator
Shaila Washington, Regulatory Supervisor
Cyra Williams, Regulatory Specialist III
Derek Nieves, Regulatory Specialist III

Court Reporter:

Donna Wolk
Magnolia Court Reporting
407-896-1813

B. OPENING REMARKS

Mr. Vazquez provided opening remarks and instructions on the conduct of the meeting. Mr. Vazquez reminded everyone that this is a publicly noticed meeting, the proceedings are being recorded, and an audio file of the meeting will be posted to both Boards' websites.

II. PROPOSED DRAFT RULE LANGUAGE.....1

Rules 64B8-9.019 & 64B15-14.014, F.A.C. – Practice Standards for the Treatment of Gender Dysphoria in Minors.

Dr. Diamond asked Mr. Tellechea to speak on the rule language being presented.

Mr. Tellechea spoke briefly advising any approved rule language will be published in the Florida Administrative Registry and there will be twenty-one days to request a rule hearing.

Dr. Diamond summarized the steps already taken, meetings held, rule workshop held, testimony heard, and public comments received since the Department presented the Boards with this task and Petition for Rulemaking. The Petition was first addressed and heard at the August 5, 2022, Board of Medicine Board meeting. Dr. Diamond advised, today, he stands in support of a rule resolution approval.

Dr. Diamond opened up discussion for both Boards' members. Dr. Diamond advised if any public officials are present and wish to address the board members, they will be invited to speak and address the members before public comment is taken.

Dr. Ackerman thanked Dr. Diamond for his opening remarks and accuracy of his description of events. He wishes to voice his support.

Dr. Vila spoke and echoed Dr. Ackerman's comment in support. Dr. Vila indicated after hearing extensive testimony, and detransition experiences, given these facts, he does not feel they are safe. Item two of the proposed draft rule reads: "Nonsurgical treatments for the treatment of gender dysphoria in minors may continue to be performed under the auspices of Institutional Review Board (IRB) approved, investigator-initiated trials conducted at any of the Florida medical schools set forth in Section 458.3145(1)(i), Florida Statutes. Such clinical trials must include long term longitudinal assessments of the patients' physiologic and psychologic outcomes." Dr. Vila stated he is not in support of item two in the proposed draft rule. Dr. Vila made a motion to strike item two from the proposed draft rule, Dr. Hunter seconded.

Dr. Hunter spoke and read an excerpt into the record. Dr. Hunter summarized the Dutch Protocol regarding the standards set by the protocol. Dr. Hunter stated we need to return to psychotherapy that respects the child's development. Safety and ethics need to prevail.

Dr. Diamond stated we have a motion from Dr. Vila to strike item two, seconded by Dr. Hunter. The motion was approved by the Board of Medicine with three in opposition – Dr. Diamond, Ms. Garcia, and Ms. Justice. Motion carried as amended on record.

Dr. Diamond recognized Dr. Schwemmer to conduct the same vote for the Board of Osteopathic Medicine. The motion from Dr. Vila to strike item was opposed by Board of Osteopathic Medicine with all five members present opposed. The motion did not pass as amended.

After further discussion, a vote was reconducted by Dr. Diamond for the Board of Medicine on 64B8-9.019, F.A.C. The motion was made by Dr. Vila to strike item two from the rule and for the rule to be renumbered accordingly. A motion was made, seconded, and carried with opposition.

Dr. Schwemmer was recognized to conduct a vote for the Board of Osteopathic Medicine on 64B15-14.014, F.A.C. as presented.

A motion was made, seconded, and carried unanimously.

SERC (Board of Medicine)

Will the proposed rule amendments have an adverse impact on small business? Is the proposed rule amendment likely to directly or indirectly increase regulatory costs to any entity, including government, in excess of $200,000 in the aggregate in Florida within one year after implementation?

A motion was made in the negative, seconded, and carried unanimously.

Will this rule amendment create an offense that would constitute a minor violation under the rule?

A motion was made in the negative, seconded, and carried unanimously.

Does the Board/Committee want to impose a sunset provision for this rule or rule amendment?

A motion was made in the negative, seconded, and carried unanimously.

SERC (Board of Osteopathic Medicine)

Will the proposed rule amendments have an adverse impact on small business? Is the proposed rule amendment likely to directly or indirectly increase regulatory costs to any entity, including government, in excess of $200,000 in the aggregate in Florida within one year after implementation?

A motion was made in the negative, seconded, and carried unanimously.

Will this rule amendment create an offense that would constitute a minor violation under the rule?

A motion was made in the negative, seconded, and carried unanimously.

Does the Board/Committee want to impose a sunset provision for this rule or rule amendment?

A motion was made in the negative, seconded, and carried with one in opposition.

Public Comment

Dr. Diamond recognized Nathan Bruemmer, LGBTQ Consumer Advocate, Florida Department of Agriculture and Consumer Services. Mr. Bruemmer addressed board members and spoke in opposition to rulemaking.

Dr. Diamond recognized Representative Anna V. Eskamani, State House District 42. Ms. Eskamani addressed board members and spoke in opposition to rulemaking.

Dr. Diamond invited the public to make comments. Each public speaker was given three minutes to speak. Individuals were chosen from the speaker cards completed prior to the meeting. A total of sixteen speaker cards were randomly chosen, allowing eight public speakers in support of and eight public speakers in opposition to rulemaking.

Action taken: Motion made, seconded, and approved by the Board of Medicine with three in opposition to adopt the proposed rule language as amended on the record.

Action taken: Motion made, seconded, and approved unanimously by the Board of Osteopathic Medicine to adopt the proposed rule language with no changes.

III. OLD/NEW BUSINESS.....No Tab

There was no old or new business to discuss.

Meeting adjourned at 3:52 P.M. EST.

Notice of Meeting/Workshop Hearing

DEPARTMENT OF HEALTH
BOARD OF MEDICINE

RULE NO.: RULE TITLE:
64B8-9.019 Standards of Practice for the Treatment of Gender Dysphoria in Minors

The Florida Boards of Medicine and Osteopathic Medicine announce a joint rule hearing to which all persons are invited.

DATE AND TIME: Friday, February 10, 2023, 1:00 p.m. EST or soon thereafter and ending no later than 5:00 p.m. EST.

PLACE: Department of Transportation Auditorium, Burns Building, 605 Suwannee Street, Tallahassee, Florida 32399.

GENERAL SUBJECT MATTER TO BE CONSIDERED: The Florida Boards of Medicine and Osteopathic Medicine will conduct a joint rule hearing relating to the standards of practice for the treatment of gender dysphoria in minors. A copy of the agenda and information regarding cancellation or changes to the meeting time or location may be obtained on the Board's website at https://flboardofmedicine.gov/meeting-information or by calling the Board office at (850) 245-4131.

Any person who wants to make public comments at the rule hearing must notify Board staff in writing. Speaker cards will be available at the rule hearing for this purpose. Public comments will be limited to three minutes per person. This time will not include time spent by the public commenter responding to questions imposed by Board members, staff, or board counsel. If a group or faction of persons consisting of five or more persons wishes to address the Boards, please identify one individual who will speak on behalf of the group. Public commenters may use pseudonyms if they do not wish to identify themselves on the record. All public comments received at the workshop will become part of the rulemaking record.

Written public comments may be submitted to the Boards between the publication of this notice until 5:00 p.m. EST on February 7, 2023. The email address for such submissions is BOMPublicComment@flhealth.gov. All comments received at this email address, including the sender's email address, are public records and will become part of the published rulemaking record.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 7 days before the workshop/meeting by contacting: the Board by email at BOM.MeetingMaterials@flhealth.gov or by calling the Board at (850) 245-4131. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1 (800) 955-8771 (TDD) or 1 (800) 955-8770 (Voice).

If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.

For more information, you may contact the Board at BOM.MeetingMaterials@flhealth.gov or by calling the Board office at (850) 245-4131.

Notice of Meeting/Workshop Hearing

DEPARTMENT OF HEALTH
BOARD OF OSTEOPATHIC MEDICINE

RULE NO.: RULE TITLE:
64B15-14.014 Standards of Practice for the Treatment of Gender Dysphoria in Minors

The Florida Boards of Medicine and Osteopathic Medicine announce a joint rule hearing to which all persons are invited.

DATE AND TIME: Friday, February 10, 2023, 1:00 p.m. EST or soon thereafter and ending no later than 5:00 p.m. EST

PLACE: Department of Transportation Auditorium, Burns Building, 605 Suwannee Street, Tallahassee, Florida 32399

GENERAL SUBJECT MATTER TO BE CONSIDERED: The Florida Boards of Medicine and Osteopathic Medicine will conduct a joint rule hearing relating to the standards of practice for the treatment of gender dysphoria in minors. A copy of the agenda and information regarding cancellation or changes to the meeting time or location may be obtained on the Board's website at https://flboardofmedicine.gov/meeting-information or by calling the Board office at (850)245-4131.

Any person who wants to make public comments at the rule hearing must notify Board staff in writing. Speaker cards will be available at the rule hearing for this purpose. Public comments will be limited to three minutes per person. This time will not include time spent by the public commenter responding to questions imposed by Board members, staff, or board counsel. If a group or faction of persons consisting of five or more persons wishes to address the Boards, please identify one individual who will speak on behalf of the group. Public commenters may use pseudonyms if they do not wish to identify themselves on the record. All public comments received at the workshop will become part of the rulemaking record.

Written public comments may be submitted to the Boards between the publication of this notice until 5:00 p.m. EST on February 7, 2023. The email address for such submissions is BOMPublicComment@flhealth.gov. All comments received at this email address, including the sender's email address, are public records and will become part of the published rulemaking record.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 7 days before the workshop/meeting by contacting: the Board by email at BOM.MeetingMaterials@flhealth.gov or by calling the Board at (850)245-4131. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.

For more information, you may contact the Board at BOM.MeetingMaterials@flhealth.gov or by calling the Board office at (850)245-4131.

Florida Boards of Medicine and Osteopathic Medicine
Rule Hearing – Standards of Practice for the Treatment of Gender Dysphoria in Minors
64B8-9.019 and 64B15-14.014, F.A.C.

Department of Transportation Auditorium
Burns Building
605 Suwannee St.
Tallahassee, FL 32399

February 10, 2023

AGENDA

Participants in this public meeting should be aware that the proceedings are being recorded and that an audio file of the meeting will be posted to the Boards' websites.

Roll call at 1:00 p.m. EST or soon thereafter. The meeting will end no later than 5:00 p.m. EST.

Rule Hearing:
Standards of Practice for the Treatment of Gender Dysphoria in Minors
Rules 64B8-9.019 and 64B15-14.014, F.A.C.

- **Roll Call**
- **Opening Remarks and Administrative Matters**
- **Presentation of Requests for Rule Hearing**
- **Public Comment**
- **Discussion and Consideration by the Boards**
- **Closing Remarks**
- **Adjournment**

Florida Boards of Medicine and Osteopathic Medicine
Rule Hearing – Standards of Practice for the Treatment of Gender Dysphoria in Minors
64B8-9.019 and 64B15-14.014, F.A.C.

Department of Transportation Auditorium
Burns Building
605 Suwannee St.
Tallahassee, FL 32399

February 10, 2023

MEETING MINUTES

CALL TO ORDER

The meeting was called to order at 1:00 P.M. EST on Friday, February 10, 2023, by Scot Ackerman, M.D., Chair. Dr. Ackerman introduced William Kirsh, D.O., Vice Chair, Board of Osteopathic Medicine and indicated Tiffany DiPietro, D.O., Chair, Board of Osteopathic Medicine would be arriving a few minutes late.

Participants in this public meeting were made aware that these proceedings were being recorded and that an audio file of the meeting would be posted to the Board's website.

ROLL CALL

Roll call for the Board of Medicine was conducted by Paul Vazquez, Executive Director.

Roll call for the Board of Osteopathic Medicine was conducted by Danielle Terrell, Executive Director. Ms. Terrell advised Dr. DiPietro is delayed in travel and will arrive later in the meeting.

Those present for all, or part of the meeting included the following:

Board of Medicine Members Present:
Scot Ackerman, M.D., Chair
Nicholas Romanello, Esq.,
Consumer Member, Vice Chair
Matthew Benson, M.D.
Gregory Coffman, M.D.
Patrick Hunter, M.D.
Nicole Justice, Consumer Member
Eleonor Pimentel, M.D.
Hector Vila, M.D.
Michael Wasylik, M.D.

Board of Medicine Members Absent:
Wael Barsoum, M.D.
Maria Garcia, Esq., Consumer Member
Amy Derick, M.D.
Luz Marina Pages, M.D.
Zachariah Zachariah, M.D.

Board of Osteopathic Medicine Members Present:
Tiffany DiPietro, D.O., Chair
William Kirsh, D.O., Vice Chair
Chris Creegan, Consumer Member
Watson Ducatel, D.O.
Monica Mortensen, D.O.
Gregory Williams, D.O.

Board of Osteopathic Medicine Members Absent:
Valerie Jackson, Consumer Member

Department Staff Present:
Paul Vazquez, J.D., Executive Director, BOM
Danielle Terrell, Executive Director, BOOM
Chris Dierlam, Board Counsel
David Flynn, Board Counsel

Court Reporter:
Cynthia Green
Magnolia Court Reporting
407-896-1813

OPENING REMARKS

Mr. Vazquez provided opening remarks and instructions on the conduct of the meeting. Mr. Vazquez reminded everyone that this is a publicly noticed meeting, the proceedings are being recorded, and an audio file of the meeting will be posted to both Boards' websites.

Mr. Vazquez summarized steps already taken, meetings held, rule workshops held, testimony heard, and public comments received. In June 2022, the boards received notice the Department intended to present a petition to initiate rulemaking, and in November 2022 both boards approved rule language. Mr. Vazquez advised this rule hearing will end no later than 5:00 p.m., and the public speaking process will be randomized. Public officials were invited to make themselves known should they wish to make public comment.

RULE HEARING
Standards of Practice for the Treatment of Gender Dysphoria in Minors
Rules 64B8-9.019 and 64B15-14.014, F.A.C.

Dr. Ackerman provided additional opening remarks summarizing steps taken since of June 2022. The Board of Medicine and the Board of Osteopathic Medicine have adopted very similar rules, except for one difference. Dr. Ackerman read the rules into record that were approved at the November 4, 2022, Joint Board of Medicine, and Board of Osteopathic Medicine Meeting (attached).

Dr. Ackerman advised that the BOM received six requests for a rule hearing, and that the purpose of the hearing was to honor those requests. It was noted that the proceedings were not a rule challenge, but a rulemaking hearing. Dr. Ackerman advised that the Boards would hear from the petitioners who formally requested the rule hearing, and then would hear from the public. The petitioners present were given 10 to 15 minutes to provide testimony.

Dr. Ackerman called petitioner James Wright to provide testimony. Mr. Wright was not present and did not provide testimony.

Dr. Ackerman called petitioner Lauren Miller to provide testimony. Ms. Miller was not present and did not provide testimony.

Dr. Ackerman called petitioner Simone Chriss, Esq., Director, Transgender Rights Initiative, Southern Legal Counsel, Inc. to speak. Ms. Chriss was present and provided testimony to the members. Ms. Chriss answered questions from Dr. Vila and Dr. Ackerman.

Dr. Ackerman called petitioner Kara Gross, Legislative Director & Senior Policy Counsel, American Civil Liberties Union of Florida to provide testimony to members. Ms. Gross was not present and did not provide testimony.

Dr. Ackerman called petitioner Zinnia Jones, Gender Analysis of Seminole County to provide testimony. Ms. Jones was not present and did not provide testimony.

Dr. Ackerman called the final petitioner, John Wilson, General Counsel, Florida Department of Health to speak and provide testimony. Mr. Wilson was present and spoke on the research exception in the Board of Osteopathic Medicine rule. Mr. Wilson summarized the reasons why the Department wanted the research exception removed from the Board of Osteopathic Medicine rule language and requested that the Board of Osteopathic Medicine remove the proposed research

exception from their rule.

Dr. Ackerman asked Mr. Wilson, to be clear, were there any changes requested to the Board of Medicine rule. Mr. Wilson confirmed that the Department was not requesting any changes to the Board of Medicine rule.

Dr. Ackerman asked Mr. Wilson, to be clear, was the Department requesting the Board of Osteopathic Medicine only to remove item 2 from their rule, which is the research exception. Mr. Wilson confirmed that there were no other requested changes.

Dr. Benson spoke on federal regulations, research, his role in clinical research, and the Institutional Review Board (IRB). Dr. Benson asked questions of Mr. Wilson regarding the role of the State in research and federal regulations. Mr. Wilson agreed that the IRB is regulated by federal law, and the Board of Medicine is not involved in what an IRB does.

Dr. Diamond spoke and addressed Mr. Wilson.

Dr. Ackerman asked if any members of the board wished to make any comments before proceeding to the public comment portion of the hearing.

Dr. Kirsh spoke and addressed members on the topic of research. Dr. Benson spoke and addressed members on the topic of research, puberty blockers, bone density, bone mass, and controlled trials.

Dr. Ackerman advised there two members from the Florida House of Representatives present and extended the courtesy of allowing each to speak first during public comments.

Dr. Ackerman recognized Ms. Rita Harris, House Representative, who spoke and addressed the members.

Dr. Ackerman recognized Ms. Anna Eskamani, House Representative, who spoke and addressed the members.

Dr. Ackerman recognized Dr. DiPietro arriving at the meeting at 1:52 p.m.

Individuals were called randomly from speaker cards that were completed prior to and during the meeting. Each speaker was given three minutes to provide testimony pursuant to Board rule. A total of forty-three individuals were called from the speaker cards and addressed the members, including Ms. Harris and Ms. Eskamani.

A ten-minute break began at 2:30 p.m., and the meeting reconvened at 2:41 p.m. Public comments resumed after the break. At the conclusion of the public comment portion of the hearing, a ten-minute break began at 4:02 p.m., and the meeting reconvened at 4:14 p.m.

Dr. Ackerman provided a recap of the rule hearing and then opened the floor to both Boards' members for discussion.

Dr. Vila spoke and addressed members.

Dr. Ackerman requested to bifurcate the meeting into two separate meetings, one for the Board of Medicine and one for the Board of Osteopathic Medicine.

Dr. Ackerman called the Board of Medicine meeting to order at 4:20 p.m. Dr. Ackerman asked the Board of Medicine members if there was any motion to modify the rule. No changes were requested to the Board of Medicine rule.

A Motion to adjourn the Board of Medicine meeting was made, seconded, and approved unanimously at 4:21 p.m.

Action taken: No action needed.

Dr. DiPietro called the Board of Osteopathic Medicine Meeting to order at 4:21 p.m. Dr. DiPietro asked the Board of Osteopathic Medicine members if there was any motion to change or modify the rule as it currently stands. Dr. Ducatel made a motion to remove the current research exception, in order to mirror the Board of Medicine rule. There was no discussion between members. The motion to remove the current research exception was seconded and approved unanimously.

A Motion to adjourn the Board of Osteopathic Medicine meeting was made, seconded, and approved unanimously at 4:23 p.m.

Action taken: Motion was made, seconded, and approved to remove the research exception from the Board of Osteopathic Medicine's rule.

Notice of Meeting/Workshop Hearing

DEPARTMENT OF HEALTH
Board of Osteopathic Medicine
The Board of Osteopathic Medicine announces a public meeting to which all persons are invited.
DATE AND TIME: April 7, 2023, 10:00 a.m. – 12:00 p.m.
PLACE: Please join my meeting from your computer, tablet or smartphone.
https://meet.goto.com/594019581
United States (Toll Free): 1 866 899 4679
Access Code: 594-019-581
GENERAL SUBJECT MATTER TO BE CONSIDERED: The general business of the Board.
A copy of the agenda may be obtained by contacting: https://floridasosteopathicmedicine.gov/meeting-information/
Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 7 days before the workshop/meeting by contacting: Board Staff, at (850) 245-4161 or MQA.Osteopath@flhealth.gov or 4052 Bald Cypress Way, #C-06, Tallahassee, FL 32399. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).
If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.
For more information, you may contact: Board Staff, at (850) 245-4161 or MQA.Osteopath@flhealth.gov or 4052 Bald Cypress Way, #C-06, Tallahassee, FL 32399.

FLORIDA | Board *of* Osteopathic Medicine

AGENDA
April 7, 2023
10:00 a.m., EST

https://meet.goto.com/594019581

Meet Me #:
1 866 899 4679

Participation Code:
594-019-581

Friday, April 7, 2023

TURN OFF OR PLACE YOUR CELL PHONE ON VIBRATE DURING THE MEETING.

Participants in this public meeting should be aware that these proceedings are being recorded and that an audio file of the meeting will be posted to the Board's website.

CALL TO ORDER Tiffany Di Pietro, DO, FACC, FACOI *Chair*

ROLL CALL Danielle Terrell, *Executive Director*

AGENDA

TAB 1: DISCUSSION OF LEGISLATION - INTERSTATE-MOBILITY AND UNIVERSAL-RECOGNITION OCCUPATIONAL LICENSING ACT (SB1364, 1366; HB 1333, 2023)

Current Bill Texts
SB 1364 – Committee Substitute 1 (Filed 03/23/2023)
SB 1366 – Committee Substitute 1 (Filed 03/23/2023); fees
HB 1333 – Original (Filed 03/02/2023)

Prior Bill Texts
SB 1364 – Original (Filed 03/01/2023)
SB 1366 – Original (Filed 03/01/2023)

ADJOURN

Next Meeting: May 19, 2023 (Tampa, FL)

FLORIDA | Board *of* Osteopathic Medicine

April 7, 2023

Draft Teleconference Meeting Minutes
Board of Osteopathic Medicine
GoTo Meeting
https://meet.goto.com/594019581
Meet-Me-Number 1 866 899 4679
Access Code: 594-019-581
April 7, 2023
10:00 a.m.

The meeting was called to order by Dr. Tiffany Di Pietro, Chair, at approximately 10:00 a.m.

Roll Call was conducted by Danielle Terrell, Executive Director for the Board of Osteopathic Medicine. Those present for all, or part of the meeting included the following:

MEMBERS PRESENT:
Tiffany Sizemore Di Pietro, DO, Chair
William Kirsh, DO, Vice-Chair
Monica Mortensen, DO
Gregory Williams, DO
Watson Ducatel, DO
Valerie Jackson, Consumer Member
Chris Creegan, Consumer Member

BOARD STAFF PRESENT:
Danielle Terrell, Executive Director
Carol Taylor, Program Administrator
Derek Nieves, RSIII

MEMBERS ABSENT
NONE

BOARD COUNSEL
Donna McNulty, Board Counsel

PROSECUTION SERVICES ATTORNEYS:
NONE

COURT REPORTER:
For the Record Court Reporting
850-222-5491

OTHERS PRESENT:
None

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.

TAB 1: DISCUSSION OF LEGISLATION - INTERSTATE-MOBILITY AND UNIVERSAL-RECOGNITION OCCUPATIONAL LICENSING ACT (SB1364, 1366; HB 1333, 2023)

Board chair informed the board that the purpose of this meeting was to discuss legislative bills which the Board of Dentistry and the Board of Medicine have opposed.

The Executive Director explained that the bills were basically a universal endorsement and noted that both the Board of Dentistry and the Board of Medicine have drafted letters of opposition to the bills.

Board counsel expounded on the issues with the proposed legislation. She noted that the presumption that the applicant meets qualifications to be licensed is always on the applicant, but these bills would shift that burden to the board. In addition, this board requires the COMLEX examination for licensure; however, certain locations do not require the COMLEX and should these bills pass, the board couldn't consider this.

Discussion continued including the fact the bills include foreign countries, that they are military style bills promoting work portability; however, there is already a military bill in effect. This is not needed.

Concern was voiced regarding the ability to ensure that the applicant is qualified to provide osteopathic medicine in the state of Florida.

The Board chair indicated her total agreement with the Board of Medicine's letter of opposition, noting it would be virtually impossible to determine if the applicants meet standards, the testing requirements, and the burden it would place on the board.

After discussion,
Motion: by Dr. Ducatel, seconded by Dr. Kirsh, to adopt a letter, similar to the Board of Medicine, in opposition to the bills. Motion carried.

A request was made that language specifically indicating the relationship between other state boards and allopathic medicine be included in the letter, to further reflect why Florida is distinct.

It was agreed that the executive director, the board counsel, and the chair would draft a letter of opposition which would be copied to the state member sponsoring the respective bills.

Further discussion reflected a desire to have a board representative in attendance at any committee meetings regarding these bills. Dr. Williams volunteered to attend committee meetings on behalf of the Board of Osteopathic Medicine.

Motion: by Dr. Kirsh, seconded by Dr. Ducatel, to have a board member attend any committee or meeting as necessary. Motion carried.

ADJOURN:

Motion: simultaneously by Dr. Williams and Ms. Jackson, to adjourn.
Meeting adjourned at 10:25 a.m.
Next Meeting: May 19, 2023
Tampa, Florida

Notice of Meeting/Workshop Hearing

DEPARTMENT OF HEALTH
Board of Medicine

The **Florida Boards of Medicine and Osteopathic Medicine's Joint Rules/Legislative Committee** announces a public meeting to which all persons are invited.

DATE AND TIME: Thursday, June 1, 2023, beginning at 2:45 PM EDT, or soon thereafter.

PLACE: The Westshore Grand, A Tribute Portfolio Hotel, 4860 W. Kennedy Blvd., Tampa, Florida 33609. The hotel's phone number is (813)286-4400. The hotel's website is https://westshoregrand.com/. The public rate is $133 per night.

GENERAL SUBJECT MATTER TO BE CONSIDERED: General business of the Committee. Committee meetings may be canceled prior to the meeting date. Please check the Board's website at https://flboardofmedicine.gov/meeting-information for cancellations or changes to the meeting date or time or call the Board at (850)245-4131 for more information.

A copy of the agenda may be obtained by contacting: https://flboardofmedicine.gov/meeting-information.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 7 days before the workshop/meeting by contacting the Board by email at BOM.MeetingMaterials@flhealth.gov or by calling the Board at (850)245-4131.

If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.

For more information, you may contact: the Board at BOM.MeetingMaterials@flhealth.gov or by calling the Board at (850)245-4131.

Notice of Meeting/Workshop Hearing

DEPARTMENT OF HEALTH
Board of Osteopathic Medicine

The Florida Boards of Osteopathic Medicine and Medicine's Joint Rules/Legislative Committee announces a public meeting to which all persons are invited.

DATE AND TIME: Thursday, June 1, 2023, 2:45 p.m., EDT, or soon thereafter.

PLACE: The Westshore Grand, A Tribute Portfolio Hotel, 4860 W. Kennedy Blvd., Tampa, Florida 33609. The hotel's phone number is (813)286-4400. The hotel's website is https://westshoregrand.com/. The public rate is $133 per night.

GENERAL SUBJECT MATTER TO BE CONSIDERED: General business of the Committee. Committee meetings may be canceled prior to the meeting date. Please check the Board's website at https://flboardofmedicine.gov/meeting-information for cancellations or changes to the meeting date or time or call the Board at (850)245-4131 for more information.

A copy of the agenda may be obtained by contacting: https://flboardofmedicine.gov/meeting- information.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 7 days before the workshop/meeting by contacting: the Board by email at BOM.MeetingMaterials@flhealth.gov or by calling the Board at (850)245-4131. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.

For more information, you may contact: the Board at BOM.MeetingMaterials@flhealth.gov or by calling the Board at (850)245-4131.

Florida Boards of Medicine and Osteopathic Medicine
Joint Rules and Legislative Committee Meeting

The Westshore Grand
4860 West Kennedy Boulevard
Tampa, FL 33609
813-286-4400

June 1, 2023

AGENDA

Participants in this public meeting should be aware that the proceedings are being recorded and that an audio file of the meeting will be posted to the boards' websites.

Roll call will be at 2:45 p.m. or shortly thereafter.

Old Business

New Business

Florida Boards of Medicine and Osteopathic Medicine
Joint Rules/Legislative Committee Meeting

The Westshore Grand
4860 West Kennedy Boulevard
Tampa, FL 33609
813-286-4400

MEETING MINUTES

The meeting was called to order at 3:19 p.m. on June 1, 2023, by Dr. Zachariah Zachariah. Roll call was conducted by Cherise Strickland, Program Operations Administrator.

Members Present:
Zachariah Zachariah, M.D., Chair
Nicholas Romanello, Esq., Consumer Member
Vice Chair
Scot Ackerman, M.D.
Matthew Benson, M.D.
Amy Derick, M.D.
Maria Garcia, Esq., Consumer Member
Patrick Hunter, M.D.
Tiffany Sizemore DiPietro, D.O.
William Kirsh, D.O.
Monica Mortensen, D.O.

Members Absent:
David Diamond, M.D.
Luz Marina Pages, M.D.

Staff Present:
Paul Vazquez, J.D., Executive Director BOM
Danielle Terrell, Executive Director BOOM
Christopher Dierlam, Board Counsel
Cassandra Fullove, Certified Paralegal
Cherise Strickland, Program Operations Administrator
Wendy Alls, Program Operations Administrator
Cyra Williams, Regulatory Specialist III
Brad Dalton, Public Information Officer

Court Reporter:
Cynthia Green
Magnolia Court Reporting
407-896-1813

Mr. Vazquez provided opening remarks and instructions on the conduct of the meeting. Mr. Vazquez reminded everyone that this is a publicly noticed meeting, the proceedings are being recorded, and an audio file of the meeting will be posted to both Boards' websites.

Old Business

There was no old business to discuss.

Action taken: No action taken

New Business

Rules 64B8-9.019 and 64B15-14.014, F.A.C. – Standards of Practice for the Treatment of Gender Dysphoria in Minors 1

- Emergency rule relating to the standard of care for the treatment of gender dysphoria in minors
- Emergency rule relating to informed consent for the treatment of gender dysphoria in Minors

- Discussion of potential rule amendments in light of Chapter 2023-90, Laws of Florida (CS/SB 254)

Mr. Vazquez summarized SB 254, which was signed into law and became effective upon Governor DeSantis' signing on May 17, 2023. The law as enacted requires the Board of Medicine and the Board of Osteopathic Medicine to adopt rules within 60 days establishing practice standards for the continuing treatment of minors already receiving treatment prior to the signing of the law, including the development of any necessary informed consent forms. The law also requires the Boards to adopt emergency rules establishing informed consent forms for adults; however, the 60-day time frame is not a requirement for the adult informed consent forms.

Mr. Vazquez advised the primary goals today are to develop practice standards for minors who were receiving sex reassignment treatment prior to the signing of the law; develop any necessary informed consent form(s) for minors; and develop informed consent form(s) for adults.

Dr. Hunter began the discussion, with all present members of the joint committee participating. A robust discussion among members continued.

A motion was made, seconded, and approved unanimously to establish an emergency rule for the board to approve physicians who had previously prescribed sex reassignment prescriptions to continue to renew that prescription for up to six months from the date of an emergency rule establishing an informed consent.

Discussion continued among members on the number of informed consent forms that will be needed for each patient to complete. Discussion continued on what parties would be required to sign the informed consent form(s).

A motion was made, seconded, and approved unanimously to allow one M.D. and one D.O. member to each separately prepare informed consent forms to be presented at the next meeting. Dr. Benson was approved as the M.D. delegate and Dr. Mortensen was approved as the D.O. delegate.

Dr. Zachariah invited the public to make comments, each public speaker was given three minutes to speak. Individuals were initially called to speak from the speaker cards completed prior to and during the meeting. After the third speaker completed their comment, the public formed a line and continued to make public comments in that format. Mr. Vazquez reminded the public to only provide comments on the scope of the agenda items.

A short break was taken at 4:45 p.m., the meeting reconvened at 4:55 p.m., and public comments continued. A total of twenty-eight individuals spoke and provided public comment.

A motion was made, seconded, and approved unanimously to hold a Joint Rules/Legislative Committee meeting on June 23, 2023, at 1:00 p.m. The meeting will be held in-person and the location is to be determined.

Action taken: Motion to establish emergency rule for boards to approve renewal of sex reassignment prescriptions up to six months for physicians who previously provided the prescriptions; motion to hold an in-person Joint Rules/Legislative Committee meeting on June 23, 2023, at 1:00 p.m., location to be determined.

Action taken: Motion to establish emergency rule for board to approve renewal of sex reassignment prescriptions up to six months for physicians who previously prescribed the prescriptions; motion to hold an in-person Joint Rules/Legislative Committee meeting on June 23, 2023, at 1:00 p.m., location to be determined.

The members were unable to discuss and address this agenda item at this meeting.

Action taken: No action taken

The meeting adjourned at 5:29 p.m.

Notice of Meeting/Workshop Hearing

DEPARTMENT OF HEALTH
Board of Medicine

The **Florida Board of Medicine** announces a public meeting to which all persons are invited.

DATE AND TIME: Friday, June 2, 2023, beginning at 8:00 AM EST, or soon thereafter.

PLACE: The Westshore Grand, A Tribute Portfolio Hotel, 4860 W. Kennedy Blvd, Tampa, Florida 33609. The hotel's phone number is (813) 286-4400. The hotel's website is https://westshoregrand.com/. The public rate is $133 per night.

GENERAL SUBJECT MATTER TO BE CONSIDERED: General business of the Board. Please check the Board's website at https://flboardofmedicine.gov/meeting-information for cancellations or changes to the meeting date or time or call the Board at (850)245-4131 for more information.

A copy of the agenda may be obtained by contacting: https://flboardofmedicine.gov/meeting-information.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 7 days before the workshop/meeting by contacting the Board by email at BOM.MeetingMaterials@flhealth.gov or by calling the Board at (850) 245-4131.

If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.

For more information, you may contact: the Board at BOM.MeetingMaterials@flhealth.gov or by calling the Board at (850) 245-4131.

Florida Board of Medicine
Board Meeting

The Westshore Grand
4860 W. Kennedy Boulevard
Tampa, Florida 33609
813-286-4400

June 2, 2023

AGENDA

NOTE: Cases shown on the agenda may be heard in a different order but will not be heard prior to 8:00 a.m. Cases are scheduled to be heard beginning at 8:00 a.m.; therefore, it is imperative that you arrive promptly at 8:00 a.m. and be prepared to be at the meeting for several hours until your case is heard.

Lunch will be taken at an appropriate time.

Participants in this public meeting should be aware that these proceedings are being recorded and that an audio file of the meeting will be posted to the board's website.

8:00 a.m. Roll Call

Disciplinary Case Schedule:

Ashutosh R. Virmani, MD – Recommended Order.....49
.....**Mr. Romanello**
.....**Addendum in Version 2**

Christopher Saputa, MD – Recommended Order.....50 **CONTINUED**
.....**Dr. Wasylik**
.....**Addendum in Version 2**

Joseph J. Castellano, MD – Settlement Agreement.....1
.....**Dr. Zachariah**

Leonard A. Benton, MD – Settlement Agreement.....2
.....**No current members**

Scott S. Katzman, MD – Settlement Agreement.....3
.....**Dr. Ackerman and Ms. Garcia**

Luis J. Batlle, MD – Settlement Agreement.....4
.....**Dr. Barsoum and Mr. Romanello**

Richard D. Berkowitz, MD – Settlement Agreement.....5
.....**No current members**

Richard J. Torricelli, MD – Settlement Agreement.....6
.....**No current members**

Joseph M. Sperduto, MD – Settlement Agreement.....7
.....**Dr. Vila and Ms. Garcia**

Anticipated Adjournment 5:00 p.m.

Florida Board of Medicine
Board Meeting

The Westshore Grand
4860 W. Kennedy Boulevard
Tampa, Florida 33609
813-286-4400

June 2, 2023

MEETING MINUTES

CALL TO ORDER

The meeting was called to order at 8:00 a.m. on Friday, June 2, 2023, by Dr. Scot Ackerman, Chair.

Participants in this public meeting were made aware that these proceedings were being recorded and that an audio file of the meeting would be posted to the Board's website.

ROLL CALL

Roll call was conducted by Cherise Strickland, Program Operations Administrator. Those present for all, or part of the meeting included the following:

Members Present:
Scot Ackerman, M.D., Chair
Nicholas Romanello, Esq., Consumer Member Vice Chair
Wael Barsoum, M.D.
Matthew Benson, M.D.
Gregory Coffman, M.D.
Amy Derick, M.D.
Maria Garcia, Esq., Consumer Member
Nicole Justice, Consumer Member
Luz Pages, M.D.
Michael Wasylik, M.D.
Zachariah Zachariah, M.D.

Staff Present:
Paul Vazquez, J.D., Executive Director
Christopher Dierlam, Board Counsel
Donna McNulty, Board Counsel
Cassandra Fullove, Senior Legal Assistant
Cherise Strickland, Program Operations Administrator
Wendy Alls, Program Operations Administrator
Cyra Williams, Regulatory Specialist III
Brad Dalton, Public Information Officer

Members Absent:
David Diamond, M.D.
Patrick Hunter, M.D.
Eleonor Pimentel, M.D.
Hector Vila, M.D.

Court Reporter:
Cynthia Green
Magnolia Court Reporting
Reportingorlando@aol.com
407-896-1813

Department of Health Prosecutors Present:
Andrew Pietrylo, Esq.
Chad Dunn, Esq.
Sarah Corrigan, Esq.
Justin Ravelo, Esq.

OPENING REMARKS

Mr. Vazquez provided opening remarks and reminded the audience that this is a publicly noticed meeting and is being recorded for the public record before moving into the case schedule.

Disciplinary Case Schedule:

Ashutosh R. Virmani, MD – Recommended Order 49
Allegations of the Amended Administrative Complaint: Count I: § 456.072(1)(o), F.S., Count II: § 458.331(1)(t), F.S., Count III: § 456.072(1)(a), F.S., and/or § 456.072(1)(m), F.S., Count IV: § 458.331(1)(nn), F.S. through a violation of Rule 64B8-30.011(5), F.A.C., Count V: § 458.331(1)(nn), F.S., through a violation of Rule 64B8-9.009(2)(o), F.A.C., Count VI: § 458.331(1)(nn), F.S., through a violation of Rules 64B8-9.009(4)(b)2.a. and/or Rule 64B8-9.009(6)(b)1.a., F.A.C., Count VII: § 458.331(1)(nn), F.S., through a violation of Rule 64B8-30.12, F.A.C., Count VIII: § 458.331(1)(nn), F.S., through a violation of Rules 64B8-9.009, and/or 64B8-9.003, F.A.C.

Dr. Ackerman provided opening statements and instructions on how the proceedings would be conducted.

Mr. Dunn represented the Department and presented the case to the Board.

Dr. Virmani was present and was represented by Bruce Lamb, Esquire.

Dr. Romanello were recused due to participation on the probable cause panel.

Following opening remarks from Dr. Ackerman, Respondent and Counsel proceeded with summarizing their exceptions to the proposed final order.

Mr. Lamb presented mitigating factors.

A motion was made, seconded, and carried unanimously to accept the Respondent's first exception to paragraph 7 of the recommended order based on competent substantial evidence.

A motion was made, seconded, and carried unanimously to deny the Respondent's second exception to paragraph 39 of the recommended order based on a proceeding that complied with the essential requirement of law.

A motion was made, seconded, and carried unanimously to accept the Respondent's third exception to paragraph 44 and 43 of the recommended order based on the ALJ's conclusion was not based on competent substantial evidence.

A motion was made, seconded, and carried unanimously to deny the Respondent's fourth exception to paragraph 45 of the recommended order based on the ALJ's conclusion of law was a reasonable interpretation of the statutes, was as or more reasonable that that of the Respondent.

A motion was made, seconded, and carried unanimously to deny the Respondent's fifth exception to paragraph 45 of the recommended order based on competent substantial evidence.

A motion was made, seconded, and carried unanimously to adopt the Findings of Fact as modified by the Board based on competent substantial evidence.

A motion was made, seconded, and carried unanimously to adopt the Conclusions of Law as modified by the Board.

A motion was made, seconded, and carried unanimously to accept the Administrative Law Judge's recommendation of penalty of suspension of license until such time the Respondent undergoes a physician assessment evaluation by Florida CARES and personally appears before the Board (Probation Committee) with said evaluation and the evaluator's recommendation.

Mr. Lamb addressed the board and asked in an abundance of caution in the event the Respondent chooses to appeal, ask to make a motion to stay the penalty if one is filed.

Motion was made, seconded, and carried unanimously to deny the request to stay the penalty pending an appeal.

A motion was made, seconded, and carried unanimously to assess costs in the amount of $9,686.41 to be paid within 90 days of date final order is filed.

Action Taken: suspension of license, Florida CARES evaluation to be presented to Probation committee to consider re-instatement, $2,500.00 fine, $9,686.41 costs, and five hours of continuing medical education in laws, rules, and ethics

Christopher Saputa, MD – Recommended Order ..... 50 CONTINUED
This case was continued.

Zamip P. Patel, MD – Settlement Agreement 13
Dr. Patel was present and represented by Gregory Chaires, Esquire.

Dr. Zachariah was recused due to participation on the probable cause panel.

Ms. Corrigan represented and presented for the Department.

Allegations of the Administrative Complaint: Violation of s. 456.072(1)(bb), F.S. (2020).

Mr. Chaires presented mitigating factors.

Dr. Derick, Ms. Justice, Mr. Romanello, and Dr. Benson addressed Dr. Patel. Dr. Patel responded to the members questions and comments.

A motion was made, seconded, and carried unanimously to accept the Settlement Agreement as presented.

Costs were imposed in the amount of $2,236.40.

Penalty imposed: letter of concern, $5,000 fine, $2,236.40 costs, five hours of continuing medical education in risk management, one hour lecture/seminar on wrong site procedure to medical staff at an approved facility within six months of the filing of final order

Carlos M. Garcia, MD – Settlement Agreement 14
Dr. Garcia was present and was represented by Chris Schulte, Esquire

Dr. Diamond was recused due to participation on the probable cause panel.

Mr. Pietrylo represented and presented for the Department.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(t), F.S. (2015-2016), s. 459.331(1)(m), F.S. (2015-2016) s. 458.331(1)(t), F.S. (2015-2017), s. 458.331(1)(m), F.S. (2015-2017) s. 458.331(1)(t), F.S. (2018-2019), s. 459.331(1)(m), F.S. (2018-2019) s. 458.331(1)(t), F.S. (2018-2019), s. 458.331(1)(m), F.S. (2018-2019) s. 458.331(1)(t), F.S. (2017-2018), s. 458.331(1)(m), F.S. (2017-2018) s. 458.331(1)(t)1, F.S. (2015-2017), s. 458.331(1)(m), F.S. (2015-2017) s. 458.331(1)(nn), F.S. (2015-2017),

Mr. Schulte presented mitigating factors.

Dr. Barsoum, Dr. Zachariah, Mr. Romanello, Dr. Pages, Dr. Derick, and Dr. Benson addressed Dr. Garcia. Dr. Garcia responded to the members questions and comments.

A motion was made, seconded, and carried unanimously to reject the Settlement Agreement as outlined and presented.

A motion was made, seconded, and carried unanimously to counteroffer a recommendation of revocation of license.

Mr. Schulte rejected the counteroffer of revocation on record.

Costs were not addressed.

Penalty imposed: revocation of license

Ravi Chandra, MD – Settlement Agreement 19

Dr. Chandra was present and was represented by Gregory Chaires, Esquire.

Mr. Dunn represented the Department and presented the case.

Mr. Chaires provided a statement presenting mitigating factors.

Dr. Barsoum was recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(g), F.S. (2021)

A motion was made, seconded, and carried unanimously to reject the Settlement Agreement.

A motion was made, seconded, and carried unanimously to dismiss the case.

A motion was made, seconded, and carried unanimously to waive fees and costs for each party.

Penalty imposed: dismissed, fees and costs waived for each party

Dr. Ackerman called a ten-minute break at 10:08 a.m. The meeting reconvened at 10:21 a.m.

Chair Recognition Award: 51

- Emily Heideman - University of South Florida, Morsani College of Medicine
- Chelsea-Jane (CJ) Arcalas - University of Florida, College of Medicine
- John Weng - Florida State University, College of Medicine

Dr. Ackerman and the Board recognized Ms. Heideman, Ms. Arcalas, and Mr. Weng.

Joseph J. Castellano, MD – Settlement Agreement.....1
Dr. Zachariah was recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(nn), F.S. (2020) by violation or rule 64B8-9.009(2)(f), F.A.C.

A motion was made, seconded, and carried unanimously to accept the Settlement Agreement as presented.

Costs were imposed in the amount of $12,584.77.

Penalty imposed: letter of concern, $10,000 fine, $12,584.77 costs, five hours of continuing medical education course in laws, rules, and ethics, permanently restricted from performing gluteal fat transfer/brazilian butt lifts (BBLs)

Leonard A. Benton, MD – Settlement Agreement.....2
No current members were recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(t)1, F.S. (2011)

A motion was made, seconded, and carried unanimously to accept the Settlement Agreement as presented.

Costs were imposed in the amount of $8,517.06.

Penalty imposed: letter of concern, $5,000 fine, $8,517.06 costs, five hours of continuing medical education in risk management

Scott S. Katzman, MD – Settlement Agreement.....3
Dr. Ackerman was recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(k), F.S. 5050 (2019-2020)

A motion was made, seconded, and carried unanimously to accept the Settlement Agreement as presented.

Costs were imposed in the amount of $7,500.00.

Penalty imposed: letter of concern, $5,000 fine, $7,500.00 costs, five hours of continuing medical education course in laws, rules, and ethics, and three hours of continuing medical education in medical recordkeeping

Luis J. Batlle, MD – Settlement Agreement 4
Dr. Barsoum and Mr. Romanello were recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 456.072(1)(bb), F.S. (2021)

A motion was made, seconded, and carried unanimously to accept the Settlement Agreement as presented.

Costs were imposed in the amount of $2,339.20.

Penalty imposed: letter of concern, $2,500 fine, $2,339.20 costs, five hours of continuing medical education in risk management, and present a one-hour lecture/seminar on wrong-site surgery to medical staff at an approved medical facility within 6 months of final order

Richard D. Berkowitz, MD – Settlement Agreement 5
No current members were recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(bb), F.S. (2020)

A motion was made, seconded, and carried unanimously to accept the Settlement Agreement as presented.

Costs were imposed in the amount of $5,443.65.

Penalty imposed: reprimand, $10,000 fine, $5,443.65 costs, five hours of continuing medical education in preventing on wrong-site procedures, and five hours of continuing medical education in risk management

Richard J. Torricelli, MD – Settlement Agreement.....6
No current members were recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(t), F.S. (2017-2019)

A motion was made, seconded, and carried unanimously to accept the Settlement Agreement as presented.

Costs were imposed in the amount of $8,383.73.

Penalty imposed: letter of concern, $5,000 fine, $8,383.73 costs, five hours of continuing medical education in treating kidney disease, and five hours of continuing medical education course in risk management

Joseph M. Sperduto, MD – Settlement Agreement 7
Dr. Vila and Ms. Garcia were recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(t)1, F.S. (2021), s. 458.331(1)(m), F.S. (2021), F.S 458.331(1)(nn), F.S. (2021)

A motion was made, seconded, and carried unanimously to accept the Settlement Agreement as presented.

Costs were imposed in the amount of $4,970.18.

Penalty imposed: Letter of concern, $7,500 fine, $4,970.18 costs, three hours continuing medical education in medical record keeping, and five hours of CME in emergency medicine with focus on cardiac issues

Dr. Wasylik and Ms. Justice were recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(t)(1), F.S. (2019)

A motion was made, seconded, and carried unanimously to accept the Settlement Agreement as presented.

Costs were imposed in the amount of $4,746.25.

Penalty imposed: letter of concern, $5,000 fine, $4,746.25 costs, five hours of continuing medical education in acute cardiac diseases, and five hours of continuing medical education in risk management

Dr. Pages was recused due to participation on the probable cause panel

Allegations of the Administrative Complaint: Violation of s. 458.331(t)1, F.S. (2020), s. 458.331(1)(m), F.S.(2020)

A motion was made, seconded, and carried unanimously to accept the Settlement Agreement as presented.

Costs were imposed in the amount of $4,770.22

Penalty imposed: letter of concern, $5,000 fine, $4,770.22 costs, five hours of continuing medical education in Laws, Rules and Ethics, five hours of continuing medical education in risk management, three hours continuing medical education in medical recordkeeping

Dr. Vila and Ms. Garcia were recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(g), F.S. (2021)

A motion was made, seconded, and carried unanimously to accept the Settlement Agreement as presented.

Costs were imposed in the amount of $2,465.98.

Penalty imposed: letter of concern, $5,000 fine, $2,465.98 costs, five hours of continuing medical education in laws, rules and ethics, and five hours of continuing medical education in risk management

Dr. Ackerman and Mr. Romanello were recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(t), F.S. (2020), s. 458.331(1)(m), F.S. (2020)

A motion was made, seconded, and carried unanimously to accept the Settlement Agreement as presented.

Costs were imposed in the amount of $4,454.56.

Penalty imposed: letter of concern, $5,000 fine, $4,454.56 costs, three hours of continuing medical education in medical recordkeeping, three hours of continuing medical education in follow-up care, five hours of continuing medical education in risk management

Peter K. Harman, MD – Settlement Agreement 12
Dr. Zachariah and Ms. Garcia were recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 456.072(1)(hh), F.S. (2020

A motion was made, seconded, and carried unanimously to accept the Settlement Agreement as presented.

Costs were imposed in the amount of $5,423.27.

Penalty imposed: letter of concern, $1,500 fine, $5,423.27 costs, five hours of continuing medical education course in laws, rules, and ethics

Kim Hiatt, MD – Settlement Agreement 15
Dr. Diamond was recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(b), F.S. (2020-2021)

A motion was made, seconded, and carried unanimously to accept the Settlement Agreement as presented.

Costs were imposed in the amount of $718.15.

Penalty imposed: letter of concern, $1,500 fine, $718.15 costs

Robert C. Estupinan, MD – Settlement Agreement 16
Dr. Pages and Ms. Garcia were recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 456.072(1)(q), F.S.

A motion was made, seconded, and carried unanimously to accept the Settlement Agreement as presented.

Costs were imposed in the amount of $8,567.05.

Penalty imposed: reprimand, $2,500 fine, $8,567.05 costs, five hours continuing medical education course in laws, rules, and ethics

Donald W. Crowe, MD – Settlement Agreement 17
Dr. Barsoum was recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(t), F.S. (2019)

A motion was made, seconded, and carried unanimously to accept the Settlement Agreement as presented.

Costs were imposed in the amount of $4,444.10.

Penalty imposed: letter of concern, $5,000 fine, $4,444.10 costs, five hours of continuing medical education course in risk management, three hours of continuing medical education related to diagnosis and treatment of sepsis

Dr. Wasylik was recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(g), F.S. (2017-2021)

A motion was made, seconded, and carried unanimously to accept the Settlement Agreement as presented.

Costs were imposed in the amount of $609.05.

Penalty imposed: letter of concern, $609.05 costs, five hours of continuing medical education course in laws, rules, and ethics

Dr. Ackerman and Mr. Romanello were recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(t)1, F.S. (2019), s. 456.072(1)(a), F.S. (2019)

A motion was made, seconded, and carried unanimously to accept the Settlement Agreement as presented.

Costs were imposed in the amount of $10,000.00.

Penalty imposed: letter of concern, $5,000.00 fine, $10,000.00 costs, five hours of continuing medical education in risk management

Dr. Ackerman and Mr. Romanello were recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 456.072(1)(bb), F.S. (2019), s. 458.331(1)(nn), F.S. (2019)

A motion was made, seconded, and carried unanimously to accept the Settlement Agreement as presented.

Costs were imposed in the amount of $5,835.18.

Penalty imposed: letter of concern, $5,000 fine, $5,835.18 costs, five hours of continuing medical education in risk management, five hours of continuing medical course in laws, rules, and ethics, lecture on wrong site surgeries to medical staff at an approved medical facility within six months from the date the final order is filed

Dr. Diamond and Ms. Justice were recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 456.072(1)(bb), F.S. (2020)

A motion was made, seconded, and carried unanimously to accept the Settlement Agreement as presented.

Costs were imposed in the amount of $3,106.00.

Penalty imposed: letter of concern, $5,000 fine, $3,106.00 costs, five hours of continuing medical education in risk management, lecture on wrong-site procedures to medical staff at an approved medical facility within six months from the date the final order is filed

Hersell O. Lindo, MD – Settlement Agreement 23
Dr. Barsoum and Mr. Romanello were recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(g), F.S. (2018)

A motion was made, seconded, and carried unanimously to accept the Settlement Agreement as presented.

Costs were imposed in the amount of $1,995.69.

Penalty imposed: permanently restricted from performing an abortion, as term is defined in Section 390.011, F.S., letter of concern, $1,995.69 costs, five hours of continuing medical education in laws, rules, and ethics, three hours of continuing medical education in record keeping

Anita Konka, MD – Determination of Waiver 24
Dr. Konka was present and was represented by Julie Gallagher, Esquire.

Mr. Dunn represented and presented for the Department.

Dr. Pimentel and Mr. Romanello were recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(g), F.S. (2017-2021)

A motion was made, seconded, and carried unanimously that respondent was properly served, and waived their right to elect a formal hearing.

A motion was made, seconded, and carried unanimously admitting the investigative file into evidence.

A motion was made, seconded, and carried unanimously to adopt the Findings of Fact.

A motion was made, seconded, and carried unanimously to adopt the Conclusions of Law and finding the Respondent violated the Florida Statute as charged. Violations set forth do not warrant disciplinary action by the Board.

A motion was made, seconded, and carried unanimously to dismiss the administrative complaint.

A motion was made, seconded, and carried unanimously to waive costs.

Action taken: dismissed

Fernando Lora, MD – Determination of Waiver.....25
Dr Lora was present and was represented by Patrick Sullivan, Esquire.

Dr. Vila and Ms. Garcia were recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(t), F.S. (2019)

A motion was made, seconded, and carried unanimously that respondent was properly served, and waived their right to elect a formal hearing.

A motion was made, seconded, and carried unanimously admitting the investigative file into evidence.

A motion was made, seconded, and carried unanimously to adopt the Findings of Fact.

A motion was made, seconded, and carried unanimously to adopt the Conclusions of Law and finding the Respondent violated the Florida Statute as charged.

A motion was made to impose a penalty of a reprimand, $5,000.00 fine, five hours continuing medical education in risk management.

A motion was made, seconded, and carried unanimously to amend the recommended penalty from a reprimand to a letter of concern, $5,000.00 fine, and five hours of continuing medical education in risk management.

A motion was made, seconded, and carried unanimously to impose costs of $4,863.11.

Penalty imposed: letter of concern, $5,000.00 fine, and five hours of continuing medical education in risk management.

Marco A. Munoz, MD – Determination of Waiver.....26 CONTINUED
This case was continued.

Leonard J. Sonne, MD – Determination of Waiver.....27
Dr. Sonne was not present or represented by counsel.

Dr Pages was recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 456.072(1)(k), F.S. (2018-2022)

A motion was made, seconded, and carried unanimously that respondent was properly served, and waived their right to elect a formal hearing.

A motion was made, seconded, and carried unanimously admitting the investigative file into evidence.

A motion was made, seconded, and carried unanimously to adopt the Findings of Fact.

A motion was made, seconded, and carried unanimously to adopt the Conclusions of Law and finding the Respondent violated the Florida Statute as charged.

A motion was made, seconded, and carried unanimously to impose a penalty of suspension of license until the licensee renews fingerprints.

A motion was made, seconded, and carried unanimously to impose costs in the amount of $435.57.

Penalty imposed: suspension until licensee renews fingerprints

John A. Hubicki, PA – Determination of Waiver 28
Ms. Hubicki was not present or represented by counsel.

Dr. Ackerman was recused due to participation on the probable cause panel. Mr. Romanello chaired this tab due to Dr. Ackerman's recusal.

Mr Pietrylo represented and presented for the Department.

Allegations of the Administrative Complaint: Violation of s. 456.072(1)(q), F.S. (2019)

A motion was made, seconded, and carried unanimously that respondent was properly served, and waived their right to elect a formal hearing.

A motion was made, seconded, and carried unanimously admitting the investigative file into evidence.

A motion was made, seconded, and carried unanimously to adopt the Findings of Fact.

A motion was made, seconded, and carried unanimously to adopt the Conclusions of Law and finding the Respondent violated the Florida Statute as charged.

A motion was made, seconded, and carried unanimously to impose a penalty of reprimand, $1,000.00 fines, five hours of continuing medical education in laws, rules, and ethics course.

A motion was made, seconded, and carried unanimously to impose costs in the amount of $528.84.

Penalty imposed: reprimand, $1,000.00 fines, $528.84 costs, five hours of continuing medical education in laws, rules, and ethics

Daniela C. Bichianu, MD – Determination of Waiver.....29
Dr. Bichianu was not present or represented by counsel.

Dr. Barsoum and Mr. Romanello were recused due to participation on the probable cause panel.

Mr. Ravelo represented and presented for the Department.

Allegations of the Administrative Complaint: Violation of s. 456.072(1)(k), F.S. (2019-2021)

A motion was made, seconded, and carried unanimously that respondent was properly served, and waived their right to elect a formal hearing.

A motion was made, seconded, and carried unanimously admitting the investigative file into evidence.

A motion was made, seconded, and carried unanimously to adopt the Findings of Fact.

A motion was made, seconded, and carried unanimously to adopt the Conclusions of Law and finding the Respondent violated the Florida Statute as charged.

A motion was made, seconded, and carried unanimously to impose a penalty of suspension of license until the licensee renews their fingerprints.

A motion was made, seconded, and carried unanimously to impose costs in the amount of $213.46.

Penalty imposed: suspension of license until licensee renews fingerprints

Donald R. Rhodes, MD – Determination of Waiver.....30
Dr. Rhodes was not present or represented by counsel.

Dr. Barsoum and Mr. Romanello were recused due to participation on the probable cause panel.

Mr. Ravelo represented and presented for the Department.

Allegations of the Administrative Complaint: Violation of s. 456.072(1)(k), F.S. (2019-2021).

Mr. Dierlam spoke and indicated on record an amendment, Dr. Rhodes did timely send election of rights, it wasn't sent to the Board, submitting request as an informal hearing, Bates Page 45665.

A motion was made, seconded, and carried unanimously to allow this case to be reconsidered at the August 2023 board meeting if Dr. Rhodes makes a request for reconsideration of this case.

A motion was made, seconded, and carried unanimously admitting the investigative file into evidence.

A motion was made, seconded, and carried unanimously to adopt the Findings of Fact.

A motion was made, seconded, and carried unanimously to adopt the Conclusions of Law and finding the Respondent violated the Florida Statute as charged.

A motion was made, seconded, and carried unanimously to impose a penalty of letter of concern, and five hours of continuing medical education in laws rules, and ethics.

A motion was made, seconded, and carried unanimously to impose costs in the amount of $245.03.

Penalty imposed: letter of concern, and five hours of continuing medical education in laws rules, and ethics, $245.03 costs

Mohammad T. Javed, MD – Hearing Not Involving Disputed Issues of Material Fact...31

Dr. Javed was present and represented by Lester Perling, Esquire.

Dr. Diamond was recused due to participation on the probable cause panel.

Mr. Pietrylo represented and presented for the Department.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(aa), F.S. (2019)

A motion was made, seconded, and carried unanimously admitting the investigative file into evidence.

A motion was made, seconded, and carried unanimously to adopt the Findings of Fact.

Mr. Perling presented mitigating factors. Dr. Ackerman and Dr. Zachariah spoke on case.

A motion was made, seconded, and carried unanimously to adopt the Conclusions of Law and finding the Respondent violated the Florida Statute as charged.

A motion was made, seconded, and carried unanimously to impose a penalty of a reprimand, $5,000 fine, and five hours of continuing medical education course in Laws, Rules, and Ethics and five hours of continuing medical education course in Risk Management.

A motion was made, seconded, and carried unanimously to impose costs in the amount of $1,881.48.

Penalty imposed: reprimand, $5,000.00 fine, $1,881.48 costs, five hours continuing medical education course on laws, rules, and ethics, and five hours continuing medical education in risk management

James F. Gillen, Jr., PA – Hearing Not Involving Disputed Issues of Material Fact….32
Mr. Gillen was present and represented by Richard Levenstein, Esquire.

Dr. Pages was recused due to participation on the probable cause panel.

Ms. Corrigan represented and presented for the Department.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(b), F.S. (2020)

A motion was made, seconded, and carried unanimously admitting the investigative file into evidence.

A motion was made, seconded, and carried unanimously to adopt the Findings of Fact.

Mr. Levenstein presented mitigating factors.

A motion was made, seconded, and carried unanimously to adopt the Conclusions of Law and finding the Respondent violated the Florida Statute as charged.

A motion was made and seconded to impose a penalty of a letter of concern, and $1,000 fine.

Mr. Levenstein requested leniency from the board and asked for no letter of concern to be issued.

A motion was made, seconded, and carried unanimously to dismiss the administrative complaint.

A motion was made, seconded, and carried unanimously to waive attorney fees and costs.

Action taken: dismissed

Michael R. Fiorucci, MD – Hearing Not Involving Disputed Issues of Material Fact, 33
Dr. Fiorucci was present and represented by David Davidson, Esquire.

Dr. Pages was recused due to participation on the probable cause panel.

Ms. Corrigan represented and presented for the Department.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(b), F.S. (2021)

A motion was made, seconded, and carried unanimously admitting the investigative file into evidence.

A motion was made, seconded, and carried unanimously to adopt the Findings of Fact.

A motion was made, seconded, and carried unanimously to adopt the Conclusions of Law and finding the Respondent violated the Florida Statute as charged.

A motion was made, seconded, and carried unanimously to impose a penalty of a letter of concern, and $1,000 fine.

A motion was made, seconded, and carried unanimously to dismiss the administrative complaint.

A motion was made, seconded, and carried unanimously to waive attorney fees and costs.

Action taken: dismissed

Walter N. Simmons, MD – Hearing Not Involving Disputed Issues of Material Fact..34
This case was continued.

Edriss Estime, MD – Hearing Not Involving Disputed Issues of Material Fact 35
Dr. Estime was present and was not represented by counsel.

Dr. Zachariah was recused due to participation on the probable cause panel.

Mr. Ravelo represented and presented for the Department.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(g), F.S. (2016-2020)

A motion was made, seconded, and carried unanimously admitting the investigative file into evidence.

A motion was made, seconded, and carried unanimously to adopt the Findings of Fact.

Dr. Estime presented mitigating factors for his case.

A motion was made, seconded, and carried unanimously to adopt the Conclusions of Law and finding the Respondent violated the Florida Statute as charged.

A motion was made, and seconded to impose a penalty of a letter of concern, $1,000 fine, and five hours of Laws, Rules, and Ethics Continuing Medical Education course.

Ms. Justice and Dr. Benson addressed Dr. Estime.

A motion was made, and seconded to dismiss the administrative complaint, two opposed.

A motion was made by Dr. Derick to withdraw the motion to dismiss.

A motion was made, and seconded to dismiss the administrative complaint, five opposed.

A motion was made, seconded, and carried unanimously to impose a penalty of $1,000.00 fine.

A motion was made, seconded, and carried unanimously to impose cost in the amount of $77.65.

Penalty imposed: $1,000.00 fine, $77.65 costs

Akhil Maheshwari, MD – Hearing Not Involving Disputed Issues of Material Fact.36
Dr. Maheshwari was present and was not represented by counsel.

Dr. Pages was recused due to participation on the probable cause panel.

Mr. Ravelo represented and presented for the Department.

Allegations of the Administrative Complaint: Violation of s. 456.072(1)(k), F.S. (2020-2022)

A motion was made, seconded, and carried unanimously admitting the investigative file into evidence.

A motion was made, seconded, and carried unanimously to adopt the Findings of Fact.

Dr. Maheshwari presented mitigating factors to the board.

A motion was made, seconded, and carried unanimously to adopt the Conclusions of Law and finding the Respondent violated the Florida Statute as charged.

A motion was made and seconded to impose a penalty of a letter of concern, and five hours of Laws, Rules, and Ethics Continuing Medical Education course.

Dr. Zachariah indicated Dr. Maheshwari has a valid explanation, and we should have empathy and show leniency in this case.

A motion was made, seconded, and carried unanimously dismiss the administrative complaint.

A motion was made, seconded, and carried unanimously to waive fees and costs.

Penalty imposed: dismissed

Marwan Wiggins, MD – Hearing Not Involving Disputed Issues of Material Fact ..37
This case was continued.

Venkatesh V. Madhav, MD – Hearing Not Involving Disputed Issues of Material Fact..38

Dr. Madhav was not present or represented by counsel.

Dr. Pimentel and Mr. Romanello were recused due to participation on the probable cause panel.

Mr. Pietrylo represented and presented for the Department.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(b), F.S. (2021)

A motion was made, seconded, and carried unanimously admitting the investigative file into evidence.

A motion was made, seconded, and carried unanimously to adopt the Findings of Fact.

A motion was made, seconded, and carried unanimously to adopt the Conclusions of Law and finding the Respondent violated the Florida Statute as charged.

A motion was made and seconded to impose a penalty of revocation.

Mr. Pietrylo advised Dr. Madhav is currently not licensed in Florida, the license status is Null and Void due to non-renewal of the license.
A motion was made, seconded, and carried unanimously to impose a penalty of suspension of license until such time as respondent can demonstrate to the Board that license is unencumbered and free from any restrictions or conditions in any and all jurisdictions where licensed.

A motion was made, seconded, and carried unanimously to impose costs in the amount of $74.14.

Penalty imposed: suspension of license, $74.14 costs

Ulysses C. Walls, MD – Hearing Not Involving Disputed Issues of Material Fact....39
Dr. Walls was present and was not represented by counsel.

Dr. Pimentel was recused due to participation on the probable cause panel.

Mr. Ravelo represented and presented for the Department.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(b), F.S.(2020)

A motion was made, seconded, and carried unanimously admitting the investigative file into evidence.

A motion was made, seconded, and carried unanimously to adopt the Findings of Fact.

Dr. Walls presented mitigating factors to the board.

A motion was made, seconded, and carried unanimously to adopt the Conclusions of Law and finding the Respondent violated the Florida Statute as charged.

A motion was made to impose a penalty of a letter of concern, $1,000 fine, and five hours of laws, rules, and ethics continuing medical education course, and two hours of HIPPA continuing medical education course.

A motion was made, seconded, and carried with one opposed to dismiss the administrative complaint.

Penalty imposed: dismissed

Sameh S. Wahba, MD – Hearing Not Involving Disputed Issues of Material Fact...40
Dr. Wahba was not present or represented by counsel.

No current members were recused due to participation on the probable cause panel.

Ms. Corrigan represented and presented for the Department.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(b), F.S. (2019)

A motion was made, seconded, and carried unanimously admitting the investigative file into evidence.

A motion was made, seconded, and carried unanimously to adopt the Findings of Fact.

A motion was made, seconded, and carried unanimously to adopt the Conclusions of Law and finding the Respondent violated the Florida Statute as charged.

A motion was made, seconded, and carried unanimously to impose a penalty of permanently restricted from prescribing controlled substances, permanently restricted from treating or examining female patients, $2,500 fine, five hours of Laws, Rules, and Ethics continuing medical education course, and five hours of Recordkeeping continuing medical education course.

A motion was made, seconded, and carried unanimously to impose costs in the amount of $183.10.

Penalty imposed: permanently restricted from prescribing controlled substances, permanently restricted from treating or examining female patients, $2,500 fine, five hours of continuing medical education in laws, rules, and ethics, and five hours of continuing medical education in recordkeeping

Gunter Rincon, MD – Hearing Not Involving Disputed Issues of Material Fact 41
This case was continued.

Enrique L. Gomez, MD – Hearing Not Involving Disputed Issues of Material Fact 42
This case was continued to October 2023 meeting.

Richard J. Schubatis, MD – Hearing Not Involving Disputed Issues of Material Fact43
Dr. Schubatis was not present or represented by counsel.

No current members were recused due to participation on the probable cause panel.

Mr. Dunn represented and presented for the Department.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(b), F.S. (2022)

A motion was made, seconded, and carried unanimously admitting the investigative file into evidence.

A motion was made, seconded, and carried unanimously to adopt the Findings of Fact.

A motion was made, seconded, and carried unanimously to adopt the Conclusions of Law and finding the Respondent violated the Florida Statute as charged.

A motion was made, seconded, and carried unanimously to impose a penalty of a reprimand.

A motion was made, seconded, and carried unanimously to impose costs in the amount of $206.76.

Penalty imposed: reprimand, $206.76 costs

Voluntary Relinquishments:
Maurice G. McCabe, MD – Voluntary Relinquishment..... 44
Dr. McCabe was not present or represented by counsel.

No current members were recused due to participation on the probable cause panel.

A motion was made, seconded, and carried unanimously to accept the voluntary relinquishment.

Action taken: voluntary relinquishment accepted

Endre Kovacs, MD – Voluntary Relinquishment.....45
Dr. Kovacs was not present or represented by counsel.

No current members were recused due to participation on the probable cause panel.

A motion was made, seconded, and carried unanimously to table.

Action taken: tabled

James A. Cocores, MD – Voluntary Relinquishment.....46
Dr. Cocores was not present or represented by counsel.

No current members were recused due to participation on the probable cause panel.

A motion was made, seconded, and carried unanimously to table.

Action taken: tabled

FINAL ORDER COMPLIANCE
Matthew D. Brown, PA. – Petition for Reinstatement 49
Dr. Brown was present and was represented by Michael Smith, Esquire.

No current members were recused.

Dr. Polles from Professional Resource Network (PRN) was in attendance, and indicated Dr. Brown remains in compliance with PRN, and is safe to practice. PRN supports Dr. Brown's reinstatement.

A motion was made, seconded, and carried unanimously to reinstate license.

Action taken: motion to reinstate license

Aivlys Perez, M.D. – Request for Modification of the Final Order.....50
Dr. Pages was recused due to participation on the probable cause panel.

A motion was made, seconded, and carried unanimously to deny the request for modification of final order.

Action taken: motion denied

UNTIMED ITEMS:

Board Chair's Remarks: .....No tab
Dr. Ackerman made spoke on attending the FSMB Conference.

Board Counsel's Remarks:.....No tab
Mr. Dierlam had no remarks.

Board Director's Remarks: 47
Mr. Vazquez spoke to the Board regarding the following topics:

- Legislative Update
- Financial Disclosure Forms
- Florida Prescription Drug Monitoring Program (PDMP) Monthly Report

Department Remarks: 53

- Year-Old Case Report.....**Addendum in Version 4**
- Appellate.....**Addendum in Version 4**

Mr. Pietrylo presented the Appellate Report and Year-Old Case Report to Board members.

Action taken: A motion was made to continue prosecution of year old and older cases, seconded, and carried unanimously

Council on Physician Assistants:
Dr. Barsoum presented the report for the Council on Physician Assistants meeting held on May 25, 2023.

Action taken: A motion was made to approve the report, seconded, and carried unanimously

Committee Reports:
Credentials Committee.....No tab
Ms. Justice presented the report for the Credentials Committee meeting held on June 1, 2023.

Action taken: A motion was made to approve the report, seconded, and carried unanimously

Boards of Medicine and Osteopathic Medicine's Joint Committee on Surgical Care/Quality Assurance Committee.....No tab
Dr. Derick presented the report for the Joint Committee on Surgical Care/Quality Assurance meeting held on June 1, 2023.

Action taken: A motion was made to approve the report, seconded, and carried unanimously

Rules/Legislative Committee.....No tab
Dr. Zachariah presented the report for the Rules and Legislative Committee meeting held on June 1, 2023.

