



**COMMONWEALTH OF KENTUCKY
OFFICE OF THE ATTORNEY GENERAL**

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OAG 24-11

Subject: (1) Does the Kentucky Board of Pharmacy have any authority to regulate non-resident pharmacists beyond what is specifically stated in KRS Chapter 315?

(2) Does the Board have authority to mandate in-state licensing of non-resident pharmacists, generally, and as proposed in the amendment to 201 KAR 2:030, specifically?

Requested by: Representative Derek Lewis
Kentucky House of Representatives, District 90
Co-Chair, Administrative Regulation Review Subcommittee

Written by: Aaron J. Silletto, Executive Director
Office of Civil and Environmental Law

Syllabus: (1) The Kentucky Board of Pharmacy lacks the legal authority to regulate non-resident pharmacists beyond that which is specifically conferred in KRS Chapter 315.

(2) The Kentucky Board of Pharmacy may not mandate the Kentucky licensure of non-resident pharmacists, except for pharmacists in charge under KRS 315.0351(1)(g). Therefore, the Board's proposed amendment to 201 KAR 2:030 exceeds its statutory authority.

Opinion of the Attorney General

The Kentucky Board of Pharmacy ("Board") seeks to amend its administrative regulations regarding licensing to practice pharmacy. Those regulations are currently pending before the General Assembly's Administrative Regulation Review Subcommittee ("ARRS"), *see* KRS 13A.290(1), and essentially would require all non-resident pharmacists filling prescriptions for Kentucky residents to hold a Kentucky license. Currently, only the pharmacist in charge of an out-of-state pharmacy must

be licensed in Kentucky. The ARRS Co-Chair has requested an Opinion from this Office to answer several questions regarding the extent of the Board's authority to license and regulate non-resident pharmacists. For the reasons that follow, it is the opinion of this Office that the Board's proposed regulations exceed the Board's authority to regulate non-resident pharmacists.

To understand the Board's proposed regulations, a brief overview of the steps in the drug dispensing process is helpful. Kentucky patients may seek to have their prescriptions filled at a pharmacy located inside or outside the Commonwealth. When a patient seeks to have a prescription filled, he or his physician must deliver or send the prescription to a pharmacy. Once received, the pharmacy's staff enters the prescription data into its computer system. A pharmacist then must conduct a drug utilization review on new or refill prescriptions to determine if there may be any drug interactions, allergies, or issues with the prescription based on the patient's medical history. After verification, the pharmacist or a pharmacy technician prepares the medication. The medication is labeled with the required information, and the pharmacist then conducts a final check on the prescription to ensure accuracy. If the patient agrees to counseling, the pharmacist will provide counseling on how to take the medication and on other clinically appropriate information such as expected results or necessary warnings. The medication is then dispensed to the patient. Delivery of the medication to the patient may occur in person, by pharmacy delivery personnel, or by common carrier. Depending on how the pharmacy structures its operations, some or all of the dispensing process may occur at more than one physical location, inside or outside Kentucky.

The specific regulation mentioned in the request for an Opinion is the Board's proposed amendment to 201 KAR 2:030.¹ As summarized in the request, the amendment would "make[] significant changes to the existing regulation by creating a licensing framework for all non-resident pharmacists. This will essentially require all out-of-state pharmacists filling prescriptions for patients in Kentucky to be licensed in-state." The ARRS Co-Chair states that the Board has not sufficiently answered the Subcommittee's questions concerning the Board's statutory authority for this amendment. Thus, the issue is one of statutory construction.

"All statutes of this state shall be liberally construed with a view to promote their objects and carry out the intent of the legislature[.]" KRS 446.080(1).

¹ Though not specifically mentioned in the ARRS Co-Chair's request, the Board points out that two other proposed regulations now pending before ARRS are also relevant. First, the Board proposes to amend 201 KAR 2:050 to impose fees for an application for, or renewal of, a non-resident pharmacy license. Second, the Board has proposed a new administrative regulation, to be numbered 201 KAR 2:465, which establishes the requirements to obtain a non-resident pharmacy permit. Though not specifically addressed in this Opinion, the Office's analysis of 201 KAR 2:030 will likely be relevant to ARRS's consideration of these other proposed regulations.

“In construing statutes, our goal, of course, is to give effect to the intent of the General Assembly. We derive that intent, if at all possible, from the language the General Assembly chose, either as defined by the General Assembly or as generally understood in the context of the matter under consideration. . . . We presume that the General Assembly intended for the statute to be construed as a whole, for all of its parts to have meaning, and for it to harmonize with related statutes. . . . We also presume that the General Assembly did not intend an absurd statute or an unconstitutional one. . . .”

Shawnee Telecom Res., Inc. v. Brown, 354 S.W.3d 542, 551 (Ky. 2011) (citations omitted). Where a statute is ambiguous, the “time-honored canons of statutory construction” may be helpful in arriving at the statute’s meaning. *Jefferson Cnty. Bd. of Educ. v. Fell*, 391 S.W.3d 713, 720 (Ky. 2012); see *Shawnee*, 354 S.W.3d at 551 (“Only if the statute is ambiguous or otherwise frustrates a plain reading, do we resort to extrinsic aids such as . . . the canons of construction[.]”).

