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## WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE

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### CLEARINGHOUSE RULE 16-079

#### 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**

a. While referenced in the plain language analysis and the title to s. Phar 7.10, the proposed rule text itself does not exclude a vaccine from the definition of a “drug product or device”, as specified under s. 450.035 (1g), Stats. This exclusion should be communicated in the text of the proposed rule rather than solely through the reference in the title. For example, s. Phar 7.10 (5) could be used to reference the inapplicability of the section to the administration of vaccines. [See, also, comment 2. a., below.]

b. It is not clear that the prescribing practitioner notification requirements of s. Phar 7.10 (1) apply to both pharmacists and persons engaged in the practice of pharmacy, as required by statute. [See s. 450.035 (1r) and (1t), Stats.]

#### **2. Form, Style and Placement in Administrative Code**

a. Generally, the agency should explain the purpose of the proposed rule in terms of the regulation it provides, beyond the requirements already included in s. 450.035, Stats. The rule appears to merely duplicate portions of s. 450.035, Stats. Also, while the cited statutory authority for the proposed rule refers to non-vaccine drug products and devices, should the agency consider a cross-reference to the regulations regarding administration of vaccines under s. 450.035, Stats.? In the current rule, the agency includes a note that directs the reader to the relevant statute.

b. Should the agency specify the list of approved alternative courses of study in the rule text rather than referring only to the possible approval of courses in s. Phar 7.10 (4)?

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

a. It is recommended that similar provisions within a rule be expressed identically whenever possible. In SECTION 1 of the rule text, consider revising s. Phar 7.10 (2) text to match the text of sub. (3) (a) and (b) (“...a course of study and training in administrative technique approved by the Accreditation Council of Pharmacy Education or the Board.”).

b. In s. Phar 7.10 (3) (intro.), “, Stats.” should follow the reference to s. 450.03 (1) (f) or (g).