Action taken: A motion was made to approve the report, seconded, and carried unanimously

Joint Rules/Legislative Committee.....No tab
Dr. Zachariah presented the report for the Joint Rules and Legislative Committee meeting held on June 1, 2023.

SERC for Emergency Rule Language

Will the proposed rule amendments have an adverse impact on small business?

A motion was made in the negative, seconded, and carried unanimously.

Is the proposed rule amendment likely to directly or indirectly increase regulatory costs to any entity, including government, in excess of $200,000 in the aggregate in Florida within one year after implementation?

A motion was made in the negative, seconded, and carried unanimously.

Will this rule amendment create an offense that would constitute a minor violation under the rule?

A motion was made in the negative, seconded, and carried unanimously.

Does the Board/Committee want to impose a sunset provision for this rule or rule amendment?

A motion was made in the negative, seconded, and carried unanimously not to impose a sunset provision.

Action taken: A motion was made to approve the report, seconded, and carried unanimously

Probation Committee.....No tab
Dr. Pages presented the report for the Probation Committee meeting held on May 25, 2023.

Action taken: A motion was made to approve the report, seconded, and carried unanimously

Approval of Meeting Minutes:.....48
March 31, 2023, Board Meeting

Action taken: A motion was made to approve minutes of the Boards February meetings, seconded, and carried unanimously.

Ratification of Applicants Pursuant to Chapter 458, F.S......52

Action taken: A motion was made to ratify applicants, seconded, and carried unanimously

Other Business

No other business to discuss.

New Business

No new business to discuss.

Meeting Adjourned at 1:35 p.m.

Notice of Meeting/Workshop Hearing

DEPARTMENT OF HEALTH
Board of Medicine

The **Florida Boards of Medicine and Osteopathic Medicine's Joint Rules/Legislative Committee** announces a public meeting to which all persons are invited.

DATE AND TIME: Friday, June 23, 2023, beginning at 1:00 PM EDT, or soon thereafter.

PLACE: The Aloft Jacksonville Tapestry Park, 4812 Deer Lake Drive West, Jacksonville, Florida 32246. The hotel's phone number is (904)998-4448. The hotel's website is https://www.marriott.com/en-us/hotels/jaxtl-aloft-jacksonville-tapestry-park/overview/. The public rate is $129 per night.

GENERAL SUBJECT MATTER TO BE CONSIDERED: General business of the Committee. Committee meetings may be canceled prior to the meeting date. Please check the Board's website at https://flboardofmedicine.gov/meeting-information for cancellations or changes to the meeting date or time or call the Board at (850)245-4131 for more information.

Any person who wants to make public comments at the rule hearing must notify Board staff in writing. Speaker cards will be available at the rule hearing for this purpose. Public comments will be limited to three minutes per person. This time will not include time spent by the public commenter responding to questions imposed by Board members, staff, or board counsel. If a group or faction of persons consisting of five or more persons wishes to address the Boards, please identify one individual who will speak on behalf of the group. Public commenters may use pseudonyms if they do not wish to identify themselves on the record. All public comments received at the workshop will become part of the rulemaking record.

Written public comments may be submitted to the Boards between the publication of this notice until 5:00 p.m. EDT on June 20, 2023. The email address for such submissions is BOMPublicComment@flhealth.gov. All comments received at this email address, including the sender's email address, are public records and will become part of the published rulemaking record.

A copy of the agenda may be obtained by contacting: https://flboardofmedicine.gov/meeting-information.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 7 days before the workshop/meeting by contacting the Board by email at BOM.MeetingMaterials@flhealth.gov or by calling the Board at (850)245-4131.

If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.

For more information, you may contact: the Board at BOM.MeetingMaterials@flhealth.gov or by calling the Board at (850)245-4131.

Notice of Meeting/Workshop Hearing

DEPARTMENT OF HEALTH

Board of Osteopathic Medicine

The Florida Boards of Medicine and Osteopathic Medicine's Joint Rules/Legislative Committee announces a public meeting to which all persons are invited.

DATE AND TIME: Friday, June 23, 2023, 1:00 p.m., EDT, or soon thereafter.

PLACE: The Aloft Jacksonville Tapestry Park, 4812 Deer Lake Drive West, Jacksonville, Florida 32246. The hotel's phone number is (904)998-4448. The hotel's website is https://www.marriott.com/en-us/hotels/jaxtl-aloft-jacksonville-tapestry-park/overview/. The public rate is $129 per night.

GENERAL SUBJECT MATTER TO BE CONSIDERED: General business of the Committee. Committee meetings may be canceled prior to the meeting date. Please check the Board's website at https://flboardofmedicine.gov/meeting-information for cancellations or changes to the meeting date or time or call the Board at (850)245-4131 for more information.

Any person who wants to make public comments at the rule hearing must notify Board staff in writing. Speaker cards will be available at the rule hearing for this purpose. Public comments will be limited to no more than three minutes per person. This time will not include time spent by the public commenter responding to questions imposed by Committee members, staff, or board counsel. If a group or faction of persons consisting of five or more persons wishes to address the Committee, please identify one individual who will speak on behalf of the group. Public commenters may use pseudonyms if they do not wish to identify themselves on the record. All public comments received at the workshop will become part of the rulemaking record.

Written public comments may be submitted to the Committee between the publication of this notice until 5:00 p.m., EDT on June 19, 2023. The email address for such submissions is BOMPublicComment@flhealth.gov. All comments received at this email address, including the sender's email address, are public records and will become part of the published rulemaking record.

A copy of the agenda may be obtained by contacting: https://flboardofmedicine.gov/meeting- information.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 7 days before the workshop/meeting by contacting: the Board by email at BOM.MeetingMaterials@flhealth.gov or by calling the Board at (850)245-4131. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.

For more information, you may contact: the Board at BOM.MeetingMaterials@flhealth.gov or by calling the Board at (850)245-4131.

Florida Boards of Medicine and Osteopathic Medicine
Joint Rules and Legislative Committee Meeting

Aloft Jacksonville Tapestry Park
4812 Deer Lake Drive West
Jacksonville, FL 32246
904-998-4448

June 23, 2023

AGENDA

Participants in this public meeting should be aware that the proceedings are being recorded and that an audio file of the meeting will be posted to the boards' websites.

Roll call will be at 1:00 p.m. or shortly thereafter.

Old Business

New Business

Florida Boards of Medicine and Osteopathic Medicine
Joint Rules/Legislative Committee Meeting

Aloft Jacksonville Tapestry Park
4812 Deer Lake Drive West
Jacksonville, FL 32246
904-998-4448

MEETING MINUTES

The meeting was called to order at 1:01 p.m. on June 23, 2023, by Mr. Nicholas Romanello. Roll call was conducted by Cherise Strickland, Program Operations Administrator.

Members Present:
Nicholas Romanello, Esq., Consumer Member, Acting Chair
Scot Ackerman, M.D.
Matthew Benson, M.D.
Amy Derick, M.D.
Tiffany Sizemore DiPietro, D.O.
William Kirsh, D.O.
Monica Mortensen, D.O.

Members Absent:
David Diamond, M.D.
Maria Garcia, Esq., Consumer Member
Patrick Hunter, M.D.
Luz Marina Pages, M.D.
Zachariah Zachariah, M.D.

Staff Present:
Paul Vazquez, J.D., Executive Director BOM
Danielle Terrell, Executive Director BOOM
Christopher Dierlam, Board Counsel
Cassandra Fullove, Certified Paralegal
Cherise Strickland, Program Operations Administrator
Cyra Williams, Regulatory Specialist III
Michelle DeVeas, Administrative Assistant II
Brad Dalton, Public Information Officer

Court Reporter:
Cynthia Green
Magnolia Court Reporting
407-896-1813

Mr. Vazquez provided opening remarks and instructions on the conduct of the meeting. Mr. Vazquez reminded everyone that this is a publicly noticed meeting, the proceedings are being recorded, and an audio file of the meeting will be posted to both Boards' websites.

Mr. Vazquez summarized SB 254, which was signed into law and became effective upon Governor DeSantis' signing on May 17, 2023. The law enacted requires the Board of Medicine and the Board of Osteopathic Medicine to adopt rules within 60 days establishing practice standards for the continuing treatment of minors already receiving treatment prior to the signing of the law, including the development of any necessary informed consent forms. The law also requires the Boards to adopt emergency rules establishing informed consent forms for adults; however, the 60-day time frame is not a requirement for the adult informed consent forms.

Mr. Vazquez advised today we will work on finalizing the practice standards for the treatment of gender dysphoria in minors, and on finalizing draft versions of the informed consent forms for the treatment of gender dysphoria in both minors and adults. Mr. Vazquez advised there will be a subsequent joint full board meeting on June 30, 2023, at 1:00 p.m.

Ms. Terrell did not provide any comments.

Old Business

There was no old business to discuss.

Action taken:

No action taken.

New Business

Mr. Romanello provided an overview of the related meetings already held on prior dates, noting the impressive number of public comments received to date. The next meeting being held will be a virtual joint board meeting on June 30, 2023. Mr. Romanello advised today, the committee has six different draft informed consent forms and two emergency rule drafts to review, the committee will take up discussion of the consent forms first and then discuss the two draft emergency rules. Mr. Romanello advised public comments will be taken until 4:30 p.m. and we will close the meeting at 5:00 p.m.

Dr. Ackerman provided welcoming remarks to the public in attendance, thanking them for being present today. Dr. Ackerman asked the public for constructive feedback and comments.

Mr. Romanello advised at the June 23, 2023, Joint Rules/Legislative Committee Meeting, the committee approved and delegated Drs. Benson and Mortensen to help develop informed consent drafts and present to the committee.

Discussion began on Bates page 264 reviewing draft consent form, Puberty Suppression Treatment for Patients with Gender Dysphoria in Minors. Dr. Derick asked will these forms be the mandatory minimum forms? Ms. McNulty answered, yes, a physician may have additional forms, if desired, but a physician must have our forms, as a minimum. Mr. Romanello, Drs. Benson, Derick, and DiPietro suggested amendments to the form, discussion continued. Motion was made, seconded, and approved unanimously to amend the form with changes as discussed on record.

Discussion began on Bates page 272 reviewing draft consent form, Feminizing Medications for Patients with Gender Dysphoria in Minors. Drs. DiPietro, Benson, and Mr. Romanello suggested amendments to the form, discussion continued. A motion was made, seconded, and approved unanimously to amend the form with all changes as discussed on record.

Discussion began on Bates page 284 reviewing draft consent form, Masculinizing Medications for Patients with Gender Dysphoria in Minors. Dr. Benson made comments and suggested amendments to the form, discussion continued. Ms. Terrell suggested a change to remove, requirement #2, from Bates page 285, it is a duplicate of requirement #1. A motion was made, seconded, and approved unanimously to amend the form with changes as discussed on record.

Discussion began on Bates page 298 reviewing draft consent form, Feminizing Medications for Patients with Gender Dysphoria in Adults. Dr. Derick made comments and suggested amendments

to the form. Discussion on this draft form will continue after public comments.

Discussion began on Bates page 308 reviewing draft consent form, Testosterone Treatment for Patients with Gender Dysphoria in Adults. Drs. DiPietro and Benson made comments and suggested amendments to the form, discussion continued. Mr. Vazquez suggested a change in the name of the form to mirror the other forms. The current name of the form reads Testosterone Treatment for Patients with Gender Dysphoria. The suggested amended name of the form would read Masculine Medications for Patients with Gender Dysphoria. A motion was made, seconded, and approved unanimously to amend the form with all changes as discussed on record.

Discussion began on Bates page 317 reviewing draft consent form, Surgical Treatment for Adults with Gender Dysphoria. Dr. Benson made comments and suggested amendments to the form, discussion continued. A motion was made, seconded, and approved unanimously to amend the form with all changes as discussed on record.

Mr. Romanello called a short break at 3:00 p.m. After the break, the draft emergency rules will be addressed, and we will take public comments until 4:30 p.m. Mr. Romanello reconvened and called the meeting back to order at 3:11p.m.

Mr. Romanello began discussion of the draft emergency rule for minors on Bates page 295, titled Sex-reassignment Standards in Minors. Ms. McNulty suggested a modification on Bates page 295 under subsection (4) Standards of Practice, to strike "Clinical determinations" from subsection (4) entirely, it is redundant. A motion to strike was made, seconded, and approved unanimously to amend as discussed on record.

Ms. McNulty suggested a modification on Bates page 296, subsection (4)(b) item #4, strike "adequate" from the sentence. A motion to strike was made, seconded, and approved unanimously to amend as discussed on record.

Ms. McNulty suggested a modification on Bates page 296 subsection (4)(g) currently reads "Bone (DEXA) Scan", strike and replace with "Bone Density Scan (DEXA)".

Dr. Derick suggested a modification of subsection (4)(c) Patient Visit. on Bates page 296 regarding the "physician or covering physician" verbiage addition. A motion to carry over the approved language from the informed consent forms was made, seconded, and approved unanimously to amend as discussed on record.

Dr. Benson asked questions regarding Bates 295 subsection (3)(a-d). What does assent to the informed consent form mean? Dr. Benson asked if this assent is the minor child signing to give permission? Ms. McNulty answered, yes that is correct.

Dr. Benson asked if it is standard to have a witness on the consent forms? Ms. McNulty answered, it is consistent with other types of consent forms. Dr. DiPietro indicated every consent form she has seen in the hospital has a witness signature.

Mr. Romanello began discussion of the draft emergency rule for adults on Bates page 323, titled Mandatory Standardized Informed Consent for Sex-reassignment Procedures in Adults. Mr. Dierlam indicated board counsel does not have any technical change amendments to request.

Mr. Romanello began the public comment portion of the meeting by inviting any public attendee to form a line who has any comments to provide on relevant scope issues related to the informed consent forms or the rules. Each speaker was given three minutes to speak. Mr. Romanello asked Dr. Ackerman to assist with the pronunciation of the drug names and four questions the public is being asked to comment on. Dr. Ackerman stated the four questions the committee would like addressed are:

1. Is there widespread use or any use of testosterone in any form?
2. Is there use of Bicalutamide (brand name Casodex) in the pediatric population?
3. Is there use of Finasteride (also more commonly known as Proscar) for hair loss for male pattern baldness in the pediatric population?
4. Is Cyproterone acetate available in the United States? Is it being prescribed by physicians? Is it being recommended by physicians?

Mr. Romanello recognized the first public speaker; a line was formed, and the public continued to make comments in that format. A total of twenty-three individuals spoke and provided public comment. Public comments continued until 4:30 p.m.

Mr. Romanello advised we will move towards consideration and vote on informed consent forms and the emergency rules.

Mr. Romanello asked the committee if they had any changes or responses to the public comments we have heard this afternoon. No comments were provided, or amendments requested by the committee.

A motion was made, seconded, and approved unanimously to adopt the informed consent forms for minors and emergency rule language as amended on record.

SERC

Will the proposed rule amendments have an adverse impact on small business? Is the proposed rule amendment likely to directly or indirectly increase regulatory costs to any entity, including government, in excess of $200,000 in the aggregate in Florida within one year after implementation?

A motion was made in the negative, seconded, and carried unanimously.

Will this rule amendment create an offense that would constitute a minor violation under the rule?

A motion was made in the negative, seconded, and carried unanimously.

Does the Board/Committee want to impose a sunset provision for this rule or rule amendment?

A motion was made in the negative, seconded, and carried unanimously not to impose a sunset provision.

Action taken:

Approved the informed consent forms for minors and the emergency rule language as amended on record.

Mr. Romanello asked the committee for any changes or responses to the public comments we have heard this afternoon.

Dr. Derick spoke on the informed consent forms for adults, she believes the audience had a lot of compelling comments. Beginning on Bates page 309 there are some items to address on both the Masculinizing Medication for Patients with Gender Dysphoria in Adults form and the Feminizing Medications for Patients with Gender Dysphoria in Adults form regarding HRT, #1 - #14. Dr. Derick indicates she thinks we should consider removing some of the requirements on the consent forms for adults. Discussion continued among the committee.

Dr. DiPietro provided a suggestion to add a recommendation statement for #9 - #14. Dr. Derick agreed this is a great compromise to separate the items and add a recommendation statement for

items #9 - #14. Dr. Derick stated it is important for us to not lose our transgender patients for lack of follow-up.

Mr. Romanello asked the committee to consider a new section that reads, "the following may also be recommended by the prescribing physician for an individual to receive or continue to receive HRT treatment". This will apply to #9 - #14 and would be placed in its own subsection. This will apply to both the masculinizing and feminizing adult informed consent forms.

A motion was made, seconded, and approved unanimously to add an additional section after #8, the following may also be recommended by the prescribing physician for an individual to receive or continue to receive HRT treatment.

A motion was made, seconded, and approved unanimously to adopt the informed consent forms as amended and the emergency rule as amended.

Action taken:

Approved the informed consent forms for adults and the emergency rule language as amended on record.

SERC

Will the proposed rule amendments have an adverse impact on small business? Is the proposed rule amendment likely to directly or indirectly increase regulatory costs to any entity, including government, in excess of $200,000 in the aggregate in Florida within one year after implementation?

A motion was made in the negative, seconded, and carried unanimously.

Will this rule amendment create an offense that would constitute a minor violation under the rule?

A motion was made in the negative, seconded, and carried unanimously.

Does the Board/Committee want to impose a sunset provision for this rule or rule amendment?

A motion was made in the negative, seconded, and carried unanimously not to impose a sunset provision.

The meeting adjourned at 4:54 p.m.

Notice of Meeting/Workshop Hearing

DEPARTMENT OF HEALTH
Board of Medicine

The **Florida Boards of Medicine and Osteopathic Medicine** announce a joint public meeting to which all persons are invited.

DATE AND TIME: Friday, June 30, 2023, beginning at 1:00 PM EDT, or soon thereafter.

PLACE: A virtual public meeting will be held via TEAMS Webinar.

GENERAL SUBJECT MATTER TO BE CONSIDERED: General business of the Board. Board meetings may be canceled prior to the meeting date. Please check the Board's website at https://flboardofmedicine.gov/meeting-information for cancellations or changes to the meeting date or time or call the Board at (850)245-4131 for more information.

Any person who wants to attend the public meeting must register at https://www.floridahealth.gov/2023-06-30_JointBoardMeeting. This link will be active from the time of publication of this notice until the conclusion of the meeting. If any member of the public wants to offer comments during the meeting relating to an item on the published agenda, they must indicate their desire to do so during the registration process. Due to time constraints, not everyone who indicates their desire to make comments will be guaranteed to have the opportunity to do so. Public comments will be limited to no more than three minutes per person. This time will not include time spent by the public commenter responding to questions imposed by Board members, staff, or Board counsel. If a group or faction of persons consisting of five or more persons wishes to address the Board, please identify one individual who will speak on behalf of the group. Public commenters may use pseudonyms if they do not wish to identify themselves on the record. In lieu of providing comments during the meeting, members of the public may participate in the public hearing as listeners only. Upon completion of the registration process, registrants will be provided a link to join the webinar at the designated time. A telephone number will also be provided for those without the necessary computer hardware to participate in the webinar via the internet and for those who desire only to listen to the webinar. The public hearing will be recorded. All public comments received at the meeting will become part of the rulemaking record. A recording of the meeting will be available on the Board's websites the week following the meeting.

Written public comments may be submitted to the Board between the publication of this notice until 24 hours following the conclusion of the meeting. The email address for such submissions is BOMPublicComment@flhealth.gov. All comments received at this email address, including the sender's email address, are public records and will become part of the rulemaking record.

A copy of the agenda may be obtained by contacting: https://flboardofmedicine.gov/meeting- information.

Public participation in this meeting is solicited without regard to race, color, national origin, age, sex, religion, disability, or family status.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 7 days before the workshop/meeting by contacting the Board by email at BOM.MeetingMaterials@flhealth.gov or by calling the Board at (850)245-4131.

If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.

For more information, you may contact: the Board at BOM.MeetingMaterials@flhealth.gov or by calling the Board at (850)245-4131.

Notice of Meeting/Workshop Hearing

DEPARTMENT OF HEALTH
Board of Osteopathic Medicine

The **Florida Boards of Medicine and Osteopathic Medicine** announce a joint public meeting to which all persons are invited.

DATE AND TIME: Friday, June 30, 2023, beginning at 1:00 PM EDT, or soon thereafter.

PLACE: A virtual public meeting will be held via TEAMS Webinar.

GENERAL SUBJECT MATTER TO BE CONSIDERED: General business of the Board. Board meetings may be canceled prior to the meeting date. Please check the Board's website at https://flboardofmedicine.gov/meeting-information for cancellations or changes to the meeting date or time or call the Board at (850)245-4131 for more information.

Any person who wants to attend the public meeting must register at https://www.floridahealth.gov/2023-06-30_JointBoardMeeting. This link will be active from the time of publication of this notice until the conclusion of the meeting. If any member of the public wants to offer comments during the meeting relating to an item on the published agenda, they must indicate their desire to do so during the registration process. Due to time constraints, not everyone who indicates their desire to make comments will be guaranteed to have the opportunity to do so. Public comments will be limited to no more than three minutes per person. This time will not include time spent by the public commenter responding to questions imposed by Board members, staff, or Board counsel. If a group or faction of persons consisting of five or more persons wishes to address the Board, please identify one individual who will speak on behalf of the group. Public commenters may use pseudonyms if they do not wish to identify themselves on the record. In lieu of providing comments during the meeting, members of the public may participate in the public hearing as listeners only. Upon completion of the registration process, registrants will be provided a link to join the webinar at the designated time. A telephone number will also be provided for those without the necessary computer hardware to participate in the webinar via the internet and for those who desire only to listen to the webinar. The public hearing will be recorded. All public comments received at the meeting will become part of the rulemaking record. A recording of the meeting will be available on the Board's websites the week following the meeting.

Written public comments may be submitted to the Board between the publication of this notice until 24 hours following the conclusion of the meeting. The email address for such submissions is BOMPublicComment@flhealth.gov. All comments received at this email address, including the sender's email address, are public records and will become part of the rulemaking record.

A copy of the agenda may be obtained by contacting: https://flboardofmedicine.gov/meeting- information.

Public participation in this meeting is solicited without regard to race, color, national origin, age, sex, religion, disability, or family status.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 7 days before the workshop/meeting by contacting the Board by email at BOM.MeetingMaterials@flhealth.gov or by calling the Board at (850)245-4131.

If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.

For more information, you may contact: the Board at BOM.MeetingMaterials@flhealth.gov or by calling the Board at (850)245-4131.

Florida Boards of Medicine and Osteopathic Medicine
Joint Board Meeting

You may register to attend the meeting from your computer, tablet, or smartphone through the following link:
https://www.floridahealth.gov/2023-06-30_JointBoardMeeting

June 30, 2023

AGENDA

Participants in this public meeting should be aware that the proceedings are being recorded and an audio file of the meeting will be posted to the boards' websites.

Roll call will be at 1:00 p.m. or shortly thereafter.

Old Business

New Business

Florida Boards of Medicine and Osteopathic Medicine
Joint Board Meeting

You may register to attend the meeting from your computer, tablet, or smartphone through the following link:
https://www.floridahealth.gov/2023-06-30_JointBoardMeeting

MEETING MINUTES

CALL TO ORDER

The meeting was called to order at 1:00 p.m. on June 30, 2023, by Scot Ackerman, M.D., Chair, Board of Medicine. Dr. Ackerman introduced William Kirsh, D.O., Acting Chair, Board of Osteopathic Medicine.

ROLL CALL

Roll call for the Board of Medicine was conducted by Cherise Strickland, Program Operations Administrator.

Roll call for the Board of Osteopathic Medicine was conducted by Danielle Terrell, Executive Director.

Those present for all or part of the meeting included the following:

Board of Medicine Members Present:
Scot Ackerman, M.D., Chair
Nicholas Romanello, Esq., Consumer Member, Vice Chair
Gregory Coffman, M.D.
Amy Derick, M.D.
Maria Garcia, Esq., Consumer Member
Patrick Hunter, M.D.
Luz Marina Pages, M.D.
Hector Vila, M.D.
Zachariah Zachariah, M.D.

Board of Medicine Members Absent:
Wael Barsoum, M.D.
Matthew Benson, M.D.
David Diamond, M.D.
Nicole Justice, Consumer Member
Eleonor Pimentel, M.D.
Michael Wasylik, M.D.

Board of Osteopathic Medicine Members Present:
William Kirsh, D.O., Vice Chair
Chris Creegan, Consumer Member
Watson Ducatel, D.O.
Valerie Jackson, Consumer Member
Monica Mortensen, D.O.
Gregory Williams, D.O.

Board of Osteopathic Medicine Members Absent:
Tiffany DiPietro, D.O., Chair

Department Staff Present:
Paul Vazquez, J.D., Executive Director, BOM
Danielle Terrell, Executive Director, BOOM
Christopher Dierlam, Board Counsel
Donna McNulty, Board Counsel
David Flynn, Board Counsel
Cassandra Fullove, Senior Legal Assistant
Cherise Strickland, Program Operations Administrator, BOM
Carol Taylor, Program Operations Administrator, BOOM
Brad Dalton, Public Information Officer

Court Reporter:
Cynthia Green
Magnolia Court Reporting
407-896-1813

OPENING REMARKS

Mr. Vazquez provided opening remarks and instructions on the conduct of the meeting. Mr. Vazquez reminded everyone that this is a publicly noticed meeting, the proceedings are being recorded, and an audio file of the meeting will be posted to both Boards' websites.

Mr. Vazquez summarized SB 254, which was signed into law and became effective upon Governor DeSantis' signing on May 17, 2023. The law as enacted requires the Board of Medicine and the Board of Osteopathic Medicine to adopt rules within 60 days establishing practice standards for the continuing treatment of minors already receiving treatment prior to the signing of the law, including the development of any necessary informed consent forms. The law also requires the Boards to adopt emergency rules establishing informed consent forms for adults; however, the 60-day time frame is not a requirement for the adult informed consent forms.

Mr. Vazquez advised the Boards will consider actions taken at the interim meeting held on June 23, 2023, where the committee worked on finalizing the practice standards for the treatment of gender dysphoria in minors and finalizing draft versions of the informed consent forms for the treatment of gender dysphoria in both minors and adults.

Ms. Terrell did not provide any comments.

Old Business

There was no old business to discuss.

New Business

Rules 64B8-9.019 and 64B15-14.014, F.A.C. – Standards of Practice for the Treatment of Gender Dysphoria in Minors 1

- Emergency rule relating to the standard of care for the treatment of gender dysphoria in minors
- Emergency rule relating to informed consent for the treatment of gender dysphoria in Minors
- Discussion of potential rule amendments in light of Chapter 2023-90, Laws of Florida (CS/SB 254)

Rules 64B8-9.XXX and 64B15-14.XXX, F.A.C. – Informed Consent for the Treatment of Gender Dysphoria in Adults 2

- Emergency rule relating to informed consent for the treatment of gender dysphoria in adults

Dr. Ackerman provided opening remarks and instructions on the conduct of the meeting. Dr. Ackerman summarized SB 254 and provided a brief overview of the related meetings held on prior dates. Dr. Ackerman advised that the discussion would begin with the emergency rule for minors.

Discussion began on Bates page 67 reviewing the draft emergency rule for minors, titled Sex-reassignment Standards of Practice in Minors. Ms. McNulty advised that form numbers had been issued for all informed consent forms. Ms. McNulty advised the informed consent forms will be available on the Board's website rather than the Department of State website. Dr. Vila expressed his views on the drafted rules and indicated that he is comfortable with them.

Discussion began on Bates page 4, Puberty Suppression Treatment for Patients with Gender Dysphoria in Minors. Mr. Vazquez advised there were no changes recommended to the form. Mr. Romanello thanked Drs. Benson and Mortensen for all the work they put in on the informed consent forms.

Discussion continued on Bates page 6, Puberty Suppression Treatment for Patients with Gender Dysphoria in Minors. Dr. Ackerman provided comments and advised he was happy with the form. Dr. Derick suggested amendments to the form, discussion continued. Dr. Derick suggested a change to the first requirement on Bates page 6, to replace the first word "Meets" with the words "Has met." A motion was made, seconded, and approved unanimously to amend the form with changes as discussed on record.

Discussion continued on Bates page 4. Dr. Hunter suggested amendments to the third paragraph to remove "with gender dysphoria" at the end of the sentence. A motion was made, seconded, and approved unanimously to amend with changes as discussed on record. Mr. Dierlam confirmed with Dr. Hunter that these same changes needed to be made throughout all consent forms and rule language.

Discussion continued on Bates page 13, 16, and 18, Feminizing Medications for Patients with Gender Dysphoria in Minors. Mr. Vazquez reviewed the technical changes needed in the form. Drs. Hunter, Coffman, Mortensen, Derick, Vila, and Pages made comments and suggested amendments. Mr. Dierlam read into record Chapter 456.001(8), F.S., which states "Sex means the classification of a person as either male or female based on the organization of the human body of such person for a specific reproductive role, as indicated by the person's sex chromosomes, naturally occurring sex hormones, and internal and external genitalia present at birth." A motion was made, seconded, and approved unanimously to amend the feminine and masculine consent forms to read, "This treatment will not change the minor's biological sex or chromosomes."

Discussion continued on Bates page 26, Masculinizing Medications for Patients with Gender Dysphoria in Adults. Mr. Vazquez reviewed the technical changes needed in the form. No comments were made by members. A motion was made, seconded, and approved unanimously to amend the consent form with the changes as discussed on record.

Discussion continued on Bates page 71, Mandatory Standardized Informed Consent for Sex-reassignment Prescriptions or Procedures in Adults. Mr. Vazquez indicated there were no technical changes recommended. Ms. McNulty advised that form numbers had been issued and will be inserted into the consent forms. Ms. McNulty again advised the informed consent forms will be available on the Board's website.

Discussion continued on Bates page 38, Feminizing Medications for Patients with Gender Dysphoria in Adults. Mr. Vazquez reviewed the technical changes needed in the form. Discussion continued on Bates page 43 regarding risks of estrogen. Dr. Derick discussed Bates page 41 and suggested an amendment to strike the third requirement which states "Gender dysphoria is marked and sustained." A motion was made, seconded, and approved unanimously to amend the form removing the third requirement from Bates page 41, and to make all other changes as discussed on

record.

Discussion continued on Bates page 50, Masculinizing Medications for Patients with Gender Dysphoria in Adults. Mr. Vazquez reviewed the technical changes needed in the form. A motion was made, seconded, and approved unanimously to amend the consent form with the changes as discussed on record.

Discussion continued on Bates page 60, Surgical Treatment for Adults with Gender Dysphoria. Mr. Vazquez indicated there were no technical changes recommended. Members provided no comments.

Dr. Ackerman began the public comment portion of the meeting at 1:51 p.m. Dr. Ackerman called from a list of meeting registrants wishing to provide public comment. Each speaker was given three minutes to speak. Dr. Ackerman recognized Anna Eskamani, District 42, House of Representatives as the first public speaker. Twenty-one individuals recognized by Dr. Ackerman provided public comments. Two additional speakers provided public comments and were called to speak by Mr. Vazquez. There was a total of twenty-three individuals who provided public comment. Public comments continued until 3:16 p.m.

Dr. Ackerman asked for any comments from the members. Mr Vazquez provided additional technical changes recommended throughout all forms. A motion was made, seconded, and approved unanimously to adopt the emergency rule language and informed consent forms for minors as amended on record.

BOM Action taken:

A motion was made, seconded, and approved unanimously to adopt the emergency rule and informed consent forms for minors as amended on record.

BOM SERC

Will the proposed rule amendments have an adverse impact on small business? Is the proposed rule amendment likely to directly or indirectly increase regulatory costs to any entity, including government, in excess of $200,000 in the aggregate in Florida within one year after implementation?

A motion was made in the negative, seconded, and carried unanimously.

Will this rule amendment create an offense that would constitute a minor violation under the rule?

A motion was made in the negative, seconded, and carried unanimously.

Does the Board/Committee want to impose a sunset provision for this rule or rule amendment?

A motion was made in the negative, seconded, and carried unanimously not to impose a sunset provision.

BOM Action taken:

A motion was made, seconded, and approved unanimously to adopt the emergency rule and informed consent forms for adults as amended on record.

BOM SERC

Will the proposed rule amendments have an adverse impact on small business? Is the proposed rule amendment likely to directly or indirectly increase regulatory costs to any entity, including

government, in excess of $200,000 in the aggregate in Florida within one year after implementation?

A motion was made in the negative, seconded, and carried unanimously.

Will this rule amendment create an offense that would constitute a minor violation under the rule?

A motion was made in the negative, seconded, and carried unanimously.

Does the Board/Committee want to impose a sunset provision for this rule or rule amendment?

A motion was made in the negative, seconded, and carried unanimously not to impose a sunset provision.

BOOM Action taken:

A motion was made, seconded, and carried with one opposed (Ms. Jackson) to adopt the emergency rule and informed consent forms for minors as amended on record.

BOOM SERC:

Will the proposed rule amendments have an adverse impact on small business? Is the proposed rule amendment likely to directly or indirectly increase regulatory costs to any entity, including government, in excess of $200,000 in the aggregate in Florida within one year after implementation?

A motion was made in the negative, seconded, and carried unanimously.

Will this rule amendment create an offense that would constitute a minor violation under the rule?

A motion was made in the negative, seconded, and carried unanimously.

Does the Board/Committee want to impose a sunset provision for this rule or rule amendment?

A motion was made in the negative, seconded, and carried unanimously not to impose a sunset provision.

BOOM Action taken:

A motion was made, seconded, and carried with one opposed (Ms. Jackson) to adopt the emergency rule language and informed consent forms for adults as amended on record.

BOOM SERC:

Will the proposed rule amendments have an adverse impact on small business? Is the proposed rule amendment likely to directly or indirectly increase regulatory costs to any entity, including government, in excess of $200,000 in the aggregate in Florida within one year after implementation?

A motion was made in the negative, seconded, and carried unanimously.

Will this rule amendment create an offense that would constitute a minor violation under the rule?

A motion was made in the negative, seconded, and carried unanimously.

Does the Board/Committee want to impose a sunset provision for this rule or rule amendment?

A motion was made in the negative, seconded, and carried unanimously not to impose a sunset provision.

The meeting adjourned at 3:50 p.m.

Notice of Meeting/Workshop Hearing

DEPARTMENT OF HEALTH
Board of Medicine

The **Florida Boards of Medicine and Osteopathic Medicine's Joint Rules/Legislative Committee** announces a public meeting to which all persons are invited.

DATE AND TIME: (UPDATED) Thursday, August 3, 2023, beginning at 4:00 PM EST, or soon thereafter.

PLACE: Renaissance Orlando Airport Hotel, 5445 Forbes Place, Orlando, Florida 32812. The hotel's phone number is (407) 240-1000. The hotel's website is https://www.marriott.com/en-us/hotels/mcora-renaissance-orlando- airport-hotel/overview/. The public rate is $129 per night.

GENERAL SUBJECT MATTER TO BE CONSIDERED: General business of the Committee. Committee meetings may be canceled prior to the meeting date. Please check the Board's website at https://flboardofmedicine.gov/meeting-information for cancellations or changes to the meeting date or time or call the Board at (850)245-4131 for more information.

A copy of the agenda may be obtained by contacting: https://flboardofmedicine.gov/meeting-information.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 7 days before the workshop/meeting by contacting the Board by email at BOM.MeetingMaterials@flhealth.gov or by calling the Board at (850) 245-4131.

If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.

For more information, you may contact: the Board at BOM.MeetingMaterials@flhealth.gov or by calling the Board at (850) 245-4131.

Notice of Meeting/Workshop Hearing

DEPARTMENT OF HEALTH

Board of Osteopathic Medicine

The Florida Boards of Medicine and Osteopathic Medicine's Joint Rules/Legislative Committee announces a public meeting to which all persons are invited.

DATE AND TIME: (UPDATED) Thursday, August 3, 2023, 4:00 p.m., EST, or soon thereafter.

PLACE: Renaissance Orlando Airport Hotel, 5445 Forbes Place, Orlando, Florida 32812. The hotel's phone number is (407)240-1000. The hotel's website is https://www.marriott.com/en-us/hotels/mcora-renaissance-orlando- airport-hotel/overview/. The public rate is $129 per night.

GENERAL SUBJECT MATTER TO BE CONSIDERED: General business of the Committee. Committee meetings may be canceled prior to the meeting date. Please check the Board's website at https://floridasosteopathicmedicine.gov/meeting-information for cancellations or changes to the meeting date or time or call the Board at (850)245-4161 for more information.

A copy of the agenda may be obtained by contacting: https://floridasosteopathicmedicine.gov/meeting-information

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 7 days before the workshop/meeting by contacting: the Board by email at BOM.MeetingMaterials@flhealth.gov or by calling the Board at (850)245-4131. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.

For more information, you may contact: the Board at BOM.MeetingMaterials@flhealth.gov or by calling the Board at (850)245-4131.

Florida Boards of Medicine and Osteopathic Medicine
Joint Rules/Legislative Committee Meeting

Renaissance Orlando Airport Hotel
5445 Forbes Place
Orlando, FL 32812
407-240-1000

August 3, 2023

AGENDA

Participants in this public meeting should be aware that the proceedings are being recorded and that an audio file of the meeting will be posted to the boards' websites.

Roll call will be at 4:00 p.m. or shortly thereafter.

Old Business

Meeting Minutes

- Approval of June 23, 2023, Joint Rules/Legislative Committee meeting minutes

New Business

Rules 64B8-9.XXX and 64B15-14.XXX, F.A.C. – Standards of Practice for the Treatment of Gender Dysphoria in Minors 1

- Discussion of permanent rule relating to the standard of care for the treatment of gender dysphoria in minors
- Discussion of permanent rule relating to informed consents for the treatment of gender dysphoria in minors

Rules 64B8-9.XXX and 64B15-14.XXX, F.A.C. – Informed Consent for the Treatment of Gender Dysphoria in Adults 2

- Discussion of permanent rule relating to informed consents for the treatment of gender dysphoria in adults

CS/HB 1133 – Physician Assistant Licensure 3

- Determine process for implementation of sections 458.347(6)(a)2.e. and 459.022(6)(a)2.e., F.S., in light of CS/HB 1133

Emergency Rules 64B8ER23-8 and 64B15ER23-10 – Mandatory Standardized Informed Consent for Sex-reassignment Prescriptions or Procedures in Adults 4

- Consideration of JAPC correspondence dated 7/21/2023 for Board of Medicine
- Consideration of JAPC correspondence dated 7/21/2023 for Board of Osteopathic Medicine

Florida Boards of Medicine and Osteopathic Medicine
Joint Rules/Legislative Committee Meeting

Renaissance Orlando Airport Hotel
5445 Forbes Place
Orlando, FL 32812
407-240-1000

MEETING MINUTES

The meeting was called to order at 4:00 p.m. on August 3, 2023, by Dr. Zachariah Zachariah. Roll call was conducted by Cherise Strickland.

Members Present:
Zachariah Zachariah, M.D., Chair
Nicholas Romanello, Esq., Vice Chair
Scot Ackerman, M.D.
Matthew Benson, M.D.
Amy Derick, M.D.
David Diamond, M.D.
Patrick Hunter, M.D.
Luz Marina Pages, M.D.
Tiffany Sizemore DiPietro, D.O.
William Kirsh, D.O.

Members Absent:
Monica Mortensen, D.O.

Staff Present:
Paul Vazquez, J.D., Executive Director BOM
Danielle Terrell, Executive Director BOOM
Christopher Dierlam, Board Counsel
Donna McNulty, Board Counsel
Cassandra Fullove, Senior Legal Assistant
Cherise Strickland, Program Operations Administrator
Cyra Williams, Regulatory Specialist III
Brad Dalton, Public Information Officer

Court Reporter:
Magnolia Court Reporting
Orlando, FL
407-896-1813

Mr. Vazquez provided opening remarks and instructions on the conduct of the meeting. Mr. Vazquez reminded everyone that this is a publicly noticed meeting, the proceedings are being recorded, and an audio file of the meeting will be posted to both Boards' websites.

CS/HB 1133 – Physician Assistant Licensure 3
Determine process for implementation of sections 458.347(6)(a)2.e. and 459.022(6)(a)2.e., F.S., in light of CS/HB 1133

Mr Vazquez advised this tab relates to new legislation, and asked for delegated authority for board staff to process and administratively approve.

A motion was made, seconded, and carried unanimously to delegate authority to board staff to issue licenses administratively to a Physician Assistant applicant who does not meet the educational requirements specified in 458.347(6)(a)2., F.S., but who has passed the Physician Assistant National Certifying Examination administered by the National Commission on Certification of Physician Assistants.

Action taken: A motion was made, seconded, and carried unanimously delegating authority to board staff to issue a license administratively to a Physician Assistant applicant who does not meet the educational requirement specified in 458.347(6)(a)2., F.S., but has passed the Physician Assistant National Certifying Examination administered by the National Commission on Certification of Physician Assistants.

Mr. Dierlam provided a brief overview of the correspondence received by both the Board of Medicine and the Board of Osteopathic Medicine from The Florida Legislature Joint Administrative Procedures Committee (JAPC). The materials begin on Bates page 46, and discussed DH5082-MQA, Feminizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Consent form, and DH5083-MQA, Masculinizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Consent form.

Dr. Diamond advised he agrees with JAPC's comments provided in the 7/21/2023 correspondence.

Dr. Derick advised she agrees with JAPC's comments provided in the 7/21/2023 correspondence.

Mr. Romanello advised he agrees with JAPC's comments provided in the 7/21/2023 correspondence to the Board of Medicine and the Board of Osteopathic Medicine.

Dr. Benson spoke and asked questions regarding JAPC's correspondence dated 7/21/2023.

Dr. Hunter disagreed and spoke regarding JAPC's correspondence dated 7/21/2023.

A motion was made, seconded, and carried with two opposed to strike the language quoted in JAPC's correspondence dated 7/21/2023 from the rules. The language quoted is from DH5082-MQA, Page 3, "to undergo a thorough psychological and social evaluation performed by a Florida licensed board-certified psychiatrist or a Florida licensed psychologist" before beginning HRT and every two years thereafter and language quoted from DH5083-MQA, Page 3, "to undergo a thorough psychological and social evaluation performed by a Florida licensed board-certified psychiatrist or a Florida licensed psychologist" before beginning HRT and every two years thereafter.

Dr. Benson and Dr Hunter were opposed.

Action taken: A motion was made, seconded, and carried with two opposed to strike the language quoted in JAPC's correspondence dated 7/21/2023 from the rules.

SERC

Will the proposed rule amendments have an adverse impact on small business? Is the proposed rule amendment likely to directly or indirectly increase regulatory costs to any entity, including government, in excess of $200,000 in the aggregate in Florida within one year after implementation?

A motion was made in the negative, seconded, and carried unanimously.

Will this rule amendment create an offense that would constitute a minor violation under the rule?

A motion was made in the negative, seconded, and carried unanimously.

Does the Board/Committee want to impose a sunset provision for this rule or rule amendment?

A motion was made in the negative, seconded, and carried unanimously not to impose a sunset provision.

New Business

Rules 64B8-9.XXX and 64B15-14.XXX, F.A.C. – Standards of Practice for the Treatment of Gender Dysphoria in Minors 1
Discussion of permanent rule relating to the standard of care for the treatment of gender dysphoria in minors
Discussion of permanent rule relating to informed consents for the treatment of gender dysphoria in minors

Rules 64B8-9.XXX and 64B15-14.XXX, F.A.C. – Informed Consent for the Treatment of Gender Dysphoria in Adults 2
Discussion of permanent rule relating to informed consents for the treatment of gender dysphoria in adults

Mr. Dierlam advised the committee there are the three primary options relating to Tabs 1 and 2 for the members to consider:
1) Move forward with adopting as formal rules the emergency rules as amended on record today.
2) Start with the emergency rules adopted and delegate authority to members to make recommendations and changes.
3) Completely scratch the emergency rules and begin a new rulemaking process to create permanent rules.

A motion was made, seconded, and carried unanimously to ask Dr. Benson and Dr. Mortenson to review the emergency rules and to provide any recommendations to the Joint Rules/Legislative Committee in October, 2023, or November, 2023.

Action taken: Dr. Benson and Dr. Mortenson will review the emergency rules and will provide any recommendations to the Joint Rules/Legislative Committee in October, 2023, or November, 2023.

A motion was made, seconded, and carried unanimously to officially notice rule development, which was applied to both Tabs 1 and 2.

Action taken: A motion was made, seconded, and carried unanimously to officially notice rule development regarding both Tabs 1 and 2

Public Comments

Dr. Zachariah invited the public to make comments, each public speaker was given three minutes to speak. Individuals were called to speak from the speaker cards completed prior to and during the meeting. A total of eighteen speakers provided public comment.

Dr. Zachariah asked committee members for any comments after public comments concluded. Dr. Derick asked Dr. Benson and committee when starting permanent rulemaking to consider whether a licensed medical health care provider could provide the required mental and suicide assessments rather than a mental health specialist

Old Business

Meeting Minutes

Approval of June 23, 2023, Joint Rules/Legislative Committee meeting minutes was not addressed at this meeting.

A motion was made, seconded, and carried unanimously to adjourn the meeting at 5:04 p.m.

08/25/2023
Minutes prepared by Cherise Strickland

Notice of Meeting/Workshop Hearing

DEPARTMENT OF HEALTH
Board of Medicine

The **Florida Board of Medicine** announces a public meeting to which all persons are invited.

DATE AND TIME: Friday, August 4, 2023, beginning at 8:00 AM EST, or soon thereafter.

PLACE: Renaissance Orlando Airport Hotel, 5445 Forbes Place, Orlando, Florida 32812. The hotel's phone number is (407) 240-1000. The hotel's website is https://www.marriott.com/en-us/hotels/mcora-renaissance-orlando- airport-hotel/overview/. The public rate is $129 per night.

GENERAL SUBJECT MATTER TO BE CONSIDERED: General business of the Board. Please check the Board's website at https://flboardofmedicine.gov/meeting-information for cancellations or changes to the meeting date or time or call the Board at (850)245-4131 for more information.

A copy of the agenda may be obtained by contacting: https://flboardofmedicine.gov/meeting-information.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 7 days before the workshop/meeting by contacting the Board by email at BOM.MeetingMaterials@flhealth.gov or by calling the Board at (850) 245-4131.

If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.

For more information, you may contact: the Board at BOM.MeetingMaterials@flhealth.gov or by calling the Board at (850) 245-4131.

Florida Board of Medicine
Board Meeting

Renaissance Orlando Airport Hotel
5445 Forbes Place
Orlando, Florida 33004
407-240-7543

August 4, 2023

AGENDA

NOTE: Cases shown on the agenda may be heard in a different order but will not be heard prior to 8:00 a.m. Cases are scheduled to be heard beginning at 8:00 a.m.; therefore, it is imperative that you arrive promptly at 8:00 a.m. and be prepared to be at the meeting for several hours until your case is heard.

Lunch will be taken at an appropriate time.

Participants in this public meeting should be aware that these proceedings are being recorded and that an audio file of the meeting will be posted to the board's website.

8:00 a.m. Roll Call

Disciplinary Case Schedule:

Anesthesiologist Assistant Joint Committee..... No Tab
July 27, 2023 (Dr. Vila)

Probation Committee .....No tab
July 27, 2023 (Dr. Pages)

Joint Rules/Legislative Committee .....No tab
June 23, 2023 (Dr. Zachariah)

Approval of Meeting Minutes:.....45

- June 2, 2023, Meeting Minutes .....**Addendum in Version 2**
- June 30, 2023, Joint Board Meeting Minutes .....**Addendum in Version 2**

Ratification of Applicants Pursuant to Chapter 458, F.S......46
.....**Addendum in Version 2**

Other Business

New Business

Anticipated Adjournment 5:00 p.m.

Florida Board of Medicine
Board Meeting

Renaissance Orlando Airport Hotel
5445 Forbes Place
Orlando, Florida 33004
407-240-7543

DRAFT MEETING MINUTES

CALL TO ORDER

The meeting was called to order at 8:00 a.m. on Friday, August 4, 2023, by Dr. Scot Ackerman, Chair.

Participants in this public meeting were made aware that these proceedings were being recorded and that an audio file of the meeting would be posted to the Board's website.

ROLL CALL

Roll call was conducted by Cherise Strickland, Program Operations Administrator. Those present for all, or part of the meeting included the following:

Members Present:
Scot Ackerman, M.D., Chair
Nicholas Romanello, Consumer Member, Vice Chair
Matthew Benson, M.D.
Gregory Coffman, M.D.
Amy Derick, M.D.
David Diamond, M.D.
Patrick Hunter, M.D.
Luz Pages, M.D.
Hector Vila, M.D.
Michael Wasylik, M.D.
Zacharia Zachariah, M.D.
Nicole Justice, Consumer Member

Members Absent:
Wael Barsoum, M.D.
Eleonor Pimentel, M.D.

Department of Health Prosecutors Present:
Chad Dunn, Esq.
Corynn Alberto, Esq
Kristen Summers, Esq.
Elizabeth Tiernan, Esq.

Staff Present:
Paul Vazquez, J.D., Executive Director
Christopher Dierlam, Board Counsel
Donna McNulty, Board Counsel
Cassandra Fullove, Senior Legal Assistant
Cherise Strickland, Program Operations Administrator
Wendy Alls, Program Operations Administrator
Cyra Williams, Regulatory Specialist III
Brad Dalton, Public Information Officer

Court Reporter:
Donna Wolk
Magnolia Court Reporting
Reportingorlando@aol.com
407-896-1813

OPENING REMARKS

Mr. Vazquez provided opening remarks and reminded the audience that this is a publicly noticed meeting and is being recorded for the public record before moving into the case schedule.

Christopher Saputa, MD – Recommended Order 1
Allegations of the Amended Administrative Complaint: Counts I-III: § 458.331(1)(t), F.S., Count IV-VI: § 458.331(1)(m), F.S., Count VII-IX: § 458.331(1)(g) by violating Rule 59A-9.025(1)(c)2 and/or Rule 64B8- 9.007, Fla. Admin. Code Count X and XII: § 458.331(1)(v), F.S.,

Dr. Ackerman provided opening statements and instructions on how the proceedings would be conducted.

Ms. Summers represented the Department and presented the case to the Board.

Dr. Saputa was present and was represented by counsel, Ms. Julie Gallagher, Esquire.

Dr. Wasylik was recused due to participation on the probable cause panel.

Following opening remarks, Respondent and Counsel proceeded with summarizing their exceptions to the proposed final order.

Ms. Summers advised exceptions are due within fifteen days, the exceptions were filed late. The two pleadings are Respondents submission to recommended order on May 4, 2023.

A motion was made, seconded, and carried unanimously to deny the Respondent's first exception based on the competent substantial evidence and complied with the essential requirements of law.

A motion was made, seconded, and carried unanimously to grant the Department's motion to strike the late filed exception due to the document having not been timely filed pursuant to section 120.57(1)(k), F.S.

Ms. Gallagher advised she does not wish to argue the exceptions, a rebuttal was not presented by Ms. Gallagher.

A motion was made, seconded, and carried unanimously to grant motion separating Part 1 of exceptions.

Ms. Gallagher advised she intends to withdraw all exceptions.

A motion was made, seconded, and carried unanimously to deny Petitioner's Exception to Paragraph 151 based on competent substantial evidence and complied with the essential requirements of law.

A motion was made, seconded, and carried unanimously to adopt the Findings of Fact.

A motion was made, seconded, and carried unanimously to adopt the Conclusions of Law.

A motion was made to accept the Administrative Law Judge's recommendation for suspension of license for a period of one year from the date of final order and permanently restricted from performing any obstetrical/gynecological services.

Ms. Summers advised the Department is recommending a penalty of revocation and provided aggravating factors.

Ms. Gallagher addressed the board regarding the penalty and opposes the Department's recommendation of penalty. Ms. Gallagher provided mitigating factors and agreed with the Administrative Law Judge's recommended penalty of suspension for one year and permanently restricted from performing any obstetrical/gynecological services.

A motion was made, seconded, and carried with two opposed to reject the Petitioner's Exception.

A motion was made, seconded, and carried with four opposed to accept the Administrative Law Judge's recommended penalty of suspension for one year and permanently restricted from performing any obstetrical/gynecological services.

A motion was made, seconded, and carried unanimously to impose costs in the amount of $32,962.35.

Action Taken: suspension, permanent restriction from performing any obstetrical/gynecological services, $5,000 fine, $32,962.35 costs

Victor F. Gonzalez, MD – Recommended Order.....2
Allegations of the Amended Administrative Complaint: Counts I: § 458.331(1)(s), F.S., Count II: 456.072(1)(hh).

Ms. Justice provided opening statements and instructions on how the proceedings would be conducted.

Ms. Tiernan represented the Department and presented the case to the Board.

Dr. Gonzalez was present and was represented by Julia Gallagher, Esquire.

Dr. Ackerman and Mr. Romanello were recused due to participation on the probable cause panel.

Ms. Tiernan indicated there were no exceptions filed.

Ms. Gallagher addressed the board and disagreed with the conclusions, and advised no exceptions were filed.

A motion was made, seconded, and carried unanimously to adopt the Findings of Fact.

A motion was made, seconded, and carried unanimously to adopt the Conclusions of Law.

A motion was made, seconded, and carried unanimously to accept the Administrative Law Judge's recommendation for penalty of suspension of license until such time Dr. Gonzalez demonstrates to the Board his ability to practice medicine with skill and safety – such demonstration shall include an evaluation from Professional Resource Network (PRN). The

Respondent shall appear before the Board (Probation Committee) with said PRN evaluation and the Board shall make the determination of whether Respondent is safe to practice medicine with reasonable skill and safety. Upon the lifting of the suspension the Respondent shall be placed on probation for a period of five years with terms and conditions to be set by the Board at the time of reinstatement.

A motion was made, seconded, and carried unanimously to accept costs in the amount of $66,325.55.

Action Taken: suspension, PRN evaluation to be presented to Probation Committee to consider re-instatement, probation for five years after re-instatement, $66,325.55 costs

David Gray, MD – Settlement Agreement.....7
Dr. Gray was present and was represented by Evan Marowitz, Esquire.

Ms. Alberto represented the Department.

Dr. Zachariah was recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 458.331(t)(1), F.S. (2020)

Mr. Marowitz provided mitigating factors.

A motion was made, seconded, and carried unanimously to reject the Settlement Agreement as presented.

A motion was made, seconded, and carried with three opposed to accept the counteroffer as amended on record.

Costs were imposed in the amount of $4,140.80.

Penalty imposed: reprimand, probation, restricted from performing any gluteal fat transfer procedures for two years from filed date of final order, indirect supervision, $7,500 fine, $4,140.80 costs, five hours of continuing medical education course in laws, rules, and ethics, five hours of continuing medical education in risk management, ten hours of continuing medical education in liposuction, and five hours of continuing medical education in the area of medical records

Karl W. Schwarz, MD – Settlement Agreement.....9
Dr. Schwarz was present and was represented by Gregory Chaires, Esquire.

Ms. Alberto was present and represented the Department.

Ms. Justice chaired this tab.

Dr. Ackerman and Mr. Romanello were recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(t)1, F.S. (2020) 458.331(1)(m), F.S. (2020), and s. 458.331(1)(nn), F.S. (2020)

A motion was made, seconded, and carried unanimously to accept the Settlement Agreement as presented.

Costs were imposed in the amount of $4,540.72.

Penalty imposed: letter of concern, $7,500 fine, $4,540.72 costs, five hours of continuing medical education course in risk management, three hours of continuing medical education course in medical record keeping

Jigneshkumar B. Patel, MD – Settlement Agreement.....11
Dr. Patel was present and was represented by Paul Nugent, Esquire.

Mr. Dunn represented the Department.

Dr. Barsoum and Mr. Romanello were recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(t), F.S. 458.331(1)(m).

A motion was made, seconded, and carried unanimously to accept the Settlement Agreement as presented.

Costs were imposed in the amount of $4,527.48.

Penalty imposed: letter of concern, $10,000 fine, $4,527.48 costs, five hours of continuing medical education course in risk management, ten hours of continuing medical education in recognizing and treating liver diseases

Jebhar R. Patterson, MD – Settlement Agreement 15
Dr. Patterson was not present or represented by counsel.

Ms. Alberto was present and represented the Department.

Dr. Pimentel and Ms. Garcia were recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(t)1, F.S. (2021)

A motion was made, seconded, and carried unanimously to reject the Settlement Agreement as presented.

A motion was made, seconded, and carried unanimously to accept the Settlement Agreement as amended on record.

Costs were imposed in the amount of $4,000.00.

Penalty imposed: letter of concern, $2,500.00 fine, $4,000.00 costs, five hours of continuing medical education related to the diagnosis of type 1 diabetes

Ashish Pal, MD – Settlement Agreement.....17
Mr. Pal was present and was represented by Kara Graham, Esquire.

Ms. Alberto represented the Department.

Dr. Ackerman and Mr. Romanello were recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(t)1, F.S. (2014), s. 458.331(1)(m), s. 458.331(1)(nn), F.S. (2014) s. 458.331(1)(t)1 F.S. (2014), and s. 458.331(1)(nn), F.S.(2014) s. 458.331(1)(t)(1), F.S. (2017), s. 458.331(1)(nn), F.S. (2017)

A motion was made, seconded, and carried unanimously to reject the Settlement Agreement as presented.

A motion was made, seconded, and carried unanimously to accept the Counter Settlement Agreement as amended on record.

Costs were imposed in the amount of $15,000.00.

Penalty imposed: reprimand, probation for period of two years from filing date of final order, permanently restricted from performing any vascular procedures on lower extremities, $20,000 fine, $15,000.00 costs

Piper L. Squire, MD – Settlement Agreement 3
Dr. Pimentel was recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(s), F.S. s. 456.072(1)(hh), F.S.
A motion was made, seconded, and carried unanimously to accept the Settlement Agreement as presented.

Costs were imposed in the amount of $3,930.08.

Penalty imposed: letter of concern, $2,000 fine, $3.930.08 costs

Ravi Krishnan, MD – Settlement Agreement.....4
Mr. Romanello was recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(b), F.S. (2021), s. 458.331(1)(kk), F.S. (2021), and s. 456.072(1)(w), F.S. (2021)

A motion was made, seconded, and carried unanimously to accept the Settlement Agreement as presented.

Costs were imposed in the amount of $1,080.42.

Penalty imposed: letter of concern, $1,000 fine, $1,080.42 costs, five hours of continuing medical education course in laws, rules, and ethics

Reza Hejazi, MD – Settlement Agreement 5
Dr. Wasylik and Ms. Justice were recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 456.072(1)(k), F.S. (2019-2022)

A motion was made, seconded, and carried unanimously to accept the Settlement Agreement as presented.

Costs were imposed in the amount of $730.80.

Penalty imposed: letter of concern, $730.80 costs, five hours of continuing medical education course in laws, rules, and ethics

Dr. Barsoum and Mr. Romanello were recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(b), F.S. (2022), s. 456.072(1)(w), F.S. (2022)

A motion was made, seconded, and carried unanimously to accept the Settlement Agreement as presented.

Costs were imposed in the amount of $1,253.06.

Penalty imposed: letter of concern, suspension, $1,000 fine, $1,253.06 costs

Dr. Pages was recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(t), F.S. (2019-2020), s. 458.331(1)(m), F.S. (2019-2020)

A motion was made, seconded, and carried unanimously to accept the Settlement Agreement as presented.

Costs were imposed in the amount of $5,903.94.

Penalty imposed: letter of concern, $5,000 fine, $5,903.94 costs, five hours of continuing medical education course in prescribing controlled substances, five hours of continuing medical education course in risk management.

Dr. Ackerman and Mr. Romanello were recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(g), F.S. (2017-2021)

A motion was made, seconded, and carried unanimously to accept the Settlement Agreement as presented.

Costs were imposed in the amount of $789.91.

Penalty imposed: letter of concern, $789.91 costs, five hours of continuing medical education course in laws, rules, and ethics

Dr. Pimentel and Ms. Garcia were recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 478.52(1)(a), F.S. (2020)

A motion was made, seconded, and carried unanimously to accept the Settlement Agreement as presented.

Costs were imposed in the amount of $2,500.00.

Penalty imposed: letter of concern, $2,500.00 fine, $2,500.00 costs, five hours of continuing medical education course in laws, rules, and ethics

Robert P. Jensen, MD – Settlement Agreement.....13
No current members were recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(s), F.S. (2016)

A motion was made, seconded, and carried unanimously to accept the Settlement Agreement as presented.

Costs were imposed in the amount of $5,998.44.

Penalty imposed: letter of concern, suspension, of license, $2,500 fine, $5,998.44 costs

Alfredo E. Mercado-Quinones, MD – Settlement Agreement.....14
Dr. Mercado-Quinones was present and was represented by Liane LaBouef, Esquire.

Ms. Alberto was present and represented the Department.

Dr. Barsoum and Mr. Romanello were recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 478.331(1)(t)1, F.S. (2016)

A motion was made, seconded, and carried unanimously to accept the Settlement Agreement as presented.

Costs were imposed in the amount of $2,548.88.

Penalty imposed: letter of concern, $5,000 fine, $2,548.88 costs, three hours of continuing medical education related to diagnosis and treatment of hydrocephalus, five hours of continuing medical education in risk management

Edward B. Baldwin, III, PA – Settlement Agreement.....16
Dr. Pimentel and Ms. Justice were recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(t), F.S. (2018)

A motion was made, seconded, and carried unanimously to accept the Settlement Agreement as presented.

Costs were imposed in the amount of $3,604.30.

Penalty imposed: letter of concern, $5,000 fine, $3,604.30 costs, five hours of continuing medical education course in risk management, five hours of continuing medical education in recognizing sepsis

Ronald E. Wollum, PA – Settlement Agreement 18
This case has been continued.

Gurprit Sekhon, MD – Settlement Agreement.....19
Dr. Pages was recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(t), F.S. (2019) s. 458.331(1)(m), F.S. (2019)

A motion was made, seconded, and carried unanimously to accept the Settlement Agreement as presented.

Costs were imposed in the amount of $7,000.00.

Penalty imposed: $2,000 fine, $7,000.00 costs, three hours of continuing medical education course in record keeping

Dr. Ackerman called a ten-minute break at 10:44 a.m. The meeting reconvened at 10:54 a.m.

Yvanne Berryer, MD – Determination of Waiver 20
Dr. Berryer was not present or represented by counsel.

Ms. Summers represented the Department.

Dr. Vila and Ms. Garcia were recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(g), F.S. (2016-2021)

A motion was made, seconded, and carried unanimously that respondent was properly served, and waived their right to elect a formal hearing.

A motion was made, seconded, and carried unanimously admitting the investigative file into evidence.

A motion was made, seconded, and carried unanimously to adopt the Findings of Fact.

A motion was made, seconded, and carried unanimously to adopt the Conclusions of Law and finding the Respondent violated the Florida Statute as charged.

A motion was made, seconded, and carried unanimously to impose a penalty of a letter of concern, a fine in the amount of $1,000, and five hours of continuing medical education course in laws, rules, and ethics.

A motion was made, seconded, and carried unanimously to impose costs in the amount of $1,188.54.

Action taken: letter of concern, $1,000 fine, $1,188.54 costs, five hours continuing medical education course in laws, rules, and ethics

Victor D. Cruz, MD – Determination of Waiver.....21
Dr. Cruz was not present or represented by counsel.

Ms. Tiernan represented the Department.

Dr. Pages was recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(g), F.S. (2017-2021)

A motion was made, seconded, and carried unanimously that respondent was properly served, and waived their right to elect a formal hearing.

A motion was made, seconded, and carried unanimously admitting the investigative file into evidence.

A motion was made, seconded, and carried unanimously to adopt the Findings of Fact.

A motion was made, seconded, and carried unanimously to adopt the Conclusions of Law and finding the Respondent violated the Florida Statute as charged.

A motion was made, seconded, and carried unanimously to impose a penalty of a letter of concern, a fine in the amount of $1,000, and five hours of continuing medical education course in laws, rules, and ethics.

A motion was made, seconded, and carried unanimously to impose costs in the amount of $619.16.

Action taken: letter of concern, $1,000 fine, $629.16, five hours continuing medical education course in laws, rules, and ethics

Marco A. Munoz, MD – Determination of Waiver.....22
Dr. Munoz was present and was represented by counsel.

Mr. Pietrylo was present and represented the Department.

Dr. Pages was recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(b), F.S. (2021) s. 458.331(1)(kk), F.S. (2021)

A motion was made, seconded, and carried unanimously that respondent was properly served, and waived their right to elect a formal hearing.

A motion was made, seconded, and carried unanimously admitting the investigative file into evidence.

A motion was made, seconded, and carried unanimously to adopt the Findings of Fact.

A motion was made, seconded, and carried unanimously to adopt the Conclusions of Law and finding the Respondent violated the Florida Statute as charged.

A motion was made, seconded, and carried unanimously to impose a penalty of a letter of concern, a fine in the amount of $2,000, and five hours of continuing medical education course in laws, rules, and ethics.

A motion was made, seconded, and carried unanimously to impose costs in the amount of $367.47.

Action taken: letter of concern, $2,000 fine, $367.47 costs, five hours continuing medical education course in laws, rules, and ethics

Donald C. Thomas, III, MD – Hearing Not Involving Disputed Issues of Material Fact 23
Dr. Thomas was not present or represented by counsel.

Ms. Alberto represented the Department.

Dr. Pages was recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(g), F.S.(2017-2021)

A motion was made, seconded, and carried unanimously admitting the investigative file into evidence.

A motion was made, seconded, and carried unanimously to adopt the Findings of Fact.

A motion was made, seconded, and carried unanimously to adopt the Conclusions of Law and finding the Respondent violated the Florida Statute as charged.

A motion was made, seconded, and carried unanimously to impose a penalty of a letter of concern, $1,000 fine, and five hours of Laws, Rules, and Ethics Continuing Medical Education course.

A motion was made, seconded, and carried unanimously to impose costs in the amount of $70.77.

Penalty imposed: letter of concern, $70.77 costs, five hours laws, rules, and ethics continuing medical education

Halima Ghafoor, MD – Hearing Not Involving Disputed Issues of Material Fact....24
Mr. Ghafoor was present and represented by William Bonezzi, Esquire.

Ms. Alberto was present and represented the Department.

Dr. Pimentel and Ms. Justice were recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(t)(1), F.S. (2018)

A motion was made, seconded, and carried unanimously admitting the investigative file into evidence.

A motion was made, seconded, and carried unanimously to adopt the Findings of Fact.

A motion was made, seconded, and carried unanimously to adopt the Conclusions of Law and finding the Respondent violated the Florida Statute as charged.

A motion was made, seconded, and carried unanimously to impose a penalty of a letter of concern, $10,000 fine, and five hours of continuing medical education in risk management, and five hours of continuing medical education in diagnosis of treatment of cardiac conditions.

A motion was made, seconded, and carried unanimously to impose costs in the amount of $1,053.35.

Penalty imposed: reprimand, $10,000.00 fine, $1,053.35 costs, five hours continuing medical education in risk management, five hours continuing medical education in diagnosis of treatment of cardiac conditions

Richard I. Silver, MD – Determination of Waiver 25
This case was continued.

Morton Hyson, MD – Determination of Waiver.....26
Mr. Hyson was not present and was not represented by counsel.

Ms. Summers represented the Department.

Dr. Vila and Ms. Garcia were recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(b), F.S. (2022)

A motion was made, seconded, and carried unanimously that respondent was properly served, and waived their right to elect a formal hearing.

A motion was made, seconded, and carried unanimously admitting the investigative file into evidence.

A motion was made, seconded, and carried unanimously to adopt the Findings of Fact.

A motion was made, seconded, and carried unanimously to adopt the Conclusions of Law and finding the Respondent violated the Florida Statute as charged.

A motion was made, seconded, and carried unanimously to impose a penalty of revocation.

A motion was made, seconded, and carried unanimously to waive costs in the amount of $381.10.

Action taken: Revocation

Nancy N. Sage, MD – Hearing Not Involving Disputed Issues of Material Fact.....27
This case was continued.

Donna G. Hurlock, MD – Hearing Not Involving Disputed Issues of Material Fact...28
Dr. Hurlock was present and was not represented by counsel.

Ms. Alberto represented the Department.

Dr. Wasylik was recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(b), F.S. (2022)

A motion was made, seconded, and carried unanimously admitting the investigative file into evidence.

A motion was made, seconded, and carried unanimously to adopt the Findings of Fact.

Dr. Hurlock addressed the board and provided mitigating factors.

A motion was made, seconded, and carried unanimously to adopt the Conclusions of Law and finding the Respondent violated the Florida Statute as charged.

A motion was made, seconded, and carried unanimously to impose a penalty of a reprimand, and a $1,000 fine.

A motion was made, seconded, and carried unanimously to impose costs in the amount of $107.84.

Penalty imposed: reprimand, $107.84 costs

Kerry S. Lane, MD – Hearing Not Involving Disputed Issues of Material Fact.....29
Dr. Lane was present and represented by Jonathan Meltz, Esquire.

Ms. Tiernan represented the Department.

Dr. Wasylik and Mr. Romanello were recused due to participation on the probable cause panel.
Allegations of the Administrative Complaint: Violation of s. 458.331(1)(c), F.S. (2021)

A motion was made, seconded, and carried unanimously admitting the investigative file into evidence.

A motion was made, seconded, and carried unanimously to adopt the Findings of Fact.

A motion was made, seconded, and carried unanimously to adopt the Conclusions of Law and finding the Respondent violated the Florida Statute as charged.

A motion was made, seconded, and carried unanimously to impose a penalty of revocation.

A motion was made, seconded, and carried unanimously to waive costs in the amount of $1,717.43.

Penalty imposed: revocation

Janet E. Miley, MD – Hearing Not Involving Disputed Issues of Material Fact.....30
This case was continued.

Janet E. Miley, MD – Hearing Not Involving Disputed Issues of Material Fact.....31
This case was continued.

Terry L. Adams, MD – Hearing Not Involving Disputed Issues of Material Fact.....32
This case was continued.

Jebhar R. Patterson, MD – Hearing Not Involving Disputed Issues of Material Fact.....33
Dr. Patterson was not present or represented by counsel.

Ms. Alberto represented the Department.

Dr. Zachariah was recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(g), F.S. (2016-2020)

A motion was made, seconded, and carried unanimously admitting the investigative file into evidence.

A motion was made, seconded, and carried unanimously to adopt the Findings of Fact.
A motion was made, seconded, and carried unanimously to adopt the Conclusions of Law and finding the Respondent violated the Florida Statute as charged.

A motion was made, seconded, and carried unanimously to impose a penalty of a letter of concern, $1,000 fine, and five hours of Laws, Rules, and Ethics Continuing Medical Education course.

A motion was made, seconded, and carried unanimously to impose costs in the amount of $760.23.

Penalty imposed: letter of concern, $760.23 costs, five hours continuing medical education in laws, rules, and ethics

Pankaj Merchia, MD – Hearing Not Involving Disputed Issues of Material Fact.....34
This case was continued.

Paul A. Aiello, MD – Hearing Not Involving Disputed Issues of Material Fact.....35
Dr. Aiello was not present and was not represented by counsel.

Ms. Alberto represented the Department.

Dr. Pimentel and Ms. Justice were recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(b), F.S. (2022) s. 458.331(1)(kk), F.S. (2022)

A motion was made, seconded, and carried unanimously admitting the investigative file into evidence.

A motion was made, seconded, and carried unanimously to adopt the Findings of Fact.

A motion was made, seconded, and carried unanimously to adopt the Conclusions of Law and finding the Respondent violated the Florida Statute as charged.