We turn first to the statutory text. The practice of pharmacy in Kentucky is governed in large part by KRS Chapter 315, the purpose of which is to “promote, preserve, and protect public health, safety, and welfare by and through . . . the licensure, control, and regulation of *all sites or persons who are required to obtain a license, certificate, or permit from the Board of Pharmacy, whether located in or outside the Commonwealth*, that distribute, manufacture, or sell drugs within the Commonwealth.” KRS 315.005 (emphasis added). KRS Chapter 315 provides for permits to operate a pharmacy and licenses to engage in the practice of pharmacy.

Every “pharmacy within this Commonwealth” is required to have a permit issued by the Board. KRS 315.035. In addition, every “out-of-state pharmacy” doing business in the Commonwealth (*e.g.*, a mail order or internet pharmacy) must hold a permit from the Board. KRS 315.0351. Thus, KRS Chapter 315 clearly provides that, wherever *a pharmacy* is physically located, if it is doing business in Kentucky, it must hold a valid Kentucky permit.

But KRS Chapter 315 is less clear regarding the licensure of non-resident *pharmacists*. KRS 315.020(3) provides that, with several exceptions not relevant here, “no person shall engage in the practice of pharmacy unless licensed to practice under the provisions of KRS Chapter 315.”² That chapter prescribes the qualifications for licensure of pharmacists, KRS 315.050; the continuing education requirements for

² The “practice of pharmacy” includes the “interpretation, evaluation, and implementation of medical orders and prescription drug orders; responsibility for dispensing prescription drug orders, including radioactive substances; participation in drug and drug-related device selection; administration of medications or biologics in the course of dispensing or maintaining a prescription drug order; . . . drug evaluation, utilization, or regimen review; . . . and provision of patient counseling and those professional acts, professional decisions, or professional services necessary to maintain and manage all areas of a patient’s pharmacy-related care.” KRS 315.010(22).

pharmacists, KRS 315.065; and the requirements for renewal of a pharmacist license, KRS 315.110. But none of these statutes prescribes an express residency requirement or geographic limitation on their reach.

Looking to other parts of KRS Chapter 315 provides a clue as to the geographic reach of KRS 315.020(3). Every out-of-state pharmacy is required to “have a *pharmacist in charge* who is licensed to engage in the practice of pharmacy by the Commonwealth.” KRS 315.0351(1)(g) (emphasis added). Notably, the statute requires only the “pharmacist in charge” of an out-of-state pharmacy to be licensed by the Board. In addition, the out-of-state pharmacy need only “disclose to the [B]oard the *location, names, and titles* of . . . all pharmacists who are dispensing prescription drugs to residents of the Commonwealth.” KRS 315.0351(1)(b) (emphasis added). The upshot of these requirements is that, with the exception of the pharmacist in charge, an out-of-state pharmacy need only disclose the identities of its pharmacists to the Board. There is no explicit licensure requirement in the statute for these other pharmacists for them to “dispens[e] prescription drugs to residents of the Commonwealth.” *Id.*

On the other hand, the Board contends that “[t]here is no language [in KRS Chapter 315] distinguishing between a pharmacist located in Kentucky and a pharmacist located outside of Kentucky.” It is true that nothing in KRS 315.020(3) specifically excludes pharmacists located outside Kentucky. Thus, the statute is ambiguous with respect to whether “no person” refers to a person located in the Commonwealth, or instead, to a person no matter where he is located. And so, we turn to the “time-honored canons of statutory construction” to determine the meaning of KRS 315.020(3). *Fell*, 391 S.W.3d at 720.

Under the “extraterritoriality canon,” it must be presumed that a statute has no extraterritorial application. Scalia & Garner, *Reading Law: The Interpretation of Legal Texts* (West 2012), at 268–72; see also *Restatement (First) of Conflict of Laws* § 57 (1934) (observing that, in general, “a state cannot exercise executive jurisdiction within the territory of another state”). Kentucky law has embraced “the well-established presumption against extraterritorial operation of statutes.” *Union Underwear Co. v. Barnhart*, 50 S.W.3d 188, 190 (Ky. 2001). In other words, “unless a contrary intent appears within the language of the statute, we presume that the statute is meant to apply only within the territorial boundaries of the Commonwealth.” *Id.* (citation omitted). Kentucky courts do not infer the extraterritorial reach of a statute “absent a positive showing . . . that the General Assembly intended that the Act be applied extraterritorially.” *Id.* at 191. And the statutory use of broad adjectives such as “any” and “all” when referring to persons covered by the law “does *not* imply that the enacting legislature intended that the legislation be applied extraterritorially.” *Id.* (emphasis in original).

