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CLEARINGHOUSE RULE 96-081

Comments

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

1. Statutory Authority

a. On the cover page of this rule, the department cites s. 252.04 (2), Stats., as the statutory authority for this rule. On the top of page 2 of the rule, the department cites that provision and s. 252.04 (10), Stats. The two recitations of statutory authority should be consistent with each other.

b. Section HSS 144.03 (10) contains newly created language relating to the release of “immunization information,” both between “vaccine providers” and school or day care centers and among vaccine providers, such as local health departments and physicians’ offices. [The term “immunization information” is not defined either in the current or proposed rule language and there is a problem with the definition of “vaccine provider.” See the comment under heading 4, below.] Section HSS 144.03 (10) (a) permits a vaccine provider to disclose a student’s immunization information, including day, month, year and name of vaccine administered, to a school or day care center upon written or verbal request from the school or day care center, without written or verbal permission from the student or his or her parent. Section HSS 144.03 (10) (b) permits disclosure of immunization information among vaccine providers without written or verbal permission from the student or his or her parent.

It is unclear upon what statutory authority the department relies in creating these provisions. In the two provisions cited as statutory authority for the rule, s. 252.04 (2) and (10), Stats., no mention is made of release of immunization information between vaccine providers and schools or day care centers or among vaccine providers. Section 252.04 (1), Stats., which is not cited as statutory authority for the rule, provides that a person who immunizes an individual

under this section must maintain records identifying the manufacturer and lot number of the vaccine used, the date of immunization and the name and title of the person who immunized the individual. These records are to be available to the individual or, if a minor, to his or her parent, guardian or legal custodian upon request.

In general, pursuant to s. 146.82 (1), Stats., all patient health care records must remain confidential and may be released only to designated persons or with the informed consent of the patient or a person authorized by the patient. There are certain exceptions to the general rule, set forth in s. 146.82 (2), Stats., in which patient health care records must be released upon request without the patient's consent. With regard to the release of immunization information to schools, is the department relying on the confidentiality exception in s. 146.82 (2) (a) 12., Stats., which permits release of patient health care records to school districts in specified circumstances? With regard to the release of immunization information among vaccine providers, is the department relying on the exception in s. 146.82 (2) (a) 2., Stats., which permits disclosure of records by one health care provider to another if the second health care provider is also rendering assistance to the patient? Upon what authority is the department relying in permitting the release of the immunization information by vaccine providers to day care centers? There is no reference to day care centers in s. 146.82, Stats. The department should provide justification, with specific statutory authority cited, for permitting release of immunization information in all situations covered by s. HSS 144.03 (10).

2. Form, Style and Placement in Administrative Code

a. In SECTION 5 of the rule, the newly created paragraph in s. HSS 144.02 should be designated “(4m)” rather than “(4g).” [See s. 1.03 (7), Manual.]

b. In s. HSS 144.02 (6), the definition of “parent” does not need to specifically include the plural “parents” as well as the singular “parent,” since the singular already includes the plural. Section 1.01 (6), Manual, states that the singular form should be used. [See also ss. 227.27 and 990.001 (1), Stats.]

c. In SECTION 15 of the rule, the newly created subs. (4) and (5) should each have a title, for consistency with other subsections in s. HSS 144.03. [See s. 1.05 (1), Manual.]

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

In the definition of “vaccine provider” in s. HSS 144.02 (13), reference is made to a health care facility, “as defined in s. HSS 155.01 (6).” Section HSS 155.01 (6) does not exist and there is no definition of “health care facility” in ch. HSS 155 as a whole. This citation should be reviewed and corrected.

