

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.