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CAMPUS

They Support Sex Changes for Children, With Safeguards. A Top Child Psychiatry Group Won't Let Them Speak at Its Annual Conference.

The American Academy of Child and Adolescent Psychiatry has vetoed at least three panels with European clinicians about their efforts to limit gender care.

Transgender rights protesters / Getty Images

Aaron Sibarium
August 11, 2023

A top pediatric psychiatry organization has nixed at least three panels with leading European psychologists about Europe's move away from chemical interventions for children with gender dysphoria, raising questions about the politicization of American medicine and underscoring a clinical divide between the United States and much of the world.

The American Academy of Child and Adolescent Psychiatry (AACAP), which sets practice guidelines for the field, rejected one panel in 2022 and two more this May on the advice of its "Gender Identity Committee," whose co-chair, Aron Janssen, has described restrictions on puberty blockers and cross-sex hormones as an "effort to oppress."

Each panel would have taken place at the group's annual conferences—research-cum-networking bonanzas that draw thousands of professionals—and would have featured clinicians from countries that have restricted access to those drugs, allowing their use only in clinical trials or after long periods of psychological vetting. The speakers planned to discuss the data that led Finland, Sweden, and England to abandon the more laissez-faire treatment model now dominant in the United States, according to emails and panel proposals reviewed by the *Washington Free Beacon*.

It is "highly unusual" for the academy to axe events with international speakers, said Kristopher Kaliebe, a psychiatrist at the University of Southern Florida who organized the panels. And it was odder still given that the speakers were some of the biggest names in gender medicine, most with a long track record of transitioning children.

All three panels would have included Riittakerttu Kaltiala, the chief psychiatrist at one of Finland's two pediatric gender clinics, who has been prescribing puberty blockers since 2011 but—amid skyrocketing referrals to her service—has in recent years called for more guardrails on what can sometimes be irreversible treatments.

"There are people who benefit from medical transition, even early transition initiated during developmental years," Kaltiala told the *Free Beacon*. But, she added, there are also people for whom "rapidly proceeding to gender reassignment will result in harm."

The academy's unwillingness to host Kaltiala and other likeminded clinicians suggests that even this moderate stance may now be a bridge too far for America's premier child psychiatry association, where even senior officials are raising concerns about ideological capture.

AACAP has chosen "advocacy over science," Kaliebe said in an email to James McGough, who oversees conference programming, after the second two panels were nixed. In

response, McGough conceded that politics likely played a role.

"I actually share some of your concerns about AACAP … coming down too heavily on one side of politically charged topics," McGough told Kaliebe in a May email. Decisions about conference programming, he added, are "based on input from various AACAP committees." If the gender committee is "too one sided, the program committee is in a tough spot. Our committees are considered our experts."

The exchange illustrates how a small group of activist doctors can suppress the viewpoints of clinicians who disagree with them, creating the appearance of medical consensus where none exists.

A similar dust-up occurred at the American Academy of Pediatrics in 2021 when it barred clinicians skeptical of "gender-affirming care" from setting up a booth at its annual conference. The pediatric group—which has close ties to AACAP—also blocked two separate resolutions calling for a review of its gender policies, only agreeing to such a study last week after years of pressure.

The belated reckoning reflects what Kaliebe says is a "spiral of silence" in which professional associations look to each other for cues. "Until they change their stance, we don't want to change ours," said Kaliebe, who served as an AACAP liaison to the American Academy of Pediatrics.

The no-guardrails approach to gender care now commands support from nearly every

major medical group in the United States. Citing guidance from the World Professional Association for Transgender Health—which last year endorsed "castration" for "those who identify as eunuchs"—the American Psychological Association in 2021 condemned restrictions on puberty blockers and cross-sex hormones. The American Psychiatric Association, the American Medical Association, the American College of Physicians, and the Endocrine Society have all issued similar statements, partly in reaction to red states outlawing hormone therapy for minors.

The panels with European clinicians were an attempt to puncture that consensus. The first one, rejected from AACAP's 2022 conference in Toronto, Canada, would have presented new research on the changing demographics of gender dysphoria, which used to present mostly in young boys but is now concentrated among teenage girls, many of whom have other mental health problems. Invited speakers included Kaltiala and Lisa

Littman—the doctor who popularized the idea that gender dysphoria could be driven by social forces—as well as two laypeople, Corinna Cohn and Grace Lidinsky-Smith, who had gender reassignment surgery but later regretted their transition.

