

STATEMENT OF SCOPE

PHARMACY EXAMINING BOARD

Rule No.: Phar 7 and 10

Relating to: Required disclosures to consumers

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 revise the Pharmacy administrative code, including but not necessarily limited to chs. Phar 7 and 10, to bring the code into compliance with current statutory provisions as modified by 2021 Wisconsin Act 9.

The Pharmacy Examining Board is required under Act 9 to create and maintain a list of the 100 most commonly prescribed generic drug product equivalents, including the generic and brand name of the drug, which shall be made available to each pharmacy on an annual basis either directly or on the board's website.

Act 9 created several new requirements for pharmacies as well. A pharmacy must make available to the public information on how to access the list of 100 most commonly prescribed generic drug product equivalents maintained by the Pharmacy Examining Board. Pharmacies also must make available to the public information on how to access the FDA's list of all currently approved interchangeable biological products.

Pharmacies also must have available a list of the retail price of each of the 100 most commonly prescribed prescription drugs, including brand name and generic equivalent drugs and biological products and interchangeable biological products that are available for purchase at the pharmacy. Finally, a pharmacy must maintain disclosures to the public in a conspicuous place near where drugs are dispensed regarding the ability of a pharmacist to substitute a less expensive drug or interchangeable biological product.

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 Board intends to update the Pharmacy code to bring it into alignment with the new disclosure and list creation and access requirements enacted by Act 9. An alternative would be to not revise the code to reflect these new requirements, which would create confusion and a lack of clarity for stakeholders as to what is required of pharmacists and the board as it relates to the new statutory requirements.

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

Section 15.08 (5) (b), Stats. states that "The Board shall promulgate rules for its own guidance and for the guidance of the trade or profession to which it pertains, and define and enforce professional conduct and unethical practices not inconsistent with the law relating to the particular trade or profession."

Section 450.02 (3) (a), Stats. allows the board to “promulgate rules relating to the manufacture of drugs and the distribution and dispensing of prescription drugs.”

Section 450.02 (3) (d), Stats. says that the board “may promulgate rules necessary for the administration and enforcement of this chapter and ch. 961.”

Section 450.02 (3) (e), Stats. provides that the board “may promulgate rules establishing minimum standards for the practice of pharmacy.”

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

Approximately 80 hours.

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

Pharmacies, pharmacists, and consumers of pharmaceuticals.

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 federal government does not generally regulate the practice of pharmacy including requiring any disclosures relating to interchangeability of drugs or biological products, or requiring the maintenance and publication of commonly prescribed drugs and biological products and their equivalents.

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

None to minimal. It is not likely to have a significant economic impact on small businesses.

Contact Person: Nilajah Hardin, (608) 267-7139, DSPSAdminRules@wisconsin.gov

Approved for publication:



Authorized Signature

9/3/2021

Date Submitted

Approved for implementation:



Authorized Signature

11/30/2021

Date Submitted