A motion was made, seconded, and carried unanimously to impose a penalty of a letter of concern, $2,500 fine, and five hours of Laws, Rules, and Ethics Continuing Medical Education course.

A motion was made, seconded, and carried unanimously to impose costs in the amount of $80.88.

Penalty imposed: letter of concern, $2,500.00 fine, $80.88 costs, five hours laws, rules, and ethics continuing medical education course, three hours radiology continuing medical education course

Walter N. Simmons, MD – Hearing Not Involving Disputed Issues of Material Fact……36
Dr. Simmons was present and although he is represented by Martin Dix, Esquire, his counsel was not present with him today. Dr. Simmons confirmed he wishes to proceed without counsel today.

Mr. Dunn represented the Department.

Dr. Vila was recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(c), F.S. (2020)

A motion was made, seconded, and carried unanimously admitting the investigative file into evidence.
A motion was made, seconded, and carried unanimously to adopt the Findings of Fact.

Dr. Simmons addressed the Board and provided mitigating factors.

A motion was made, seconded, and carried unanimously to adopt the Conclusions of Law and finding the Respondent violated the Florida Statute as charged.

A motion was made to impose a penalty of revocation.

A motion was made, seconded, and carried unanimously to table and bring back to next meeting, October 6, 2023 as either a Voluntary Relinquishment or as the same posture.

Action taken: tabled until the next meeting as a Voluntary Relinquishment or as the same posture

Marwan Wiggins, MD – Hearing Not Involving Disputed Issues of Material Fact.....37
Dr. Wiggins was present and represented by Julie Gallagher, Esquire.

Mr. Dunn represented the Department.

No current members were recused due to participation on the probable cause panel.

Ms. Alexus Polles, Medial Director, Professional Resource Network also appeared and spoke in support of Dr. Wiggins.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(b), F.S. (2021)

A motion was made, seconded, and carried unanimously admitting the investigative file into evidence.

A motion was made, seconded, and carried unanimously to adopt the Findings of Fact.

Ms. Gallagher spoke and addressed the board; she wishes to hear the penalty recommended by the Department before she addresses the board any further.

A motion was made, seconded, and carried unanimously to adopt the Conclusions of Law and finding the Respondent violated the Florida Statute as charged.

A motion was made, seconded, and carried unanimously to impose a penalty of a letter of concern, $1,000 fine, and five hours of Laws, Rules, and Ethics Continuing Medical Education course.

Ms. Gallagher spoke and addressed the board providing mitigating factors.

A motion was made, seconded, and carried unanimously to impose costs in the amount of $210.32.

Penalty imposed: letter of concern, practice restriction, $210.32 costs, five hours laws, rules, and ethics continuing medical education course

Gunther Rincon, MD – Hearing Not Involving Disputed Issues of Material Fact.....38
Dr. Rincon was present and represented by Susanne Riedhammer, Esquire.
Ms. Alberto was present and represented the Department.

Dr. Diamond and Ms. Justice were recused due to participation on the probable cause panel.

Allegations of the Administrative Complaint: Violation of s. 458.331(1)(t), F.S. (2017)

A motion was made, seconded, and carried unanimously admitting the investigative file into evidence.

A motion was made, seconded, and carried unanimously to adopt the Findings of Fact.

Ms. Riedhammer addressed the Board and asked the Board to limit the penalty to a letter of concern, continuing medical education, and fines.

A motion was made, seconded, and carried unanimously to adopt the Conclusions of Law and finding the Respondent violated the Florida Statute as charged.

A motion was made, seconded, and carried unanimously to impose a penalty of a letter of concern, $10,000 fine, and five hours of Risk Management Continuing Medical Education course, and 1 year probation.

Dr. Zachariah and Dr. Vila spoke against any continuing medical education course, and probation.

A motion was made, seconded, and carried unanimously to dismiss the case.

A motion was made seconded, and carried unanimously to waive all costs and each side bear their own.

Penalty imposed: Dismissed

Voluntary Relinquishments:

Joel E. Richter, MD – Voluntary Relinquishment.....39
Mr. Richter was not present or represented by counsel.

Probable Cause Waived.

A motion was made, seconded, and carried unanimously to accept the voluntary relinquishment.

Action taken: Voluntary relinquishment

Hamilton C. Platt, III, MD – Voluntary Relinquishment.....40
Mr. Platt was not present or represented by counsel.

Dr. Ackerman and Mr. Romanello were recused due to participation on the probable cause panel.

A motion was made, seconded, and carried unanimously to accept the voluntary relinquishment.

Action taken: Voluntary relinquishment

David B. Coffey, MD – Voluntary Relinquishment.....41
Dr. Coffey was not present or represented by counsel.

Dr. Wasylik and Dr. Vila were recused due to participation on the probable cause panel.

A motion was made, seconded, and carried unanimously to accept the voluntary relinquishment.

Action taken: Voluntary relinquishment

Susan K. Holland, MD – Voluntary Relinquishment.....42
Mr. Holland was not present or represented by counsel.

Dr. Zachariah and Ms. Garcia were recused due to participation on the probable cause panel.

A motion was made, seconded, and carried unanimously to accept the voluntary relinquishment.

Action taken: Voluntary relinquishment

UNTIMED ITEMS:

Chair Recognition Award: ..... **No tab**

- Julia Fortier- University of Florida College of Medicine
- Charles Maggitas- Florida State University College of Medicine
- Emily Littman-University of Central Florida College of Medicine

Dr. Ackerman and the Board recognized Ms. Fortier, Mr. Maggitas, and Ms. Littman.

Board Chair's Remarks: ..... **No tab**
Dr. Ackerman spoke and informed the Board Ms. Maria Garcia, Consumer Member resigned effective July 24, 2023.

Board Counsel's Remarks: ..... **No tab**
Mr. Dierlam asked the Board to delegate authority for the Annual Regulatory Plan.

Board Director's Remarks: ..... **No tab**
Mr. Vazquez spoke to the Board regarding the following topics:

- E-Licensing

Department Remarks: ..... **No tab**
Mr. Dunn presented the Appellate Report and year-Old Case Report to Board members.

Action taken: A motion was made to continue prosecution of year old and older cases, seconded, and carried unanimously

Council on Physician Assistants:

The report for the Council on Physician Assistants meeting held on January 27, 2023 was presented.

Action taken: A motion was made to approve the report, seconded, and carried unanimously

Committee Reports:
Credentials Committee ..... **No tab**

Ms. Justice presented the report for the Credentials Committee meeting held on August 3, 2023.

Action taken: A motion was made to approve the report, seconded, and carried unanimously

Boards of Medicine and Osteopathic Medicine's Joint Committee on Surgical Care/Quality Assurance Committee ..... **No tab**

Dr. Diamond presented the report for the Boards of Medicine and Osteopathic Medicine's Joint Committee on Surgical Care/Quality Assurance Committee meeting held on August 3, 2023.

Action taken: A motion was made to approve the report, seconded, and carried unanimously

Joint Rules/Legislative Committee.....No tab

Dr. Zachariah presented the report for the Joint Rules and Legislative Committee meeting held on August 3, 2023.

Mr. Dierlam advised during the Joint Rules and Legislative Committee meeting it was voted to notice formal rulemaking and approved to be filed.

Action taken: A motion was made to approve the report, seconded, and carried unanimously

Anesthesiologist Assistant Joint Committee.....No Tab

Dr. Vila presented the report for the Anesthesiologist Assistants Committee meeting held on July 27, 2023.

Action taken: A motion was made to approve the report, seconded, and carried unanimously

Probation Committee.....No tab

Dr. Pages presented the report for the Probation Committee meeting held on July 27, 2023.

Action taken: A motion was made to approve the report, seconded, and carried unanimously

Joint Rules/Legislative Committee.....No tab

Dr. Zachariah presented the report for the Joint Rules and Legislative Committee meeting held on June 23, 2023.

Action taken: A motion was made to approve the report, seconded, and carried unanimously

Approval of Meeting Minutes:.....No tab

Action taken: A motion was made to approve minutes of the June 2, 2023 Board of Medicine meeting.

Ratification of Applicants Pursuant to Chapter 458, F.S.....No tab

Action taken: A motion was made to ratify applicants, seconded, and carried unanimously.

Other Business

New Business

Meeting adjourned at 12:24 p.m.

Notice of Meeting/Workshop Hearing

DEPARTMENT OF HEALTH
Board of Osteopathic Medicine

The Board of Osteopathic Medicine announces a public meeting to which all persons are invited.
DATE AND TIME: August 11, 2023, 9:00 a.m.
PLACE: Holiday Inn, Disney Springs, 1805 Hotel Plaza Boulevard, Lake Buena Vista, FL 32830
GENERAL SUBJECT MATTER TO BE CONSIDERED: The general business of the Board.
A copy of the agenda may be obtained by contacting: https://floridasosteopathicmedicine.gov/meeting-information/.
Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 7 days before the workshop/meeting by contacting: Board Staff, at (850)245-4161 or MQA.Osteopath@flhealth.gov or 4052 Bald Cypress Way, #C-06, Tallahassee, FL 32399. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).
If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.
For more information, you may contact: Board Staff, at (850)245-4161 or MQA.Osteopath@flhealth.gov or 4052 Bald Cypress Way, #C-06, Tallahassee, FL 32399.

FLORIDA | Board *of* Osteopathic Medicine

Agenda
August 11, 2023
9:00 a.m., EST

Holiday Inn-Disney Springs
1805 Hotel Plaza Boulevard
Lake Buena Vista, FL 32830

Friday August 11, 2023

TURN OFF OR PLACE YOUR CELL PHONE ON VIBRATE DURING THE MEETING.

Participants in this public meeting should be aware that these proceedings are being recorded and that an audio file of the meeting will be posted to the Board's website.

CALL TO ORDER Tiffany Di Pietro, DO, FACC, FACOI *Chair*

ROLL CALL Danielle Terrell, *Executive Director*

AGENDA

TAB 1. PRESENTATION OF AWARDS

DISCIPLINARY ACTIONS

Settlement Agreement
TAB 2: Hadi Shalhaub, D.O. **(Case 2022-08691)**
PCP: Rose & Kirsh

Voluntary Relinquishment
TAB 3: Michael John Ligotti, D.O. **(Case 2020-26092)**
PCP: Rose, Kirsh & Mendez

TAB 4: PROSECUTION SERVICES REPORT - *Sarah Corrigan, Esq.*

TAB 5: REVIEW AND APPROVAL OF MINUTES
May 19, 2023 Meeting Minutes, *General Business Meeting*

PROBATION AND COMPLIANCE
Petition for Reinstatement and Formal Approval of Monitor
CONTINUED TAB 6: Alexander Ralys, D.O. (License #5790)

PETITION FOR HEARING
TAB 7: Jeffrey Piccirillo (File #12001)

APPLICATIONS
Applications for Osteopathic Physician Licensure
TAB 8: James Milani, DO (File# 20455)
TAB 9: Michael Sistare, D.O. (File# 20202)
TAB 10: Donata Vaiciunaite, DO. (File# 20500)
TAB 11: Edward Waseleski, D.O. (File# 18066)
TAB 12: Paul Bisios, D.O. (File# 20260)
CONTINUED TAB 13: Timothy Mynes, D.O. (File# 20263)
TAB 14: Bruce Rubinowicz, D.O. (File# 20644)

Applications for Osteopathic Physician in Training Licensure
TAB 15: Jeffery Kuhary, D.O. (File# 9171)
TAB 16: Christopher Blaisdell, D.O. (File# 9815)
TAB 17: Morgan Thorn, D.O. (File# 9821)

RATIFICATION OF LICENSURE

TAB 18: Osteopathic Physician Licenses (4.28.2023 – 7.26.2023)
TAB 19: Osteopathic Physician in Training Initial Registrations (4.28.2023 – 7.26.2023)

TAB 20: GENERAL DISCUSSION

1917 - Osteopathic Physician Expert Witness Certificates Issued - 4.28.2023 – 7.26.2023 (for informational purposes only)
Provider Change Status Report -4.28.2023 – 7.31.2023 (for informational purposes only)

TAB 21: BOARD COUNSEL REPORT - *Donna McNulty, Esq.*

RULES REPORTS

Rules Report – July 2023
Rules Report – June 2023

RULES DISCUSSION

TAB 22: Annual Regulatory Plan (ARP)

TAB 23: EXECUTIVE DIRECTOR REPORT – Danielle Terrell

TAB 24: BOARD CHAIR REPORT – Tiffany Di Pietro, DO, FACC, FACOI

TAB 25: JOINT COMMITTEE MEETING UPDATES

A: Anesthesiology Assistants Committee

Meeting Minutes
Roll Call

B: Council on Physician Assistants Committee

5.25.23 Meeting Minutes
5.25.23 Roll Call
5.25.23 Summary
7.31.23 Cancelled

C: Boards of Medicine and Osteopathic Medicine Joint Rules/Legislative Committee Meeting

June 1, 2023

Meeting Minutes

August 3, 2023

Meeting Minutes
Roll Call

D: Boards of Medicine and Osteopathic Medicine Joint Surgical Care/Quality Assurance Committee

August 3, 2023

Meeting Minutes
Roll Call
Summary

E: Boards of Medicine and Osteopathic Medicine Joint Surgical Care/Quality Assurance Joint Rules Hearing

August 3, 2023

Meeting Minutes
Roll Call
Summary

TAB 26: LIAISON REPORTS

A: Budget Liaison Report - William Kirsh, D.O.

Total Expenditures (Direct and Allocated) by Board for 9 Months Ending Mar. 31, 2023

Expenditures by Function for Period Ending Mar. 31, 2023

Allocations to Boards by Source Organization and Category for 9 Months Ending Mar. 31, 2023

Cash Balance Report for 9 Months Ending Dec. 31, 2023

Revenue Report – May 2023

Revenue Report – June 2023

B: Legislative Liaison Report

C: Unlicensed Activity Liaison Report

TAB 27: OLD BUSINESS

TAB 28: NEW BUSINESS

ADJOURN

Next Meeting: November 17, 2023 (Tampa, FL)

ADDENDUM:

TAB 26A: Anesthesiology Assistants Committee

7.27.23 Meeting Minutes

TAB 29: Ratification of Telehealth Licenses

FLORIDA | Board of Osteopathic Medicine

August 11, 2023

DRAFT MEETING MINUTES
Board of Osteopathic Medicine
Holiday Inn at Disney Springs
1805 Hotel Plaza Boulevard
Lake Buena Vista, Fl 32830
August 11, 2023
9 a.m.

The meeting was called to order by Dr. Tiffany Di Pietro, Chair, at approximately 9:01 a.m.

Roll Call was conducted by Danielle Terrell, Executive Director for the Board of Osteopathic Medicine. Those present for all, or part of the meeting included the following:

MEMBERS PRESENT:
Tiffany Sizemore Di Pietro, DO, Chair
Monica Mortensen, DO
Gregory Williams, DO
Watson Ducatel, DO
Chris Creegan, Consumer Member

BOARD STAFF PRESENT:
Danielle Terrell, Executive Director
Danielle Mullins, RSIII

MEMBERS ABSENT
William Kirsh, DO, Vice-Chair
Valerie Jackson, Consumer Member

BOARD COUNSEL
Donna McNulty, Board Counsel

PROSECUTION SERVICES ATTORNEYS:
Michael Williams, Assistant General Counsel

COURT REPORTER:
Magnolia Court Reporting
(407) 896-1813
Email: reportingorlando@aol.com

OTHERS PRESENT:
None

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.

CALL TO ORDER Tiffany Di Pietro, DO, FACC, FACOI *Chair*

ROLL CALL Danielle Terrell, *Executive Director*

AGENDA

TAB 1. PRESENTATION OF AWARDS
This item was tabled for next meeting.
Action Taken: No action was required.

DISCIPLINARY ACTIONS
Settlement Agreement
TAB 2: Hadi Shalhaub, D.O., 2022-08691
PCP: Rose & Kirsh
Respondent was not present. Respondent's counsel was present.

Michael Williams represented the Department and presented the settlement to the board.

After discussion,
Action Taken: Motion: by Dr. Williams to issue a letter of concern, to issue an administrative fine of five thousand dollars ($5,000.00) to be paid within 30 days, to pay the reimbursement of costs at five thousand eight hundred fifty-nine dollars and eighty-seven cents ($5,859.87) within 30 days, and to complete 5 hours of continuing medical education in the subject of Florida Laws and Rules within 1 year of the filing of the Final Order, seconded by Mr. Creegan. Motion carried unanimously.

Voluntary Relinquishment
TAB 3: Michael John Ligotti, D.O. **(Case 2020-26092)**
PCP: Rose, Kirsh & Mendez

After discussion,
Action Taken: Motion: by Dr. Watson to accept the voluntary relinquishment, seconded by Dr. Mortensen. Motion carried unanimously.

TAB 4: PROSECUTION SERVICES REPORT - *Sarah Corrigan, Esq.*
Michael Williams represented the Department and presented the prosecution services report (PSU) to the Board.

Action Taken: Motion: by Dr. Ducatel to accept the report and allow PSU to continue prosecuting cases one year and older, seconded by Dr. Mortensen. Motion carried unanimously.

TAB 5: REVIEW AND APPROVAL OF MINUTES
May 19, 2023, Meeting Minutes, *General Business Meeting*
Action Taken: Motion: by Dr. Williams to approve the May 19, 2023, General Business Meeting minutes, seconded by Dr. Mortensen. Motion carried unanimously.

PROBATION AND COMPLIANCE

Petition for Reinstatement and Formal Approval of Monitor

TAB 6: Alexander Ralys, D.O. (License #5790)

This matter was continued.
Action Taken: No action was required.

APPLICATIONS

Applications for Osteopathic Physician Licensure

TAB 8: James Milani, DO (File# 20455)

Applicant was present. Applicant was not represented by counsel.

After discussion,
Action Taken: Motion: by Dr. DiPietro to approve the application under the condition that prior to licensure, within 12 months of the filing of the Notice of Intent to Approve Licensure with Conditions, the applicant pass the Comprehensive Osteopathic Medical Variable-Purpose Examination (COMVEX), seconded by Dr. Williams. Motion passed unanimously.

TAB 9: Michael Sistare, D.O. (File# 20202)

Applicant was present. Applicant was represented by Sara Bazzigaluppi, Esq. Dr. Ted Bowles appeared on behalf of the Professions Resource Network (PRN).

After discussion,
Action Taken: Motion: by Dr. Williams to approve the license unencumbered, seconded by Mr. Creegan. Motion passed unanimously.

TAB 10: Donata Vaiciunaite, DO. (File# 20500)

Applicant was present. Applicant was not represented by counsel.

After discussion,
Action Taken: Motion: by Dr. Williams to approve the license unencumbered, seconded by Dr. Mortensen. Motion passed unanimously.

Dr. DiPietro was recused from agenda Tabs 11 and 14; therefore, Dr. Ducatel chaired the meeting for both items.

TAB 11: Edward Waseleski, D.O. (File# 18066)

Applicant was present. Applicant was represented by Sara Bazzigaluppi, Esq.
Dr. DiPietro was recused.

After discussion,
Action Taken: Motion: by Mr. Creegan to approve the application under the condition that prior to licensure, within 12 months of the filing of the Notice of Intent to Approve Licensure with Conditions, the applicant pass the Comprehensive Osteopathic Medical Variable-Purpose Examination (COMVEX) and then upon licensure the applicant will need to be supervised for 12 months, seconded by Dr. Ducatel. The motion passed unanimously.

TAB 14: Bruce Rubinowicz, D.O. (File# 20644)
Applicant was present. Applicant was not represented by counsel.

After discussion,
Action Taken: Motion: by Mr. Creegan to approve the application under the condition that prior to licensure, within 12 months of the filing of the Notice of Intent to Approve Licensure with Conditions, the applicant pass the Comprehensive Osteopathic Medical Variable-Purpose Examination (COMVEX), and to extend the applicant's previous fines deadline to twenty-four (24) months, seconded by Dr. Williams. The motion passed unanimously.

TAB 12: Paul Bisios, D.O. (File# 20260)
After discussion,
Action Taken: Motion: by Mr. Creegan to approve the license unencumbered, seconded Dr. Mortensen. The motion carried unanimously.

TAB 13: Timothy Mynes, D.O. (File# 20263)
This item was continued at the request of the applicant.
Action Taken: No action was required.

Applications for Osteopathic Physician in Training Licensure
TAB 15: Jeffery Kuhary, D.O. (File# 9171)
Applicant was present. Applicant was not represented by counsel.

After discussion,
Action Taken: Motion: by Dr. Williams to issue the license unencumbered. Motion was seconded by Dr. Mortensen, which carried unanimously.

TAB 16: Christopher Blaisdell, D.O. (File# 9815)
Applicant was present. Applicant was represented by Sara Bazzigaluppi, Esq. Dr. Ted Bowles appeared on behalf of the Professions Resource Network (PRN).

After discussion,
Action Taken: Motion: by Dr. Williams to approve the training license, seconded by Dr. Mortensen. Motion carried unanimously.

TAB 17: Morgan Thorn, D.O. (File# 9821)
Applicant was present. Applicant was not represented by counsel.

After discussion,
Action Taken: Motion: by Dr. Ducatel to approve the application, seconded by Dr. Mortensen. Motion carried unanimously.

PETITION FOR HEARING
TAB 7: Jeffrey Piccirillo (File #12001)
Applicant was not present. Applicant was represented by Sara Bazzigaluppi, Esq.

After discussion,
Action Taken: Motion: by Dr. DiPietro to deny the petition because it is not disputing material facts, seconded by Mr. Creegan. Motion carried unanimously.

After discussion,
Action Taken: Motion: by Dr. DiPietro to move the complete licensure file and the file's correspondence into the record, seconded by Dr. Mortensen. Motion carried unanimously.

After discussion,
Action Taken: Motion: by Dr. DiPietro to adopt the facts set forth in the notice of intent to deny, seconded by Dr. Williams. Motion carried unanimously.

After discussion,
Action Taken: Motion: by Mr. Creegan to find that Dr. Piccirillo violated Florida statutes for getting a previous license revoked and not practicing Osteopathic medicine for 2 years, seconded by Dr. DiPietro. Motion carried unanimously.

After discussion,
Action Taken: Based on the facts, Motion: by Mr. Creegan to deny the petition, seconded by Dr. Williams. Motion carried unanimously.

RATIFICATION OF LICENSURE

TABS 18, 19, and 29 were taken en-masse.

TAB 18: Osteopathic Physician Licenses (4.28.2023 – 7.26.2023)

TAB 19: Osteopathic Physician in Training Initial Registrations (4.28.2023 – 7.26.2023)

TAB 29: Ratification of Telehealth Licenses

Action Taken: Motion: by Dr. Williams to accept the ratification of Osteopathic Physician license numbers 20045 through 20368 totaling 324 licenses approved between 4.28.23 and 7.26.23; Osteopathic Physician in Training Initial Registration numbers 8862 through 9501 totaling 640 registrations approved between 4.28.23 and 7.26.23: and Osteopathic Telehealth License numbers 1 through 619 totaling 619 licenses approved between 7.1.19 and 6.30.23, seconded by Dr. Ducatel. Motion carried unanimously.

TAB 20: GENERAL DISCUSSION

1917 - Osteopathic Physician Expert Witness Certificates Issued - 4.28.2023 – 7.26.2023 (for informational purposes only)
Provider Change Status Report -4.28.2023 – 7.31.2023 (for informational purposes only)

This information was included in the materials for informational purposes only.
Action Taken: No action was required.

TAB 21: BOARD COUNSEL REPORT - *Donna McNulty, Esq.*

RULES REPORTS

Rules Report – July 2023
Rules Report – June 2023

Board counsel informed the board that the information was included in the board materials for informational purposes only and she was available if there were any questions.
Action Taken: No action was required.

RULES DISCUSSION

TAB 22: Annual Regulatory Plan (ARP)

After discussion,

Action Taken: Motion: by Dr. Ducatel to delegate authority to the board chair to review the ARP, seconded by Dr. Mortensen. Motion carried unanimously.

TAB 23: EXECUTIVE DIRECTOR REPORT – Danielle Terrell

The Executive Director informed the board that the legislative session will be starting early in 2023. Additionally, spoke about renewals and E-Licensing. She then reminded the Board that the next board meeting will be in November and that the elections for the Board Chair and Vice Chair will be held at that meeting.

TAB 24: BOARD CHAIR REPORT – Tiffany Di Pietro, DO, FACC, FACOI

The Board Chair introduced the fact that the Board of Medicine issues certificates for exemplary work to medical students and noted that she would like to implement a similar award for Osteopathic medical students. Board staff will research the process.

TAB 25: JOINT COMMITTEE MEETING UPDATES

A: Anesthesiology Assistants Committee

Action Taken: Motion: by Dr. Williams to accept the minutes, seconded by Dr. Mortensen. Motion carried unanimously.

B: Council on Physician Assistants Committee

Action Taken: Motion: by Dr. Williams to accept the minutes, seconded by Dr. Mortensen. Motion carried unanimously.

C: Boards of Medicine and Osteopathic Medicine Joint Rules/Legislative Committee Meeting

June 1, 2023,

Action Taken: Motion: by Dr. Mortensen to accept the June 1, 2023 minutes, seconded by Dr. Ducatel. Motion carried unanimously.

August 3, 2023,

Action Taken: Motion: by Dr. Williams to accept the August 3, 2023 minutes, seconded by Dr. Ducatel. Motion carried unanimously.

D: Boards of Medicine and Osteopathic Medicine Joint Surgical Care/Quality Assurance Committee

August 3, 2023

Action Taken: Motion: by Dr. Mortensen to accept the August 3, 2023 minutes, seconded by Dr. Williams. Motion carried unanimously.

E: Boards of Medicine and Osteopathic Medicine Joint Surgical Care/Quality Assurance Joint Rules Hearing

August 3, 2023

Action Taken: Motion: by Dr. Williams to accept the August 3, 2023 minutes, seconded by Dr. Mortensen. Motion carried unanimously.

TAB 26: LIAISON REPORTS

A: Budget Liaison Report - William Kirsh, D.O.

Dr. Kirsh was not in attendance. There was no report.

B: Legislative Liaison Report
There was no report.

C: Unlicensed Activity Liaison Report
There was no report.

TAB 27: OLD BUSINESS
There was no old business.

TAB 28: NEW BUSINESS
There was no new business.

ADJOURN at 11:52 pm
Next Meeting: November 17, 2023 (Tampa, FL)

Notice of Development of Rulemaking

DEPARTMENT OF HEALTH
Board of Medicine
RULE NO.: RULE TITLE:
64B8-9.019 Practice Standards for the Treatment of Gender Dysphoria
PURPOSE AND EFFECT: The Board proposes the rule development to clarify the practice standards for the treatment of gender dysphoria in minors.
SUBJECT AREA TO BE ADDRESSED: The rule text.
RULEMAKING AUTHORITY: 458.331(1)(v), F.S.
LAW IMPLEMENTED: 458.331(1)(v), F.S.
IF REQUESTED IN WRITING AND NOT DEEMED UNNECESSARY BY THE AGENCY HEAD, A RULE DEVELOPMENT WORKSHOP WILL BE NOTICED IN THE NEXT AVAILABLE FLORIDA ADMINISTRATIVE REGISTER.
THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT AND A COPY OF THE PRELIMINARY DRAFT, IF AVAILABLE, IS: Paul Vazquez, J.D., Executive Director, Board of Medicine/MQA, 4052 Bald Cypress Way, Bin #C03, Tallahassee, Florida 32399-3253, Paul.Vazquez@flhealth.gov
THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS NOT AVAILABLE.

Notice of Proposed Rule

DEPARTMENT OF HEALTH
Board of Medicine
RULE NO.: RULE TITLE:
64B8-9.019 Standards of Practice for the Treatment of Gender Dysphoria in Minors
PURPOSE AND EFFECT: The proposed new rule will set the practice standards for the treatment of gender dysphoria in minors.
SUMMARY: The new rule will set the practice standards for treatment of gender dysphoria in minors.
SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS AND LEGISLATIVE RATIFICATION:
The Agency has determined that this will not have an adverse impact on small business or likely increase directly or indirectly regulatory costs in excess of $200,000 in the aggregate within one year after the implementation of the rule. A SERC has not been prepared by the Agency.
The Agency has determined that the proposed rule is not expected to require legislative ratification based on the statement of estimated regulatory costs or if no SERC is required, the information expressly relied upon and described herein: During discussion of the economic impact of this rule at its Board meeting, the Board concluded that this rule change will not have any impact on licensees and their businesses or the businesses that employ them. The rule will not increase any fees, business costs, personnel costs, will not decrease profit opportunities, and will not require any specialized knowledge to comply. This change will not increase any direct or indirect regulatory costs. Hence, the Board determined that a Statement of Estimated Regulatory Costs (SERC) was not necessary and that the rule will not require ratification by the Legislature. No person or interested party submitted additional information regarding the economic impact at that time.
Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.
RULEMAKING AUTHORITY: 458.331(1)(v) FS.
LAW IMPLEMENTED: 458.331(1)(v) FS.
IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAR.
THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Paul Vazquez, J.D., Executive Director, Board of Medicine/MQA, 4052 Bald Cypress Way, Bin #C03, Tallahassee, Florida 32399-3253, Paul.Vazquez@flhealth.gov

THE FULL TEXT OF THE PROPOSED RULE IS:

64B8-9.019 Standards of Practice for the Treatment of Gender Dysphoria in Minors.

(1) The following therapies and procedures performed for the treatment of gender dysphoria in minors are prohibited.

(a) Sex reassignment surgeries, or any other surgical procedures, that alter primary or secondary sexual characteristics.

(b) Puberty blocking, hormone, and hormone antagonist therapies.

(2) Minors being treated with puberty blocking, hormone, or hormone antagonist therapies prior to the effective date of this rule may continue with such therapies.

Rulemaking Authority 458.331(1)(v) FS. Law Implemented 458.331(1)(v) FS. History-New _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Rules/Legislative Committee, Board of Medicine
NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Board of Medicine
DATE PROPOSED RULE APPROVED BY AGENCY HEAD: November 4, 2022
DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: September 1, 2022

64B8-9.019 Standards of Practice for the Treatment of Gender Dysphoria in Minors.

(1) The following therapies and procedures performed for the treatment of gender dysphoria in minors are prohibited.

(a) Sex reassignment surgeries, or any other surgical procedures, that alter primary or secondary sexual characteristics.

(b) Puberty blocking, hormone, and hormone antagonist therapies.

(2) Minors being treated with puberty blocking, hormone, or hormone antagonist therapies prior to the effective date of this rule may continue with such therapies.

Rulemaking Authority 458.331(1)(v) FS. Law Implemented 458.331(1)(v) FS. History–New 3-16-23.

Notice of Development of Rulemaking

DEPARTMENT OF HEALTH
Board of Osteopathic Medicine
RULE NO.: RULE TITLE:
64B15-14.014 Practice Standards for the Treatment of Gender Dysphoria
PURPOSE AND EFFECT: The Board proposes the rule development to clarify the practice standards for the treatment of gender dysphoria in minors.
SUBJECT AREA TO BE ADDRESSED: The rule text.
RULEMAKING AUTHORITY: 459.015(1)(z), FS.
LAW IMPLEMENTED: 459.015(1)(z), FS.
IF REQUESTED IN WRITING AND NOT DEEMED UNNECESSARY BY THE AGENCY HEAD, A RULE DEVELOPMENT WORKSHOP WILL BE NOTICED IN THE NEXT AVAILABLE FLORIDA ADMINISTRATIVE REGISTER.
THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT AND A COPY OF THE PRELIMINARY DRAFT, IF AVAILABLE, IS: Danielle Terrell, Executive Director, Board of Osteopathic Medicine/MQA, 4052 Bald Cypress Way, Bin #C06, Tallahassee, Florida 32399-3256, or by email at Danielle.Terrell@flhealth.com.
THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS NOT AVAILABLE.

Notice of Proposed Rule

DEPARTMENT OF HEALTH
Board of Osteopathic Medicine
RULE NO.: RULE TITLE:
64B15-14.014 Standards of Practice for the Treatment of Gender Dysphoria in Minors
PURPOSE AND EFFECT: The proposed new rule will set the practice standards for the treatment of gender dysphoria in minors.
SUMMARY: The new rule will set the practice standards for treatment of gender dysphoria in minors
SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS AND LEGISLATIVE RATIFICATION:
The Agency has determined that this will not have an adverse impact on small business or likely increase directly or indirectly regulatory costs in excess of $200,000 in the aggregate within one year after the implementation of the rule. A SERC has not been prepared by the Agency.
The Agency has determined that the proposed rule is not expected to require legislative ratification based on the statement of estimated regulatory costs or if no SERC is required, the information expressly relied upon and described herein: During discussion of the economic impact of this rule at its Board meeting, the Board concluded that this rule change will not have any impact on licensees and their businesses or the businesses that employ them. The rule will not increase any fees, business costs, personnel costs, will not decrease profit opportunities, and will not require any specialized knowledge to comply. This change will not increase any direct or indirect regulatory costs. Hence, the Board determined that a Statement of Estimated Regulatory Costs (SERC) was not necessary and that the rule will not require ratification by the Legislature. No person or interested party submitted additional information regarding the economic impact at that time.
Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.
RULEMAKING AUTHORITY: 459.015(1)(z) FS.
LAW IMPLEMENTED: 459.015(1)(z) FS.
IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAR.
THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Danielle Terrell, Executive Director, Board of Osteopathic Medicine/MQA, 4052 Bald Cypress Way, Bin #C06, Tallahassee, Florida 32399-3256, or by email at Danielle.Terrell@flhealth.com.

THE FULL TEXT OF THE PROPOSED RULE IS:

64B15-14.014 Standards of Practice for the Treatment of Gender Dysphoria in Minors.

(1) The following therapies and procedures performed for the treatment of gender dysphoria in minors are prohibited.

(a) Sex reassignment surgeries, or any other surgical procedures, that alter primary or secondary sexual characteristics.

(b) Puberty blocking, hormone, and hormone antagonist therapies.

(2) Nonsurgical treatments for the treatment of gender dysphoria in minors may continue to be performed under the auspices of Institutional Review Board (IRB) approved, investigator-initiated clinical trials conducted at any of the Florida medical schools set forth in Section 458.3145(1)(i), Florida Statutes. Such clinical trials must include long term longitudinal assessments of the patients' physiologic and psychologic outcomes.

(3) Minors being treated with puberty blocking, hormone, or hormone antagonist therapies prior to the effective date of this rule may continue with such therapies.

Rulemaking Authority 459.015(1)(z) FS. Law Implemented 459.015(1)(z) FS. History-New _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Osteopathic Medicine
NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Board of Osteopathic Medicine

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: November 4, 2022
DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: September 1, 2022

Notice of Change/Withdrawal

DEPARTMENT OF HEALTH
Board of Osteopathic Medicine
RULE NO.: RULE TITLE:
64B15-14.014 Standards of Practice for the Treatment of Gender Dysphoria in Minors

NOTICE OF CORRECTION

Notice is hereby given that the following correction has been made to the proposed rule in Vol. 48 No. 221, November 14, 2022 issue of the Florida Administrative Register.

The notice of proposed rule filed in this matter on November 14, 2022, provided an incorrect email address for the "Person to be contacted regarding the proposed rule." This corrected notice is now being filed to provide the correct email address for the contact person. All interested persons and those who previously submitted comments or a request for hearing to the email address from the November 14, 2022, notice may submit comments or a request for hearing within 21 days of the date of the publication of this notice to the address set forth below.

The email address now reads:

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Danielle Terrell, Executive Director, Board of Osteopathic Medicine/MQA, 4052 Bald Cypress Way, Bin #C06, Tallahassee, Florida 32399-3256, or by email at Danielle.Terrell@flhealth.gov

Notice of Change/Withdrawal

DEPARTMENT OF HEALTH
Board of Osteopathic Medicine
RULE NO.: RULE TITLE:
64B15-14.014 Standards of Practice for the Treatment of Gender Dysphoria in Minors

NOTICE OF CHANGE

Notice is hereby given that the following changes have been made to the proposed rule in accordance with subparagraph 120.54(3)(d)1., F.S., published in Vol. 48 No. 221, November 14, 2022 issue of the Florida Administrative Register.

The changes are in response to written comments submitted by the public and discussion and subsequent vote by the board at a public rule hearing held February 10, 2023. The changes are as follows:

64B15-14.014 Standards of Practice for the Treatment of Gender Dysphoria in Minors.

(1) No change.

~~(2) Nonsurgical treatments for the treatment of gender dysphoria in minors may continue to be performed under the auspices of Institutional Review Board (IRB) approved, investigator-initiated clinical trials conducted at any of the Florida medical schools set forth in Section 458.3145(1)(i), Florida Statutes. Such clinical trials must include long term longitudinal assessments of the patients' physiologic and psychologic outcomes.~~

(3) renumbered (2) No change.

Rulemaking Authority 458.331(1)(v), F.S. Law Implemented 458.331(1)(v), F.S. History-New

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Danielle Terrell, Executive Director, Board of Osteopathic Medicine/MQA, 4052 Bald Cypress Way, Bin # C06, Tallahassee, Florida 32399-3256, or by email at Danielle.Terrell@flhealth.gov.

64B15-14.014 Standards of Practice for the Treatment of Gender Dysphoria in Minors.

(1) The following therapies and procedures performed for the treatment of gender dysphoria in minors are prohibited.

(a) Sex reassignment surgeries, or any other surgical procedures, that alter primary or secondary sexual characteristics.

(b) Puberty blocking, hormone, and hormone antagonist therapies.

(2) Minors being treated with puberty blocking, hormone, or hormone antagonist therapies prior to the effective date of this rule may continue with such therapies.

Rulemaking Authority 459.015(1)(z) FS. Law Implemented 459.015(1)(z) FS. History–New 3-28-23.

Notice of Emergency Rule

DEPARTMENT OF HEALTH
Board of Medicine
RULE NO.: RULE TITLE:
64B8ER23-3 Sex-reassignment Prescriptions
SPECIFIC REASONS FOR FINDING AN IMMEDIATE DANGER TO THE PUBLIC HEALTH, SAFETY OR WELFARE: On May 17, 2023, Florida Governor, Ronald DeSantis, signed CSSB 254 into law creating Ch. 2023-90, Laws of Florida and section 456.52, Florida Statutes. Pursuant to section 456.52(1), F.S., sex-reassignment prescriptions are prohibited for patients younger than 18 years of age upon the effective date of the act; however, pursuant to section 456.52(1)(a), F.S., the Board of Medicine shall within 60 days after the effective date of the act, adopt emergency rules pertaining to standards of practice by which minors may continue to be treated if such treatment was commenced before, and is still active on, the effective date of the act. Section 456.52(1)(b), F.S., also provides a minor patient meeting the criteria outlined in section 456.52(1)(a), F.S., may continue to be treated by a physician with such prescriptions according to rules adopted pursuant to paragraph (1)(a).
Further, pursuant to section 456.52(2), F.S., if sex reassignment prescriptions or procedures are prescribed for or administered to patients 18 years of age or older, consent must be voluntary, informed, and in writing on forms adopted in rule by the Board of Medicine. Pursuant to section 456.52(4), F.S., the consent required for sex-reassignment prescriptions does not apply to renewals of sex-reassignment prescriptions if a physician and his or her patient have met the requirements for consent for the initial prescription. Section 456.52(6)(a), F.S., states "[t]he Board of Medicine and the Board of Osteopathic Medicine shall adopt emergency rules to implement this section."
Accordingly, the Board of Medicine, by emergency rule, hereby allows a patient's prescribing physician to renew a prior lawfully issued sex-reassignment prescription that was initially prescribed prior to May 17, 2023, up and until six months from the effective date of the Board's emergency rule that formally adopts the required consent forms pursuant to section 456.52(1) and (2), F.S.
*** This emergency rule does not apply to Susan Doe, Gavin Goe, or Lisa Loe, or their parents or healthcare providers (see Jane Doe et al., v. Joseph A. Ladapo, et al, Preliminary Injunction, Filed June 6, 2023, Case No. 4:23cv114-RH-MAF, United States District Court for the Northern District of Florida). ***
REASON FOR CONCLUDING THAT THE PROCEDURE IS FAIR UNDER THE CIRCUMSTANCES: The procedure used for the promulgation of this emergency rule is fair under the circumstances. CSSB 254 was signed into law on May 17, 2023. The Board of Medicine was contacted by multiple licensed physicians and physician groups seeking clarification regarding the exception contained in section 465.52(4), F.S., and a timeframe for the required emergency rules shortly thereafter. In response, the Board of Medicine and the Board of Osteopathic Medicine held a Joint Rules/Legislative Committee (Joint Committee) meeting on June 1, 2023, to discuss the emergency rule. On May 19, 2023, the Board of Medicine published notice of the Joint Committee meeting both on its website and in the Florida Administrative Register. On June 2, 2023, the Board of Medicine discussed the report of the Joint Committee and voted upon emergency rule language. The Board of Medicine published notice of its June 2, 2023, meeting in the Florida Administrative Register on May 5, 2023, and on its website on May 12, 2023. Each meeting was held in person in a public forum and was able to be attended by any interested parties. Accordingly, all notice requirements contained in Rule 28-102.001, F.A.C., were properly complied with and interested parties were given ample opportunity to participate in this rulemaking process.
SUMMARY: The proposed emergency rule allows a patient's prescribing physician to renew a prior lawfully issued sex-reassignment prescription that was prescribed prior to the effective date of section 465.52, F.S., up and until six months from the effective date of the Board of Medicine's emergency rule formally adopting a consent form per sections 456.52(1) and (2), Florida Statutes.
THE PERSON TO BE CONTACTED REGARDING THE EMERGENCY RULE IS: Paul Vazquez, Executive Director, Board of Medicine, 4052 Bald Cypress Way, Bin # C-03, Tallahassee, Florida 32399-3253.

THE FULL TEXT OF THE EMERGENCY RULE IS:

64B8ER23-3 Sex-reassignment Prescriptions.

A patient's prescribing physician may renew a prior lawfully issued sex-reassignment prescription as defined in section 456.001(9)(a), Florida Statutes, that was prescribed prior to May 17, 2023, up and until six months from the effective date of the Board's emergency rule formally adopting a consent form per sections 456.52(1) and (2), Florida Statutes.

Rulemaking Authority 456.52(1)(a), (b), 456.52(6)(a) FS. Law Implemented 456.52(1), (2) FS. History – New 6-8-23.

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

EFFECTIVE DATE: June 8, 2023

Notice of Emergency Rule

DEPARTMENT OF HEALTH
Board of Osteopathic Medicine
RULE NO.: RULE TITLE:
64B15ER23-4 Sex-reassignment Prescriptions
SPECIFIC REASONS FOR FINDING AN IMMEDIATE DANGER TO THE PUBLIC HEALTH, SAFETY OR WELFARE: : On May 17, 2023, Florida Governor, Ronald DeSantis, signed CSSB 254 into law creating Ch. 2023-90, Laws of Florida and section 456.52, Florida Statutes. Pursuant to section 456.52(1), F.S., sex-reassignment prescriptions are prohibited for patients younger than 18 years of age upon the effective date of the act; however, pursuant to section 456.52(1)(a), F.S., the Board of Osteopathic Medicine shall within 60 days after the effective date of the act, adopt emergency rules pertaining to standards of practice by which minors may continue to be treated if such treatment was commenced before, and is still active on, the effective date of the act. Section 456.52(1)(b), F.S., also provides a minor patient meeting the criteria outlined in section 456.52(1)(a), F.S., may continue to be treated by a physician with such prescriptions according to rules adopted pursuant to paragraph (1)(a). Further, pursuant to section 456.52(2), F.S., if sex reassignment prescriptions or procedures are prescribed for or administered to patients 18 years of age or older, consent must be voluntary, informed, and in writing on forms adopted in rule by the Board of Osteopathic Medicine. Pursuant to section 456.52(4), F.S., the consent required for sex-reassignment prescriptions does not apply to renewals of sex-reassignment prescriptions if a physician and his or her patient have met the requirements for consent for the initial prescription. Section 456.52(6)(a), F.S., states "[t]he Board of Medicine and the Board of Osteopathic Medicine shall adopt emergency rules to implement this section." Accordingly, the Board of Osteopathic Medicine, by emergency rule, hereby allows a patient's prescribing physician to renew a prior lawfully issued sex-reassignment prescription that was initially prescribed prior to May 17, 2023, up and until six months from the effective date of the Board's emergency rule that formally adopts the required consent forms pursuant to section 456.52(1) and (2), F.S.
*** This emergency rule does not apply to Susan Doe, Gavin Goe, or Lisa Loe, or their parents or healthcare providers (see Jane Doe et al., v. Joseph A. Ladapo, et al, Preliminary Injunction, Filed June 6, 2023, Case No. 4:23cv114-RH-MAF, United States District Court for the Northern District of Florida). ***
REASON FOR CONCLUDING THAT THE PROCEDURE IS FAIR UNDER THE CIRCUMSTANCES: The procedure used for the promulgation of this emergency rule is fair under the circumstances. CSSB 254 was signed into law on May 17, 2023. The Board of Medicine was contacted by multiple licensed physicians and physician groups seeking clarification regarding the exception contained in section 465.52(4), F.S., and a timeframe for the required emergency rules shortly thereafter. In response, the Board of Medicine and the Board of Osteopathic Medicine held a Joint Rules/Legislative Committee (Joint Committee) meeting on June 1, 2023, to discuss the emergency rule. On May 19, 2023, the Board of Osteopathic Medicine published notice of the Joint Committee meeting both on its website and in the Florida Administrative Register. On June 2, 2023, the Board of Medicine discussed the report of the Joint Committee and voted upon emergency rule language. Likewise, on June 20, 2023, the Board of Osteopathic Medicine discussed the Joint committee report and voted upon emergency rule language. The Board of Osteopathic Medicine published notice of its June 20, 2023, meeting in the Florida Administrative Register and on its website on June 6, 2023. Each meeting was held in a public forum and was able to be attended by any interested parties. Accordingly, all notice requirements contained in Rule 28-102.001, F.A.C., were properly complied with and interested parties were given ample opportunity to participate in this rulemaking process.
SUMMARY: The proposed emergency rule allows a patient's prescribing physician to renew a prior lawfully issued sex-reassignment prescription that was prescribed prior to the effective date of section 465.52, F.S., up and until six months from the effective date of the Board of Osteopathic Medicine's emergency rule formally adopting a consent form per sections 456.52(1) and (2), Florida Statutes.
THE PERSON TO BE CONTACTED REGARDING THE EMERGENCY RULE IS: Danielle Terrell, Executive Director, Board of Osteopathic Medicine/MQA, 4052 Bald Cypress Way, Bin #C06, Tallahassee, Florida 32399-3256, or by email at Danielle.Terrell@flhealth.gov.

THE FULL TEXT OF THE EMERGENCY RULE IS:

64B15ER23-4 Sex-reassignment Prescriptions.

A patient's prescribing physician may renew a prior lawfully issued sex-reassignment prescription as defined in section 456.001(9)(a), Florida Statutes, that was prescribed prior to May 17, 2023, up and until six months from the effective date of the Board's emergency rule formally adopting a consent form per sections 456.52(1) and (2), Florida Statutes.

Rulemaking Authority 456.52(1)(a), (b), 456.52(6)(a) FS. Law Implemented 456.52(1), (2) FS., New 6-20-23.

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

EFFECTIVE DATE: June 20, 2023

Notice of Emergency Rule

DEPARTMENT OF HEALTH
Board of Medicine
RULE NO.: RULE TITLE:
64B8ER23-7 Sex-reassignment Standards of Practice in Minors
SPECIFIC REASONS FOR FINDING AN IMMEDIATE DANGER TO THE PUBLIC HEALTH, SAFETY OR WELFARE: On May 17, 2023, Florida Governor, Ronald DeSantis, signed CSSB 254 into law creating Ch. 2023-90, Laws of Florida and section 456.52, Florida Statutes. Pursuant to section 456.52(1), F.S., sex-reassignment prescriptions are prohibited for patients younger than 18 years of age upon the effective date of the act; however, pursuant to section 456.52(1)(a), F.S., the Board of Medicine shall within 60 days after the effective date of the act, adopt emergency rules pertaining to standards of practice by which minors may continue to be treated if such treatment was commenced before, and is still active on, the effective date of the act. Section 456.52(1)(b), F.S., also provides a minor patient meeting the criteria outlined in section 456.52(1)(a), F.S., may continue to be treated by a physician with such prescriptions according to rules adopted pursuant to paragraph (1)(a).
Further, pursuant to section 456.52(2), F.S., if sex reassignment prescriptions or procedures are prescribed for or administered to patients 18 years of age or older, consent must be voluntary, informed, and in writing on forms adopted in rule by the Board of Medicine. Pursuant to section 456.52(4), F.S., the consent required for sex-reassignment prescriptions does not apply to renewals of sex-reassignment prescriptions if a physician and his or her patient have met the requirements for consent for the initial prescription. Section 456.52(6)(a), F.S., states "[t]he Board of Medicine and the Board of Osteopathic Medicine shall adopt emergency rules to implement this section."
Accordingly, the Board of Medicine, by emergency rule, hereby adopts the incorporated standards of practice and mandated consent forms for the treatment of gender dysphoria with puberty blockers and hormone replacement therapy in minors.
*** This emergency rule does not apply to Susan Doe, Gavin Goe, or Lisa Loe, or their parents or healthcare providers (see Jane Doe et al., v. Joseph A. Ladapo, et al, Preliminary Injunction, Filed June 6, 2023, Case No. 4:23cv114-RH-MAF, United States District Court for the Northern District of Florida). ***
REASON FOR CONCLUDING THAT THE PROCEDURE IS FAIR UNDER THE CIRCUMSTANCES: The procedure used for the promulgation of this emergency rule is fair under the circumstances. CSSB 254 was signed into law on May 17, 2023. The Board of Medicine was contacted by multiple licensed physicians and physician groups seeking clarification regarding the exception contained in section 465.52(4), F.S., and a timeframe for the required emergency rules shortly thereafter. In response, the Board of Medicine and the Board of Osteopathic Medicine held a Joint Rules/Legislative Committee (Joint Committee) meeting on June 1, 2023, to discuss the emergency rule. On May 19, 2023, the Board of Medicine published notice of the Joint Committee's June meeting both on its website and in the Florida Administrative Register. On June 2, 2023, the Board of Medicine discussed the report of the Joint Committee and voted upon emergency rule language that would allow for the renewal of previous prescriptions while the Board worked on consent forms. The Board of Medicine published notice of its June 2, 2023, meeting in the Florida Administrative Register on May 5, 2023, and on its website on May 12, 2023.
The Joint Committee held another meeting on June 23, 2023, to discuss an emergency rule adopting draft consent forms that were under consideration. On June 6, 2023, the Board of Medicine published notice of the Joint Committee's June 23, 2023, meeting to its website and in the Florida Administrative Register. On June 30, 2023, the Boards of Medicine and Osteopathic Medicine held a Joint Board meeting (Joint Board Meeting) to discuss the draft consent forms that were approved by the Joint Committee on June 23, 2023. Prior to conclusion of the Joint Board Meeting, the Boards each separately voted to approve the draft consent forms via emergency rule. The Joint Board Meeting was held via Microsoft Teams and notice of the same was published to the Board of Medicine's website and in the Florida Administrative Register on June 22, 2023.
Each Joint Committee meeting was held in person in a public forum and was able to be attended by any interested persons. The Joint Board Meeting was held via Microsoft Teams and also was able to be attended by any interested persons. Public comment was accepted at all of the aforementioned meetings. Further, the Boards accepted written public comment on the proposed rules up and until 24 hours prior to the Joint Board Meeting. Accordingly, all

notice requirements contained in Rule 28-102.001, F.A.C., were properly complied with and interested persons were given ample opportunity to participate in this rulemaking process.
SUMMARY: The proposed emergency rule formally adopts the required consent forms that must be executed for a minor patient who was already receiving sex-reassignment prescriptions to continue to receive said prescriptions per section 456.52(1), Florida Statutes.
THE PERSON TO BE CONTACTED REGARDING THE EMERGENCY RULE IS: Paul Vazquez, Executive Director, Board of Medicine, 4052 Bald Cypress Way, Bin # C-03, Tallahassee, Florida 32399-3253, Paul.Vazquez@flhealth.gov

THE FULL TEXT OF THE EMERGENCY RULE IS:

64B8ER23-7 Sex-reassignment Standards of Practice in Minors.
The standards of practice in this rule do not supersede the level of care, skill, and treatment recognized in general law related to healthcare licensure.

(1) Pursuant to Section 456.52, Florida Statutes, sex-reassignment prescriptions and procedures are prohibited for patients younger than 18 years of age, except that a physician may continue to treat such patient with a prescription if such treatment for sex-reassignment was commenced before, and is still active on, May 17, 2023. The physician is required to obtain voluntary, informed consent while physically present in the same room as the patient. Consent is not required for renewal of such prescriptions if a physician and his or her patient have met the requirements for consent for the initial prescription or renewal; however, a separate consent is required for any new prescription for a pharmaceutical product not previously prescribed to the patient.

(2) Informed Consent. The Board has approved the following mandatory informed consent forms for the continued treatment of minors with sex-reassignment prescriptions:

(a) For patients prescribed puberty blocking medications, form DH5079-MQA, (06/23), entitled "Puberty Suppression Treatment for Patients with Gender Dysphoria, Patient Information and Informed Parental Consent and Assent for Minors," which is hereby incorporated by reference and available from the Board's website at https://flboardofmedicine.gov/forms/Puberty-Suppression-Treatment-for-Patients-with-Gender-Dysphoria-Patient-Information-and-Parental-Consent-and-Assent-for-Minors.pdf.

(b) For patients prescribed sex-reassignment feminizing medications, form DH5080-MQA, (06/23), entitled "Feminizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Parental Consent and Assent for Minors," which is hereby incorporated by reference and available from the Board's website at https://flboardofmedicine.gov/forms/Feminizing-Medications-for-Patients-with-Gender-Dysphoria-Patient-Information-and-Parental-Consent-and-Assent-for-Minors.pdf.

(c) For patients prescribed sex-reassignment masculinizing medications, form DH5081-MQA, (06/23), entitled "Masculinizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Parental Consent and Assent for Minors," which is hereby incorporated by reference and available from the Board's website at https://flboardofmedicine.gov/forms/Masculinizing-Medications-for-Patients-with-Gender-Dysphoria-Patient-Information-and-Parental-Consent-and-Assent-for-Minors.pdf.

(3) A Board-approved informed consent form is not executed until:

(a) The physician issuing the prescription, while physically present in the same room as the patient, has informed the patient and the patient's parent or legal guardian of the nature and risks of the prescription, and has provided and received the written acknowledgement of the patient and the patient's legal guardian before the prescription is prescribed or administered. The physician is prohibited from delegating this responsibility to another person. The physician is also required to sign the informed consent form.

(b) The patient's parent or legal guardian is required to sign the informed consent form.

(c) The patient is required to assent to the informed consent form.

(d) A competent witness is also required to sign the informed consent form.

(4) Standards of Practice. The nature and extent of the requirements set forth below will vary depending on the practice setting and circumstances presented to the prescribing physician. A prescribing physician who continues to treat a minor patient with sex-reassignment prescriptions pursuant to section 456.52(1)(a), Florida Statutes, shall comply with the following:

(a) Patient Evaluation. An in-person thorough medical history and physical examination of the patient conducted by the physician must be documented in the patient's medical record prior to prescribing any new sex-reassignment prescription.

(b) Clinical Determinations. Based on the patient evaluation, the following must be confirmed:

1. The patient has met the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders (DSM) or International Classification of Diseases (ICD);

2. The patient has pubertal changes resulting in an increase in gender dysphoria;

3. The patient does not suffer from a psychiatric comorbidity that interferes with the diagnostic work-up or treatment;

4. The patient will have psychological and social support during treatment;

5. The patient has experienced puberty to at least Tanner Stage 2; and

6. The patient demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of puberty suppression, future cross-sex hormone treatment, as well as the medical and social risks and benefits of sex reassignment surgery based on the patient's current treatment status.

(c) Patient Visit. The physician or their designated covering physician must meet with the patient in-person every six (6) months for the purpose of monitoring the patient and must document each visit in the patient's medical records.

(d) Suicide Risk Assessment. A suicide risk assessment by a licensed mental health care professional must be performed every three (3) months.

(e) Laboratory Testing. Relevant laboratory testing must be performed every four (4) months.

(f) X-rays. X-rays of the hand must be performed each year to monitor and document the patient's bone age progression.

(g) Bone Density Scan. An annual bone density (DEXA) scan must be performed to monitor the patient's bone density during treatment.

(h) Mental Health Assessment. The physician must have the patient undergo an annual mental health assessment to be performed by a board-certified Florida licensed psychiatrist or psychologist.

(i) Counseling. The physician must refer the patient for counseling with a licensed mental health care professional during the treatment period, with a frequency as recommended by the licensed mental health care professional.

(j) Additional Consultations. The physician must refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives.

Rulemaking Authority 456.52 FS. Law Implemented 456.52 FS. History–New 7-5-23.

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

EFFECTIVE DATE: July 5, 2023

Notice of Emergency Rule

DEPARTMENT OF HEALTH
Board of Medicine
RULE NO.: RULE TITLE:
64B8ER23-8 Mandatory Standardized Informed Consent for Sex-reassignment Prescriptions or Procedures in Adults
SPECIFIC REASONS FOR FINDING AN IMMEDIATE DANGER TO THE PUBLIC HEALTH, SAFETY OR WELFARE: On May 17, 2023, Florida Governor, Ronald DeSantis, signed CSSB 254 into law creating Ch. 2023-90, Laws of Florida and section 456.52, Florida Statutes. Pursuant to section 456.52(1), F.S., sex-reassignment prescriptions are prohibited for patients younger than 18 years of age upon the effective date of the act; however, pursuant to section 456.52(1)(a), F.S., the Board of Medicine shall within 60 days after the effective date of the act, adopt emergency rules pertaining to standards of practice by which minors may continue to be treated if such treatment was commenced before, and is still active on, the effective date of the act. Section 456.52(1)(b), F.S., also provides a minor patient meeting the criteria outlined in section 456.52(1)(a), F.S., may continue to be treated by a physician with such prescriptions according to rules adopted pursuant to paragraph (1)(a).
Further, pursuant to section 456.52(2), F.S., if sex reassignment prescriptions or procedures are prescribed for or administered to patients 18 years of age or older, consent must be voluntary, informed, and in writing on forms adopted in rule by the Board of Medicine. Pursuant to section 456.52(4), F.S., the consent required for sex-reassignment prescriptions does not apply to renewals of sex-reassignment prescriptions if a physician and his or her patient have met the requirements for consent for the initial prescription. Section 456.52(6)(a), F.S., states "[t]he Board of Medicine and the Board of Osteopathic Medicine shall adopt emergency rules to implement this section."
Accordingly, the Board of Medicine, by emergency rule, hereby adopts the incorporated mandated consent forms for the treatment of gender dysphoria with hormone replacement therapy and surgical treatment.
*** This emergency rule does not apply to Susan Doe, Gavin Goe, or Lisa Loe, or their parents or healthcare providers (see Jane Doe et al., v. Joseph A. Ladapo, et al, Preliminary Injunction, Filed June 6, 2023, Case No. 4:23cv114-RH-MAF, United States District Court for the Northern District of Florida). ***
REASON FOR CONCLUDING THAT THE PROCEDURE IS FAIR UNDER THE CIRCUMSTANCES: The procedure used for the promulgation of this emergency rule is fair under the circumstances. CSSB 254 was signed into law on May 17, 2023. The Board of Medicine was contacted by multiple licensed physicians and physician groups seeking clarification regarding the exception contained in section 465.52(4), F.S., and a timeframe for the required emergency rules shortly thereafter. In response, the Board of Medicine and the Board of Osteopathic Medicine held a Joint Rules/Legislative Committee (Joint Committee) meeting on June 1, 2023, to discuss the emergency rule. On May 19, 2023, the Board of Medicine published notice of the Joint Committee's June meeting both on its website and in the Florida Administrative Register. On June 2, 2023, the Board of Medicine discussed the report of the Joint Committee and voted upon emergency rule language that would allow for the renewal of previous prescriptions while the Board worked on consent forms. The Board of Medicine published notice of its June 2, 2023, meeting in the Florida Administrative Register on May 5, 2023, and on its website on May 12, 2023.
The Joint Committee held another meeting on June 23, 2023, to discuss an emergency rule adopting draft consent forms that were under consideration. On June 6, 2023, the Board of Medicine published notice of the Joint Committee's June 23, 2023, meeting to its website and in the Florida Administrative Register. On June 30, 2023, the Boards of Medicine and Osteopathic Medicine held a Joint Board meeting (Joint Board Meeting) to discuss the draft consent forms that were approved by the Joint Committee on June 23, 2023. The Joint Board Meeting was held via Microsoft Teams and notice of the same was published to the Board of Medicine's website and in the Florida Administrative Register on June 22, 2023.
Each Joint Committee meeting was held in person in a public forum and was able to be attended by any interested persons. The Joint Board Meeting was held via Microsoft Teams and also was able to be attended by any interested persons. Public comment was accepted at all of the aforementioned meetings. Further, the Board's accepted written public comment on the proposed rules up and until 24 hours prior to the Joint Board Meeting. Accordingly, all notice requirements contained in Rule 28-102.001, F.A.C., were properly complied with and interested persons were given ample opportunity to participate in this rulemaking process.

SUMMARY: The proposed emergency rule formally adopts the required consent forms for a patient to receive sex-reassignment prescriptions and/or procedures per section 456.52(2), Florida Statutes.
THE PERSON TO BE CONTACTED REGARDING THE EMERGENCY RULE IS: Paul Vazquez, Executive Director, Board of Medicine, 4052 Bald Cypress Way, Bin # C-03, Tallahassee, Florida 32399-3253, Paul.Vazquez@flhealth.gov

THE FULL TEXT OF THE EMERGENCY RULE IS:

64B8ER23-8 Mandatory Standardized Informed Consent for Sex-reassignment Prescriptions or Procedures in Adults.

Pursuant to Section 456.52, Florida Statutes, when sex-reassignment prescriptions or procedures are prescribed for or administered or performed on patients 18 years of age or older, the physician is required to obtain voluntary, informed consent while physically present in the same room as the patient. Consent is not required for renewal of such prescriptions if a physician and the physician's patient have met the requirements for consent for the initial prescription or renewal; however, a separate consent is required for any new prescription for a pharmaceutical product not previously prescribed to the patient.

(1) Informed Consent. The Board has approved the following mandatory informed consent forms for sex-reassignment prescriptions or procedures for patients 18 years of age or older:

(a) For patients prescribed sex-reassignment feminizing medication, form DH5082-MQA, (06/23), entitled "Feminizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Consent," which is hereby incorporated by reference and available from the Board's website at https://flboardofmedicine.gov/forms/Feminizing-Medications-for-Patients-with-Gender-Dysphoria-Patient-Information-and-Informed-Consent.pdf.

(b) For patients prescribed sex-reassignment masculinizing medications, form DH5083-MQA, (06/23), entitled "Masculinizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Consent," which is hereby incorporated by reference and available from the Board's website at https://flboardofmedicine.gov/forms/Masculinizing-Medications-for-Patients-with-Gender-Dysphoria-Patient-Information-and-Informed-Consent.pdf.

(c) For patients undergoing surgical treatment, form DH5084-MQA, (06/23), entitled "Surgical Treatment for Adults with Gender Dysphoria, Patient Information and Informed Consent," which is hereby incorporated by reference and available from the Board's website at https://flboardofmedicine.gov/forms/Surgical-Treatment-for-Adults-with-Gender-Dysphoria-Patients-Information-and-Informed-Consent.pdf.

(2) A Board-approved informed consent form is not executed until:

(a) The physician issuing the prescription or performing the procedure, while physically present in the same room as the patient, has informed the patient of the nature and risks of the prescription or procedure and has provided and received the patient's written acknowledgement before the prescription is prescribed, administered, or performed. The physician is prohibited from delegating this responsibility to another person. The physician is also required to sign the informed consent form.

(b) The patient is required to sign the informed consent form.

(c) A competent witness is also required to sign the informed consent form.

Rulemaking Authority 456.52 FS. Law Implemented 456.52 FS. History – New 7-5-23.

THIS RULE TAKES EFFECT UPON BEING FILED WITH THE DEPARTMENT OF STATE UNLESS A LATER TIME AND DATE IS SPECIFIED IN THE RULE.
EFFECTIVE DATE: July 5, 2023

Notice of Emergency Rule

DEPARTMENT OF HEALTH
Board of Osteopathic Medicine
RULE NO.: RULE TITLE:
64B15ER23-9 Sex-reassignment Standards of Practice in Minors
SPECIFIC REASONS FOR FINDING AN IMMEDIATE DANGER TO THE PUBLIC HEALTH, SAFETY OR WELFARE: On May 17, 2023, Florida Governor, Ronald DeSantis, signed CSSB 254 into law creating Ch. 2023-90, Laws of Florida and section 456.52, Florida Statutes. Pursuant to section 456.52(1), F.S., sex-reassignment prescriptions are prohibited for patients younger than 18 years of age upon the effective date of the act; however, pursuant to section 456.52(1)(a), F.S., the Board of Osteopathic Medicine shall within 60 days after the effective date of the act, adopt emergency rules pertaining to standards of practice by which minors may continue to be treated if such treatment was commenced before, and is still active on, the effective date of the act. Section 456.52(1)(b), F.S., also provides a minor patient meeting the criteria outlined in section 456.52(1)(a), F.S., may continue to be treated by a physician with such prescriptions according to rules adopted pursuant to paragraph (1)(a). Further, pursuant to section 456.52(2), F.S., if sex reassignment prescriptions or procedures are prescribed for or administered to patients 18 years of age or older, consent must be voluntary, informed, and in writing on forms adopted in rule by the Board of Osteopathic Medicine. Pursuant to section 456.52(4), F.S., the consent required for sex-reassignment prescriptions does not apply to renewals of sex-reassignment prescriptions if a physician and his or her patient have met the requirements for consent for the initial prescription. Section 456.52(6)(a), F.S., states "[t]he Board of Medicine and the Board of Osteopathic Medicine shall adopt emergency rules to implement this section."
Accordingly, the Board of Osteopathic Medicine, by emergency rule, hereby adopts the incorporated standards of practice and mandated consent forms for the treatment of gender dysphoria with puberty blockers and hormone replacement therapy in minors.
*** This emergency rule does not apply to Susan Doe, Gavin Goe, or Lisa Loe, or their parents or healthcare providers (see Jane Doe et al., v. Joseph A. Ladapo, et al, Preliminary Injunction, Filed June 6, 2023, Case No. 4:23cv114-RH-MAF, United States District Court for the Northern District of Florida). ***
REASON FOR CONCLUDING THAT THE PROCEDURE IS FAIR UNDER THE CIRCUMSTANCES: The procedure used for the promulgation of this emergency rule is fair under the circumstances. CSSB 254 was signed into law on May 17, 2023. The Board of Osteopathic Medicine was contacted by multiple licensed physicians and physician groups seeking clarification regarding the exception contained in section 465.52(4), F.S., and a timeframe for the required emergency rules shortly thereafter. In response, the Board of Medicine and the Board of Osteopathic Medicine held a Joint Rules/Legislative Committee (Joint Committee) meeting on June 1, 2023, to discuss the emergency rule. On May 19, 2023, the Board of Osteopathic Medicine published notice of the Joint Committee's June meeting both on its website and in the Florida Administrative Register. On June 2, 2023, the Board of Osteopathic Medicine discussed the report of the Joint Committee and voted upon emergency rule language that would allow for the renewal of previous prescriptions while the Board worked on consent forms. The Board of Osteopathic Medicine published notice of its June 2, 2023, meeting in the Florida Administrative Register on May 5, 2023, and on its website on May 12, 2023.
The Joint Committee held another meeting on June 23, 2023, to discuss an emergency rule adopting draft consent forms that were under consideration. On June 6, 2023, the Board of Osteopathic Medicine published notice of the Joint Committee's June 23, 2023, meeting to its website and in the Florida Administrative Register. On June 30, 2023, the Boards of Medicine and Osteopathic Medicine held a Joint Board meeting (Joint Board Meeting) to discuss the draft consent forms that were approved by the Joint Committee on June 23, 2023. Prior to conclusion of the Joint Board Meeting, the Boards each separately voted to approve the draft consent forms via emergency rule. The Joint Board Meeting was held via Microsoft Teams and notice of the same was published to the Board of Osteopathic Medicine's website and in the Florida Administrative Register on June 22, 2023.
Each Joint Committee meeting was held in person in a public forum and was able to be attended by any interested persons. The Joint Board Meeting was held via Microsoft Teams and also was able to be attended by any interested persons. Public comment was accepted at all of the aforementioned meetings. Further, the Boards accepted written public comment on the proposed rules up and until 24 hours prior to the Joint Board Meeting. Accordingly, all

notice requirements contained in Rule 28-102.001, F.A.C., were properly complied with and interested persons were given ample opportunity to participate in this rulemaking process.
SUMMARY: The proposed emergency rule formally adopts the required consent forms that must be executed for a minor patient who was already receiving sex-reassignment prescriptions to continue to receive said prescriptions per section 456.52(1), Florida Statutes.
THE PERSON TO BE CONTACTED REGARDING THE EMERGENCY RULE IS: Danielle Terrell, Executive Director, Board of Osteopathic Medicine/MQA, 4052 Bald Cypress Way, Bin #C06, Tallahassee, Florida 32399-3256, or by email at Danielle.Terrell@flhealth.gov.

THE FULL TEXT OF THE EMERGENCY RULE IS:

64B15ER23-9 Sex-reassignment Standards of Practice in Minors.
The standards of practice in this rule do not supersede the level of care, skill, and treatment recognized in general law related to healthcare licensure.

(1) Pursuant to Section 456.52, Florida Statutes, sex-reassignment prescriptions and procedures are prohibited for patients younger than 18 years of age, except that a physician may continue to treat such patient with a prescription if such treatment for sex-reassignment was commenced before, and is still active on, May 17, 2023. The physician is required to obtain voluntary, informed consent while physically present in the same room as the patient. Consent is not required for renewal of such prescriptions if a physician and his or her patient have met the requirements for consent for the initial prescription or renewal; however, a separate consent is required for any new prescription for a pharmaceutical product not previously prescribed to the patient.

(2) Informed Consent. The Board has approved the following mandatory informed consent forms for the continued treatment of minors with sex-reassignment prescriptions:

(a) For patients prescribed puberty blocking medications, form DH5079-MQA, (06/23), entitled "Puberty Suppression Treatment for Patients with Gender Dysphoria, Patient Information and Informed Parental Consent and Assent for Minors," which is hereby incorporated by reference and available from the Board's website at https://flboardofmedicine.gov/forms/Puberty-Suppression-Treatment-for-Patients-with-Gender-Dysphoria-Patient-Information-and-Parental-Consent-and-Assent-for-Minors.pdf.

(b) For patients prescribed sex-reassignment feminizing medications, form DH5080-MQA, (06/23), entitled "Feminizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Parental Consent and Assent for Minors," which is hereby incorporated by reference and available from the Board's website at https://flboardofmedicine.gov/forms/Feminizing-Medications-for-Patients-with-Gender-Dysphoria-Patient-Information-and-Parental-Consent-and-Assent-for-Minors.pdf.

(c) For patients prescribed sex-reassignment masculinizing medications, form DH5081-MQA, (06/23), entitled "Masculinizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Parental Consent and Assent for Minors," which is hereby incorporated by reference and available from the Board's website at https://flboardofmedicine.gov/forms/Masculinizing-Medications-for-Patients-with-Gender-Dysphoria-Patient-Information-and-Parental-Consent-and-Assent-for-Minors.pdf.

