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ALABAMA COURT OF CIVIL APPEALS

OCTOBER TERM, 2014-2015

2130524

Serve You Custom Prescription Management

v.

Alabama State Board of Pharmacy

Appeal from Jefferson Circuit Court (CV-13-901272)

DONALDSON, Judge.

Serve You Custom Prescription Management ("Serve You") appeals a judgment of the Jefferson Circuit Court ("the circuit court") dated March 13, 2014, in which the circuit court affirmed a decision of the Alabama State Board of

Pharmacy ("the Board") to sanction Serve You for violations of certain proscribed acts and offenses set forth in §§ 34-23-33(a)(2) and 20-2-54(a)(4), Ala. Code 1975, in regard to the distribution of controlled substances. The circuit court entered a summary judgment affirming the Board's decision. For the reasons stated herein, we affirm the circuit court's judgment.

The facts of this case are undisputed. Serve You is a mail-order pharmacy based in Wisconsin. Alabama is one of the states to which Serve You has a permit to ship prescription medications. On February 15, 2011, Serve You entered into a "Stipulation and Final Agency Order" ("the stipulation") with the State of Colorado regarding violations of the Colorado Electronic Prescription Drug Monitoring Program ("PDMP"). In the stipulation, Serve You admitted that it

"failed to submit the required data to the PDMP reporting dispensing transactions of controlled substances in the State of Colorado for the reporting period of January 1 through January 10, 2011, and did not submit a 'zero' report indicating no dispensing transactions for said reporting period as required by Board rule."

The stipulation imposed fines and charges totaling \$11,000 on Serve You.

Based on the stipulation, the Board served a "Statement of Charges and Notice of Hearing" on Serve You on November 27, 2012. The Board charged Serve You with violations of \$\$ 34-23-33(a)(2), 34-23-33(a)(6), and 20-2-54(a)(4). Serve You

"

"(2) Violation of the laws regulating the sale or dispensing of narcotics, exempt narcotics, or drugs bearing the label 'caution, federal law prohibits dispensing without prescription,' or similar wording which causes the drugs to be classified as prescription legend drugs.

"

"(6) Gross malpractice or repeated malpractice or gross negligence in the practice of pharmacy."

 2 Section 20-2-54(a)(4) provides that "[a] registration under Section 20-2-52 to manufacture, distribute or dispense a controlled substance may be suspended or revoked by the certifying boards upon a finding that the registrant ... [h]as

¹Section 34-23-33(a) provides, in pertinent part:

[&]quot;(a) The board may revoke, suspend, place on probation, or require remediation for any licensed pharmacist or a holder of a pharmacy intern or extern certificate for a specified time as determined by the board and take the same or similar action against the permit to operate any pharmacy in this state, whenever the board finds by a preponderance of the evidence, or pursuant to a consent decree, that the pharmacist has been guilty of any of the following acts or offenses:

filed a motion with the Board to dismiss the charges, and the Board denied that motion. The Board held a hearing on February 19, 2013. On March 7, 2013, the Board entered a "Final Order" finding that Serve You had violated §§ 34-23-33(a)(2) and 20-2-54(a)(4), imposed a fine of \$2,000, and placed Serve You's Alabama pharmacy and controlled-substance permits on probation for one year.

On April 4, 2013, Serve You filed a "Petition for Judicial Review" of the Board's decision in the circuit court pursuant to §§ 34-23-94 and 41-22-20, Ala. Code 1975, and the Board answered the petition. On June 20, 2013, Serve You filed a motion for a judgment on the pleadings or, in the alternative, for a summary judgment. On February 25, 2014, the Board filed its opposition to Serve You's motions and filed a motion for a summary judgment. The circuit court held a hearing on the motions. On March 5, 2014, the circuit court issued a detailed order denying Serve You's motions. By a separate order of March 13, 2014, the circuit court incorporated its March 5, 2014, order and granted the Board's motion for a summary judgment.

violated the provisions of Chapter 23 of Title 34"

Serve You filed its timely notice of appeal to this court on March 13, 2014. This court has jurisdiction over the appeal. § 12-3-10, Ala. Code 1975. On appeal, Serve You argues that the Board does not have statutory authority to discipline a nonresident, mail-order pharmacy; that Serve You is not subject to § 34-23-33(a) because it is not a pharmacist and does not operate in Alabama; and that Serve You is not subject to discipline under § 34-23-33(a) (2) because Serve You violated Colorado law and not Alabama law.