The inclusion of detransitioners was "not appropriate given our format," McGough wrote in a 2022 email explaining the rejection. But an academy member familiar with the approval process said it was unheard of for the group to nix a panel presenting new research, especially from such prominent doctors.

"I've never seen a research symposium be rejected," the member said.

McGough and Janssen, the gender committee co-chair, did not respond to requests for comment. The American Academy of Child and Adolescent Psychiatry did not respond to a request for comment.

After the first rejection, Kaliebe took pains to make his next submissions as evenhanded as possible. He organized two other panels, both without detransitioners, and asked Janssen in February to appear on one of them, meaning there would be at least one voice in favor of unrestricted transition.

Janssen refused, Kaliebe said, so the clinicians tapped Colleen Craft—a former president of the American Academy Academy of Pediatrics who presided over its embrace of "gender-affirming care"—to participate instead. Other big names included Swedish psychiatrist Mikael Landen, whose research on puberty blockers prompted the country to restrict their use, as well as Kaltiala and Michael Biggs, an Oxford sociologist who studies suicidality in transgender adolescents, according to the panel proposals.

The academy declined to host both panels, which had been handpicked to include affirmative perspectives, at its October 2023 conference in New York City, citing "space and time constraints."

It nonetheless accepted over 10 other presentations on transgender issues, including "InterSEXionality: Discussing Sex and Gender with Gen Z in A Politicized World," "BIPOC LGBTQ Media Matters: Tools for Facilitating Discussions of Intersectionality and Mental

Health," and "Beyond the Sum of Its Parts: The Intersectionality of Chinese/Chinese American Sexual- and Gender-Minority Transitional-Aged Youth and Young Adults," according to a list of scheduled programming.

The double standard reflects a widening gulf between the organization's party line and the views of its rank-and-file members. While Janssen has attacked the idea that social forces play any role in gender dysphoria—dismissing it as "speculation" in an amicus brief submitted to a Tennessee district court—83 percent of AACAP members say social media is "often" a factor in their patients' gender identity, according to a poll conducted by the group's Social Media Institute.

Driving that perception is an unprecedented uptick in gender dysphoria among young people, which is now being felt in clinicians' day to day work. "10 years ago, maybe one out of every 500 of my patients identified as trans," one psychiatrist said, adding that his practice focuses on children with severe mental health problems. "Now, among middle school girls, it's something like 40 percent."

Clinics across the world have experienced similar spikes, with rates of gender dysphoria rising by 1,500 percent in Sweden and 4,000 percent in England between 2008 and 2018. The pattern was one of the main reasons why European countries pivoted on puberty blockers, which were first used to treat gender dysphoria in the Netherlands—only in children without other conditions and after at least six months of therapy.

Eventually, Kaltiala said, those "original safeguards were dropped and the intervention

was applied to patient populations that did not at all match the original group." By 2015, 68 percent of her clinics' patients had preexisting mental health problems, and many "did not benefit from hormonal treatments."

In some patients, she added, psychiatric functioning even declined. "It was necessary to reconsider the situation."

While the debate about gender care has broken down along partisan lines in the United States, it is considerably less polarized in other parts of the world. Liberals formed an

important part of the coalition that pushed for restrictions on puberty blockers in England, and when Kaliebe attended a conference on gender therapy in Finland, "nobody there was a conservative," he said.

"The people raising questions about this type of care are not coming from a political point of view. But the people squashing debate are."

Published under: Academia , Children , LGBT , sex-change , Transgenderism

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Doctors Group to Examine Guidelines for Treatment of Transgender Youths

The American Academy of Pediatrics plans to review the evidence for gender-affirming medical care and potentially amend its policies.

By Jathon Sapsford and Stephanie Armour

The American Academy of Pediatrics, the nation's premier association of pediatricians, plans to review the evidence for gender-affirming medical care and potentially amend its policies that help guide doctors and clinicians providing the treatment to transgender youth.

The exact scope of the review has yet to be determined, but is expected to include an evaluation of medical interventions such as puberty blockers and hormones, which are in some cases used to delay puberty or boost physical features associated with a gender different from the patient's sex at birth.

The process, known as a systematic evidence review, typically looks at all relevant evidence behind any given treatment, adjusting for bias and other potential flaws. It will be conducted by an external organization, the AAP said.