(3) A Board-approved informed consent form is not executed until:

(a) The physician issuing the prescription, while physically present in the same room as the patient, has informed the patient and the patient's parent or legal guardian of the nature and risks of the prescription, and has provided and received the written acknowledgement of the patient and the patient's legal guardian before the prescription is prescribed or administered. The physician is prohibited from delegating this responsibility to another person. The physician is also required to sign the informed consent form.

(b) The patient's parent or legal guardian is required to sign the informed consent form.

(c) The patient is required to assent to the informed consent form.

(d) A competent witness is also required to sign the informed consent form.

(4) Standards of Practice. The nature and extent of the requirements set forth below will vary depending on the practice setting and circumstances presented to the prescribing physician. A prescribing physician who continues to treat a minor patient with sex-reassignment prescriptions pursuant to section 456.52(1)(a), Florida Statutes, shall comply with the following:

(a) Patient Evaluation. An in-person thorough medical history and physical examination of the patient conducted by the physician must be documented in the patient's medical record prior to prescribing any new sex-reassignment prescription.

(b) Clinical Determinations. Based on the patient evaluation, the following must be confirmed:

1. The patient has met the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders (DSM) or International Classification of Diseases (ICD);

2. The patient has pubertal changes resulting in an increase in gender dysphoria;

3. The patient does not suffer from a psychiatric comorbidity that interferes with the diagnostic work-up or treatment;

4. The patient will have psychological and social support during treatment;

5. The patient has experienced puberty to at least Tanner Stage 2; and

6. The patient demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of puberty suppression, future cross-sex hormone treatment, as well as the medical and social risks and benefits of sex reassignment surgery based on the patient's current treatment status.

(c) Patient Visit. The physician or their designated covering physician must meet with the patient in-person every six (6) months for the purpose of monitoring the patient and must document each visit in the patient's medical records.

(d) Suicide Risk Assessment. A suicide risk assessment by a licensed mental health care professional must be performed every three (3) months.

(e) Laboratory Testing. Relevant laboratory testing must be performed every four (4) months.

(f) X-rays. X-rays of the hand must be performed each year to monitor and document the patient's bone age progression.

(g) Bone Density Scan. An annual bone density (DEXA) scan must be performed to monitor the patient's bone density during treatment.

(h) Mental Health Assessment. The physician must have the patient undergo an annual mental health assessment to be performed by a board-certified Florida licensed psychiatrist or psychologist.

(i) Counseling. The physician must refer the patient for counseling with a licensed mental health care professional during the treatment period, with a frequency as recommended by the licensed mental health care professional.

(j) Additional Consultations. The physician must refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives.

Rulemaking Authority 456.52 FS. Law Implemented 456.52 FS. History – New 7-5-23.

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

EFFECTIVE DATE: July 5, 2023

Notice of Emergency Rule

DEPARTMENT OF HEALTH
Board of Osteopathic Medicine
RULE NO.: RULE TITLE:
64B15ER23-10 Mandatory Standardized Informed Consent for Sex-reassignment Prescriptions or Procedures in Adults
SPECIFIC REASONS FOR FINDING AN IMMEDIATE DANGER TO THE PUBLIC HEALTH, SAFETY OR WELFARE: On May 17, 2023, Florida Governor, Ronald DeSantis, signed CSSB 254 into law creating Ch. 2023-90, Laws of Florida and section 456.52, Florida Statutes. Pursuant to section 456.52(1), F.S., sex-reassignment prescriptions are prohibited for patients younger than 18 years of age upon the effective date of the act; however, pursuant to section 456.52(1)(a), F.S., the Board of Osteopathic Medicine shall within 60 days after the effective date of the act, adopt emergency rules pertaining to standards of practice by which minors may continue to be treated if such treatment was commenced before, and is still active on, the effective date of the act. Section 456.52(1)(b), F.S., also provides a minor patient meeting the criteria outlined in section 456.52(1)(a), F.S., may continue to be treated by a physician with such prescriptions according to rules adopted pursuant to paragraph (1)(a). Further, pursuant to section 456.52(2), F.S., if sex reassignment prescriptions or procedures are prescribed for or administered to patients 18 years of age or older, consent must be voluntary, informed, and in writing on forms adopted in rule by the Board of Osteopathic Medicine. Pursuant to section 456.52(4), F.S., the consent required for sex-reassignment prescriptions does not apply to renewals of sex-reassignment prescriptions if a physician and his or her patient have met the requirements for consent for the initial prescription. Section 456.52(6)(a), F.S., states "[t]he Board of Medicine and the Board of Osteopathic Medicine shall adopt emergency rules to implement this section." Accordingly, the Board of Osteopathic Medicine, by emergency rule, hereby adopts the incorporated mandated consent forms for the treatment of gender dysphoria with hormone replacement therapy and surgical treatment.
*** This emergency rule does not apply to Susan Doe, Gavin Goe, or Lisa Loe, or their parents or healthcare providers (see Jane Doe et al., v. Joseph A. Ladapo, et al, Preliminary Injunction, Filed June 6, 2023, Case No. 4:23cv114-RH-MAF, United States District Court for the Northern District of Florida). ***
REASON FOR CONCLUDING THAT THE PROCEDURE IS FAIR UNDER THE CIRCUMSTANCES: The procedure used for the promulgation of this emergency rule is fair under the circumstances. CSSB 254 was signed into law on May 17, 2023. The Board of Medicine was contacted by multiple licensed physicians and physician groups seeking clarification regarding the exception contained in section 465.52(4), F.S., and a timeframe for the required emergency rules shortly thereafter. In response, the Board of Medicine and the Board of Osteopathic Medicine held a Joint Rules/Legislative Committee (Joint Committee) meeting on June 1, 2023, to discuss the emergency rule. On May 19, 2023, the Board of Medicine published notice of the Joint Committee's June meeting both on its website and in the Florida Administrative Register. On June 2, 2023, the Board of Osteopathic Medicine discussed the report of the Joint Committee and voted upon emergency rule language that would allow for the renewal of previous prescriptions while the Board worked on consent forms. The Board of Osteopathic Medicine published notice of its June 2, 2023, meeting in the Florida Administrative Register on May 5, 2023, and on its website on May 12, 2023.
The Joint Committee held another meeting on June 23, 2023, to discuss an emergency rule adopting draft consent forms that were under consideration. On June 6, 2023, the Board of Osteopathic Medicine published notice of the Joint Committee's June 23, 2023, meeting to its website and in the Florida Administrative Register. On June 30, 2023, the Boards of Medicine and Osteopathic Medicine held a Joint Board meeting (Joint Board Meeting) to discuss the draft consent forms that were approved by the Joint Committee on June 23, 2023. The Joint Board Meeting was held via Microsoft Teams and notice of the same was published to the Board of Osteopathic Medicine's website and in the Florida Administrative Register on June 22, 2023.
Each Joint Committee meeting was held in person in a public forum and was able to be attended by any interested persons. The Joint Board Meeting was held via Microsoft Teams and also was able to be attended by any interested persons. Public comment was accepted at all of the aforementioned meetings. Further, the Board's accepted written public comment on the proposed rules up and until 24 hours prior to the Joint Board Meeting. Accordingly, all

notice requirements contained in Rule 28-102.001, F.A.C., were properly complied with and interested persons were given ample opportunity to participate in this rulemaking process.
SUMMARY: The proposed emergency rule formally adopts the required consent forms for a patient to receive sex-reassignment prescriptions and/or procedures per section 456.52(2), Florida Statutes.
THE PERSON TO BE CONTACTED REGARDING THE EMERGENCY RULE IS: Danielle Terrell, Executive Director, Board of Osteopathic Medicine/MQA, 4052 Bald Cypress Way, Bin #C06, Tallahassee, Florida 32399-3256, or by email at Danielle.Terrell@flhealth.gov.

THE FULL TEXT OF THE EMERGENCY RULE IS:

64B15ER23-10 Mandatory Standardized Informed Consent for Sex-reassignment Prescriptions or Procedures in Adults.
Pursuant to Section 456.52, Florida Statutes, when sex-reassignment prescriptions or procedures are prescribed for or administered or performed on patients 18 years of age or older, the physician is required to obtain voluntary, informed consent while physically present in the same room as the patient. Consent is not required for renewal of such prescriptions if a physician and the physician's patient have met the requirements for consent for the initial prescription or renewal; however, a separate consent is required for any new prescription for a pharmaceutical product not previously prescribed to the patient.

(1) Informed Consent. The Board has approved the following mandatory informed consent forms for sex-reassignment prescriptions or procedures for patients 18 years of age or older:

(a) For patients prescribed sex-reassignment feminizing medication, form DH5082-MQA, (06/23), entitled "Feminizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Consent," which is hereby incorporated by reference and available from the Board's website at https://flboardofmedicine.gov/forms/Feminizing-Medications-for-Patients-with-Gender-Dysphoria-Patient-Information-and-Informed-Consent.pdf.

(b) For patients prescribed sex-reassignment masculinizing medications, form DH5083-MQA, (06/23), entitled "Masculinizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Consent," which is hereby incorporated by reference and available from the Board's website at https://flboardofmedicine.gov/forms/Masculinizing-Medications-for-Patients-with-Gender-Dysphoria-Patient-Information-and-Informed-Consent.pdf.

(c) For patients undergoing surgical treatment, form DH5084-MQA, (06/23), entitled "Surgical Treatment for Adults with Gender Dysphoria, Patient Information and Informed Consent," which is hereby incorporated by reference and available from the Board's website at https://flboardofmedicine.gov/forms/Surgical-Treatment-for-Adults-with-Gender-Dysphoria-Patients-Information-and-Informed-Consent.pdf.

(2) A Board-approved informed consent form is not executed until:

(a) The physician issuing the prescription or performing the procedure, while physically present in the same room as the patient, has informed the patient of the nature and risks of the prescription or procedure and has provided and received the patient's written acknowledgement before the prescription is prescribed, administered, or performed. The physician is prohibited from delegating this responsibility to another person. The physician is also required to sign the informed consent form.

(b) The patient is required to sign the informed consent form.

(c) A competent witness is also required to sign the informed consent form.

Rulemaking Authority 456.52 FS. Law Implemented 456.52 FS. History – New 7-5-23.

THIS RULE TAKES EFFECT UPON BEING FILED WITH THE DEPARTMENT OF STATE UNLESS A LATER TIME AND DATE IS SPECIFIED IN THE RULE.
EFFECTIVE DATE: July 5, 2023

Notice of Emergency Rule

DEPARTMENT OF HEALTH
Board of Medicine
RULE NO.: RULE TITLE:
64B8ER23-11 Mandatory Standardized Informed Consent for Sex-reassignment Prescriptions or Procedures in Adults
SPECIFIC REASONS FOR FINDING AN IMMEDIATE DANGER TO THE PUBLIC HEALTH, SAFETY OR WELFARE: On May 17, 2023, Florida Governor, Ronald DeSantis, signed CSSB 254 into law creating Ch. 2023-90, Laws of Florida and section 456.52, Florida Statutes. Pursuant to section 456.52(2), F.S., if sex reassignment prescriptions or procedures are prescribed for or administered to patients 18 years of age or older, consent must be voluntary, informed, and in writing on forms adopted in rule by the Board of Medicine. Pursuant to section 456.52(4), F.S., the consent required for sex-reassignment prescriptions does not apply to renewals of sex-reassignment prescriptions if a physician and his or her patient have met the requirements for consent for the initial prescription. Section 456.52(6)(a), F.S., states "[t]he Board of Medicine and the Board of Osteopathic Medicine shall adopt emergency rules to implement this section."
Accordingly, the Board of Medicine, by emergency rule, hereby adopts the incorporated mandated consent forms for the treatment of gender dysphoria with hormone replacement therapy and surgical treatment for patients 18 years of age or older.
*** This emergency rule does not apply to Susan Doe, Gavin Goe, or Lisa Loe, or their parents or healthcare providers (see Jane Doe et al., v. Joseph A. Ladapo, et al, Preliminary Injunction, Filed June 6, 2023, Case No. 4:23cv114-RH-MAF, United States District Court for the Northern District of Florida). ***
REASON FOR CONCLUDING THAT THE PROCEDURE IS FAIR UNDER THE CIRCUMSTANCES: The procedure used for the promulgation of this emergency rule is fair under the circumstances. CSSB 254 was signed into law on May 17, 2023. The Board of Medicine was contacted by multiple licensed physicians and physician groups seeking clarification regarding the exception contained in section 465.52(4), F.S., and a timeframe for the required emergency rules shortly thereafter. In response, the Board of Medicine and the Board of Osteopathic Medicine held a Joint Rules/Legislative Committee (Joint Committee) meeting on June 1, 2023, to discuss the emergency rule. On May 19, 2023, the Board of Medicine published notice of the Joint Committee's June meeting both on its website and in the Florida Administrative Register. On June 2, 2023, the Board of Medicine discussed the report of the Joint Committee and voted upon emergency rule language that would allow for the renewal of previous prescriptions while the Board worked on consent forms. The Board of Medicine published notice of its June 2, 2023, meeting in the Florida Administrative Register on May 5, 2023, and on its website on May 12, 2023.
The Joint Committee held yet another meeting on June 23, 2023, to discuss an emergency rule adopting draft consent forms that were under consideration. On June 6, 2023, the Board of Medicine published notice of the Joint Committee's June 23 meeting to its website and in the Florida Administrative Register. On June 30, 2023, the Boards of Medicine and Osteopathic Medicine held a Joint Board meeting (Joint Board Meeting) to discuss the draft consent forms that were approved by the Joint Committee on June 23. The Joint Board meeting was held via Microsoft Teams and notice of the same was published to the Board of Medicine's website and in the Florida Administrative Register on June 22, 2023. During the June 30, 2023, Joint Board Meeting, the Boards voted to approve consent forms and adopted them via emergency rule filed on July 5, 2023.
On July 21, 2023, the Board received correspondence from the Joint Administrative Procedures Committee (JAPC) questioning the Board's statutory authority for requiring that adult patients "undergo a thorough psychological and social evaluation performed by a Florida licensed board-certified psychiatrist or a Florida licensed psychologist" before beginning hormone replacement therapy and every two years thereafter. Accordingly, the Florida Board of Medicine and Osteopathic Medicine's Joint Rules/Legislative Committee held a public meeting on August 3, 2023, and voted to remove the provision addressed by JAPC. The Board of Medicine discussed the Joint Committee's report and affirmed the decision at its August 4, 2023, Board meeting.
The August 3 Joint Committee meeting was held in person in a public forum and was able to be attended by any interested parties. Notice of the Joint Committee meeting was published to the Board of Medicine's website and in the Florida Administrative Register on July 13, 2023. The August 4 Board Meeting was also held in person in a

public forum and was able to be attended by any interested parties. Notice for the August 4 Board Meeting was published to the Board of Medicine's website on July 13, 2023, and in the Florida Administrative Register on July 12, 2023.

Public comment was accepted at all of the aforementioned board and committee meetings. Further, the Boards accepted written public comment on the initial proposed rules up and until 24 hours prior to the Joint Board Meeting. The Board also accepted written comments up and until 24 hours prior to the August 3, 2023, Joint Rules/Legislative Committee meeting as well. Accordingly, all notice requirements contained in Rule 28-102.001, F.A.C., were properly complied with at all points during the rulemaking process and interested parties were given ample opportunity to participate at all points during this rulemaking process.

SUMMARY: The proposed emergency rule formally adopts the required consent forms for an adult patient to receive sex-reassignment prescriptions and/or procedures per section 456.52(2), Florida Statutes.

THE PERSON TO BE CONTACTED REGARDING THE EMERGENCY RULE IS: Paul Vazquez, Executive Director, Board of Medicine, 4052 Bald Cypress Way, Bin # C-03, Tallahassee, Florida 32399-3253.

THE FULL TEXT OF THE EMERGENCY RULE IS:

64B8ER23-11 Mandatory Standardized Informed Consent for Sex-reassignment Prescriptions or Procedures in Adults

Pursuant to Section 456.52, Florida Statutes, when sex-reassignment prescriptions or procedures are prescribed for or administered or performed on patients 18 years of age or older, the physician is required to obtain voluntary, informed consent while physically present in the same room as the patient. Consent is not required for renewal of such prescriptions if a physician and the physician's patient have met the requirements for consent for the initial prescription or renewal; however, a separate consent is required for any new prescription for a pharmaceutical product not previously prescribed to the patient.

(1) Informed Consent. The Board has approved the following mandatory informed consent forms for sex-reassignment prescriptions or procedures for patients 18 years of age or older:

(a) For patients prescribed sex-reassignment feminizing medication, form DH5082-MQA, (Rev. 08/23), entitled "Feminizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Consent," which is hereby incorporated by reference and available from the Board's website at https://flboardofmedicine.gov/forms/Feminizing-Medications-for-Patients-with-Gender-Dysphoria-Patient-Information-and-Informed-Consent.pdf.

(b) For patients prescribed sex-reassignment masculinizing medications, form DH5083-MQA, (Rev. 08/23), entitled "Masculinizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Consent," which is hereby incorporated by reference and available from the Board's website at https://flboardofmedicine.gov/forms/Masculinizing-Medications-for-Patients-with-Gender-Dysphoria-Patient-Information-and-Informed-Consent.pdf.

(c) For patients undergoing surgical treatment, form DH5084-MQA, (06/23), entitled "Surgical Treatment for Adults with Gender Dysphoria, Patient Information and Informed Consent," which is hereby incorporated by reference and available from the Board's website at https://flboardofmedicine.gov/forms/Surgical-Treatment-for-Adults-with-Gender-Dysphoria-Patients-Information-and-Informed-Consent.pdf.

(2) A Board-approved informed consent form is not executed until:

(a) The physician issuing the prescription or performing the procedure, while physically present in the same room as the patient, has informed the patient of the nature and risks of the prescription or procedure and has provided and received the patient's written acknowledgement before the prescription is prescribed, administered, or performed. The physician is prohibited from delegating this responsibility to another person. The physician is also required to sign the informed consent form.

(b) The patient is required to sign the informed consent form.

(c) A competent witness is also required to sign the informed consent form.

Rulemaking Authority 456.52 FS. Law Implemented 456.52 FS. History – New 8-18-23.

THIS RULE TAKES EFFECT UPON BEING FILED WITH THE DEPARTMENT OF STATE UNLESS A LATER TIME AND DATE IS SPECIFIED IN THE RULE.
EFFECTIVE DATE: August 18, 2023

Notice of Emergency Rule

DEPARTMENT OF HEALTH
Board of Osteopathic Medicine
RULE NO.: RULE TITLE:
64B15ER23-12 Mandatory Standardized Informed Consent for Sex-reassignment Prescriptions or Procedures in Adults
SPECIFIC REASONS FOR FINDING AN IMMEDIATE DANGER TO THE PUBLIC HEALTH, SAFETY OR WELFARE: On May 17, 2023, Florida Governor, Ronald DeSantis, signed CSSB 254 into law creating Ch. 2023-90, Laws of Florida and section 456.52, Florida Statutes. Pursuant to section 456.52(2), F.S., if sex reassignment prescriptions or procedures are prescribed for or administered to patients 18 years of age or older, consent must be voluntary, informed, and in writing on forms adopted in rule by the Board of Osteopathic Medicine. Pursuant to section 456.52(4), F.S., the consent required for sex-reassignment prescriptions does not apply to renewals of sex-reassignment prescriptions if a physician and his or her patient have met the requirements for consent for the initial prescription. Section 456.52(6)(a), F.S., states "[t]he Board of Medicine and the Board of Osteopathic Medicine shall adopt emergency rules to implement this section."
Accordingly, the Board of Osteopathic Medicine, by emergency rule, hereby adopts the incorporated mandated consent forms for the treatment of gender dysphoria with hormone replacement therapy and surgical treatment for patients 18 years of age or older.
*** This emergency rule does not apply to Susan Doe, Gavin Goe, or Lisa Loe, or their parents or healthcare providers (see Jane Doe et al., v. Joseph A. Ladapo, et al, Preliminary Injunction, Filed June 6, 2023, Case No. 4:23cv114-RH-MAF, United States District Court for the Northern District of Florida). ***
REASON FOR CONCLUDING THAT THE PROCEDURE IS FAIR UNDER THE CIRCUMSTANCES: The procedure used for the promulgation of this emergency rule is fair under the circumstances. CSSB 254 was signed into law on May 17, 2023. The Board of Osteopathic Medicine was contacted by multiple licensed physicians and physician groups seeking clarification regarding the exception contained in section 465.52(4), F.S., and a timeframe for the required emergency rules shortly thereafter. In response, the Board of Medicine and the Board of Osteopathic Medicine held a Joint Rules/Legislative Committee (Joint Committee) meeting on June 1, 2023, to discuss the emergency rule. On May 19, 2023, the Board of Medicine published notice of the Joint Committee's June meeting both on its website and in the Florida Administrative Register. On June 20, 2023, the Board of Osteopathic Medicine discussed the report of the Joint Committee and voted upon emergency rule language that would allow for the renewal of previous prescriptions while the Board worked on consent forms. The Board of Osteopathic Medicine published notice of its June 20, 2023, meeting in the Florida Administrative Register on May 5, 2023, and on its website on May 12, 2023.
The Joint Committee held another meeting on June 23, 2023, to discuss an emergency rule adopting draft consent forms that were under consideration. On June 6, 2023, the Board of Osteopathic Medicine published notice of the Joint Committee's June 23, 2023, meeting to its website and in the Florida Administrative Register. On June 30, 2023, the Boards of Medicine and Osteopathic Medicine held a Joint Board meeting (Joint Board Meeting) to discuss the draft consent forms that were approved by the Joint Committee on June 23, 2023. The Joint Board meeting was held via Microsoft Teams and notice of the same was published to the Board of Medicine's website and in the Florida Administrative Register on June 22, 2023. During the June 30, 2023, Joint Board Meeting, the Boards voted to approve consent forms and adopted them via emergency rule filed on July 5, 2023.
On July 21, 2023, the Board received correspondence from the Joint Administrative Procedures Committee (JAPC) questioning the Board's statutory authority for requiring adult patients "undergo a thorough psychological and social evaluation performed by a Florida licensed board-certified psychiatrist or a Florida licensed psychologist" before beginning hormone replacement therapy and every two years thereafter. Accordingly, the Florida Board of Medicine and Osteopathic Medicine's Joint Rules/Legislative Committee held a public meeting on August 3, 2023, and voted to remove the provision addressed by JAPC. The Board of Osteopathic Medicine discussed the Joint Committee's report and affirmed the decision at its August 11, 2023, Board meeting.
The August 3, 2023, Joint Committee meeting was held in person in a public forum and was able to be attended by any interested parties. Notice of the Joint Committee meeting was published to the Board of Osteopathic Medicine's

website on July 19, 2023, and in the Florida Administrative Register on July 13, 2023. The August 11, 2023, Board Meeting was also held in person in a public forum and was able to be attended by any interested parties. Notice for the August 11, 2023, Board Meeting was published to the Board of Osteopathic Medicine's website on June 1, 2023, and in the Florida Administrative Register on May 24, 2023.

Public comment was accepted at all of the aforementioned board and committee meetings. Further, the Boards accepted written public comment on the initial proposed rules up and until 24 hours prior to the Joint Board Meeting. The Board also accepted written comments up and until 24 hours prior to the August 3, 2023, Joint Rules/Legislative Committee meeting as well. Accordingly, all notice requirements contained in Rule 28-102.001, F.A.C., were properly complied with at all points during the rulemaking process and interested parties were given ample opportunity to participate at all points during this rulemaking process.

SUMMARY: The proposed emergency rule formally adopts the required consent forms for an adult patient to receive sex-reassignment prescriptions and/or procedures per section 456.52(2), Florida Statutes.

THE PERSON TO BE CONTACTED REGARDING THE EMERGENCY RULE IS: : Danielle Terrell, Executive Director, Board of Osteopathic Medicine/MQA, 4052 Bald Cypress Way, Bin #C06, Tallahassee, Florida 32399-3256, or by email at Danielle.Terrell@flhealth.gov.

THE FULL TEXT OF THE EMERGENCY RULE IS:

64B15ER23-12 - Mandatory Standardized Informed Consent for Sex-reassignment Prescriptions or Procedures in Adults.

Pursuant to Section 456.52, Florida Statutes, when sex-reassignment prescriptions or procedures are prescribed for or administered or performed on patients 18 years of age or older, the physician is required to obtain voluntary, informed consent while physically present in the same room as the patient. Consent is not required for renewal of such prescriptions if a physician and the physician's patient have met the requirements for consent for the initial prescription or renewal; however, a separate consent is required for any new prescription for a pharmaceutical product not previously prescribed to the patient.

(1) Informed Consent. The Board has approved the following mandatory informed consent forms for sex-reassignment prescriptions or procedures for patients 18 years of age or older:

(a) For patients prescribed sex-reassignment feminizing medication, form DH5082-MQA, (Rev. 08/23), entitled "Feminizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Consent," which is hereby incorporated by reference and available from the Board's website at https://flboardofmedicine.gov/forms/Feminizing-Medications-for-Patients-with-Gender-Dysphoria-Patient-Information-and-Informed-Consent.pdf.

(b) For patients prescribed sex-reassignment masculinizing medications, form DH5083-MQA, (Rev. 08/23), entitled "Masculinizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Consent," which is hereby incorporated by reference and available from the Board's website at https://flboardofmedicine.gov/forms/Masculinizing-Medications-for-Patients-with-Gender-Dysphoria-Patient-Information-and-Informed-Consent.pdf.

(c) For patients undergoing surgical treatment, form DH5084-MQA, (06/23), entitled "Surgical Treatment for Adults with Gender Dysphoria, Patient Information and Informed Consent," which is hereby incorporated by reference and available from the Board's website at https://flboardofmedicine.gov/forms/Surgical-Treatment-for-Adults-with-Gender-Dysphoria-Patients-Information-and-Informed-Consent.pdf.

(2) A Board-approved informed consent form is not executed until:

(a) The physician issuing the prescription or performing the procedure, while physically present in the same room as the patient, has informed the patient of the nature and risks of the prescription or procedure and has provided and received the patient's written acknowledgement before the prescription is prescribed, administered, or performed. The physician is prohibited from delegating this responsibility to another person. The physician is also required to sign the informed consent form.

(b) The patient is required to sign the informed consent form.

(c) A competent witness is also required to sign the informed consent form.

Rulemaking Authority 456.52 FS. Law Implemented 456.52 FS. History – New 8-18-23.

THIS RULE TAKES EFFECT UPON BEING FILED WITH THE DEPARTMENT OF STATE UNLESS A LATER TIME AND DATE IS SPECIFIED IN THE RULE.
EFFECTIVE DATE: August 18, 2023

FLORIDA DEPARTMENT of STATE

RON DESANTIS
Governor

CORD BYRD
Secretary of State

February 24, 2023

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

Dear Cassandra Fullove:

Your adoption package for Rule 64B8-9.019, F.A.C. was received, electronically, by the Florida Department of State, Administrative Code and Register at 1:16 p.m. on February 24, 2023. 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 March 16, 2023.

Sincerely,

Anya C. Owens
Program Administrator

ACO/rra

R. A. Gray Building • 500 South Bronough Street • Tallahassee, Florida 32399-0250
Telephone: (850) 245-6270

Aman, Rustie R.

From: Cassandra Fullove <Cassandra.Fullove@myfloridalegal.com>
Sent: Friday, February 24, 2023 1:16 PM
To: Owens, Anya C.; Swain, Margaret A.; RuleAdoptions
Subject: Rule 64B8-9.019, F.A.C.
Attachments: 64B8-9.019, F.A.C. - Rule Adoption.pdf; Text.docx

Hello Anya and Margaret,

Attached is the rule adoption packet for rule 64B8-9.019, F.A.C. If you have any questions do not hesitate to contact me. Thank you.

Cassandra P. Fullove
Senior Legal Assistant
Administrative Law Bureau
Office of the Attorney General
PL-01, The Capitol
Tallahassee, FL 32399-1050
Office: (850) 414-3766
Fax: (850) 922-6425
Cassandra.Fullove@myfloridalegal.com

KENNETH J. PLANTE
COORDINATOR
Room 680, Pepper Building
111 West Madison Street
Tallahassee, Florida 32399-1400
Telephone (850) 488-9110
Fax (850) 922-6934
www.japc.state.fl.us
japc@leg.state.fl.us

CERTIFICATION

Department:	Department of Health
Agency:	Board of Medicine
Rule No(s):	64B8-9.019
File Control No:	189107

As required by subparagraph 120.54(3)(e)4 F.S., the Joint Administrative Procedures Committee hereby certifies that:

☒ There were no material and timely written comments or written inquiries made on behalf of the committee regarding the above listed rule; or

☐ The adopting agency has responded in writing to all material and timely written comments or written inquiries made on behalf of the committee regarding the above listed rules; or

☐ The adopting agency has not responded in writing to all material and timely written comments or written inquiries made on behalf of the Committee regarding the above listed rules.

Certification Date: 2/24/2023

This certification expires after: 3/3/2023

Certifying Attorney: Marjorie Holladay

NOTE:

☐ *The above certified rules include materials incorporated by reference.*

☒ *The above certified rules do not include materials incorporated by reference.*

Form Updated 12/9/2021

ASHLEY MOODY
ATTORNEY GENERAL
STATE OF FLORIDA

OFFICE OF THE ATTORNEY GENERAL
Cassandra P. Fullove
Senior Legal Assistant
Administrative Law Bureau

PL-01 The Capitol
Tallahassee, FL 32399-1050
Phone (850) 414-3300
Fax (850) 922-6425
Cassandra.Fullove@myfloridalegal.com
http://www.myfloridalegal.com

M E M O R A N D U M

TO: Anya C. Owens, Program Administrator
Bureau of Administrative Code

FROM: Cassandra P. Fullove, Senior Legal Assistant

RE: Rule 64B8-9.019, F.A.C.

DATE: February 24, 2023

Attached please find the above-referenced rule, which is scheduled to be filed for final adoption. Please forward the stamped copy of the rule to me.

Should you have any questions regarding the rule do not hesitate to contact me.

Thank you.

CERTIFICATION OF BOARD OF MEDICINE

ADMINISTRATIVE RULES FILED WITH THE DEPARTMENT OF STATE

I hereby certify:

[xx] (1) That all statutory rulemaking requirements of Chapter 120, F.S., and all rulemaking requirements of the Department of State have been complied with; and

[xx] (2) That there is no administrative determination under subsection 120.56(2), F.S., pending on any rule covered by this certification; and

[xx] (3) All rules covered by this certification are filed within the prescribed time limitations of paragraph 120.54(3)(e), F.S. They are filed not less than 28 days after the notice required by paragraph 120.54(3)(a), F.S., and;

[ ] (a) Are filed not more than 90 days after the notice; or

[ ] (b) Are filed more than 90 days after the notice, but not more than 60 days after the administrative law judge files the final order with the clerk or until 60 days after subsequent judicial review is complete; or

[ ] (c) Are filed more than 90 days after the notice, but not less than 21 days nor more than 45 days from the date of publication of the notice of change; or

[xx] (d) Are filed more than 90 days after the notice, but not less than 14 nor more than 45 days after the adjournment of the final public hearing on the rule; or

[ ] (e) Are filed more than 90 days after the notice, but within 21 days after the date of receipt of all material authorized to be submitted at the hearing; or

[ ] (f) Are filed more than 90 days after the notice, but within 21 days after the date the transcript was received by this agency; or

[ ] (g) Are filed not more than 90 days after the notice, not including the days the adoption of the rule was postponed following notification from the Joint Administrative Procedures Committee that an objection to the rule was being considered; or

[ ] (h) Are filed more than 90 days after the notice, but within 21 days after a good faith written proposal for a lower cost regulatory alternative to a proposed rule is submitted which substantially accomplishes the objectives of the law being implemented; or

[ ] (i) Are filed more than 90 days after the notice, but within 21 days after a regulatory alternative is offered by the ombudsman in the Executive Office of the governor.

The rules are hereby adopted by the undersigned agency by and upon their filing with the Department of State.

Rule No(s).

64B8-9.019

Under the provision of subparagraph 120.54(3)(e)6., F.S., the rules take effect 20 days from the date filed with the Department of State or a later date as set out below:

Effective: _____

(Month) (Day) (Year)

Signature, Person Authorized
To Certify Rules

Executive Director for Scot Ackerman, 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).

64B8-9.019

Signature of Agency Head

Executive Director for Scot Ackerman, M.D., Chair
Title

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

DEPARTMENT OF HEALTH

BOARD OF MEDICINE

ADDITIONAL STATEMENT TO THE SECRETARY OF STATE

RULE TITLE:	RULE NO.:
Standards of Practice for the Treatment of Gender Dysphoria in Minors	64B8-9.019

SUMMARY: The proposed new rule will set the practice standards for treatment of gender dysphoria in minors.

SUMMARY OF THE HEARING ON THE RULE:

A hearing was held on this matter on February 10, 2023, in Tallahassee, Florida. There were no changes to the rule and rule is being filed as published in the Florida Administrative Register.

STATEMENT OF FACTS AND CIRCUMSTANCES JUSTIFYING RULE PROPOSAL:

The proposed new rule will set the practice standards for the treatment of gender dysphoria in minors.

64B8-9.019 Standards of Practice for the Treatment of Gender Dysphoria in Minors.

(1) The following therapies and procedures performed for the treatment of gender dysphoria in minors are prohibited.

(a) Sex reassignment surgeries, or any other surgical procedures, that alter primary or secondary sexual characteristics.

(b) Puberty blocking, hormone, and hormone antagonist therapies.

(2) Minors being treated with puberty blocking, hormone, or hormone antagonist therapies prior to the effective date of this rule may continue with such therapies.

Rulemaking Authority 458.331(1)(v), F.S. Law Implemented 458.331(1)(v), F.S. History-New _____.

FLORIDA DEPARTMENT of STATE

RON DESANTIS
Governor

CORD BYRD
Secretary of State

March 8, 2023

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

Dear Cassandra Fullove:

Your adoption package for Rule 64B15-14.014, F.A.C. was received, electronically, by the Florida Department of State, Administrative Code and Register at 11:48 p.m. on March 8, 2023. 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 March 28, 2023.

Sincerely,

Anya C. Owens
Program Administrator

ACO/mas

Swain, Margaret A.

From: Cassandra Fullove <Cassandra.Fullove@myfloridalegal.com>
Sent: Wednesday, March 8, 2023 11:48 AM
To: Owens, Anya C.; Swain, Margaret A.; RuleAdoptions
Subject: 64B15-14.014, F.A.C.
Attachments: 64B15-14.014, F.A.C. - Rule Adoption.pdf; Text.docx

Hi Anya and Margaret,

Attached is the technical change memo and rule adoption packet for 64B15-14.014, F.A.C., to be filed today. If you have any questions do not hesitate to contact me. Thank you.

Cassandra P. Fullove
Senior Legal Assistant
Administrative Law Bureau
Office of the Attorney General
PL-01, The Capitol
Tallahassee, FL 32399-1050
Office: (850) 414-3766
Fax: (850) 922-6425
Cassandra.Fullove@myfloridalegal.com

CERTIFICATION

Department: Department of Health
Agency: Board of Osteopathic Medicine
Rule No(s): 64B15-14.014
File Control No: 189108

As required by subparagraph 120.54(3)(e)4 F.S., the Joint Administrative Procedures Committee hereby certifies that:

☒ There were no material and timely written comments or written inquiries made on behalf of the committee regarding the above listed rule; or

☐ The adopting agency has responded in writing to all material and timely written comments or written inquiries made on behalf of the committee regarding the above listed rules; or

☐ The adopting agency has not responded in writing to all material and timely written comments or written inquiries made on behalf of the Committee regarding the above listed rules.

Certification Date: 3/8/2023

This certification expires after: 3/15/2023

Certifying Attorney: Marjorie Holladay

NOTE:

☐ *The above certified rules include materials incorporated by reference.*

☒ *The above certified rules do not include materials incorporated by reference.*

Form Updated 12/9/2021

ASHLEY MOODY
ATTORNEY GENERAL
STATE OF FLORIDA

OFFICE OF THE ATTORNEY GENERAL
Cassandra P. Fullove
Senior Legal Assistant
Administrative Law Bureau

PL-01 The Capitol
Tallahassee, FL 32399-1050
Phone (850) 414-3300
Fax (850) 922-6425
Cassandra.Fullove@myfloridalegal.com
http://www.myfloridalegal.com

M E M O R A N D U M

TO: Anya C. Owens, Program Administrator
Bureau of Administrative Code

FROM: Cassandra P. Fullove, Senior Legal Assistant

RE: Rule 64B15-14.014, F.A.C.

DATE: March 8, 2023

Please make the following technical change for the Notice of Change filed on February 15, 2023. The incorrect Rulemaking and Law Implemented was listed.

64B15-14.014 Standards of Practice for the Treatment of Gender Dysphoria in Minors.
(1) No change.
~~(2) Nonsurgical treatments for the treatment of gender dysphoria in minors may continue to be performed under the auspices of Institutional Review Board (IRB) approved, investigator initiated clinical trials conducted at any of the Florida medical schools set forth in Section 458.3145(1)(i), Florida Statutes. Such clinical trials must include long term longitudinal assessments of the patients' physiologic and psychologic outcomes.~~
(3) renumbered to (2) No change.

Rulemaking Authority 459.015(1)(z) ~~458.331(1)(v)~~, F.S. Law Implemented 459.015(1)(z) ~~458.331(1)(v)~~, F.S. History-New

Please contact me if you have any questions regarding the rule.

cc: Marjorie Holladay, Chief Attorney
Joint Administrative Procedures Committee

ASHLEY MOODY
ATTORNEY GENERAL
STATE OF FLORIDA

OFFICE OF THE ATTORNEY GENERAL
Cassandra P. Fullove
Senior Legal Assistant
Administrative Law Bureau

PL-01 The Capitol
Tallahassee, FL 32399-1050
Phone (850) 414-3300
Fax (850) 922-6425
Cassandra.Fullove@myfloridalegal.com
http://www.myfloridalegal.com

M E M O R A N D U M

TO: Anya C. Owens, Program Administrator
Bureau of Administrative Code

FROM: Cassandra P. Fullove, Senior Legal Assistant

RE: Rule 64B15-14.014, F.A.C.

DATE: March 8, 2023

Attached please find the above-referenced rule, which is scheduled to be filed for final adoption. Please forward the stamped copy of the rule to me.

Should you have any questions regarding the rule do not hesitate to contact me.

Thank you.

CERTIFICATION OF BOARD OF OSTEOPATHIC MEDICINE

ADMINISTRATIVE RULES FILED WITH THE DEPARTMENT OF STATE

I hereby certify:

[xx] (1) That all statutory rulemaking requirements of Chapter 120, F.S., and all rulemaking requirements of the Department of State have been complied with; and

[xx] (2) That there is no administrative determination under subsection 120.56(2), F.S., pending on any rule covered by this certification; and

[xx] (3) All rules covered by this certification are filed within the prescribed time limitations of paragraph 120.54(3)(e), F.S. They are filed not less than 28 days after the notice required by paragraph 120.54(3)(a), F.S., and;

[ ] (a) Are filed not more than 90 days after the notice; or

[ ] (b) Are filed more than 90 days after the notice, but not more than 60 days after the administrative law judge files the final order with the clerk or until 60 days after subsequent judicial review is complete; or

[xx] (c) Are filed more than 90 days after the notice, but not less than 21 days nor more than 45 days from the date of publication of the notice of change; or

[ ] (d) Are filed more than 90 days after the notice, but not less than 14 nor more than 45 days after the adjournment of the final public hearing on the rule; or

[ ] (e) Are filed more than 90 days after the notice, but within 21 days after the date of receipt of all material authorized to be submitted at the hearing; or

[ ] (f) Are filed more than 90 days after the notice, but within 21 days after the date the transcript was received by this agency; or

[ ] (g) Are filed not more than 90 days after the notice, not including the days the adoption of the rule was postponed following notification from the Joint Administrative Procedures Committee that an objection to the rule was being considered; or

[ ] (h) Are filed more than 90 days after the notice, but within 21 days after a good faith written proposal for a lower cost regulatory alternative to a proposed rule is submitted which substantially accomplishes the objectives of the law being implemented; or

[ ] (i) Are filed more than 90 days after the notice, but within 21 days after a regulatory alternative is offered by the ombudsman in the Executive Office of the governor.

The rules are hereby adopted by the undersigned agency by and upon their filing with the Department of State.

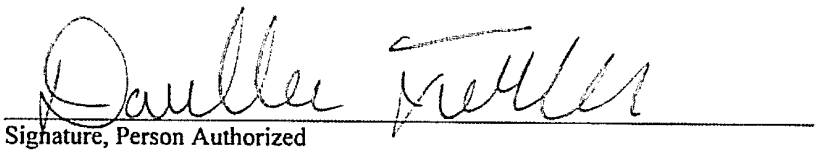
Rule No(s).

64B15-14.014

Under the provision of subparagraph 120.54(3)(e)6., F.S., the rules take effect 20 days from the date filed with the Department of State or a later date as set out below:

Effective: _____

(Month) (Day) (Year)



Signature, Person Authorized
To Certify Rules

Executive Director for Tiffany Sizemore Di Pietro , DO, FACC, FACOI, Chair
Title

1
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).

64B15-14.014

Signature of Agency Head

Executive Director for Tiffany Sizemore Di Pietro , DO, FACC, FACOI, Chair
Title

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

DEPARTMENT OF HEALTH

BOARD OF OSTEOPATHIC MEDICINE

ADDITIONAL STATEMENT TO THE SECRETARY OF STATE

RULE TITLE:	RULE NO.:
Standards of Practice for the Treatment of Gender Dysphoria in Minors	64B15-14.014

SUMMARY: The new rule will set the practice standards for treatment of gender dysphoria in minors.

SUMMARY OF THE HEARING ON THE RULE:

A hearing was held on this matter on February 10, 2023, in Tallahassee, Florida. A Notice of Change was published on February 15, 2023, in Vol. 49, No 31, issue of the Florida Administrative Register in response to comments received at the hearing held on February 10, 2023.

STATEMENT OF FACTS AND CIRCUMSTANCES JUSTIFYING RULE PROPOSAL:

The proposed new rule will set the practice standards for the treatment of gender dysphoria in minors.

64B15-14.014 Standards of Practice for the Treatment of Gender Dysphoria in Minors.

(1) The following therapies and procedures performed for the treatment of gender dysphoria in minors are prohibited.

(a) Sex reassignment surgeries, or any other surgical procedures, that alter primary or secondary sexual characteristics.

(b) Puberty blocking, hormone, and hormone antagonist therapies.

(2) Minors being treated with puberty blocking, hormone, or hormone antagonist therapies prior to the effective date of this rule may continue with such therapies.

Rulemaking Authority 459.015(1)(z) FS. Law Implemented 459.015(1)(z) FS. History-New _____.

FLORIDA DEPARTMENT of STATE

RON DESANTIS
Governor

CORD BYRD
Secretary of State

June 8, 2023

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 64B8ER23-3 was received, electronically, by the Florida Department of State, Administrative Code and Register at 11:37 a.m. on June 8, 2023. 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 8, 2023.

Sincerely,

Anya C. Owens
Administrative Code and Register Director

Owens, Anya C.

From: Cassandra Fullove <Cassandra.Fullove@myfloridalegal.com>
Sent: Thursday, June 8, 2023 11:37 AM
To: Owens, Anya C.; Harris, Whitley; RuleAdoptions
Subject: Emergency Rule 64B8ER23-3
Attachments: 64B8ER23-3.pdf; Text 1.docx

Hello,

Attached is the emergency rule filing for the above referenced rule. If you have any questions do not hesitate to contact me. Thank you.

Cassandra P. Fullove
Senior Legal Assistant
Administrative Law Bureau
Office of the Attorney General
PL-01, The Capitol
Tallahassee, FL 32399-1050
Office: (850) 414-3766
Fax: (850) 922-6425
Cassandra.Fullove@myfloridalegal.com

ASHLEY MOODY
ATTORNEY GENERAL
STATE OF FLORIDA

OFFICE OF THE ATTORNEY GENERAL
Cassandra P. Fullove
Senior Legal Assistant
Administrative Law Bureau

PL-01 The Capitol
Tallahassee, FL 32399-1050
Phone (850) 414-3300
Fax (850) 922-6425
Cassandra.Fullove@myfloridalegal.com
http://www.myfloridalegal.com

M E M O R A N D U M

TO: Anya C. Owens, Program Administrator
Bureau of Administrative Code

FROM: Cassandra P. Fullove, Senior Legal Assistant

RE: Emergency Rule 64B8ER23-3

DATE: June 8, 2023

Attached please find the above-referenced rule, which is scheduled to be filed for emergency rule. Please forward the stamped copy of the rule to me.

Should you have any questions regarding the rule do not hesitate to contact me.

Thank you.

CERTIFICATION OF BOARD OF MEDICINE

EMERGENCY RULE FILED WITH THE

DEPARTMENT OF STATE

I hereby certify that pursuant to Ch 2023-90 Laws of Florida, Section 5, section 456.52, Florida Statutes was created and pursuant to subparagraphs 456.52(1)(a) and (6)(a), F.S., the Board of Medicine is required to adopt emergency rules to implement the section. 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), F.S. 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.

64B8ER23-3

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 Scot Ackerman, 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), F.S., 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).:

64B8ER23-3

Signature of Agency Head

Paul Vazquez, Executive Director for
Scot Ackerman, 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.:

Sex-reassignment Prescriptions 64B8ER23-3

SPECIFIC REASONS FOR FINDING AN IMMEDIATE DANGER TO THE PUBLIC HEALTH, SAFETY OR WELFARE: On May 17, 2023, Florida Governor, Ronald DeSantis, signed CSSB 254 into law creating Ch. 2023-90, Laws of Florida and section 456.52, Florida Statutes. Pursuant to section 456.52(1), F.S., sex-reassignment prescriptions are prohibited for patients younger than 18 years of age upon the effective date of the act; however, pursuant to section 456.52(1)(a), F.S., the Board of Medicine shall within 60 days after the effective date of the act, adopt emergency rules pertaining to standards of practice by which minors may continue to be treated if such treatment was commenced before, and is still active on, the effective date of the act. Section 456.52(1)(b), F.S., also provides a minor patient meeting the criteria outlined in section 456.52(1)(a), F.S., may continue to be treated by a physician with such prescriptions according to rules adopted pursuant to paragraph (1)(a).

Further, pursuant to section 456.52(2), F.S., if sex reassignment prescriptions or procedures are prescribed for or administered to patients 18 years of age or older, consent must be voluntary, informed, and in writing on forms adopted in rule by the Board of Medicine. Pursuant to section 456.52(4), F.S., the consent required for sex-reassignment prescriptions does not apply to renewals of sex-reassignment prescriptions if a physician and his or her patient have met the requirements for consent for the initial prescription. Section 456.52(6)(a), F.S., states "[t]he Board of Medicine and the Board of Osteopathic Medicine shall adopt emergency rules to implement this section."

Accordingly, the Board of Medicine, by emergency rule, hereby allows a patient's prescribing physician to renew a prior lawfully issued sex-reassignment prescription that was initially prescribed prior to May 17, 2023, up and until six months from the effective date of the Board's emergency rule that formally adopts the required consent forms pursuant to section 456.52(1) and (2), F.S.

*** This emergency rule does not apply to Susan Doe, Gavin Goe, or Lisa Loe, or their parents or healthcare providers (see Jane Doe et al., v. Joseph A. Ladapo, et al, Preliminary Injunction, Filed June 6, 2023, Case No. 4:23cv114-RH-MAF, United States District Court for the Northern District of Florida). ***

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. CSSB 254 was signed into law on May 17, 2023. The Board of Medicine was contacted by multiple licensed physicians and physician groups seeking clarification regarding the exception contained in section 465.52(4), F.S., and a timeframe for the required emergency rules shortly thereafter. In response, the Board of Medicine and the Board of Osteopathic Medicine held a Joint Rules/Legislative Committee (Joint Committee) meeting on June 1, 2023, to discuss the emergency rule. On May 19, 2023, the Board of Medicine published notice of the Joint Committee meeting both on its website and in the Florida Administrative Register. On June 2, 2023, the Board of Medicine discussed the report of the Joint Committee and voted upon emergency rule language. The Board of Medicine published notice of its June 2, 2023, meeting in the Florida Administrative Register on May 5, 2023, and on its website on May 12, 2023. Each meeting was held in person in a public forum and was able to be attended by any interested parties. Accordingly, all notice requirements contained in Rule 28-102.001, F.A.C., were properly complied with and interested parties were given ample opportunity to participate in this rulemaking process.

SUMMARY: The proposed emergency rule allows a patient's prescribing physician to renew a prior lawfully issued sex-reassignment prescription that was prescribed prior to the effective date of section 465.52, F.S., up and until six months from the effective date of the Board of Medicine's emergency rule formally adopting a consent form per sections 456.52(1) and (2), Florida Statutes.

THE PERSON TO BE CONTACTED REGARDING THE EMERGENCY RULE IS: Paul Vazquez, Executive Director, Board of Medicine, 4052 Bald Cypress Way, Bin # C-03, Tallahassee, Florida 32399-3253.

THE FULL TEXT OF THE EMERGENCY RULE IS:

64B8ER23-3 Sex-reassignment Prescriptions.

A patient's prescribing physician may renew a prior lawfully issued sex-reassignment prescription as defined in section 456.001(9)(a), Florida Statutes, that was prescribed prior to May 17, 2023, up and until six months from the effective date of the Board's emergency rule formally adopting a consent form per sections 456.52(1) and (2), Florida Statutes.

Rulemaking Authority 456.52(1)(a), (b), 456.52(6)(a) FS. Law Implemented 456.52(1), (2) FS.

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

THE FULL TEXT OF THE EMERGENCY RULE IS:

64B8ER23-3 Sex-reassignment Prescriptions.

A patient's prescribing physician may renew a prior lawfully issued sex-reassignment prescription as defined in section 456.001(9)(a), Florida Statutes, that was prescribed prior to May 17, 2023, up and until six months from the effective date of the Board's emergency rule formally adopting a consent form per sections 456.52(1) and (2), Florida Statutes.

Rulemaking Authority 456.52(1)(a), (b), 456.52(6)(a) FS. Law Implemented 456.52(1), (2) FS.

FLORIDA DEPARTMENT of STATE

RON DESANTIS
Governor

CORD BYRD
Secretary of State

June 21, 2023

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 64B15ER23-4 was received, electronically, by the Florida Department of State, Administrative Code and Register at 3:09 p.m. on June 20, 2023After 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 20, 2023.

Sincerely,

Anya C. Owens
Administrative Code and Register Director

R. A. Gray Building • 500 South Bronough Street • Tallahassee, Florida 32399-0250
Telephone: (850) 245-6270

Owens, Anya C.

From: Cassandra Fullove <Cassandra.Fullove@myfloridalegal.com>
Sent: Tuesday, June 20, 2023 3:09 PM
To: Owens, Anya C.; Harris, Whitley; RuleAdoptions
Subject: 64B15ER23-4, F.A.C.
Attachments: 64B15ER23-4, F.A.C.pdf; THE FULL TEXT OF THE EMERGENCY RULE IS.docx

Hello,

Attached is emergency rule 64B15ER23-4, F.A.C. If you have any questions do not hesitate to contact me. Thank you.

Cassandra P. Fullove
Senior Legal Assistant
Administrative Law Bureau
Office of the Attorney General
PL-01, The Capitol
Tallahassee, FL 32399-1050
Office: (850) 414-3766
Fax: (850) 922-6425
Cassandra.Fullove@myfloridalegal.com

ASHLEY MOODY
ATTORNEY GENERAL
STATE OF FLORIDA

OFFICE OF THE ATTORNEY GENERAL
Cassandra P. Fullove
Senior Legal Assistant
Administrative Law Bureau

PL-01 The Capitol
Tallahassee, FL 32399-1050
Phone (850) 414-3300
Fax (850) 922-6425
Cassandra.Fullove@myfloridalegal.com
http://www.myfloridalegal.com

M E M O R A N D U M

TO: Anya C. Owens, Program Administrator
Bureau of Administrative Code

FROM: Cassandra P. Fullove, Senior Legal Assistant

RE: Emergency Rule 64B15ER23-4

DATE: June 20, 2023

Attached please find the above-referenced rule, which is scheduled to be filed for emergency rule. Please forward the stamped copy of the rule to me.

Should you have any questions regarding the rule do not hesitate to contact me.

Thank you.

CERTIFICATION OF BOARD OF OSTEOPATHIC MEDICINE

EMERGENCY RULE FILED WITH THE

DEPARTMENT OF STATE

I hereby certify that pursuant to Ch 2023-90 Laws of Florida, Section 5, section 456.52, Florida Statutes was created and pursuant to subparagraphs 456.52(1)(a) and (6)(a), F.S., the Board of Osteopathic Medicine is required to adopt emergency rules to implement the section. 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), F.S. 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.

64B15ER23-4

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 Tiffany Sizemore Di Pietro , DO, FACC, FACOI, 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), F.S., 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).:

64B15ER23-4

Signature of Agency Head

Executive Director for Tiffany Sizemore Di Pietro , DO, FACC, FACOI, 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 Osteopathic Medicine

RULE TITLE: RULE NO.:

Sex-reassignment Prescriptions 64B15ER23-4

SPECIFIC REASONS FOR FINDING AN IMMEDIATE DANGER TO THE PUBLIC HEALTH, SAFETY OR WELFARE: On May 17, 2023, Florida Governor, Ronald DeSantis, signed CSSB 254 into law creating Ch. 2023-90, Laws of Florida and section 456.52, Florida Statutes. Pursuant to section 456.52(1), F.S., sex-reassignment prescriptions are prohibited for patients younger than 18 years of age upon the effective date of the act; however, pursuant to section 456.52(1)(a), F.S., the Board of Osteopathic Medicine shall within 60 days after the effective date of the act, adopt emergency rules pertaining to standards of practice by which minors may continue to be treated if such treatment was commenced before, and is still active on, the effective date of the act. Section 456.52(1)(b), F.S., also provides a minor patient meeting the criteria outlined in section 456.52(1)(a), F.S., may continue to be treated by a physician with such prescriptions according to rules adopted pursuant to paragraph (1)(a).

Further, pursuant to section 456.52(2), F.S., if sex reassignment prescriptions or procedures are prescribed for or administered to patients 18 years of age or older, consent must be voluntary, informed, and in writing on forms adopted in rule by the Board of Osteopathic Medicine. Pursuant to section 456.52(4), F.S., the consent required for sex-reassignment prescriptions does not apply to renewals of sex-reassignment prescriptions if a physician and his or her patient have met the requirements for consent for the initial prescription. Section 456.52(6)(a), F.S., states "[t]he Board of Medicine and the Board of Osteopathic Medicine shall adopt emergency rules to implement this section."

Accordingly, the Board of Osteopathic Medicine, by emergency rule, hereby allows a patient's prescribing physician to renew a prior lawfully issued sex-reassignment prescription that was initially prescribed prior to May 17, 2023, up and until six months from the effective date of the Board's emergency rule that formally adopts the required consent forms pursuant to section 456.52(1) and (2), F.S.

*** This emergency rule does not apply to Susan Doe, Gavin Goe, or Lisa Loe, or their parents or healthcare providers (see Jane Doe et al., v. Joseph A. Ladapo, et al, Preliminary Injunction, Filed June 6, 2023, Case No. 4:23cv114-RH-MAF, United States District Court for the Northern District of Florida). ***

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. CSSB 254 was

signed into law on May 17, 2023. The Board of Medicine was contacted by multiple licensed physicians and physician groups seeking clarification regarding the exception contained in section 465.52(4), F.S., and a timeframe for the required emergency rules shortly thereafter. In response, the Board of Medicine and the Board of Osteopathic Medicine held a Joint Rules/Legislative Committee (Joint Committee) meeting on June 1, 2023, to discuss the emergency rule. On May 19, 2023, the Board of Osteopathic Medicine published notice of the Joint Committee meeting both on its website and in the Florida Administrative Register. On June 2, 2023, the Board of Medicine discussed the report of the Joint Committee and voted upon emergency rule language. Likewise, on June 20, 2023, the Board of Osteopathic Medicine discussed the Joint committee report and voted upon emergency rule language. The Board of Osteopathic Medicine published notice of its June 20, 2023, meeting in the Florida Administrative Register and on its website on June 6, 2023. Each meeting was held in a public forum and was able to be attended by any interested parties. Accordingly, all notice requirements contained in Rule 28-102.001, F.A.C., were properly complied with and interested parties were given ample opportunity to participate in this rulemaking process.

SUMMARY: The proposed emergency rule allows a patient's prescribing physician to renew a prior lawfully issued sex-reassignment prescription that was prescribed prior to the effective date of section 465.52, F.S., up and until six months from the effective date of the Board of Osteopathic Medicine's emergency rule formally adopting a consent form per sections 456.52(1) and (2), Florida Statutes.

THE PERSON TO BE CONTACTED REGARDING THE EMERGENCY RULE IS: Danielle Terrell, Executive Director, Board of Osteopathic Medicine/MQA, 4052 Bald Cypress Way, Bin #C06, Tallahassee, Florida 32399-3256, or by email at Danielle.Terrell@flhealth.gov.

THE FULL TEXT OF THE EMERGENCY RULE IS:

64B15ER23-4 Sex-reassignment Prescriptions.

A patient's prescribing physician may renew a prior lawfully issued sex-reassignment prescription as defined in section 456.001(9)(a), Florida Statutes, that was prescribed prior to May 17, 2023, up and until six months from the effective date of the Board's emergency rule formally adopting a consent form per sections 456.52(1) and (2), Florida Statutes.

Rulemaking Authority 456.52(1)(a), (b), 456.52(6)(a) FS. Law Implemented 456.52(1), (2) FS.

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

THE FULL TEXT OF THE EMERGENCY RULE IS:

64B15ER23-4 Sex-reassignment Prescriptions.

A patient's prescribing physician may renew a prior lawfully issued sex-reassignment prescription as defined in section 456.001(9)(a), Florida Statutes, that was prescribed prior to May 17, 2023, up and until six months from the effective date of the Board's emergency rule formally adopting a consent form per sections 456.52(1) and (2), Florida Statutes.

Rulemaking Authority 456.52(1)(a), (b), 456.52(6)(a) FS. Law Implemented 456.52(1), (2) FS.

FLORIDA DEPARTMENT of STATE

RON DESANTIS
Governor

CORD BYRD
Secretary of State

July 6, 2023

Angela Southwell
Paralegal Specialist
Office of the Attorney General
PL 01, The Capitol
Tallahassee, FL 32399

Dear Angela Southwell:

Your adoption package for Emergency Rule 64B8ER23-7 was received, electronically, by the Florida Department of State, Administrative Code and Register at 5:35 p.m. on July 5, 2023. 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 July 5, 2023.

Sincerely,

Anya C. Owens
Administrative Code and Register Director

R. A. Gray Building • 500 South Bronough Street • Tallahassee, Florida 32399-0250
Telephone: (850) 245-6270

Owens, Anya C.

From: Angela Southwell <Angela.Southwell@myfloridalegal.com>
Sent: Wednesday, July 5, 2023 5:35 PM
To: RuleAdoptions
Cc: Owens, Anya C.; Christopher Dierlam; Donna McNulty; Cassandra Fullove
Subject: Adoption Packet for Emergency Rule 64B8ER23-7
Attachments: Adoption pkt 64B8ER23-7.pdf; THE FULL TEXT OF THE EMERGENCY RULE IS.docx

Good Afternoon:

Attached please find the adoption packet and text.

Angela M. Southwell
Paralegal Specialist
Office of the Attorney General
Administrative Law
PL-01 The Capitol
Bin #4100
Tallahassee, Florida 32399-1050
Telephone: (850) 414-3772
angela.southwell@myfloridalegal.com

ASHLEY MOODY
ATTORNEY GENERAL
STATE OF FLORIDA

OFFICE OF THE ATTORNEY GENERAL
Administrative Law

Angela Southwell
Paralegal Specialist
PL-01 The Capitol
Tallahassee, FL 32399-1050
Phone (850) 414-3772
Fax (850) 922-6425
angela.southwell@myfloridalegal.com

MEMORANDUM

TO: Anya Owens, Program Administrator
Administrative Code and Register

FROM: Angela Southwell, Paralegal Specialist

RE: Department of Health
Board of Medicine
Emergency Rule 64B8ER23-7

DATE: July 5, 2023

Attached are the following documents regarding the above-referenced emergency rule adoption packet for the above-referenced emergency rule:

- Notice of Emergency Rule
- Adoption text for Emergency Rule 64B8ER23-7 (double spaced)
- Certification of Board of Medicine Emergency Rule Filed With the Department of State
- Designation of Rule the Violation of Which is a Minor Violation Certification
- Certification of Materials Incorporated by Reference in Rules Filed with the Department of State
- Form DH5079-MQA, (06/23), entitled "Puberty Suppression Treatment for Patients with Gender Dysphoria, Patient Information and Informed Parental Consent and Assent for Minors"
- Form DH5080-MQA, (06/23), entitled "Feminizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Parental Consent and Assent for Minors"
- Form DH5081-MQA, (06/23), entitled "Masculinizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Parental Consent and Assent for Minors"

Should you have any questions regarding the rule, please contact me at angela.southwell@myfloridalegal.com or by telephone at 850-414-3772.

Thank you for your attention to this matter.

Attachments

CERTIFICATION OF BOARD OF MEDICINE

EMERGENCY RULE FILED WITH THE

DEPARTMENT OF STATE

I hereby certify that pursuant to Ch 2023-90 Laws of Florida, Section 5, section 456.52, Florida Statutes was created and pursuant to subparagraphs 456.52(1)(a) and (6)(a), F.S., the Board of Medicine is required to adopt emergency rules to implement the section. 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), F.S. 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.

64B8ER23-7

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 Scot Ackerman, 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), F.S., 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).:

64B8ER23-7

Signature of Agency Head

Paul Vazquez, Executive Director for
Scot Ackerman, 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 NO.: RULE TITLE:

64B8ER23-7 Sex-reassignment Standards of Practice in Minors

SPECIFIC REASONS FOR FINDING AN IMMEDIATE DANGER TO THE PUBLIC HEALTH, SAFETY OR WELFARE: On May 17, 2023, Florida Governor, Ronald DeSantis, signed CSSB 254 into law creating Ch. 2023-90, Laws of Florida and section 456.52, Florida Statutes. Pursuant to section 456.52(1), F.S., sex-reassignment prescriptions are prohibited for patients younger than 18 years of age upon the effective date of the act; however, pursuant to section 456.52(1)(a), F.S., the Board of Medicine shall within 60 days after the effective date of the act, adopt emergency rules pertaining to standards of practice by which minors may continue to be treated if such treatment was commenced before, and is still active on, the effective date of the act. Section 456.52(1)(b), F.S., also provides a minor patient meeting the criteria outlined in section 456.52(1)(a), F.S., may continue to be treated by a physician with such prescriptions according to rules adopted pursuant to paragraph (1)(a).

Further, pursuant to section 456.52(2), F.S., if sex reassignment prescriptions or procedures are prescribed for or administered to patients 18 years of age or older, consent must be voluntary, informed, and in writing on forms adopted in rule by the Board of Medicine. Pursuant to section 456.52(4), F.S., the consent required for sex-reassignment prescriptions does not apply to renewals of sex-reassignment prescriptions if a physician and his or her patient have met the requirements for consent for the initial prescription. Section 456.52(6)(a), F.S., states "[t]he Board of Medicine and the Board of Osteopathic Medicine shall adopt emergency rules to implement this section."

Accordingly, the Board of Medicine, by emergency rule, hereby adopts the incorporated standards of practice and mandated consent forms for the treatment of gender dysphoria with puberty blockers and hormone replacement therapy in minors.

*** This emergency rule does not apply to Susan Doe, Gavin Goe, or Lisa Loe, or their parents or healthcare providers (see Jane Doe et al., v. Joseph A. Ladapo, et al, Preliminary Injunction, Filed June 6, 2023, Case No. 4:23cv114-RH-MAF, United States District Court for the Northern District of Florida). ***

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. CSSB 254 was signed into law on May 17, 2023. The Board of Medicine was contacted by multiple licensed physicians and

physician groups seeking clarification regarding the exception contained in section 465.52(4), F.S., and a timeframe for the required emergency rules shortly thereafter. In response, the Board of Medicine and the Board of Osteopathic Medicine held a Joint Rules/Legislative Committee (Joint Committee) meeting on June 1, 2023, to discuss the emergency rule. On May 19, 2023, the Board of Medicine published notice of the Joint Committee's June meeting both on its website and in the Florida Administrative Register. On June 2, 2023, the Board of Medicine discussed the report of the Joint Committee and voted upon emergency rule language that would allow for the renewal of previous prescriptions while the Board worked on consent forms. The Board of Medicine published notice of its June 2, 2023, meeting in the Florida Administrative Register on May 5, 2023, and on its website on May 12, 2023.

The Joint Committee held another meeting on June 23, 2023, to discuss an emergency rule adopting draft consent forms that were under consideration. On June 6, 2023, the Board of Medicine published notice of the Joint Committee's June 23, 2023, meeting to its website and in the Florida Administrative Register. On June 30, 2023, the Boards of Medicine and Osteopathic Medicine held a Joint Board meeting (Joint Board Meeting) to discuss the draft consent forms that were approved by the Joint Committee on June 23, 2023. Prior to conclusion of the Joint Board Meeting, the Boards each separately voted to approve the draft consent forms via emergency rule. The Joint Board Meeting was held via Microsoft Teams and notice of the same was published to the Board of Medicine's website and in the Florida Administrative Register on June 22, 2023.

Each Joint Committee meeting was held in person in a public forum and was able to be attended by any interested persons. The Joint Board Meeting was held via Microsoft Teams and also was able to be attended by any interested persons. Public comment was accepted at all of the aforementioned meetings. Further, the Boards accepted written public comment on the proposed rules up and until 24 hours prior to the Joint Board Meeting. Accordingly, all notice requirements contained in Rule 28-102.001, F.A.C., were properly complied with and interested persons were given ample opportunity to participate in this rulemaking process.

SUMMARY: The proposed emergency rule formally adopts the required consent forms that must be executed for a minor patient who was already receiving sex-reassignment prescriptions to continue to receive said prescriptions per section 456.52(1), Florida Statutes.

THE PERSON TO BE CONTACTED REGARDING THE EMERGENCY RULE IS: Paul Vazquez, Executive Director, Board of Medicine, 4052 Bald Cypress Way, Bin # C-03, Tallahassee, Florida 32399-3253, Paul.Vazquez@flhealth.gov

THE FULL TEXT OF THE EMERGENCY RULE IS:

64B8ER23-7 Sex-reassignment Standards of Practice in Minors.

The standards of practice in this rule do not supersede the level of care, skill, and treatment recognized in general law related to healthcare licensure.

(1) Pursuant to Section 456.52, Florida Statutes, sex-reassignment prescriptions and procedures are prohibited for patients younger than 18 years of age, except that a physician may continue to treat such patient with a prescription if such treatment for sex-reassignment was commenced before, and is still active on, May 17, 2023. The physician is required to obtain voluntary, informed consent while physically present in the same room as the patient. Consent is not required for renewal of such prescriptions if a physician and his or her patient have met the requirements for consent for the initial prescription or renewal; however, a separate consent is required for any new prescription for a pharmaceutical product not previously prescribed to the patient.

(2) Informed Consent. The Board has approved the following mandatory informed consent forms for the continued treatment of minors with sex-reassignment prescriptions:

(a) For patients prescribed puberty blocking medications, form DH5079-MQA, (06/23), entitled "Puberty Suppression Treatment for Patients with Gender Dysphoria, Patient Information and Informed Parental Consent and Assent for Minors," which is hereby incorporated by reference and available from the Board's website at https://flboardofmedicine.gov/forms/Puberty-Suppression-Treatment-for-Patients-with-Gender-Dysphoria-Patient-Information-and-Parental-Consent-and-Assent-for-Minors.pdf.

(b) For patients prescribed sex-reassignment feminizing medications, form DH5080-MQA, (06/23), entitled "Feminizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Parental Consent and Assent for Minors," which is hereby incorporated by reference and available from the Board's website at https://flboardofmedicine.gov/forms/Feminizing-Medications-for-Patients-with-Gender-Dysphoria-Patient-Information-and-Parental-Consent-and-Assent-for-Minors.pdf.

(c) For patients prescribed sex-reassignment masculinizing medications, form DH5081-MQA, (06/23), entitled "Masculinizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Parental Consent and Assent for Minors," which is hereby incorporated by reference and available from the Board's website

at https://flboardofmedicine.gov/forms/Masculinizing-Medications-for-Patients-with-Gender-Dysphoria-Patient-Information-and-Parental-Consent-and-Assent-for-Minors.pdf.

(3) A Board-approved informed consent form is not executed until:

(a) The physician issuing the prescription, while physically present in the same room as the patient, has informed the patient and the patient's parent or legal guardian of the nature and risks of the prescription, and has provided and received the written acknowledgement of the patient and the patient's legal guardian before the prescription is prescribed or administered. The physician is prohibited from delegating this responsibility to another person. The physician is also required to sign the informed consent form.

(b) The patient's parent or legal guardian is required to sign the informed consent form.

(c) The patient is required to assent to the informed consent form.

(d) A competent witness is also required to sign the informed consent form.

(4) Standards of Practice. The nature and extent of the requirements set forth below will vary depending on the practice setting and circumstances presented to the prescribing physician. A prescribing physician who continues to treat a minor patient with sex-reassignment prescriptions pursuant to section 456.52(1)(a), Florida Statutes, shall comply with the following:

(a) Patient Evaluation. An in-person thorough medical history and physical examination of the patient conducted by the physician must be documented in the patient's medical record prior to prescribing any new sex-reassignment prescription.

(b) Clinical Determinations. Based on the patient evaluation, the following must be confirmed:

1. The patient has met the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders (DSM) or International Classification of Diseases (ICD);

2. The patient has pubertal changes resulting in an increase in gender dysphoria;

3. The patient does not suffer from a psychiatric comorbidity that interferes with the diagnostic work-up or treatment;

4. The patient will have psychological and social support during treatment;

5. The patient has experienced puberty to at least Tanner Stage 2; and

6. The patient demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of puberty suppression, future cross-sex hormone treatment, as well as the medical and social risks and benefits of sex reassignment surgery based on the patient's current treatment status.

(c) Patient Visit. The physician or their designated covering physician must meet with the patient in-person every six (6) months for the purpose of monitoring the patient and must document each visit in the patient's medical records.

(d) Suicide Risk Assessment. A suicide risk assessment by a licensed mental health care professional must be performed every three (3) months.

(e) Laboratory Testing. Relevant laboratory testing must be performed every four (4) months.

(f) X-rays. X-rays of the hand must be performed each year to monitor and document the patient's bone age progression.

(g) Bone Density Scan. An annual bone density (DEXA) scan must be performed to monitor the patient's bone density during treatment.

(h) Mental Health Assessment. The physician must have the patient undergo an annual mental health assessment to be performed by a board-certified Florida licensed psychiatrist or psychologist.

(i) Counseling. The physician must refer the patient for counseling with a licensed mental health care professional during the treatment period, with a frequency as recommended by the licensed mental health care professional.

(j) Additional Consultations. The physician must refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives.

Rulemaking Authority 456.52 FS. Law Implemented 456.52 FS. History–New ___.

