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RULES CLEARINGHOUSE

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CLEARINGHOUSE RULE 99–166

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 September 1998.]

2. Form, Style and Placement in Administrative Code

a. The department's analysis of the rule describes the need for and objective of the rule but does not adequately summarize the content of the rule. [See s. 1.02 (2) (b), Manual.]

b. In Phar 7.09 (1), the phrase "but is not limited to" should not be used with the word "means" in a definition. [See s. 1.01 (7) (c), Manual.] More importantly, it is not clear why "but is not limited to" is included in the definition; if other systems are contemplated as being included within the definition of "automated dispensing system," those should be specified in the definition, if possible.

c. In Phar 7.09 (2), "automated dispensing system" should be in the singular and reference should be to a "pharmacy" rather than "licensed pharmacies"; see the definition of "pharmacy" in Phar 1.02 (10).

d. The relationship of subs. (2) and (3) is unclear. Reference in sub. (2) to "where legally permissible" is vague. Does sub. (3) specify when an automated dispensing system is "legally permissible" in an inpatient health care facility? Better coordination of the subsections is in order.

e. In Phar 7.09 (3), ", where there is" should be replaced by "that have." Who determines whether an inpatient health care facility has an established program of pharmaceutical care that ensures medication orders are reviewed by a pharmacist in accordance

with established policies and procedures and good pharmacy practice? Reference to "inpatient health care facilities" in this subsection should be in the singular.

f. In s. Phar 7.09 (4) (intro.), "is" should replace "shall be" and "all of the following" should be inserted before the colon. The latter language also needs to be inserted elsewhere in the rule.

g. In s. Phar 7.09 (4) (c) (intro.), it appears that ", but is not limited to the" should be replaced by "all of the following:".

h. In subd. 1. of s. Phar 7.09 (4) (c), should "or the inpatient health care facility" be added?

i. It is suggested that Phar 7.09 (5) (intro.) be deleted and that all the paragraphs following that introductory clause be changed into separate subsections. This change will necessitate making specific reference, as appropriate, to an automated dispensing system in some of the new subsections. See current pars. (a) (intro.), (b) and (i).

j. It is suggested that Phar 7.09 (5) (a) (intro.) be revised to read: "A pharmacy shall maintain on-site the following documentation relating to an automated dispensing system:". Reference to serial numbers should then be added to the list of required information following the introductory clause. It is not clear why the original introductory clause states "may include, but is not limited to." Is the intent that the documentation may include additional information if desired or that the board may require additional information?

k. Section Phar 7.09 (5) (b) appears inconsistent with the requirement of sub. (5) (a) (intro.) that policies and procedures be maintained "on-site in the pharmacy."

l. It is suggested that s. Phar 7.09 (5) (c) not be subdivided; the paragraph can be stated in a single sentence.

m. It appears that s. Phar 7.09 (5) (e) unnecessarily repeats par. (c). Also, "must" should be replaced by "shall" if the provision is retained. The latter change should also be made in par. (f).

n. In s. Phar 7.09 (5) (i), "all" should be deleted.

o. In s. Phar 7.09 (j), "all" and "existing" should be deleted and "laws" should be singular.

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

a. In s. Phar 7.09 (1) (a), "collects," "controls," and "maintains" should reflect the plural subject "systems."

b. In s. Phar 7.09 (1) (b), "sanitorium" should replace "sanitarium."

c. In s. Phar 7.09 (5) (d) 2. a., "the" should be inserted after "of."

d. The use of "managing pharmacist" in s. Phar 7.09 (4) (intro.) raises questions concerning who has the listed responsibilities for an automated dispensing system located in an inpatient health care facility. See the definition of "managing pharmacist" in s. Phar 1.02 (6). Section Phar 7.09 (5) (f) raises the question why an automated dispensing system that is not located in a pharmacy is subject to apparently less stringent supervision of its stocking than when located within a pharmacy. In general, it appears that the rule could be clearer regarding the treatment of an automated dispensing system that is located in an inpatient health care facility rather than a pharmacy.