S-3763.1

SENATE BILL 6424

State of Washington 62nd Legislature 2012 Regular Session

By Senator Kline

Read first time 01/23/12. Referred to Committee on Health & Long-Term Care.

AN ACT Relating to prohibiting pharmacists from substituting opioid analgesic drugs for an opioid analgesic drug incorporating a tamper resistance technology without verifying equivalence or obtaining the written, signed consent of the prescribing physician; and adding new sections to chapter 69.41 RCW.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

NEW SECTION. **Sec. 1.** DEFINITIONS. The definitions in this section apply to section 2 of this act unless the context clearly requires otherwise.

(1) "Interchange or substitution of an opioid analgesic drug" means the substitution of any opioid analgesic drug, brand, or generic, for the opioid analgesic drug incorporating a tamper resistance technology originally prescribed, irrespective of whether the substituted drug is rated as pharmaceutically and therapeutically equivalent by the United States food and drug administration or board of pharmacy or whether the opioid analgesic drug incorporating a tamper resistance technology bears a labeling claim with respect to reduction of tampering, abuse, or abuse potential.

(2) "Opioid analgesic drug" means a drug in the opioid analgesic drug class prescribed to treat moderate to severe pain or other conditions, whether in immediate release or extended release form and whether or not combined with other drug substances to form a single tablet or other dosage form.

(3)(a) "Opioid analgesic drug incorporating a tamper resistance technology" means an opioid analgesic drug that:

(i) Incorporates a tamper resistance technology; and

(ii) 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 comparing the tamper or abuse resistance properties of the drug to one or more opioid analgesic drugs that (A) have been approved by the United States food and drug administration; and (B) serve as a positive control.

(b) A drug may not be required to bear a labeling claim with respect to reduction of tampering, abuse, or abuse potential.

(4) "Pharmacist" for purposes of this chapter includes any pharmacist dispensing drugs under the jurisdiction of the board of pharmacy including, but not limited to, community pharmacists, pharmacists in hospital-based pharmacies when filling prescriptions for inpatient or outpatient care, and pharmacists in mail order pharmacies licensed by the state to distribute in the state.

NEW SECTION. **Sec. 2.** PROHIBITION. Notwithstanding RCW 69.41.120, a pharmacist may not interchange or substitute an opioid analgesic drug, brand, or generic for an opioid analgesic drug incorporating a tamper resistance technology unless: (1) The drug provides tamper resistance properties substantially similar to the prescribed opioid analgesic drug incorporating a tamper resistance technology; or (2) obtaining written, signed consent from the prescribing physician for the interchange or substitution.

NEW SECTION. **Sec. 3.** Sections 1 and 2 of this act are each added to chapter 69.41 RCW, to be codified between RCW 69.41.280 and 69.41.300, under the new subchapter heading, "SUBSTITUTABILITY OF

OPIOID ANALGESICS."

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