



Wisconsin Legislative Council

RULES CLEARINGHOUSE

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CLEARINGHOUSE RULE 21-074

Comments

[NOTE: All citations to “Manual” in the comments below are to the Administrative Rules Procedures Manual, prepared by the Legislative Council Staff and the Legislative Reference Bureau, dated November 2020.]

2. Form, Style and Placement in Administrative Code

a. In the caption for the proposed rule, the designation “Phar” should be listed only once for each series of affected rule sections within each type of treatment. For example, the listing of repealed provisions should appear as “Phar 6.04 (2), (3) (a) 2., 3., and 7., (b), and (c), and (4), and ch. Phar 11”. [s. 1.01 (1) (Example), Manual.]

b. In the text of the proposed rule, the designation for SECTION 2 occurs twice. The number for the second occurrence and all following SECTIONS should be corrected to be sequential.

c. SECTION 3 of the proposed rule should be separated into two SECTIONS: first, to repeal and recreate s. Phar 6.04 (3) (title); and second, to renumber and amend s. Phar 6.04 (3) (a) (intro.) and 1. The caption for the proposed rule should also be updated to reflect this change.

d. In the renumbering and amending of s. Phar 6.04 (3) (a) 5. and 6., the board should revise the amended text to show only the new designations. The former designations should not be stricken through or shown. [s. 1.04 (6) (b), Manual.]

4. Adequacy of References to Related Statutes, Rules and Forms

In s. Phar 12.04, the material from 1984 USC ss. 351 and 352 and 1985 21 CFR ss. 210 and 211 that was incorporated by reference is updated to “federal and state laws and regulations”. The board should reconsider the use of the general reference to “federal and state laws and regulations”. References should be as specific as possible, in order to adequately inform a reader as to what requirements must be met. [s. 1.15 (1) (c), Manual.] Additionally, if the board instead updates to revised federal law citations, that incorporation or update may be done only with the consent of the Attorney General. The rule summary should be revised to include a comment on compliance with that requirement, if a specific provision is incorporated. [s. 227.21 (2) (a), Stats.; and s. 1.14, Manual.]

6. Potential Conflicts With, and Comparability to, Related Federal Regulations

In the board's summary for the proposed rule, the entry for comparison to federal regulations says "none". However, elsewhere in the summary, the board notes that the current rules are inconsistent with federal law, and separately notes that a different part of federal law has been superseded. An explanation of the current status of federal law and the rules' relationship to those laws would be helpful.