

## CHAPTER 136

## (SB 23)

AN ACT relating to drugs.

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

SECTION 1. A NEW SECTION OF KRS CHAPTER 194A IS CREATED TO READ AS FOLLOWS:

*For the purposes of Sections 1 to 5 of this Act:*

- (1) *"Controlled substance" has the same meaning as in KRS 218A.010;*
- (2) *"Dispense" has the same meaning as in KRS 217.015;*
- (3) *"Health care provider" has the same meaning as in KRS 304.17A-005;*
- (4) *"Health facility" has the same meaning as in KRS 216B.015;*
- (5) *"Legend drug" has the same meaning as KRS 217.015;*
- (6) *"Pharmacist" has the same meaning as in KRS 315.010; and*
- (7) *"Prescription drug" has the same meaning as in KRS 315.010.*

SECTION 2. A NEW SECTION OF KRS CHAPTER 194A IS CREATED TO READ AS FOLLOWS:

- (1) *The Cabinet for Health Services shall establish and maintain a legend drug repository program to support the donation of a legend drug or supplies needed to administer a legend drug for use by an individual who meets the eligibility criteria specified by an administrative regulation promulgated by the cabinet. The repository program shall not accept any controlled substance.*
- (2) *Donations may be made on the premises of a health facility or pharmacy that elects to participate in the program and meets requirements specified by the cabinet by an administrative regulation promulgated by the cabinet.*
- (3) *The health facility may charge a handling fee to an individual who received a legend drug or supplies under the program established under this section, except that the fee shall not exceed the amount establish by an administrative regulation promulgated by the cabinet.*
- (4) *A health facility or pharmacy that receives a donated legend drug under this section may distribute the legend drug or supplies to another eligible health facility or pharmacy for use under the program created under this section.*
- (5) *Nothing in Section 2 or Section 3 of this Act shall require a health facility, pharmacy, pharmacist, or practitioner to participate in the program established in Section 2 of this Act.*

SECTION 3. A NEW SECTION OF KRS CHAPTER 194A IS CREATED TO READ AS FOLLOWS:

- (1) *A legend drug or supplies used to administer a legend drug may be accepted and dispensed under the program established in Section 2 of this Act only if the following requirements are met:*

- (a) *The legend drug or supplies needed to administer the legend drug is in its original, unopened, sealed, and tamper-evident unit dose packaging or, if packaged in single-unit doses, the single-unit dose packaging is unopened;*
  - (b) *The legend drug is not classified as a controlled substance;*
  - (c) *The legend drug or supplies needed to administer a legend drug is not adulterated or misbranded, as determined by a pharmacist employed by, or under contract with, the health facility or pharmacy, who shall inspect the drug or supplies needed to administer a legend drug before the drug or supplies are dispensed; and*
  - (d) *The legend drug or supplies needed to administer a legend drug are prescribed by a physician, advanced registered nurse practitioner, or physician assistant and dispensed by a pharmacist.*
- (2) *No legend drug or supplies needed to administer a legend drug that are donated for use under this section may be resold.*

SECTION 4. A NEW SECTION OF KRS CHAPTER 194A IS CREATED TO READ AS FOLLOWS:

- (1) *Unless the manufacturer of a legend drug or supply needed to administer a legend drug exercises bad faith or fails to exercise ordinary care, the manufacturer of a legend drug or supply shall not be subject to criminal or civil liability for injury, death, or loss to a person or property for matters related to the donation, acceptance, or dispensing of the drug or supply under the legend drug repository created under Section 2 of this Act, including liability for failure to transfer or communicate product or consumer information or the expiration date of the donated drug or supply.*
- (2) *Health facilities, pharmacies, and health care providers shall be immune from civil liability for injury to or the death of an individual to whom a legend drug or supply is dispensed and shall not be subject to disciplinary action for unprofessional conduct for their acts or omissions related to donating, accepting, distributing, or dispensing a legend drug or supply under Sections 1 to 5 of this Act, unless the act or omission involves reckless, wanton, or intentional misconduct or the act or omission results from failure to exercise ordinary care.*

SECTION 5. A NEW SECTION OF KRS CHAPTER 194A IS CREATED TO READ AS FOLLOWS:

*The Cabinet for Health Services shall promulgate administrative regulations to establish:*