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

a. Section 1.02 (2) (b), Manual, states that the plain language analysis to a rule should contain sufficient detail to enable the reader to understand the content of the rule and the changes made, if any, in existing rules. While the Manual notes that the analysis is not intended to be an

exhaustive discussion of the rule, the analysis to this rule does not provide sufficient detail to enable the reader to understand the rule's contents. The first two paragraphs of the analysis on page 1 indicate that this is an "updating" of the department's rules for immunization of children, following passage of 1993 Wisconsin Act 27, which reorganized and updated the public health statutes. However, there is no indication in the analysis of the particular "updates" contained in the rule. These should be briefly explained in the analysis. Also, no mention is made in the analysis of the creation of the new provision, s. HSS 144.03 (10), relating to the release by vaccine providers of a student's immunization information to schools, day care centers and other vaccine providers. The analysis should be expanded to include a brief explanation of all changes contained in the rule. The analysis does a good job of explaining the reasons for adding Haemophilus influenzae b (Hib) and Hepatitis B (Hep B) to the list of diseases against which students are to be immunized. It is suggested that the parenthetical acronyms for these two diseases be inserted on line 1 of the third paragraph of the analysis, where the two diseases are first mentioned. In the fourth paragraph, the acronyms should be used throughout. Also, the analysis should indicate the school year in which those immunizations will first be required.

b. The second sentence of s. HSS 144.01 (1) is amended to add Hib and Hep B to the list of diseases for which children must be immunized prior to entering an elementary, middle, junior or senior high school or a day care center. As amended, this sentence gives the impression that children entering school must be immunized against Hib when, in fact, immunization against that disease is only required of children entering day care centers, and not schools, according to the rule analysis and the information set forth in Table 144.03-A. It is suggested that the sentence should be rewritten to clarify that only children entering day care are to be immunized against Hib. Similarly, the language in current s. HSS 144.03 (1) should be rewritten to reflect that the required immunization for Hib pertains only to children entering day care centers and not schools.

c. In s. HSS 144.02 (12) (b) 4., is the meaning of a "wild-virus type" of polio generally known or should the term be defined to distinguish this type of polio from any others?

d. Section HSS 144.03 (2) (a) and Table 144.03-A, as repealed and recreated in this rule, set forth immunization requirements for the 1995-96 school year and subsequent school years. Since that school year will have ended prior to promulgation of this rule, what is the reason for showing the 1995-96 requirements in this rule? It seems logical that a person referring to ch. HSS 144 after promulgation of this rule would want to know about requirements for the 1996-97 school year and beyond. If the department feels it is necessary to set forth the requirements for the 1995-96 school year, it is suggested that those requirements be combined with the 1996-97 requirements in a separate table from those covering subsequent school years, since the requirements will change with the addition of required immunization for Hib and Hep B beginning with the 1997-98 school year. The 1995-96 and 1996-97 requirements (or the 1996-97 requirements alone) could be in Table 144.03-A, entitled "IMMUNIZATION REQUIREMENTS FOR 1995-96 and 1996-97 SCHOOL YEARS", and the requirements for 1997-98 and beyond could be in Table HSS 144.03-B, entitled "IMMUNIZATION REQUIREMENTS FOR THE 1997-98 AND SUBSEQUENT SCHOOL YEARS." The substantive provisions relating to the new Table A would be placed in s. HSS 144.03 (2) and those relating to the new Table B would be placed in s. HSS 144.03 (3). If this reorganization is done, some of the comments in comments e to j, below, may become irrelevant.

e. In Table 144.03-A, is the information contained in Footnote 4 necessary, given that the entry for the Hib vaccine for the period 12 months through 23 months indicates that a third Hib is necessary at that age?

f. In s. HSS 144.03 (2) (c), it is suggested that the word “Children” on line 2 be changed to “Students,” for consistency with other provisions such as ss. HSS 144.01 (1) and 144.03 (2) (e) and (3).

g. Section HSS 144.03 (2) (e) states that students who began the Hib series at 12 to 14 months are only required to receive two doses. Over what period of time or at what ages are those two doses to be received?