Its goal will seek to confirm best practices for treatments of transgender youth, adolescents and young adults, the AAP said. The association's board, voting in its headquarters in the Chicago area, approved the external review on Thursday afternoon.

The vote comes after a number of Republican-run states introduced bans or other restrictions on gender-affirming care, saying the science doesn't support medical interventions. The systematic review "reflects the fact that the board is very concerned about the restrictions," said AAP Chief Executive Mark Del Monte.

The AAP issued a policy statement in 2018 supporting the use of gender-affirming care. The older policy was up for its mandatory, five-year review later this year. The board voted to reaffirm the policy, but officials said it could possibly be revised subject to the review.

The stakes are potentially significant, with the review coming as the nation's doctors face intense and growing scrutiny of their treatment of gender-diverse youth. The AAP is one of a number of medical associations whose guidelines for such treatments are cited in everything from court cases to insurance claims to media reports over whether medical interventions are appropriate for children.

In Europe, systematic evidence reviews have led to at least five European countries—the U.K., Sweden, Finland, Norway and France—to urge more caution in the use of puberty blockers and other medical interventions, noting that there isn't enough evidence to support claims that the benefits outweigh the risks.

In the U.S., about 1.6 million people ages 13 and above identify as transgender, according to the Williams Institute at University of California, Los Angeles. But in recent months, the treatment of this community has become a focal point for the nation's politics.

Transgender activists and their allies, including many Democrats, say such treatments are medically necessary and lifesaving. Critics, including evangelicals and conservative politicians, say the treatments are inappropriate for young patients because of the risks associated with puberty blockers and hormones.

The Food and Drug Administration has approved such drugs for treatment of early puberty, but hasn't approved them for minors with gender dysphoria who are transitioning their gender, though doctors prescribe them "off label" for the use. Gender

dysphoria refers to the sense of unease when a patient's gender identity differs from sex at birth.

Some 21 Republican-run states have enacted bans on transgender-related medical interventions involving youth, saying the risks outweigh the benefits.

Systematic reviews are based on a thorough review of all relevant evidence related to a given treatment or procedure, and are designed to help shape the practices of physicians for the best possible outcomes. They can prevent doctors from relying just on their own experiences or select studies that might support their views or experiences.

Restrictions on care

The aim is to reduce the risk of bias in medical decision making, while encouraging treatment that is based exclusively on science. Systematic reviews often assess an entire body of research, usually giving a mix of recommendations depending on the strength of the evidence, with strong recommendations based on strong evidence and weak recommendations with weak evidence.

Clinicians who defend providing gender-affirming care to minors say there is more harm in denying the care to youth and that the matter has been subject to extensive study and research.

"Gender affirmative models of care are based on detailed and thoughtful medical interviews and biopsychosocial assessments that clinicians are trained to do in order to take care of all of our patients," Michelle Forcier, a doctor at Folx Health, a national healthcare provider for the LGBTQ community, said in an interview last month.

When the AAP issued its first policy statement on transgender care of youths in 2018, the group recommended clinicians take a nonjudgmental approach that included providing access to gender-affirming healthcare, in which the clinician supports the patient's self-described gender identity.

"Pediatric providers have an essential role in assessing gender concerns and providing evidence-based information to assist youth and families in medical decision-making. Not doing so can prolong or exacerbate gender dysphoria and contribute to abuse and stigmatization," the AAP policy said.

The policy also warned against delaying interventions, which advocates say can increase stress as the patient enters puberty. Instead, the guidelines said transgender youth "know their gender as clearly and as consistently as their developmentally equivalent peers who