- (1) *The requirements for health facilities and pharmacies to accept and dispense donated legend drugs or supplies needed to administer legend drugs under Sections 2 and 3 of this Act, including all of the following:*
- (a) *Eligibility criteria for health facilities;*
  - (b) *Standards and procedures for accepting, safely storing, and dispensing donated legend drugs or supplies needed to administer legend drugs;*
  - (c) *Standards and procedures for inspecting donated legend drugs or supplies needed to administer legend drugs to determine if these are in their original, unopened, sealed, and tamper-evident unit dose packaging or, if packaged in single-unit doses, the single-unit dose packaging is unopened; and*

- (d) Standards and procedures for inspecting donated legend drugs or supplies needed to administer legend drugs to determine that these are not adulterated or misbranded;*
- (2) Eligibility criteria for individuals to receive donated legend drugs or supplies needed to administer legend drugs dispensed under Sections 2 and 3 of this Act;*
- (3) Standards for prioritizing the dispensation to individuals who are uninsured or indigent, or to others if an uninsured or indigent individual is unavailable;*
- (4) A means by which an individual who is eligible to receive a donated legend drug or supplies needed to administer a legend drug may indicate that eligibility;*
- (5) Necessary forms for administration of the legend drug repository program;*
- (6) The maximum handling fee that a health facility may charge for accepting, distributing, or dispensing donated legend drugs or supplies needed to administer legend drugs;*
- (7) A list of legend drugs and supplies needed to administer legend drugs that the legend drug repository program may accept for dispensing; and*
- (8) A list of legend drugs and supplies needed to administer legend drugs that the legend drug repository program shall not accept for dispensing, including the reason why the legend drug or supply is ineligible for donation.*

SECTION 6. A NEW SECTION OF KRS 205.510 TO 205.645 IS CREATED TO READ AS FOLLOWS:

*As used in Sections 6 to 11 of this Act:*

- (1) "Asset test" means the asset limits as defined by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub.L.No. 108-173;*
- (2) "Commissioner" means the commissioner of the Department for Medicaid Services;*
- (3) "Contractor" means the person, partnership, or corporate entity that has an approved contract with the department to administer the Kentucky Pharmaceutical Assistance Program;*
- (4) "Department" means the Department for Medicaid Services;*
- (5) "Enrollee" means a resident of this state who meets the conditions relating to eligibility for the Kentucky Pharmaceutical Assistance Program and whose application for enrollment has been approved by the department;*
- (6) "Federal poverty guidelines" means the federal poverty guidelines updated annually in the Federal Register by the United States Department of Health and Human Services under the authority of 42 U.S.C. sec. 9902(2);*
- (7) "Liquid assets" means assets used in the eligibility determination process and defined by the MMA;*
- (8) "Medicaid dual eligible" or "dual eligible" means a person who is eligible for Medicare and Medicaid as defined by the MMA;*
- (9) "Medicare Modernization Act" or "MMA" means the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub.L.No. 108-173;*
- (10) "Medicare Part D prescription drug benefit" means the prescription benefit provided under the MMA, as it may vary from one (1) PDP to another;*

- (11) *"Participating pharmacy" means a pharmacy that elects to participate as a pharmaceutical provider and enters into a participating network agreement with the department;*
- (12) *"Prescription drug plan" or "PDP" means a nongovernmental drug plan under contract with the Centers for Medicare and Medicaid Services to provide prescription benefits under the MMA;*
- (13) *"Program" means the Kentucky Pharmaceutical Assistance Program established in Sections 6 to 11 of this Act; and*
- (14) *"Resident" means a person who has lived within this state for a period of at least ninety (90) consecutive days and who meets the conditions as set forth in Section 10 of this Act. A person shall be considered a resident until the person establishes a permanent residence outside of the state.*

SECTION 7. A NEW SECTION OF KRS 205.510 TO 205.645 IS CREATED TO READ AS FOLLOWS:

