WISCONSIN LEGISLATIVE COUNCIL
RULES CLEARINGHOUSE

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CLEARINGHOUSE RULE 12-009

Comments

[NOTE: All citations to "Manual" in the comments below are to the Administrative Rules Procedures Manual, prepared by the Legislative Reference Bureau and the Legislative Council Staff, dated November 2011.]

2. Form, Style and Placement in Administrative Code

The entire rule should be reviewed and redrafted as necessary to conform to proper drafting style of introductory material and punctuation at the end of subunits. In particular, introductory material should end with a colon and contain words like "all of the following" or "any of the following". Each subunit following the introduction should form a complete sentence when read with the introduction. Subunits of a rule should not end with "and" or "or". [See s. 1.03 (3) and (4) of the Manual.] Many provisions of the rule need to be redrafted in this regard. Section Phar 18.02 (23) is in particular need of editing.

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

a. In the Statutes Interpreted section of the analysis, more specific citations than "Chapters 961 and 450, Stats." should be provided.

b. In the Explanation of Agency Authority for the rule, the phrase "as amended by 2009 Act 362" is not necessary because all amendments to the statutes that were made by Acts of 2009 have been incorporated in the current version of the Wisconsin statutes.

c. In s. Phar 18.02 (7), (14), and (15), the acronyms that are used should be defined. In addition, citations to the federal laws or regulations that are mentioned should be provided.

d. Section Phar 18.02 (10) should indicate how it may be determined that a person licensed in another state is recognized by this state as a person authorized to dispense drugs. This material could be included in a Note. [s. 1.09 (1) and (2), Manual.]

e. In s. Phar 18.03 (2) (p), is there a method for a dispenser to determine a patient's gender other than by visual observation? Is this a concern for instances in which a prescription may be picked up by another person or at a drive-through location, when it may not be possible to determine which passenger in a car is the patient? Is a dispenser obligated to inquire as to gender if the dispenser is not sure?

f. In several instances, notes should be created to disclose where or how particular information, including forms, may be obtained. For example, a note should be inserted following s. Phar 18.04 (2) to explain where the ASAP implementation guide may be obtained, and all provisions of the rule that refer to forms, such as a form for an extension of time to file data in s. Phar 18.04 (3) (b), should include a note explaining how the required form may be obtained. [See s. 1.09 (1) of the Manual.]

g. In s. Phar 18.04 (4) (a), "requirements of this section" should be changed to "requirements of sub. (2)."

5. Clarity, Grammar, Punctuation and Use of Plain Language

a. In s. Phar 18.02 (11), "it" should be changed to "the dispenser". Likewise, in s. Phar 18.02 (21), "it" should be changed to "the practitioner".

b. In s. Phar 18.02 (18), the phrase "and other information pertaining to the program" is vague. Could it be made more specific?

c. It appears that it is unnecessary to define "submit", which is done in s. Phar 18.02 (26), because the text of the rule sets forth the requirement that data be delivered electronically. In any event, the definition is not properly drafted, since it defines a noun, while the word "submit" is a verb.

d. In s. Phar 18.03 (2), it appears that it would be more precise to state that the data shall "consist of" rather than "contain" the specified data.

e. In s. Phar 18.03 (2) (h), the phrase "provided by the amount of drug dispensed" or similar language, should be added.

f. Section Phar 18.03 (3) states that a dispenser is subject to disciplinary action by the "appropriate licensing board". Would it be more informative to state that a dispenser is subject to disciplinary action by the board that issued the license under which the dispenser is authorized to dispense prescription drugs?

g. In all provisions of the rule that create a right to request a waiver or extension of any requirement, the rule should set forth a timeframe for submission of the request and for action by the board, as well as a description of the process by which a person may appeal a denial of the request. Likewise, the rule should set forth a process for appeal of a suspension, revocation, or

restriction imposed by the board under s. Phar 18.09 (intro). In addition, consistent terminology should be used when referring to "waivers" and "extensions". It appears that s. Phar 18.04 (3) refers to a waiver, while sub. (3) (b) refers to the same item as an "extension".

h. It appears that the intent of s. Phar 18.04 (4) (intro) would be more accurately conveyed if it were written as follows: "The board may grant a waiver from the requirements of subs. (1) and (6) to a dispenser who does not dispense prescription drugs to humans if the dispenser does all of the following:".

i. In s. Phar 18.04 (5) (b) 1., the phrase "Compliance would result in" should be inserted before "A substantial hardship".

j. In s. Phar 18.04 (6), "a prescription drug" should be replaced with "any prescription drugs".

k. May a dispenser provide the information required in s. Phar 18.05 electronically?

l. The rule should explain what is meant by "health care facility staff committee" and "accreditation or health care services review organization", referred to in s. Phar 18.08 (4) (c). This comment also applies to "public health official", referred to in s. Phar 18.08 (4) (d).

m. Should the rule, in s. Phar 18.09, impose a requirement that an individual notify the board if they are no longer appropriately licensed to dispense prescription drugs? Is there a procedure in place by which the board will be notified of: (1) disciplinary actions taken against Wisconsin dispensers by agencies in other states; or (2) revocation of delegations by practitioners?