CERTIFICATION OF MATERIALS INCORPORATED
BY REFERENCE IN EMERGENCY RULES FILED WITH THE DEPARTMENT OF STATE

I hereby certify pursuant to Rule 1-1.013, Florida Administrative Code, that materials incorporated by reference in Emergency Rule 64B8ER23-7 have been:

[x] (1) Filed with the Department of State and included as part of the Emergency Rule adoption packet.

[ ] (2) That because there would be a violation of federal copyright laws if the submitting agency filed the incorporated materials as described in option (1) above, a true and complete copy of the incorporated materials has been provided to the Department of State as outlined in paragraph 1-1.013(5)(c), F.A.C.

Copies of the incorporated materials below may be obtained at the agency by [include address(es)/location(s)].

List form number(s) and form title(s), or title of document(s) below:

DH5079-MWA Puberty Suppession Treatment for Patients with Gender Dysphoria-Patient Information and Parental Consent and Assent for Minors

DH5080-MQA Feminizing Medications for Patients with Gender Dysphoria-Patient Information and Partental Cosnent and Assent for Minors

DH5081-MQA Masculinizing Medications for Patients with Gender Dysphoria-Patient Information and Parental Consent and Assent for Minors

Under the provisions of Section 120.54(4)(d), F.S., the attached material(s) take effect upon filing with the Department of State, or a date less than 20 days thereafter if specified in the rule if the adopting agency finds that such effective date is necessary because of immediate danger to the public health, safety, or welfare.

Signature, Person Authorized to Certify Rules

Paul Vazquez, Executive Director for
Scot Ackerman, M.D., Chair
Title

Puberty Suppression Treatment for Patients with Gender Dysphoria

Patient Information and Informed Parental Consent and Assent for Minors

Before a minor continues treatment to suppress puberty with puberty blockers, you and the minor need to be aware of the effects and possible risks associated with the use of these medications. After your questions or concerns are addressed and you have decided to have the minor continue treatment with puberty blockers, a parent/legal guardian and the minor must initial the statements below and sign this form. Both the parent/legal guardian and the minor must sign in person.

Medical treatment of people with gender dysphoria is based on very limited, poor-quality research with only subtle improvements seen in some patient's psychological functioning in some, but not all, research studies. This practice is purely speculative, and the possible psychological benefits may not outweigh the substantial risks of medical treatments and, in many cases, the need for lifelong medical treatments.

What are other options if I do not wish to have the minor continue treatment with puberty blockers?

One option available is psychological therapy with a mental health provider. This is recommended regardless of whether the minor undergoes suppression of puberty or not, due to the high risk of anxiety, depression, self-harm, and suicide. Other options may be discussed with your prescribing physician.

What are different medications that are used to suppress puberty?

The main mechanism by which physical changes of puberty can be put on hold is by using medication to block the signal from the brain to the organs that make hormones. These hormones are estrogen and testosterone. Estrogen is made by the ovaries. Testosterone is made by the testicles.

Please initial below to acknowledge your understanding of the information on this page.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

DH5079-MQA (Rev. 06/23)
Rules 64B8ER23-7 and 64B15ER23-9

Pediatric endocrinologists (children's doctors who specialize in hormones and puberty) use these medications frequently to suppress puberty in children with precocious (early) puberty, which is the U.S. Food and Drug Administration (FDA) approved use. None of the medications have been approved by the FDA to be used in minors with gender dysphoria. In other words, using these medications for gender dysphoria is considered "off label" use because they are not being used for their intended purpose.

Lupron and Histrelin are called GnRH analogs and are the most effective forms of treatment for puberty suppression. When used for precocious puberty, Lupron is given as a monthly or every 3-month intramuscular injection. When used for precocious puberty, Histrelin (brand name Supprelin) is an implant that is surgically placed under the skin and needs to be replaced every 1 to 2 years.

Provera is a pill that needs to be taken twice a day and is approved to be used in female adolescents with abnormal uterine bleeding. Provera is less effective than Lupron and Histrelin. Depo-Provera injections are approved for the use in females with abnormal bleeding and as birth control.

Please initial below to acknowledge your understanding of the information on this page.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

What are the requirements to receive puberty suppression for gender dysphoria?

To receive treatment with puberty blockers, there are specific requirements that must be met before and during treatment. These requirements will allow the prescribing physician to monitor the minor's medical and mental health status during treatment. If these requirements are not met, treatment with puberty blockers may be discontinued by the prescribing physician.

The specific requirements for a minor to receive and continue treatment include the following:

1. Has met the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders or International Classification of Diseases;
2. Has pubertal changes resulting in an increase in gender dysphoria;
3. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
4. Has psychological and social support during treatment;
5. Has experienced puberty to at least Tanner Stage 2 (this is the first stage of puberty and refers to breast or testicle growth), which must be confirmed by a physician;
6. Demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of puberty suppression, future cross-sex hormone treatment, as well as the medical and social risks and benefits of sex reassignment surgery.
7. Undergoes an in-person evaluation by the prescribing physician or their designated covering physician at least every 6 months;
8. Undergoes a suicide risk assessment by a licensed mental health care professional at least every 3 months;
9. Undergoes relevant laboratory testing at least every 4 months;
10. X-ray of the hand (bone age) no less than once a year;
11. Annual bone density scan (DEXA) which will allow monitoring of the minor's bone density (bone strength) during treatment, as puberty blockers may decrease bone density if given for long periods of time;
12. Annual mental health assessment by a Board-certified Florida-licensed psychiatrist or psychologist; and
13. Continued counseling with a licensed mental health care professional during the treatment period, with the frequency recommended by the licensed mental health care professional.

Please initial below to acknowledge your understanding of the information on this page.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

Please initial each statement on this form to show that you understand the benefits, risks, and changes associated with providing puberty suppression treatment to the minor.

Effects of Treatment of Suppression of Puberty

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Puberty blockers are used to temporarily suspend or block the physical changes of puberty for minors
			If a minor stops treatment with puberty blockers, in a few months their body may restart the changes of puberty at the developmental stage they were before starting medication. However, the effects of these medications could be permanent.
			It can take several months for the medications to be effective. It cannot be predicted how quickly or slowly or even if a minor's body will respond to the medication.
			Taking these medications, will cause a minor's body to stop producing testosterone or estrogen.
			These medications will not change a minor's sex (chromosomes), and it will not change a minor's internal or external reproductive structures.
			Puberty blockers can interfere with fertility.
			Puberty blockers do not affect the minor's ability to contract a sexually transmitted infection.
			The use of puberty blockers in minors for the treatment of gender dysphoria is an off-label use. This means these medications are not approved by the FDA to treat this specific diagnosis.

Risks of Treatment of Suppression of Puberty

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			The adverse effects and safety of puberty blockers used for the treatment of gender dysphoria in minors is not well known.
			Treatment with puberty blockers will not prevent serious psychiatric events such as a suicide.
			Treatment with puberty blockers may cause new or worsened psychiatric problems, including: • Crying • Irritability • Restlessness (impatience)

			• Anger • Acting aggressive
			It is the responsibility of the parent/guardian to notify the prescribing physician if the minor has any new or worsening physical or psychiatric problems while taking this medication.
			During the first 4 weeks of treatment, puberty blockers can cause an increase in some hormones. During this time, a minor may notice more signs of puberty, including vaginal bleeding.
			Seizures are a risk associated with taking puberty blockers. The risk of seizures may be higher in people who: • Have a history of seizures • Have a history of epilepsy • Have a history of brain or brain vessel (cerebrovascular) problems or tumors • Are taking a medicine that has been connected to seizures, such as bupropion or selective serotonin reuptake inhibitors (SSRIs).
			It is the responsibility of the parent/guardian to immediately notify the appropriate health care providers including the minor's prescribing physician if the minor has a seizure while taking puberty blockers.
			Increased pressure in the fluid around the brain is a risk associated with taking puberty blockers. It is the responsibility of the parent/guardian to notify the minor's prescribing physician if the minor has any of the following symptoms while taking puberty blockers: • Headache • Eye problems including blurred vision, double vision, and decreased eyesight • Eye pain • Ringing in the ears • Dizziness • Nausea
			Puberty blockers should not be used if a minor is: • Allergic to GnRH, GnRH agonist medicines, or Progesterones. • Pregnant or becomes pregnant because puberty blockers can cause birth defects or loss of the baby. It is the responsibility of the parent/guardian to notify the prescribing physician if a minor becomes pregnant while taking puberty blockers.
			The most common side effects of puberty blockers include: • Injection site reactions such as pain, swelling, and abscess which may result in surgery

			• Weight gain • Pain throughout body • Headache • Acne or red, itchy rash and white scales (seborrhea) • Serious skin rash (erythema multiforme) • Mood changes • Swelling of vagina (vaginitis), vaginal bleeding, and vaginal discharge • Upper stomach pain • Diarrhea • Bleeding • Nausea and vomiting • Fever • Itching • Pain in extremities • Rash • Back pain • Ligament sprain • Fracture • Breast tenderness • Difficulty sleeping • Chest pain • Excessive sweating
			Puberty blockers may decrease bone density.
			Minors may grow less than their peers while taking puberty blockers.
			Puberty blockers may cause stalling of typical cognitive or brain development in minors.

Requirements of Treatment of Suppression of Puberty

I understand the following:

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Compliance with the requirements explained above is a prerequisite to receive treatment for puberty suppression.
			The prescribing physician may stop prescribing puberty blockers if the prescribing physician or mental health care professionals providing treatment pursuant to this consent determine the benefit of treatment no longer outweighs the risks, there is insufficient social or psychological support, or the requirements in this consent are not met.

			The parent/guardian or the minor can change their mind and stop treatment at any time.

PARENTAL CONSENT:

The signature(s) below confirm(s) the following:

1. The minor's prescribing physician has fully informed me about:
   a. the benefits and risks of treatment with puberty blockers;
   b. the possible or likely consequences of treatment with puberty blockers and puberty suppression; and
   c. potential alternative treatments.

2. The information provided to me in this form and by the prescribing physician includes the known effects and risks of treatment with puberty blockers. I know that there may be other unknown short-term and long-term effects or risks which may be irreversible.

3. I have had sufficient time and opportunity to discuss relevant treatment options with my minor's prescribing physician.

4. All my questions have been answered to my satisfaction by the minor's prescribing physician.

5. I know enough to give informed consent for my minor to take, refuse, or postpone using puberty blocking medications.

6. The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.52, F.S. This form contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your physician.

7. My signature below attests to my consent for my minor to begin treatment for suppression of puberty.

_____
Parent/legal guardian's name (required)

_____ _____
Parent/legal guardian's signature (required) Date

Parent/legal guardian's name (optional)

Parent/legal guardian's signature (optional) Date

PRESCRIBING PHYSICIAN SIGNATURE:

My signature below attests to my compliance with section 456.52, Florida Statutes.

Prescribing physician's name (required)

Prescribing physician's signature (required) Date

ASSENT OF MINOR:

I have discussed the benefits and risks of treatment to suppress puberty with my prescribing physician and my parent(s) or legal guardian(s), and I wish to receive it.

Minor's name (required)

Minor's signature (required) Date

WITNESS:

Witness printed name

Witness signature Date

FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:

I certify that I am fluent in English and in the native language of the person indicating consent and/or assent on the above form. I certify that I have accurately and completely interpreted the contents of this form, and that the patient and/or adult(s) legally responsible for the minor child has indicated understanding of the contents of this form.

Interpreter's printed name

Interpreter's signature Date

Feminizing Medications for Patients with Gender Dysphoria

Patient Information and Informed Parental Consent and Assent for Minors

Before a minor starts or continues treatment with hormones or hormone antagonists, you and the minor need to be aware of the effects and possible risks associated with use of these medications.

After your questions or concerns are addressed and you have decided to have the minor start or continue treatment with hormones or hormone antagonists, a parent/legal guardian and the minor must initial the statements below and sign this form. Both the parent/legal guardian and the minor must sign in person.

Medical treatment of people with gender dysphoria is based on very limited, poor-quality research with only subtle improvements seen in some patient's psychological functioning in some, but not all, research studies. This practice is purely speculative, and the possible psychological benefits may not outweigh the substantial risks of medical treatments and, in many cases, the need for lifelong medical treatments.

What are the medications that can feminize one's appearance?

Treatment with hormones is called hormone replacement therapy or HRT. HRT will require taking estrogen, as well as medicines to block the body from producing or utilizing testosterone. Use of these medications by minors even when the criteria listed below are followed, does not have U.S. Food and Drug Administration (FDA) approval to be used by minors and its use in this population is considered "off label" because they are not being used for their intended purpose.

Different forms of estrogen are used to feminize one's appearance. Estrogen can be given as an injection either weekly or every other week, as a pill that is taken daily or twice a day, or as a patch that is changed weekly or every three or four days.

Please initial below to acknowledge your understanding of the information on this page.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

DH5080-MQA (Rev. 06/23)
Rules 64B8ER23-7 and 64B15ER23-9

Medications that block the production or effects of testosterone are called androgen blockers. Spironolactone is the androgen blocker that is most commonly used in the United States. In some cases, Bicalutamide, an antiandrogen, is used to block the effects of testosterone, though it will not reduce testosterone levels. Bicalutamide (brand name Casodex) is a cancer drug approved for the treatment of prostate cancer. Fulminant hepatotoxicity, a severe liver injury often resulting in death, has been noted with bicalutamide use.

Every medication has risks, benefits, and side effects that are important to understand before taking. The effects and side effects of medicines used to treat gender dysphoria must be monitored with laboratory studies and regular visits to the minor's prescribing physician to make sure that there are no negative medical or mental health effects.

HRT, the use of androgen blockers and antiandrogens, and the treatment process can affect a minor's mood. Therefore, minors must be under the care of a licensed mental health care professional while undergoing treatment. This professional can work with the minor, your family and friends, and your school staff.

What are my other options if I do not wish to start or continue my minor's treatment with hormones, hormone antagonists, or antiandrogens?

One option available is psychological therapy with a mental health. This is recommended regardless of whether or not the minor undergoes treatment with hormones, hormone antagonists, or antiandrogens due to the high risk of anxiety, depression, self-harm, and suicide. Other options may be discussed with your prescribing physician.

What are the requirements to receive hormone replacement therapy (HRT)?

To receive HRT, there are specific requirements that need to be met before and during treatment. These requirements will allow the prescribing physician to monitor the minor's medical and mental health status during treatment. If these requirements are not met, HRT may be discontinued by the prescribing physician.

Please initial below to acknowledge your understanding of the information on this page.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

Before beginning or continuing HRT, a minor must undergo a thorough psychological and social evaluation performed by a Florida licensed board-certified psychiatrist or a Florida licensed psychologist. The psychiatrist or psychologist must submit a letter to the prescribing physician confirming this.

The specific requirements for a minor to receive and continue HRT treatment include the following:

1. Has met the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders or International Classification of Diseases;
2. Has pubertal changes resulting in an increase in gender dysphoria;
3. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
4. Has psychological and social support during treatment;
5. Has experienced puberty to at least Tanner Stage 2 (first stage of puberty), which must be confirmed by a physician;
6. Demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of HRT as well as the medical and social risks and benefits of sex reassignment surgery;
7. Undergoes an in-person evaluation by the prescribing physician or their designated covering physician at least every 6 months;
8. Undergoes a suicide risk assessment by a licensed mental health care professional at least every 3 months;
9. Undergoes relevant laboratory testing at least every 4 months;
10. X-ray of the hand (bone age) at least once a year if the minor is still growing;
11. Annual bone density scan (DEXA) which will allow monitoring of the minor's bone density (bone strength) during treatment, which can be altered by HRT;
12. Annual mental health assessments by a Board-certified Florida licensed psychiatrist or psychologist; and
13. Continued counseling with a licensed mental health care professional during the treatment period, with the frequency recommended by the licensed mental health care professional.

Please initial below to acknowledge your understanding of the information on this page.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

Please initial each statement on this form to show that you understand the benefits, risks, and changes associated with treating a minor with feminizing medications.

Effects of Feminizing Medications

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Feminizing medications, including estrogen, androgen blockers, or antiandrogens, given singularly or in combination, may be prescribed to make a minor appear less masculine and more feminine
			It can take several months or longer for the effects of feminizing medications to become noticeable and no one can predict how fast or how much change will occur.
			This treatment will not change the minor's biological sex or chromosomes.
			If a minor takes estrogen, the following changes in a minor's breasts will occur: • Breasts will develop but will not reach their full size for several years • Breasts will remain even if estrogen treatment is discontinued • A milky discharge from the nipples may appear, which should be reported the minor's prescribing physician • The minor's risk of breast cancer may significantly increase
			If a minor takes feminizing medications, the minor's body will make less testosterone, which may affect the minor's sex life in different ways, including: • The minor's testicles may shrink • The minor's penis may never fully develop, particularly if the minor has previously taken puberty blockers • The minor will have fewer spontaneous erections • The minor's sperm may no longer mature causing infertility which may be permanent

			even if treatment is discontinued, the risk of which is increased if the minor took puberty blockers prior to starting feminizing medications • Conversely, it is possible that a minor's sperm could still mature while taking feminizing medications and the minor may cause someone to get pregnant
			To improve the possibility that the minor may have biological children in the future, the options for sperm banking by the minor have been explained.
			If a minor takes feminizing medications, some parts of the minor's body will not change much, including: • If present, the minor's facial hair may grow more slowly, but it will not go away completely even after taking feminizing medications for many years • If present, the minor's body hair may grow more slowly, but it will not go away completely even after taking feminizing medications for many years • If the minor went through puberty and has a deep voice, the pitch of the minor's voice will not rise and the minor's speech patterns will not become more like a woman's • If present, the minor's Adam's apple will not shrink
			Even if a minor stops taking feminizing medications, the following changes may occur: • The minor's body fat may be redistributed with less fat on the abdomen and more on the buttocks, hips, and thighs creating a more female shape • The minor may have decreased muscle mass and strength in the upper body • The minor's skin may become softer
			Mood changes may be caused by these medicines, and the minor will continue therapy with a licensed mental health care professional during treatment.
			Using these medicines to feminize a minor is an off-label use of the medications. This means these medications are not approved by the FDA for this

			purpose. I know that the medicine and dose that is recommended is based solely on the judgment and experience of the minor's prescribing physician and there is no data in the medical literature or controlled research studies that support the timing, dosing, and type of administration of feminizing medications for minors.

Risks of Feminizing Medications

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			The medical effects and the safety of minors taking femininizing medications are not completely known and there may be unknown long-term risks.
			Taking feminizing medications causes changes that other people will notice.
			Treatment with femininizing medications will not prevent serious psychiatric events, including suicide.
			The minor must not take more feminizing medication than prescribed. Taking too much medication: • Will increase health risks • Will not make changes happen more quickly or more significantly
			Taking feminizing medication can damage the liver and possibly lead to liver disease.

Risks of Estrogen

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Estrogen **SHOULD NOT** be used by anyone who has a history of: • Any estrogen-dependent cancer • Any disorder that makes them more likely to get blood clots that could travel to the lungs unless they are also taking blood thinners and are being followed by a specialist

			Estrogen should be used **WITH CAUTION** and only after a full discussion of risks by anyone who: • Has a family history of breast cancer or other cancers that grow more quickly when estrogens are present • Has a family history of heart disease • Has diabetes • Has chronic hepatitis or other liver disease • Has high levels of cholesterol • Has migraines or seizures • Is obese • Smokes cigarettes or uses tobacco products
			Taking estrogen increases the risk of blood clots and problems with blood vessels that can result in: • Chronic problems with veins in the legs, which may require surgery • Heart attack which may cause permanent heart damage or death • Pulmonary embolism (blood clot in the lungs), which may cause permanent lung damage or death • Stroke, which may cause permanent brain damage or death
			The risk of blood clots while take estrogen is much greater if the minor smokes cigarettes. The danger is so high that the minor should stop smoking completely while taking estrogen.
			Taking estrogen can increase the deposits of fat around internal organs, which increases the risk for diabetes and heart disease, which in turn increases the risk of heart attack and stroke.
			Taking estrogen can raise blood pressure, which increases the risk of heart attack and stroke.
			Taking estrogen increases the risk of gallstones (stones in the gallbladder). Any long-term abdominal pain experience by the minor while taking estrogen must be reported to the minor's prescribing physician.
			Taking estrogen increases the risk of elevated prolactin levels and prolactinomas, which are non-cancerous tumors of the pituitary gland. While not typically life threatening, prolactinomas can damage the

			minor's vision and cause headaches if not treated properly. Any changes in the minor's vision, the occurrence of headaches that are worse when waking up in the morning, or any milky discharge from the nipples must be reported to the minor's prescribing physician.
			Taking estrogen can cause nausea and vomiting. Any long-term nausea or vomiting must be reported to the minor's prescribing physician.
			Taking estrogen can cause migraines or can make them worse if the minor already has them.
			Taking estrogen can cause hot flashes.
			Taking estrogen can cause the minor to feel tired and have difficulty focusing.

Risks of Androgen Blockers and Antiandrogens (Spironolactone and Bicalutamide)

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Taking Spironolactone affects the balance of water and salt in the kidneys, which may: • Increase the amount of urine produced by the minor's kidneys, making it necessary to urinate more frequently • Increase the minor's thirst • Increase the minor's risk of dehydration, which can be evidenced by less frequent urination than usual, dark and strong-smelling urine, thirst, and light-headedness
			Taking Spironolactone affects the balance of potassium in the kidneys, which may result in the minor experience high potassium levels resulting in: • Changes in heart rhythms that may be life threatening • Low blood pressure, which can cause: o Fatigue o Lightheadedness o Tingling feelings o Muscle weakness o Shortness of breath

			• The minor's need for regular blood tests to monitor risks while on the medication
			Taking Bicalutamide may cause numerous side effects which should be reported to the minor's prescribing physician, including: • Hot flashes or flushing • Bone, back, or pelvic pain • Muscle weakness • Muscle or joint pain • Headaches • Shortness of breath • Chest pain • Elevated blood pressure • Swelling of the hands, feet, ankles, or lower legs • Cough • Constipation • Nausea • Vomiting • Abdominal pain • Diarrhea • Gas • Changes in weight (loss or gain) • Loss of appetite • Dizziness • Pain, burning, or tingling in the hands or feet • Difficulty sleeping • Feeling of uneasiness or dread • Rash • Sweating • Need to urinate frequently during the night • Bloody urine • Painful or difficult urination • Frequent and urgent need to urinate • Difficulty emptying bladder • Painful or swollen breasts • Yellowing of the skin or eyes • Pain in the upper right part of the abdomen • Extreme tiredness • Unusual bleeding or bruising • Lack of energy • Upset stomach

			• Loss of appetite • Flu-like symptoms • Dull or sharp side pain

Requirements of Treatment with Feminizing Medications

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Compliance with the requirements explained above is a prerequisite for a minor to receive treatment with feminizing medications.
			The prescribing physician may stop prescribing feminizing medications if the prescribing physician or mental health care professionals providing treatment pursuant to this consent determine the benefit of treatment no longer outweighs the risks, there is insufficient social or psychological support, or the requirements in this consent are not met.
			The parent/guardian or the minor can change their mind and stop treatment at any time although some effects of HRT may be permanent.

Prevention of Complications while under Treatment with Feminizing Medications

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			The undersigned parent(s)/legal guardian(s) agree(s) to notify the minor's prescribing physician if the minor suffers from any side effects during treatment or is unhappy with the treatment in any way, particularly if the parent(s)/legal guardian(s) has/have any concerns that the minor has worsening signs of depression or anxiety or expresses a desire harm themselves or attempt suicide.
			The prescribing physician is required to monitor the minor for any side effects during treatment and may refer the minor to another physician or specialist for treatment. The undersigned

			parent(s)/legal guardian(s) agree(s) to take the minor to physicians and specialists as recommended by the prescribing physician.

PARENTAL CONSENT:

The signature(s) below confirm(s) the following:

1. The minor's prescribing physician has fully informed me about:
   a. the benefits and risks of taking feminizing medications;
   b. the possible or likely consequences of hormone therapy; and
   c. potential alternative treatments.

2. The information provided to me in this form and by the prescribing physician includes the known effects and risks of treatment with feminizing medications. I know that there may be other unknown short-term and long-term effects or risks which may be irreversible.

3. I have had sufficient time and opportunity to discuss relevant treatment options with the minor's prescribing physician.

4. All my questions have been answered to my satisfaction by the minor's prescribing physician.

5. I know enough to give informed consent for the minor to take, refuse, or postpone taking feminizing medications.

6. The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.52, F.S. This form contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your physician.

7. My signature below attests to my consent for the minor to begin treatment with feminizing medications.

_____

Parent/legal guardian's printed name (required)

_____ _____

Parent/legal guardian's signature (required) Date

Parent/legal guardian's printed name (optional)

Parent/legal guardian's signature (optional) Date

PRESCRIBING PHYSICIAN SIGNATURE:

My signature below attests to my compliance with section 456.52, Florida Statutes.

Prescribing physician's printed name (required)

Prescribing physician's signature (required) Date

ASSENT OF A MINOR:

I have discussed the benefits and risks of treatment with feminizing medications with my prescribing physician, parent(s) or legal guardian(s), and I wish to receive them.

Minor's printed name (required)

Minor's signature (required) Date

WITNESS:

Witness' printed name (required)

Witness' signature (required) Date

FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:

I certify that I am fluent in English and in the native language of the person indicating consent and/or assent on the above form. I certify that I have accurately and completely interpreted the contents of this form, and that the patient and/or adult(s) legally responsible for the minor child has indicated understanding of the contents of this form.

Interpreter's printed name

Interpreter's signature Date

Masculinizing Medications for Patients with Gender Dysphoria

Patient Information and Informed Parental Consent and Assent for Minors

Before a minor starts or continues treatment with hormones or hormone antagonists, you and the minor need to be aware of the effects and possible risks associated with use of these medications.

After your questions or concerns are addressed and you have decided to have the minor start or continue treatment with hormones or hormone antagonists, a parent/legal guardian and the minor must initial the statements below and sign this form. Both the parent/legal guardian and the minor must sign in person.

Medical treatment of people with gender dysphoria is based on very limited, poor-quality research with only subtle improvements seen in some patient's psychological functioning in some, but not all, research studies. This practice is purely speculative, and the possible psychological benefits may not outweigh the substantial risks of medical treatments and, in many cases, the need for lifelong medical treatments.

What are the medications that can masculinize one's appearance?

Treatment with hormones is called hormone replacement therapy or HRT. HRT will require taking testosterone, which increases muscle mass and causes the development of facial hair and a deeper voice. Testosterone when used by minors, even when the criteria listed below are followed, does not have U.S. Food and Drug Administration (FDA) approval to be used by minors and its use in this population is considered "off label" because they are not being used for their intended purpose.

Please initial below to acknowledge your understanding of the information on this page.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

DH5081-MQA (Rev. 06/23)
Rules 64B8ER23-7 and 64B15ER23-9

What are my other options if I do not wish to start or continue my minor's treatment with hormones or hormone antagonists?

One option available is psychological therapy with a mental health care provider. This is recommended regardless of whether or not the minor undergoes treatment with hormones or hormone antagonists due to the high risk of anxiety, depression, self-harm, and suicide. Other options may be discussed with your prescribing physician.

How is testosterone taken?

Testosterone is usually injected every one to four weeks. Typically, it is not given in pill form because the body may not absorb it properly which may cause potentially fatal liver problems. The doses used for injection differ from product to product and from patient to patient. The injections are given in the muscle (intramuscular) or can be given with a smaller needle under the skin (subcutaneous). A minor taking testosterone may experience unwanted swings in hormone levels based on the amount and how often doses are given.

Every medication has risks, benefits, and side effects that are important to understand before taking. The effects and side effects of medicines used to treat gender dysphoria must be monitored with laboratory studies and regular visits to the minor's prescribing physician to make sure that there are no negative medical or mental health effects.

Both testosterone and the treatment process can affect a minor's mood. Therefore, minors must be under the care of a licensed mental health care professional while undergoing treatment. This professional can work with the minor, your family and friends, and your school staff.

What are the requirements to receive hormone replacement therapy (HRT)?

To receive HRT, there are specific requirements that need to be met before and during treatment. These requirements will allow the prescribing physician to monitor the minor's medical and mental health status during treatment. If these requirements are not met, HRT may be discontinued by the prescribing physician.

Please initial below to acknowledge your understanding of the information on this page.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

Before beginning or continuing HRT, a minor needs to undergo a thorough psychological and social evaluation performed by a Florida licensed board-certified psychiatrist or a Florida licensed psychologist. The psychiatrist or psychologist must submit a letter to the prescribing physician confirming this.

The specific requirements for a minor to receive and continue HRT treatment include the following:

1. Has met the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders (DSM) or International Classification of Diseases (ICD);
2. Has pubertal changes resulting in an increase in gender dysphoria;
3. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
4. Has psychological and social support during treatment;
5. Has experienced puberty to at least Tanner Stage 2 (first stage of puberty), which must be confirmed by a physician;
6. Demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of HRT as well as the medical and social risks and benefits of sex reassignment surgery;
7. Undergoes an in-person evaluation by the prescribing physician or their designated covering physician at least every 6 months;
8. Undergoes a suicide risk assessment by a licensed mental health care professional at least every 3 months;
9. Undergoes relevant laboratory testing, at least every 4 months;
10. X-ray of the hand (bone age) at least once a year if the minor is still growing;
11. Annual bone density scan (DEXA) which will allow monitoring of the minor's bone density (bone strength) during treatment, which can be altered by HRT
12. Annual mental health assessments by a Board-certified Florida licensed psychiatrist or psychologist; and
13. Continued counseling with a licensed mental health care professional during the treatment period, with the frequency recommended by the licensed mental health care professional.

Please initial below to acknowledge your understanding of the information on this page.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

Summary of Testosterone Benefits and Risks

BENEFITS	RISKS
• Appear more like a man • Bigger clitoris • Coarser skin • Lower voice • More body hair • More facial hair • More muscle mass • More strength • No or minimal menstrual periods • More physical energy • More sex drive	• Acne (may permanently scar) • Blood clots (thrombophlebitis), risk significantly increased by smoking • Emotional changes, for example, more aggression • Headache • High blood pressure (hypertension) • Increased red-blood-cell count • Infertility • Inflamed liver • Interaction with drugs for diabetes and blood thinning such as Coumadin and Warfarin • Male pattern baldness • More abdominal fat -- redistributed to a male shape • Risk of heart disease • Swelling of hands, feet, and legs • Weight gain

---

Please initial below to acknowledge your understanding of the information on this page.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

Please initial each statement on this form to show that you understand the benefits, risks, and changes associated with a minor taking testosterone.

Masculinizing Effects

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Testosterone may be prescribed to make a minor appear less like a female and more like a male.
			It can take several months or longer for the effects of testosterone to become noticeable and no one can predict how fast or how much change will occur.
			Changes from testosterone may not be complete for 2 to 5 years after treatment is started.
			The following changes are likely to be permanent even if testosterone is discontinued: • Bigger clitoris - typically about half an inch to a little more than an inch • Deeper voice • Gradual growth of moustache and beard • Hair loss at the temples and crown of the head and the possibility of being completely bald • More, thicker, and coarser hair on abdomen, arms, back, chest, and legs
			The following changes could be permanent, but may improve if I stop taking testosterone: • Acne (although there may be permanent scars) • Menstrual periods (if present), typically stop one to six months after starting • More abdominal fat – redistributed to a male shape: decreased on buttocks, hips, and thighs; increased in abdomen – changing from "pear shape" to "apple shape" • More muscle mass and strength • More sexual interest • Vaginal dryness • Vaginal tearing • Vaginal bleeding • Vaginal pain • Vaginal infection • Painful intercourse

			This treatment will not change the minor's biological sex or chromosomes.
			Testosterone may reduce the minor's ability to become pregnant, but it will not eliminate the risk of pregnancy. A person can become pregnant while on testosterone. I agree to inform the minor's prescribing physician if the minor becomes pregnant.
			Some aspects of the minor's body will not change: • Fat loss may make breasts appear slightly smaller (if present) • The voice will deepen, but other aspects of the way the minor speaks may not sound more masculine
			Mood changes may be caused by these medicines, and the minor will continue therapy with a licensed mental health care professional during treatment.
			Using these medicines to masculinize a minor is an off-label use of the medications. This means these medications are not approved by the FDA for this purpose. I know that the medicine and dose that is recommended is based solely on the judgment and experience of the minor's prescribing physician and there is no data in the medical literature or controlled research studies that support the timing, dosing, and type of administration of HRT for minors.

Risks of Testosterone

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Testosterone **SHOULD NOT** be used by anyone who: • Is pregnant • Has uncontrolled coronary artery disease as it could increase your risk for a fatal heart attack
			Testosterone should be used **WITH CAUTION** and only after a full discussion of risks by anyone who: • Has acne • Has a family history of heart disease or breast cancer • Has had a blood clot • Has high levels of cholesterol • Has liver disease

			• Has a high red blood cell count • Is obese • Smokes cigarettes or uses tobacco products
			The medical effects and the safety of minors taking testosterone are not completely known and there may be unknown long-term risks.
			Taking testosterone causes changes that other people will notice.
			Treatment with testosterone will not prevent serious psychiatric events, including suicide.
			The minor must not take more testosterone than prescribed. Taking too much testosterone: • Will increase health risks; • Will not make changes happen more quickly or more significantly; and • May cause the body to convert extra testosterone into estrogen that can slow down or stop the minor appearing more masculine
			Taking testosterone can cause changes that increase the risk of heart disease into adulthood. These changes include: • Less good cholesterol (HDL) that may protect against heart disease and more bad cholesterol (LDL) that may increase the risk of heart disease; • Higher blood pressure; and • More deposits of fat around the internal organs
			Taking testosterone can damage the liver and possibly lead to liver disease.
			Taking testosterone can increase red blood cells and hemoglobin, which may increase my risk of life-threatening problems such as stroke or heart attack.
			Taking testosterone can increase the risk for diabetes (high blood sugars), which decrease the body's response to insulin, cause weight gain, and increase deposits of fat around internal organs increasing the risk of heart disease and stroke.
			Treatment with testosterone can cause ovaries to not release eggs and may cause infertility.
			Treatment with testosterone increases the risk of cancer to the uterus, ovaries, or breasts. It is unclear if taking testosterone plays any role in HPV infection or cervical cancer.
			Taking testosterone causes or worsen migraines.

			Taking testosterone can cause emotional changes, such as irritability, frustration, aggression, and anger.

Requirements of Treatment with HRT

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Compliance with the requirements explained above is a prerequisite for a minor to receive treatment with testosterone.
			The prescribing physician may stop prescribing testosterone if the prescribing physician or mental health care professionals providing treatment pursuant to this consent determine the benefit of treatment no longer outweighs the risks, there is insufficient social or psychological support, or the requirements in this consent are not met.
			The parent/guardian or the minor can change their mind and stop treatment at any time although some effects of HRT may be permanent.

Prevention of Complications while under Treatment with HRT

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			The undersigned parent(s)/legal guardian(s) agree(s) to notify the minor's prescribing physician if the minor suffers from any side effects during treatment or is unhappy with the treatment in any way, particularly if the parent(s)/legal guardian(s) has/have any concerns that the minor has worsening signs of depression or anxiety or expresses a desire harm themselves or attempt suicide.
			The prescribing physician is required to monitor the minor for any side effects during treatment and may refer the minor to another physician or specialist for treatment. The undersigned parent(s)/legal guardian(s) agree(s) to take the minor physicians and specialists as recommended by the prescribing physician.

PARENTAL CONSENT:

The signature(s) below confirm(s) the following:

1. The minor's prescribing physician has fully informed me about:
   a. the benefits and risks of taking testosterone;
   b. the possible or likely consequences of hormone therapy; and
   c. potential alternative treatments.

2. The information provided to me in this form and by the prescribing physician includes the known effects and risks of treatment with testosterone. I know that there may be other unknown short-term and long-term effects or risks which may be irreversible.

3. I have had sufficient time and opportunity to discuss relevant treatment options with the minor's prescribing physician.

4. All my questions have been answered to my satisfaction by the minor's prescribing physician.

5. I know enough to give informed consent for the minor to take, refuse, or postpone taking testosterone.

6. The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.52, F.S. This form contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your physician.

7. My signature below attests to my consent for the minor to begin treatment with testosterone.

_____

Parent/legal guardian's printed name (required)

_____ _____

Parent/legal guardian's signature (required) Date

Parent/legal guardian's printed name (optional)

Parent/legal guardian's signature (optional) Date

PRESCRIBING PHYSICIAN:

My signature below attests to my compliance with 456.52, Florida Statutes.

Prescribing physician's printed name (required)

Prescribing physician's signature (required) Date

ASSENT OF A MINOR:

I have discussed the benefits and risks of treatment with masculinizing medication with my prescribing physician, parent(s) or legal guardian(s), and I wish to receive it.

Minor's printed name (required)

Minor's signature (required) Date

WITNESS:

Witness' printed name (required)

Witness' signature (required) Date

FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:

I certify that I am fluent in English and in the native language of the person indicating consent and/or assent on the above form. I certify that I have accurately and completely interpreted the contents of this form, and that the patient and/or adult(s) legally responsible for the minor child has indicated understanding of the contents of this form.

Interpreter's printed name

Interpreter's signature Date

FLORIDA DEPARTMENT of STATE

RON DESANTIS
Governor

CORD BYRD
Secretary of State

July 6, 2023

Angela Southwell
Paralegal Specialist
Office of the Attorney General
PL 01, The Capitol
Tallahassee, FL 32399

Dear Angela Southwell:

Your adoption package for Emergency Rule 64B8ER23-8 was received, electronically, by the Florida Department of State, Administrative Code and Register at 5:37 p.m. on July 5, 2023. 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 July 5, 2023.

Sincerely,

Anya C. Owens
Administrative Code and Register Director

Owens, Anya C.

From: Angela Southwell <Angela.Southwell@myfloridalegal.com>
Sent: Wednesday, July 5, 2023 5:37 PM
To: RuleAdoptions
Cc: Owens, Anya C.; Donna McNulty; Christopher Dierlam; Cassandra Fullove
Subject: Adoption Packet for Emergency Rule 64B8ER23-8
Attachments: Adoption Pkt 64B8ER23-8.pdf; THE FULL TEXT OF THE EMERGENCY RULE IS.docx

Good Afternoon:

Attached please find the adoption packet and text.

Angela M. Southwell
Paralegal Specialist
Office of the Attorney General
Administrative Law
PL-01 The Capitol
Bin #4100
Tallahassee, Florida 32399-1050
Telephone: (850) 414-3772
angela.southwell@myfloridalegal.com

ASHLEY MOODY
ATTORNEY GENERAL
STATE OF FLORIDA

OFFICE OF THE ATTORNEY GENERAL
Administrative Law

Angela Southwell
Paralegal Specialist
PL-01 The Capitol
Tallahassee, FL 32399-1050
Phone (850) 414-3772
Fax (850) 922-6425
angela.southwell@myfloridalegal.com

MEMORANDUM

TO: Anya Owens, Program Administrator
Administrative Code and Register

FROM: Angela Southwell, Paralegal Specialist

RE: Department of Health
Board of Medicine
Emergency Rule 64B8ER23-8

DATE: July 5, 2023

Attached are the following documents regarding the above-referenced emergency rule adoption packet for the above-referenced emergency rule:

- Notice of Emergency Rule
- Adoption text for Emergency Rule 64B8ER23-8 (double spaced)
- Certification of Board of Medicine Emergency Rule Filed With the Department of State
- Designation of Rule the Violation of Which is a Minor Violation Certification
- Certification of Materials Incorporated by Reference in Rules Filed with the Department of State
- Form DH5082-MQA, (06/23), entitled "Feminizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Consent"
- Form DH5083-MQA, (06/23), entitled "Masculinizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Consent,"
- Form DH5084-MQA, (06/23), entitled "Surgical Treatment for Adults with Gender Dysphoria, Patient Information and Informed Consent"

Should you have any questions regarding the rule, please contact me at angela.southwell@myfloridalegal.com or by telephone at 850-414-3772.

Thank you for your attention to this matter.

Attachments

CERTIFICATION OF BOARD OF MEDICINE

EMERGENCY RULE FILED WITH THE

DEPARTMENT OF STATE

I hereby certify that pursuant to Ch 2023-90 Laws of Florida, Section 5, section 456.52, Florida Statutes was created and pursuant to subparagraphs 456.52(1)(a) and (6)(a), F.S., the Board of Medicine is required to adopt emergency rules to implement the section. 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), F.S. 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.

64B8ER23-8

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 Scot Ackerman, 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), F.S., 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).:

64B8ER23-8

Signature of Agency Head

Paul Vazquez, Executive Director for
Scot Ackerman, 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 NO.: RULE TITLE:

64B8ER23-8 Mandatory Standardized Informed Consent for Sex-reassignment Prescriptions or Procedures in Adults.

SPECIFIC REASONS FOR FINDING AN IMMEDIATE DANGER TO THE PUBLIC HEALTH, SAFETY OR WELFARE: On May 17, 2023, Florida Governor, Ronald DeSantis, signed CSSB 254 into law creating Ch. 2023-90, Laws of Florida and section 456.52, Florida Statutes. Pursuant to section 456.52(1), F.S., sex-reassignment prescriptions are prohibited for patients younger than 18 years of age upon the effective date of the act; however, pursuant to section 456.52(1)(a), F.S., the Board of Medicine shall within 60 days after the effective date of the act, adopt emergency rules pertaining to standards of practice by which minors may continue to be treated if such treatment was commenced before, and is still active on, the effective date of the act. Section 456.52(1)(b), F.S., also provides a minor patient meeting the criteria outlined in section 456.52(1)(a), F.S., may continue to be treated by a physician with such prescriptions according to rules adopted pursuant to paragraph (1)(a).

Further, pursuant to section 456.52(2), F.S., if sex reassignment prescriptions or procedures are prescribed for or administered to patients 18 years of age or older, consent must be voluntary, informed, and in writing on forms adopted in rule by the Board of Medicine. Pursuant to section 456.52(4), F.S., the consent required for sex-reassignment prescriptions does not apply to renewals of sex-reassignment prescriptions if a physician and his or her patient have met the requirements for consent for the initial prescription. Section 456.52(6)(a), F.S., states "[t]he Board of Medicine and the Board of Osteopathic Medicine shall adopt emergency rules to implement this section."

Accordingly, the Board of Medicine, by emergency rule, hereby adopts the incorporated mandated consent forms for the treatment of gender dysphoria with hormone replacement therapy and surgical treatment.

*** This emergency rule does not apply to Susan Doe, Gavin Goe, or Lisa Loe, or their parents or healthcare providers (see Jane Doe et al., v. Joseph A. Ladapo, et al, Preliminary Injunction, Filed June 6, 2023, Case No. 4:23cv114-RH-MAF, United States District Court for the Northern District of Florida). ***

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. CSSB 254 was signed into law on May 17, 2023. The Board of Medicine was contacted by multiple licensed physicians and

physician groups seeking clarification regarding the exception contained in section 465.52(4), F.S., and a timeframe for the required emergency rules shortly thereafter. In response, the Board of Medicine and the Board of Osteopathic Medicine held a Joint Rules/Legislative Committee (Joint Committee) meeting on June 1, 2023, to discuss the emergency rule. On May 19, 2023, the Board of Medicine published notice of the Joint Committee's June meeting both on its website and in the Florida Administrative Register. On June 2, 2023, the Board of Medicine discussed the report of the Joint Committee and voted upon emergency rule language that would allow for the renewal of previous prescriptions while the Board worked on consent forms. The Board of Medicine published notice of its June 2, 2023, meeting in the Florida Administrative Register on May 5, 2023, and on its website on May 12, 2023.

The Joint Committee held another meeting on June 23, 2023, to discuss an emergency rule adopting draft consent forms that were under consideration. On June 6, 2023, the Board of Medicine published notice of the Joint Committee's June 23, 2023, meeting to its website and in the Florida Administrative Register. On June 30, 2023, the Boards of Medicine and Osteopathic Medicine held a Joint Board meeting (Joint Board Meeting) to discuss the draft consent forms that were approved by the Joint Committee on June 23, 2023. The Joint Board Meeting was held via Microsoft Teams and notice of the same was published to the Board of Medicine's website and in the Florida Administrative Register on June 22, 2023.

Each Joint Committee meeting was held in person in a public forum and was able to be attended by any interested persons. The Joint Board Meeting was held via Microsoft Teams and also was able to be attended by any interested persons. Public comment was accepted at all of the aforementioned meetings. Further, the Board's accepted written public comment on the proposed rules up and until 24 hours prior to the Joint Board Meeting. Accordingly, all notice requirements contained in Rule 28-102.001, F.A.C., were properly complied with and interested persons were given ample opportunity to participate in this rulemaking process.

SUMMARY: The proposed emergency rule formally adopts the required consent forms for a patient to receive sex-reassignment prescriptions and/or procedures per section 456.52(2), Florida Statutes.

THE PERSON TO BE CONTACTED REGARDING THE EMERGENCY RULE IS: Paul Vazquez, Executive Director, Board of Medicine, 4052 Bald Cypress Way, Bin # C-03, Tallahassee, Florida 32399-3253, Paul.Vazquez@flhealth.gov

THE FULL TEXT OF THE EMERGENCY RULE IS:

64B8ER23-8 Mandatory Standardized Informed Consent for Sex-reassignment Prescriptions or Procedures in Adults.

Pursuant to Section 456.52, Florida Statutes, when sex-reassignment prescriptions or procedures are prescribed for or administered or performed on patients 18 years of age or older, the physician is required to obtain voluntary, informed consent while physically present in the same room as the patient. Consent is not required for renewal of such prescriptions if a physician and the physician's patient have met the requirements for consent for the initial prescription or renewal; however, a separate consent is required for any new prescription for a pharmaceutical product not previously prescribed to the patient.

(1) Informed Consent. The Board has approved the following mandatory informed consent forms for sex-reassignment prescriptions or procedures for patients 18 years of age or older:

(a) For patients prescribed sex-reassignment feminizing medication, form DH5082-MQA, (06/23), entitled "Feminizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Consent," which is hereby incorporated by reference and available from the Board's website at https://flboardofmedicine.gov/forms/Feminizing-Medications-for-Patients-with-Gender-Dysphoria-Patient-Information-and-Informed-Consent.pdf.

(b) For patients prescribed sex-reassignment masculinizing medications, form DH5083-MQA, (06/23), entitled "Masculinizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Consent," which is hereby incorporated by reference and available from the Board's website at https://flboardofmedicine.gov/forms/Masculinizing-Medications-for-Patients-with-Gender-Dysphoria-Patient-Information-and-Informed-Consent.pdf.

(c) For patients undergoing surgical treatment, form DH5084-MQA, (06/23), entitled "Surgical Treatment for Adults with Gender Dysphoria, Patient Information and Informed Consent," which is hereby incorporated by reference and available from the Board's website at https://flboardofmedicine.gov/forms/Surgical-Treatment-for-Adults-with-Gender-Dysphoria-Patients-Information-and-Informed-Consent.pdf.

(2) A Board-approved informed consent form is not executed until:

(a) The physician issuing the prescription or performing the procedure, while physically present in the same room as the patient, has informed the patient of the nature and risks of the prescription or procedure and has provided and received the patient's written acknowledgement before the prescription is prescribed, administered, or performed. The physician is prohibited from delegating this responsibility to another person. The physician is also required to sign the informed consent form.

(b) The patient is required to sign the informed consent form.

(c) A competent witness is also required to sign the informed consent form.

Rulemaking Authority 456.52 FS. Law Implemented 456.52 FS. History – New ____.

CERTIFICATION OF MATERIALS INCORPORATED

BY REFERENCE IN EMERGENCY RULES FILED WITH THE DEPARTMENT OF STATE

I hereby certify pursuant to Rule 1-1.013, Florida Administrative Code, that materials incorporated by reference in Emergency Rule 64B8ER23-8 have been:

[x] (1) Filed with the Department of State and included as part of the Emergency Rule adoption packet.

[ ] (2) That because there would be a violation of federal copyright laws if the submitting agency filed the incorporated materials as described in option (1) above, a true and complete copy of the incorporated materials has been provided to the Department of State as outlined in paragraph 1-1.013(5)(c), F.A.C.

Copies of the incorporated materials below may be obtained at the agency by [include address(es)/location(s)].

List form number(s) and form title(s), or title of document(s) below:

DH5082-MQA Feminizing Medications for Patient with Gender Dysphoria-Patient Information and Informed Consent

DH5083-MQA Masculinizing Medications for Patients with Gender Dysphoria-Patient Information and Informed Consent

DH5084 Surgical Treatment for Adults with Gender Dysphoria-Patients Information and Informed Consent

Under the provisions of Section 120.54(4)(d), F.S., the attached material(s) take effect upon filing with the Department of State, or a date less than 20 days thereafter if specified in the rule if the adopting agency finds that such effective date is necessary because of immediate danger to the public health, safety, or welfare.

Signature, Person Authorized to Certify Rules

Paul Vazquez, Executive Director for
Scot Ackerman, M.D., Chair
Title

Feminizing Medications for Patients with Gender Dysphoria

Patient Information and Informed Consent

Before starting or continuing treatment with hormones or hormone antagonists, you need to be aware of the effects and possible risks associated with use of these medications.

Your prescribing physician will make a medical decision in consultation with you about the medications that are best for you, keeping in mind your overall health during the treatment process. Your prescribing physician will discuss with you all of the available information relating to hormone therapy. You are asked to read and understand the following information and to discuss any questions you have with your prescribing physician.

After your questions or concerns are addressed and you have decided to start or continue treatment with hormones or hormone antagonists, you must initial the statements below and sign this form in person with your prescribing physician.

Medical treatment of people with gender dysphoria is based on very limited, poor-quality research with only subtle improvements seen in some patient's psychological functioning in some, but not all, research studies. This practice is purely speculative, and the possible psychological benefits may not outweigh the substantial risks of medical treatments and, in many cases, the need for lifelong medical treatments.

What are the different medications that can feminize one's appearance?

Treatment with hormones is called hormone replacement therapy or HRT. HRT will require taking estrogen, as well as medicines to block the body from producing or utilizing testosterone. Use of these medications, even when the criteria listed below are followed, does not have U.S. Food and Drug Administration (FDA) approval and its use to treat gender dysphoria is considered "off label" because they are not being used for their intended purpose

Different forms of estrogen are used to feminize a person's appearance. Estrogen can be given as an injection either weekly or every other week, as a pill that is taken daily or twice a day, or as a patch that is changed weekly or every three or four days.

Please initial below to acknowledge your understanding of the information on this page.

Patient

DH5082-MQA (Rev. 06/23)
Rules 64B8ER23-8 and 64B15ER23-10

Medications that block the production or effects of testosterone are called androgen blockers. Spironolactone is the androgen blocker that is most commonly used in the United States. In some cases, Bicalutamide, an antiandrogen, is used to block the effects of testosterone, though it will not reduce testosterone levels. Bicalutamide (brand name Casodex) is a cancer drug approved for the treatment of prostate cancer. Fulminant hepatotoxicity, a severe liver injury often resulting in death, has been noted with bicalutamide use.

Cyproterone acetate, a synthetic progestogen with strong antiandrogen activity, is commonly used in many countries. When paired with estrogen, cyproterone acetate is associated with elevated prolactin, decreased HDL cholesterol, and rare meningiomas (tumors). Cyproterone acetate has also been associated with uncommon episodes of fulminant hepatitis.

The administration of finasteride blocks the conversion of testosterone to the more potent androgen dihydrotestosterone. The FDA approved uses of finasteride include the treatment benign prostatic hypertrophy and androgenic alopecia. Finasteride is not recommended for routine use in treating populations with gender dysphoria.

Various forms of progestins may also be used. This class includes micronized bioidentical progesterone (Prometrium) as well as oral medroxyprogesterone acetate (Provera). Although there are anecdotal reports of progesterone use for breast development and mood management, there is currently insufficient evidence that the potential benefits of progesterone administration outweigh the potential risks. There is also a theoretical risk of breast cancer associated with long-term exogenous progesterone.

Every medication has risks, benefits, and side effects that are important to understand before taking. The effects and side effects of medicines used to treat gender dysphoria must be monitored with laboratory studies and regular visits to your prescribing physician to make sure that there are no negative medical or mental health effects.

HRT, the use of androgen blockers and antiandrogens, and the treatment process can affect your mood. Therefore, you must be under the care of a licensed mental health care professional while undergoing treatment.

Please initial below to acknowledge your understanding of the information on this page.

Patient

What are my other options if I do not wish to start or continue treatment with hormones, hormone antagonists, or antiandrogens?

One option available is psychological therapy with a mental health provider. This is recommended regardless of whether or not the person undergoes treatment with hormones, hormone antagonists, or antiandrogens due to the high risk of anxiety, depression, self-harm, and suicide. Other options may be discussed with your prescribing physician.

What are the requirements to receive hormone replacement therapy (HRT)?

To receive HRT, there are specific requirements that need to be met before and during treatment. These requirements will allow the prescribing physician to monitor your medical and mental health status during treatment. If these requirements are not met, HRT may be discontinued by the prescribing physician.

Before beginning HRT and every two years thereafter, you must undergo a thorough psychological and social evaluation performed by a Florida licensed board-certified psychiatrist or a Florida licensed psychologist. The psychiatrist or psychologist must submit a letter to the prescribing physician confirming this.

Please initial below to acknowledge your understanding of the information on this page.

Patient

The specific requirements for you to receive and continue HRT treatment include the following:

1. Has met the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders or International Classification of Diseases;
2. Mental health and physical conditions that could negatively impact the outcome of treatment have been assessed, with risks and benefits discussed;
3. Demonstrates capacity to consent for the specific gender dysphoria hormone treatment;
4. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
5. Has psychological and social support during treatment;
6. Demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of HRT as well as the medical and social risks and benefits of sex reassignment surgery; and
7. Understands the effect of hormone treatment on reproduction and they have explored reproductive options;

The following may also be recommended by your prescribing physician:

1. Undergoes an in-person evaluation by the prescribing physician or their designated covering physician every 3 months for the initial year and at least annually thereafter;
2. Undergoes a suicide risk assessment by a licensed mental health care professional at least every 3 months for the initial year and at least annually thereafter;
3. Undergoes relevant laboratory testing at least every 6 months;
4. Annual bone density scan (DEXA) once a year for the first 5 years to allow monitoring of your bone density (bone strength) during treatment, which can be altered by HRT;
5. Annual mental health assessments by a board-certified Florida licensed psychiatrist or psychologist; and
6. Continued counseling with a licensed mental health care professional during the treatment period, with the frequency recommended by the licensed mental health care professional.

Please initial below to acknowledge your understanding of the information on this page.

Patient

Please initial each statement on this form to show that you understand the benefits, risks, and changes associated with taking feminizing medications.

Effects of Feminizing Medications

Patient	Statement
	Feminizing medications, including estrogen, androgen blockers, or antiandrogens, given singularly or in combination, may be prescribed to make me appear less like a male and more like a female.
	It can take several months or longer for the effects of feminizing medications to become noticeable and no one can predict how fast or how much change will occur.
	This treatment will not change my biological sex or chromosomes.
	If I take estrogen, the following changes in my breasts will occur: • Breasts will develop but will not reach their full size for several years • Breasts will remain even if estrogen treatment is discontinued • A milky discharge from the nipples may appear, which should be reported to my prescribing physician • My risk of breast cancer may significantly increase
	If I take feminizing medications, my body will make less testosterone, which may affect my sex life in different ways, including: • My testicles may shrink • My penis may never fully develop, particularly if I previously took puberty blockers • I will have fewer spontaneous erections • My sperm may no longer mature causing infertility which may be permanent even if treatment is discontinued, the risk of which is increased if I took puberty blockers prior to starting feminizing medications • Conversely, it is possible that my sperm could still mature while taking feminizing medications and I may cause someone to get pregnant
	The options for sperm banking have been explained.
	If I take feminizing medications, some parts of my body will not change much, including: • If present, my facial hair may grow more slowly, but it will not go away completely even after taking feminizing medications for many years • If present, my body hair may grow more slowly, but it will not go away completely even after taking feminizing medications for many years • If I went through puberty and have a deep voice, the pitch of my voice will not rise and my speech patterns will not become more like a woman's • If present, my Adam's apple will not shrink

	Even if I stop taking feminizing medications, the following changes may occur: • My body fat may be redistributed with less fat on the abdomen and more on the buttocks, hips, and thighs creating a more female shape • I may have decreased muscle mass and strength in the upper body • My skin may become softer
	Mood changes may be caused by these medicines, and I will continue therapy with a licensed mental health care professional during treatment.
	Using these medicines to feminize my body is an off-label use of the medications. This means these medications are not approved by the FDA for this purpose. I know that the medicine and dose that is recommended is based solely on the judgment and experience of my prescribing physician and there is no data in the medical literature or controlled research studies that support the timing, dosing, and type of administration of feminizing medications.

Risks of Feminizing Medications

Patient	Statement
	The medical effects and the safety of taking femininizing medications are not completely known and there may be unknown long-term risks.
	Taking femininizing medications causes changes that other people will notice.
	Treatment with femininizing medications will not prevent serious psychiatric events, including suicide.
	I must not take more feminizing medication than prescribed. Taking too much medication: • Will increase health risks • Will not make changes happen more quickly or more significantly
	Taking feminizing medication can damage the liver and possibly lead to liver disease.

Risks of Estrogen

Patient	Statement
	Estrogen **SHOULD NOT** be used by anyone who has: • Any estrogen-dependent cancer • Any disorder that makes them more likely to get blood clots that could travel to the lungs unless they are also taking blood thinners and are being followed by a specialist
	Estrogen should be used **WITH CAUTION** and only after a full discussion of risks by anyone who: • Has a family history of breast cancer or other cancers that grow more quickly when estrogens are present • Has a family history of heart disease

	• Has diabetes • Has chronic hepatitis or other liver disease • Has high levels of cholesterol • Has migraines or seizures • Is obese • Smokes cigarettes or uses tobacco products
	Taking estrogen increases the risk of blood clots and problems with blood vessels that can result in: • Chronic problems with veins in the legs, which may require surgery • Heart attack which may cause permanent heart damage or death • Pulmonary embolism (blood clot in the lungs), which may cause permanent lung damage or death • Stroke, which may cause permanent brain damage or death
	The risk of blood clots while take estrogen is much greater if you smoke cigarettes. The danger is so high that you should stop smoking completely while taking estrogen.
	Taking estrogen can increase the deposits of fat around internal organs, which increases the risk for diabetes and heart disease, which in turn increases the risk of heart attack and stroke.
	Taking estrogen can raise blood pressure, which increases the risk of heart attack and stroke.
	Taking estrogen increases the risk of gallstones (stones in the gallbladder). Any long-term abdominal pain you experience while taking estrogen must be reported to your prescribing physician.
	Taking estrogen increases the risk of elevated prolactin levels and prolactinomas, which are non-cancerous tumors of the pituitary gland. While not typically life threatening, prolactinomas can damage your vision and cause headaches if not treated properly. Any changes in your vision, the occurrence of headaches that are worse when waking up in the morning, or any milky discharge from the nipples must be reported to your prescribing physician.
	Taking estrogen can cause nausea and vomiting. Any long-term nausea or vomiting must be reported to your prescribing physician.
	Taking estrogen can cause migraines or can make them worse if you already have them.
	Taking estrogen can cause hot flashes.
	Taking estrogen can cause you to feel tired and have difficulty focusing.

Risks of Androgen Blockers and Antiandrogens (Spironolactone and Bicalutamide)

Patient	Statement
	Taking Spironolactone affects the balance of water and salt in the kidneys, which may: • Increase the amount of urine produced by your kidneys, making it necessary to urinate more frequently • Increase your thirst • Increase your risk of dehydration, which can be evidenced by less frequent urination than usual, dark and strong-smelling urine, thirst, and light-headedness
	Taking Spironolactone affects the balance of potassium in the kidneys, which may result in you experiencing high potassium levels resulting in: • Changes in heart rhythms that may be life threatening • Low blood pressure, which can cause: o Fatigue o Lightheadedness o Tingling feelings o Muscle weakness o Shortness of breath • Your need for regular blood tests to monitor risks while on the medication
	Taking Bicalutamide may cause numerous side effects which should be reported to your prescribing physician, including: • Hot flashes or flushing • Bone, back, or pelvic pain • Muscle weakness • Muscle or joint pain • Headaches • Shortness of breath • Chest pain • Elevated blood pressure • Swelling of the hands, feet, ankles, or lower legs • Cough • Constipation • Nausea • Vomiting • Abdominal pain • Diarrhea • Gas • Changes in weight (loss or gain) • Loss of appetite

	• Dizziness • Pain, burning, or tingling in the hands or feet • Difficulty sleeping • Feeling of uneasiness or dread • Rash • Sweating • Need to urinate frequently during the night • Bloody urine • Painful or difficult urination • Frequent and urgent need to urinate • Difficulty emptying bladder • Painful or swollen breasts • Yellowing of the skin or eyes • Pain in the upper right part of the abdomen • Extreme tiredness • Unusual bleeding or bruising • Lack of energy • Upset stomach • Loss of appetite • Flu-like symptoms • Dull or sharp side pain

Requirements of Treatment with Feminizing Medications

Patient	Statement
	Compliance with the requirements explained above is a prerequisite for you to receive treatment with feminizing medications.
	The prescribing physician may stop prescribing feminizing medications if the prescribing physician or mental health care professionals providing treatment pursuant to this consent determine the benefit of treatment no longer outweighs the risks, there is insufficient social or psychological support, or the requirements in this consent are not met.
	I can change my mind and stop treatment at any time.

Prevention of Complications while under Treatment with Feminizing Medications

Patient	Statement
	I agree to notify the prescribing physician if I suffer from any side effects during treatment or are unhappy with the treatment in any way, particularly if I have any concerns about worsening signs of depression or anxiety or if I desire to harm myself or attempt suicide.

	I acknowledge that taking feminizing medications is only a part of my overall health, and that a range of preventative health activities are necessary so that remain healthy. These include, but are not limited to: • Monthly breast self-examination (report any new lumps to the prescribing physician) • Regular age-appropriate breast mammograms • Regular age-appropriate prostate examinations • Appropriate immunizations • Regular STI screening depending on my level of risk • HIV prevention depending on my level of risk • Regular physical activity, including resistance exercise for bone health • Healthy eating • Quitting smoking
	The prescribing physician is required to monitor me for any side effects during treatment and may refer me to another physician or specialist for treatment. I agree to go to any physicians and specialists recommended by the prescribing physician.

CONSENT:

The signature below confirms the following:

1. The prescribing physician has fully informed me about:
   a. the benefits and risks of taking feminizing medications;
   b. the possible or likely consequences of hormone therapy; and
   c. potential alternative treatments.

2. The information provided to me in this form and by the prescribing physician includes the known effects and risks of treatment with feminizing medications. I know that there may be other unknown short-term and long-term effects or risks which may be irreversible.

3. I have had sufficient time and opportunity to discuss relevant treatment options with the prescribing physician.

4. All my questions have been answered to my satisfaction by the prescribing physician.

5. I know enough to give informed consent for me to take, refuse, or postpone taking feminizing medications.

6. The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.52, F.S. This form contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your physician.

7. My signature below attests to my consent to begin treatment with feminizing medications.

_____
Patient's printed name (required)

_____ _____
Patient's signature (required) Date

PRESCRIBING PHYSICIAN SIGNATURE:

My signature below attests to my compliance with section 456.52, Florida Statutes.

_____
Prescribing physician's printed name (required)

_____ _____
Prescribing physician's signature (required) Date

WITNESS:

_____
Witness' printed name (required)

_____ _____
Witness' signature (required) Date

FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:

I certify that I am fluent in English and in the native language of the person indicating consent on the above form. I certify that I have accurately and completely interpreted the contents of this form, and that the patient has indicated understanding of the contents of this form.

_____
Interpreter's printed name

_____ _____
Interpreter's signature Date

DH5082-MQA (Rev. 06/23)
Rules 64B8ER23-8 and 64B15ER23-10

Masculinizing Medications for Patients with Gender Dysphoria

Patient Information and Informed Consent

Before starting or continuing treatment with hormones or hormone antagonists, you need to be aware of the effects and possible risks associated with the use of these medications.

The prescribing physician will make a medical decision, in consultation with you, about the medications that are best for you, keeping in mind your overall health during your gender transition process. The effects and possible risks associated with the use of these medications will be discussed with you. It your responsibility to read and understand the following information and raise any questions you have with your prescribing physician.

After your questions or concerns are addressed and you have decided to start or continue hormones or hormone antagonists, you will need to initial the statements below and sign this form.

Medical treatment of people with gender dysphoria is based on very limited, poor-quality research with only subtle improvements seen in some patient's psychological functioning in some, but not all, research studies. This practice is purely speculative, and the possible psychological benefits may not outweigh the substantial risks of medical treatments and, in many cases, the need for lifelong medical treatments.

What are the medications that can masculinize one's appearance?

Treatment with hormones is called hormone replacement therapy or HRT. HRT will require taking testosterone, which increases muscle mass and causes the development of facial hair and a deeper voice. Testosterone when used by biological women, even when the criteria listed below are followed, does not have the U.S. Food and Drug Administration (FDA) approval to be used in the treatment of gender dysphoria and is considered "off label" use because they are not being used for their intended purpose.

Please initial below to acknowledge your understanding of the information on this page.

Patient

DH5083-MQA (Rev. 06/23)
Rules 64B8ER23-8 and 64B15ER23-10

How is testosterone taken?

Testosterone is usually injected every one to four weeks. Typically, it is not used as a pill because the body may not absorb it properly and may cause potentially fatal liver problems. The doses used for injection differ from product to product and from patient to patient. The injections are given in the muscle (intramuscular) or can be given with a smaller needle under the skin (subcutaneous). Taking testosterone may cause unwanted swings in hormone levels based on the amount and how often doses are given. Skin creams and patches may also be used. Both testosterone and the treatment process can affect mood. Therefore, individuals must be under the care of a licensed mental health care professional while undergoing treatment.

Finasteride is a treatment option for individuals experiencing bothersome alopecia resulting from higher dihydrotestosterone levels. The administration of 5α-reductase inhibitors block the conversion of testosterone to the more potent androgen dihydrotestosterone. The FDA approved indications of finasteride administration include benign prostatic hypertrophy and androgenetic alopecia. The use of 5α-reductase inhibitors may impair clitoral growth and the development of facial and body hair. Future studies are needed to assess the efficacy and safety of 5α-reductase inhibitors in treatment for gender dysphoria.

Every medication has risks, benefits, and side effects that are important to understand before taking. The effects and side effects of medicines used to treat gender dysphoria must be monitored with laboratory studies and regular visits to the prescribing physician to make sure that there are no negative medical or mental health effects.

What are my other options if I do not wish to start or continue medical treatments?

One option available is psychological therapy with a mental health care provider. This is recommended regardless of whether the individual undergoes treatment with hormones or hormone antagonists or not, due to the high risk of anxiety, depression, self-harm, and suicide. Other options may be discussed with your prescribing physician.

Please initial below to acknowledge your understanding of the information on this page.

Patient

What are the requirements to receive hormone replacement therapy?

To receive hormone replacement therapy, there are specific requirements that need to be met before and during the treatment. These requirements will allow the prescribing physician to monitor medical as well as mental health wellbeing during HRT. If these requirements are not met, HRT may be discontinued by the prescribing physician.

Before beginning HRT and every two years thereafter, the individual needs to undergo a thorough psychological and social evaluation performed by a Florida licensed board-certified psychiatrist or a Florida licensed psychologist. The psychiatrist or psychologist must submit a letter to the prescribing physician confirming this.

The specific requirements for an individual to receive and continue HRT treatment include the following:

1. Has met the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders (DSM) or International Classification of Diseases (ICD);
2. Mental health and physical conditions that could negatively impact the outcome of treatment have been assessed, with risks and benefits discussed;
3. Demonstrates capacity to consent for the specific gender dysphoria hormone treatment;
4. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
5. Has psychological and social support during treatment;
6. Demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of HRT as well as the medical and social risks and benefits of sex reassignment surgery; and
7. Understands the effect of hormone treatment on reproduction and they have explored reproductive options.

Please initial below to acknowledge your understanding of the information on this page.

Patient

The following may also be recommended by your prescribing physician:

1. Undergoes an in-person evaluation by the prescribing physician or their designated covering physician every 3 months for the initial year and at least annually thereafter;
2. Undergoes a suicide risk assessment by a licensed mental health care professional at least every 3 months for the initial year and at least annually thereafter;
3. Undergoes relevant laboratory testing, at least every 6 months;
4. Annual bone scan (DEXA) once a year for the first 5 years to allow monitoring of bone density (bone strength) during treatment, which can be altered by HRT;
5. Annual mental health assessments by a board-certified Florida licensed psychiatrist or psychologist; and
6. Continued counseling with a licensed mental health care professional during the treatment period, with the frequency recommended by the licensed mental health care professional.

Summary of Testosterone Benefits and Risk

BENEFITS	RISKS
• Appear more like a man • Bigger clitoris • Coarser skin • Lower voice • More body hair • More facial hair • More muscle mass • More strength • No or minimal menstrual periods • More physical energy • More sex drive	• Acne (may permanently scar) • Blood clots (thrombophlebitis), risk significantly increased by smoking • Emotional changes, for example, more aggression • Headache • High blood pressure (hypertension) • Increased red-blood-cell count • Infertility • Inflamed liver • Interaction with drugs for diabetes and blood thinning — for example Coumadin and Warfarin • Male pattern baldness • More abdominal fat — redistributed to a male shape • Risk of heart disease • Swelling of hands, feet, and legs • Weight gain

Please initial below to acknowledge your understanding of the information on this page.

Patient

Please initial each statement on this form to show that you understand the benefits, risks, and changes that may occur from taking testosterone.

Masculinizing Effects

Patient	Statement
	Testosterone may be prescribed to make me appear less like a female and more like a male.
	It can take several months or longer for the effects of testosterone to become noticeable and no one can predict how fast or how much change will occur.
	The following changes are likely to be permanent even if testosterone is discontinued: • Bigger clitoris - typically about half an inch to a little more than an inch • Deeper voice • Gradual growth of moustache and beard • Hair loss at the temples and crown of the head and the possibility of being completely bald • More, thicker, and coarser hair on abdomen, arms, back, chest, and legs
	The following changes could be permanent, but may improve if I stop taking testosterone: • Acne (although there may be permanent scars) • Menstrual periods (if present), typically stop one to six months after starting • More abdominal fat – redistributed to a male shape: decreased on buttocks, hips, and thighs; increased in abdomen – changing from "pear shape" to "apple shape" • More muscle mass and strength • More sexual interest • Vaginal dryness • Vaginal Tearing • Vaginal Bleeding • Vaginal Pain • Vaginal infection • Painful intercourse
	This treatment will not change the individual' s biological sex or chromosomes.
	Testosterone may reduce the ability to become pregnant, but it will not eliminate the risk of pregnancy. A person may become pregnant while on testosterone. I agree to inform the prescribing physician if I become pregnant.
	Some aspects of my body will not change:

	• Fat loss may make breasts appear slightly smaller • The voice will deepen, but other aspects of the way I speak may not sound more masculine
	Mood changes may be caused by these medicines, and I will continue therapy with a licensed mental health care professional during treatment.
	Using these medicines to masculinize is an off-label use of the medications. This means these medications are not approved by the FDA for this purpose. I know that the medicine and dose that is recommended is based solely on the judgment and experience of the prescribing physician and there is no data in the medical literature or controlled research studies that support the timing, dosing, and type of administration of HRT.

