WISCONSIN LEGISLATIVE COUNCIL
RULES CLEARINGHOUSE

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CLEARINGHOUSE RULE 19-023

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 December 2014.]

1. Statutory Authority

The agency should consider adding s. 227.11 (2) (a), Stats., to the statutory authority section of the rule summary.

2. Form, Style and Placement in Administrative Code

a. "Product verification" should be in quotation marks under the treatment to s. Phar 7.20 (1), in SECTION 1 of the proposed rule. Additionally, within s. Phar 7.20 (1), "the drug product" should be changed to "a drug product".

b. The treatment to s. Phar 7.20 (2), in SECTION 1 of the rule, is confusing and needs revision and reorganization. It appears the objective of the provision is to set out the requirements for automated technology, but the material appears to set out a list of requirements of a prescription. Additionally, pars. (a) to (d) do not comprise a coherent list that can follow the language "meets all of the following:" in the introduction. The same comment applies to the list in s. Phar 7.20 (4). Paragraphs (c) and (d) relate to validation of automated technology and may best be separated from pars. (a) and (b). The agency should consider clarifying what person or entity is required to validate automated technology.

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

a. Should "of a prescription" be added after "verification" in the first sentence of the plain language analysis section of the rule summary?

b. Should "(machines)" be removed from the second sentence of the plain language analysis section of the rule summary because "automated technology" is not referred to as "machines" anywhere else in the rule?

c. The first sentence of the summary of factual data and analytical methodologies section of the rule summary is confusing. Should the word "the" before "product verification" be removed or should material be added after "product verification"?

d. A period should be placed at the end of the material in s. Phar 7.20 (2) (c) and (4) (b).

e. The treatment to s. Phar 7.20 (3) is confusing and needs revision. It is not clear what person or entity "identifies" a supervising pharmacist or what the phrase "each technology" means.

f. What is the difference between "product verification" as used throughout the proposed rule and automated technology "validation" as used in s. Phar 7.20 (2) (c) and (d)?

g. The treatment to s. Phar 7.20 (4) is confusing and needs revision. For example, should "of a prescription" be added after "product verification"? The section refers to "medications", but the term "prescriptions" is used in other parts of the rule. The agency should consider modifying the language for uniformity.

h. The treatment to s. Phar 7.20 (6) (a) 3. should be revised. Should it instead say "Documentation of the responsibilities of any managing pharmacist and supervising pharmacist"?