As Introduced

132nd General Assembly
Regular Session
2017-2018

H. B. No. 701

Representative Huffman

A BILL

To enact section 3715.641 of the Revised Code regarding the promotion of drugs and devices for off-label uses.

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

Section 1. That section 3715.641 of the Revised Code be enacted to read as follows:

Sec. 3715.641. (A) As used in this section:

(1) "Political subdivision" has the same meaning as in section 2744.01 of the Revised Code.

(2) "State agency" has the same meaning as in section 1.60 of the Revised Code.

(3) "Third-party payer" has the same meaning as in section 3901.38 of the Revised Code.

(B) A manufacturer may promote the use of a drug, including a biological product, or a device in a manner other than the use approved by the United States food and drug administration only if both of the following conditions are met:

(1) The manufacturer promotes its use to a licensed health

professional authorized to prescribe drugs or third-party payer.

(2) The manufacturer shares with the prescriber or payer information about the drug or device that is consistent with generally accepted scientific principles and is neither misleading nor contrary to fact.

(C) Notwithstanding any conflicting provision of the Revised Code, no person shall enforce or apply section 3715.64 or 3715.68 of the Revised Code against or otherwise prosecute a manufacturer for a violation of section 3715.52 of the Revised Code for promoting the use of a drug or device as described in division (B) of this section.

(D)(1) Notwithstanding any conflicting provision of the Revised Code, with respect to a manufacturer licensed by the state board of pharmacy, the board shall not suspend, revoke, or refuse to renew the manufacturer's license or take any other disciplinary action against the manufacturer solely for promoting the use of a drug or device as described in division (B) of this section.

(2) Notwithstanding any conflicting provision of the Revised Code, with respect to a prescriber, the board authorized to issue a license to the prescriber shall not suspend, revoke, or refuse to renew the prescriber's license or take any other disciplinary action against the prescriber solely for having received information about the use of a drug or device as described in division (B) of this section.

(3) Notwithstanding any conflicting provision of the Revised Code, with respect to a third-party payer, the superintendent of insurance shall not sanction or take any other disciplinary action against the payer solely for having received

information about the use of a drug or device as described in division (B) of this section.

(E) No state agency or political subdivision shall assist in the enforcement or application of 21 U.S.C. 331 or 21 U.S.C. 352 against a manufacturer or in the prosecution of a manufacturer for a violation of the "Federal Food, Drug, and Cosmetic Act," 21 U.S.C. 301 et seq., solely for promoting the use of a drug or device as described in division (B) of this section.