## Senate Bill 716

Sponsored by Senator LINTHICUM (Presession filed.)

## **SUMMARY**

The following summary is not prepared by the sponsors of the measure and is not a part of the body thereof subject to consideration by the Legislative Assembly. It is an editor's brief statement of the essential features of the measure as introduced.

Allows health care practitioner to prescribe or dispense drug for off-label indication. Defines "off-label indication." Prohibits health professional regulatory board from disciplining health care practitioner for prescribing or dispensing drug for off-label indication. Allows pharmacist to dispense drug prescribed for off-label indication. Prohibits State Board of Pharmacy from disciplining pharmacist for dispensing drug prescribed for off-label indication.

Takes effect on 91st day following adjournment sine die.

## A BILL FOR AN ACT 1

- Relating to off-label indications for prescription drugs; and prescribing an effective date. 2
  - Be It Enacted by the People of the State of Oregon:
- 4 **SECTION 1.** (1) As used in this section:
- 5 (a) "Drug" has the meaning given that term in ORS 689.005.
  - (b) "Health care practitioner" means a person who is authorized:
- 7 (A) By a health professional regulatory board to practice a health care profession; and
- 8 (B) To prescribe drugs.

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- (c) "Health professional regulatory board" means: q
- (A) The Oregon Board of Dentistry; 10
- (B) The Oregon Medical Board;
- 12 (C) The Oregon State Board of Nursing; and
- 13 (D) The State Board of Pharmacy.
  - (d) "Off-label indication" means a drug use that is not approved by the United States Food and Drug Administration.
  - (2) A health care practitioner may prescribe or dispense a drug for an off-label indication if:
    - (a) Credible scientific or medical evidence demonstrates the safety and efficacy of the drug's off-label indication; and
      - (b) The health care practitioner:
    - (A) Provides to the patient to whom the drug is prescribed and dispensed a disclosure that the drug is prescribed for an off-label indication; and
    - (B) Obtains from the patient signed informed consent indicating that the patient understands that the drug is prescribed for an off-label indication.
    - (3) A health professional regulatory board may not discipline a health care practitioner regulated by the health professional regulatory board for prescribing or dispensing a drug for an off-label indication pursuant to subsection (2) of this section.
    - (4) A health professional regulatory board may adopt rules to carry out this section with regard to health care practitioners regulated by the health professional regulatory board.

**NOTE:** Matter in **boldfaced** type in an amended section is new: matter [italic and bracketed] is existing law to be omitted. New sections are in **boldfaced** type.

- SECTION 2. Section 3 of this 2023 Act is added to and made a part of ORS chapter 689. 1 2 SECTION 3. (1) A pharmacist may dispense a prescription drug prescribed by a practi
  - tioner for an off-label indication, as defined in section 1 of this 2023 Act.
  - (2) The State Board of Pharmacy may not discipline a pharmacist for dispensing a prescription drug pursuant to subsection (1) of this section.
    - (3) The board may adopt rules to carry out this section.

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- SECTION 4. Sections 1 and 3 of this 2023 Act apply to prescriptions written on and after the operative date specified in section 5 of this 2023 Act.
  - SECTION 5. (1) Sections 1 and 3 of this 2023 Act become operative on January 1, 2024.
- (2) The Oregon Board of Dentistry, the Oregon Medical Board, the Oregon State Board of Nursing and the State Board of Pharmacy may take any action before the operative date specified in subsection (1) of this section that is necessary to enable the boards to exercise, on and after the operative date specified in subsection (1) of this section, all of the duties, functions and powers conferred on the boards by sections 1 and 3 of this 2023 Act.
- SECTION 6. This 2023 Act takes effect on the 91st day after the date on which the 2023 regular session of the Eighty-second Legislative Assembly adjourns sine die.

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