



Ohio Legislative Service Commission

Bill Analysis

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H.B. 373

129th General Assembly
(As Introduced)

Reps. Johnson and Gonzales, Bubp, Buchy, Hackett, McClain, Reece, Stebelton, Terhar

BILL SUMMARY

- Requires the State Board of Pharmacy to create a list of opioid analgesic drugs incorporating tamper resistance technologies that includes (1) each drug for which a drug manufacturer or distributor submits satisfactory evidence of specified criteria and (2) a determination as to which listed drugs have substantially similar tamper resistance properties.
 - Prohibits a pharmacist from substituting a brand or generic drug for a prescribed opioid analgesic drug that appears on the Board's list without satisfying certain requirements.
 - Prohibits the Board from requiring that a drug initially considered for inclusion on the list bear on its labeling a claim regarding the reduction of tampering, abuse, or abuse potential.
 - Requires the Board to initially publish the list when it receives evidence that satisfies the criteria for inclusion on the list and to update and republish the list every time it receives such evidence.
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CONTENT AND OPERATION

Prohibition on substituting drugs

The bill prohibits a pharmacist from substituting a brand or generic drug for a prescribed opioid analgesic drug that appears on a list published by the State Board of Pharmacy (see "**State Board of Pharmacy list**," below) without one or the other 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.¹

All written and signed consents received for the purposes of the bill must be preserved on file at the pharmacy for three years.²

"Opioid analgesic drug" is defined by the bill as a drug in the opioid analgesic drug class, whether in immediate or extended release form and whether or not combined with another drug.³ Opioid analgesic drugs are drugs used to reduce moderate to severe chronic pain, such as hydrocodone and oxycodone.⁴

State Board of Pharmacy list

Under the bill, the State Board of Pharmacy is required to create a list of opioid analgesic drugs incorporating tamper resistance technologies that includes both of the following:

(1) 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:

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

(b) That the drug has been approved by the United States Food and Drug Administration (FDA) 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 FDA and served as a positive control for the experiment.

¹ R.C. 4729.38 and 4729.382.

² R.C. 4729.37.

³ R.C. 4729.382.

⁴ WebMD, *Opiate Pain Relievers for Chronic Pain* (last visited December 11, 2011), available at <<http://www.webmd.com/pain-management/opioid-analgesics-for-chronic-pain>>.

(2) A determination by the Board as to which drugs included on the list have substantially similar tamper resistance properties. This determination must be based solely on studies submitted by the drug manufacturer to the FDA as described above.

For drugs initially considered for inclusion on the list, the Board is prohibited from requiring that the drug bear on its labeling, as approved by the FDA, a claim regarding the reduction of tampering, abuse, or abuse potential.

The Board must initially publish the list when it receives evidence from a drug manufacturer or distributor that satisfies the criteria discussed above, and it must update and republish the list every time it receives such evidence.⁵

HISTORY

ACTION	DATE
Introduced	11-09-11

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⁵ R.C. 4729.382.