Risks of Testosterone

Patient	Statement
	Testosterone **SHOULD NOT** be used by anyone who: • Is pregnant • Has uncontrolled coronary artery disease as it could increase your risk for a fatal heart attack
	It should be used **WITH CAUTION** and only after a full discussion of risks by anyone who: • Has acne • Has a family history of heart disease or breast cancer • Has had a blood clot • Has high levels of cholesterol • Has liver disease • Has a high red blood cell count • Is obese • Smokes cigarettes
	The medical effects and the safety of testosterone are not completely known and there may be unknown long-term risks.
	Taking testosterone causes changes that other people will notice.
	Treatment with testosterone will not prevent serious psychiatric events, including suicide.
	Taking more testosterone than prescribed: • Will increase health risks; • Will not make changes happen more quickly or more significantly; and • May cause the body to convert extra testosterone into estrogen that can slow down or stop me from appearing more masculine.
	Taking testosterone can cause changes that increase the risk of heart disease. These changes include:

	• Less good cholesterol (HDL) that may protect against heart disease and more bad cholesterol (LDL) that may increase the risk of heart disease; • Higher blood pressure; and • More deposits of fat around the internal organs
	Taking testosterone can damage the liver and possibly lead to liver disease.
	Taking testosterone can increase red blood cells and hemoglobin, which may increase my risk of life-threatening problems such as stroke or heart attack.
	Taking testosterone can increase the risk for diabetes (high blood sugars), which decrease the body's response to insulin, cause weight gain, and increase deposits of fat around internal organs increasing the risk of heart disease and stroke.
	Treatment with testosterone can cause ovaries to not release eggs and may cause infertility.
	Treatment with testosterone increases the risk of cancer to the uterus, ovaries, or breasts. It is unclear if taking testosterone plays any role in HPV infection or cervical cancer.
	Taking testosterone causes or worsens migraines.
	Taking testosterone can cause emotional changes, such as irritability, frustration, aggression, and anger.

Risks of Finasteride

Patient	Statement
	Finasteride may be an appropriate treatment option in individuals experiencing bothersome alopecia resulting from testosterone treatment.
	Finasteride may have side effects which include: • decreased libido • dry skin • acne • Breast swelling and tenderness • headache • irregular menstruation • dizziness • increased body hair
	Finasteride is not approved by the FDA for use in biological women and is forbidden in pregnant women due to birth defects.

Requirements of Treatment with HRT

Patient	Statement
	Compliance with the requirements explained above is a prerequisite to receive treatment with testosterone.
	The prescribing physician may stop prescribing testosterone if the prescribing physician or mental health care professionals providing treatment pursuant to this consent determine the benefit of treatment no longer outweighs the risks, there is insufficient social or psychological support, or the requirements in this consent are not met.
	I understand that I may decide to stop treatment at any time.

Prevention of Complications while under Treatment of HRT

Patient	Statement
	I agree to notify the prescribing physician if I suffer from any side effects during treatment or am unhappy with the treatment in any way, and if I have any concerns that I have worsening signs of depression or anxiety or wants to harm myself or attempt suicide or attempt suicide.
	The prescribing physician is required to monitor me for any side effects during treatment and may refer me to another physician or specialist for treatment.

CONSENT:

My signature below confirms that:

1. My prescribing physician has talked with me about:
   a. the benefits and risks of taking testosterone;
   b. the possible or likely consequences of hormone therapy; and
   c. potential alternative treatments.

2. The information provided to me in this form and by the prescribing physician includes the known effects and risks of treatment with testosterone. I know that there may be other unknown short-term and long-term effects or risks which may be irreversible.

3. I have had sufficient time and opportunity to discuss relevant treatment options with my prescribing physician.

4. All my questions have been answered to my satisfaction by my prescribing physician.

5. I know enough to give informed consent to take, refuse, or postpone taking testosterone.

6. The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.52, F.S. This form contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your physician.

7. My signature below attests to my consent to begin treatment with testosterone.

Based on all this information:

_____ I want to begin or continue taking testosterone
_____ I want to begin or continue taking finasteride
_____ I do not wish to begin or continue taking masculinizing medication

_____
Patient's printed name (required)

_____ _____
Patient's signature (required) Date

PRESCRIBING PHYSICIAN:

My signature below attests to my compliance with 456.52, Florida Statutes.

_____
Prescribing physician's printed name (required)

_____ _____
Prescribing physician's signature (required) Date

DH5083-MQA (Rev. 06/23)
Rules 64B8ER23-8 and 64B15ER23-10

WITNESS:

_____

Witness' printed name (required)

_____ _____

Witness' signature (required) Date

FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:

I certify that I am fluent in English and in the native language of the person indicating consent and/or assent on the above form. I certify that I have accurately and completely interpreted the contents of this form, and that the patient has indicated understanding of the contents of this form.

_____

Interpreter's printed name

_____ _____

Interpreter's signature Date

Surgical Treatment for Adults with Gender Dysphoria

Patient Information and Informed Consent

Before having surgery to treat gender dysphoria, you need to be aware of the effects and possible risks of these procedures. Your surgeon will make a medical decision, in consultation with you, about the procedures that are best for you, keeping in mind your overall health.

Your surgeon will discuss with you all the information relating to the surgery. You are asked to read and understand the following information and to discuss any questions you have with your surgeon. After your questions or concerns are addressed and you have decided to have surgery you must initial the statements below and sign this form in person with your surgeon.

Medical treatment of people with gender dysphoria is based on very limited, poor-quality research with only subtle improvements seen in some patient's psychological functioning in some, but not all, research studies. This practice is purely speculative, and the possible psychological benefits may not outweigh the substantial risks of medical treatments and, in many cases, the need for lifelong medical treatments.

What are the types of surgery to treat gender dysphoria?

Surgery to treat gender dysphoria may involve procedures on the face, chest, or genitalia. Common surgery options include:

- **Facial reconstructive surgery** to make facial features more masculine or feminine.
- **Chest or "Top" surgery** to remove breast tissue for a more masculine appearance or enhance breast size and shape for a more feminine appearance.
- **Genital or "Bottom" surgery** to transform and reconstruct the genitalia.
  - **Orchiectomy:** A bilateral orchiectomy is a procedure performed by a urologist that involves surgical removal of the testicles through a small scrotal incision. This procedure is done with a particular technique that allows for vaginoplasty later, if desired. Afterward, patients may adjust their dose of estrogens downward and no longer require spironolactone. Recovery takes approximately 2 weeks. Individuals seeking orchiectomy may wish to consider semen banking to preserve future fertility options.

Please initial below to acknowledge your understanding of the information on this page.

Patient

DH5084-MQA (Rev. 06/23)
Rules 64B8ER23-8 and 64B15ER23-10

- **Vaginoplasty:** In addition to an orchiectomy, a person may elect to undergo a vaginoplasty, which is a surgical procedure that involves reconstructing the genitals to create external female genitalia with or without a vaginal cavity. For those patients treated with puberty blockers as a minor, such treatment may lead to insufficient penile tissue that could necessitate the use other tissues, such as the colon, to create a vagina.
- **Phalloplasty:** This surgery involves a multi-staged procedure for the creation of a penis, urinary channel to allow urination, scrotum, and the obliteration of the vaginal cavity with closure. The removal of the female genital organs such as the uterus and ovaries and fallopian tubes are required and usually performed separately and prior to the phalloplasty surgery. The creation of the penis is performed with use of tissue from other parts of the body, which could include, more commonly the radial forearm free flap, or anterolateral thigh flap, and latissimus dorsi (MLD) flap. Prosthetics such as silicone or saline testicles can be placed as well as inflatable penile prosthetics in the final stage.
- **Metoidioplasty:** In this procedure, the surrounding tissue of the clitoris is released to achieve maximal length and a more natural-looking male position. A urethra is also reconstructed using either local skin tissue or a graft from the mouth depending on the amount of tissue present. Construction of a scrotum with testicular prosthetics can also be performed at the same time.
- **Hysterectomy:** Removal of the uterus and cervix via laparoscopic or vaginal techniques.
- **Salpingo-oophorectomy:** Removal of the fallopian tubes and ovaries.
- **Vaginectomy:** Obliteration of the vaginal canal and opening.

Is surgery the only treatment for gender dysphoria?

Surgery is just one option. Not everyone who has gender dysphoria chooses to have surgery. Depending on your age and preferences, you may choose:

- Treatment by a licensed mental health care professional that has experience in treating people with gender dysphoria, which is recommend regardless of whether you undergo surgery due to the high risk of anxiety, depression, self-harm, and suicide.
- Hormone replacement therapy to increase masculine or feminine characteristics.

Other options may be discussed with your prescribing physician.

Please initial below to acknowledge your understanding of the information on this page.

Patient

What are some potential complications of surgery to treat gender dysphoria?

Potential complications include:

- Changes in sexual sensation
- Diminishment of bladder function
- Problems with urination
- Bleeding
- Infection
- Nerve damage
- Poor healing
- Scarring that can cause pain, firmness, asymmetry
- Side effects of anesthesia, including death

What happens after surgery to treat gender dysphoria?

Recovery times vary based on what procedures or combination of procedures you have as follows:

- **Cheek and nose surgery:** Swelling lasts for around two to four weeks.
- **Chin and jaw surgery:** Most swelling fades within two weeks but may take up to four months for swelling to completely disappear.
- **Chest surgery:** Swelling and soreness lasts for one to two weeks with physical limitations lasting at least one month.
- **Bottom surgery:** Most people do not resume usual activities until at least six weeks after surgery and weekly follow-up visits with your surgeon for several months will be necessary.

When should I see my surgeon?

After surgery, you should see your surgeon if you experience:

- Bleeding for more than a few days.
- Pain that does not go away after several weeks.
- Signs of infection, such as a wound that changes color or does not heal.

Please initial below to acknowledge your understanding of the information on this page.

Patient

DH5084-MQA (Rev. 06/23)
Rules 64B8ER23-8 and 64B15ER23-10

Please initial each statement on this form to show that you understand the risks and changes associated with gender dysphoria surgeries.

Patient	Statement
	I understand that my surgeon will discuss with me during the preoperative process the available surgical procedures to treat gender dysphoria, the aftercare needs following surgery, and the importance of postoperative follow-up.
	I understand that these surgeries are permanent.
	I understand that if I have my breasts removed, I must undergo reconstructive surgery if I wish to have breasts in the future. If implants are used, complications may include pain, numbness, infection, bleeding, asymmetry, hardening, rippling, scarring, and the possible need for multiple surgeries.
	I understand that if I have my breasts removed that breast feeding will never be possible.
	I understand that if I have breast augmentation surgery, complications may include pain, numbness, infection, bleeding, asymmetry, hardening, rippling, scarring, and the possible need for multiple surgeries.
	I understand that my surgeon will assess me for risk factors associated with breast cancer prior to breast augmentation or mastectomy, including genetic mutations (e.g.., BRCA1, BRCA2), family history, age, radiation, exposure to estrogen, and the amount of breast tissue anticipated to remain after surgery.
	I understand that if I undergo metoidioplasty/phalloplasty I will need lifelong urological treatment.
	I understand that complications following metoidioplasty/phalloplasty include: • urinary tract strictures and fistulas • mucoceles due to vaginal remnant • hair growth within the neourethra • compromised sexual function including absent tactile and/or erogenous sensation, difficulties achieving orgasm • complications with penile prosthetics
	I understand that if I undergo vaginoplasty I will need lifelong treatment with my surgeon, primary care physician, and/or gynecologist.

	I understand that if I undergo vaginoplasty, complications can include: • the formation of granulation tissue • intravaginal hair growth • delayed wound healing and/or wound disruption • introital stenosis (closing, narrowing, or closure) • painful sex
	I understand that my surgeon may stop further treatment because the risks of treatment outweigh the benefits of treatment.
	I understand that this treatment will not prevent serious psychiatric events, including suicide.
	I agree to tell my surgeon if I have any problems or side effects or am unhappy with the surgery, including if I have worsening signs of depression or anxiety or want to harm myself or attempt suicide.
	I understand that my surgeon may be required to refer me to one or more specialists for surgery-related complications, and I agree to go to those specialists as recommended.
	I acknowledge that surgery to treat gender dysphoria is only part of my overall health and that a range of preventative health activities are recommended including: • cervical/prostrate screening tests at appropriate intervals as recommended by my doctor • regularly checking my breasts for lumps, even if I have had a mastectomy • regular mammograms from an appropriate age in consultation with my doctor • quitting smoking • immunizations • regular STI screening, depending on my level of risk • HIV prevention, depending on my level of risk • regular physical activity, including resistance exercise for bone health • healthy eating

CONSENT:

My signature below confirms that:

1. My surgeon has talked with me about:
   a. the benefits and risks of surgery to treat gender dysphoria;
   b. the possible or likely consequences of surgery to treat gender dysphoria;
   c. potential alternative treatments.

2. The information provided to me in this form and by the surgeon includes the known effects and risks of surgery to treat gender dysphoria. I know that there may be other unknown short-term and long-term effects or risks which may be irreversible.

3. I have had sufficient time and opportunity to discuss relevant treatment options with my surgeon.

4. All my questions have been answered to my satisfaction by my surgeon.

5. I know enough to give informed consent to have, refuse, or postpone surgery to treat gender dysphoria.

6. The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.52, F.S. This form contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your surgeon.

7. My signature below attests to my consent to surgery to treat gender dysphoria.

My signature below confirms the following:

_____ _____

Patient's signature (required) Date

_____ _____

Patient's signature (required) Date

SURGEON:

My signature below attests to my compliance with 456.52, Florida Statutes.

_____

Surgeon's printed name (required)

_____ _____

Surgeon's signature (required) Date

WITNESS:

_____

Witness' printed name (required)

_____ _____

Witness' signature (required) Date

FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:

I certify that I am fluent in English and in the native language of the person indicating consent on the above form. I certify that I have accurately and completely interpreted the contents of this form, and that the patient has indicated understanding of the contents of this form.

_____

Interpreter's printed name

_____ _____

Interpreter's signature Date

FLORIDA DEPARTMENT of STATE

RON DESANTIS
Governor

CORD BYRD
Secretary of State

July 6, 2023

Angela Southwell
Paralegal Specialist
Office of the Attorney General
PL 01, The Capitol
Tallahassee, FL 32399

Dear Angela Southwell:

Your adoption package for Emergency Rule 64B15ER23-9 was received, electronically, by the Florida Department of State, Administrative Code and Register at 5:38 p.m. on July 5, 2023. 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 July 5, 2023.

Sincerely,

Anya C. Owens
Administrative Code and Register Director

R. A. Gray Building • 500 South Bronough Street • Tallahassee, Florida 32399-0250
Telephone: (850) 245-6270

Owens, Anya C.

From: Angela Southwell <Angela.Southwell@myfloridalegal.com>
Sent: Wednesday, July 5, 2023 5:38 PM
To: RuleAdoptions
Cc: Owens, Anya C.; Donna McNulty; Christopher Dierlam; Cassandra Fullove
Subject: Adoption Packet for Emergency Rule 64B15ER23-9
Attachments: Adoption pkt 64B15ER23-9.pdf; THE FULL TEXT OF THE EMERGENCY RULE IS.docx

Good Afternoon:

Attached please find the adoption packet and text.

Angela M. Southwell
Paralegal Specialist
Office of the Attorney General
Administrative Law
PL-01 The Capitol
Bin #4100
Tallahassee, Florida 32399-1050
Telephone: (850) 414-3772
angela.southwell@myfloridalegal.com

ASHLEY MOODY
ATTORNEY GENERAL
STATE OF FLORIDA

OFFICE OF THE ATTORNEY GENERAL
Administrative Law

Angela Southwell
Paralegal Specialist
PL-01 The Capitol
Tallahassee, FL 32399-1050
Phone (850) 414-3772
Fax (850) 922-6425
angela.southwell@myfloridalegal.com

MEMORANDUM

TO: Anya Owens, Program Administrator
Administrative Code and Register

FROM: Angela Southwell, Paralegal Specialist

RE: Department of Health
Board of Osteopathic Medicine
Emergency Rule 64B15ER23-9

DATE: July 5, 2023

Attached are the following documents regarding the above-referenced emergency rule adoption packet for the above-referenced emergency rule:

- Notice of Emergency Rule
- Adoption text for Emergency Rule 64B15ER23-9 (double spaced)
- Certification of Board of Osteopathic Medicine Emergency Rule Filed With the Department of State
- Designation of Rule the Violation of Which is a Minor Violation Certification
- Certification of Materials Incorporated by Reference in Rules Filed with the Department of State
- Form DH5079-MQA, (06/23), entitled "Puberty Suppression Treatment for Patients with Gender Dysphoria, Patient Information and Informed Parental Consent and Assent for Minors"
- Form DH5080-MQA, (06/23), entitled "Feminizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Parental Consent and Assent for Minors"
- Form DH5081-MQA, (06/23), entitled "Masculinizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Parental Consent and Assent for Minors"

Should you have any questions regarding the rule, please contact me at angela.southwell@myfloridalegal.com or by telephone at 850-414-3772.

Thank you for your attention to this matter.

Attachments

CERTIFICATION OF BOARD OF OSTEOPATHIC MEDICINE

EMERGENCY RULE FILED WITH THE

DEPARTMENT OF STATE

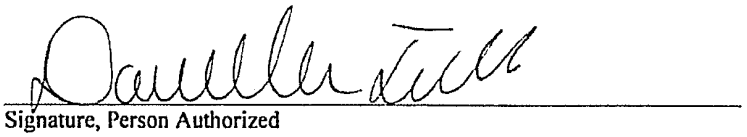
I hereby certify that pursuant to Ch 2023-90 Laws of Florida, Section 5, section 456.52, Florida Statutes was created and pursuant to subparagraphs 456.52(1)(a) and (6)(a), F.S., the Board of Osteopathic Medicine is required to adopt emergency rules to implement the section. I further certify that the 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), F.S. 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.

64B15ER23-9

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 Tiffany Sizemore Di Pietro , DO, FACC, FACOI, 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), F.S., 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).:

64B15ER23-9

Signature of Agency Head

Danielle Terrell, Executive Director for Tiffany Sizemore Di Pietro, DO, FACC, FACOI, 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 Osteopathic Medicine

RULE NO.: RULE TITLE:

64B15ER23-9 Sex-reassignment Standards of Practice in Minors.

SPECIFIC REASONS FOR FINDING AN IMMEDIATE DANGER TO THE PUBLIC HEALTH, SAFETY OR WELFARE: On May 17, 2023, Florida Governor, Ronald DeSantis, signed CSSB 254 into law creating Ch. 2023-90, Laws of Florida and section 456.52, Florida Statutes. Pursuant to section 456.52(1), F.S., sex-reassignment prescriptions are prohibited for patients younger than 18 years of age upon the effective date of the act; however, pursuant to section 456.52(1)(a), F.S., the Board of Osteopathic Medicine shall within 60 days after the effective date of the act, adopt emergency rules pertaining to standards of practice by which minors may continue to be treated if such treatment was commenced before, and is still active on, the effective date of the act. Section 456.52(1)(b), F.S., also provides a minor patient meeting the criteria outlined in section 456.52(1)(a), F.S., may continue to be treated by a physician with such prescriptions according to rules adopted pursuant to paragraph (1)(a).

Further, pursuant to section 456.52(2), F.S., if sex reassignment prescriptions or procedures are prescribed for or administered to patients 18 years of age or older, consent must be voluntary, informed, and in writing on forms adopted in rule by the Board of Osteopathic Medicine. Pursuant to section 456.52(4), F.S., the consent required for sex-reassignment prescriptions does not apply to renewals of sex-reassignment prescriptions if a physician and his or her patient have met the requirements for consent for the initial prescription. Section 456.52(6)(a), F.S., states "[t]he Board of Medicine and the Board of Osteopathic Medicine shall adopt emergency rules to implement this section."

Accordingly, the Board of Osteopathic Medicine, by emergency rule, hereby adopts the incorporated standards of practice and mandated consent forms for the treatment of gender dysphoria with puberty blockers and hormone replacement therapy in minors.

*** This emergency rule does not apply to Susan Doe, Gavin Goe, or Lisa Loe, or their parents or healthcare providers (see Jane Doe et al., v. Joseph A. Ladapo, et al, Preliminary Injunction, Filed June 6, 2023, Case No. 4:23cv114-RH-MAF, United States District Court for the Northern District of Florida). ***

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. CSSB 254 was signed into law on May 17, 2023. The Board of Osteopathic Medicine was contacted by multiple licensed physicians

and physician groups seeking clarification regarding the exception contained in section 465.52(4), F.S., and a timeframe for the required emergency rules shortly thereafter. In response, the Board of Medicine and the Board of Osteopathic Medicine held a Joint Rules/Legislative Committee (Joint Committee) meeting on June 1, 2023, to discuss the emergency rule. On May 19, 2023, the Board of Osteopathic Medicine published notice of the Joint Committee's June meeting both on its website and in the Florida Administrative Register. On June 2, 2023, the Board of Osteopathic Medicine discussed the report of the Joint Committee and voted upon emergency rule language that would allow for the renewal of previous prescriptions while the Board worked on consent forms. The Board of Osteopathic Medicine published notice of its June 2, 2023, meeting in the Florida Administrative Register on May 5, 2023, and on its website on May 12, 2023.

The Joint Committee held another meeting on June 23, 2023, to discuss an emergency rule adopting draft consent forms that were under consideration. On June 6, 2023, the Board of Osteopathic Medicine published notice of the Joint Committee's June 23, 2023, meeting to its website and in the Florida Administrative Register. On June 30, 2023, the Boards of Medicine and Osteopathic Medicine held a Joint Board meeting (Joint Board Meeting) to discuss the draft consent forms that were approved by the Joint Committee on June 23, 2023. Prior to conclusion of the Joint Board Meeting, the Boards each separately voted to approve the draft consent forms via emergency rule. The Joint Board Meeting was held via Microsoft Teams and notice of the same was published to the Board of Osteopathic Medicine's website and in the Florida Administrative Register on June 22, 2023.

Each Joint Committee meeting was held in person in a public forum and was able to be attended by any interested persons. The Joint Board Meeting was held via Microsoft Teams and also was able to be attended by any interested persons. Public comment was accepted at all of the aforementioned meetings. Further, the Boards accepted written public comment on the proposed rules up and until 24 hours prior to the Joint Board Meeting. Accordingly, all notice requirements contained in Rule 28-102.001, F.A.C., were properly complied with and interested persons were given ample opportunity to participate in this rulemaking process.

SUMMARY: The proposed emergency rule formally adopts the required consent forms that must be executed for a minor patient who was already receiving sex-reassignment prescriptions to continue to receive said prescriptions per section 456.52(1), Florida Statutes.

THE PERSON TO BE CONTACTED REGARDING THE EMERGENCY RULE IS: Danielle Terrell, Executive Director, Board of Osteopathic Medicine/MQA, 4052 Bald Cypress Way, Bin #C06, Tallahassee, Florida 32399-

3256, or by email at Danielle.Terrell@flhealth.gov.

THE FULL TEXT OF THE EMERGENCY RULE IS:

64B15ER23-9 Sex-reassignment Standards of Practice in Minors.

The standards of practice in this rule do not supersede the level of care, skill, and treatment recognized in general law related to healthcare licensure.

(1) Pursuant to Section 456.52, Florida Statutes, sex-reassignment prescriptions and procedures are prohibited for patients younger than 18 years of age, except that a physician may continue to treat such patient with a prescription if such treatment for sex-reassignment was commenced before, and is still active on, May 17, 2023. The physician is required to obtain voluntary, informed consent while physically present in the same room as the patient. Consent is not required for renewal of such prescriptions if a physician and his or her patient have met the requirements for consent for the initial prescription or renewal; however, a separate consent is required for any new prescription for a pharmaceutical product not previously prescribed to the patient.

(2) Informed Consent. The Board has approved the following mandatory informed consent forms for the continued treatment of minors with sex-reassignment prescriptions:

(a) For patients prescribed puberty blocking medications, form DH5079-MQA, (06/23), entitled "Puberty Suppression Treatment for Patients with Gender Dysphoria, Patient Information and Informed Parental Consent and Assent for Minors," which is hereby incorporated by reference and available from the Board's website at https://flboardofmedicine.gov/forms/Puberty-Suppression-Treatment-for-Patients-with-Gender-Dysphoria-Patient-Information-and-Parental-Consent-and-Assent-for-Minors.pdf.

(b) For patients prescribed sex-reassignment feminizing medications, form DH5080-MQA, (06/23), entitled "Feminizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Parental Consent and Assent for Minors," which is hereby incorporated by reference and available from the Board's website at https://flboardofmedicine.gov/forms/Feminizing-Medications-for-Patients-with-Gender-Dysphoria-Patient-Information-and-Parental-Consent-and-Assent-for-Minors.pdf.

(c) For patients prescribed sex-reassignment masculinizing medications, form DH5081-MQA, (06/23), entitled "Masculinizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Parental Consent and Assent for Minors," which is hereby incorporated by reference and available from the Board's website

at https://flboardofmedicine.gov/forms/Masculinizing-Medications-for-Patients-with-Gender-Dysphoria-Patient-Information-and-Parental-Consent-and-Assent-for-Minors.pdf.

(3) A Board-approved informed consent form is not executed until:

(a) The physician issuing the prescription, while physically present in the same room as the patient, has informed the patient and the patient's parent or legal guardian of the nature and risks of the prescription, and has provided and received the written acknowledgement of the patient and the patient's legal guardian before the prescription is prescribed or administered. The physician is prohibited from delegating this responsibility to another person. The physician is also required to sign the informed consent form.

(b) The patient's parent or legal guardian is required to sign the informed consent form.

(c) The patient is required to assent to the informed consent form.

(d) A competent witness is also required to sign the informed consent form.

(4) Standards of Practice. The nature and extent of the requirements set forth below will vary depending on the practice setting and circumstances presented to the prescribing physician. A prescribing physician who continues to treat a minor patient with sex-reassignment prescriptions pursuant to section 456.52(1)(a), Florida Statutes, shall comply with the following:

(a) Patient Evaluation. An in-person thorough medical history and physical examination of the patient conducted by the physician must be documented in the patient's medical record prior to prescribing any new sex-reassignment prescription.

(b) Clinical Determinations. Based on the patient evaluation, the following must be confirmed:

1. The patient has met the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders (DSM) or International Classification of Diseases (ICD);

2. The patient has pubertal changes resulting in an increase in gender dysphoria;

3. The patient does not suffer from a psychiatric comorbidity that interferes with the diagnostic work-up or treatment;

4. The patient will have psychological and social support during treatment;

5. The patient has experienced puberty to at least Tanner Stage 2; and

6. The patient demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of puberty suppression, future cross-sex hormone treatment, as well as the medical and social risks and benefits of sex reassignment surgery based on the patient's current treatment status.

(c) Patient Visit. The physician or their designated covering physician must meet with the patient in-person every six (6) months for the purpose of monitoring the patient and must document each visit in the patient's medical records.

(d) Suicide Risk Assessment. A suicide risk assessment by a licensed mental health care professional must be performed every three (3) months.

(e) Laboratory Testing. Relevant laboratory testing must be performed every four (4) months.

(f) X-rays. X-rays of the hand must be performed each year to monitor and document the patient's bone age progression.

(g) Bone Density Scan. An annual bone density (DEXA) scan must be performed to monitor the patient's bone density during treatment.

(h) Mental Health Assessment. The physician must have the patient undergo an annual mental health assessment to be performed by a board-certified Florida licensed psychiatrist or psychologist.

(i) Counseling. The physician must refer the patient for counseling with a licensed mental health care professional during the treatment period, with a frequency as recommended by the licensed mental health care professional.

(j) Additional Consultations. The physician must refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives.

Rulemaking Authority 456.52 FS. Law Implemented 456.52 FS. History – New ____.

CERTIFICATION OF MATERIALS INCORPORATED

BY REFERENCE IN EMERGENCY RULES FILED WITH THE DEPARTMENT OF STATE

I hereby certify pursuant to Rule 1-1.013, Florida Administrative Code, that materials incorporated by reference in Emergency Rule 64B15ER23-9 have been:

[x] (1) Filed with the Department of State and included as part of the Emergency Rule adoption packet.

[ ] (2) That because there would be a violation of federal copyright laws if the submitting agency filed the incorporated materials as described in option (1) above, a true and complete copy of the incorporated materials has been provided to the Department of State as outlined in paragraph 1-1.013(5)(c), F.A.C.

Copies of the incorporated materials below may be obtained at the agency by [include address(es)/location(s)].

List form number(s) and form title(s), or title of document(s) below:

DH5079-MWA Puberty Suppession Treatment for Patients with Gender Dysphoria-Patient Information and Parental Consent and Assent for Minors

DH5080-MQA Feminizing Medications for Patients with Gender Dysphoria-Patient Information and Partental Cosnent and Assent for Minors

DH5081-MQA Masculinizing Medications for Patients with Gender Dysphoria-Patient Information and Parental Consent and Assent for Minors

Under the provisions of Section 120.54(4)(d), F.S., the attached material(s) take effect upon filing with the Department of State, or a date less than 20 days thereafter if specified in the rule if the adopting agency finds that such effective date is necessary because of immediate danger to the public health, safety, or welfare.

Signature, Person Authorized
To Certify Rules

Danielle Terrell, Executive Director for Tiffany Sizemore Di Pietro, DO, FACC, FACOI, Chair
Title

Puberty Suppression Treatment for Patients with Gender Dysphoria

Patient Information and Informed Parental Consent and Assent for Minors

Before a minor continues treatment to suppress puberty with puberty blockers, you and the minor need to be aware of the effects and possible risks associated with the use of these medications. After your questions or concerns are addressed and you have decided to have the minor continue treatment with puberty blockers, a parent/legal guardian and the minor must initial the statements below and sign this form. Both the parent/legal guardian and the minor must sign in person.

Medical treatment of people with gender dysphoria is based on very limited, poor-quality research with only subtle improvements seen in some patient's psychological functioning in some, but not all, research studies. This practice is purely speculative, and the possible psychological benefits may not outweigh the substantial risks of medical treatments and, in many cases, the need for lifelong medical treatments.

What are other options if I do not wish to have the minor continue treatment with puberty blockers?

One option available is psychological therapy with a mental health provider. This is recommended regardless of whether the minor undergoes suppression of puberty or not, due to the high risk of anxiety, depression, self-harm, and suicide. Other options may be discussed with your prescribing physician.

What are different medications that are used to suppress puberty?

The main mechanism by which physical changes of puberty can be put on hold is by using medication to block the signal from the brain to the organs that make hormones. These hormones are estrogen and testosterone. Estrogen is made by the ovaries. Testosterone is made by the testicles.

Please initial below to acknowledge your understanding of the information on this page.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

DH5079-MQA (Rev. 06/23)
Rules 64B8ER23-7 and 64B15ER23-9

Pediatric endocrinologists (children's doctors who specialize in hormones and puberty) use these medications frequently to suppress puberty in children with precocious (early) puberty, which is the U.S. Food and Drug Administration (FDA) approved use. None of the medications have been approved by the FDA to be used in minors with gender dysphoria. In other words, using these medications for gender dysphoria is considered "off label" use because they are not being used for their intended purpose.

Lupron and Histrelin are called GnRH analogs and are the most effective forms of treatment for puberty suppression. When used for precocious puberty, Lupron is given as a monthly or every 3-month intramuscular injection. When used for precocious puberty, Histrelin (brand name Supprelin) is an implant that is surgically placed under the skin and needs to be replaced every 1 to 2 years.

Provera is a pill that needs to be taken twice a day and is approved to be used in female adolescents with abnormal uterine bleeding. Provera is less effective than Lupron and Histrelin. Depo-Provera injections are approved for the use in females with abnormal bleeding and as birth control.

Please initial below to acknowledge your understanding of the information on this page.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

What are the requirements to receive puberty suppression for gender dysphoria?

To receive treatment with puberty blockers, there are specific requirements that must be met before and during treatment. These requirements will allow the prescribing physician to monitor the minor's medical and mental health status during treatment. If these requirements are not met, treatment with puberty blockers may be discontinued by the prescribing physician.

The specific requirements for a minor to receive and continue treatment include the following:

1. Has met the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders or International Classification of Diseases;
2. Has pubertal changes resulting in an increase in gender dysphoria;
3. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
4. Has psychological and social support during treatment;
5. Has experienced puberty to at least Tanner Stage 2 (this is the first stage of puberty and refers to breast or testicle growth), which must be confirmed by a physician;
6. Demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of puberty suppression, future cross-sex hormone treatment, as well as the medical and social risks and benefits of sex reassignment surgery.
7. Undergoes an in-person evaluation by the prescribing physician or their designated covering physician at least every 6 months;
8. Undergoes a suicide risk assessment by a licensed mental health care professional at least every 3 months;
9. Undergoes relevant laboratory testing at least every 4 months;
10. X-ray of the hand (bone age) no less than once a year;
11. Annual bone density scan (DEXA) which will allow monitoring of the minor's bone density (bone strength) during treatment, as puberty blockers may decrease bone density if given for long periods of time;
12. Annual mental health assessment by a Board-certified Florida-licensed psychiatrist or psychologist; and
13. Continued counseling with a licensed mental health care professional during the treatment period, with the frequency recommended by the licensed mental health care professional.

Please initial below to acknowledge your understanding of the information on this page.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

Please initial each statement on this form to show that you understand the benefits, risks, and changes associated with providing puberty suppression treatment to the minor.

Effects of Treatment of Suppression of Puberty

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Puberty blockers are used to temporarily suspend or block the physical changes of puberty for minors
			If a minor stops treatment with puberty blockers, in a few months their body may restart the changes of puberty at the developmental stage they were before starting medication. However, the effects of these medications could be permanent.
			It can take several months for the medications to be effective. It cannot be predicted how quickly or slowly or even if a minor's body will respond to the medication.
			Taking these medications, will cause a minor's body to stop producing testosterone or estrogen.
			These medications will not change a minor's sex (chromosomes), and it will not change a minor's internal or external reproductive structures.
			Puberty blockers can interfere with fertility.
			Puberty blockers do not affect the minor's ability to contract a sexually transmitted infection.
			The use of puberty blockers in minors for the treatment of gender dysphoria is an off-label use. This means these medications are not approved by the FDA to treat this specific diagnosis.

Risks of Treatment of Suppression of Puberty

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			The adverse effects and safety of puberty blockers used for the treatment of gender dysphoria in minors is not well known.
			Treatment with puberty blockers will not prevent serious psychiatric events such as a suicide.
			Treatment with puberty blockers may cause new or worsened psychiatric problems, including: • Crying • Irritability • Restlessness (impatience)

			• Anger • Acting aggressive
			It is the responsibility of the parent/guardian to notify the prescribing physician if the minor has any new or worsening physical or psychiatric problems while taking this medication.
			During the first 4 weeks of treatment, puberty blockers can cause an increase in some hormones. During this time, a minor may notice more signs of puberty, including vaginal bleeding.
			Seizures are a risk associated with taking puberty blockers. The risk of seizures may be higher in people who: • Have a history of seizures • Have a history of epilepsy • Have a history of brain or brain vessel (cerebrovascular) problems or tumors • Are taking a medicine that has been connected to seizures, such as bupropion or selective serotonin reuptake inhibitors (SSRIs).
			It is the responsibility of the parent/guardian to immediately notify the appropriate health care providers including the minor's prescribing physician if the minor has a seizure while taking puberty blockers.
			Increased pressure in the fluid around the brain is a risk associated with taking puberty blockers. It is the responsibility of the parent/guardian to notify the minor's prescribing physician if the minor has any of the following symptoms while taking puberty blockers: • Headache • Eye problems including blurred vision, double vision, and decreased eyesight • Eye pain • Ringing in the ears • Dizziness • Nausea
			Puberty blockers should not be used if a minor is: • Allergic to GnRH, GnRH agonist medicines, or Progesterones. • Pregnant or becomes pregnant because puberty blockers can cause birth defects or loss of the baby. It is the responsibility of the parent/guardian to notify the prescribing physician if a minor becomes pregnant while taking puberty blockers.
			The most common side effects of puberty blockers include: • Injection site reactions such as pain, swelling, and abscess which may result in surgery

			• Weight gain • Pain throughout body • Headache • Acne or red, itchy rash and white scales (seborrhea) • Serious skin rash (erythema multiforme) • Mood changes • Swelling of vagina (vaginitis), vaginal bleeding, and vaginal discharge • Upper stomach pain • Diarrhea • Bleeding • Nausea and vomiting • Fever • Itching • Pain in extremities • Rash • Back pain • Ligament sprain • Fracture • Breast tenderness • Difficulty sleeping • Chest pain • Excessive sweating
			Puberty blockers may decrease bone density.
			Minors may grow less than their peers while taking puberty blockers.
			Puberty blockers may cause stalling of typical cognitive or brain development in minors.

Requirements of Treatment of Suppression of Puberty

I understand the following:

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Compliance with the requirements explained above is a prerequisite to receive treatment for puberty suppression.
			The prescribing physician may stop prescribing puberty blockers if the prescribing physician or mental health care professionals providing treatment pursuant to this consent determine the benefit of treatment no longer outweighs the risks, there is insufficient social or psychological support, or the requirements in this consent are not met.

			The parent/guardian or the minor can change their mind and stop treatment at any time.

PARENTAL CONSENT:

The signature(s) below confirm(s) the following:

1. The minor's prescribing physician has fully informed me about:
   a. the benefits and risks of treatment with puberty blockers;
   b. the possible or likely consequences of treatment with puberty blockers and puberty suppression; and
   c. potential alternative treatments.

2. The information provided to me in this form and by the prescribing physician includes the known effects and risks of treatment with puberty blockers. I know that there may be other unknown short-term and long-term effects or risks which may be irreversible.

3. I have had sufficient time and opportunity to discuss relevant treatment options with my minor's prescribing physician.

4. All my questions have been answered to my satisfaction by the minor's prescribing physician.

5. I know enough to give informed consent for my minor to take, refuse, or postpone using puberty blocking medications.

6. The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.52, F.S. This form contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your physician.

7. My signature below attests to my consent for my minor to begin treatment for suppression of puberty.

_____
Parent/legal guardian's name (required)

_____ _____
Parent/legal guardian's signature (required) Date

Parent/legal guardian's name (optional)

Parent/legal guardian's signature (optional) Date

PRESCRIBING PHYSICIAN SIGNATURE:

My signature below attests to my compliance with section 456.52, Florida Statutes.

Prescribing physician's name (required)

Prescribing physician's signature (required) Date

ASSENT OF MINOR:

I have discussed the benefits and risks of treatment to suppress puberty with my prescribing physician and my parent(s) or legal guardian(s), and I wish to receive it.

Minor's name (required)

Minor's signature (required) Date

WITNESS:

_____
Witness printed name

_____ _____
Witness signature Date

FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:

I certify that I am fluent in English and in the native language of the person indicating consent and/or assent on the above form. I certify that I have accurately and completely interpreted the contents of this form, and that the patient and/or adult(s) legally responsible for the minor child has indicated understanding of the contents of this form.

_____
Interpreter's printed name

_____ _____
Interpreter's signature Date

Feminizing Medications for Patients with Gender Dysphoria

Patient Information and Informed Parental Consent and Assent for Minors

Before a minor starts or continues treatment with hormones or hormone antagonists, you and the minor need to be aware of the effects and possible risks associated with use of these medications.

After your questions or concerns are addressed and you have decided to have the minor start or continue treatment with hormones or hormone antagonists, a parent/legal guardian and the minor must initial the statements below and sign this form. Both the parent/legal guardian and the minor must sign in person.

Medical treatment of people with gender dysphoria is based on very limited, poor-quality research with only subtle improvements seen in some patient's psychological functioning in some, but not all, research studies. This practice is purely speculative, and the possible psychological benefits may not outweigh the substantial risks of medical treatments and, in many cases, the need for lifelong medical treatments.

What are the medications that can feminize one's appearance?

Treatment with hormones is called hormone replacement therapy or HRT. HRT will require taking estrogen, as well as medicines to block the body from producing or utilizing testosterone. Use of these medications by minors even when the criteria listed below are followed, does not have U.S. Food and Drug Administration (FDA) approval to be used by minors and its use in this population is considered "off label" because they are not being used for their intended purpose.

Different forms of estrogen are used to feminize one's appearance. Estrogen can be given as an injection either weekly or every other week, as a pill that is taken daily or twice a day, or as a patch that is changed weekly or every three or four days.

Please initial below to acknowledge your understanding of the information on this page.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

DH5080-MQA (Rev. 06/23)
Rules 64B8ER23-7 and 64B15ER23-9

Medications that block the production or effects of testosterone are called androgen blockers. Spironolactone is the androgen blocker that is most commonly used in the United States. In some cases, Bicalutamide, an antiandrogen, is used to block the effects of testosterone, though it will not reduce testosterone levels. Bicalutamide (brand name Casodex) is a cancer drug approved for the treatment of prostate cancer. Fulminant hepatotoxicity, a severe liver injury often resulting in death, has been noted with bicalutamide use.

Every medication has risks, benefits, and side effects that are important to understand before taking. The effects and side effects of medicines used to treat gender dysphoria must be monitored with laboratory studies and regular visits to the minor's prescribing physician to make sure that there are no negative medical or mental health effects.

HRT, the use of androgen blockers and antiandrogens, and the treatment process can affect a minor's mood. Therefore, minors must be under the care of a licensed mental health care professional while undergoing treatment. This professional can work with the minor, your family and friends, and your school staff.

What are my other options if I do not wish to start or continue my minor's treatment with hormones, hormone antagonists, or antiandrogens?

One option available is psychological therapy with a mental health. This is recommended regardless of whether or not the minor undergoes treatment with hormones, hormone antagonists, or antiandrogens due to the high risk of anxiety, depression, self-harm, and suicide. Other options may be discussed with your prescribing physician.

What are the requirements to receive hormone replacement therapy (HRT)?

To receive HRT, there are specific requirements that need to be met before and during treatment. These requirements will allow the prescribing physician to monitor the minor's medical and mental health status during treatment. If these requirements are not met, HRT may be discontinued by the prescribing physician.

Please initial below to acknowledge your understanding of the information on this page.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

Before beginning or continuing HRT, a minor must undergo a thorough psychological and social evaluation performed by a Florida licensed board-certified psychiatrist or a Florida licensed psychologist. The psychiatrist or psychologist must submit a letter to the prescribing physician confirming this.

The specific requirements for a minor to receive and continue HRT treatment include the following:

1. Has met the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders or International Classification of Diseases;
2. Has pubertal changes resulting in an increase in gender dysphoria;
3. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
4. Has psychological and social support during treatment;
5. Has experienced puberty to at least Tanner Stage 2 (first stage of puberty), which must be confirmed by a physician;
6. Demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of HRT as well as the medical and social risks and benefits of sex reassignment surgery;
7. Undergoes an in-person evaluation by the prescribing physician or their designated covering physician at least every 6 months;
8. Undergoes a suicide risk assessment by a licensed mental health care professional at least every 3 months;
9. Undergoes relevant laboratory testing at least every 4 months;
10. X-ray of the hand (bone age) at least once a year if the minor is still growing;
11. Annual bone density scan (DEXA) which will allow monitoring of the minor's bone density (bone strength) during treatment, which can be altered by HRT;
12. Annual mental health assessments by a Board-certified Florida licensed psychiatrist or psychologist; and
13. Continued counseling with a licensed mental health care professional during the treatment period, with the frequency recommended by the licensed mental health care professional.

Please initial below to acknowledge your understanding of the information on this page.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

Please initial each statement on this form to show that you understand the benefits, risks, and changes associated with treating a minor with feminizing medications.

Effects of Feminizing Medications

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Feminizing medications, including estrogen, androgen blockers, or antiandrogens, given singularly or in combination, may be prescribed to make a minor appear less masculine and more feminine
			It can take several months or longer for the effects of feminizing medications to become noticeable and no one can predict how fast or how much change will occur.
			This treatment will not change the minor's biological sex or chromosomes.
			If a minor takes estrogen, the following changes in a minor's breasts will occur: • Breasts will develop but will not reach their full size for several years • Breasts will remain even if estrogen treatment is discontinued • A milky discharge from the nipples may appear, which should be reported the minor's prescribing physician • The minor's risk of breast cancer may significantly increase
			If a minor takes feminizing medications, the minor's body will make less testosterone, which may affect the minor's sex life in different ways, including: • The minor's testicles may shrink • The minor's penis may never fully develop, particularly if the minor has previously taken puberty blockers • The minor will have fewer spontaneous erections • The minor's sperm may no longer mature causing infertility which may be permanent

			even if treatment is discontinued, the risk of which is increased if the minor took puberty blockers prior to starting feminizing medications • Conversely, it is possible that a minor's sperm could still mature while taking feminizing medications and the minor may cause someone to get pregnant
			To improve the possibility that the minor may have biological children in the future, the options for sperm banking by the minor have been explained.
			If a minor takes feminizing medications, some parts of the minor's body will not change much, including: • If present, the minor's facial hair may grow more slowly, but it will not go away completely even after taking feminizing medications for many years • If present, the minor's body hair may grow more slowly, but it will not go away completely even after taking feminizing medications for many years • If the minor went through puberty and has a deep voice, the pitch of the minor's voice will not rise and the minor's speech patterns will not become more like a woman's • If present, the minor's Adam's apple will not shrink
			Even if a minor stops taking feminizing medications, the following changes may occur: • The minor's body fat may be redistributed with less fat on the abdomen and more on the buttocks, hips, and thighs creating a more female shape • The minor may have decreased muscle mass and strength in the upper body • The minor's skin may become softer
			Mood changes may be caused by these medicines, and the minor will continue therapy with a licensed mental health care professional during treatment.
			Using these medicines to feminize a minor is an off-label use of the medications. This means these medications are not approved by the FDA for this

			purpose. I know that the medicine and dose that is recommended is based solely on the judgment and experience of the minor's prescribing physician and there is no data in the medical literature or controlled research studies that support the timing, dosing, and type of administration of feminizing medications for minors.

Risks of Feminizing Medications

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			The medical effects and the safety of minors taking femininizing medications are not completely known and there may be unknown long-term risks.
			Taking feminizing medications causes changes that other people will notice.
			Treatment with femininizing medications will not prevent serious psychiatric events, including suicide.
			The minor must not take more feminizing medication than prescribed. Taking too much medication: • Will increase health risks • Will not make changes happen more quickly or more significantly
			Taking feminizing medication can damage the liver and possibly lead to liver disease.

Risks of Estrogen

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Estrogen **SHOULD NOT** be used by anyone who has a history of: • Any estrogen-dependent cancer • Any disorder that makes them more likely to get blood clots that could travel to the lungs unless they are also taking blood thinners and are being followed by a specialist

			Estrogen should be used **WITH CAUTION** and only after a full discussion of risks by anyone who: • Has a family history of breast cancer or other cancers that grow more quickly when estrogens are present • Has a family history of heart disease • Has diabetes • Has chronic hepatitis or other liver disease • Has high levels of cholesterol • Has migraines or seizures • Is obese • Smokes cigarettes or uses tobacco products
			Taking estrogen increases the risk of blood clots and problems with blood vessels that can result in: • Chronic problems with veins in the legs, which may require surgery • Heart attack which may cause permanent heart damage or death • Pulmonary embolism (blood clot in the lungs), which may cause permanent lung damage or death • Stroke, which may cause permanent brain damage or death
			The risk of blood clots while take estrogen is much greater if the minor smokes cigarettes. The danger is so high that the minor should stop smoking completely while taking estrogen.
			Taking estrogen can increase the deposits of fat around internal organs, which increases the risk for diabetes and heart disease, which in turn increases the risk of heart attack and stroke.
			Taking estrogen can raise blood pressure, which increases the risk of heart attack and stroke.
			Taking estrogen increases the risk of gallstones (stones in the gallbladder). Any long-term abdominal pain experience by the minor while taking estrogen must be reported to the minor's prescribing physician.
			Taking estrogen increases the risk of elevated prolactin levels and prolactinomas, which are non-cancerous tumors of the pituitary gland. While not typically life threatening, prolactinomas can damage the

			minor's vision and cause headaches if not treated properly. Any changes in the minor's vision, the occurrence of headaches that are worse when waking up in the morning, or any milky discharge from the nipples must be reported to the minor's prescribing physician.
			Taking estrogen can cause nausea and vomiting. Any long-term nausea or vomiting must be reported to the minor's prescribing physician.
			Taking estrogen can cause migraines or can make them worse if the minor already has them.
			Taking estrogen can cause hot flashes.
			Taking estrogen can cause the minor to feel tired and have difficulty focusing.

Risks of Androgen Blockers and Antiandrogens (Spironolactone and Bicalutamide)

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Taking Spironolactone affects the balance of water and salt in the kidneys, which may: • Increase the amount of urine produced by the minor's kidneys, making it necessary to urinate more frequently • Increase the minor's thirst • Increase the minor's risk of dehydration, which can be evidenced by less frequent urination than usual, dark and strong-smelling urine, thirst, and light-headedness
			Taking Spironolactone affects the balance of potassium in the kidneys, which may result in the minor experience high potassium levels resulting in: • Changes in heart rhythms that may be life threatening • Low blood pressure, which can cause: o Fatigue o Lightheadedness o Tingling feelings o Muscle weakness o Shortness of breath

			• The minor's need for regular blood tests to monitor risks while on the medication
			Taking Bicalutamide may cause numerous side effects which should be reported to the minor's prescribing physician, including: • Hot flashes or flushing • Bone, back, or pelvic pain • Muscle weakness • Muscle or joint pain • Headaches • Shortness of breath • Chest pain • Elevated blood pressure • Swelling of the hands, feet, ankles, or lower legs • Cough • Constipation • Nausea • Vomiting • Abdominal pain • Diarrhea • Gas • Changes in weight (loss or gain) • Loss of appetite • Dizziness • Pain, burning, or tingling in the hands or feet • Difficulty sleeping • Feeling of uneasiness or dread • Rash • Sweating • Need to urinate frequently during the night • Bloody urine • Painful or difficult urination • Frequent and urgent need to urinate • Difficulty emptying bladder • Painful or swollen breasts • Yellowing of the skin or eyes • Pain in the upper right part of the abdomen • Extreme tiredness • Unusual bleeding or bruising • Lack of energy • Upset stomach

			• Loss of appetite • Flu-like symptoms • Dull or sharp side pain

Requirements of Treatment with Feminizing Medications

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Compliance with the requirements explained above is a prerequisite for a minor to receive treatment with feminizing medications.
			The prescribing physician may stop prescribing feminizing medications if the prescribing physician or mental health care professionals providing treatment pursuant to this consent determine the benefit of treatment no longer outweighs the risks, there is insufficient social or psychological support, or the requirements in this consent are not met.
			The parent/guardian or the minor can change their mind and stop treatment at any time although some effects of HRT may be permanent.

Prevention of Complications while under Treatment with Feminizing Medications

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			The undersigned parent(s)/legal guardian(s) agree(s) to notify the minor's prescribing physician if the minor suffers from any side effects during treatment or is unhappy with the treatment in any way, particularly if the parent(s)/legal guardian(s) has/have any concerns that the minor has worsening signs of depression or anxiety or expresses a desire harm themselves or attempt suicide.
			The prescribing physician is required to monitor the minor for any side effects during treatment and may refer the minor to another physician or specialist for treatment. The undersigned

			parent(s)/legal guardian(s) agree(s) to take the minor to physicians and specialists as recommended by the prescribing physician.

PARENTAL CONSENT:

The signature(s) below confirm(s) the following:

1. The minor's prescribing physician has fully informed me about:
   a. the benefits and risks of taking feminizing medications;
   b. the possible or likely consequences of hormone therapy; and
   c. potential alternative treatments.

2. The information provided to me in this form and by the prescribing physician includes the known effects and risks of treatment with feminizing medications. I know that there may be other unknown short-term and long-term effects or risks which may be irreversible.

3. I have had sufficient time and opportunity to discuss relevant treatment options with the minor's prescribing physician.

4. All my questions have been answered to my satisfaction by the minor's prescribing physician.

5. I know enough to give informed consent for the minor to take, refuse, or postpone taking feminizing medications.

6. The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.52, F.S. This form contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your physician.

7. My signature below attests to my consent for the minor to begin treatment with feminizing medications.

_____
Parent/legal guardian's printed name (required)

_____ _____
Parent/legal guardian's signature (required) Date

Parent/legal guardian's printed name (optional)

Parent/legal guardian's signature (optional) Date

PRESCRIBING PHYSICIAN SIGNATURE:

My signature below attests to my compliance with section 456.52, Florida Statutes.

Prescribing physician's printed name (required)

Prescribing physician's signature (required) Date

ASSENT OF A MINOR:

I have discussed the benefits and risks of treatment with feminizing medications with my prescribing physician, parent(s) or legal guardian(s), and I wish to receive them.

Minor's printed name (required)

Minor's signature (required) Date

WITNESS:

_____

Witness' printed name (required)

_____ _____

Witness' signature (required) Date

FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:

I certify that I am fluent in English and in the native language of the person indicating consent and/or assent on the above form. I certify that I have accurately and completely interpreted the contents of this form, and that the patient and/or adult(s) legally responsible for the minor child has indicated understanding of the contents of this form.

_____

Interpreter's printed name

_____ _____

Interpreter's signature Date

Masculinizing Medications for Patients with Gender Dysphoria

Patient Information and Informed Parental Consent and Assent for Minors

Before a minor starts or continues treatment with hormones or hormone antagonists, you and the minor need to be aware of the effects and possible risks associated with use of these medications.

After your questions or concerns are addressed and you have decided to have the minor start or continue treatment with hormones or hormone antagonists, a parent/legal guardian and the minor must initial the statements below and sign this form. Both the parent/legal guardian and the minor must sign in person.

Medical treatment of people with gender dysphoria is based on very limited, poor-quality research with only subtle improvements seen in some patient's psychological functioning in some, but not all, research studies. This practice is purely speculative, and the possible psychological benefits may not outweigh the substantial risks of medical treatments and, in many cases, the need for lifelong medical treatments.

What are the medications that can masculinize one's appearance?

Treatment with hormones is called hormone replacement therapy or HRT. HRT will require taking testosterone, which increases muscle mass and causes the development of facial hair and a deeper voice. Testosterone when used by minors, even when the criteria listed below are followed, does not have U.S. Food and Drug Administration (FDA) approval to be used by minors and its use in this population is considered "off label" because they are not being used for their intended purpose.

Please initial below to acknowledge your understanding of the information on this page.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

DH5081-MQA (Rev. 06/23)
Rules 64B8ER23-7 and 64B15ER23-9

What are my other options if I do not wish to start or continue my minor's treatment with hormones or hormone antagonists?

One option available is psychological therapy with a mental health care provider. This is recommended regardless of whether or not the minor undergoes treatment with hormones or hormone antagonists due to the high risk of anxiety, depression, self-harm, and suicide. Other options may be discussed with your prescribing physician.

How is testosterone taken?

Testosterone is usually injected every one to four weeks. Typically, it is not given in pill form because the body may not absorb it properly which may cause potentially fatal liver problems. The doses used for injection differ from product to product and from patient to patient. The injections are given in the muscle (intramuscular) or can be given with a smaller needle under the skin (subcutaneous). A minor taking testosterone may experience unwanted swings in hormone levels based on the amount and how often doses are given.

Every medication has risks, benefits, and side effects that are important to understand before taking. The effects and side effects of medicines used to treat gender dysphoria must be monitored with laboratory studies and regular visits to the minor's prescribing physician to make sure that there are no negative medical or mental health effects.

Both testosterone and the treatment process can affect a minor's mood. Therefore, minors must be under the care of a licensed mental health care professional while undergoing treatment. This professional can work with the minor, your family and friends, and your school staff.

What are the requirements to receive hormone replacement therapy (HRT)?

To receive HRT, there are specific requirements that need to be met before and during treatment. These requirements will allow the prescribing physician to monitor the minor's medical and mental health status during treatment. If these requirements are not met, HRT may be discontinued by the prescribing physician.

Please initial below to acknowledge your understanding of the information on this page.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

Before beginning or continuing HRT, a minor needs to undergo a thorough psychological and social evaluation performed by a Florida licensed board-certified psychiatrist or a Florida licensed psychologist. The psychiatrist or psychologist must submit a letter to the prescribing physician confirming this.

The specific requirements for a minor to receive and continue HRT treatment include the following:

1. Has met the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders (DSM) or International Classification of Diseases (ICD);
2. Has pubertal changes resulting in an increase in gender dysphoria;
3. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
4. Has psychological and social support during treatment;
5. Has experienced puberty to at least Tanner Stage 2 (first stage of puberty), which must be confirmed by a physician;
6. Demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of HRT as well as the medical and social risks and benefits of sex reassignment surgery;
7. Undergoes an in-person evaluation by the prescribing physician or their designated covering physician at least every 6 months;
8. Undergoes a suicide risk assessment by a licensed mental health care professional at least every 3 months;
9. Undergoes relevant laboratory testing, at least every 4 months;
10. X-ray of the hand (bone age) at least once a year if the minor is still growing;
11. Annual bone density scan (DEXA) which will allow monitoring of the minor's bone density (bone strength) during treatment, which can be altered by HRT
12. Annual mental health assessments by a Board-certified Florida licensed psychiatrist or psychologist; and
13. Continued counseling with a licensed mental health care professional during the treatment period, with the frequency recommended by the licensed mental health care professional.

Please initial below to acknowledge your understanding of the information on this page.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

Summary of Testosterone Benefits and Risks

BENEFITS	RISKS
• Appear more like a man • Bigger clitoris • Coarser skin • Lower voice • More body hair • More facial hair • More muscle mass • More strength • No or minimal menstrual periods • More physical energy • More sex drive	• Acne (may permanently scar) • Blood clots (thrombophlebitis), risk significantly increased by smoking • Emotional changes, for example, more aggression • Headache • High blood pressure (hypertension) • Increased red-blood-cell count • Infertility • Inflamed liver • Interaction with drugs for diabetes and blood thinning such as Coumadin and Warfarin • Male pattern baldness • More abdominal fat – redistributed to a male shape • Risk of heart disease • Swelling of hands, feet, and legs • Weight gain

Please initial below to acknowledge your understanding of the information on this page.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

Please initial each statement on this form to show that you understand the benefits, risks, and changes associated with a minor taking testosterone.

Masculinizing Effects

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Testosterone may be prescribed to make a minor appear less like a female and more like a male.
			It can take several months or longer for the effects of testosterone to become noticeable and no one can predict how fast or how much change will occur.
			Changes from testosterone may not be complete for 2 to 5 years after treatment is started.
			The following changes are likely to be permanent even if testosterone is discontinued: • Bigger clitoris - typically about half an inch to a little more than an inch • Deeper voice • Gradual growth of moustache and beard • Hair loss at the temples and crown of the head and the possibility of being completely bald • More, thicker, and coarser hair on abdomen, arms, back, chest, and legs
			The following changes could be permanent, but may improve if I stop taking testosterone: • Acne (although there may be permanent scars) • Menstrual periods (if present), typically stop one to six months after starting • More abdominal fat – redistributed to a male shape: decreased on buttocks, hips, and thighs; increased in abdomen – changing from "pear shape" to "apple shape" • More muscle mass and strength • More sexual interest • Vaginal dryness • Vaginal tearing • Vaginal bleeding • Vaginal pain • Vaginal infection • Painful intercourse

			This treatment will not change the minor's biological sex or chromosomes.
			Testosterone may reduce the minor's ability to become pregnant, but it will not eliminate the risk of pregnancy. A person can become pregnant while on testosterone. I agree to inform the minor's prescribing physician if the minor becomes pregnant.
			Some aspects of the minor's body will not change: • Fat loss may make breasts appear slightly smaller (if present) • The voice will deepen, but other aspects of the way the minor speaks may not sound more masculine
			Mood changes may be caused by these medicines, and the minor will continue therapy with a licensed mental health care professional during treatment.
			Using these medicines to masculinize a minor is an off-label use of the medications. This means these medications are not approved by the FDA for this purpose. I know that the medicine and dose that is recommended is based solely on the judgment and experience of the minor's prescribing physician and there is no data in the medical literature or controlled research studies that support the timing, dosing, and type of administration of HRT for minors.

Risks of Testosterone

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Testosterone **SHOULD NOT** be used by anyone who: • Is pregnant • Has uncontrolled coronary artery disease as it could increase your risk for a fatal heart attack
			Testosterone should be used **WITH CAUTION** and only after a full discussion of risks by anyone who: • Has acne • Has a family history of heart disease or breast cancer • Has had a blood clot • Has high levels of cholesterol • Has liver disease

			• Has a high red blood cell count • Is obese • Smokes cigarettes or uses tobacco products
			The medical effects and the safety of minors taking testosterone are not completely known and there may be unknown long-term risks.
			Taking testosterone causes changes that other people will notice.
			Treatment with testosterone will not prevent serious psychiatric events, including suicide.
			The minor must not take more testosterone than prescribed. Taking too much testosterone: • Will increase health risks; • Will not make changes happen more quickly or more significantly; and • May cause the body to convert extra testosterone into estrogen that can slow down or stop the minor appearing more masculine
			Taking testosterone can cause changes that increase the risk of heart disease into adulthood. These changes include: • Less good cholesterol (HDL) that may protect against heart disease and more bad cholesterol (LDL) that may increase the risk of heart disease; • Higher blood pressure; and • More deposits of fat around the internal organs
			Taking testosterone can damage the liver and possibly lead to liver disease.
			Taking testosterone can increase red blood cells and hemoglobin, which may increase my risk of life-threatening problems such as stroke or heart attack.
			Taking testosterone can increase the risk for diabetes (high blood sugars), which decrease the body's response to insulin, cause weight gain, and increase deposits of fat around internal organs increasing the risk of heart disease and stroke.
			Treatment with testosterone can cause ovaries to not release eggs and may cause infertility.
			Treatment with testosterone increases the risk of cancer to the uterus, ovaries, or breasts. It is unclear if taking testosterone plays any role in HPV infection or cervical cancer.
			Taking testosterone causes or worsen migraines.

			Taking testosterone can cause emotional changes, such as irritability, frustration, aggression, and anger.

Requirements of Treatment with HRT

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Compliance with the requirements explained above is a prerequisite for a minor to receive treatment with testosterone.
			The prescribing physician may stop prescribing testosterone if the prescribing physician or mental health care professionals providing treatment pursuant to this consent determine the benefit of treatment no longer outweighs the risks, there is insufficient social or psychological support, or the requirements in this consent are not met.
			The parent/guardian or the minor can change their mind and stop treatment at any time although some effects of HRT may be permanent.

Prevention of Complications while under Treatment with HRT

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			The undersigned parent(s)/legal guardian(s) agree(s) to notify the minor's prescribing physician if the minor suffers from any side effects during treatment or is unhappy with the treatment in any way, particularly if the parent(s)/legal guardian(s) has/have any concerns that the minor has worsening signs of depression or anxiety or expresses a desire harm themselves or attempt suicide.
			The prescribing physician is required to monitor the minor for any side effects during treatment and may refer the minor to another physician or specialist for treatment. The undersigned parent(s)/legal guardian(s) agree(s) to take the minor physicians and specialists as recommended by the prescribing physician.

PARENTAL CONSENT:

The signature(s) below confirm(s) the following:

1. The minor's prescribing physician has fully informed me about:
   a. the benefits and risks of taking testosterone;
   b. the possible or likely consequences of hormone therapy; and
   c. potential alternative treatments.

2. The information provided to me in this form and by the prescribing physician includes the known effects and risks of treatment with testosterone. I know that there may be other unknown short-term and long-term effects or risks which may be irreversible.

3. I have had sufficient time and opportunity to discuss relevant treatment options with the minor's prescribing physician.

4. All my questions have been answered to my satisfaction by the minor's prescribing physician.

5. I know enough to give informed consent for the minor to take, refuse, or postpone taking testosterone.

6. The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.52, F.S. This form contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your physician.

7. My signature below attests to my consent for the minor to begin treatment with testosterone.

_____

Parent/legal guardian's printed name (required)

_____ _____

Parent/legal guardian's signature (required) Date

Parent/legal guardian's printed name (optional)

Parent/legal guardian's signature (optional) Date

PRESCRIBING PHYSICIAN:

My signature below attests to my compliance with 456.52, Florida Statutes.

Prescribing physician's printed name (required)

Prescribing physician's signature (required) Date

ASSENT OF A MINOR:

I have discussed the benefits and risks of treatment with masculinizing medication with my prescribing physician, parent(s) or legal guardian(s), and I wish to receive it.

Minor's printed name (required)

Minor's signature (required) Date

WITNESS:

Witness' printed name (required)

Witness' signature (required) Date

FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:

I certify that I am fluent in English and in the native language of the person indicating consent and/or assent on the above form. I certify that I have accurately and completely interpreted the contents of this form, and that the patient and/or adult(s) legally responsible for the minor child has indicated understanding of the contents of this form.

Interpreter's printed name

Interpreter's signature Date

FLORIDA DEPARTMENT of STATE

RON DESANTIS
Governor

CORD BYRD
Secretary of State

July 6, 2023

Angela Southwell
Paralegal Specialist
Office of the Attorney General
PL 01, The Capitol
Tallahassee, FL 32399

Dear Angela Southwell:

Your adoption package for Emergency Rule 64B15ER23-10 was received, electronically, by the Florida Department of State, Administrative Code and Register at 5:39 p.m. on July 5, 2023. 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 July 5, 2023.

Sincerely,

Anya C. Owens
Administrative Code and Register Director

Owens, Anya C.

From: Angela Southwell <Angela.Southwell@myfloridalegal.com>
Sent: Wednesday, July 5, 2023 5:39 PM
To: RuleAdoptions
Cc: Owens, Anya C.; Donna McNulty; Christopher Dierlam; Cassandra Fullove
Subject: Adoption Packet for Emergency Rule 64B15ER23-10
Attachments: Adoption pkt 64B15ER23-10.pdf; THE FULL TEXT OF THE EMERGENCY RULE IS.docx

Good Afternoon:

Attached please find the adoption packet and text.

Angela M. Southwell
Paralegal Specialist
Office of the Attorney General
Administrative Law
PL-01 The Capitol
Bin #4100
Tallahassee, Florida 32399-1050
Telephone: (850) 414-3772
angela.southwell@myfloridalegal.com

ASHLEY MOODY
ATTORNEY GENERAL
STATE OF FLORIDA

OFFICE OF THE ATTORNEY GENERAL
Administrative Law

Angela Southwell
Paralegal Specialist
PL-01 The Capitol
Tallahassee, FL 32399-1050
Phone (850) 414-3772
Fax (850) 922-6425
angela.southwell@myfloridalegal.com

MEMORANDUM

TO: Anya Owens, Program Administrator
Administrative Code and Register

FROM: Angela Southwell, Paralegal Specialist

RE: Department of Health
Board of Osteopathic Medicine
Emergency Rule 64B15ER23-10

DATE: July 5, 2023

Attached are the following documents regarding the above-referenced emergency rule adoption packet for the above-referenced emergency rule:

- Notice of Emergency Rule
- Adoption text for Emergency Rule 64B15ER23-10 (double spaced)
- Certification of Board of Osteopathic Medicine Emergency Rule Filed With the Department of State
- Designation of Rule the Violation of Which is a Minor Violation Certification
- Certification of Materials Incorporated by Reference in Rules Filed with the Department of State
- Form DH5082-MQA, (06/23), entitled "Feminizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Consent"
- Form DH5083-MQA, (06/23), entitled "Masculinizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Consent,"
- Form DH5084-MQA, (06/23), entitled "Surgical Treatment for Adults with Gender Dysphoria, Patient Information and Informed Consent"

Should you have any questions regarding the rule, please contact me at angela.southwell@myfloridalegal.com or by telephone at 850-414-3772.

Thank you for your attention to this matter.

Attachments

CERTIFICATION OF BOARD OF OSTEOPATHIC MEDICINE

EMERGENCY RULE FILED WITH THE

DEPARTMENT OF STATE

I hereby certify that pursuant to Ch 2023-90 Laws of Florida, Section 5, section 456.52, Florida Statutes was created and pursuant to subparagraphs 456.52(1)(a) and (6)(a), F.S., the Board of Osteopathic Medicine is required to adopt emergency rules to implement the section. 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), F.S. 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.

64B15ER23-10

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 Tiffany Sizemore Di Pietro , DO, FACC, FACOI, 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), F.S., 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)..

64B15ER23-10

Signature of Agency Head

Danielle Terrell, Executive Director for Tiffany Sizemore Di Pietro, DO, FACC, FACOI, 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 Osteopathic Medicine

RULE NO.: RULE TITLE:

64B15ER23-10 Mandatory Standardized Informed Consent for Sex-reassignment Prescriptions or Procedures in Adults.

SPECIFIC REASONS FOR FINDING AN IMMEDIATE DANGER TO THE PUBLIC HEALTH, SAFETY OR WELFARE: On May 17, 2023, Florida Governor, Ronald DeSantis, signed CSSB 254 into law creating Ch. 2023-90, Laws of Florida and section 456.52, Florida Statutes. Pursuant to section 456.52(1), F.S., sex-reassignment prescriptions are prohibited for patients younger than 18 years of age upon the effective date of the act; however, pursuant to section 456.52(1)(a), F.S., the Board of Osteopathic Medicine shall within 60 days after the effective date of the act, adopt emergency rules pertaining to standards of practice by which minors may continue to be treated if such treatment was commenced before, and is still active on, the effective date of the act. Section 456.52(1)(b), F.S., also provides a minor patient meeting the criteria outlined in section 456.52(1)(a), F.S., may continue to be treated by a physician with such prescriptions according to rules adopted pursuant to paragraph (1)(a).

Further, pursuant to section 456.52(2), F.S., if sex reassignment prescriptions or procedures are prescribed for or administered to patients 18 years of age or older, consent must be voluntary, informed, and in writing on forms adopted in rule by the Board of Osteopathic Medicine. Pursuant to section 456.52(4), F.S., the consent required for sex-reassignment prescriptions does not apply to renewals of sex-reassignment prescriptions if a physician and his or her patient have met the requirements for consent for the initial prescription. Section 456.52(6)(a), F.S., states "[t]he Board of Medicine and the Board of Osteopathic Medicine shall adopt emergency rules to implement this section."

Accordingly, the Board of Osteopathic Medicine, by emergency rule, hereby adopts the incorporated mandated consent forms for the treatment of gender dysphoria with hormone replacement therapy and surgical treatment.

*** This emergency rule does not apply to Susan Doe, Gavin Goe, or Lisa Loe, or their parents or healthcare providers (see Jane Doe et al., v. Joseph A. Ladapo, et al, Preliminary Injunction, Filed June 6, 2023, Case No. 4:23cv114-RH-MAF, United States District Court for the Northern District of Florida). ***

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. CSSB 254 was signed into law on May 17, 2023. The Board of Medicine was contacted by multiple licensed physicians and

physician groups seeking clarification regarding the exception contained in section 465.52(4), F.S., and a timeframe for the required emergency rules shortly thereafter. In response, the Board of Medicine and the Board of Osteopathic Medicine held a Joint Rules/Legislative Committee (Joint Committee) meeting on June 1, 2023, to discuss the emergency rule. On May 19, 2023, the Board of Medicine published notice of the Joint Committee's June meeting both on its website and in the Florida Administrative Register. On June 2, 2023, the Board of Osteopathic Medicine discussed the report of the Joint Committee and voted upon emergency rule language that would allow for the renewal of previous prescriptions while the Board worked on consent forms. The Board of Osteopathic Medicine published notice of its June 2, 2023, meeting in the Florida Administrative Register on May 5, 2023, and on its website on May 12, 2023.