- (1) *The Kentucky Pharmaceutical Assistance Program may be established, contingent upon approval from the Centers for Medicare and Medicaid Services.*
- (2) *If established, the program shall be administered by the department. The program shall coordinate prescription drug coverage with the prescription drug benefit under the MMA. A person shall be eligible for drug benefits under this program if the person:*
  - (a) *Is a resident who is:*
    - 1. *Sixty-five (65) years of age or older; or*
    - 2. *Disabled and receiving a Social Security benefit and is enrolled in the Medicare program;*
  - (b) *Has a household income at or below one hundred fifty percent (150%) of the federal poverty guidelines;*
  - (c) *Meets the asset test;*
  - (d) *Is not a member of a Medicare Advantage Plan that provides a prescription drug benefit; and*
  - (e) *Is not a member of a retirement plan that is receiving a benefit under the MMA.*
- (2) (a) *The department shall give initial enrollment priority to the Medicaid dual eligible population. A second enrollment priority shall be offered to Medicare eligible applicants who have annual household incomes up to one hundred fifty percent (150%) of the federal poverty guidelines and who meet the asset test.*
- (b) *Enrollment for Medicaid dual eligible persons shall take effect no later than October 1, 2005. Medicaid dual eligible persons may be automatically enrolled into the program, except that they may choose to opt out of the program. The department shall determine the procedures for automatic enrollment into and election out of the program. Applicants meeting the qualifications set forth in Sections 6 to 11 of this Act may begin enrolling into the program at a time and in a manner as determined by the department.*
- (3) *An individual or married couple meeting the eligibility requirements in subsection (1) of this section and not Medicaid dual eligible may apply for enrollment in the program by*

*submitting an application to the department that attests to the age, residence, household income, and liquid assets of the individual or couple.*

SECTION 8. A NEW SECTION OF KRS 205.510 TO 205.645 IS CREATED TO READ AS FOLLOWS:

- (1) *In providing program benefits, the department may:*
  - (a) *Enter into a contract with one (1) or more prescription drug plans to coordinate the prescription benefits of the program and the federal law;*
  - (b) *Preliminarily enroll beneficiaries into a preferred Medicare Part D plan, with an opt-out provision for individuals. Individuals who opt out of the preferred PDP shall remain enrolled in the program unless they choose to disenroll from the program;*
  - (c) *Prescribe the application and enrollment procedures for prospective enrollees;*
  - (d) *Select, in accordance with applicable state law, a contractor to assist in the administration of the program or negotiate program administrative functions with a preferred PDP plan;*
  - (e) *Determine which drugs will be covered by the plan; and*
  - (f) *Negotiate with manufacturers for rebates.*
- (2) *Program benefits shall begin January 1, 2006.*
- (3) *For persons meeting eligibility requirements, the program may pay all or some of the deductibles, coinsurance payments, premiums, and copayments required under the Medicare Part D pharmacy benefit program.*

SECTION 9. A NEW SECTION OF KRS 205.510 TO 205.645 IS CREATED TO READ AS FOLLOWS:

- (1) *Benefits provided under the program shall be limited to the amount of appropriations.*
- (2) *The program shall be the payor of last resort. The program shall cover costs for participants who are not covered by the Medicare Part D program.*
- (3) *Except for dual eligibles during the transition period, during which they are being moved from Medicaid to a Medicare Part D program, applicants who are qualified for coverage of payments for prescription drugs under a public assistance program shall be ineligible for the program for so long as they are so qualified.*
- (4) *Applicants who are qualified for full coverage of payments for prescription drugs under another plan of assistance or insurance shall be ineligible to receive benefits from the program for so long as they are eligible to receive pharmacy benefits from the other plan.*
- (5) *Applicants who are qualified for partial payments for prescription drugs under another insurance plan shall be eligible for the program but may receive reduced assistance from the program.*

SECTION 10. A NEW SECTION OF KRS 205.510 TO 205.645 IS CREATED TO READ AS FOLLOWS:

- (1) *A resident in the program shall be a person who has lived within this state for at least ninety (90) consecutive days immediately preceding the date that the person's application to participate in the program is received by the department. The applicant shall have or intend to have a fixed place of abode in this state, with the present intent of maintaining a*

*permanent home in this state for the indefinite future. The burden of establishing proof of residence within this state is on the applicant. A resident shall also include those persons residing in long-term care institutions located within this state.*

- (2) *The department shall create standards for documenting proof of residence in this state. Documents used to demonstrate proof of residence shall show the applicant's name and address.*

**Approved March 18, 2005.**