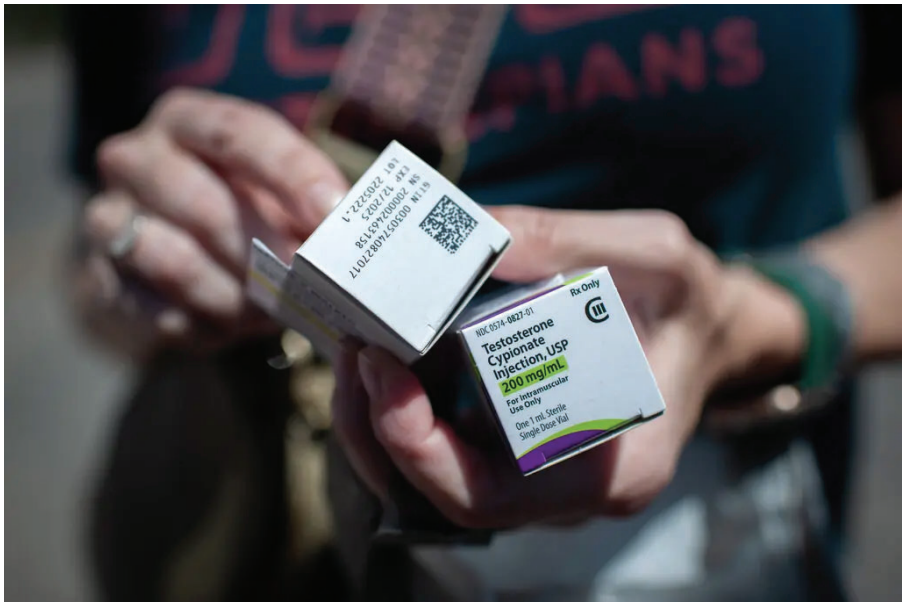
identify as cisgender and benefit from the same level of social acceptance."

The statement has helped shape treatment and care for transgender minors, advancing the use of puberty blockers, hormones and sometimes surgery. Many in the medical community have treated the matter as settled even as some European countries backed away from the approach now widely used in the U.S.

Write to Jathon Sapsford at jathon.sapsford@wsj.com and Stephanie Armour at Stephanie.Armour@wsj.com

Medical Group Backs Youth Gender Treatments, but Calls for Research Review

The American Academy of Pediatrics renewed its support of gender care for minors while commissioning a fresh look at the evidence.



A mother held her 17-year-old's testosterone supply after filling a prescription. Rory Doyle for The Washington Post, via Getty Images

By Azeen Ghorayshi

Aug. 3, 2023,
4:57 p.m. ET

The American Academy of Pediatrics backed gender-related treatments for children on Thursday, reaffirming its position from 2018 on a medical approach that has since been banned in 19 states.

But the influential group of doctors also took an extra step of commissioning a systematic review of medical research on the

conducted during a systematic review of medical research on the treatments, following similar efforts in Europe that found uncertain evidence for their effectiveness in adolescents.

Critics across the political spectrum — including a small but vocal group of pediatricians — have been calling for a closer look at the evidence in recent years, particularly as the number of adolescents who identify as transgender has rapidly increased.

The treatments are relatively new, and few studies have tracked their long-term effects. Health bodies in England and Sweden have limited access to the treatments after carrying out systematic reviews, the gold standard for evaluating medical research.

"The board has confidence that the existing evidence is such that the current policy is appropriate," said Mark Del Monte, the chief executive of the A.A.P. "At the same time, the board recognized that additional detail would be helpful here."

As for the policy changes in Europe, he said, "they engaged in their process, we're engaging in our process."

After completing the review, he said, the group will issue additional clinical guidance for doctors and likely update its recommendations.

All 16 board members of the A.A.P., which represents 67,000 pediatricians across the United States, voted to reaffirm the 2018 guidelines at a meeting on Thursday in Itasca, Ill. The vote comes at a time of intense political pressures on transgender people and the doctors who care for them.

Over the past two years, Republican lawmakers across the country have banned what's known as gender-affirming care, which can include psychotherapy, puberty-blocking drugs, hormones and, rarely, surgeries. Opponents of the care argue that it is experimental and children lack the maturity to consent to it.

The A.A.P. has roundly condemned the legislative bans as a dangerous intrusion into complex medical decisions between doctors and families, and has filed amicus briefs to support the many legal challenges brought against the bans by civil rights groups.

Much of the academy's support for gender-affirming care rests on its 2018 previous position statement, which said the treatments were essential and should be covered by health insurers. Transgender adolescents have high rates of anxiety, depression and suicide attempts, and early evidence suggested that gender

affirming care could improve their mental health.

Position statements like those voted on today remain valid for five years before they are up for review, at which point they may be reaffirmed, retired or revised in light of new evidence. One example of such a reversal is the academy's 2017 endorsement of infant peanut consumption, based on a landmark study showing that early exposure could help prevent lethal allergies.

Some scientists criticized the decision to continue to recommend the treatments for young people before completing a rigorous review.