The scope of judicial review of an agency decision issued by the Board is provided in \$ 41-22-20(k), Ala. Code 1975:

"Except where judicial review is by trial de novo, the agency order shall be taken as prima facie just and reasonable and the court shall not substitute its judgment for that of the agency as to the weight of the evidence on questions of fact, except where otherwise authorized by statute. The court may affirm the agency action or remand the case to the agency for taking additional testimony and evidence or for further proceedings. The court may reverse or modify the decision or grant other appropriate relief from the agency action, equitable or legal, including declaratory relief, if the court finds that the agency action is due to be set aside or modified under standards set forth in appeal or review statutes applicable to that agency or if substantial rights of the petitioner have been prejudiced because the agency action is any one or more of the following:

- "(1) In violation of constitutional or statutory provisions;
- "(2) In excess of the statutory authority of the agency;
- "(3) In violation of any pertinent agency rule;
 - "(4) Made upon unlawful procedure;
 - "(5) Affected by other error of law;
- "(6) Clearly erroneous in view of the reliable, probative, and substantial evidence on the whole record; or
- "(7) Unreasonable, arbitrary, or capricious, or characterized by an abuse of discretion or a clearly unwarranted exercise of discretion."

Serve You first argues that the Board does not have statutory authority to discipline a nonresident, mail-order pharmacy. Section 34-23-30(a), Ala. Code 1975, provides the requirements for all entities engaged in "the sale, offering for sale, compounding, or dispensing of drugs in this state, or any person performing pharmacy services in this state," and it further provides that "[n]o mail order pharmacy shall transact business in this state without a permit from the board." Section 34-23-31, Ala Code 1975, provides, in its entirety:

"Every mail-order house which dispenses drugs or medicines through the United States mail or otherwise from any point in the State of Alabama to any point outside of the State of Alabama, and every such business which dispenses drugs or medicines through the United States mail or otherwise from any point outside of the State of Alabama to any point within the State of Alabama shall obtain a permit from the State Board of Pharmacy as a condition precedent to being qualified and authorized to transact such business in the State of Alabama."

Neither statute differentiates the permit required to be obtained by a mail-order pharmacy from the permit required to be obtained by other entities under the provisions of § 34-23-30. Authorized by the enabling provisions of § 34-23-92, Ala. Code 1975, the Board has also adopted Rule 680-X-2-.07, Ala. Admin. Code (State Bd. of Pharmacy), regulating mail-order Because the Alabama Code and the Alabama prescriptions. Administrative Code contain specific provisions regulations applicable to mail-order pharmacies, Serve You "acknowledges that the Board has authority, generally, to discipline mail order pharmacies," but it argues that

"[n]on-resident, mail order pharmacies are subject to these specific laws, but they are not subject to the laws generally applicable to resident pharmacies unless a statute or regulation expressly states as such. Recognizing this distinction, the Board crafted its own administrative regulations that set forth the specific rules with which non-resident, mail order pharmacies must comply."

(Footnote omitted.) Serve You argues that, therefore, the Board lacks authority to discipline nonresident, mail-order pharmacies for violation of § 34-23-33(a), which identifies certain acts and offenses for which "[t]he board may revoke, suspend, place on probation, or require remediation for any licensed pharmacist ... and take the same or similar action against the permit to operate any pharmacy in this state."

Serve You argues that applying the legal maxim of expressio unius est exclusio alterius, "Administrative Rule 680-X-2-.07(5) fully encompasses the universe of 'compliance' required by non-resident, mail order pharmacies." However, our supreme court has stated:

"The maxim at issue generally applies only when a statute or rule utilizes a listing or group of things. Further, it applies only when the 'things' expressed are of the same nature as 'others' that have been excluded. In <u>Barnhart v. Peabody Coal Co.</u>, 537 U.S. 149, 168, 123 S.Ct. 748, 154 L.Ed.2d 653 (2003), the United States Supreme Court explained:

"'As we have held repeatedly, the canon expressio unius est exclusio alterius does not apply to every statutory listing or grouping; it has force only when the items expressed are members of an "associated group or series," justifying the inference that items not mentioned were excluded by deliberate choice, not inadvertence.'

