

**STATE OF TENNESSEE
OFFICE OF THE ATTORNEY GENERAL**

January 9, 2014,

Opinion No. 14-05

Inspection Fees for Out-of-State Pharmacies Licensed in Tennessee

QUESTIONS

1. Does the Tennessee Board of Pharmacy have the statutory authority to enact a rule imposing a fee or charge on Tennessee-licensed pharmacies that are physically located in other states and that engage in the practice of compounding sterile products, where such fee or charge is related to the additional expense incurred in inspecting these pharmacies and would not be imposed on similar pharmacies located inside the state?

2. Would such a rule violate the Commerce Clause of the United States Constitution?

OPINIONS

1. Based upon the provisions of the Tennessee Pharmacy Practice Act, and particularly of recently enacted Tenn. Code Ann. § 63-10-216, the Tennessee Board of Pharmacy is not authorized to enact a rule that would implement licensing-related inspections of out-of-state compounding pharmacies by Board personnel and that would impose additional fees or charges upon those pharmacies for the costs of such inspections.

2. Because of the answer to the first question, the question about the Commerce Clause is pretermitted.

ANALYSIS

In an effort to ensure that the same compounding standards are followed by all licensees that compound sterile products, regardless of physical location, the Tennessee Board of Pharmacy is considering the promulgation of a rule related to the inspection of Tennessee-licensed pharmacies that are physically located in other states and engage in the practice of compounding sterile products. The Board inspects only in-state pharmacies at present. If it were to undertake an out-of-state

inspection process, the Board would incur additional operating expenses in the form of personnel and travel fees or would need to expend additional funds in order to contract for such services. In order to raise revenue to pay these expenses, the Board is considering promulgating a rule that would impose fees or charges on compounding pharmacies located outside Tennessee that would not be imposed on similar pharmacies located inside the state.

1. The Board of Pharmacy can enact a rule imposing additional fees or charges upon out-of-state pharmacies for the costs of performing licensing-related inspections of those pharmacies only if the rule would be consistent with governing statutes. If rules and regulations promulgated by an administrative agency or board are inconsistent with the enabling statute, they are void and invalid. *Holiday Inns, Inc. v. Olsen*, 692 S.W.2d 850, 853 (Tenn. 1985) (citations omitted).

Tenn. Code Ann. § 63-10-307(a) of the Tennessee Pharmacy Practice Act provides the Board or its designated agents with power and authority “to inspect any site or professional pharmacy practice, other than storage sites utilized by manufacturer’s representatives, where drugs, medicines, chemicals, pharmaceuticals or poisons are manufactured, stored, sold, dispensed, distributed or administered.” Tenn. Code Ann. § 63-10-308(a) gives the Board broad authority to enact rules “establish[ing] fees necessary to carry out [the Tennessee Pharmacy Practice Act].”

However, Tenn. Code Ann. § 63-10-210, which requires pharmacies that dispense and mail prescription drugs into Tennessee from another state to pay licensure fees required of Tennessee pharmacies, specifically states that “[t]he license fees for out-of-state pharmacies and pharmacists shall not exceed those charged to Tennessee pharmacies and pharmacists.” Furthermore, effective April 25, 2013, Public Chapter 266 of the Acts of 2013 evinces the Tennessee Legislature’s intent with respect to conducting inspections of out-of-state compounding pharmacies that seek licensure in Tennessee. The 2013 legislation added a new statute to the Tennessee Pharmacy Practice Act, Tenn. Code Ann. § 63-10-216, which provides, in pertinent part:

- (a) Prior to initial licensure in this state as a compounding pharmacy, a pharmacy located outside of this state must have an inspection by the regulatory or licensing agency of the state in which the pharmacy practice site is physically located. Out-of-state pharmacy practice sites must provide a copy of the most recent inspection by the regulatory or licensing agency of the state in which the pharmacy practice site is physically located, which must have been within the previous twelve (12) months. Prior to renewal of its license in this state, an out-of-state pharmacy practice site must provide the most recent inspection by the regulatory or licensing

agency of the state in which the pharmacy practice site is physically located or equivalent regulatory entity, and which must have been within the previous twelve (12) months. The board of pharmacy shall have the right to require additional information before issuing or renewing a pharmacy license to insure compliance with applicable laws of this state and any rules and policies of the board.

While the 2013 legislation requires that out-of-state compounding pharmacies must be inspected before they may be licensed in Tennessee, it also provides that such inspections be made by the appropriate agency of the state in which the pharmacy is physically located.

Therefore, we conclude that the Tennessee Board of Pharmacy is not authorized to enact a rule requiring that out-of-state compounding pharmacies be inspected by Board personnel or contractors. We also conclude that the Board lacks authority to impose additional fees or charges upon those pharmacies for the costs of such inspections.

2. Because of the answer to the first question, the question about the Commerce Clause is pretermitted.

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