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SUPERIOR COURT OF NEW JERSEY
APPELLATE DIVISION
DOCKET NO. A-1116-18T1

IN THE MATTER OF THE
APPLICATION OF

SUMMIT MEDICAL GROUP,
d/b/a SMG PHARMACY

TO OPERATE A PHARMACY
IN THE STATE OF NEW JERSEY.

Argued telephonically December 3, 2019 –
Decided May 12, 2020

Before Judges Hoffman, Currier and Firko.

On appeal from the New Jersey Board of Pharmacy.

Richard J. Cino argued the cause for appellant Summit Medical Group (Jackson Lewis, PC, attorneys; Richard J. Cino and Carla D. Macaluso, of counsel and on the briefs; Joshua D. Allen, on the briefs).

Jodi Claire Krugman, Deputy Attorney General, argued the cause for respondent New Jersey Board of Pharmacy (Gurbir S. Grewal, Attorney General, attorney; Jason Wade Rockwell and Melissa H. Raksa, Assistant Attorneys General, of counsel; Jodi Claire Krugman, on the brief).

Fox Rothchild LLP, attorneys for amicus curiae Regional Cancer Care Associates, LLC (R. James Kravitz, of counsel and on the brief; A. William Henkel, on the brief).

PER CURIAM

Summit Medical Group (SMG) appeals from the final agency decision of the State Board of Pharmacy (the Board) denying its application for a specialty pharmacy license. SMG filed an application seeking to establish a pharmacy practice located in the same building where SMG conducts its oncology practice. The pharmacy was to be wholly owned by the physicians who own SMG's medical practice and would have exclusively filled prescriptions written by SMG physicians for SMG patients. In denying SMG's application, the Board concluded the proposed pharmacy would violate the Codey Law,¹ which prohibits physicians from referring patients to health care services in which they maintain a financial interest. SMG asserts the Board acted arbitrarily, capriciously, and unreasonably in denying its license. We affirm.

I

¹ N.J.S.A. 45:9-22.4 to -22.9.

We discern the following facts from the agency record. On November 24, 2017, SMG filed an application for a permit to operate a specialty pharmacy located on the ground floor of the building where SMG conducts its oncology practice. SMG's application set forth the history of its practice as the "largest and oldest physician-owned multispecialty practice in New Jersey." SMG also advised it recently entered a partnership with MD Anderson Cancer Center to create Summit Medical Group MD Anderson Cancer Center.

SMG explained the pharmacy was to be wholly owned by the same group of physicians who hold an ownership interest in SMG's medical practice. The pharmacy would fill prescriptions exclusively written by SMG physicians for SMG patients.

SMG requested that the proposed pharmacy be designated as a specialty pharmacy under N.J.A.C. 13:39-4.16. SMG explained that the pharmacy was to be "closed door," that is, limited to SMG patients who elect to use its services but not open to the general public. The proposed pharmacy would only dispense medications needed by patients according to oncologic treatment protocols and would not dispense any other medications prescribed for the patients by other physicians for other conditions. SMG also offered to post a notice and obtain

an additional acknowledgment from the patient that he or she understood the prescription may be filled at any pharmacy.

SMG asserted that an on-site pharmacy would help provide oversight of its patients and assist in compliance with drug regimes. It also suggested an in-house pharmacy would decrease the amount of time required to obtain medications and provide for coordination of insurance claims and expedite any necessary interventions for the patients.

SMG's application also indicated that revenue generated by the pharmacy would not be used to pay the referring physicians, thereby intending to ensure the proposed pharmacy would operate in a manner that did not violate the Board's anti-steering provisions, N.J.S.A. 13:39-3.10. Instead, pharmacy profits would be allocated as general operating income and used for the development of additional clinical programs to support oncology patients, such as integrated behavioral health specialists to provide supportive therapy, social workers to assist with linkage to social services, and cancer care navigators to assist patients with coordinating their complex care.

Following an initial review of the application, the Board requested additional information from SMG. Specifically, the Board requested that SMG

address whether the proposed ownership structure and operation of the pharmacy would violate the Codey Law, or the federal Stark Law.²

In response, SMG submitted a February 22, 2018 letter for the Board's consideration, attaching several exhibits, including two advisory opinions of the New Jersey Board of Medical Examiners. The letter acknowledged that a pharmacy is a "health care service" within the meaning of the Codey Law, N.J.S.A. 45:9-22.4, and that the physicians of SMG would have a financial interest in the pharmacy as that term is set forth in the statute. Nevertheless, the letter emphasized the proposed pharmacy would fall within an exception to the Codey Law, which allows for "a medical treatment or a procedure that is provided at the practitioner's medical office and for which a bill is issued directly in the name of the practitioner or the practitioner's medical office." N.J.S.A. 45:9-22.5c(1).