(Emphasis added.) See also <u>Carver v. Lehman</u>, 558 F.3d 869, 876 n. 13 (9th Cir. 2009) (to same effect as <u>Barnhart</u>); 2A Norman J. Singer & J.D. Shambie Singer, <u>Sutherland Statutory Construction</u> § 47:23 (7th ed. 2009) (explaining that the maxim 'has force only when the items expressed are members of an <u>associated group or series</u>, justifying the inference that the items not mentioned were excluded by deliberate choice' (emphasis added))."

Fraternal Order of Police, Lodge No. 64 v. Personnel Bd. of Jefferson Cnty., 103 So. 3d 17, 27-28 (Ala. 2012). The provisions to which Serve You points are not part of "an associated group or series." Rather, the Alabama Code and the regulations adopted by the Board contain specific provisions regarding mail-order pharmacies that express no intent to exempt mail-order pharmacies from compliance with the provisions in the Alabama Code and the regulations adopted by the Board applicable to all pharmacy-permit holders.

Serve You also argues:

"In the present case, Serve You's violation of a Colorado-specific reporting requirement could not possibly violate Administrative Rule 680-X-2-.07(5) because the violation was not of an Alabama law --necessary under subsections (a), (b), & (d) -- and did not involve drug labeling -- necessary under subsection (c). As the regulations are currently written, the Board lacks the authority to charge a nonresident pharmacy with violations under any other statute or regulation."

Alabama Admin. Code, Rule 680-X-2-.07(5), provides:

- "(5) Compliance. Each nonresident pharmacy shall comply with the following:
 - "(a) All statutory and regulatory requirements of the State of Alabama for controlled substances, including those that are different from federal law or regulation.
 - "(b) All the statutory and regulatory requirements of the State of Alabama regarding drug product selection laws.
 - "(c) Labeling of all prescriptions dispensed, to include but not limited to identification of the product and quantity dispensed.
 - "(d) All the statutory and regulatory requirements of the State of Alabama for the dispensing of prescriptions in accordance with the quantities indicated by the prescriber."

(Emphasis added.)

"The fundamental rule of statutory construction is to ascertain and give effect to the intent of the legislature in enacting the statute. Words used in a statute must be given their natural, plain, ordinary, and commonly understood meaning, and where plain language is used a court is bound to interpret that language to mean exactly what it says. If the language of the statute is unambiguous, then there is no room for judicial construction and the clearly expressed intent of the legislature must be given effect. Tuscaloosa County Comm'n v. Deputy Sheriffs' Ass'n of Tuscaloosa County, 589 So. 2d 687 (Ala. 1991)."

IMED Corp. v. Systems Eng'q Assocs. Corp., 602 So. 2d 344, 346 (Ala. 1992). Because Rule 680-X-2-.07(5)(a) specifically requires compliance with "[a]ll statutory and regulatory State of Alabama requirements of the for controlled substances," there is no rational basis for holding that Serve You is therefore exempt from the statutory requirements of the State of Alabama regarding controlled substances codified in \$34-23-33(a). Moreover, there is no provision in \$\$34-23-30or 34-23-31 indicating that nonresident, mail-order pharmacies operate under a different type of pharmacy permit or that such permits are subject to fewer than all the regulations applicable to all pharmacy-permit holders.

Serve You further argues that, pursuant to Ala. Admin. Code, Rule 680-X-2-.07(7),

"if a non-resident pharmacy violates a statute or regulation of Alabama, even if the conduct causes serious bodily or psychological injury, the Board's remedy is to file a complaint with the out-of-state board of pharmacy in the non-resident pharmacy's home state ... The Alabama Board can only take direct action as a last resort."

Rule 680-X-2-.07(7) provides:

"(7) Disciplinary Action. Except in emergencies that constitute an immediate threat to public health and require prompt action by the Board, the Alabama Board of Pharmacy shall file a complaint against any

nonresident pharmacy that violates any statute or regulation of Alabama for conduct which causes serious bodily or psychological injury to a resident of this state. This complaint shall be filed with the Board in which the nonresident pharmacy is located. If the Board in the state in which the nonresident pharmacy is based fails to resolve the violation complained of within a reasonable time, (not less than forty-five (45) days from the date complaint is filed), disciplinary the proceedings may be instituted in Alabama before the Board."

