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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 1176 Session of 2013

INTRODUCED BY BARRAR, BAKER, BENNINGHOFF, V. BROWN, CHRISTIANA, COHEN, CORBIN, DiGIROLAMO, GIBBONS, GINGRICH, GROVE, HEFFLEY, HELM, KAVULICH, KORTZ, MILNE, MURT, PYLE, QUINN, RAPP, READSHAW AND SWANGER, APRIL 15, 2013

REFERRED TO COMMITEE ON PROFESSIONAL LICENSURE, APRIL 15, 2013

AN ACT

Amending the act of September 27, 1961 (P.L.1700, No.699), entitled "An act relating to the regulation of the practice of pharmacy, including the sales, use and distribution of drugs and devices at retail; and amending, revising, consolidating and repealing certain laws relating thereto," limiting substitution of certain opioid analgesic drugs by pharmacists.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. Section 2 of the act of September 27, 1961 (P.L.1700, No.699), known as the Pharmacy Act, is amended by adding a clause to read:

Section 2. Definitions.--As used in this act:

* * *

(19) "Opioid analgesic drug" means a drug in the opioid analgesic drug class prescribed to treat moderate to severe pain or other conditions, whether:

(i) in immediate release or extended release form; or

(ii) combined with other drug substances to form a single tablet or other dosage form.

Section 2. The act is amended by adding a section to read:

Section 9.5. List of Opioid Analgesic Drugs Incorporating Abuse-Deterrent Technology.--(a) The board shall create a list of opioid analgesic drugs that incorporate an abuse-deterrent technology. A drug shall not be included on the list unless:

(1) A drug manufacturer or distributor submits evidence to the board that the opioid analgesic drug incorporates an abuse-deterrent technology.

(2) The opioid analgesic drug has been approved by the Food and Drug Administration pursuant to an application that includes at least one human tampering or abuse potential study or a laboratory study comparing the tamper-resistant or abuse-deterrent properties of the drug to one or more opioid analgesic drugs that:

(i) have been approved by the Food and Drug Administration; and

(ii) serve as a positive control.

(b) The list shall include a determination by the board as to which opioid analgesic drugs incorporating abuse-deterrent technologies provide substantially similar abuse-deterrent properties, based solely upon studies submitted by the drug manufacturer consistent with subsection (a).

(c) Nothing in this section may be construed to require that a drug included on the list bear a labeling claim with respect to reduction of tampering, abuse or abuse potential at the time of listing.

(d) Notwithstanding the act of November 24, 1976 (P.L.1163, No.259), referred to as the Generic Equivalent Drug Law, a

pharmacist may not interchange or substitute an opioid analgesic drug, brand or generic, unless the pharmacist:

(1) verifies from the list under subsection (a) that the substituted opioid analgesic drug has substantially similar abuse-deterrent properties to the originally prescribed drug; or

(2) obtains written, signed consent for the substitution from the prescriber for the interchange or substitution.

Section 3. This act shall take effect in 60 days.