The Joint Committee held another meeting on June 23, 2023, to discuss an emergency rule adopting draft consent forms that were under consideration. On June 6, 2023, the Board of Osteopathic Medicine published notice of the Joint Committee's June 23, 2023, meeting to its website and in the Florida Administrative Register. On June 30, 2023, the Boards of Medicine and Osteopathic Medicine held a Joint Board meeting (Joint Board Meeting) to discuss the draft consent forms that were approved by the Joint Committee on June 23, 2023. The Joint Board Meeting was held via Microsoft Teams and notice of the same was published to the Board of Osteopathic Medicine's website and in the Florida Administrative Register on June 22, 2023.

Each Joint Committee meeting was held in person in a public forum and was able to be attended by any interested persons. The Joint Board Meeting was held via Microsoft Teams and also was able to be attended by any interested persons. Public comment was accepted at all of the aforementioned meetings. Further, the Board's accepted written public comment on the proposed rules up and until 24 hours prior to the Joint Board Meeting. Accordingly, all notice requirements contained in Rule 28-102.001, F.A.C., were properly complied with and interested persons were given ample opportunity to participate in this rulemaking process.

SUMMARY: The proposed emergency rule formally adopts the required consent forms for a patient to receive sex-reassignment prescriptions and/or procedures per section 456.52(2), Florida Statutes.

THE PERSON TO BE CONTACTED REGARDING THE EMERGENCY RULE IS: Danielle Terrell, Executive Director, Board of Osteopathic Medicine/MQA, 4052 Bald Cypress Way, Bin #C06, Tallahassee, Florida 32399-3256, or by email at Danielle.Terrell@flhealth.gov.

THE FULL TEXT OF THE EMERGENCY RULE IS:

64B15ER23-10 Mandatory Standardized Informed Consent for Sex-reassignment Prescriptions or Procedures in Adults.

Pursuant to Section 456.52, Florida Statutes, when sex-reassignment prescriptions or procedures are prescribed for or administered or performed on patients 18 years of age or older, the physician is required to obtain voluntary, informed consent while physically present in the same room as the patient. Consent is not required for renewal of such prescriptions if a physician and the physician's patient have met the requirements for consent for the initial prescription or renewal; however, a separate consent is required for any new prescription for a pharmaceutical product not previously prescribed to the patient.

(1) Informed Consent. The Board has approved the following mandatory informed consent forms for sex-reassignment prescriptions or procedures for patients 18 years of age or older:

(a) For patients prescribed sex-reassignment feminizing medication, form DH5082-MQA, (06/23), entitled "Feminizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Consent," which is hereby incorporated by reference and available from the Board's website at https://flboardofmedicine.gov/forms/Feminizing-Medications-for-Patients-with-Gender-Dysphoria-Patient-Information-and-Informed-Consent.pdf.

(b) For patients prescribed sex-reassignment masculinizing medications, form DH5083-MQA, (06/23), entitled "Masculinizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Consent," which is hereby incorporated by reference and available from the Board's website at https://flboardofmedicine.gov/forms/Masculinizing-Medications-for-Patients-with-Gender-Dysphoria-Patient-Information-and-Informed-Consent.pdf.

(c) For patients undergoing surgical treatment, form DH5084-MQA, (06/23), entitled "Surgical Treatment for Adults with Gender Dysphoria, Patient Information and Informed Consent," which is hereby incorporated by reference and available from the Board's website at https://flboardofmedicine.gov/forms/Surgical-Treatment-for-Adults-with-Gender-Dysphoria-Patients-Information-and-Informed-Consent.pdf.

(2) A Board-approved informed consent form is not executed until:

(a) The physician issuing the prescription or performing the procedure, while physically present in the same room as the patient, has informed the patient of the nature and risks of the prescription or procedure and has provided and received the patient's written acknowledgement before the prescription is prescribed, administered, or performed. The physician is prohibited from delegating this responsibility to another person. The physician is also required to sign the informed consent form.

(b) The patient is required to sign the informed consent form.

(c) A competent witness is also required to sign the informed consent form.

Rulemaking Authority 456.52 FS. Law Implemented 456.52 FS. History – New____.

CERTIFICATION OF MATERIALS INCORPORATED
BY REFERENCE IN EMERGENCY RULES FILED WITH THE DEPARTMENT OF STATE

I hereby certify pursuant to Rule 1-1.013, Florida Administrative Code, that materials incorporated by reference in Emergency Rule 64B15ER23-10 have been:

[x] (1) Filed with the Department of State and included as part of the Emergency Rule adoption packet.

[ ] (2) That because there would be a violation of federal copyright laws if the submitting agency filed the incorporated materials as described in option (1) above, a true and complete copy of the incorporated materials has been provided to the Department of State as outlined in paragraph 1-1.013(5)(c), F.A.C.

Copies of the incorporated materials below may be obtained at the agency by [include address(es)/location(s)].

List form number(s) and form title(s), or title of document(s) below:

DH5082-MQA Feminizing Medications for Patient with Gender Dysphoria-Patient Information and Informed Consent

DH5083-MQA Masculinizing Medications for Patients with Gender Dysphoria-Patient Information and Informed Consent

DH5084 Surgical Treatment for Adults with Gender Dysphoria-Patients Information and Informed Consent

Under the provisions of Section 120.54(4)(d), F.S., the attached material(s) take effect upon filing with the Department of State, or a date less than 20 days thereafter if specified in the rule if the adopting agency finds that such effective date is necessary because of immediate danger to the public health, safety, or welfare.

Signature, Person Authorized to Certify Rules

Danielle Terrell, Executive Director for Tiffany Sizemore Di Pietro, DO, FACC, FACOI, Chair
Title

Feminizing Medications for Patients with Gender Dysphoria

Patient Information and Informed Consent

Before starting or continuing treatment with hormones or hormone antagonists, you need to be aware of the effects and possible risks associated with use of these medications.

Your prescribing physician will make a medical decision in consultation with you about the medications that are best for you, keeping in mind your overall health during the treatment process. Your prescribing physician will discuss with you all of the available information relating to hormone therapy. You are asked to read and understand the following information and to discuss any questions you have with your prescribing physician.

After your questions or concerns are addressed and you have decided to start or continue treatment with hormones or hormone antagonists, you must initial the statements below and sign this form in person with your prescribing physician.

Medical treatment of people with gender dysphoria is based on very limited, poor-quality research with only subtle improvements seen in some patient's psychological functioning in some, but not all, research studies. This practice is purely speculative, and the possible psychological benefits may not outweigh the substantial risks of medical treatments and, in many cases, the need for lifelong medical treatments.

What are the different medications that can feminize one's appearance?

Treatment with hormones is called hormone replacement therapy or HRT. HRT will require taking estrogen, as well as medicines to block the body from producing or utilizing testosterone. Use of these medications, even when the criteria listed below are followed, does not have U.S. Food and Drug Administration (FDA) approval and its use to treat gender dysphoria is considered "off label" because they are not being used for their intended purpose

Different forms of estrogen are used to feminize a person's appearance. Estrogen can be given as an injection either weekly or every other week, as a pill that is taken daily or twice a day, or as a patch that is changed weekly or every three or four days.

Please initial below to acknowledge your understanding of the information on this page.

Patient

DH5082-MQA (Rev. 06/23)
Rules 64B8ER23-8 and 64B15ER23-10

Medications that block the production or effects of testosterone are called androgen blockers. Spironolactone is the androgen blocker that is most commonly used in the United States. In some cases, Bicalutamide, an antiandrogen, is used to block the effects of testosterone, though it will not reduce testosterone levels. Bicalutamide (brand name Casodex) is a cancer drug approved for the treatment of prostate cancer. Fulminant hepatotoxicity, a severe liver injury often resulting in death, has been noted with bicalutamide use.

Cyproterone acetate, a synthetic progestogen with strong antiandrogen activity, is commonly used in many countries. When paired with estrogen, cyproterone acetate is associated with elevated prolactin, decreased HDL cholesterol, and rare meningiomas (tumors). Cyproterone acetate has also been associated with uncommon episodes of fulminant hepatitis.

The administration of finasteride blocks the conversion of testosterone to the more potent androgen dihydrotestosterone. The FDA approved uses of finasteride include the treatment benign prostatic hypertrophy and androgenic alopecia. Finasteride is not recommended for routine use in treating populations with gender dysphoria.

Various forms of progestins may also be used. This class includes micronized bioidentical progesterone (Prometrium) as well as oral medroxyprogesterone acetate (Provera). Although there are anecdotal reports of progesterone use for breast development and mood management, there is currently insufficient evidence that the potential benefits of progesterone administration outweigh the potential risks. There is also a theoretical risk of breast cancer associated with long-term exogenous progesterone.

Every medication has risks, benefits, and side effects that are important to understand before taking. The effects and side effects of medicines used to treat gender dysphoria must be monitored with laboratory studies and regular visits to your prescribing physician to make sure that there are no negative medical or mental health effects.

HRT, the use of androgen blockers and antiandrogens, and the treatment process can affect your mood. Therefore, you must be under the care of a licensed mental health care professional while undergoing treatment.

Please initial below to acknowledge your understanding of the information on this page.

Patient

What are my other options if I do not wish to start or continue treatment with hormones, hormone antagonists, or antiandrogens?

One option available is psychological therapy with a mental health provider. This is recommended regardless of whether or not the person undergoes treatment with hormones, hormone antagonists, or antiandrogens due to the high risk of anxiety, depression, self-harm, and suicide. Other options may be discussed with your prescribing physician.

What are the requirements to receive hormone replacement therapy (HRT)?

To receive HRT, there are specific requirements that need to be met before and during treatment. These requirements will allow the prescribing physician to monitor your medical and mental health status during treatment. If these requirements are not met, HRT may be discontinued by the prescribing physician.

Before beginning HRT and every two years thereafter, you must undergo a thorough psychological and social evaluation performed by a Florida licensed board-certified psychiatrist or a Florida licensed psychologist. The psychiatrist or psychologist must submit a letter to the prescribing physician confirming this.

Please initial below to acknowledge your understanding of the information on this page.

Patient

The specific requirements for you to receive and continue HRT treatment include the following:

1. Has met the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders or International Classification of Diseases;
2. Mental health and physical conditions that could negatively impact the outcome of treatment have been assessed, with risks and benefits discussed;
3. Demonstrates capacity to consent for the specific gender dysphoria hormone treatment;
4. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
5. Has psychological and social support during treatment;
6. Demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of HRT as well as the medical and social risks and benefits of sex reassignment surgery; and
7. Understands the effect of hormone treatment on reproduction and they have explored reproductive options;

The following may also be recommended by your prescribing physician:

1. Undergoes an in-person evaluation by the prescribing physician or their designated covering physician every 3 months for the initial year and at least annually thereafter;
2. Undergoes a suicide risk assessment by a licensed mental health care professional at least every 3 months for the initial year and at least annually thereafter;
3. Undergoes relevant laboratory testing at least every 6 months;
4. Annual bone density scan (DEXA) once a year for the first 5 years to allow monitoring of your bone density (bone strength) during treatment, which can be altered by HRT;
5. Annual mental health assessments by a board-certified Florida licensed psychiatrist or psychologist; and
6. Continued counseling with a licensed mental health care professional during the treatment period, with the frequency recommended by the licensed mental health care professional.

Please initial below to acknowledge your understanding of the information on this page.

Patient

Please initial each statement on this form to show that you understand the benefits, risks, and changes associated with taking feminizing medications.

Effects of Feminizing Medications

Patient	Statement
	Feminizing medications, including estrogen, androgen blockers, or antiandrogens, given singularly or in combination, may be prescribed to make me appear less like a male and more like a female.
	It can take several months or longer for the effects of feminizing medications to become noticeable and no one can predict how fast or how much change will occur.
	This treatment will not change my biological sex or chromosomes.
	If I take estrogen, the following changes in my breasts will occur: • Breasts will develop but will not reach their full size for several years • Breasts will remain even if estrogen treatment is discontinued • A milky discharge from the nipples may appear, which should be reported to my prescribing physician • My risk of breast cancer may significantly increase
	If I take feminizing medications, my body will make less testosterone, which may affect my sex life in different ways, including: • My testicles may shrink • My penis may never fully develop, particularly if I previously took puberty blockers • I will have fewer spontaneous erections • My sperm may no longer mature causing infertility which may be permanent even if treatment is discontinued, the risk of which is increased if I took puberty blockers prior to starting feminizing medications • Conversely, it is possible that my sperm could still mature while taking feminizing medications and I may cause someone to get pregnant
	The options for sperm banking have been explained.
	If I take feminizing medications, some parts of my body will not change much, including: • If present, my facial hair may grow more slowly, but it will not go away completely even after taking feminizing medications for many years • If present, my body hair may grow more slowly, but it will not go away completely even after taking feminizing medications for many years • If I went through puberty and have a deep voice, the pitch of my voice will not rise and my speech patterns will not become more like a woman's • If present, my Adam's apple will not shrink

	Even if I stop taking feminizing medications, the following changes may occur: • My body fat may be redistributed with less fat on the abdomen and more on the buttocks, hips, and thighs creating a more female shape • I may have decreased muscle mass and strength in the upper body • My skin may become softer
	Mood changes may be caused by these medicines, and I will continue therapy with a licensed mental health care professional during treatment.
	Using these medicines to feminize my body is an off-label use of the medications. This means these medications are not approved by the FDA for this purpose. I know that the medicine and dose that is recommended is based solely on the judgment and experience of my prescribing physician and there is no data in the medical literature or controlled research studies that support the timing, dosing, and type of administration of feminizing medications.

Risks of Feminizing Medications

Patient	Statement
	The medical effects and the safety of taking femininizing medications are not completely known and there may be unknown long-term risks.
	Taking femininizing medications causes changes that other people will notice.
	Treatment with femininizing medications will not prevent serious psychiatric events, including suicide.
	I must not take more feminizing medication than prescribed. Taking too much medication: • Will increase health risks • Will not make changes happen more quickly or more significantly
	Taking feminizing medication can damage the liver and possibly lead to liver disease.

Risks of Estrogen

Patient	Statement
	Estrogen **SHOULD NOT** be used by anyone who has: • Any estrogen-dependent cancer • Any disorder that makes them more likely to get blood clots that could travel to the lungs unless they are also taking blood thinners and are being followed by a specialist
	Estrogen should be used **WITH CAUTION** and only after a full discussion of risks by anyone who: • Has a family history of breast cancer or other cancers that grow more quickly when estrogens are present • Has a family history of heart disease

	• Has diabetes • Has chronic hepatitis or other liver disease • Has high levels of cholesterol • Has migraines or seizures • Is obese • Smokes cigarettes or uses tobacco products
	Taking estrogen increases the risk of blood clots and problems with blood vessels that can result in: • Chronic problems with veins in the legs, which may require surgery • Heart attack which may cause permanent heart damage or death • Pulmonary embolism (blood clot in the lungs), which may cause permanent lung damage or death • Stroke, which may cause permanent brain damage or death
	The risk of blood clots while take estrogen is much greater if you smoke cigarettes. The danger is so high that you should stop smoking completely while taking estrogen.
	Taking estrogen can increase the deposits of fat around internal organs, which increases the risk for diabetes and heart disease, which in turn increases the risk of heart attack and stroke.
	Taking estrogen can raise blood pressure, which increases the risk of heart attack and stroke.
	Taking estrogen increases the risk of gallstones (stones in the gallbladder). Any long-term abdominal pain you experience while taking estrogen must be reported to your prescribing physician.
	Taking estrogen increases the risk of elevated prolactin levels and prolactinomas, which are non-cancerous tumors of the pituitary gland. While not typically life threatening, prolactinomas can damage your vision and cause headaches if not treated properly. Any changes in your vision, the occurrence of headaches that are worse when waking up in the morning, or any milky discharge from the nipples must be reported to your prescribing physician.
	Taking estrogen can cause nausea and vomiting. Any long-term nausea or vomiting must be reported to your prescribing physician.
	Taking estrogen can cause migraines or can make them worse if you already have them.
	Taking estrogen can cause hot flashes.
	Taking estrogen can cause you to feel tired and have difficulty focusing.

Risks of Androgen Blockers and Antiandrogens (Spironolactone and Bicalutamide)

Patient	Statement
	Taking Spironolactone affects the balance of water and salt in the kidneys, which may: • Increase the amount of urine produced by your kidneys, making it necessary to urinate more frequently • Increase your thirst • Increase your risk of dehydration, which can be evidenced by less frequent urination than usual, dark and strong-smelling urine, thirst, and light-headedness
	Taking Spironolactone affects the balance of potassium in the kidneys, which may result in you experiencing high potassium levels resulting in: • Changes in heart rhythms that may be life threatening • Low blood pressure, which can cause: o Fatigue o Lightheadedness o Tingling feelings o Muscle weakness o Shortness of breath • Your need for regular blood tests to monitor risks while on the medication
	Taking Bicalutamide may cause numerous side effects which should be reported to your prescribing physician, including: • Hot flashes or flushing • Bone, back, or pelvic pain • Muscle weakness • Muscle or joint pain • Headaches • Shortness of breath • Chest pain • Elevated blood pressure • Swelling of the hands, feet, ankles, or lower legs • Cough • Constipation • Nausea • Vomiting • Abdominal pain • Diarrhea • Gas • Changes in weight (loss or gain) • Loss of appetite

	• Dizziness • Pain, burning, or tingling in the hands or feet • Difficulty sleeping • Feeling of uneasiness or dread • Rash • Sweating • Need to urinate frequently during the night • Bloody urine • Painful or difficult urination • Frequent and urgent need to urinate • Difficulty emptying bladder • Painful or swollen breasts • Yellowing of the skin or eyes • Pain in the upper right part of the abdomen • Extreme tiredness • Unusual bleeding or bruising • Lack of energy • Upset stomach • Loss of appetite • Flu-like symptoms • Dull or sharp side pain

Requirements of Treatment with Feminizing Medications

Patient	Statement
	Compliance with the requirements explained above is a prerequisite for you to receive treatment with feminizing medications.
	The prescribing physician may stop prescribing feminizing medications if the prescribing physician or mental health care professionals providing treatment pursuant to this consent determine the benefit of treatment no longer outweighs the risks, there is insufficient social or psychological support, or the requirements in this consent are not met.
	I can change my mind and stop treatment at any time.

Prevention of Complications while under Treatment with Feminizing Medications

Patient	Statement
	I agree to notify the prescribing physician if I suffer from any side effects during treatment or are unhappy with the treatment in any way, particularly if I have any concerns about worsening signs of depression or anxiety or if I desire to harm myself or attempt suicide.

	I acknowledge that taking feminizing medications is only a part of my overall health, and that a range of preventative health activities are necessary so that remain healthy. These include, but are not limited to: • Monthly breast self-examination (report any new lumps to the prescribing physician) • Regular age-appropriate breast mammograms • Regular age-appropriate prostate examinations • Appropriate immunizations • Regular STI screening depending on my level of risk • HIV prevention depending on my level of risk • Regular physical activity, including resistance exercise for bone health • Healthy eating • Quitting smoking
	The prescribing physician is required to monitor me for any side effects during treatment and may refer me to another physician or specialist for treatment. I agree to go to any physicians and specialists recommended by the prescribing physician.

CONSENT:

The signature below confirms the following:

1. The prescribing physician has fully informed me about:
   a. the benefits and risks of taking feminizing medications;
   b. the possible or likely consequences of hormone therapy; and
   c. potential alternative treatments.

2. The information provided to me in this form and by the prescribing physician includes the known effects and risks of treatment with feminizing medications. I know that there may be other unknown short-term and long-term effects or risks which may be irreversible.

3. I have had sufficient time and opportunity to discuss relevant treatment options with the prescribing physician.

4. All my questions have been answered to my satisfaction by the prescribing physician.

5. I know enough to give informed consent for me to take, refuse, or postpone taking feminizing medications.

6. The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.52, F.S. This form contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your physician.

7. My signature below attests to my consent to begin treatment with feminizing medications.

_____
Patient's printed name (required)

_____ _____
Patient's signature (required) Date

PRESCRIBING PHYSICIAN SIGNATURE:

My signature below attests to my compliance with section 456.52, Florida Statutes.

_____
Prescribing physician's printed name (required)

_____ _____
Prescribing physician's signature (required) Date

WITNESS:

_____
Witness' printed name (required)

_____ _____
Witness' signature (required) Date

FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:

I certify that I am fluent in English and in the native language of the person indicating consent on the above form. I certify that I have accurately and completely interpreted the contents of this form, and that the patient has indicated understanding of the contents of this form.

_____
Interpreter's printed name

_____ _____
Interpreter's signature Date

DH5082-MQA (Rev. 06/23)
Rules 64B8ER23-8 and 64B15ER23-10

Masculinizing Medications for Patients with Gender Dysphoria

Patient Information and Informed Consent

Before starting or continuing treatment with hormones or hormone antagonists, you need to be aware of the effects and possible risks associated with the use of these medications.

The prescribing physician will make a medical decision, in consultation with you, about the medications that are best for you, keeping in mind your overall health during your gender transition process. The effects and possible risks associated with the use of these medications will be discussed with you. It your responsibility to read and understand the following information and raise any questions you have with your prescribing physician.

After your questions or concerns are addressed and you have decided to start or continue hormones or hormone antagonists, you will need to initial the statements below and sign this form.

Medical treatment of people with gender dysphoria is based on very limited, poor-quality research with only subtle improvements seen in some patient's psychological functioning in some, but not all, research studies. This practice is purely speculative, and the possible psychological benefits may not outweigh the substantial risks of medical treatments and, in many cases, the need for lifelong medical treatments.

What are the medications that can masculinize one's appearance?

Treatment with hormones is called hormone replacement therapy or HRT. HRT will require taking testosterone, which increases muscle mass and causes the development of facial hair and a deeper voice. Testosterone when used by biological women, even when the criteria listed below are followed, does not have the U.S. Food and Drug Administration (FDA) approval to be used in the treatment of gender dysphoria and is considered "off label" use because they are not being used for their intended purpose.

Please initial below to acknowledge your understanding of the information on this page.

Patient

DH5083-MQA (Rev. 06/23)
Rules 64B8ER23-8 and 64B15ER23-10

How is testosterone taken?

Testosterone is usually injected every one to four weeks. Typically, it is not used as a pill because the body may not absorb it properly and may cause potentially fatal liver problems. The doses used for injection differ from product to product and from patient to patient. The injections are given in the muscle (intramuscular) or can be given with a smaller needle under the skin (subcutaneous). Taking testosterone may cause unwanted swings in hormone levels based on the amount and how often doses are given. Skin creams and patches may also be used. Both testosterone and the treatment process can affect mood. Therefore, individuals must be under the care of a licensed mental health care professional while undergoing treatment.

Finasteride is a treatment option for individuals experiencing bothersome alopecia resulting from higher dihydrotestosterone levels. The administration of 5α-reductase inhibitors block the conversion of testosterone to the more potent androgen dihydrotestosterone. The FDA approved indications of finasteride administration include benign prostatic hypertrophy and androgenetic alopecia. The use of 5α-reductase inhibitors may impair clitoral growth and the development of facial and body hair. Future studies are needed to assess the efficacy and safety of 5α-reductase inhibitors in treatment for gender dysphoria.

Every medication has risks, benefits, and side effects that are important to understand before taking. The effects and side effects of medicines used to treat gender dysphoria must be monitored with laboratory studies and regular visits to the prescribing physician to make sure that there are no negative medical or mental health effects.

What are my other options if I do not wish to start or continue medical treatments?

One option available is psychological therapy with a mental health care provider. This is recommended regardless of whether the individual undergoes treatment with hormones or hormone antagonists or not, due to the high risk of anxiety, depression, self-harm, and suicide. Other options may be discussed with your prescribing physician.

Please initial below to acknowledge your understanding of the information on this page.

Patient

What are the requirements to receive hormone replacement therapy?

To receive hormone replacement therapy, there are specific requirements that need to be met before and during the treatment. These requirements will allow the prescribing physician to monitor medical as well as mental health wellbeing during HRT. If these requirements are not met, HRT may be discontinued by the prescribing physician.

Before beginning HRT and every two years thereafter, the individual needs to undergo a thorough psychological and social evaluation performed by a Florida licensed board-certified psychiatrist or a Florida licensed psychologist. The psychiatrist or psychologist must submit a letter to the prescribing physician confirming this.

The specific requirements for an individual to receive and continue HRT treatment include the following:

1. Has met the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders (DSM) or International Classification of Diseases (ICD);
2. Mental health and physical conditions that could negatively impact the outcome of treatment have been assessed, with risks and benefits discussed;
3. Demonstrates capacity to consent for the specific gender dysphoria hormone treatment;
4. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
5. Has psychological and social support during treatment;
6. Demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of HRT as well as the medical and social risks and benefits of sex reassignment surgery; and
7. Understands the effect of hormone treatment on reproduction and they have explored reproductive options.

Please initial below to acknowledge your understanding of the information on this page.

Patient

The following may also be recommended by your prescribing physician:

1. Undergoes an in-person evaluation by the prescribing physician or their designated covering physician every 3 months for the initial year and at least annually thereafter;
2. Undergoes a suicide risk assessment by a licensed mental health care professional at least every 3 months for the initial year and at least annually thereafter;
3. Undergoes relevant laboratory testing, at least every 6 months;
4. Annual bone scan (DEXA) once a year for the first 5 years to allow monitoring of bone density (bone strength) during treatment, which can be altered by HRT;
5. Annual mental health assessments by a board-certified Florida licensed psychiatrist or psychologist; and
6. Continued counseling with a licensed mental health care professional during the treatment period, with the frequency recommended by the licensed mental health care professional.

Summary of Testosterone Benefits and Risk

BENEFITS	RISKS
• Appear more like a man • Bigger clitoris • Coarser skin • Lower voice • More body hair • More facial hair • More muscle mass • More strength • No or minimal menstrual periods • More physical energy • More sex drive	• Acne (may permanently scar) • Blood clots (thrombophlebitis), risk significantly increased by smoking • Emotional changes, for example, more aggression • Headache • High blood pressure (hypertension) • Increased red-blood-cell count • Infertility • Inflamed liver • Interaction with drugs for diabetes and blood thinning — for example Coumadin and Warfarin • Male pattern baldness • More abdominal fat — redistributed to a male shape • Risk of heart disease • Swelling of hands, feet, and legs • Weight gain

Please initial below to acknowledge your understanding of the information on this page.

Patient

Please initial each statement on this form to show that you understand the benefits, risks, and changes that may occur from taking testosterone.

Masculinizing Effects

Patient	Statement
	Testosterone may be prescribed to make me appear less like a female and more like a male.
	It can take several months or longer for the effects of testosterone to become noticeable and no one can predict how fast or how much change will occur.
	The following changes are likely to be permanent even if testosterone is discontinued: • Bigger clitoris - typically about half an inch to a little more than an inch • Deeper voice • Gradual growth of moustache and beard • Hair loss at the temples and crown of the head and the possibility of being completely bald • More, thicker, and coarser hair on abdomen, arms, back, chest, and legs
	The following changes could be permanent, but may improve if I stop taking testosterone: • Acne (although there may be permanent scars) • Menstrual periods (if present), typically stop one to six months after starting • More abdominal fat – redistributed to a male shape: decreased on buttocks, hips, and thighs; increased in abdomen – changing from "pear shape" to "apple shape" • More muscle mass and strength • More sexual interest • Vaginal dryness • Vaginal Tearing • Vaginal Bleeding • Vaginal Pain • Vaginal infection • Painful intercourse
	This treatment will not change the individual' s biological sex or chromosomes.
	Testosterone may reduce the ability to become pregnant, but it will not eliminate the risk of pregnancy. A person may become pregnant while on testosterone. I agree to inform the prescribing physician if I become pregnant.
	Some aspects of my body will not change:

	• Fat loss may make breasts appear slightly smaller • The voice will deepen, but other aspects of the way I speak may not sound more masculine
	Mood changes may be caused by these medicines, and I will continue therapy with a licensed mental health care professional during treatment.
	Using these medicines to masculinize is an off-label use of the medications. This means these medications are not approved by the FDA for this purpose. I know that the medicine and dose that is recommended is based solely on the judgment and experience of the prescribing physician and there is no data in the medical literature or controlled research studies that support the timing, dosing, and type of administration of HRT.

Risks of Testosterone

Patient	Statement
	Testosterone **SHOULD NOT** be used by anyone who: • Is pregnant • Has uncontrolled coronary artery disease as it could increase your risk for a fatal heart attack
	It should be used **WITH CAUTION** and only after a full discussion of risks by anyone who: • Has acne • Has a family history of heart disease or breast cancer • Has had a blood clot • Has high levels of cholesterol • Has liver disease • Has a high red blood cell count • Is obese • Smokes cigarettes
	The medical effects and the safety of testosterone are not completely known and there may be unknown long-term risks.
	Taking testosterone causes changes that other people will notice.
	Treatment with testosterone will not prevent serious psychiatric events, including suicide.
	Taking more testosterone than prescribed: • Will increase health risks; • Will not make changes happen more quickly or more significantly; and • May cause the body to convert extra testosterone into estrogen that can slow down or stop me from appearing more masculine.
	Taking testosterone can cause changes that increase the risk of heart disease. These changes include:

	• Less good cholesterol (HDL) that may protect against heart disease and more bad cholesterol (LDL) that may increase the risk of heart disease; • Higher blood pressure; and • More deposits of fat around the internal organs
	Taking testosterone can damage the liver and possibly lead to liver disease.
	Taking testosterone can increase red blood cells and hemoglobin, which may increase my risk of life-threatening problems such as stroke or heart attack.
	Taking testosterone can increase the risk for diabetes (high blood sugars), which decrease the body's response to insulin, cause weight gain, and increase deposits of fat around internal organs increasing the risk of heart disease and stroke.
	Treatment with testosterone can cause ovaries to not release eggs and may cause infertility.
	Treatment with testosterone increases the risk of cancer to the uterus, ovaries, or breasts. It is unclear if taking testosterone plays any role in HPV infection or cervical cancer.
	Taking testosterone causes or worsens migraines.
	Taking testosterone can cause emotional changes, such as irritability, frustration, aggression, and anger.

Risks of Finasteride

Patient	Statement
	Finasteride may be an appropriate treatment option in individuals experiencing bothersome alopecia resulting from testosterone treatment.
	Finasteride may have side effects which include: • decreased libido • dry skin • acne • Breast swelling and tenderness • headache • irregular menstruation • dizziness • increased body hair
	Finasteride is not approved by the FDA for use in biological women and is forbidden in pregnant women due to birth defects.

Requirements of Treatment with HRT

Patient	Statement
	Compliance with the requirements explained above is a prerequisite to receive treatment with testosterone.
	The prescribing physician may stop prescribing testosterone if the prescribing physician or mental health care professionals providing treatment pursuant to this consent determine the benefit of treatment no longer outweighs the risks, there is insufficient social or psychological support, or the requirements in this consent are not met.
	I understand that I may decide to stop treatment at any time.

Prevention of Complications while under Treatment of HRT

Patient	Statement
	I agree to notify the prescribing physician if I suffer from any side effects during treatment or am unhappy with the treatment in any way, and if I have any concerns that I have worsening signs of depression or anxiety or wants to harm myself or attempt suicide or attempt suicide.
	The prescribing physician is required to monitor me for any side effects during treatment and may refer me to another physician or specialist for treatment.

CONSENT:

My signature below confirms that:

1. My prescribing physician has talked with me about:
   a. the benefits and risks of taking testosterone;
   b. the possible or likely consequences of hormone therapy; and
   c. potential alternative treatments.

2. The information provided to me in this form and by the prescribing physician includes the known effects and risks of treatment with testosterone. I know that there may be other unknown short-term and long-term effects or risks which may be irreversible.

3. I have had sufficient time and opportunity to discuss relevant treatment options with my prescribing physician.

4. All my questions have been answered to my satisfaction by my prescribing physician.

5. I know enough to give informed consent to take, refuse, or postpone taking testosterone.

6. The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.52, F.S. This form contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your physician.

7. My signature below attests to my consent to begin treatment with testosterone.

Based on all this information:

_____ I want to begin or continue taking testosterone
_____ I want to begin or continue taking finasteride
_____ I do not wish to begin or continue taking masculinizing medication

_____
Patient's printed name (required)

_____ _____
Patient's signature (required) Date

PRESCRIBING PHYSICIAN:

My signature below attests to my compliance with 456.52, Florida Statutes.

_____
Prescribing physician's printed name (required)

_____ _____
Prescribing physician's signature (required) Date

WITNESS:

Witness' printed name (required)

Witness' signature (required) Date

FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:

I certify that I am fluent in English and in the native language of the person indicating consent and/or assent on the above form. I certify that I have accurately and completely interpreted the contents of this form, and that the patient has indicated understanding of the contents of this form.

Interpreter's printed name

Interpreter's signature Date

Surgical Treatment for Adults with Gender Dysphoria

Patient Information and Informed Consent

Before having surgery to treat gender dysphoria, you need to be aware of the effects and possible risks of these procedures. Your surgeon will make a medical decision, in consultation with you, about the procedures that are best for you, keeping in mind your overall health.

Your surgeon will discuss with you all the information relating to the surgery. You are asked to read and understand the following information and to discuss any questions you have with your surgeon. After your questions or concerns are addressed and you have decided to have surgery you must initial the statements below and sign this form in person with your surgeon.

Medical treatment of people with gender dysphoria is based on very limited, poor-quality research with only subtle improvements seen in some patient's psychological functioning in some, but not all, research studies. This practice is purely speculative, and the possible psychological benefits may not outweigh the substantial risks of medical treatments and, in many cases, the need for lifelong medical treatments.

What are the types of surgery to treat gender dysphoria?

Surgery to treat gender dysphoria may involve procedures on the face, chest, or genitalia. Common surgery options include:

- **Facial reconstructive surgery** to make facial features more masculine or feminine.
- **Chest or "Top" surgery** to remove breast tissue for a more masculine appearance or enhance breast size and shape for a more feminine appearance.
- **Genital or "Bottom" surgery** to transform and reconstruct the genitalia.
  - **Orchiectomy:** A bilateral orchiectomy is a procedure performed by a urologist that involves surgical removal of the testicles through a small scrotal incision. This procedure is done with a particular technique that allows for vaginoplasty later, if desired. Afterward, patients may adjust their dose of estrogens downward and no longer require spironolactone. Recovery takes approximately 2 weeks. Individuals seeking orchiectomy may wish to consider semen banking to preserve future fertility options.

Please initial below to acknowledge your understanding of the information on this page.

Patient

DH5084-MQA (Rev. 06/23)
Rules 64B8ER23-8 and 64B15ER23-10

- **Vaginoplasty:** In addition to an orchiectomy, a person may elect to undergo a vaginoplasty, which is a surgical procedure that involves reconstructing the genitals to create external female genitalia with or without a vaginal cavity. For those patients treated with puberty blockers as a minor, such treatment may lead to insufficient penile tissue that could necessitate the use other tissues, such as the colon, to create a vagina.
- **Phalloplasty:** This surgery involves a multi-staged procedure for the creation of a penis. urinary channel to allow urination, scrotum, and the obliteration of the vaginal cavity with closure. The removal of the female genital organs such as the uterus and ovaries and fallopian tubes are required and usually performed separately and prior to the phalloplasty surgery. The creation of the penis is performed with use of tissue from other parts of the body, which could include, more commonly the radial forearm free flap. or anterolateral thigh flap, and latissimus dorsi (MLD) flap. Prosthetics such as silicone or saline testicles can be placed as well as inflatable penile prosthetics in the final stage.
- **Metoidioplasty:** In this procedure, the surrounding tissue of the clitoris is released to achieve maximal length and a more natural-looking male position. A urethra is also reconstructed using either local skin tissue or a graft from the mouth depending on the amount of tissue present. Construction of a scrotum with testicular prosthetics can also be performed at the same time.
- **Hysterectomy:** Removal of the uterus and cervix via laparoscopic or vaginal techniques.
- **Salpingo-oophorectomy:** Removal of the fallopian tubes and ovaries.
- **Vaginectomy:** Obliteration of the vaginal canal and opening.

Is surgery the only treatment for gender dysphoria?

Surgery is just one option. Not everyone who has gender dysphoria chooses to have surgery. Depending on your age and preferences, you may choose:

- Treatment by a licensed mental health care professional that has experience in treating people with gender dysphoria, which is recommend regardless of whether you undergo surgery due to the high risk of anxiety, depression, self-harm, and suicide.
- Hormone replacement therapy to increase masculine or feminine characteristics.

Other options may be discussed with your prescribing physician.

Please initial below to acknowledge your understanding of the information on this page.

Patient

What are some potential complications of surgery to treat gender dysphoria?

Potential complications include:

- Changes in sexual sensation
- Diminishment of bladder function
- Problems with urination
- Bleeding
- Infection
- Nerve damage
- Poor healing
- Scarring that can cause pain, firmness, asymmetry
- Side effects of anesthesia, including death

What happens after surgery to treat gender dysphoria?

Recovery times vary based on what procedures or combination of procedures you have as follows:

- **Cheek and nose surgery:** Swelling lasts for around two to four weeks.
- **Chin and jaw surgery:** Most swelling fades within two weeks but may take up to four months for swelling to completely disappear.
- **Chest surgery:** Swelling and soreness lasts for one to two weeks with physical limitations lasting at least one month.
- **Bottom surgery:** Most people do not resume usual activities until at least six weeks after surgery and weekly follow-up visits with your surgeon for several months will be necessary.

When should I see my surgeon?

After surgery, you should see your surgeon if you experience:

- Bleeding for more than a few days.
- Pain that does not go away after several weeks.
- Signs of infection, such as a wound that changes color or does not heal.

Please initial below to acknowledge your understanding of the information on this page.

Patient

Please initial each statement on this form to show that you understand the risks and changes associated with gender dysphoria surgeries.

Patient	Statement
	I understand that my surgeon will discuss with me during the preoperative process the available surgical procedures to treat gender dysphoria, the aftercare needs following surgery, and the importance of postoperative follow-up.
	I understand that these surgeries are permanent.
	I understand that if I have my breasts removed, I must undergo reconstructive surgery if I wish to have breasts in the future. If implants are used, complications may include pain, numbness, infection, bleeding, asymmetry, hardening, rippling, scarring, and the possible need for multiple surgeries.
	I understand that if I have my breasts removed that breast feeding will never be possible.
	I understand that if I have breast augmentation surgery, complications may include pain, numbness, infection, bleeding, asymmetry, hardening, rippling, scarring, and the possible need for multiple surgeries.
	I understand that my surgeon will assess me for risk factors associated with breast cancer prior to breast augmentation or mastectomy, including genetic mutations (e.g.., BRCA1, BRCA2), family history, age, radiation, exposure to estrogen, and the amount of breast tissue anticipated to remain after surgery.
	I understand that if I undergo metoidioplasty/phalloplasty I will need lifelong urological treatment.
	I understand that complications following metoidioplasty/phalloplasty include: • urinary tract strictures and fistulas • mucoceles due to vaginal remnant • hair growth within the neourethra • compromised sexual function including absent tactile and/or erogenous sensation, difficulties achieving orgasm • complications with penile prosthetics
	I understand that if I undergo vaginoplasty I will need lifelong treatment with my surgeon, primary care physician, and/or gynecologist.
	I understand that if I undergo vaginoplasty, complications can include: • the formation of granulation tissue • intravaginal hair growth • delayed wound healing and/or wound disruption • introital stenosis (closing, narrowing, or closure)

	• painful sex
	I understand that my surgeon may stop further treatment because the risks of treatment outweigh the benefits of treatment.
	I understand that this treatment will not prevent serious psychiatric events, including suicide.
	I agree to tell my surgeon if I have any problems or side effects or am unhappy with the surgery, including if I have worsening signs of depression or anxiety or want to harm myself or attempt suicide.
	I understand that my surgeon may be required to refer me to one or more specialists for surgery-related complications, and I agree to go to those specialists as recommended.
	I acknowledge that surgery to treat gender dysphoria is only part of my overall health and that a range of preventative health activities are recommended including: • cervical/prostrate screening tests at appropriate intervals as recommended by my doctor • regularly checking my breasts for lumps, even if I have had a mastectomy • regular mammograms from an appropriate age in consultation with my doctor • quitting smoking • immunizations • regular STI screening, depending on my level of risk • HIV prevention, depending on my level of risk • regular physical activity, including resistance exercise for bone health • healthy eating

CONSENT:

My signature below confirms that:

1. My surgeon has talked with me about:
   a. the benefits and risks of surgery to treat gender dysphoria;
   b. the possible or likely consequences of surgery to treat gender dysphoria;
   c. potential alternative treatments.

2. The information provided to me in this form and by the surgeon includes the known effects and risks of surgery to treat gender dysphoria. I know that there may be other unknown short-term and long-term effects or risks which may be irreversible.

3. I have had sufficient time and opportunity to discuss relevant treatment options with my surgeon.

4. All my questions have been answered to my satisfaction by my surgeon.

5. I know enough to give informed consent to have, refuse, or postpone surgery to treat gender dysphoria.

6. The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.52, F.S. This form contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your surgeon.

7. My signature below attests to my consent to surgery to treat gender dysphoria.

My signature below confirms the following:

_____ _____

Patient's signature (required) Date

_____ _____

Patient's signature (required) Date

SURGEON:

My signature below attests to my compliance with 456.52, Florida Statutes.

_____
Surgeon's printed name (required)

_____ _____
Surgeon's signature (required) Date

WITNESS:

_____
Witness' printed name (required)

_____ _____
Witness' signature (required) Date

FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:

I certify that I am fluent in English and in the native language of the person indicating consent on the above form. I certify that I have accurately and completely interpreted the contents of this form, and that the patient has indicated understanding of the contents of this form.

_____

Interpreter's printed name

_____ _____

Interpreter's signature Date

FLORIDA DEPARTMENT of STATE

RON DESANTIS
Governor

CORD BYRD
Secretary of State

August 18, 2023

Cassandra P. Fullove
Senior Legal Assistant
Office of the Attorney General
PL-01, The Capitol
Tallahassee, FL 32399-1050

Dear Cassandra P. Fullove:

Your adoption package for Emergency Rule 64B8ER23-11 was received, electronically, by the Florida Department of State, Administrative Code and Register 3:49 p.m. on August 18, 2023. 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 August 18, 2023.

Sincerely,

Anya C. Owens
Administrative Code and Register Director

ACO/al

R. A. Gray Building • 500 South Bronough Street • Tallahassee, Florida 32399-0250
Telephone: (850) 245-6270

Leijon, Alexandra

From: Cassandra Fullove <Cassandra.Fullove@myfloridalegal.com>
Sent: Friday, August 18, 2023 3:49 PM
To: Owens, Anya C.; Leijon, Alexandra; RuleAdoptions
Subject: 64B8ER23-11, F.A.C.
Attachments: 64B8ER23-11 emergency rule packet.pdf; Text.docx

Hello,

Attached is the emergency rule filing for 64B8ER23-11, F.A.C. If you have any questions do not hesitate to contact me. Thank you.

Cassandra P. Fullove
Senior Legal Assistant
Administrative Law Bureau
Office of the Attorney General
PL-01, The Capitol
Tallahassee, FL 32399-1050
Office: (850) 414-3766
Fax: (850) 922-6425
Cassandra.Fullove@myfloridalegal.com

ASHLEY MOODY
ATTORNEY GENERAL
STATE OF FLORIDA

OFFICE OF THE ATTORNEY GENERAL
Cassandra P. Fullove
Senior Legal Assistant
Administrative Law Bureau

PL-01 The Capitol
Tallahassee, FL 32399-1050
Phone (850) 414-3300
Fax (850) 922-6425
Cassandra.Fullove@myfloridalegal.com
http://www.myfloridalegal.com

M E M O R A N D U M

TO: Anya C. Owens, Program Administrator
Bureau of Administrative Code

FROM: Cassandra P. Fullove, Senior Legal Assistant

RE: Department of Health
Board of Medicine
Emergency Rule 64B8ER23-11

DATE: August 18, 2023

Attached are the following documents regarding the above-referenced emergency rule adoption packet.

1. Notice of Emergency Rule
2. Adoption text for Emergency Rule 64B8ER23-11
3 Certification of Board of Medicine Emergency Rule
3. Designation of Rule the Violation of Which is a Minor Violation
4. Certification of Materials Incorporated by Reference in Emergency Rules
5. Form DH-5082-MQA (08/23)
6. Form DH-5083-MQA (08/23)
7. Form DH-5084-MQA (08/23)

Should you have any questions regarding the rule do not hesitate to contact me.

Thank you.

CERTIFICATION OF BOARD OF MEDICINE

EMERGENCY RULE FILED WITH THE

DEPARTMENT OF STATE

I hereby certify that pursuant to Ch 2023-90 Laws of Florida, Section 5, section 456.52, Florida Statutes was created and pursuant to subparagraphs 456.52(1)(a) and (6)(a), F.S., the Board of Medicine is required to adopt emergency rules to implement the section. 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), F.S. 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.

64B8ER23-11

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 Scot Ackerman, 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), F.S., 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).:

64B8ER23-11

Signature of Agency Head

Paul Vazquez, Executive Director for
Scot Ackerman, 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 NO.: RULE TITLE:

64B8ER23-11 Mandatory Standardized Informed Consent for Sex-reassignment Prescriptions or Procedures in Adults

SPECIFIC REASONS FOR FINDING AN IMMEDIATE DANGER TO THE PUBLIC HEALTH, SAFETY OR WELFARE: On May 17, 2023, Florida Governor, Ronald DeSantis, signed CSSB 254 into law creating Ch. 2023-90, Laws of Florida and section 456.52, *Florida Statutes*. Pursuant to section 456.52(2), F.S., if sex reassignment prescriptions or procedures are prescribed for or administered to patients 18 years of age or older, consent must be voluntary, informed, and in writing on forms adopted in rule by the Board of Medicine. Pursuant to section 456.52(4), F.S., the consent required for sex-reassignment prescriptions does not apply to renewals of sex-reassignment prescriptions if a physician and his or her patient have met the requirements for consent for the initial prescription. Section 456.52(6)(a), F.S., states "[t]he Board of Medicine and the Board of Osteopathic Medicine shall adopt emergency rules to implement this section."

Accordingly, the Board of Medicine, by emergency rule, hereby adopts the incorporated mandated consent forms for the treatment of gender dysphoria with hormone replacement therapy and surgical treatment for patients 18 years of age or older.

*** This emergency rule does not apply to Susan Doe, Gavin Goe, or Lisa Loe, or their parents or healthcare providers (see Jane Doe et al., v. Joseph A. Ladapo, et al, Preliminary Injunction, Filed June 6, 2023, Case No. 4:23cv114-RH-MAF, United States District Court for the Northern District of Florida). ***

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. CSSB 254 was signed into law on May 17, 2023. The Board of Medicine was contacted by multiple licensed physicians and physician groups seeking clarification regarding the exception contained in section 465.52(4), F.S., and a timeframe for the required emergency rules shortly thereafter. In response, the Board of Medicine and the Board of Osteopathic Medicine held a Joint Rules/Legislative Committee (Joint Committee) meeting on June 1, 2023, to discuss the emergency rule. On May 19, 2023, the Board of Medicine published notice of the Joint Committee's June meeting both on its website and in the Florida Administrative Register. On June 2, 2023, the Board of Medicine discussed

the report of the Joint Committee and voted upon emergency rule language that would allow for the renewal of previous prescriptions while the Board worked on consent forms. The Board of Medicine published notice of its June 2, 2023, meeting in the Florida Administrative Register on May 5, 2023, and on its website on May 12, 2023.

The Joint Committee held yet another meeting on June 23, 2023, to discuss an emergency rule adopting draft consent forms that were under consideration. On June 6, 2023, the Board of Medicine published notice of the Joint Committee's June 23 meeting to its website and in the Florida Administrative Register. On June 30, 2023, the Boards of Medicine and Osteopathic Medicine held a Joint Board meeting (Joint Board Meeting) to discuss the draft consent forms that were approved by the Joint Committee on June 23. The Joint Board meeting was held via Microsoft Teams and notice of the same was published to the Board of Medicine's website and in the Florida Administrative Register on June 22, 2023. During the June 30, 2023, Joint Board Meeting, the Boards voted to approve consent forms and adopted them via emergency rule filed on July 5, 2023.

On July 21, 2023, the Board received correspondence from the Joint Administrative Procedures Committee (JAPC) questioning the Board's statutory authority for requiring that adult patients "undergo a thorough psychological and social evaluation performed by a Florida licensed board-certified psychiatrist or a Florida licensed psychologist" before beginning hormone replacement therapy and every two years thereafter. Accordingly, the Florida Board of Medicine and Osteopathic Medicine's Joint Rules/Legislative Committee held a public meeting on August 3, 2023, and voted to remove the provision addressed by JAPC. The Board of Medicine discussed the Joint Committee's report and affirmed the decision at its August 4, 2023, Board meeting.

The August 3 Joint Committee meeting was held in person in a public forum and was able to be attended by any interested parties. Notice of the Joint Committee meeting was published to the Board of Medicine's website and in the Florida Administrative Register on July 13, 2023. The August 4 Board Meeting was also held in person in a public forum and was able to be attended by any interested parties. Notice for the August 4 Board Meeting was published to the Board of Medicine's website on July 13, 2023, and in the Florida Administrative Register on July 12, 2023.

Public comment was accepted at all of the aforementioned board and committee meetings. Further, the Boards accepted written public comment on the initial proposed rules up and until 24 hours prior to the Joint Board Meeting. The Board also accepted written comments up and until 24 hours prior to the August 3, 2023, Joint Rules/Legislative Committee meeting as well. Accordingly, all notice requirements contained in Rule 28-102.001,

F.A.C., were properly complied with at all points during the rulemaking process and interested parties were given ample opportunity to participate at all points during this rulemaking process.

SUMMARY: The proposed emergency rule formally adopts the required consent forms for an adult patient to receive sex-reassignment prescriptions and/or procedures per section 456.52(2), *Florida Statutes*.

THE PERSON TO BE CONTACTED REGARDING THE EMERGENCY RULE IS: Paul Vazquez, Executive Director, Board of Medicine, 4052 Bald Cypress Way, Bin # C-03, Tallahassee, Florida 32399-3253.

64B8ER23-11 Mandatory Standardized Informed Consent for Sex-reassignment Prescriptions or Procedures in Adults

Pursuant to Section 456.52, Florida Statutes, when sex-reassignment prescriptions or procedures are prescribed for or administered or performed on patients 18 years of age or older, the physician is required to obtain voluntary, informed consent while physically present in the same room as the patient. Consent is not required for renewal of such prescriptions if a physician and the physician's patient have met the requirements for consent for the initial prescription or renewal; however, a separate consent is required for any new prescription for a pharmaceutical product not previously prescribed to the patient.

(1) Informed Consent. The Board has approved the following mandatory informed consent forms for sex-reassignment prescriptions or procedures for patients 18 years of age or older:

(a) For patients prescribed sex-reassignment feminizing medication, form DH5082-MQA, (Rev. 08/23), entitled "Feminizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Consent," which is hereby incorporated by reference and available from the Board's website at https://flboardofmedicine.gov/forms/Feminizing-Medications-for-Patients-with-Gender-Dysphoria-Patient-Information-and-Informed-Consent.pdf.

(b) For patients prescribed sex-reassignment masculinizing medications, form DH5083-MQA, (Rev. 08/23), entitled "Masculinizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Consent," which is hereby incorporated by reference and available from the Board's website at https://flboardofmedicine.gov/forms/Masculinizing-Medications-for-Patients-with-Gender-Dysphoria-Patient-Information-and-Informed-Consent.pdf.

(c) For patients undergoing surgical treatment, form DH5084-MQA, (06/23), entitled "Surgical Treatment for Adults with Gender Dysphoria, Patient Information and Informed Consent," which is hereby incorporated by reference and available from the Board's website at https://flboardofmedicine.gov/forms/Surgical-Treatment-for-Adults-with-Gender-Dysphoria-Patients-Information-and-Informed-Consent.pdf.

(2) A Board-approved informed consent form is not executed until:

(a) The physician issuing the prescription or performing the procedure, while physically present in the same room as the patient, has informed the patient of the nature and risks of the prescription or procedure and has provided and received the patient's written acknowledgement before the prescription is prescribed, administered, or performed. The

physician is prohibited from delegating this responsibility to another person. The physician is also required to sign the informed consent form.

(b) The patient is required to sign the informed consent form.

(c) A competent witness is also required to sign the informed consent form.

Rulemaking Authority 456.52 FS. Law Implemented 456.52 FS. History – New____.

CERTIFICATION OF MATERIALS INCORPORATED

BY REFERENCE IN EMERGENCY RULES FILED WITH THE DEPARTMENT OF STATE

I hereby certify pursuant to Rule 1-1.013, Florida Administrative Code, that materials incorporated by reference in Emergency Rule 64B8ER23-11 have been:

[x] (1) Filed with the Department of State and included as part of the Emergency Rule adoption packet.

[ ] (2) That because there would be a violation of federal copyright laws if the submitting agency filed the incorporated materials as described in option (1) above, a true and complete copy of the incorporated materials has been provided to the Department of State as outlined in paragraph 1-1.013(5)(c), F.A.C.

Copies of the incorporated materials below may be obtained at the agency by [include address(es)/location(s)].

List form number(s) and form title(s), or title of document(s) below:

DH5082-MQA Feminizing Medications for Patient with Gender Dysphoria-Patient Information and Informed Consent

DH5083-MQA Masculinizing Medications for Patients with Gender Dysphoria-Patient Information and Informed Consent

DH5084-MQA Surgical Treatment for Adults with Gender Dysphoria-Patients Information and Informed Consent

Under the provisions of Section 120.54(4)(d), F.S., the attached material(s) take effect upon filing with the Department of State, or a date less than 20 days thereafter if specified in the rule if the adopting agency finds that such effective date is necessary because of immediate danger to the public health, safety, or welfare.

Signature, Person Authorized to Certify Rules

Paul Vazquez, Executive Director for
Scot Ackerman, M.D., Chair
Title

Feminizing Medications for Patients with Gender Dysphoria

Patient Information and Informed Consent

Before starting or continuing treatment with hormones or hormone antagonists, you need to be aware of the effects and possible risks associated with use of these medications.

Your prescribing physician will make a medical decision in consultation with you about the medications that are best for you, keeping in mind your overall health during the treatment process. Your prescribing physician will discuss with you all of the available information relating to hormone therapy. You are asked to read and understand the following information and to discuss any questions you have with your prescribing physician.

After your questions or concerns are addressed and you have decided to start or continue treatment with hormones or hormone antagonists, you must initial the statements below and sign this form in person with your prescribing physician.

Medical treatment of people with gender dysphoria is based on very limited, poor-quality research with only subtle improvements seen in some patient's psychological functioning in some, but not all, research studies. This practice is purely speculative, and the possible psychological benefits may not outweigh the substantial risks of medical treatments and, in many cases, the need for lifelong medical treatments.

What are the different medications that can feminize one's appearance?

Treatment with hormones is called hormone replacement therapy or HRT. HRT will require taking estrogen, as well as medicines to block the body from producing or utilizing testosterone. Use of these medications, even when the criteria listed below are followed, does not have U.S. Food and Drug Administration (FDA) approval and its use to treat gender dysphoria is considered "off label" because they are not being used for their intended purpose

Different forms of estrogen are used to feminize a person's appearance. Estrogen can be given as an injection either weekly or every other week, as a pill that is taken daily or twice a day, or as a patch that is changed weekly or every three or four days.

Please initial below to acknowledge your understanding of the information on this page.

Patient

DH5082-MQA (Rev. 08/23)
Rules 64B8ER23-11 and 64B15ER23-12

Medications that block the production or effects of testosterone are called androgen blockers. Spironolactone is the androgen blocker that is most commonly used in the United States. In some cases, Bicalutamide, an antiandrogen, is used to block the effects of testosterone, though it will not reduce testosterone levels. Bicalutamide (brand name Casodex) is a cancer drug approved for the treatment of prostate cancer. Fulminant hepatotoxicity, a severe liver injury often resulting in death, has been noted with bicalutamide use.

Cyproterone acetate, a synthetic progestogen with strong antiandrogen activity, is commonly used in many countries. When paired with estrogen, cyproterone acetate is associated with elevated prolactin, decreased HDL cholesterol, and rare meningiomas (tumors). Cyproterone acetate has also been associated with uncommon episodes of fulminant hepatitis.

The administration of finasteride blocks the conversion of testosterone to the more potent androgen dihydrotestosterone. The FDA approved uses of finasteride include the treatment benign prostatic hypertrophy and androgenic alopecia. Finasteride is not recommended for routine use in treating populations with gender dysphoria.

Various forms of progestins may also be used. This class includes micronized bioidentical progesterone (Prometrium) as well as oral medroxyprogesterone acetate (Provera). Although there are anecdotal reports of progesterone use for breast development and mood management, there is currently insufficient evidence that the potential benefits of progesterone administration outweigh the potential risks. There is also a theoretical risk of breast cancer associated with long-term exogenous progesterone.

Every medication has risks, benefits, and side effects that are important to understand before taking. The effects and side effects of medicines used to treat gender dysphoria must be monitored with laboratory studies and regular visits to your prescribing physician to make sure that there are no negative medical or mental health effects.

HRT, the use of androgen blockers and antiandrogens, and the treatment process can affect your mood. Therefore, you must be under the care of a licensed mental health care professional while undergoing treatment.

Please initial below to acknowledge your understanding of the information on this page.

Patient

What are my other options if I do not wish to start or continue treatment with hormones, hormone antagonists, or antiandrogens?

One option available is psychological therapy with a mental health provider. This is recommended regardless of whether or not the person undergoes treatment with hormones, hormone antagonists, or antiandrogens due to the high risk of anxiety, depression, self-harm, and suicide. Other options may be discussed with your prescribing physician.

What are the requirements to receive hormone replacement therapy (HRT)?

To receive HRT, there are specific requirements that need to be met before and during treatment. These requirements will allow the prescribing physician to monitor your medical and mental health status during treatment. If these requirements are not met, HRT may be discontinued by the prescribing physician.

Please initial below to acknowledge your understanding of the information on this page.

Patient

The specific requirements for you to receive and continue HRT treatment include the following:

1. Has met the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders or International Classification of Diseases;
2. Mental health and physical conditions that could negatively impact the outcome of treatment have been assessed, with risks and benefits discussed;
3. Demonstrates capacity to consent for the specific gender dysphoria hormone treatment;
4. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
5. Has psychological and social support during treatment;
6. Demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of HRT as well as the medical and social risks and benefits of sex reassignment surgery; and
7. Understands the effect of hormone treatment on reproduction and they have explored reproductive options;

The following may also be recommended by your prescribing physician:

1. Undergoes an in-person evaluation by the prescribing physician or their designated covering physician every 3 months for the initial year and at least annually thereafter;
2. Undergoes a suicide risk assessment by a licensed mental health care professional at least every 3 months for the initial year and at least annually thereafter;
3. Undergoes relevant laboratory testing at least every 6 months;
4. Annual bone density scan (DEXA) once a year for the first 5 years to allow monitoring of your bone density (bone strength) during treatment, which can be altered by HRT;
5. Annual mental health assessments by a board-certified Florida licensed psychiatrist or psychologist; and
6. Continued counseling with a licensed mental health care professional during the treatment period, with the frequency recommended by the licensed mental health care professional.

Please initial below to acknowledge your understanding of the information on this page.

Patient

Please initial each statement on this form to show that you understand the benefits, risks, and changes associated with taking feminizing medications.

Effects of Feminizing Medications

Patient	Statement
	Feminizing medications, including estrogen, androgen blockers, or antiandrogens, given singularly or in combination, may be prescribed to make me appear less like a male and more like a female.
	It can take several months or longer for the effects of feminizing medications to become noticeable and no one can predict how fast or how much change will occur.
	This treatment will not change my biological sex or chromosomes.
	If I take estrogen, the following changes in my breasts will occur: • Breasts will develop but will not reach their full size for several years • Breasts will remain even if estrogen treatment is discontinued • A milky discharge from the nipples may appear, which should be reported to my prescribing physician • My risk of breast cancer may significantly increase
	If I take feminizing medications, my body will make less testosterone, which may affect my sex life in different ways, including: • My testicles may shrink • My penis may never fully develop, particularly if I previously took puberty blockers • I will have fewer spontaneous erections • My sperm may no longer mature causing infertility which may be permanent even if treatment is discontinued, the risk of which is increased if I took puberty blockers prior to starting feminizing medications • Conversely, it is possible that my sperm could still mature while taking feminizing medications and I may cause someone to get pregnant
	The options for sperm banking have been explained.
	If I take feminizing medications, some parts of my body will not change much, including: • If present, my facial hair may grow more slowly, but it will not go away completely even after taking feminizing medications for many years • If present, my body hair may grow more slowly, but it will not go away completely even after taking feminizing medications for many years • If I went through puberty and have a deep voice, the pitch of my voice will not rise and my speech patterns will not become more like a woman's • If present, my Adam's apple will not shrink

	Even if I stop taking feminizing medications, the following changes may occur: • My body fat may be redistributed with less fat on the abdomen and more on the buttocks, hips, and thighs creating a more female shape • I may have decreased muscle mass and strength in the upper body • My skin may become softer
	Mood changes may be caused by these medicines, and I will continue therapy with a licensed mental health care professional during treatment.
	Using these medicines to feminize my body is an off-label use of the medications. This means these medications are not approved by the FDA for this purpose. I know that the medicine and dose that is recommended is based solely on the judgment and experience of my prescribing physician and there is no data in the medical literature or controlled research studies that support the timing, dosing, and type of administration of feminizing medications.

Risks of Feminizing Medications

Patient	Statement
	The medical effects and the safety of taking femininizing medications are not completely known and there may be unknown long-term risks.
	Taking femininizing medications causes changes that other people will notice.
	Treatment with femininizing medications will not prevent serious psychiatric events, including suicide.
	I must not take more feminizing medication than prescribed. Taking too much medication: • Will increase health risks • Will not make changes happen more quickly or more significantly
	Taking feminizing medication can damage the liver and possibly lead to liver disease.

Risks of Estrogen

Patient	Statement
	Estrogen **SHOULD NOT** be used by anyone who has: • Any estrogen-dependent cancer • Any disorder that makes them more likely to get blood clots that could travel to the lungs unless they are also taking blood thinners and are being followed by a specialist
	Estrogen should be used **WITH CAUTION** and only after a full discussion of risks by anyone who: • Has a family history of breast cancer or other cancers that grow more quickly when estrogens are present • Has a family history of heart disease

	• Has diabetes • Has chronic hepatitis or other liver disease • Has high levels of cholesterol • Has migraines or seizures • Is obese • Smokes cigarettes or uses tobacco products
	Taking estrogen increases the risk of blood clots and problems with blood vessels that can result in: • Chronic problems with veins in the legs, which may require surgery • Heart attack which may cause permanent heart damage or death • Pulmonary embolism (blood clot in the lungs), which may cause permanent lung damage or death • Stroke, which may cause permanent brain damage or death
	The risk of blood clots while take estrogen is much greater if you smoke cigarettes. The danger is so high that you should stop smoking completely while taking estrogen.
	Taking estrogen can increase the deposits of fat around internal organs, which increases the risk for diabetes and heart disease, which in turn increases the risk of heart attack and stroke.
	Taking estrogen can raise blood pressure, which increases the risk of heart attack and stroke.
	Taking estrogen increases the risk of gallstones (stones in the gallbladder). Any long-term abdominal pain you experience while taking estrogen must be reported to your prescribing physician.
	Taking estrogen increases the risk of elevated prolactin levels and prolactinomas, which are non-cancerous tumors of the pituitary gland. While not typically life threatening, prolactinomas can damage your vision and cause headaches if not treated properly. Any changes in your vision, the occurrence of headaches that are worse when waking up in the morning, or any milky discharge from the nipples must be reported to your prescribing physician.
	Taking estrogen can cause nausea and vomiting. Any long-term nausea or vomiting must be reported to your prescribing physician.
	Taking estrogen can cause migraines or can make them worse if you already have them.
	Taking estrogen can cause hot flashes.
	Taking estrogen can cause you to feel tired and have difficulty focusing.

Risks of Androgen Blockers and Antiandrogens (Spironolactone and Bicalutamide)

Patient	Statement
	Taking Spironolactone affects the balance of water and salt in the kidneys, which may: • Increase the amount of urine produced by your kidneys, making it necessary to urinate more frequently • Increase your thirst • Increase your risk of dehydration, which can be evidenced by less frequent urination than usual, dark and strong-smelling urine, thirst, and light-headedness

	Taking Spironolactone affects the balance of potassium in the kidneys, which may result in you experiencing high potassium levels resulting in:
	• Changes in heart rhythms that may be life threatening
	• Low blood pressure, which can cause:
	  o Fatigue
	  o Lightheadedness
	  o Tingling feelings
	  o Muscle weakness
	  o Shortness of breath
	• Your need for regular blood tests to monitor risks while on the medication

	Taking Bicalutamide may cause numerous side effects which should be reported to your prescribing physician, including: • Hot flashes or flushing • Bone, back, or pelvic pain • Muscle weakness • Muscle or joint pain • Headaches • Shortness of breath • Chest pain • Elevated blood pressure • Swelling of the hands, feet, ankles, or lower legs • Cough • Constipation • Nausea • Vomiting • Abdominal pain • Diarrhea • Gas • Changes in weight (loss or gain) • Loss of appetite

	• Dizziness • Pain, burning, or tingling in the hands or feet • Difficulty sleeping • Feeling of uneasiness or dread • Rash • Sweating • Need to urinate frequently during the night • Bloody urine • Painful or difficult urination • Frequent and urgent need to urinate • Difficulty emptying bladder • Painful or swollen breasts • Yellowing of the skin or eyes • Pain in the upper right part of the abdomen • Extreme tiredness • Unusual bleeding or bruising • Lack of energy • Upset stomach • Loss of appetite • Flu-like symptoms • Dull or sharp side pain

Requirements of Treatment with Feminizing Medications

Patient	Statement
	Compliance with the requirements explained above is a prerequisite for you to receive treatment with feminizing medications.
	The prescribing physician may stop prescribing feminizing medications if the prescribing physician or mental health care professionals providing treatment pursuant to this consent determine the benefit of treatment no longer outweighs the risks, there is insufficient social or psychological support, or the requirements in this consent are not met.
	I can change my mind and stop treatment at any time.

Prevention of Complications while under Treatment with Feminizing Medications

Patient	Statement
	I agree to notify the prescribing physician if I suffer from any side effects during treatment or are unhappy with the treatment in any way, particularly if I have any concerns about worsening signs of depression or anxiety or if I desire to harm myself or attempt suicide.

	I acknowledge that taking feminizing medications is only a part of my overall health, and that a range of preventative health activities are necessary so that remain healthy. These include, but are not limited to: • Monthly breast self-examination (report any new lumps to the prescribing physician) • Regular age-appropriate breast mammograms • Regular age-appropriate prostate examinations • Appropriate immunizations • Regular STI screening depending on my level of risk • HIV prevention depending on my level of risk • Regular physical activity, including resistance exercise for bone health • Healthy eating • Quitting smoking
	The prescribing physician is required to monitor me for any side effects during treatment and may refer me to another physician or specialist for treatment. I agree to go to any physicians and specialists recommended by the prescribing physician.

CONSENT:

The signature below confirms the following:

1. The prescribing physician has fully informed me about:
   a. the benefits and risks of taking feminizing medications;
   b. the possible or likely consequences of hormone therapy; and
   c. potential alternative treatments.

2. The information provided to me in this form and by the prescribing physician includes the known effects and risks of treatment with feminizing medications. I know that there may be other unknown short-term and long-term effects or risks which may be irreversible.

3. I have had sufficient time and opportunity to discuss relevant treatment options with the prescribing physician.

4. All my questions have been answered to my satisfaction by the prescribing physician.

5. I know enough to give informed consent for me to take, refuse, or postpone taking feminizing medications.

6. The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.52, F.S. This form contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your physician.

7. My signature below attests to my consent to begin treatment with feminizing medications.

_____

Patient's printed name (required)

_____ _____

Patient's signature (required) Date

DH5082-MQA (Rev. 08/23)
Rules 64B8ER23-11 and 64B15ER23-12

PRESCRIBING PHYSICIAN SIGNATURE:

My signature below attests to my compliance with section 456.52, Florida Statutes.

_____
Prescribing physician's printed name (required)

_____ _____
Prescribing physician's signature (required) Date

WITNESS:

_____
Witness' printed name (required)

_____ _____
Witness' signature (required) Date

FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:

I certify that I am fluent in English and in the native language of the person indicating consent on the above form. I certify that I have accurately and completely interpreted the contents of this form, and that the patient has indicated understanding of the contents of this form.

_____
Interpreter's printed name

_____ _____
Interpreter's signature Date

DH5082-MQA (Rev. 08/23)
Rules 64B8ER23-11 and 64B15ER23-12

Masculinizing Medications for Patients with Gender Dysphoria

Patient Information and Informed Consent

Before starting or continuing treatment with hormones or hormone antagonists, you need to be aware of the effects and possible risks associated with the use of these medications.

The prescribing physician will make a medical decision, in consultation with you, about the medications that are best for you, keeping in mind your overall health during your gender transition process. The effects and possible risks associated with the use of these medications will be discussed with you. It your responsibility to read and understand the following information and raise any questions you have with your prescribing physician.

After your questions or concerns are addressed and you have decided to start or continue hormones or hormone antagonists, you will need to initial the statements below and sign this form.

Medical treatment of people with gender dysphoria is based on very limited, poor-quality research with only subtle improvements seen in some patient's psychological functioning in some, but not all, research studies. This practice is purely speculative, and the possible psychological benefits may not outweigh the substantial risks of medical treatments and, in many cases, the need for lifelong medical treatments.

What are the medications that can masculinize one's appearance?

Treatment with hormones is called hormone replacement therapy or HRT. HRT will require taking testosterone, which increases muscle mass and causes the development of facial hair and a deeper voice. Testosterone when used by biological women, even when the criteria listed below are followed, does not have the U.S. Food and Drug Administration (FDA) approval to be used in the treatment of gender dysphoria and is considered "off label" use because they are not being used for their intended purpose.

Please initial below to acknowledge your understanding of the information on this page.

Patient

DH5083-MQA (Rev. 08/23)
Rules 64B8ER23-11 and 64B15ER23-12

How is testosterone taken?

Testosterone is usually injected every one to four weeks. Typically, it is not used as a pill because the body may not absorb it properly and may cause potentially fatal liver problems. The doses used for injection differ from product to product and from patient to patient. The injections are given in the muscle (intramuscular) or can be given with a smaller needle under the skin (subcutaneous). Taking testosterone may cause unwanted swings in hormone levels based on the amount and how often doses are given. Skin creams and patches may also be used. Both testosterone and the treatment process can affect mood. Therefore, individuals must be under the care of a licensed mental health care professional while undergoing treatment.

Finasteride is a treatment option for individuals experiencing bothersome alopecia resulting from higher dihydrotestosterone levels. The administration of 5α-reductase inhibitors block the conversion of testosterone to the more potent androgen dihydrotestosterone. The FDA approved indications of finasteride administration include benign prostatic hypertrophy and androgenetic alopecia. The use of 5α-reductase inhibitors may impair clitoral growth and the development of facial and body hair. Future studies are needed to assess the efficacy and safety of 5α-reductase inhibitors in treatment for gender dysphoria.

Every medication has risks, benefits, and side effects that are important to understand before taking. The effects and side effects of medicines used to treat gender dysphoria must be monitored with laboratory studies and regular visits to the prescribing physician to make sure that there are no negative medical or mental health effects.

What are my other options if I do not wish to start or continue medical treatments?