(Emphasis added.) Serve You would apparently read Rule 680-X-2-.07(7) as requiring the Board first to file all complaints against nonresident pharmacies in their home state. However, the disciplinary procedures set out in Rule 680-X-2-.07(7) are specifically limited to violations of statutes or regulations "for conduct which causes serious bodily or psychological injury to a resident of this state." There is no allegation that any bodily or psychological injury resulted from Serve You's violations. Further, Serve You's interpretation of the regulation would invite an illogical result by which the Board would have stripped itself of authority to discipline a nonresident pharmacy-permit holder for even the most minor of violations of pertinent statutes and regulations without first filing a complaint in another

state. Therefore, Serve You's argument on this issue is without merit.

Serve You next argues that it "is not subject to discipline under Alabama Code § 34-23-33(a) because it is not a pharmacist and it does not operate a pharmacy in Alabama." Section 34-23-33(a) provides, in pertinent part:

"The board may revoke, suspend, place on probation, or require remediation for any licensed pharmacist ... and take the same or similar action against the permit to operate any pharmacy in this state, whenever the board finds by a preponderance of the evidence, or pursuant to a consent decree, that the pharmacist has been guilty of [certain enumerated] acts or offenses"

This argument is inconsistent with the plain language of this statute. Section 34-23-33(a) specifically provides that the Board may "take the same or similar action against the permit to operate any pharmacy in this state" as it does against a pharmacist. This intent is further evidenced by subsections within § 34-23-33(a). Section 34-23-33(a)(1) states that it is a violation to obtain "the permit to operate a pharmacy by fraudulent means." Section 34-23-33(a)(7) states that it is a violation to fail to comply with "any [of the] provisions in this chapter," which include §§ 34-23-30 and 34-23-31, the very statutes under which Serve You admits the Board has

authority over its pharmacy permit. Section 34-23-33(a)(8) states that it is a violation to employ, assist, or enable an unlicensed person to practice pharmacy. Moreover, Serve You's argument that \$34-23-33(a)\$ does not apply to it as anonresident pharmacy because it does not "operate [a] pharmacy in this state" is contradicted by the plain language of § 34-23-31, which requires a permit in order for a nonresident, mail-order pharmacy to be "qualified and authorized to transact such business in the State of Alabama." (Emphasis added.) The fact that Serve You is not located in Alabama does not negate the fact that it conducts pharmacy transactions in the State of Alabama, and there is no indication in § 34-23-33(a) that the legislature intended to leave the citizens of Alabama unprotected from violations committed by nonresident pharmacies.

Serve You next argues that it "is not subject to discipline under Alabama Code § 34-23-33(a)(2) because the statute only applies to violations of Alabama law." Section 34-23-33(a)(2) provides that the Board may impose discipline for a "[v]iolation of the laws regulating the sale or dispensing of narcotics, exempt narcotics, or drugs bearing

the label 'caution, federal law prohibits dispensing without prescription, ' or similar wording which causes the drugs to be classified as prescription legend drugs." Serve You argues that because Alabama's laws regulating controlled substances could hypothetically conflict with those of another state, "the only proper interpretation of the statute is one that permits Alabama to punish only violations of its own laws." Aside from citation to the statute itself, Serve You cites no authority in support of this argument and does not argue that its violation of Colorado's law conflicts with any Alabama law. Serve You fails to demonstrate that the phrase "the laws regulating the sale or dispensing of narcotics" plainly refers only to Alabama laws. Further, such an interpretation would render the statutory provision largely ineffectual because it would recognize violations of Alabama narcotics law but not violations of federal law.

It was within the discretion afforded to the Board to determine whether Serve You's stipulated violation of Colorado law was a violation of §§ 34-23-33(a)(2) and 20-2-54(a)(4), Ala. Code 1975. Applying the required deferential standard to the Board's decision, the undisputed evidence is insufficient

to show that the Board exceeded its authority, violated any rules, or rendered an unreasonable, arbitrary, or capricious decision by making its determination to discipline Serve You. Applying \$ 41-22-20(k), we have no basis to reverse that decision. Therefore, we affirm the trial court's summary judgment affirming the Board's decision against Serve You.

AFFIRMED.

Thompson, P.J., and Pittman, Thomas, and Moore, JJ., concur.