h. Is the language in s. HSS 144.03 (3) necessary? It states that for the 1996-97 and subsequent school years, the requirements in Table 144.03-A, as qualified by sub. (2) (b) to (e) that apply for measles, mumps and rubella (MMR) shall apply to students in grades K to 12. Table 144.03-A, which sets forth requirements for the 1995-96 school year and subsequent school years, states that children in kindergarten through grade 12 are to have two MMR vaccines. There is no footnote qualifying that requirement in the Table, nor is there any exception in sub. (2) (b) to (e) which alters that requirement in any way. The only other reference to MMR is in sub. (2) (b), which states that immunization against MMR shall have been received on or after the first birthday. Since the Table indicates that two MMR vaccines are required for children in grades K through 12 for the 1995-96 and subsequent school years, what does the information in s. HSS 144.03 (3) add to the information in the Table? These two provisions should be reviewed and any unnecessary language omitted.

i. It appears that the information in sub. (5), which indicates how the Hep B vaccine is to be phased in in years subsequent to the 1997-98 school year, should either be included as part of Footnote 3 to Table 144.03-A or should be referenced in that footnote, so that the reader knows that the Hep B requirements for the 1998-99 school year and beyond are found in sub. (5). Also, in sub. (5), a semicolon should be inserted after the number “2002-03.”

j. In s. HSS 144.03 (8), reference is added to the third dose of Hep B in grades required “under subs. (2) and (3).” However, sub. (3) only relates to the MMR vaccine and not to Hep B. This reference should be reviewed and corrected.

k. The following comments pertain to s. HSS 144.03 (10). If all or a part of this language is retained following review of the statutory authority comments pertaining to the subsection in comment 1, b, above, the following comments should be noted. In par. (a), presumably the vaccine provider would disclose the student’s name and perhaps other identifying information, in addition to the information mentioned in this provision. All items which are authorized to be disclosed should be listed. Also, a definition of “immunization information” would be helpful, as none is provided. In par. (b), it is not clearly stated that immunization information may be provided by one vaccine provider to another. The sentence merely states that immunization information “may be disclosed to vaccine providers.” It should be clear who is authorized to disclose the information and to whom. Also, if both pars. (a) and (b) are retained, consistent terminology should be used. In par. (a), the person whose immunization information may be released is referred to as a “student,” while in par. (b), the person is referred to as “the recipient of the vaccine or the recipient’s parent.” Finally, it appears that the phrase “, including local

health departments and physicians' offices" could be deleted, since the term "vaccine providers" is defined.

l. In s. HSS 144.06, why is the reference to "physicians" changed to "clinics"? Also, if the term "vaccine provider," defined in s. HSS 144.02 (13) and used elsewhere in the rule, covers the various persons and entities which provide vaccines to students, why is that term not used in this provision in place of the listing of entities?

m. In s. HSS 144.07 (1m), it is suggested that the phrase "child or adult" on lines 1 and 2 be changed to "student," for consistency with the statutory provision relating to these time limits. Also, it appears that the word "the" on line 6 should be deleted or an additional phrase, such as "requirements of" should be added.

n. Section HSS 144.07 (3) provides that if a student fails to comply with immunization requirements, the school or day care center must, within 60 school days of the failure to comply, notify the district attorney in writing. Section 252.04 (6), Stats., as affected by 1995 Wisconsin Act 77, provides that a school, day care center or nursery school must notify the district attorney regarding a student who fails to present written evidence of completed immunizations or a written waiver within 60 school days after being admitted to the school, day care center or nursery school. The rule would be clarified if the phrase "60 school days of that failure to comply" were modified to reflect that the 60-day period begins to run after the student has been admitted.

o. In s. HSS 144.07 (4) (intro.), a colon should be inserted at the end of the second line, in order to be consistent with the current text of the rule.

p. In s. HSS 144.08 (1), it is suggested that the phrase "is responsible for making available" on line 2 should be changed to "shall make available."

q. In s. HSS 144.08 (3), it appears that the phrase "the provisions of" should be inserted after the word "of" on line 2, in order to be consistent with the current text of the rule.

r. In s. HSS 144.09 (1) (a), what "appropriate agencies" are being referred to on line 3?