

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

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

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

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

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

15 NOW, THEREFORE,

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

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

19 *(1) As used in this section:*

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

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

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

3 (2) When prescribing an abuse-deterrent opioid analgesic drug product, a healthcare
4 practitioner shall comply with the provisions of KRS 217.822.

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

7 (1) As used in this section:

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

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

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

20 (2) Cost sharing for brand name abuse-deterrent opioid analgesic drug products
21 shall not exceed the lowest cost-sharing level applied to brand name prescription
22 drugs covered under the same health benefit plan.

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

26 (4) A health benefit plan is encouraged to provide coverage for at least two (2) abuse-
27 deterrent opioid analgesic drug products on its formulary.

1 (5) A health benefit plan may use reasonable medical management techniques
2 related to the coverage of abuse-deterrent opioid analgesic drug products but
3 shall not require an insured or enrollee to first use a nonabuse-deterrent opioid
4 analgesic drug product before providing coverage for an abuse-deterrent opioid
5 analgesic drug product.

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

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

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

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

18 ➔Section 4. KRS 217.186 is amended to read as follows:

19 (1) A licensed health-care provider who, acting in good faith, directly or by standing
20 order, prescribes or dispenses the drug naloxone to a person or agency who, in the
21 judgment of the health-care provider, is capable of administering the drug for an
22 emergency opioid overdose, shall not, as a result of his or her acts or omissions, be
23 subject to disciplinary or other adverse action under KRS Chapter 311, 311A, 314,
24 or 315 or any other professional licensing statute. As used in this subsection,
25 "licensed health-care provider" includes a pharmacist as defined in KRS 315.010
26 who holds a separate certification issued by the Kentucky Board of Pharmacy
27 authorizing the initiation of the dispensing of naloxone under subsection (5) of this

1 section.

2 (2) A prescription for naloxone may include authorization for administration of the
3 drug to the person for whom it is prescribed by a third party if the prescribing
4 instructions indicate the need for the third party upon administering the drug to
5 immediately notify a local public safety answering point of the situation
6 necessitating the administration.

7 (3) A person or agency, including a peace officer, jailer, firefighter, paramedic, or
8 emergency medical technician or a school employee authorized to administer
9 medication under KRS 156.502, may:

10 (a) Receive a prescription for the drug naloxone;

11 (b) Possess naloxone pursuant to this subsection and any equipment needed for its
12 administration;~~and~~

13 (c) *Dispense naloxone in accordance with a standing order from a licensed*
14 *health-care provider; and*

15 *(d)* Administer naloxone to an individual suffering from an apparent opiate-
16 related overdose.

17 (4) A person acting in good faith who administers naloxone received under this section
18 shall be immune from criminal and civil liability for the administration, unless
19 personal injury results from the gross negligence or willful or wanton misconduct of
20 the person administering the drug.

21 (5) (a) The Board of Pharmacy, in consultation with the Kentucky Board of Medical
22 Licensure, shall promulgate administrative regulations to establish
23 certification, educational, operational, and protocol requirements to
24 implement this section.

25 (b) Administrative regulations promulgated under this subsection shall:

26 1. Require that any dispensing under this section be done only in
27 accordance with a physician-approved protocol and specify the

- 1 minimum required components of any such protocol;
- 2 2. Include a required mandatory education requirement as to the
- 3 mechanism and circumstances for the administration of naloxone for the
- 4 person to whom the naloxone is dispensed; and
- 5 3. Require that a record of the dispensing be made available to a physician
- 6 signing a protocol under this subsection, if desired by the physician.
- 7 (c) Administrative regulations promulgated under this subsection may include:
- 8 1. A supplemental educational or training component for a pharmacist
- 9 seeking certification under this subsection; and
- 10 2. A limitation on the forms of naloxone and means of its administration
- 11 that may be dispensed pursuant to this subsection.
- 12 (6) (a) The board of each local public school district and the governing body of each
- 13 private and parochial school or school district may permit a school to keep
- 14 naloxone on the premises and regulate the administration of naloxone to any
- 15 individual suffering from an apparent opiate-related overdose.
- 16 (b) In collaboration with local health departments, local health providers, and
- 17 local schools and school districts, the Kentucky Department for Public Health
- 18 shall develop clinical protocols to address supplies of naloxone kept by
- 19 schools under this section and to advise on the clinical administration of
- 20 naloxone.