AN ACT relating to abuse-deterrent opioid analgesic drug products.

WHEREAS, some individuals have abused and misused opioid analgesics, creating urgent and growing public health concerns; and

WHEREAS, drug overdoses are the leading cause of accidental deaths in the United States, with special significance in Kentucky, with many people dying annually from overdosing on prescription opioids and illicit drugs; and

WHEREAS, the General Assembly recognizes the need to eliminate barriers to abuse-deterrent formulations as an important step in reducing abuse of opiates while ensuring that these medicines remain available to those who need them for legitimate medical purposes; and

WHEREAS, advances in pharmaceutical research and manufacturing processes have created a potentially better alternative form of potentially addictive medications, namely abuse deterrent opioids containing physical or chemical barriers that prevent crushing or injection or reduce tampering;

NOW, THEREFORE,

Be it enacted by the General Assembly of the Commonwealth of Kentucky:

➔SECTION 1. A NEW SECTION OF KRS CHAPTER 217 IS CREATED TO READ AS FOLLOWS:

(1) As used in this section:

(a) "Abuse-deterrent opioid analgesic drug product" means a brand or generic opioid analgesic drug product, approved by the United States Food and Drug Administration in accordance with 21 U.S.C. sec. 355 et.seq., with abuse-deterrence labeling claims that indicate the drug product is expected to deter or reduce its abuse; and

(b) "Opioid analgesic drug product" means a drug product in the opioid analgesic drug class prescribed to treat moderate to severe pain or other condition, whether in immediate release or extended release long-acting

form, and whether or not combined with other drug substances to form a single drug product or dosage form.

(2) Notwithstanding KRS 217.822, when a prescribing healthcare practitioner determines it is in the best interest of the patient to prescribe an abuse-deterrent opioid analgesic drug product, no pharmacist shall substitute or dispense an equivalent opioid analgesic drug product, whether brand or generic, that does not have a United States Food and Drug Administration abuse-deterrence labeling claim for the prescribed abuse-deterrent opioid analgesic drug product without documenting verbal or written signed consent from the prescribing healthcare practitioner

➔SECTION 2. A NEW SECTION OF SUBTITLE 17A OF KRS CHAPTER 304 IS CREATED TO READ AS FOLLOWS:

(1) As used in this section:

(a) "Abuse-deterrent opioid analgesic drug product" means a brand or generic opioid analgesic drug product, approved by the United States Food and Drug Administration in accordance with 21 U.S.C. sec. 355 et seq., with abuse-deterrence labeling claims that indicate the drug product is expected to deter or reduce its abuse;

(b) "Cost sharing" means any coverage limit, copayment, coinsurance, deductible, or other out-of-pocket expense requirements; and

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

(2) Cost sharing for brand name abuse-deterrent opioid analgesic drug products shall not exceed the lowest cost-sharing level applied to brand name prescription

drugs covered under the same health benefit plan.

(3) Cost sharing for generic abuse-deterrent opioid analgesic drug products shall not exceed the lowest cost-sharing level applied to generic prescription drugs covered under the same health benefit plan.

(4) A health benefit plan shall provide coverage for at least two (2) abuse-deterrent opioid analgesic drug products per opioid analgesic active ingredient on its formulary.

(5) A health benefit plan shall not require an insured or enrollee to first use a nonabuse-deterrent opioid analgesic drug product before providing coverage for an abuse-deterrent opioid analgesic drug product.

(6) A health benefit plan shall not create disincentives for prescribers or dispensers to prescribe or dispense abuse-deterrent opioid analgesic drug products to achieve compliance with this section.

(7) Nothing in this section shall be construed to prevent an insurer or health benefit plan from applying utilization review requirements, including prior authorization, to abuse-deterrent opioid analgesic drug products, provided the requirements are applied to all opioid analgesic drug products with the same type of drug release, whether immediate or extended.

➔SECTION 3. A NEW SECTION OF KRS CHAPTER 205 IS CREATED TO READ AS FOLLOWS:

The Department for Medicaid Services or a managed care organization contracted to provide services pursuant to this chapter may comply with Sections 1 and 2 of this Act.