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Opinion No. 01-091

Need for the Pharmacy Based Immunization Program Guidelines to be Promulgated as a Rule Under the Tennessee Uniform Administrative Procedures Act.

QUESTIONS

1. Are the Pharmacy Based Immunization Program ("PBIP") Guidelines adopted by the Tennessee Board of Pharmacy "rules" as defined in the Tennessee Uniform Administrative Procedures Act?

2. If the answer to Question No. 1 above is in the affirmative, are such rules void for failure to be promulgated pursuant to the UAPA?

OPINIONS

1. Yes. Because the PBIP Guidelines are a statement of general applicability that implements a policy and describes the practice requirements of the Board of Pharmacy, they are a "rule" as defined by the Uniform Administrative Procedures Act (UAPA) at Tenn. Code Ann. § 4-5-102(10). None of the various exceptions to the definition of "rule" contained in this statute are applicable to the Guidelines.

2. Yes. The PBIP Guidelines are void and cannot be enforced as a "rule" because the Board of Pharmacy did not promulgate them as such pursuant to the provisions of the UAPA.

ANALYSIS

1. The Tennessee Board of Pharmacy is an "agency" as that term is defined in Tenn. Code Ann. § 4-5-102(2):

> "Agency" means each state board, commission, committee, department, officer, or any other unit of state government authorized or required by any statute or constitutional provision to make rules or to determine contested cases.

Pursuant to Tenn. Code Ann. § 63-10-501, the Pharmacy Board is a state board. Tenn. Code Ann. § 63-10-504(b)(1) mandates that the Board adopt rules "for the proper administration and enforcement of parts 4-6 of [the Tennessee Pharmacy Practice Act of 1996] . . . ."

The Tennessee Board of Pharmacy adopted guidelines for its "Pharmacy Based Immunization Program" on July 23, 1997. The text of these guidelines is as follows:

> Any pharmacist who wished to participate in a pharmacy based immunization program must meet the following specifications.
>
> 1. Complete an immunization training program recognized by the Board of Pharmacy.
> 2. Have a emergency plan protocol to deal with emergencies when giving immunizations. An example would be a written plan that alerts a local physician or emergency center that you will be giving immunizations and notifies them of the particular date and time you are offering the service.
> 3. Notify appropriate health care professionals that immunizations are being offered in your facility, including health departments, physician's offices, etc.
> 4. Be Basic Cardiac Life Support or Cardiopulmonary Resuscitation Certified, at a minimum.

"Rule" is defined in Tenn. Code Ann. § 4-5-102(10) as

> each agency statement of general applicability that implements or prescribes law or policy or describes the procedures or practice requirements of any agency. "Rule" includes the amendment or repeal of a prior rule, but does not include:
> (A) Statements concerning only the internal management of state government and not affecting private rights, privileges or procedures available to the public;
> (B) Declaratory orders issued pursuant to § 4-5-223;
> (C) Intra-agency memoranda;
> (D) General policy statements which are substantially repetitious of existing law; or
> (E) Agency statements which:
>
> (i) Relate to the use of the highways and are made known to the public by means of signs or signals; or
>
> (ii) Relate to the curriculum of individual state supported institutions of postsecondary education or to the admission or graduation of students of such individual institutions but not to the discipline or housing of students;
>
> (F) Rate filings pursuant to title 56, chapters 5 and 6; or
> (G) Statements concerning inmates of correctional or detention facility.

The introductory paragraph of the PBIP Guidelines states "[a]ny pharmacist who wished to participate in a pharmacy based immunization program **must meet** the following specifications." (emphasis added). Thus, the Board appears to be making the Guidelines mandatory on any pharmacist who wants to participate in a pharmacy based immunization program. A common sense reading of the Guidelines shows that they describe the procedures or practice requirements of the Board -- if any pharmacist does not comply with the "specifications" enumerated in the Guidelines, they cannot participate in a pharmacy based immunization program. Thus, the Guidelines meet the general definition of "rule" contained in Tenn. Code Ann. § 4-5-102(10).

The only exceptions to this definition that might conceivably apply to the Guidelines are those in subsections (A), (C), and (D). However, the Guidelines cannot be considered "[s]tatements concerning only the internal management of state government and not affecting private rights, privileges or procedures available to the public" since the Guidelines apparently apply to practicing pharmacists outside of state government and indeed would serve to limit the rights of pharmacists who do not abide by their specifications.

Similarly, the Guidelines are not an intra-agency memoranda since they are meant to apply to practicing pharmacists who are regulated by the Board and they are not limited in their application to the Board or other divisions of state government. This office has also been advised by the Board that the Guidelines, after adoption, were posted on the Board's Internet website and otherwise distributed for purposes of notice.

Finally, the Guidelines are not "substantially repetitious of existing law." There are not any statutory or regulatory provisions similar in substance to the Guidelines or that arguably infer the requirements of the Guidelines. The Guidelines cite two statutes and one Rule. Tenn. Code Ann. § 63-10-404(1) is the general definition of "administer" for the Pharmacy Practice Act and does refer to "injection" as one means of the application of a drug to a patient or research subject. Tenn. Code Ann. § 63-10-404(31) is the definition of "Practice of pharmacy." Neither of these statutes mentions a "Pharmacy Based Immunization Program" or discusses any requirements that are binding on a pharmacist who wants to give immunizations. Similarly Rule 1140-3-.01, "Responsibilities For Pharmaceutical Care," does not contain any provisions mandating the specific requirements of the Guidelines or any statements that arguably include the requirements.

The PBIP Guidelines developed and published by the Board of Pharmacy are a "rule" as defined in the UAPA.

2. Boards and agencies with the authority to promulgate rules must do so according to the rulemaking process outlined in the UAPA. Tenn. Code Ann. § 4-5-203(a). Pursuant to Tenn. Code Ann. § 4-5-202(a) a board or agency must give the public notice that it is going to promulgate rules and it must provide a rulemaking hearing. Rules that are not promulgated pursuant to the UAPA's public notice

requirements are void. Tenn. Code Ann. § 4-5-216. No rule is effective until approved by the Attorney General and filed with the Secretary of State. Tenn. Code Ann. § 4-5-207. An agency's policy statements and other directives that are "rules" as defined by the UAPA must be promulgated as such. *See Tennessee Cable Television Associates v. Tennessee Public Service Commission*, 844 S.W.2d 151, 163 (Tenn. Ct. App. 1992).

This Office has been informed by the Board of Pharmacy that the PBIP Guidelines that are the subject of this Opinion request were not promulgated as rules under the provisions of the UAPA. Because the PBIP Guidelines are a rule or rules as defined in the UAPA they are void and unenforceable because the Board of Pharmacy did not promulgate them pursuant to the process mandated in the UAPA.

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