The move is "very clearly putting the cart before the horse," said Dr. Gordon Guyatt, a clinical epidemiologist at McMaster University who helped develop the field of evidence-based medicine.

Based on previous systematic reviews, Dr. Guyatt said, the A.A.P.'s report will most likely find low-quality evidence for pediatric gender care. "The policies of the Europeans are much more aligned with the evidence than are the Americans'," he said.

In June, England's National Health Service announced that it would restrict the use of puberty blockers to clinical trials because "there is not enough evidence to support their safety or clinical effectiveness as a routinely available treatment." Last year, Sweden's national health care oversight body similarly determined that, on the basis of its systematic review, "the risks of puberty-inhibiting and gender-affirming hormone treatment for those under 18 currently outweigh the possible benefits."

In the United States, a small group of pediatricians has pushed for a similar review from the A.A.P., one of the few institutions with enough centralized power to influence health care practices. Dr. Julia Mason, a pediatrician in Gresham, Ore., co-founded a group called the Society for Evidence-Based Gender Medicine that has been highly critical of gender treatments for minors. Since 2020, she said, she has unsuccessfully lobbied the academy's leadership to commission a systematic review.

Dr. Mason said she was pleased the group finally decided to take a close look at the data. "We are making strong recommendations based on weak evidence," she said.

But Dr. Marci Bowers, a gynecologic and reconstructive surgeon and the president of the World Professional Association for

Transgender Health, was heartened by the A.A.P.'s endorsement of the care, which she said profoundly improves many children's lives.

"They know this population," said Dr. Bowers, who is a transgender woman. "They know the stories. Anecdotally, it's overwhelmingly positive."

She also pointed out that doctors in many specialties, and particularly in pediatrics, routinely use medicines that haven't yet been tested in large and rigorous clinical trials. And Europe, unlike many U.S. states, has not banned the care entirely.

"What they're saying is this population needs to be studied," she said, referring to European policies. "And I agree with that."

Azeen Ghorayshi covers the intersection of sex, gender and science for The Times. More about Azeen Ghorayshi

WSJ | OPINION

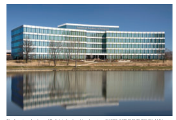
OPINION | COMMENTARY

Second Thoughts on 'Gender-Affirming Care'

The American Academy of Pediatrics orders a scientific review. Will it be conducted honestly?

By Leor Sapir

Aug. 6, 2023 at 3:49 pm ET



The American Academy of Pediatrics' national headquarters. PHOTO: SERHII CHRUCKY/ALAMY

The American Academy of Pediatrics said last week that it will commission a systematic review of the evidence for pediatric sex-trait modification, known euphemistically as "gender-affirming care." This marks a turning point in the battle over the controversial medical protocol. To those who favor evidence-based rather than eminence-based medicine, it is a step in the right direction.

But it is a small step. Two key questions: Will the systematic review follow a transparent, impartial scientific process? And what should the AAP do in the meantime?

In explaining the decision to commission a systematic review, the AAP's CEO, Mark Del Monte, said that the academy's board "has confidence that the existing evidence is such that the current policy is appropriate. At the same time, the board recognized that additional detail would be helpful here."

If the AAP's position is that it is "confident" the systematic review will vindicate its position and merely add "additional detail," that raises suspicions about the honesty and independence of the process and shows the need for strong guardrails against AAP influence over the inquiry.

The AAP is, first and foremost, a trade union. "Professional medical association" is a less apt description than "association of medical professionals." Teachers unions care about education but give their own and their members' interests priority over those of students. So too the AAP has strong incentives to defend its own interests and those of member doctors—especially those who have publicly endorsed or facilitated sex-trait modification—even when that is harmful to patients.

The AAP and prominent members have consistently assured policy makers and judges that sex-trait modification is safe and effective and based on strong science. Insurance companies have based their coverage decisions on these claims. Democrats have used them to cast opponents as bigots. The Biden administration regularly cites the AAP in its efforts to guarantee minors unfettered access to hormonal drugs and life-altering surgery. Parents have accepted AAP claims and agreed to allow doctors to disrupt their children's natural puberty, flood their bodies with synthetic hormones, and amputate their healthy breasts.

Should we therefore expect AAP leadership to be genuinely curious about the findings of a systematic review? Should we trust that the AAP won't try to influence the outcome by tinkering with the process?

