

Report From Agency

**STATE OF WISCONSIN
PHARMACY EXAMINING BOARD**

**IN THE MATTER OF RULEMAKING :
PROCEEDINGS BEFORE THE : REPORT TO THE LEGISLATURE
PHARMACY EXAMINING BOARD : CR 16-072**

I. THE PROPOSED RULE:

The proposed rule, including the analysis and text, is attached.

II. REFERENCE TO APPLICABLE FORMS: None

III. FISCAL ESTIMATE AND EIA:

The Fiscal Estimate and EIA is attached.

IV. DETAILED STATEMENT EXPLAINING THE BASIS AND PURPOSE OF THE PROPOSED RULE, INCLUDING HOW THE PROPOSED RULE ADVANCES RELEVANT STATUTORY GOALS OR PURPOSES:

2015 Act 3 created licensure for home medical oxygen providers. This rule establishes licensure and professional conduct requirements for home medical oxygen providers.

V. SUMMARY OF PUBLIC COMMENTS AND THE BOARD'S RESPONSES, EXPLANATION OF MODIFICATIONS TO PROPOSED RULES PROMPTED BY PUBLIC COMMENTS:

The Pharmacy Examining Board held a public hearing on December 14, 2016. No one testified at the hearing, or submitted written comments. The Pharmacy Examining Board did not make any modifications prompted by public comments.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

Comment 1b: Section 450.076 (4), Stats., requires the board to promulgate rules governing the professional conduct of licensed providers and their employees and agents. While s. Phar 14.02 is titled "Standards of Professional Conduct", it does not appear to include a code of ethical responsibilities. Compare, for example, the standards of professional conduct given in s. Phar 10.03, for the types of ethical responsibilities. That section identifies a number of actions as unprofessional conduct, such as falsifying records, disclosing confidential patient information, and aiding or abetting unlicensed practice. The board should review the proposed rule to ensure that it is complying with this requirements.

Response: In s. Phar 14.02 the board is listing several specific conduct which is required as professional conduct and failing to do so may result in disciplinary actions. Several of these provisions are similar to other professional conduct provisions, including s. Phar 14.03, such as requiring professionals to follow rules and regulations, maintaining the required accreditation, proper record-keeping, safe storage and sanitation requirements. While promulgating the rule, the Board reviewed other states' rules and regulations for home medical oxygen providers and medical gas providers and Phar 14.03 is in line with the other states' professional conduct requirements.

Comment 2c: In s. Phar 14.02, consider reorganizing and renaming the section. The title "Standards of Professional" conduct suggests a code of ethical responsibilities, but most of the included items are standards of practice or other requirements. For example, sub. (1) could be placed in its own section with the title "Accreditation Requirement". The other subsections could be reviewed to determine if they could be grouped into related requirements and placed in separate sections for duties and practice requirements, such as "compliance with Tate and Federal Regulations", "Quality and Safety Standards", "Patient Plans" and "Records".

Response: The Board's position is the organization of this section as proposed is a clear and precise manner in which to list the required professional conduct standards. Standards of practice are ethical responsibilities. The following are unprofessional conduct: failing to maintain required accreditation, failing to comply with state or federal law, having a unsafe or unsanitary environment and failing to maintain patient records.

Comment 4a.: In s. Phar 14.02 (2), the rule should identify whether the source of the transportation rule is the U.S. Department of Transportation, the Wisconsin Department of Transportation, or both. Consider adding references to specific provisions of the U.S. Code, Code of Federal Regulations, or transportation provisions of the Wisconsin Administrative Code.

Response: The Board accepted in part by adding "federal" and "state". The Board recognizes that laws relating to the transportation of medical gasses may not be limited to the code of the two departments of transportation.

Comment 4b: In s. Phar 14.02 (3), it appears that "U.S." should be inserted before the phrase "food and drug administration", and that the phrase "rules and regulations" should be inserted after the word "administration". Consider adding references to specific provisions of the U.S. Code or Code of Federal Regulations.

Response: The Board inserted "U.S." and "rules and regulations". The Board declines adding specific provisions in order to be inclusive.

Comment 5: In s. Phar 14.02, the introduction material for subs. (5), (6), and (11) use the phrase "including all of the following". That phrase suggests that the list is not exhaustive and that other unlisted items may be part of that list. Consider revising each instance of the phrase to "all of the following" (without the word "including"), and, if appropriate in the provision, adding a final paragraph for such other procedures as may be relevant.

Response: The Board intended for the safety inspection requirements in sub (5), the recall procedure requirements in sub. (6) and the counseling requirements in sub. (11) to not be exhaustive and therefore, it was a deliberate choice of the phrase “including all of the following”.

All of the remaining recommendations suggested in the Clearinghouse Report have been accepted in whole.

VII. REPORT FROM THE SBRRB AND FINAL REGULATORY FLEXIBILITY ANALYSIS:

This rule will not have an impact on small business.