Applying the extraterritoriality canon to this case, it must be presumed that KRS 315.020(3) does not apply to persons located outside Kentucky. While the

presumption can be overcome by a “positive showing” of legislative intent “within the language of the statute” itself, *Barnhart*, 50 S.W.3d at 190–91, it is not overcome here.³

The Board makes several arguments in favor of its claimed authority to require the Kentucky licensure of all non-resident pharmacists dispensing medications to Kentucky residents. First, the Board points to “the policy statement conveyed in KRS 315.005 that jurisdiction is to be applied to ‘sites and persons’ located outside the Commonwealth.” But that is not exactly what KRS 315.005 says. Rather, it states that the purpose of KRS Chapter 315 is to allow the licensure and regulation of “all sites or persons *who are required to obtain a license . . . from the Board of Pharmacy*” (emphasis added). In other words, as a statement of legislative purpose, KRS 315.005 does not itself provide any statutory authority to the Board to license or regulate. It merely evinces the purpose that the Board license and regulate those pharmacies and pharmacists “who are required” by another statute in the chapter “to obtain a license.” Read in its entirety, KRS 315.005 does not authorize the Board to require the licensure of all non-resident pharmacists serving Kentuckians.

Next, the Board points to the titles of KRS 315.035 and KRS 315.0351 as some evidence of its authority to “exercise[e] jurisdiction over pharmacists not located in Kentucky.” But the titles are not part of the law, as they are not subject to the bicameralism and presentment requirements in the Kentucky Constitution. *See* Ky. Const. §§ 46, 56, 88. Rather, they are added by the Reviser of Statutes after a bill becomes law. *See* KRS 7.136(1)(b); KRS 7.140(1). Thus, the titles of statutes “do not constitute any part of the law.” KRS 446.140. The titles of KRS 315.035 and KRS 315.0351 therefore provide no support for an extraterritorial application of KRS 315.020(3).

The Board also disputes that the pharmacist identification and pharmacist-in-charge requirements of KRS 315.0351(1)(b) and (g) do not weigh against its broad claim to extraterritorial jurisdiction. But this argument runs headlong into another canon of construction: *expressio unius est exclusio alterius*, meaning “the mention of one thing implies the exclusion of another.” *Fox v. Grayson*, 317 S.W.3d 1, 8 (Ky. 2010). Under the statute, out-of-state pharmacies are required to have only a licensed pharmacist in charge. Other pharmacists working at the out-of-state pharmacy need only be identified on the pharmacy’s annual report to the Board. These statutory requirements imply that further licensure of the non-resident pharmacists, beyond merely identifying them, is not required.

Finally, in assessing the Board’s claimed authority to require the licensure of every non-resident pharmacist dispensing medications to Kentucky residents, it must

³ Further, the use of “no” to modify “person” in KRS 315.020(3) is no more evidence of legislative intent that the statute should apply extraterritorially than “any” or “all” were in *Barnhart*, 50 S.W.3d at 191.

be remembered that “Executive Branch agencies or administrative agencies have no inherent authority and may exercise only such authority as may be legislatively conferred.” *Herndon v. Herndon*, 139 S.W.3d 822, 826 (Ky. 2004). “[A]n administrative agency’s authority ‘is limited to a direct implementation of the functions assigned to the agency by the statute.’” *United Sign, Ltd. v. Commonwealth, Transp. Cabinet, Dep’t of Highways*, 44 S.W.3d 794, 798 (Ky. App. 2000) (quoting *Flying J Travel Plaza v. Commonwealth, Transp. Cabinet, Dep’t of Highways*, 928 S.W.2d 344, 347 (Ky. 1996)). “Any doubts concerning the existence or extent of an administrative agency’s power should be resolved against the agency.” *Id.* (citing *Henry v. Parrish*, 211 S.W.2d 418, 422 (Ky. 1948)). The Board is only authorized to promulgate administrative regulations that are “necessary to regulate and control *all matters set forth in [KRS Chapter 315]* relating to pharmacists.” KRS 315.191(1)(a) (emphasis added).⁴ At a minimum, the Board’s claimed authority to further regulate non-resident pharmacists is unclear and lacks express legislative authorization. Such authority is certainly not “set forth in” KRS Chapter 315 but requires a strained reading of the statutory text. Without clear legislative authorization, the Board may not impose greater regulations on non-resident pharmacists.

In sum, considering both the statutory text and the applicable canons of construction, it is the opinion of this Office that the Board lacks the legal authority to regulate non-resident pharmacists beyond that which is specifically conferred in KRS Chapter 315. Absent greater statutory authority, the Board may not mandate the Kentucky licensure of non-resident pharmacists, except for pharmacists in charge under KRS 315.0351(1)(g). Therefore, it is also the opinion of this Office that the Board’s proposed amendment to 201 KAR 2:030 exceeds its statutory authority.⁵

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⁴ The Board also cites its authority to promulgate administrative regulations that are “necessary and [*sic*] to control the storage, retrieval, dispensing, refilling, and transfer of prescription drug orders within and between pharmacists and pharmacies licensed or issued a permit by it.” KRS 315.191(1)(f). But authority to regulate the transfer or dispensing of medications by licensed pharmacists does not carry with it the authority to determine which pharmacists must be licensed.

⁵ The ARRS Co-Chair’s request for an Opinion also asked, “[T]o what extent does the Board have authority to impose requirements and restrictions that accompany licensing of non-resident pharmacists, such as those in the amendment to 201 KAR 2:030?” But given the answers provided to the other questions asked, it is not necessary to reach this issue.