Unlike narrative literature reviews, systematic reviews follow a transparent, reproducible methodology on the same body of research. Anyone who uses the same methodology should arrive at more or less the same result. The existing systematic reviews on the benefits and risks of puberty blockers and cross-sex hormones, conducted by health authorities in three European countries, all found "very low" quality evidence for these interventions.

Given the finding of every existing systematic review to date that the evidence for "gender-affirming care" is exceptionally weak, the AAP should immediately recommend extreme caution in the use of puberty blockers, cross-sex hormones and surgeries in treating youth gender dysphoria. This is a no-brainer; health authorities in the U.K., Norway, Sweden, Finland and France have done it. "There is not enough evidence to support the safety, clinical effectiveness and cost effectiveness to make the treatment routinely available at this time," said the statement from England's National Health Service.

Systematic reviews can take six to 18 months to complete. Because the AAP apparently recognizes the superiority of systematic reviews, it should defer, while the review process is under way, to the systematic reviews conducted by the U.K. National Institute for Health Care Excellence in 2020 and updated last week. A slew of new systematic reviews touching on a wide range of topics related to pediatric gender medicine is expected to come out in the U.K. well before the AAP systematic review is completed. When they do, the AAP should embrace their findings.

Last August the AAP president said that her organization's policy was based on "the best science." But if systematic reviews are the appropriate way to evaluate the evidence, and if every systematic review to date has found that the evidence is exceptionally weak, how can the AAP continue to maintain that its current approach is evidence-based? Mr. Del Monte was evasive on this point. The Europeans, he said, "engaged in their process, we're engaging in our process."

In a press release, the AAP has promised a "policy update process" that is "transparent and inclusive." The AAP "will invite members and other stakeholders to share input." Will those members include the pediatricians who have demanded that a systematic review be done? Will it include researchers who have found evidence of socially influenced transgender identity? Will "other stakeholders" include "detransitioners," who were inappropriately prescribed drugs and surgery when they should have received only mental-health support? Will it include parents of children who thought they were transgender and wanted drugs and surgeries, but changed their minds and now feel better?

The organization's consistent attempts to suppress debate on this sensitive issue, the recent remarks of its chief executive, and its profound conflict of interest as a trade association don't inspire confidence that it will act scientifically and in the best interests of children and families.

Mr. Del Monte and the AAP can rest assured that the group's actions will be carefully watched over the months ahead. If the AAP wants to regain the public's trust, it must allow for a truly transparent and inclusive process, not one that involves only those who agree with its existing position. Above all, the AAP must commit itself to follow the science, wherever it leads.

Mr. Sapir is a fellow at the Manhattan Institute.

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RECOMMENDED VIDEOS

As protests erupted outside a Glendale, Calif., school board meeting discussing LGBTQ+ issues in the classroom on June 6, 2023, opponents highlighted their concerns about teachers discussing sexual orientation and gender identity with children. Images: The Orange County Register via AP/Zuma Press Composite: Mark Kelly

SHOW CONVERSATION (1004)

What to Read Next

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

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.

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

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

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 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

From: juanantoniobasteiro=gmail.com@mg.gospringboard.io on behalf of Juan Antonio Basteiro
To: BOM Public Comment
Subject: Reject rules to restrict access to gender affirming care
Date: Thursday, July 20, 2023 5:01:48 PM

Dear

I am writing to you today to urge the Florida State Board of Medicine to reject rule 64B8-9.019 and the Florida State Board of Osteopathic Medicine to reject rule 64B15-14.014. Both proposed rules cover Standards of Practice for the Treatment of Gender Dysphoria in Minors, to restrict access to gender-affirming healthcare.

Care providers, doctors, and leading medical associations have been clear that gender-affirming care is safe, effective, evidence-based, and lifesaving.

The nation's leading health organizations support gender-affirming care for transgender and gender non-conforming people, including the American Academy of Pediatrics; the American Medical Association; The American College of Obstetricians and Gynecologists; The American College of Physicians; The American Psychiatric Association; The American Psychological Association; The American Academy of Family Physicians; The Endocrine Society; The Pediatric Endocrine Society; American Nurses Association; American Public Health Association; American Heart Association; National Association of Social Workers; World Medical Association; and The World Professional Association for Transgender Health, among others.

