DECLARATORY RULING OF
THE ALABAMA STATE BOARD OF MEDICAL EXAMINERS

On November 13, 2025, the Alabama State Board of Medical Examiners ("the Board") considered a request submitted by Rachel Roberts, M.D., ("Petitioner") for a declaratory ruling pursuant to Ala. Code § 41-22-11 and Ala. Admin. Code r. 540-X-1-.10, concerning the application of Ala. Code § 34-24-360.2 to the use of placental stem cell injections by physicians as "off-label" treatments of conditions such as chronic joint pain, autoimmune disorders, and tissue degeneration.

FACTS PRESENTED

Petitioner presents the following factual background[1]:

"This memorandum respectfully asks the Alabama Board of Medical Examiners to clarify whether, pursuant to Ala. Code § 34-24-360.2, licensed physicians may prescribe placental stem cell injections, derived from donated placental tissue and explicitly excluding embryonic stem cells, as an off-label treatment for various medical conditions where conventional therapies have failed. This proposal presents a compelling case in the affirmative supported by clinical evidence, robust safety protocols, and strict ethical boundaries to ensure physician confidence, patient safety, and access to innovative regenerative therapies. . . ."

"This proposal involves the use of mesenchymal stem cells derived from donated placental tissue, processed and approved by the FDA as a biological product under Section 351 of the Public Health Service Act or as human cells, tissues, and cellular and tissue-based products (HCT/Ps) under 21 CFR 1271, for indications such as tissue repair, but not specifically for the conditions targeted in this proposal. The treatment is intended for patients with various medical conditions—

[1] A complete copy of Petitioner's petition is attached as Attachment A.

such as chronic joint pain, autoimmune disorders, or tissue degeneration—who have not responded to conventional therapies (e.g., medications, physical therapy, or surgery). This off-label use, explicitly excluding embryonic stem cells [and stem cells derived from aborted fetal tissue], [which] aligns with the protections and ethical standards [intended by] Alabama Code 34-24-360.2."

"Ala. Code 34-24-360.2's exemption for controlled substances (Section 1(c)) does not apply, as placental stem cells are not classified as controlled substances under Section 20-2-2, Code of Alabama 1975."

The proposed treatment, as presented by Dr. Roberts, appears to meet the safety and compliance requirements of Ala. Code 34-24-360.2, insofar as the proposal claims: (1) "studies report adverse event rates below 5%, with only mild, transient effects (e.g., injection site discomfort) and no serious complications;" (2)informed consent and patient monitoring align with ethical standards and FDA guidelines for off-label use;" and (3) "stem cells are sourced from FDA-compliant facilities, ensuring quality, safety, and exclusion of embryonic stem cells" and stem cells derived from aborted fetal tissue.

To enable physicians to confidently provide placental stem cell therapy, Petitioner urges the Board to issue the following clarification:

> 1. **Authorization**: Licensed physicians may prescribe or administer placental stem cell injections, derived from donated placental tissue and explicitly excluding embryonic stem cells, for various medical conditions as an off-label treatment, provided they:
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> > • Use FDA-approved placental stem cell products sourced from compliant facilities.
> > • Obtain detailed informed patient consent, compliant with [Ala. Code § 34-24-360.2], explaining the off-label nature, potential benefits, risks, and alternatives.
> > • Follow evidence-based protocols supported by peer-reviewed studies.

2. **Safety and Monitoring**: Physicians must implement a monitoring plan to track patient outcomes and report adverse events to the Board within 72 hours.

3. **Protection Under Ala. Code 34-24-360.2**: No adverse action will be taken against a physician's license for this off-label use unless the treatment presents a significant harm, as determined by the Board based on clinical evidence.

4. **Review Period**: The clarification will be reviewed annually to incorporate new clinical data or FDA guidance.

QUESTION PRESENTED

Under Ala. Code § 34-24-360.2, may a licensed physician prescribe or administer placental stem cell injections for legitimate medical conditions as an off-label treatment when the stem cells are derived from donated placental tissue and explicitly exclude embryonic stem cells without posing a threat of significant harm to his or her patients or to the general public; provided, the physician uses placental stem cells from FDA registered facilities; obtains detailed informed consent from the patient and explains to the patient the off-label nature of the treatment, the costs, benefits, and alternatives, and the costs associated with the procedure; and follows evidence-based protocols supported by peer-reviewed studies?

ANSWER

A licensed physician may prescribe or administer placental stem cell injections for legitimate medical conditions as an off-label treatment when (1) the stem cells are derived from donated placental tissue, are sourced from FDA registered facilities, and explicitly exclude embryonic stem cells and stem cells derived from aborted fetal tissue; (2) the physician obtains a detailed informed consent from the patient and explains to the patient the risks, benefits, and reasonable alternatives, as well as the costs associated with the procedure; (3) the physician follows evidence-based protocols supported by peer-reviewed studies; and (4) the treatment does not pose a significant risk of harm to the patient such that the treatment is medically unjustified.

DISCUSSION

The Board is charged with licensing and regulating those persons engaged in the practice of medicine or osteopathy in the state of Alabama. The Board's evaluation of a physician's conduct is always individualized and will turn on such factors as the physician's training and experience, the known or reasonably discoverable risks and benefits of a medical treatment to an individual patient, the physician's actual performance and medical decision-making, the presence or absence of reliable efficacy and safety data, and federal and state laws and regulations. Under Ala. Code § 34-24-360.2(b), the Board is prohibited from taking a disciplinary action against a licensed physician "based solely on his or her recommended or prescribed off-label treatment, unless the physician's recommended or prescribed off-label treatment presents a threat of significant harm to his or her patients or to the general public." The phrase "off-label medical treatment" is defined as "[t]he use of a drug, biological product, or device approved by the United States Food and Drug Administration (FDA) in any manner other than the use approved by the FDA." Ala. Code § 34-24-360.2(a)(4). Petitioner seeks a declaratory ruling construing the application of this code section to the recommendation, prescription, or administration of placental stem cells by a licensed physician as an off-label medical treatment.

