CLEARINGHOUSE RULE 98−076

Comments

[<u>NOTE</u>: All citations to "Manual" in the comments below are to the <u>Administrative Rules Procedures Manual</u>, prepared by the Revisor of Statutes Bureau and the Legislative Council Staff, dated October 1994.]

2. Form, Style and Placement in Administrative Code

a. Section Phar 1.02 (intro.) should be amended so that the definitions set forth in that section also apply to ch. Phar 15. A similar change should be made in s. Phar 1.01.

b. The rule incorporates various technical standards by reference. For example, s. Phar 15.02 (2) refers to "national sanitation foundations standard 49" and sub. (3) refers to "federal standard 209." The board should review s. 2.08, Manual, regarding incorporation of standards by reference and required consent of the Attorney General and Revisor of Statutes.

c. Section Phar 15.03 refers to a policy and procedure manual and describes the contents of the manual. Presumably, this manual is prepared by a pharmacy. Subsection (1) needs to be written in the active voice to clarify this; i.e., "A pharmacy shall prepare . . . ."

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

Section Phar 15.04 (2) (b) refers to "OSHA regulations." Can these regulations be cited specifically?

Also, s. Phar 15.08 (2) refers to "other protective apparel as determined by OSHA." How does OSHA determine this? Can specific regulations be cited?

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

a. In s. Phar 15.02 (1), "the technique involving" could be deleted.

b. In s. Phar 15.02 (2), a hyphen should be inserted after "low" and after "moderate."

c. In the Note to s. Phar 15.02 (3), it is unclear what "current revision" means. Also, it appears that the comma after "agencies" should be deleted.

d. In s. Phar 15.02 (4) and (5), "by" could be replaced with "due to."

e. In s. Phar 15.04 (1) and in several other provisions of the rule, "A" should replace "The."   [For other examples, see s. Phar 15.05 (2) (intro.) and (3).]   Also, in the second sentence, should "facility" be replaced with "area"?

f. In s. Phar 15.04 (2) (a), "that are" should be inserted before "capable." Also, it appears that the last sentence could be deleted and "during normal activity" could be inserted after "class 100 conditions" in the first sentence.

g. In s. Phar 15.04 (2) (b), the comma after "used needles" should be replaced with "and" and "as well as" should be replaced with "and." Also, the comma after "compounding" should be moved to follow "and."

h. In s. Phar 15.04 (2) (c), "to include" should be replaced with "including." Also, it appears that "when" should be replaced with "in pharmacies where." Also, that paragraph refers to "class II biological safety cabinet." Although "biological safety cabinetry" is defined, "class II" is not. Also, see s. Phar 15.08 (1).

i. In s. Phar 15.04 (2) (e), "should be" should be deleted.

j. In s. Phar 15.04 (3) (f), it is unclear what "administration devices" are. Could this paragraph be deleted?

k. In s. Phar 15.04 (4), "should" should be replaced with "shall." This change needs to be made in several provisions of the rule.

l. In s. Phar 15.05 (1), "must" should be replaced with "shall" and a hyphen should be inserted between "pharmacy" and "prepared." Throughout the rule, "must" should be replaced with "shall."

m. In s. Phar 15.05 (1) (a), "of personnel" should be inserted at the end of the sentence.

n. In s. Phar 15.05 (2) (intro.), "must" should be replaced with "shall." Also, should "by a single patient" be replaced with "for a single patient"? Also, it appears that "when they" should be replaced with "if the pharmaceuticals." Finally, it appears that "by including it on the label only" should be deleted.

o. In s. Phar 15.05 (2) (a) to (d), "The" should be inserted at the beginning of each sentence.

p. In s. Phar 15.05 (2) (a), it appears that "and" should be replaced with "on."

q. In s. Phar 15.05 (2) (d), the comma after "date" should be moved to follow "requirements."

r. In s. Phar 15.07 (1), "their" should be replaced with "the patient's."

s. In s. Phar 15.07 (2), "associated with" should be replaced with "requirements for."

t. In s. Phar 15.08 (1), "should" in the first sentence should be replaced with "shall" and "should" in the second sentence should be replaced with "may." Also, in the second sentence, "If" should replace "In the event" and the first "other" should be deleted.

u. In s. Phar 15.08 (2), (5) and (6), "must" should be replaced with "shall."

v. In s. Phar 15.09 (intro.), "as part of the labeling" should be replaced with "on the labels."

w. In s. Phar 15.09 (2), "to include" should be replaced with "and" and the comma after "date" should be moved to follow "time."

x. In s. Phar 15.10, "this type" should be replaced with "the type" and "self-" should be deleted.

y. In s. Phar 15.11 (2), the comma after "clean rooms" should be replaced with "and."

z. In s. Phar 15.11 (3), "as well as" should be replaced with "and."

aa. In s. Phar 15.11 (4), in the second sentence, "the" should replace "such." In the last sentence, a hyphen should be inserted between "particulate" and "free."

ab. In s. Phar 15.11 (5), a hyphen should be inserted between "pharmacy" and "prepared."

ac. The excessive use of the passive voice in s. Phar 15.11 makes it difficult for a reader to know who must take the required action. [See s. 1.01, Manual.] In every subsection that begins with "There shall be," these words should be replaced with "A pharmacy shall have . . ." or "A pharmacy shall maintain . . ." or a similar phrase. The second sentence of sub. (1) should begin "_____ shall examine . . . ." The last sentence of sub. (2) should begin "_____ shall maintain . . . ."