As Introduced

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Representatives Johnson, Gonzales

Cosponsors: Representatives Bubp, Buchy, Hackett, McClain, Reece, Stebelton, Terhar

A B I L L

To amend sections 4729.37 and 4729.38 and to enact section 4729.382 of the Revised Code to prohibit a pharmacist from substituting another drug for a tamper resistant opioid analgesic drug unless the substituted drug is also tamper resistant or consent is obtained from the prescribing health professional.

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

Section 1. That sections 4729.37 and 4729.38 be amended and section 4729.382 of the Revised Code be enacted to read as follows:

Sec. 4729.37. A copy of an original prescription may only be filled in accordance with the rules and regulations adopted by the state board of pharmacy.

Prescriptions received electronically or by word of mouth, telephone, telegraph, or other means of communication shall be recorded in writing by the pharmacist and the record so made by the pharmacist shall constitute the original prescription to be filled by the pharmacist. ~~All prescriptions~~

Both of the following shall be preserved on file at the pharmacy for a period of three years, subject to inspection by the proper officers of the law:

(1) All prescriptions;

(2) All written and signed consents received under section 4729.382 of the Revised Code.

Sec. 4729.38. (A) Unless instructed otherwise by the person receiving the drug pursuant to the prescription, a pharmacist filling a prescription for a drug prescribed by its brand name may select a generically equivalent drug, as defined in section 3715.01 of the Revised Code, subject to the following conditions:

(1) The pharmacist shall not select a generically equivalent drug if the prescriber handwrites "dispense as written," or "D.A.W.," on the written prescription, or, when ordering a prescription electronically or orally, the prescriber specifies that the prescribed drug is medically necessary. These designations shall not be preprinted or stamped on the prescription. Division (A)(1) of this section does not preclude a reminder of the procedure required to prohibit the selection of a generically equivalent drug from being preprinted on the prescription.

(2) If the prescribed drug is an opioid analgesic drug as defined in division (A) of section 4729.382 of the Revised Code, the pharmacist shall not select a generically equivalent drug except as provided in section 4729.382 of the Revised Code.

(3) The pharmacist shall not select a generically equivalent drug unless its price to the patient is less than or equal to the price of the prescribed drug.

~~(3)~~(4) The pharmacist, or the pharmacist's agent, assistant, or employee shall inform the patient or the patient's agent if a

generically equivalent drug is available at a lower or equal cost, and of the person's right to refuse the drug selected. Division (A)(3) of this section does not apply to any:

(a) Prescription that is billed to any agency, division, or department of this state which will reimburse the pharmacy;

(b) Prescriptions for patients of a hospital, nursing home, or similar patient care facility.

(B) Unless the prescriber instructs otherwise, the label for every drug dispensed shall include the drug's brand name, if any, or its generic name and the name of the distributor, using abbreviations if necessary. When dispensing at retail a generically equivalent drug for the brand name drug prescribed, the pharmacist shall indicate on the drug's label or container that a generic substitution was made. The labeling requirements established by this division are in addition to all other labeling requirements of Chapter 3715. of the Revised Code.

(C) A pharmacist who selects a generically equivalent drug pursuant to this section assumes no greater liability for selecting the dispensed drug than would be incurred in filling a prescription for a drug prescribed by its brand name.

(D) The failure of a prescriber to restrict a prescription by specifying "dispense as written," or "D.A.W.," pursuant to division (A)(1) of this section shall not constitute evidence of the prescriber's negligence unless the prescriber had reasonable cause to believe that the health condition of the patient for whom the drug was intended warranted the prescription of a specific brand name drug and no other. No prescriber shall be liable for civil damages or in any criminal prosecution arising from the interchange of a generically equivalent drug for a prescribed brand name drug by a pharmacist, unless the prescribed brand name drug would have reasonably caused the same loss, damage, injury,

or death.

Sec. 4729.382. (A) As used in this section, "opioid analgesic drug" means a drug in the opioid analgesic drug class, whether in immediate or extended release form and whether or not combined with another drug.

(B)(1) The state board of pharmacy shall create a list of opioid analgesic drugs incorporating tamper resistance technologies that includes both of the following:

(a) Each opioid analgesic drug incorporating tamper resistance technologies for which a drug manufacturer or distributor has submitted satisfactory evidence, as determined by the board, of both of the following:

(i) That the drug incorporates a tamper resistance technology;

(ii) That the drug has been approved by the United States food and drug administration pursuant to an application that includes at least one human tampering or abuse potential study or a laboratory study. The study must be one that compared the tamper or abuse resistance properties of the drug to one or more opioid analgesic drugs that have been approved by the United States food and drug administration and served as a positive control for the experiment.

(b) A determination by the board as to which drugs included on the list under division (B)(1)(a) of this section have substantially similar tamper resistance properties. This determination shall be based solely on studies submitted by the drug manufacturer to the United States food and drug administration as described in division (B)(1)(a)(ii) of this section.

(2) When a drug is initially considered for inclusion on the

list created under division (B)(1) of this section, the board shall not require that the drug bear on its labeling, as approved by the United States food and drug administration, a claim regarding the reduction of tampering, abuse, or abuse potential.

(3) The board shall publish the list created under division (B)(1) on receiving from a drug manufacturer or distributor evidence that satisfies the criteria in divisions (B)(1)(a)(i) and (ii) of this section. The board shall update and republish the list every time it receives such evidence from a drug manufacturer or distributor.

(C) If a prescribed drug is on the list published under division (B)(3) of this section, a pharmacist shall not substitute a brand or generic drug for the prescribed drug without one of the following:

(1) A determination by the board, as indicated on the list, that the drug to be substituted has substantially similar tamper resistance properties to the prescribed drug;

(2) Receipt by the pharmacist of written and signed consent to the substitution from the prescriber.

Section 2. That existing sections 4729.37 and 4729.38 of the Revised Code are hereby repealed.