

SB72 INTRODUCED



1 SB72
2 FVQB5CD-1
3 By Senators Orr, Melson
4 RFD: Healthcare
5 First Read: 07-Feb-24



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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



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29 treatments; and to create a cause of action.

30 BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:

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

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

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

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

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

41 (2) LICENSE. The same meaning as defined in Section
42 41-9A-1, Code of Alabama 1975.

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

47 (4) OFF-LABEL MEDICAL TREATMENT. The use of a drug,
48 biological product, or device approved by the United States
49 Food and Drug Administration (FDA) in any manner other than
50 the use approved by the FDA.

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

56 a. An explanation of the current medical treatments and



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

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

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

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

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

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



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

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

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

105 Section 2. This act shall become effective October 1,
106 2024.