One option available is psychological therapy with a mental health care provider. This is recommended regardless of whether the individual undergoes treatment with hormones or hormone antagonists or not, due to the high risk of anxiety, depression, self-harm, and suicide. Other options may be discussed with your prescribing physician.

Please initial below to acknowledge your understanding of the information on this page.

Patient

What are the requirements to receive hormone replacement therapy?

To receive hormone replacement therapy, there are specific requirements that need to be met before and during the treatment. These requirements will allow the prescribing physician to monitor medical as well as mental health wellbeing during HRT. If these requirements are not met, HRT may be discontinued by the prescribing physician.

The specific requirements for an individual to receive and continue HRT treatment include the following:

1. Has met the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders (DSM) or International Classification of Diseases (ICD);
2. Mental health and physical conditions that could negatively impact the outcome of treatment have been assessed, with risks and benefits discussed;
3. Demonstrates capacity to consent for the specific gender dysphoria hormone treatment;
4. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
5. Has psychological and social support during treatment;
6. Demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of HRT as well as the medical and social risks and benefits of sex reassignment surgery; and
7. Understands the effect of hormone treatment on reproduction and they have explored reproductive options.

Please initial below to acknowledge your understanding of the information on this page.

Patient

The following may also be recommended by your prescribing physician:

1. Undergoes an in-person evaluation by the prescribing physician or their designated covering physician every 3 months for the initial year and at least annually thereafter;
2. Undergoes a suicide risk assessment by a licensed mental health care professional at least every 3 months for the initial year and at least annually thereafter;
3. Undergoes relevant laboratory testing, at least every 6 months;
4. Annual bone scan (DEXA) once a year for the first 5 years to allow monitoring of bone density (bone strength) during treatment, which can be altered by HRT;
5. Annual mental health assessments by a board-certified Florida licensed psychiatrist or psychologist; and
6. Continued counseling with a licensed mental health care professional during the treatment period, with the frequency recommended by the licensed mental health care professional.

Summary of Testosterone Benefits and Risk

BENEFITS	RISKS
• Appear more like a man • Bigger clitoris • Coarser skin • Lower voice • More body hair • More facial hair • More muscle mass • More strength • No or minimal menstrual periods • More physical energy • More sex drive	• Acne (may permanently scar) • Blood clots (thrombophlebitis), risk significantly increased by smoking • Emotional changes, for example, more aggression • Headache • High blood pressure (hypertension) • Increased red-blood-cell count • Infertility • Inflamed liver • Interaction with drugs for diabetes and blood thinning — for example Coumadin and Warfarin • Male pattern baldness • More abdominal fat — redistributed to a male shape • Risk of heart disease • Swelling of hands, feet, and legs • Weight gain

Please initial below to acknowledge your understanding of the information on this page.

Patient

Please initial each statement on this form to show that you understand the benefits, risks, and changes that may occur from taking testosterone.

Masculinizing Effects

Patient	Statement
	Testosterone may be prescribed to make me appear less like a female and more like a male.
	It can take several months or longer for the effects of testosterone to become noticeable and no one can predict how fast or how much change will occur.
	The following changes are likely to be permanent even if testosterone is discontinued: • Bigger clitoris - typically about half an inch to a little more than an inch • Deeper voice • Gradual growth of moustache and beard • Hair loss at the temples and crown of the head and the possibility of being completely bald • More, thicker, and coarser hair on abdomen, arms, back, chest, and legs
	The following changes could be permanent, but may improve if I stop taking testosterone: • Acne (although there may be permanent scars) • Menstrual periods (if present), typically stop one to six months after starting • More abdominal fat – redistributed to a male shape: decreased on buttocks, hips, and thighs; increased in abdomen – changing from "pear shape" to "apple shape" • More muscle mass and strength • More sexual interest • Vaginal dryness • Vaginal Tearing • Vaginal Bleeding • Vaginal Pain • Vaginal infection • Painful intercourse
	This treatment will not change the individual' s biological sex or chromosomes.
	Testosterone may reduce the ability to become pregnant, but it will not eliminate the risk of pregnancy. A person may become pregnant while on testosterone. I agree to inform the prescribing physician if I become pregnant.
	Some aspects of my body will not change:

	• Fat loss may make breasts appear slightly smaller • The voice will deepen, but other aspects of the way I speak may not sound more masculine
	Mood changes may be caused by these medicines, and I will continue therapy with a licensed mental health care professional during treatment.
	Using these medicines to masculinize is an off-label use of the medications. This means these medications are not approved by the FDA for this purpose. I know that the medicine and dose that is recommended is based solely on the judgment and experience of the prescribing physician and there is no data in the medical literature or controlled research studies that support the timing, dosing, and type of administration of HRT.

Risks of Testosterone

Patient	Statement
	Testosterone **SHOULD NOT** be used by anyone who: • Is pregnant • Has uncontrolled coronary artery disease as it could increase your risk for a fatal heart attack
	It should be used **WITH CAUTION** and only after a full discussion of risks by anyone who: • Has acne • Has a family history of heart disease or breast cancer • Has had a blood clot • Has high levels of cholesterol • Has liver disease • Has a high red blood cell count • Is obese • Smokes cigarettes
	The medical effects and the safety of testosterone are not completely known and there may be unknown long-term risks.
	Taking testosterone causes changes that other people will notice.
	Treatment with testosterone will not prevent serious psychiatric events, including suicide.
	Taking more testosterone than prescribed: • Will increase health risks; • Will not make changes happen more quickly or more significantly; and • May cause the body to convert extra testosterone into estrogen that can slow down or stop me from appearing more masculine.
	Taking testosterone can cause changes that increase the risk of heart disease. These changes include:

	• Less good cholesterol (HDL) that may protect against heart disease and more bad cholesterol (LDL) that may increase the risk of heart disease; • Higher blood pressure; and • More deposits of fat around the internal organs
	Taking testosterone can damage the liver and possibly lead to liver disease.
	Taking testosterone can increase red blood cells and hemoglobin, which may increase my risk of life-threatening problems such as stroke or heart attack.
	Taking testosterone can increase the risk for diabetes (high blood sugars), which decrease the body's response to insulin, cause weight gain, and increase deposits of fat around internal organs increasing the risk of heart disease and stroke.
	Treatment with testosterone can cause ovaries to not release eggs and may cause infertility.
	Treatment with testosterone increases the risk of cancer to the uterus, ovaries, or breasts. It is unclear if taking testosterone plays any role in HPV infection or cervical cancer.
	Taking testosterone causes or worsens migraines.
	Taking testosterone can cause emotional changes, such as irritability, frustration, aggression, and anger.

Risks of Finasteride

Patient	Statement
	Finasteride may be an appropriate treatment option in individuals experiencing bothersome alopecia resulting from testosterone treatment.
	Finasteride may have side effects which include: • decreased libido • dry skin • acne • Breast swelling and tenderness • headache • irregular menstruation • dizziness • increased body hair
	Finasteride is not approved by the FDA for use in biological women and is forbidden in pregnant women due to birth defects.

Requirements of Treatment with HRT

Patient	Statement
	Compliance with the requirements explained above is a prerequisite to receive treatment with testosterone.
	The prescribing physician may stop prescribing testosterone if the prescribing physician or mental health care professionals providing treatment pursuant to this consent determine the benefit of treatment no longer outweighs the risks, there is insufficient social or psychological support, or the requirements in this consent are not met.
	I understand that I may decide to stop treatment at any time.

Prevention of Complications while under Treatment of HRT

Patient	Statement
	I agree to notify the prescribing physician if I suffer from any side effects during treatment or am unhappy with the treatment in any way, and if I have any concerns that I have worsening signs of depression or anxiety or wants to harm myself or attempt suicide or attempt suicide.
	The prescribing physician is required to monitor me for any side effects during treatment and may refer me to another physician or specialist for treatment.

CONSENT:

My signature below confirms that:

1. My prescribing physician has talked with me about:
   a. the benefits and risks of taking testosterone;
   b. the possible or likely consequences of hormone therapy; and
   c. potential alternative treatments.

2. The information provided to me in this form and by the prescribing physician includes the known effects and risks of treatment with testosterone. I know that there may be other unknown short-term and long-term effects or risks which may be irreversible.

3. I have had sufficient time and opportunity to discuss relevant treatment options with my prescribing physician.

4. All my questions have been answered to my satisfaction by my prescribing physician.

5. I know enough to give informed consent to take, refuse, or postpone taking testosterone.

6. The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.52, F.S. This form contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your physician.

7. My signature below attests to my consent to begin treatment with testosterone.

Based on all this information:

_____ I want to begin or continue taking testosterone
_____ I want to begin or continue taking finasteride
_____ I do not wish to begin or continue taking masculinizing medication

_____
Patient's printed name (required)

_____ _____
Patient's signature (required) Date

PRESCRIBING PHYSICIAN:

My signature below attests to my compliance with 456.52, Florida Statutes.

_____
Prescribing physician's printed name (required)

_____ _____
Prescribing physician's signature (required) Date

WITNESS:

_____

Witness' printed name (required)

_____ _____

Witness' signature (required) Date

FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:

I certify that I am fluent in English and in the native language of the person indicating consent and/or assent on the above form. I certify that I have accurately and completely interpreted the contents of this form, and that the patient has indicated understanding of the contents of this form.

_____

Interpreter's printed name

_____ _____

Interpreter's signature Date

Surgical Treatment for Adults with Gender Dysphoria

Patient Information and Informed Consent

Before having surgery to treat gender dysphoria, you need to be aware of the effects and possible risks of these procedures. Your surgeon will make a medical decision, in consultation with you, about the procedures that are best for you, keeping in mind your overall health.

Your surgeon will discuss with you all the information relating to the surgery. You are asked to read and understand the following information and to discuss any questions you have with your surgeon. After your questions or concerns are addressed and you have decided to have surgery you must initial the statements below and sign this form in person with your surgeon.

Medical treatment of people with gender dysphoria is based on very limited, poor-quality research with only subtle improvements seen in some patient's psychological functioning in some, but not all, research studies. This practice is purely speculative, and the possible psychological benefits may not outweigh the substantial risks of medical treatments and, in many cases, the need for lifelong medical treatments.

What are the types of surgery to treat gender dysphoria?

Surgery to treat gender dysphoria may involve procedures on the face, chest, or genitalia. Common surgery options include:

- **Facial reconstructive surgery** to make facial features more masculine or feminine.
- **Chest or "Top" surgery** to remove breast tissue for a more masculine appearance or enhance breast size and shape for a more feminine appearance.
- **Genital or "Bottom" surgery** to transform and reconstruct the genitalia.
  - **Orchiectomy:** A bilateral orchiectomy is a procedure performed by a urologist that involves surgical removal of the testicles through a small scrotal incision. This procedure is done with a particular technique that allows for vaginoplasty later, if desired. Afterward, patients may adjust their dose of estrogens downward and no longer require spironolactone. Recovery takes approximately 2 weeks. Individuals seeking orchiectomy may wish to consider semen banking to preserve future fertility options.

Please initial below to acknowledge your understanding of the information on this page.

Patient

DH5084-MQA (Rev. 06/23)
Rules 64B8ER23-11 and 64B15ER23-12

- **Vaginoplasty:** In addition to an orchiectomy, a person may elect to undergo a vaginoplasty, which is a surgical procedure that involves reconstructing the genitals to create external female genitalia with or without a vaginal cavity. For those patients treated with puberty blockers as a minor, such treatment may lead to insufficient penile tissue that could necessitate the use other tissues, such as the colon, to create a vagina.
- **Phalloplasty:** This surgery involves a multi-staged procedure for the creation of a penis, urinary channel to allow urination, scrotum, and the obliteration of the vaginal cavity with closure. The removal of the female genital organs such as the uterus and ovaries and fallopian tubes are required and usually performed separately and prior to the phalloplasty surgery. The creation of the penis is performed with use of tissue from other parts of the body, which could include, more commonly the radial forearm free flap, or anterolateral thigh flap, and latissimus dorsi (MLD) flap. Prosthetics such as silicone or saline testicles can be placed as well as inflatable penile prosthetics in the final stage.
- **Metoidioplasty:** In this procedure, the surrounding tissue of the clitoris is released to achieve maximal length and a more natural-looking male position. A urethra is also reconstructed using either local skin tissue or a graft from the mouth depending on the amount of tissue present. Construction of a scrotum with testicular prosthetics can also be performed at the same time.
- **Hysterectomy:** Removal of the uterus and cervix via laparoscopic or vaginal techniques.
- **Salpingo-oophorectomy:** Removal of the fallopian tubes and ovaries.
- **Vaginectomy:** Obliteration of the vaginal canal and opening.

Is surgery the only treatment for gender dysphoria?

Surgery is just one option. Not everyone who has gender dysphoria chooses to have surgery. Depending on your age and preferences, you may choose:

- Treatment by a licensed mental health care professional that has experience in treating people with gender dysphoria, which is recommend regardless of whether you undergo surgery due to the high risk of anxiety, depression, self-harm, and suicide.
- Hormone replacement therapy to increase masculine or feminine characteristics.

Other options may be discussed with your prescribing physician.

Please initial below to acknowledge your understanding of the information on this page.

Patient

DH5084-MQA (Rev. 06/23)
Rules 64B8ER23-11 and 64B15ER23-12

What are some potential complications of surgery to treat gender dysphoria?

Potential complications include:

- Changes in sexual sensation
- Diminishment of bladder function
- Problems with urination
- Bleeding
- Infection
- Nerve damage
- Poor healing
- Scarring that can cause pain, firmness, asymmetry
- Side effects of anesthesia, including death

What happens after surgery to treat gender dysphoria?

Recovery times vary based on what procedures or combination of procedures you have as follows:

- **Cheek and nose surgery:** Swelling lasts for around two to four weeks.
- **Chin and jaw surgery:** Most swelling fades within two weeks but may take up to four months for swelling to completely disappear.
- **Chest surgery:** Swelling and soreness lasts for one to two weeks with physical limitations lasting at least one month.
- **Bottom surgery:** Most people do not resume usual activities until at least six weeks after surgery and weekly follow-up visits with your surgeon for several months will be necessary.

When should I see my surgeon?

After surgery, you should see your surgeon if you experience:

- Bleeding for more than a few days.
- Pain that does not go away after several weeks.
- Signs of infection, such as a wound that changes color or does not heal.

Please initial below to acknowledge your understanding of the information on this page.

Patient

Please initial each statement on this form to show that you understand the risks and changes associated with gender dysphoria surgeries.

Patient	Statement
	I understand that my surgeon will discuss with me during the preoperative process the available surgical procedures to treat gender dysphoria, the aftercare needs following surgery, and the importance of postoperative follow-up.
	I understand that these surgeries are permanent.
	I understand that if I have my breasts removed, I must undergo reconstructive surgery if I wish to have breasts in the future. If implants are used, complications may include pain, numbness, infection, bleeding, asymmetry, hardening, rippling, scarring, and the possible need for multiple surgeries.
	I understand that if I have my breasts removed that breast feeding will never be possible.
	I understand that if I have breast augmentation surgery, complications may include pain, numbness, infection, bleeding, asymmetry, hardening, rippling, scarring, and the possible need for multiple surgeries.
	I understand that my surgeon will assess me for risk factors associated with breast cancer prior to breast augmentation or mastectomy, including genetic mutations (e.g.., BRCA1, BRCA2), family history, age, radiation, exposure to estrogen, and the amount of breast tissue anticipated to remain after surgery.
	I understand that if I undergo metoidioplasty/phalloplasty I will need lifelong urological treatment.
	I understand that complications following metoidioplasty/phalloplasty include: • urinary tract strictures and fistulas • mucoceles due to vaginal remnant • hair growth within the neourethra • compromised sexual function including absent tactile and/or erogenous sensation, difficulties achieving orgasm • complications with penile prosthetics
	I understand that if I undergo vaginoplasty I will need lifelong treatment with my surgeon, primary care physician, and/or gynecologist.
	I understand that if I undergo vaginoplasty, complications can include: • the formation of granulation tissue • intravaginal hair growth • delayed wound healing and/or wound disruption • introital stenosis (closing, narrowing, or closure)

	• painful sex
	I understand that my surgeon may stop further treatment because the risks of treatment outweigh the benefits of treatment.
	I understand that this treatment will not prevent serious psychiatric events, including suicide.
	I agree to tell my surgeon if I have any problems or side effects or am unhappy with the surgery, including if I have worsening signs of depression or anxiety or want to harm myself or attempt suicide.
	I understand that my surgeon may be required to refer me to one or more specialists for surgery-related complications, and I agree to go to those specialists as recommended.
	I acknowledge that surgery to treat gender dysphoria is only part of my overall health and that a range of preventative health activities are recommended including: • cervical/prostrate screening tests at appropriate intervals as recommended by my doctor • regularly checking my breasts for lumps, even if I have had a mastectomy • regular mammograms from an appropriate age in consultation with my doctor • quitting smoking • immunizations • regular STI screening, depending on my level of risk • HIV prevention, depending on my level of risk • regular physical activity, including resistance exercise for bone health • healthy eating

CONSENT:

My signature below confirms that:

1. My surgeon has talked with me about:
    a. the benefits and risks of surgery to treat gender dysphoria;
    b. the possible or likely consequences of surgery to treat gender dysphoria;
    c. potential alternative treatments.

2. The information provided to me in this form and by the surgeon includes the known effects and risks of surgery to treat gender dysphoria. I know that there may be other unknown short-term and long-term effects or risks which may be irreversible.

3. I have had sufficient time and opportunity to discuss relevant treatment options with my surgeon.

4. All my questions have been answered to my satisfaction by my surgeon.

5. I know enough to give informed consent to have, refuse, or postpone surgery to treat gender dysphoria.

6. The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.52, F.S. This form contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your surgeon.

7. My signature below attests to my consent to surgery to treat gender dysphoria.

My signature below confirms the following:

_____ _____

Patient's signature (required) Date

_____ _____

Patient's signature (required) Date

DH5084-MQA (Rev. 06/23)
Rules 64B8ER23-11 and 64B15ER23-12

SURGEON:

My signature below attests to my compliance with 456.52, Florida Statutes.

_____

Surgeon's printed name (required)

_____ _____

Surgeon's signature (required) Date

WITNESS:

_____

Witness' printed name (required)

_____ _____

Witness' signature (required) Date

FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:

I certify that I am fluent in English and in the native language of the person indicating consent on the above form. I certify that I have accurately and completely interpreted the contents of this form, and that the patient has indicated understanding of the contents of this form.

_____

Interpreter's printed name

_____ _____

Interpreter's signature Date

FLORIDA DEPARTMENT of STATE

RON DESANTIS
Governor

CORD BYRD
Secretary of State

August 18, 2023

Cassandra P. Fullove
Senior Legal Assistant
Office of the Attorney General
PL-01, The Capitol
Tallahassee, FL 32399-1050

Dear Cassandra P. Fullove:

Your adoption package for Emergency Rule 64B15ER23-12 was received, electronically, by the Florida Department of State, Administrative Code and Register 3:54 p.m. on August 18, 2023. 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 August 18, 2023.

Sincerely,

Anya C. Owens
Administrative Code and Register Director

ACO/al

Leijon, Alexandra

From: Cassandra Fullove <Cassandra.Fullove@myfloridalegal.com>
Sent: Friday, August 18, 2023 3:54 PM
To: Owens, Anya C.; Leijon, Alexandra; RuleAdoptions
Subject: 64B15ER23-12, F.A.C.
Attachments: 64B15ER23-12 emergency rule adoption packet.pdf; DH5082-MQA.pdf; DH5083-MQA.pdf; DH5084-MQA.pdf; Text.docx

Hello,

Attached are the emergency rule documents for 64B15ER23-12, F.A.C. If you have any questions do not hesitate to contact me. Thank you.

Cassandra P. Fullove
Senior Legal Assistant
Administrative Law Bureau
Office of the Attorney General
PL-01, The Capitol
Tallahassee, FL 32399-1050
Office: (850) 414-3766
Fax: (850) 922-6425
Cassandra.Fullove@myfloridalegal.com

ASHLEY MOODY
ATTORNEY GENERAL
STATE OF FLORIDA

OFFICE OF THE ATTORNEY GENERAL
Cassandra P. Fullove
Senior Legal Assistant
Administrative Law Bureau

PL-01 The Capitol
Tallahassee, FL 32399-1050
Phone (850) 414-3300
Fax (850) 922-6425
Cassandra.Fullove@myfloridalegal.com
http://www.myfloridalegal.com

M E M O R A N D U M

TO: Anya C. Owens, Program Administrator
Bureau of Administrative Code

FROM: Cassandra P. Fullove, Senior Legal Assistant

RE: Department of Health
Board of Osteopathic Medicine
Emergency Rule 64B15ER23-12

DATE: August 18, 2023

Attached are the following documents regarding the above-referenced emergency rule adoption packet.

1. Notice of Emergency Rule
2. Adoption text for Emergency Rule 64B15ER23-12
3 Certification of Board of Osteopathic Medicine Emergency Rule
3. Designation of Rule the Violation of Which is a Minor Violation
4. Certification of Materials Incorporated by Reference in Emergency Rules
5. Form DH5082-MQA (08/23)
6. Form DH5083-MQA (08/23)
7. Form DH5084-MQA (08/23)

Should you have any questions regarding the rule do not hesitate to contact me.

Thank you.

CERTIFICATION OF BOARD OF OSTEOPATHIC MEDICINE

EMERGENCY RULE FILED WITH THE

DEPARTMENT OF STATE

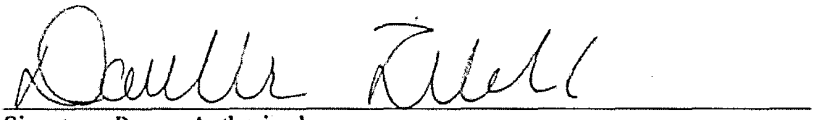
I hereby certify that pursuant to Ch 2023-90 Laws of Florida, Section 5, section 456.52, Florida Statutes was created and pursuant to subparagraphs 456.52(1)(a) and (6)(a), F.S., the Board of Osteopathic Medicine is required to adopt emergency rules to implement the section. I further certify that the 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), F.S. 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.

64B15ER23-12

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 Tiffany Sizemore Di Pietro , DO, FACC, FACOI, 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), F.S., 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).:

64B15ER23-12

Signature of Agency Head

Executive Director for Tiffany Sizemore Di Pietro , DO, FACC, FACOI, 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 Osteopathic Medicine

RULE NO.: RULE TITLE:

64B15ER23-12 Mandatory Standardized Informed Consent for Sex-reassignment Prescriptions or Procedures in Adults

SPECIFIC REASONS FOR FINDING AN IMMEDIATE DANGER TO THE PUBLIC HEALTH, SAFETY OR WELFARE: On May 17, 2023, Florida Governor, Ronald DeSantis, signed CSSB 254 into law creating Ch. 2023-90, Laws of Florida and section 456.52, *Florida Statutes*. Pursuant to section 456.52(2), F.S., if sex reassignment prescriptions or procedures are prescribed for or administered to patients 18 years of age or older, consent must be voluntary, informed, and in writing on forms adopted in rule by the Board of Osteopathic Medicine. Pursuant to section 456.52(4), F.S., the consent required for sex-reassignment prescriptions does not apply to renewals of sex-reassignment prescriptions if a physician and his or her patient have met the requirements for consent for the initial prescription. Section 456.52(6)(a), F.S., states "[t]he Board of Medicine and the Board of Osteopathic Medicine shall adopt emergency rules to implement this section."

Accordingly, the Board of Osteopathic Medicine, by emergency rule, hereby adopts the incorporated mandated consent forms for the treatment of gender dysphoria with hormone replacement therapy and surgical treatment for patients 18 years of age or older.

*** This emergency rule does not apply to Susan Doe, Gavin Goe, or Lisa Loe, or their parents or healthcare providers (see Jane Doe et al., v. Joseph A. Ladapo, et al, Preliminary Injunction, Filed June 6, 2023, Case No. 4:23cv114-RH-MAF, United States District Court for the Northern District of Florida). ***

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. CSSB 254 was signed into law on May 17, 2023. The Board of Osteopathic Medicine was contacted by multiple licensed physicians and physician groups seeking clarification regarding the exception contained in section 465.52(4), F.S., and a timeframe for the required emergency rules shortly thereafter. In response, the Board of Medicine and the Board of Osteopathic Medicine held a Joint Rules/Legislative Committee (Joint Committee) meeting on June 1, 2023, to discuss the emergency rule. On May 19, 2023, the Board of Medicine published notice of the Joint Committee's June meeting both on its website and in the Florida Administrative Register. On June 20, 2023, the Board of

Osteopathic Medicine discussed the report of the Joint Committee and voted upon emergency rule language that would allow for the renewal of previous prescriptions while the Board worked on consent forms. The Board of Osteopathic Medicine published notice of its June 20, 2023, meeting in the Florida Administrative Register on May 5, 2023, and on its website on May 12, 2023.

The Joint Committee held another meeting on June 23, 2023, to discuss an emergency rule adopting draft consent forms that were under consideration. On June 6, 2023, the Board of Osteopathic Medicine published notice of the Joint Committee's June 23, 2023, meeting to its website and in the Florida Administrative Register. On June 30, 2023, the Boards of Medicine and Osteopathic Medicine held a Joint Board meeting (Joint Board Meeting) to discuss the draft consent forms that were approved by the Joint Committee on June 23, 2023. The Joint Board meeting was held via Microsoft Teams and notice of the same was published to the Board of Medicine's website and in the Florida Administrative Register on June 22, 2023. During the June 30, 2023, Joint Board Meeting, the Boards voted to approve consent forms and adopted them via emergency rule filed on July 5, 2023.

On July 21, 2023, the Board received correspondence from the Joint Administrative Procedures Committee (JAPC) questioning the Board's statutory authority for requiring adult patients "undergo a thorough psychological and social evaluation performed by a Florida licensed board-certified psychiatrist or a Florida licensed psychologist" before beginning hormone replacement therapy and every two years thereafter. Accordingly, the Florida Board of Medicine and Osteopathic Medicine's Joint Rules/Legislative Committee held a public meeting on August 3, 2023, and voted to remove the provision addressed by JAPC. The Board of Osteopathic Medicine discussed the Joint Committee's report and affirmed the decision at its August 11, 2023, Board meeting.

The August 3, 2023, Joint Committee meeting was held in person in a public forum and was able to be attended by any interested parties. Notice of the Joint Committee meeting was published to the Board of Osteopathic Medicine's website on July 19, 2023, and in the Florida Administrative Register on July 13, 2023. The August 11, 2023, Board Meeting was also held in person in a public forum and was able to be attended by any interested parties. Notice for the August 11, 2023, Board Meeting was published to the Board of Osteopathic Medicine's website on June 1, 2023, and in the Florida Administrative Register on May 24, 2023.

Public comment was accepted at all of the aforementioned board and committee meetings. Further, the Boards accepted written public comment on the initial proposed rules up and until 24 hours prior to the Joint Board Meeting. The Board also accepted written comments up and until 24 hours prior to the August 3, 2023, Joint

Rules/Legislative Committee meeting as well. Accordingly, all notice requirements contained in Rule 28-102.001, F.A.C., were properly complied with at all points during the rulemaking process and interested parties were given ample opportunity to participate at all points during this rulemaking process.

SUMMARY: The proposed emergency rule formally adopts the required consent forms for an adult patient to receive sex-reassignment prescriptions and/or procedures per section 456.52(2), *Florida Statutes*.

THE PERSON TO BE CONTACTED REGARDING THE EMERGENCY RULE IS: Danielle Terrell, Executive Director, Board of Osteopathic Medicine/MQA, 4052 Bald Cypress Way, Bin #C06, Tallahassee, Florida 32399-3256, or by email at Danielle.Terrell@flhealth.gov.

64B15ER23-12 - Mandatory Standardized Informed Consent for Sex-reassignment Prescriptions or Procedures in Adults.

Pursuant to Section 456.52, Florida Statutes, when sex-reassignment prescriptions or procedures are prescribed for or administered or performed on patients 18 years of age or older, the physician is required to obtain voluntary, informed consent while physically present in the same room as the patient. Consent is not required for renewal of such prescriptions if a physician and the physician's patient have met the requirements for consent for the initial prescription or renewal; however, a separate consent is required for any new prescription for a pharmaceutical product not previously prescribed to the patient.

(1) Informed Consent. The Board has approved the following mandatory informed consent forms for sex-reassignment prescriptions or procedures for patients 18 years of age or older:

(a) For patients prescribed sex-reassignment feminizing medication, form DH5082-MQA, (Rev. 08/23), entitled "Feminizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Consent," which is hereby incorporated by reference and available from the Board's website at https://flboardofmedicine.gov/forms/Feminizing-Medications-for-Patients-with-Gender-Dysphoria-Patient-Information-and-Informed-Consent.pdf.

(b) For patients prescribed sex-reassignment masculinizing medications, form DH5083-MQA, (Rev. 08/23), entitled "Masculinizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Consent," which is hereby incorporated by reference and available from the Board's website at https://flboardofmedicine.gov/forms/Masculinizing-Medications-for-Patients-with-Gender-Dysphoria-Patient-Information-and-Informed-Consent.pdf.

(c) For patients undergoing surgical treatment, form DH5084-MQA, (06/23), entitled "Surgical Treatment for Adults with Gender Dysphoria, Patient Information and Informed Consent," which is hereby incorporated by reference and available from the Board's website at https://flboardofmedicine.gov/forms/Surgical-Treatment-for-Adults-with-Gender-Dysphoria-Patients-Information-and-Informed-Consent.pdf.

(2) A Board-approved informed consent form is not executed until:

(a) The physician issuing the prescription or performing the procedure, while physically present in the same room as the patient, has informed the patient of the nature and risks of the prescription or procedure and has provided and received the patient's written acknowledgement before the prescription is prescribed, administered, or performed. The

physician is prohibited from delegating this responsibility to another person. The physician is also required to sign the informed consent form.

(b) The patient is required to sign the informed consent form.

(c) A competent witness is also required to sign the informed consent form.

Rulemaking Authority 456.52 FS. Law Implemented 456.52 FS. History – New____.

CERTIFICATION OF MATERIALS INCORPORATED
BY REFERENCE IN EMERGENCY RULES FILED WITH THE DEPARTMENT OF STATE

I hereby certify pursuant to Rule 1-1.013, Florida Administrative Code, that materials incorporated by reference in Emergency Rule 64B15ER23-12 have been:

[x] (1) Filed with the Department of State and included as part of the Emergency Rule adoption packet.

[ ] (2) That because there would be a violation of federal copyright laws if the submitting agency filed the incorporated materials as described in option (1) above, a true and complete copy of the incorporated materials has been provided to the Department of State as outlined in paragraph 1-1.013(5)(c), F.A.C.

Copies of the incorporated materials below may be obtained at the agency by [include address(es)/location(s)].

List form number(s) and form title(s), or title of document(s) below:

DH5082-MQA Feminizing Medications for Patient with Gender Dysphoria-Patient Information and Informed Consent

DH5083-MQA Masculinizing Medications for Patients with Gender Dysphoria-Patient Information and Informed Consent

DH5084-MQA Surgical Treatment for Adults with Gender Dysphoria-Patients Information and Informed Consent

Under the provisions of Section 120.54(4)(d), F.S., the attached material(s) take effect upon filing with the Department of State, or a date less than 20 days thereafter if specified in the rule if the adopting agency finds that such effective date is necessary because of immediate danger to the public health, safety, or welfare.

Signature, Person Authorized to Certify Rules

Danielle Terrell, Executive Director for Tiffany Sizemore Di Pietro, DO, FACC, FACOI, Chair
Title

Feminizing Medications for Patients with Gender Dysphoria

Patient Information and Informed Consent

Before starting or continuing treatment with hormones or hormone antagonists, you need to be aware of the effects and possible risks associated with use of these medications.

Your prescribing physician will make a medical decision in consultation with you about the medications that are best for you, keeping in mind your overall health during the treatment process. Your prescribing physician will discuss with you all of the available information relating to hormone therapy. You are asked to read and understand the following information and to discuss any questions you have with your prescribing physician.

After your questions or concerns are addressed and you have decided to start or continue treatment with hormones or hormone antagonists, you must initial the statements below and sign this form in person with your prescribing physician.

Medical treatment of people with gender dysphoria is based on very limited, poor-quality research with only subtle improvements seen in some patient's psychological functioning in some, but not all, research studies. This practice is purely speculative, and the possible psychological benefits may not outweigh the substantial risks of medical treatments and, in many cases, the need for lifelong medical treatments.

What are the different medications that can feminize one's appearance?

Treatment with hormones is called hormone replacement therapy or HRT. HRT will require taking estrogen, as well as medicines to block the body from producing or utilizing testosterone. Use of these medications, even when the criteria listed below are followed, does not have U.S. Food and Drug Administration (FDA) approval and its use to treat gender dysphoria is considered "off label" because they are not being used for their intended purpose

Different forms of estrogen are used to feminize a person's appearance. Estrogen can be given as an injection either weekly or every other week, as a pill that is taken daily or twice a day, or as a patch that is changed weekly or every three or four days.

Please initial below to acknowledge your understanding of the information on this page.

Patient

DH5082-MQA (Rev. 08/23)
Rules 64B8ER23-11 and 64B15ER23-12

Medications that block the production or effects of testosterone are called androgen blockers. Spironolactone is the androgen blocker that is most commonly used in the United States. In some cases, Bicalutamide, an antiandrogen, is used to block the effects of testosterone, though it will not reduce testosterone levels. Bicalutamide (brand name Casodex) is a cancer drug approved for the treatment of prostate cancer. Fulminant hepatotoxicity, a severe liver injury often resulting in death, has been noted with bicalutamide use.

Cyproterone acetate, a synthetic progestogen with strong antiandrogen activity, is commonly used in many countries. When paired with estrogen, cyproterone acetate is associated with elevated prolactin, decreased HDL cholesterol, and rare meningiomas (tumors). Cyproterone acetate has also been associated with uncommon episodes of fulminant hepatitis.

The administration of finasteride blocks the conversion of testosterone to the more potent androgen dihydrotestosterone. The FDA approved uses of finasteride include the treatment benign prostatic hypertrophy and androgenic alopecia. Finasteride is not recommended for routine use in treating populations with gender dysphoria.

Various forms of progestins may also be used. This class includes micronized bioidentical progesterone (Prometrium) as well as oral medroxyprogesterone acetate (Provera). Although there are anecdotal reports of progesterone use for breast development and mood management, there is currently insufficient evidence that the potential benefits of progesterone administration outweigh the potential risks. There is also a theoretical risk of breast cancer associated with long-term exogenous progesterone.

Every medication has risks, benefits, and side effects that are important to understand before taking. The effects and side effects of medicines used to treat gender dysphoria must be monitored with laboratory studies and regular visits to your prescribing physician to make sure that there are no negative medical or mental health effects.

HRT, the use of androgen blockers and antiandrogens, and the treatment process can affect your mood. Therefore, you must be under the care of a licensed mental health care professional while undergoing treatment.

Please initial below to acknowledge your understanding of the information on this page.

Patient

What are my other options if I do not wish to start or continue treatment with hormones, hormone antagonists, or antiandrogens?

One option available is psychological therapy with a mental health provider. This is recommended regardless of whether or not the person undergoes treatment with hormones, hormone antagonists, or antiandrogens due to the high risk of anxiety, depression, self-harm, and suicide. Other options may be discussed with your prescribing physician.

What are the requirements to receive hormone replacement therapy (HRT)?

To receive HRT, there are specific requirements that need to be met before and during treatment. These requirements will allow the prescribing physician to monitor your medical and mental health status during treatment. If these requirements are not met, HRT may be discontinued by the prescribing physician.

Please initial below to acknowledge your understanding of the information on this page.

Patient

The specific requirements for you to receive and continue HRT treatment include the following:

1. Has met the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders or International Classification of Diseases;
2. Mental health and physical conditions that could negatively impact the outcome of treatment have been assessed, with risks and benefits discussed;
3. Demonstrates capacity to consent for the specific gender dysphoria hormone treatment;
4. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
5. Has psychological and social support during treatment;
6. Demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of HRT as well as the medical and social risks and benefits of sex reassignment surgery; and
7. Understands the effect of hormone treatment on reproduction and they have explored reproductive options;

The following may also be recommended by your prescribing physician:

1. Undergoes an in-person evaluation by the prescribing physician or their designated covering physician every 3 months for the initial year and at least annually thereafter;
2. Undergoes a suicide risk assessment by a licensed mental health care professional at least every 3 months for the initial year and at least annually thereafter;
3. Undergoes relevant laboratory testing at least every 6 months;
4. Annual bone density scan (DEXA) once a year for the first 5 years to allow monitoring of your bone density (bone strength) during treatment, which can be altered by HRT;
5. Annual mental health assessments by a board-certified Florida licensed psychiatrist or psychologist; and
6. Continued counseling with a licensed mental health care professional during the treatment period, with the frequency recommended by the licensed mental health care professional.

Please initial below to acknowledge your understanding of the information on this page.

Patient

Please initial each statement on this form to show that you understand the benefits, risks, and changes associated with taking feminizing medications.

Effects of Feminizing Medications

Patient	Statement
	Feminizing medications, including estrogen, androgen blockers, or antiandrogens, given singularly or in combination, may be prescribed to make me appear less like a male and more like a female.
	It can take several months or longer for the effects of feminizing medications to become noticeable and no one can predict how fast or how much change will occur.
	This treatment will not change my biological sex or chromosomes.
	If I take estrogen, the following changes in my breasts will occur: • Breasts will develop but will not reach their full size for several years • Breasts will remain even if estrogen treatment is discontinued • A milky discharge from the nipples may appear, which should be reported to my prescribing physician • My risk of breast cancer may significantly increase
	If I take feminizing medications, my body will make less testosterone, which may affect my sex life in different ways, including: • My testicles may shrink • My penis may never fully develop, particularly if I previously took puberty blockers • I will have fewer spontaneous erections • My sperm may no longer mature causing infertility which may be permanent even if treatment is discontinued, the risk of which is increased if I took puberty blockers prior to starting feminizing medications • Conversely, it is possible that my sperm could still mature while taking feminizing medications and I may cause someone to get pregnant
	The options for sperm banking have been explained.
	If I take feminizing medications, some parts of my body will not change much, including: • If present, my facial hair may grow more slowly, but it will not go away completely even after taking feminizing medications for many years • If present, my body hair may grow more slowly, but it will not go away completely even after taking feminizing medications for many years • If I went through puberty and have a deep voice, the pitch of my voice will not rise and my speech patterns will not become more like a woman's • If present, my Adam's apple will not shrink

	Even if I stop taking feminizing medications, the following changes may occur: • My body fat may be redistributed with less fat on the abdomen and more on the buttocks, hips, and thighs creating a more female shape • I may have decreased muscle mass and strength in the upper body • My skin may become softer
	Mood changes may be caused by these medicines, and I will continue therapy with a licensed mental health care professional during treatment.
	Using these medicines to feminize my body is an off-label use of the medications. This means these medications are not approved by the FDA for this purpose. I know that the medicine and dose that is recommended is based solely on the judgment and experience of my prescribing physician and there is no data in the medical literature or controlled research studies that support the timing, dosing, and type of administration of feminizing medications.

Risks of Feminizing Medications

Patient	Statement
	The medical effects and the safety of taking femininizing medications are not completely known and there may be unknown long-term risks.
	Taking femininizing medications causes changes that other people will notice.
	Treatment with femininizing medications will not prevent serious psychiatric events, including suicide.
	I must not take more feminizing medication than prescribed. Taking too much medication: • Will increase health risks • Will not make changes happen more quickly or more significantly
	Taking feminizing medication can damage the liver and possibly lead to liver disease.

Risks of Estrogen

Patient	Statement
	Estrogen **SHOULD NOT** be used by anyone who has: • Any estrogen-dependent cancer • Any disorder that makes them more likely to get blood clots that could travel to the lungs unless they are also taking blood thinners and are being followed by a specialist
	Estrogen should be used **WITH CAUTION** and only after a full discussion of risks by anyone who: • Has a family history of breast cancer or other cancers that grow more quickly when estrogens are present • Has a family history of heart disease

	• Has diabetes • Has chronic hepatitis or other liver disease • Has high levels of cholesterol • Has migraines or seizures • Is obese • Smokes cigarettes or uses tobacco products
	Taking estrogen increases the risk of blood clots and problems with blood vessels that can result in: • Chronic problems with veins in the legs, which may require surgery • Heart attack which may cause permanent heart damage or death • Pulmonary embolism (blood clot in the lungs), which may cause permanent lung damage or death • Stroke, which may cause permanent brain damage or death
	The risk of blood clots while take estrogen is much greater if you smoke cigarettes. The danger is so high that you should stop smoking completely while taking estrogen.
	Taking estrogen can increase the deposits of fat around internal organs, which increases the risk for diabetes and heart disease, which in turn increases the risk of heart attack and stroke.
	Taking estrogen can raise blood pressure, which increases the risk of heart attack and stroke.
	Taking estrogen increases the risk of gallstones (stones in the gallbladder). Any long-term abdominal pain you experience while taking estrogen must be reported to your prescribing physician.
	Taking estrogen increases the risk of elevated prolactin levels and prolactinomas, which are non-cancerous tumors of the pituitary gland. While not typically life threatening, prolactinomas can damage your vision and cause headaches if not treated properly. Any changes in your vision, the occurrence of headaches that are worse when waking up in the morning, or any milky discharge from the nipples must be reported to your prescribing physician.
	Taking estrogen can cause nausea and vomiting. Any long-term nausea or vomiting must be reported to your prescribing physician.
	Taking estrogen can cause migraines or can make them worse if you already have them.
	Taking estrogen can cause hot flashes.
	Taking estrogen can cause you to feel tired and have difficulty focusing.

Risks of Androgen Blockers and Antiandrogens (Spironolactone and Bicalutamide)

Patient	Statement
	Taking Spironolactone affects the balance of water and salt in the kidneys, which may: • Increase the amount of urine produced by your kidneys, making it necessary to urinate more frequently • Increase your thirst • Increase your risk of dehydration, which can be evidenced by less frequent urination than usual, dark and strong-smelling urine, thirst, and light-headedness
	Taking Spironolactone affects the balance of potassium in the kidneys, which may result in you experiencing high potassium levels resulting in: • Changes in heart rhythms that may be life threatening • Low blood pressure, which can cause: o Fatigue o Lightheadedness o Tingling feelings o Muscle weakness o Shortness of breath • Your need for regular blood tests to monitor risks while on the medication
	Taking Bicalutamide may cause numerous side effects which should be reported to your prescribing physician, including: • Hot flashes or flushing • Bone, back, or pelvic pain • Muscle weakness • Muscle or joint pain • Headaches • Shortness of breath • Chest pain • Elevated blood pressure • Swelling of the hands, feet, ankles, or lower legs • Cough • Constipation • Nausea • Vomiting • Abdominal pain • Diarrhea • Gas • Changes in weight (loss or gain) • Loss of appetite

	• Dizziness • Pain, burning, or tingling in the hands or feet • Difficulty sleeping • Feeling of uneasiness or dread • Rash • Sweating • Need to urinate frequently during the night • Bloody urine • Painful or difficult urination • Frequent and urgent need to urinate • Difficulty emptying bladder • Painful or swollen breasts • Yellowing of the skin or eyes • Pain in the upper right part of the abdomen • Extreme tiredness • Unusual bleeding or bruising • Lack of energy • Upset stomach • Loss of appetite • Flu-like symptoms • Dull or sharp side pain

Requirements of Treatment with Feminizing Medications

Patient	Statement
	Compliance with the requirements explained above is a prerequisite for you to receive treatment with feminizing medications.
	The prescribing physician may stop prescribing feminizing medications if the prescribing physician or mental health care professionals providing treatment pursuant to this consent determine the benefit of treatment no longer outweighs the risks, there is insufficient social or psychological support, or the requirements in this consent are not met.
	I can change my mind and stop treatment at any time.

Prevention of Complications while under Treatment with Feminizing Medications

Patient	Statement
	I agree to notify the prescribing physician if I suffer from any side effects during treatment or are unhappy with the treatment in any way, particularly if I have any concerns about worsening signs of depression or anxiety or if I desire to harm myself or attempt suicide.

	I acknowledge that taking feminizing medications is only a part of my overall health, and that a range of preventative health activities are necessary so that remain healthy. These include, but are not limited to: • Monthly breast self-examination (report any new lumps to the prescribing physician) • Regular age-appropriate breast mammograms • Regular age-appropriate prostate examinations • Appropriate immunizations • Regular STI screening depending on my level of risk • HIV prevention depending on my level of risk • Regular physical activity, including resistance exercise for bone health • Healthy eating • Quitting smoking
	The prescribing physician is required to monitor me for any side effects during treatment and may refer me to another physician or specialist for treatment. I agree to go to any physicians and specialists recommended by the prescribing physician.

CONSENT:

The signature below confirms the following:

1. The prescribing physician has fully informed me about:
   a. the benefits and risks of taking feminizing medications;
   b. the possible or likely consequences of hormone therapy; and
   c. potential alternative treatments.

2. The information provided to me in this form and by the prescribing physician includes the known effects and risks of treatment with feminizing medications. I know that there may be other unknown short-term and long-term effects or risks which may be irreversible.

3. I have had sufficient time and opportunity to discuss relevant treatment options with the prescribing physician.

4. All my questions have been answered to my satisfaction by the prescribing physician.

5. I know enough to give informed consent for me to take, refuse, or postpone taking feminizing medications.

6. The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.52, F.S. This form contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your physician.

7. My signature below attests to my consent to begin treatment with feminizing medications.

_____

Patient's printed name (required)

_____ _____

Patient's signature (required) Date

DH5082-MQA (Rev. 08/23)
Rules 64B8ER23-11 and 64B15ER23-12

PRESCRIBING PHYSICIAN SIGNATURE:

My signature below attests to my compliance with section 456.52, Florida Statutes.

_____
Prescribing physician's printed name (required)

_____ _____
Prescribing physician's signature (required) Date

WITNESS:

_____
Witness' printed name (required)

_____ _____
Witness' signature (required) Date

FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:

I certify that I am fluent in English and in the native language of the person indicating consent on the above form. I certify that I have accurately and completely interpreted the contents of this form, and that the patient has indicated understanding of the contents of this form.

_____
Interpreter's printed name

_____ _____
Interpreter's signature Date

Masculinizing Medications for Patients with Gender Dysphoria

Patient Information and Informed Consent

Before starting or continuing treatment with hormones or hormone antagonists, you need to be aware of the effects and possible risks associated with the use of these medications.

The prescribing physician will make a medical decision, in consultation with you, about the medications that are best for you, keeping in mind your overall health during your gender transition process. The effects and possible risks associated with the use of these medications will be discussed with you. It your responsibility to read and understand the following information and raise any questions you have with your prescribing physician.

After your questions or concerns are addressed and you have decided to start or continue hormones or hormone antagonists, you will need to initial the statements below and sign this form.

Medical treatment of people with gender dysphoria is based on very limited, poor-quality research with only subtle improvements seen in some patient's psychological functioning in some, but not all, research studies. This practice is purely speculative, and the possible psychological benefits may not outweigh the substantial risks of medical treatments and, in many cases, the need for lifelong medical treatments.

What are the medications that can masculinize one's appearance?

Treatment with hormones is called hormone replacement therapy or HRT. HRT will require taking testosterone, which increases muscle mass and causes the development of facial hair and a deeper voice. Testosterone when used by biological women, even when the criteria listed below are followed, does not have the U.S. Food and Drug Administration (FDA) approval to be used in the treatment of gender dysphoria and is considered "off label" use because they are not being used for their intended purpose.

Please initial below to acknowledge your understanding of the information on this page.

Patient

DH5083-MQA (Rev. 08/23)
Rules 64B8ER23-11 and 64B15ER23-12

How is testosterone taken?

Testosterone is usually injected every one to four weeks. Typically, it is not used as a pill because the body may not absorb it properly and may cause potentially fatal liver problems. The doses used for injection differ from product to product and from patient to patient. The injections are given in the muscle (intramuscular) or can be given with a smaller needle under the skin (subcutaneous). Taking testosterone may cause unwanted swings in hormone levels based on the amount and how often doses are given. Skin creams and patches may also be used. Both testosterone and the treatment process can affect mood. Therefore, individuals must be under the care of a licensed mental health care professional while undergoing treatment.

Finasteride is a treatment option for individuals experiencing bothersome alopecia resulting from higher dihydrotestosterone levels. The administration of 5α-reductase inhibitors block the conversion of testosterone to the more potent androgen dihydrotestosterone. The FDA approved indications of finasteride administration include benign prostatic hypertrophy and androgenetic alopecia. The use of 5α-reductase inhibitors may impair clitoral growth and the development of facial and body hair. Future studies are needed to assess the efficacy and safety of 5α-reductase inhibitors in treatment for gender dysphoria.

Every medication has risks, benefits, and side effects that are important to understand before taking. The effects and side effects of medicines used to treat gender dysphoria must be monitored with laboratory studies and regular visits to the prescribing physician to make sure that there are no negative medical or mental health effects.

What are my other options if I do not wish to start or continue medical treatments?

One option available is psychological therapy with a mental health care provider. This is recommended regardless of whether the individual undergoes treatment with hormones or hormone antagonists or not, due to the high risk of anxiety, depression, self-harm, and suicide. Other options may be discussed with your prescribing physician.

Please initial below to acknowledge your understanding of the information on this page.

Patient

What are the requirements to receive hormone replacement therapy?

To receive hormone replacement therapy, there are specific requirements that need to be met before and during the treatment. These requirements will allow the prescribing physician to monitor medical as well as mental health wellbeing during HRT. If these requirements are not met, HRT may be discontinued by the prescribing physician.

The specific requirements for an individual to receive and continue HRT treatment include the following:

1. Has met the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders (DSM) or International Classification of Diseases (ICD);
2. Mental health and physical conditions that could negatively impact the outcome of treatment have been assessed, with risks and benefits discussed;
3. Demonstrates capacity to consent for the specific gender dysphoria hormone treatment;
4. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
5. Has psychological and social support during treatment;
6. Demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of HRT as well as the medical and social risks and benefits of sex reassignment surgery; and
7. Understands the effect of hormone treatment on reproduction and they have explored reproductive options.

Please initial below to acknowledge your understanding of the information on this page.

Patient

The following may also be recommended by your prescribing physician:

1. Undergoes an in-person evaluation by the prescribing physician or their designated covering physician every 3 months for the initial year and at least annually thereafter;
2. Undergoes a suicide risk assessment by a licensed mental health care professional at least every 3 months for the initial year and at least annually thereafter;
3. Undergoes relevant laboratory testing, at least every 6 months;
4. Annual bone scan (DEXA) once a year for the first 5 years to allow monitoring of bone density (bone strength) during treatment, which can be altered by HRT;
5. Annual mental health assessments by a board-certified Florida licensed psychiatrist or psychologist; and
6. Continued counseling with a licensed mental health care professional during the treatment period, with the frequency recommended by the licensed mental health care professional.

Summary of Testosterone Benefits and Risk

BENEFITS	RISKS
• Appear more like a man • Bigger clitoris • Coarser skin • Lower voice • More body hair • More facial hair • More muscle mass • More strength • No or minimal menstrual periods • More physical energy • More sex drive	• Acne (may permanently scar) • Blood clots (thrombophlebitis), risk significantly increased by smoking • Emotional changes, for example, more aggression • Headache • High blood pressure (hypertension) • Increased red-blood-cell count • Infertility • Inflamed liver • Interaction with drugs for diabetes and blood thinning — for example Coumadin and Warfarin • Male pattern baldness • More abdominal fat — redistributed to a male shape • Risk of heart disease • Swelling of hands, feet, and legs • Weight gain

Please initial below to acknowledge your understanding of the information on this page.

Patient

Please initial each statement on this form to show that you understand the benefits, risks, and changes that may occur from taking testosterone.

Masculinizing Effects

Patient	Statement
	Testosterone may be prescribed to make me appear less like a female and more like a male.
	It can take several months or longer for the effects of testosterone to become noticeable and no one can predict how fast or how much change will occur.
	The following changes are likely to be permanent even if testosterone is discontinued: • Bigger clitoris - typically about half an inch to a little more than an inch • Deeper voice • Gradual growth of moustache and beard • Hair loss at the temples and crown of the head and the possibility of being completely bald • More, thicker, and coarser hair on abdomen, arms, back, chest, and legs
	The following changes could be permanent, but may improve if I stop taking testosterone: • Acne (although there may be permanent scars) • Menstrual periods (if present), typically stop one to six months after starting • More abdominal fat – redistributed to a male shape: decreased on buttocks, hips, and thighs; increased in abdomen – changing from "pear shape" to "apple shape" • More muscle mass and strength • More sexual interest • Vaginal dryness • Vaginal Tearing • Vaginal Bleeding • Vaginal Pain • Vaginal infection • Painful intercourse
	This treatment will not change the individual' s biological sex or chromosomes.
	Testosterone may reduce the ability to become pregnant, but it will not eliminate the risk of pregnancy. A person may become pregnant while on testosterone. I agree to inform the prescribing physician if I become pregnant.
	Some aspects of my body will not change:

	• Fat loss may make breasts appear slightly smaller • The voice will deepen, but other aspects of the way I speak may not sound more masculine
	Mood changes may be caused by these medicines, and I will continue therapy with a licensed mental health care professional during treatment.
	Using these medicines to masculinize is an off-label use of the medications. This means these medications are not approved by the FDA for this purpose. I know that the medicine and dose that is recommended is based solely on the judgment and experience of the prescribing physician and there is no data in the medical literature or controlled research studies that support the timing, dosing, and type of administration of HRT.

Risks of Testosterone

Patient	Statement
	Testosterone **SHOULD NOT** be used by anyone who: • Is pregnant • Has uncontrolled coronary artery disease as it could increase your risk for a fatal heart attack
	It should be used **WITH CAUTION** and only after a full discussion of risks by anyone who: • Has acne • Has a family history of heart disease or breast cancer • Has had a blood clot • Has high levels of cholesterol • Has liver disease • Has a high red blood cell count • Is obese • Smokes cigarettes
	The medical effects and the safety of testosterone are not completely known and there may be unknown long-term risks.
	Taking testosterone causes changes that other people will notice.
	Treatment with testosterone will not prevent serious psychiatric events, including suicide.
	Taking more testosterone than prescribed: • Will increase health risks; • Will not make changes happen more quickly or more significantly; and • May cause the body to convert extra testosterone into estrogen that can slow down or stop me from appearing more masculine.
	Taking testosterone can cause changes that increase the risk of heart disease. These changes include:

	• Less good cholesterol (HDL) that may protect against heart disease and more bad cholesterol (LDL) that may increase the risk of heart disease; • Higher blood pressure; and • More deposits of fat around the internal organs
	Taking testosterone can damage the liver and possibly lead to liver disease.
	Taking testosterone can increase red blood cells and hemoglobin, which may increase my risk of life-threatening problems such as stroke or heart attack.
	Taking testosterone can increase the risk for diabetes (high blood sugars), which decrease the body's response to insulin, cause weight gain, and increase deposits of fat around internal organs increasing the risk of heart disease and stroke.
	Treatment with testosterone can cause ovaries to not release eggs and may cause infertility.
	Treatment with testosterone increases the risk of cancer to the uterus, ovaries, or breasts. It is unclear if taking testosterone plays any role in HPV infection or cervical cancer.
	Taking testosterone causes or worsens migraines.
	Taking testosterone can cause emotional changes, such as irritability, frustration, aggression, and anger.

Risks of Finasteride

Patient	Statement
	Finasteride may be an appropriate treatment option in individuals experiencing bothersome alopecia resulting from testosterone treatment.
	Finasteride may have side effects which include: • decreased libido • dry skin • acne • Breast swelling and tenderness • headache • irregular menstruation • dizziness • increased body hair
	Finasteride is not approved by the FDA for use in biological women and is forbidden in pregnant women due to birth defects.

Requirements of Treatment with HRT

Patient	Statement
	Compliance with the requirements explained above is a prerequisite to receive treatment with testosterone.
	The prescribing physician may stop prescribing testosterone if the prescribing physician or mental health care professionals providing treatment pursuant to this consent determine the benefit of treatment no longer outweighs the risks, there is insufficient social or psychological support, or the requirements in this consent are not met.
	I understand that I may decide to stop treatment at any time.

Prevention of Complications while under Treatment of HRT

Patient	Statement
	I agree to notify the prescribing physician if I suffer from any side effects during treatment or am unhappy with the treatment in any way, and if I have any concerns that I have worsening signs of depression or anxiety or wants to harm myself or attempt suicide or attempt suicide.
	The prescribing physician is required to monitor me for any side effects during treatment and may refer me to another physician or specialist for treatment.

CONSENT:

My signature below confirms that:

1. My prescribing physician has talked with me about:
   a. the benefits and risks of taking testosterone;
   b. the possible or likely consequences of hormone therapy; and
   c. potential alternative treatments.

2. The information provided to me in this form and by the prescribing physician includes the known effects and risks of treatment with testosterone. I know that there may be other unknown short-term and long-term effects or risks which may be irreversible.

3. I have had sufficient time and opportunity to discuss relevant treatment options with my prescribing physician.

4. All my questions have been answered to my satisfaction by my prescribing physician.

5. I know enough to give informed consent to take, refuse, or postpone taking testosterone.

6. The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.52, F.S. This form contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your physician.

7. My signature below attests to my consent to begin treatment with testosterone.

Based on all this information:

_____ I want to begin or continue taking testosterone
_____ I want to begin or continue taking finasteride
_____ I do not wish to begin or continue taking masculinizing medication

_____
Patient's printed name (required)

_____ _____
Patient's signature (required) Date

PRESCRIBING PHYSICIAN:

My signature below attests to my compliance with 456.52, Florida Statutes.

_____
Prescribing physician's printed name (required)

_____ _____
Prescribing physician's signature (required) Date

WITNESS:

_____

Witness' printed name (required)

_____ _____

Witness' signature (required) Date

FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:

I certify that I am fluent in English and in the native language of the person indicating consent and/or assent on the above form. I certify that I have accurately and completely interpreted the contents of this form, and that the patient has indicated understanding of the contents of this form.

_____

Interpreter's printed name

_____ _____

Interpreter's signature Date

Surgical Treatment for Adults with Gender Dysphoria

Patient Information and Informed Consent

Before having surgery to treat gender dysphoria, you need to be aware of the effects and possible risks of these procedures. Your surgeon will make a medical decision, in consultation with you, about the procedures that are best for you, keeping in mind your overall health.

Your surgeon will discuss with you all the information relating to the surgery. You are asked to read and understand the following information and to discuss any questions you have with your surgeon. After your questions or concerns are addressed and you have decided to have surgery you must initial the statements below and sign this form in person with your surgeon.

Medical treatment of people with gender dysphoria is based on very limited, poor-quality research with only subtle improvements seen in some patient's psychological functioning in some, but not all, research studies. This practice is purely speculative, and the possible psychological benefits may not outweigh the substantial risks of medical treatments and, in many cases, the need for lifelong medical treatments.

What are the types of surgery to treat gender dysphoria?

Surgery to treat gender dysphoria may involve procedures on the face, chest, or genitalia. Common surgery options include:

- **Facial reconstructive surgery** to make facial features more masculine or feminine.
- **Chest or "Top" surgery** to remove breast tissue for a more masculine appearance or enhance breast size and shape for a more feminine appearance.
- **Genital or "Bottom" surgery** to transform and reconstruct the genitalia.
  - **Orchiectomy:** A bilateral orchiectomy is a procedure performed by a urologist that involves surgical removal of the testicles through a small scrotal incision. This procedure is done with a particular technique that allows for vaginoplasty later, if desired. Afterward, patients may adjust their dose of estrogens downward and no longer require spironolactone. Recovery takes approximately 2 weeks. Individuals seeking orchiectomy may wish to consider semen banking to preserve future fertility options.

Please initial below to acknowledge your understanding of the information on this page.

Patient

DH5084-MQA (Rev. 06/23)
Rules 64B8ER23-11 and 64B15ER23-12

- **Vaginoplasty**: In addition to an orchiectomy, a person may elect to undergo a vaginoplasty, which is a surgical procedure that involves reconstructing the genitals to create external female genitalia with or without a vaginal cavity. For those patients treated with puberty blockers as a minor, such treatment may lead to insufficient penile tissue that could necessitate the use other tissues, such as the colon, to create a vagina.
- **Phalloplasty:** This surgery involves a multi-staged procedure for the creation of a penis, urinary channel to allow urination, scrotum, and the obliteration of the vaginal cavity with closure. The removal of the female genital organs such as the uterus and ovaries and fallopian tubes are required and usually performed separately and prior to the phalloplasty surgery. The creation of the penis is performed with use of tissue from other parts of the body, which could include, more commonly the radial forearm free flap, or anterolateral thigh flap, and latissimus dorsi (MLD) flap. Prosthetics such as silicone or saline testicles can be placed as well as inflatable penile prosthetics in the final stage.
- **Metoidioplasty:** In this procedure, the surrounding tissue of the clitoris is released to achieve maximal length and a more natural-looking male position. A urethra is also reconstructed using either local skin tissue or a graft from the mouth depending on the amount of tissue present. Construction of a scrotum with testicular prosthetics can also be performed at the same time.
- **Hysterectomy:** Removal of the uterus and cervix via laparoscopic or vaginal techniques.
- **Salpingo-oophorectomy:** Removal of the fallopian tubes and ovaries.
- **Vaginectomy:** Obliteration of the vaginal canal and opening.

Is surgery the only treatment for gender dysphoria?

Surgery is just one option. Not everyone who has gender dysphoria chooses to have surgery. Depending on your age and preferences, you may choose:

- Treatment by a licensed mental health care professional that has experience in treating people with gender dysphoria, which is recommend regardless of whether you undergo surgery due to the high risk of anxiety, depression, self-harm, and suicide.
- Hormone replacement therapy to increase masculine or feminine characteristics.

Other options may be discussed with your prescribing physician.

Please initial below to acknowledge your understanding of the information on this page.

Patient

What are some potential complications of surgery to treat gender dysphoria?

Potential complications include:

- Changes in sexual sensation
- Diminishment of bladder function
- Problems with urination
- Bleeding
- Infection
- Nerve damage
- Poor healing
- Scarring that can cause pain, firmness, asymmetry
- Side effects of anesthesia, including death

What happens after surgery to treat gender dysphoria?

Recovery times vary based on what procedures or combination of procedures you have as follows:

- **Cheek and nose surgery:** Swelling lasts for around two to four weeks.
- **Chin and jaw surgery:** Most swelling fades within two weeks but may take up to four months for swelling to completely disappear.
- **Chest surgery:** Swelling and soreness lasts for one to two weeks with physical limitations lasting at least one month.
- **Bottom surgery:** Most people do not resume usual activities until at least six weeks after surgery and weekly follow-up visits with your surgeon for several months will be necessary.

When should I see my surgeon?

After surgery, you should see your surgeon if you experience:

- Bleeding for more than a few days.
- Pain that does not go away after several weeks.
- Signs of infection, such as a wound that changes color or does not heal.

Please initial below to acknowledge your understanding of the information on this page.

Patient

Please initial each statement on this form to show that you understand the risks and changes associated with gender dysphoria surgeries.

Patient	Statement
	I understand that my surgeon will discuss with me during the preoperative process the available surgical procedures to treat gender dysphoria, the aftercare needs following surgery, and the importance of postoperative follow-up.
	I understand that these surgeries are permanent.
	I understand that if I have my breasts removed, I must undergo reconstructive surgery if I wish to have breasts in the future. If implants are used, complications may include pain, numbness, infection, bleeding, asymmetry, hardening, rippling, scarring, and the possible need for multiple surgeries.
	I understand that if I have my breasts removed that breast feeding will never be possible.
	I understand that if I have breast augmentation surgery, complications may include pain, numbness, infection, bleeding, asymmetry, hardening, rippling, scarring, and the possible need for multiple surgeries.
	I understand that my surgeon will assess me for risk factors associated with breast cancer prior to breast augmentation or mastectomy, including genetic mutations (e.g.., BRCA1, BRCA2), family history, age, radiation, exposure to estrogen, and the amount of breast tissue anticipated to remain after surgery.
	I understand that if I undergo metoidioplasty/phalloplasty I will need lifelong urological treatment.
	I understand that complications following metoidioplasty/phalloplasty include: • urinary tract strictures and fistulas • mucoceles due to vaginal remnant • hair growth within the neourethra • compromised sexual function including absent tactile and/or erogenous sensation, difficulties achieving orgasm • complications with penile prosthetics
	I understand that if I undergo vaginoplasty I will need lifelong treatment with my surgeon, primary care physician, and/or gynecologist.
	I understand that if I undergo vaginoplasty, complications can include: • the formation of granulation tissue • intravaginal hair growth • delayed wound healing and/or wound disruption • introital stenosis (closing, narrowing, or closure)

	• painful sex
	I understand that my surgeon may stop further treatment because the risks of treatment outweigh the benefits of treatment.
	I understand that this treatment will not prevent serious psychiatric events, including suicide.
	I agree to tell my surgeon if I have any problems or side effects or am unhappy with the surgery, including if I have worsening signs of depression or anxiety or want to harm myself or attempt suicide.
	I understand that my surgeon may be required to refer me to one or more specialists for surgery-related complications, and I agree to go to those specialists as recommended.
	I acknowledge that surgery to treat gender dysphoria is only part of my overall health and that a range of preventative health activities are recommended including: • cervical/prostrate screening tests at appropriate intervals as recommended by my doctor • regularly checking my breasts for lumps, even if I have had a mastectomy • regular mammograms from an appropriate age in consultation with my doctor • quitting smoking • immunizations • regular STI screening, depending on my level of risk • HIV prevention, depending on my level of risk • regular physical activity, including resistance exercise for bone health • healthy eating

CONSENT:

My signature below confirms that:

1. My surgeon has talked with me about:
    a. the benefits and risks of surgery to treat gender dysphoria;
    b. the possible or likely consequences of surgery to treat gender dysphoria;
    c. potential alternative treatments.

2. The information provided to me in this form and by the surgeon includes the known effects and risks of surgery to treat gender dysphoria. I know that there may be other unknown short-term and long-term effects or risks which may be irreversible.

3. I have had sufficient time and opportunity to discuss relevant treatment options with my surgeon.

4. All my questions have been answered to my satisfaction by my surgeon.

5. I know enough to give informed consent to have, refuse, or postpone surgery to treat gender dysphoria.

6. The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.52, F.S. This form contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your surgeon.

7. My signature below attests to my consent to surgery to treat gender dysphoria.

My signature below confirms the following:

_____ _____

Patient's signature (required) Date

_____ _____

Patient's signature (required) Date

DH5084-MQA (Rev. 06/23)
Rules 64B8ER23-11 and 64B15ER23-12

SURGEON:

My signature below attests to my compliance with 456.52, Florida Statutes.

_____

Surgeon's printed name (required)

_____ _____

Surgeon's signature (required) Date

WITNESS:

_____

Witness' printed name (required)

_____ _____

Witness' signature (required) Date

FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:

I certify that I am fluent in English and in the native language of the person indicating consent on the above form. I certify that I have accurately and completely interpreted the contents of this form, and that the patient has indicated understanding of the contents of this form.

_____

Interpreter's printed name

_____ _____

Interpreter's signature Date

KENNETH J. PLANTE
COORDINATOR
Room 680, Pepper Building
111 West Madison Street
Tallahassee, Florida 32399-1400
Telephone (850) 488-9110
Fax (850) 922-6934
www.japc.state.fl.us
japc@leg.state.fl.us

July 21, 2023

Mr. Christopher Dierlam
Senior Assistant Attorney General
Office of the Attorney General
PL-01, The Capitol
Tallahassee, Florida 32399-1050

RE: Department of Health: Board of Medicine
Emergency Rule 64B8ER23-8

Dear Mr. Dierlam:

I have reviewed the above-referenced emergency rule, which was effective on July 5, 2023, and advertised in the Florida Administrative Register on July 7, 2023. I have the following comments.

64B8ER23-8: The board may want to consider citing section 458.331(1)(v) as rulemaking authority and as a law implemented.

64B8ER23-8(1)(a): DH5082-MQA, Feminizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Consent
Page 3: Please explain the board's statutory authority for requiring that adults receiving these medications "to undergo a thorough psychological and social evaluation performed by a Florida licensed board-certified psychiatrist or a Florida licensed psychologist" before beginning HRT and every two years thereafter. *See* § 120.52(8)(c), Fla. Stat.

Also, please explain why this informed consent contains substantive requirements for adults to receive hormone replacement therapy. Section 456.52(2) requires the consent form to provide information regarding the nature and risks of the prescription and an acknowledgment from the patient. It appears that substantive requirements for hormone replacement therapy should be in the rule text, not in the informed consent form. *See* § 120.52(8)(c), Fla. Stat.

64B8ER23-8(1)(b): DH5083-MQA, Masculinizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Consent
See comments to 64B8ER23-8(1)(a) regarding form DH5082.

Please let me know if you have any questions. Otherwise, I look forward to your response.

Sincerely,

Marjorie C. Holladay
Chief Attorney

cc: Mr. Edward A. Tellechea, Chief Assistant Attorney General

MCH:df #190463

KATHLEEN PASSIDOMO
President

PAUL RENNER
Speaker

THE FLORIDA LEGISLATURE

JOINT ADMINISTRATIVE PROCEDURES COMMITTEE

Representative Tobin Rogers "Toby" Overdorf, Chair
Senator Blaise Ingoglia, Vice Chair
Senator Colleen Burton
Senator Erin Grall
Senator Rosalind Osgood
Senator Darryl Ervin Rouson
Representative Shane G. Abbott
Representative Kimberly Berfield
Representative Jervonte "Tae" Edmonds
Representative Alina Garcia
Representative Yvonne Hayes Hinson

KENNETH J. PLANTE
COORDINATOR
Room 680, Pepper Building
111 West Madison Street
Tallahassee, Florida 32399-1400
Telephone (850) 488-9110
Fax (850) 922-6934
www.japc.state.fl.us
japc@leg.state.fl.us

July 21, 2023

Ms. Donna McNulty
Special Counsel
Office of the Attorney General
PL-01, The Capitol
Tallahassee, Florida 32399-1050

RE: Department of Health: Board of Osteopathic Medicine
Emergency Rule 64B15ER23-10

Dear Ms. McNulty:

I have reviewed the above-referenced emergency rule, which was effective on July 5, 2023, and advertised in the Florida Administrative Register on July 7, 2023. I have the following comments.

64B15ER23-10: The board may want to consider citing section 459.015(1)(z) as rulemaking authority and as a law implemented.

64B15ER23-10(1)(a): DH5082-MQA, Feminizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Consent
Page 3: Please explain the board's statutory authority for requiring that adults receiving these medications "to undergo a thorough psychological and social evaluation performed by a Florida licensed board-certified psychiatrist or a Florida licensed psychologist" before beginning HRT and every two years thereafter. *See* § 120.52(8)(c), Fla. Stat.

Also, please explain why this informed consent contains substantive requirements for adults to receive hormone replacement therapy. Section 456.52(2) requires the consent form to provide information regarding the nature and risks of the prescription and an acknowledgment from the patient. It appears that substantive requirements for hormone replacement therapy should be in the rule

text, not in the informed consent form. *See* § 120.52(8)(c), Fla. Stat.

64B15ER23-10(1)(b): DH5083-MQA, Masculinizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Consent
See comments to 64B15ER23-10(1)(a) regarding form DH5082.

Please let me know if you have any questions. Otherwise, I look forward to your response.

Sincerely,

Marjorie C. Holladay
Chief Attorney

cc: Mr. Edward A. Tellechea, Chief Assistant Attorney General

MCH:df #190465