

# STATEMENT OF SCOPE

## Pharmacy Examining Board

**Rule No.:** Phar 1, 6, 7, 8, 12 and 13

**Relating to:** Electronic Track and Trace Pedigree System, Drug Supply Chain Security, Manufacturers, and Distributors

**Rule Type:** Permanent

**1. Finding/nature of emergency (Emergency Rule only):** N/A

**2. Detailed description of the objective of the proposed rule:**

The objective of the proposed rule is to implement 2007 Act 20 as it relates to electronic track and trace pedigree system and the federal Drug Supply Chain Security Act (Title II of the Drug Quality and Security Act). In addition, the Pharmacy Examining Board will conduct a comprehensive review of chapters Phar 12 and 13 and make revisions to ensure the chapters are statutorily compliant with state and federal law and are current with professional standards and practices.

**3. Description of the existing policies relevant to the rule, new policies proposed to be included in the rule, and an analysis of policy alternatives:**

The new policies proposed are to implement an electronic track and trace pedigree system in Wisconsin as well as drug supply chain security.

In addition, the Pharmacy Examining Board will be conducting a comprehensive review of chs. Phar 12 and 13. The Pharmacy Examining Board will make revisions to these chapters to create clarity, remove obsolete provisions and ensure statutory compliance.

**4. Detailed explanation of statutory authority for the rule (including the statutory citation and language):**

450.02 (2) The board shall adopt rules defining the active practice of pharmacy. The rules shall apply to all applicants for licensure under s. 450.05.

450.02 (3) The board may promulgate rules:

- (a) Relating to the manufacture of drugs and the distribution and dispensing of prescription drugs.
- (b) Establishing security standards for pharmacies.
- (c) Relating to the manufacture, distribution and dispensing of hypodermic syringes, needles and other objects used, intended for use or designed for use in injecting a drug.
- (d) Necessary for the administration and enforcement of this chapter and ch. 961.
- (e) Establishing minimum standards for the practice of pharmacy.

450.071 (4) The board may set, by rule, continuing education requirements for designated representatives under this section.

450.073 (3) The board shall promulgate rules implementing an electronic track and trace pedigree system. Not later than July 1, 2010, the board shall determine the date on which the system will be implemented. The system may not be implemented before July 1, 2011, and the board may delay the implementation date in increments if the board determines that the technology to implement the system is not yet universally available across the prescription drug supply chain or is not capable of adequately protecting patient safety.

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**5. Estimate of amount of time that state employees will spend developing the rule and of other resources necessary to develop the rule:**

300 hours

**6. List with description of all entities that may be affected by the proposed rule:**

Pharmacies, pharmacists, manufacturers, distributors, and consumers.

**7. Summary and preliminary comparison with any existing or proposed federal regulation that is intended to address the activities to be regulated by the proposed rule:**

The Drug Quality and Security Act (DQSA) was enacted in 2013 and the Title II of that Act, the Drug Supply Chain Security Act (DSCSA), outlines requirements for an electronic, interoperable system to identify and trace prescription drugs as they move through the supply chain in the United States. The system is to enhance the Food and Drug Administration's ability to protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful, and to improve detection and removal of potentially dangerous drugs from the drug supply chain to protect consumers. DSCSA requires the establishment of national licensure standards for wholesale distributors and third-party logistics providers.

**8. Anticipated economic impact of implementing the rule (note if the rule is likely to have a significant economic impact on small businesses):**

This rule is anticipated to have a moderate economic impact and may have a significant economic impact on small businesses.

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Authorized Signature

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Date Submitted