There is overwhelming evidence to support the positive mental health impacts of gender-affirming medical care for transgender adolescents - including in some of the very studies cited by the DOH and Board of Medicine. Prohibiting social transition is clear government intrusion on personal and parental decision-making. Numerous studies have found that after social transition, transgender youth report similar mental health levels to the general youth population, eliminating mental health disparities typically seen. When transgender youth are affirmed by people around them, reported rates of depression and suicidality drop significantly. This rule will deny them this life-saving treatment.

The Florida State Board of Medicine and the Florida Board of Osteopathic Medicine must reject proposed policies like these that are not grounded in science and research and are clearly based on prejudice and political agendas. The evidence is clear: denying transgender youth the ability to access critical healthcare is dangerous and life-threatening.

I urge you to reject these rules.

Sincerely,

Juan Antonio Basteiro

From: Kristin Dayton
To: BOM Public Comment
Subject: Comment regarding Emergency Rule and Consents for Gender Care for Minors
Date: Friday, June 30, 2023 4:16:27 PM

Board of Medicine,

I am a physician who cares for hundreds of children with gender dysphoria, and this care many times includes providing gender affirming hormonal prescriptions. **I have spoken with you previously as an expert on the matter**, and have been providing this care for over 6 years. I provide thorough informed consent for all of my patients, both children and adults. I have several issues to bring up regarding the current proposed (and now passed) consent forms that you have created.

1. Requirement for mental health evaluation and suicide assessment by **licensed mental health professional** every 3 months - this is a barrier to care for many patients. We complete mental health assessments at each visit for our gender clinic patients, and include an assessment of suicidality. As physicians, it is well within our scope of practice to carry out this evaluation. So, requiring this to be done by a mental health professional is creating undue burden for our patients. Furthermore, many of our patients may not need that frequent of follow up visits with mental health professionals as they may be well adjusted and not experiencing significant emotional distress (especially once they are able to obtain the appropriate gender-affirming treatment). So, this may be taking away mental health resources from those that truly need it in order to "check a box" for continuing to receive gender care. Contrary to some of the comments made by board members, my experience practicing with this patient population is that it is VERY challenging for them to find mental health professionals and even then they may not be able to obtain appropriate insurance coverage for that continued mental health support.

2. Required labs, imaging studies: The requirements for lab studies and imaging studies should be changed to recommendations. This is not because we don't do these tests, but the frequencies of them are inappropriate and may lead to undue harm for patients. For instance, a bone age study is not required for someone undergoing gender care - it is only recommended if clinically indicated (see Endocrine Society Guidelines) and exposes them to radiation. It is an optional part of monitoring for certain patients, but should not be a yearly requirement as it does not have any added value to care for most patients. By guidelines, DEXA scans are recommended to be done every 1-2 years for patients on pubertal blocking medication but not for patients on gender affirming hormones (HRT as worded in your document). This is again exposing patients to unnecessary radiation with no evidence of the need for this to be done. Lastly, lab testing every 4 months is again an inappropriate frequency of testing. Patients on puberty blocking treatment, especially once they reach a steady state of suppression, typically do not need more than once yearly lab assessments and this would place them at undue financial and physical burden to make them do labs more often.

3. Language regarding the low quality evidence is misleading: The language in the BOM

consent forms that points to the "limited, poor quality research" and "speculative" nature of this treatment is misleading and false. Further, the use of the term "poor quality research" is in fact an opinion and not a medical fact - a more appropriate medical term using the GRADE evidence system (see GRADE system explained) may be "low quality evidence". You imply in this form that this may be unusual in medical practice, yet, low quality evidence is used every day to make important, life altering medical decisions. Therefore the fact that it is introduced at the beginning of every consent form is misleading to those not familiar with this commonality in medical practice.

Please feel free to reach out to me for any other questions or concerns,

Sincerely,
Kristin Dayton, MD

Public Comment Florida Boards of Medicine and Osteopathic Medicine Joint Meeting June 30 2023

Author: Jerrica Kirkley, MD

Organization: Plume

Title: Chief Medical Officer and co-founder

My name is Dr. Jerrica Kirkley, I am the co-founder and chief medical officer at Plume, and I'm also a trans woman. At Plume we focus entirely on serving the trans and gender non-conforming community and are the largest provider of gender affirming care in the country, and do that all via a telehealth platform. Our clinical team collectively brings several hundred years of experience and expertise in this space.

KEY POINTS

SB254 is in direct opposition of evidence-based care and undermines long-established medical standards of care and practice protocols.

