

1 AN ACT relating to the regulation of pharmacists.

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

3 ➔Section 1. KRS 315.408 is amended to read as follows:

- 4 (1) The board shall not require the use of an electronic track and trace system to
5 initiate, provide, receive, or maintain a pedigree by a person or entity licensed to
6 possess, distribute, dispense, or administer prescription drugs for use by an end user
7 until the FDA develops and implements standards for identification, validation,
8 authentication, and tracking and tracing of prescription drugs pursuant to 21 U.S.C.
9 sec. 355e. The electronic track and trace system requirements by the board shall
10 meet the FDA's standards for all prescription drugs covered by the FDA standards.
- 11 (2) Upon implementation of FDA standards for an electronic track and trace system,
12 the requirements relating to a pedigree in KRS 315.406 shall be superseded by the
13 FDA standards and shall not apply to any prescription drugs specified in the FDA
14 standards.
- 15 (3) Prior to promulgation of any administrative regulation under KRS Chapter 13A that
16 requires the use of an electronic track and trace system, the board shall consult with
17 manufacturers, wholesale distributors, and pharmacies regarding implementation of
18 the electronic track and trace system requirements and publish a report on its
19 website~~[Web site]~~ about implementation issues, including but not limited to
20 universal availability, technical and operational feasibility, and reliability for
21 manufacturers, wholesale distributors, and pharmacies.