As with all medical care, the patient's safety must be the physician's preeminent concern. Under Ala. Code § 34-24-360, a physician's license may be disciplined by the Medical Licensure Commission ("the Commission") if he or she "practice[es] medicine or osteopathy in such a manner as to endanger the health of the patient." Similarly, a physician may also be disciplined for "gross negligence," which the Commission defines in pertinent part as "the conscious doing of an act or the omission of some duty to act with a conscious disregard of known conditions of danger or with careless and reckless indifference to the consequences of such act or omission." Ala. Admin. Code r. 545-X-1-.11(l). Notably, gross negligence "may be established without proof of

actual injury or harm to the patient, provided that the act or omission complained of created a substantial risk of harm to the health and wellbeing of the patient which risk was known or should have been known to a reasonably prudent practitioner and which was not medically justified by the expected benefits to the patient from the act or omission." *Id.* Accordingly, the physician's medical decision-making must always include an evaluation of whether a medical treatment, whether "on-label" or "off-label," will treat the patient's condition without posing a significant risk of harm to the patient such that the risks outweigh the anticipated benefits of the medical treatment.

Reading Ala. Code § 34-24-360.2(b) together with Ala. Admin. Code r. 545-X-1-.11(l), it is clear that the Legislature intended to prohibit the Board or Commission from disciplining a physician for recommending or prescribing a medical treatment solely on account of the medical treatment being "off-label." Many medicines are used "off-label" prior to FDA approval when safety and efficacy data is produced and peer-reviewed by the physician community. Indeed, an off-label medical treatment may gain widespread acceptance and be used by the physician community for a significant time before gaining FDA approval. Consequently, the disciplinary bar provided by Section 34-24-360.2(b) accords with the long-standing medical practice embracing the off-label use of medical treatment when it supported by safety and efficacy data and rejecting an analysis that turns solely on whether the medical treatment is FDA-approved.

The Legislature preserved the Board and Commission's obligation to discipline gross negligence with the provision that Section 34-24-360.2's bar to prosecution is inapplicable when the physician's recommendation or prescription of an off-label medical treatment "presents a threat of significant harm" to the physician's patients "or to the general public." Ala. Code § 34-24-360.2(b). At a minimum, an off-label medical treatment poses a "substantial" risk of harm to a

patient when the risks of the treatment are not medically justified by its expected benefits. Examples of this include, but are not limited to: experimenting on patients without their knowledge and consent; prescribing or administering an off-label medical treatment without peer-reviewed or evidence-based data to support it; prescribing or administering an off-label medical treatment in the face of known or reasonably suspected contraindications; risking life-altering or life-ending complications for cosmetic or minor conditions; and using substandard medical products, drugs, or techniques when proven alternatives are available.

Petitioner's question presents a scenario where a licensed physician is appropriately weighing the expected benefits of placental stem cell treatment against its known or likely risks. The physician is mitigating the risk to the patient by confining his or her usage of stem cells to those derived from donated placental tissue sourced from FDA-registered facilities and excluding embryonic stem cells. Petitioner also shows the physician in the scenario to be using a detailed informed consent process, which is necessary for involving the patient in weighing of the costs, risks, and benefits of the proposed medical treatment. Petitioner is not asking the patient to waive his or her right to safe medical care; indeed, a physician cannot escape discipline for violating the standard of care or the Medical Practice Act by claiming the patient consented to the violation. Instead, what Petitioner's scenario shows is a physician using informed consent to discuss the clinical evidence supporting the use of placental stem cells "off label," the associated risks and alternatives, and sharing the physician's medical judgment with the patient to make sense of these datapoints. This type of exchange is the beating heart of the physician-patient relationship.

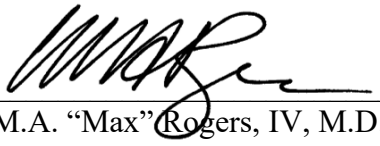
Finally, the use of evidence-based protocols supported by peer-reviewed studies shows that the physician in Petitioner's scenario is appropriately using efficacy and safety data to guide the medical treatment. Consequently, the physician in Petitioner's scenario, based on the information

provided, does not appear to be posing a significant risk of harm to his or her patient through the recommendation or prescribing of placental stem cells as a medical treatment unless the physician willfully disregards a known or reasonably likely to be known contraindication present in a particular patient and an unreasonable complication risk.

The Board specially notes that it does not hold that a physician – either in Petitioner's scenario or generally – must discuss the "off-label" nature of a medical treatment with a patient, nor must the physician require the patient to agree to receive an "off-label" medical treatment. To require otherwise would be inconsistent with good clinical practice and would potentially run afoul of the Legislature's prohibition on disciplining a physician merely because he or she provides an "off-label" medical treatment. Ala. Code § 34-24-360.2(b). Put differently, when a physician considers whether to use an FDA-approved medical treatment on a patient for an "off-label" purpose, the risks and benefits to the patient are weighed based on the medical science and not according to labels. The discussion of whether an FDA-approved medical treatment is being used for an "off-label" purpose is not a necessary part of the informed consent process.

This ruling is based upon the precise facts presented and upon statutes and rules currently in existence. Should any relevant statutes or rules be amended or repealed, this ruling may no longer be valid.

DONE this 13th day of November, 2025.



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