SB72

FVQB5CD-1

By Senators Orr, Melson

RFD: Healthcare

First Read: 07-Feb-24

SYNOPSIS:

This bill would prohibit an occupational licensing board from taking adverse action against a health care professional, including a physician, physician assistant, or nurse practitioner, who recommends an off-label medical treatment.

This bill would require a patient's written, informed consent to receive a health care professional's recommended off-label medical treatment if the treatment is not used in a manner approved by the FDA.

This bill would provide a cause of action against an occupational licensing board that violates the provisions of this bill.

A BILL

TO BE ENTITLED

AN ACT

Relating to off-label medical treatment; to prohibit an occupational licensing board from taking adverse action against a health care professional who recommends certain off-label medical treatments; to require a patient's written, informed consent to receive certain off-label medical

treatments; and to create a cause of action.

BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:

Section 1. (a) For the purposes of this section, the following terms have the following meanings:

(1) HEALTH CARE PROFESSIONAL. Any of the following individuals:

a. A physician licensed to practice medicine in this state.

b. A physician assistant licensed by the Board of Medical Examiners.

c. A certified registered nurse practitioner certified by the Board of Nursing.

(2) LICENSE. The same meaning as defined in Section 41-9A-1, Code of Alabama 1975.

(3) OCCUPATIONAL LICENSING BOARD. Any board, agency, commission, or other entity, issuing licenses or certificates, or both, in order for an individual to practice a health profession in the state.

(4) OFF-LABEL MEDICAL TREATMENT. The 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.

(5) WRITTEN, INFORMED CONSENT. A written document that is signed by the patient, the patient's legal guardian or designated attorney-in-fact, or the patient's parent or legal guardian if the patient is a minor, and includes, at a minimum, all of the following:

a. An explanation of the current medical treatments and

products approved by the FDA for the medical issue that the off-label medical treatment is recommended or prescribed to treat.

b. Clear identification of the specific proposed procedure, protocol, drug, or remedy that the patient wants to use to treat his or her medical issue.

c. A description of the potential outcomes of investigational use of a drug, biological product, or other device, including the best, worst, and most likely outcomes. The description must include the possibility that new, unanticipated, different, or more severe symptoms may result and death may be hastened by the proposed treatment.

(b) An occupational licensing board shall not revoke, suspend, fail to renew, or take action against a health care professional's license based solely on his or her recommended or prescribed off-label medical treatment if the health care professional exercised independent medical judgment and believes that the medical treatment is in the best interest of the patient, and the patient provided written, informed consent before receiving the treatment.

(c) Any health care professional who is subject to any adverse action by an occupational licensing board, as described in subsection (b), may bring a civil cause of action against the occupational licensing board for a violation of this section.

(d) A patient shall not have a civil cause of action against an occupational licensing board if that cause of action is based solely on the fact that a health care

professional recommended or prescribed an off-label medical treatment, if the prescribing health care professional is licensed by that board.

(e)(1) If an off-label medical treatment is specifically requested by the patient, the patient shall not have a civil cause of action against the prescribing health care professional or a licensed health care provider, hospital, or health care facility if the cause of action is based solely on the fact that the health care professional prescribed an off-label medical treatment, provided that the prescribing health care professional complied with the provisions of this act and the administration of the off-label medical treatment meets the applicable standard of care.

(2) Nothing in this subsection shall be construed to establish a new or separate standard of care for hospitals or health care professionals and their patients or otherwise modify, amend, or supersede any provision of the Alabama Medical Liability Act of 1987 or the Alabama Medical Liability Act of 1996, or any amendment or judicial interpretation of either act.

Section 2. This act shall become effective October 1, 2024.