Gender-affirming care, including gender-affirming hormone therapy, is supported by every major healthcare organization and expert in the field including the World Professional Association of Transgender Health, the American Academy of Pediatrics, the American Medical Association, the Endocrine Society, and many more.[1] In fact, just last week, the American Medical Association and the Endocrine Society passed a resolution opposing any criminal and legal penalties against patients seeking gender-affirming care, family members or guardians who support them in seeking medical care, and health care facilities and clinicians who provide gender-affirming care.[2] They reiterated that there is strong clinical research supporting gender-affirming care including over 2000 studies which have examined aspects of gender-affirming care since 1975. This is in direct contrast to the medical boards' claim that there is a paucity of clinical research and support or that gender-affirming care is "experimental".

[1] https://transhealthproject.org/resources/medical-organization-statements/
[2] https://www.endocrine.org/news-and-advocacy/news-room/2023/ama-gender-affirming-care

Having access to gender-affirming care improves health outcomes including decreasing rates of depression, anxiety, and suicidality.[3] This is supported by published clinical research and at Plume, we have seen rapid and significant reduction in depression scores with access to gender-affirming hormone therapy and virtual peer support groups. We know that gender affirming care saves lives and we're deeply concerned that SB254 actually puts real peoples' lives at risk -- many of whom are your neighbors, your co-workers or your family members.

The warnings around off-label prescription drug use in the consent forms is misleading: as practicing clinicians we're fully aware that there are over 500 off-label medications for youth alone that do not involve gender-affirming care and hundreds for adults as well outside of gender-affirming care.[4]

While our practice serves adults, we cannot ignore that the ban on youth gender affirming care is devastating and has serious implications for their future wellbeing and safety.

Finally and most importantly, SB254 sets a dangerous precedent as it fundamentally creates a two-tiered health system in Florida, where trans or gender diverse individuals will not be able or will be severely restricted in their ability to access the care they need, as compared to cisgender individuals.

Adult patients seeking gender affirming care will be segregated from the rest of the population and only be allowed to be seen by an MD or DO rather than an NP or PA, who we know provide the majority of primary care and gender-affirming care in Florida.[5]

In addition, these patients will be required to be initially seen in-person, imposing a major barrier for telehealth providers to prescribe gender-affirming medication, despite the fact that it's a

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3 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5010234/#:~:text=Published%20in%202010%2C%20the%20review,and%20overall%20quality%20of%20life.

4 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6677268/

5 https://www.pbs.org/newshour/health/floridas-ban-on-gender-affirming-care-for-minors-also-limits-access-for-trans-adults

well-established care delivery platform for all people, and especially the gender diverse community - 85% of trans individuals did not go to a healthcare facility when they needed to in 2022 due to fear of discrimination and mistreatment.[6]

Furthermore, no other medical practice requires a written informed consent, including care for diabetes, hypertension, heart disease, erectile function, hormone replacement for cisgender men and cisgender women, body modifying surgeries for cisgender people or any other surgery, and many more conditions. The **requirement to have an evaluation and letter from a FL-licensed psychiatrist or psychologist to start or continue gender-affirming hormone therapy and annual assessment thereafter,** as noted in the drafted consent forms in the public book, is in direct opposition to the WPATH standards of care version 8, and is yet another barrier to lifesaving care.

Finally, these laws, which have no scientific basis, also threaten clinicians with severe penalties for looking after their patients' health care needs, sending a chilling message to the entire medical community.

This month alone, several bipartisan federally appointed judges around the country, including here in Florida, have made it clear that anti-trans legislation is unconstitutional, and this includes bans on and restriction to healthcare access.[7] [8]

As clinicians and as part of the broader community, I urge the Florida Board of Medicine and the Florida Board of Osteopathic Medicine to stand by evidence-based medicine, to stand by the Florida clinicians you represent, to stand by your community and permit individuals access to life saving gender-affirming care and specifically:

- Do not require an evaluation and/or a letter from a psychiatrist or psychologist to access gender-affirming care

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6 https://rockhealth.com/insights/startup-innovation-for-underserved-groups-2021-digital-health-consumer-adoption-insights/?mc_cid=0bfc248bda&mc_eid=bd247e782c

7 https://www.politico.com/news/2023/06/06/florida-gender-affirming-care-ruling-00100387

8 https://www.politico.com/news/2023/06/21/florida-gender-affirming-ban-00103067