Reviewed As To Form By
Legislative Service Commission

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136th General Assembly
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Sub. H. B. No. 324

To enact section 3715.39 of the Revised Code to prohibit sales of prescription drugs causing severe adverse effects, to establish conditions on the prescribing of such drugs, and to name this act the Patient Protection Act.

**BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF OHIO:**

**Section 1.** That section 3715.39 of the Revised Code be enacted to read as follows:

**Sec. 3715.39.** (A) As used in this section:

(1) "Dangerous drug," "prescriber," "terminal distributor of dangerous drugs," and "wholesale distributor of dangerous drugs" have the same meanings as in section 4729.01 of the Revised Code, except that a prescriber does not include a veterinarian licensed under Chapter 4741. of the Revised Code.

(2) "Severe adverse effect" means any of the following:

(a) Death;

(b) Infection requiring hospitalization;

(c) Hemorrhaging requiring hospitalization;

(d) Organ failure;

(e) Sepsis.

(B)(1) A terminal distributor of dangerous drugs or wholesale distributor of dangerous drugs shall not sell, or offer to sell, including by mail to any patient, any dangerous drug for human use that causes one or more severe adverse effects in greater than five per cent of the drug's users.

(2) Before a prescriber may issue for a patient a prescription for a dangerous drug that causes one or more severe adverse effects in greater than five per cent of the drug's users, the prescriber shall do all of the following:

(a) Conduct an in-person examination of the patient;

(b) Inform the patient that the drug causes one or more severe adverse effects in greater than five per cent of the drug's users;

(c) Schedule the patient for a follow-up appointment.

(C)(1) For purposes of this section, the director of health is responsible for determining if a dangerous drug causes one or more severe adverse effects in greater than five per cent of the drug's users. In making such a determination, both of the following apply:

(a) The director shall consult with the superintendent of insurance and executive directors of the state board of pharmacy and state medical board.

(b) The director shall base the determination on the greater of insurance claims, patient reports of severe adverse effects to health care professionals, and any applicable data available from the United States food and drug administration.

(2) The director of health shall prepare and update as needed a list containing each dangerous drug that the director determines causes one or more severe adverse effects in greater than five per cent of the drug's users. The director shall make the list, and each of its updates, available to the public on the internet web site maintained by the department of health.

**Section 2.** This act shall be known as the Patient Protection Act.