In supporting its contention, SMG explained the pharmacy would bill under the same tax identification number (TIN) as its medical practice. It further argued that the proposed pharmacy would, for all purposes, be fully owned within SMG's medical practice. In doing so, SMG indicated that the staff of the

² 42 U.S.C. § 1395nn.

pharmacy, including pharmacists, would be directly employed by SMG; the assets of the pharmacy would be owned by SMG; and bills for pharmaceuticals would be in SMG's name and billed under SMG's TIN.

The matter proceeded to a Board review and discussion at the August 22 and September 29, 2018 Board meetings. Several SMG representatives, including Becky Levy, SMG's general counsel, and Laura Balsamini, SMG's Director of Pharmacy Services, appeared before the Board to discuss the new cancer center and answer questions concerning the pharmacy permit application. At the September meeting, Levy read a prepared statement in which she noted that the Board had previously granted a pharmacy permit to a physician-owned medical practice. She also emphasized SMG's position that the proposed pharmacy would fall within what is referred to as the "extension of practice" or "in-house" exception to the Codey Law. Levy maintained that an in-house pharmacy would enhance patient care and optimize patient outcomes.

Following deliberations, after considering all the materials presented, including oral argument, the Board voted to deny SMG's application for a specialty pharmacy license at the conclusion of its September 27, 2018 meeting. In its October 24, 2018 order and decision, the Board found that granting SMG's

permit under the circumstances would endorse a practice structure that is in violation of New Jersey law.

In its analysis, the Board noted that SMG conceded its physicians would have a significant beneficial interest in the proposed pharmacy, and that only SMG physicians would be writing prescriptions. The Board therefore concluded the proposed pharmacy and its operation fell squarely within the strictures of the Codey Law. Moreover, the Board noted there would be no question that a "referral" would occur, for the purposes of the Codey Law, when the pharmacy would fill prescriptions written by SMG physicians, who also own the pharmacy. As the Board explained, "To suggest otherwise would make meaningless the statutory inclusion of a pharmacy as a 'health care service' pursuant to N.J.S.A. 45:9-22.4."

The Board also addressed SMG's reliance on two prior advisory opinions issued by the Board of Medical Examiners. It explained that the opinions, which supported the "extension of practice" exemption, involved referrals made by physicians to a sleep study service and to an ambulatory surgical center, entities where the referring physicians held a significant financial stake. However, the Board noted those referrals were recognized as "medical treatments" or "medical procedures" provided by practitioners at the practitioner's medical office, and

explicitly exempt under the statute. N.J.S.A. 45:9-22.5c(1). In contrast, the Board noted that pharmacies provide neither "medical treatments" nor "medical procedures."

In addressing SMG's proposed financial structure, the Board observed that reimbursements for physician-dispensed medications differed from those dispensed by a pharmacy, so "there would appear to be a direct financial incentive for SMG physicians to prescribe (where the physicians secure additional profits from being owners of the pharmacy at which the prescription is filled) rather than to dispense directly to patients." The Board nevertheless declined to reach a conclusion if the pharmacy's proposed structure would violate the Codey Law's additional requirements because it found the "in-house" exemption inapplicable.

In denying SMG's application, the Board considered SMG's position that allowing a pharmacy to operate on-site may provide significant convenience and benefits to its patients. However, the Board found it "unclear just how significant those benefits may be, given that the patients will still have to fill all prescriptions that are not oncology related at other pharmacies."

On November 8, 2018, SMG filed its notice of appeal. On February 13, 2019, SMG filed a motion to supplement the record on appeal to include

application of another registered pharmacy and publications illustrating the importance of an oncology pharmacy. On April 5, 2019, after considering opposition filed by the Board, we denied SMG's motion. On July 17, 2019, Regional Cancer Care Associates, LLC filed a motion to intervene as amicus curiae, which we granted.

II

On appeal, SMG argues the Board acted arbitrarily, capriciously, and unreasonably in denying its application for a specialty pharmacy license. SMG contends the Board erred in its statutory interpretation of the plain language of the Codey Law because pharmacies can provide "medical treatment." Specifically, SMG contends that its pharmacy would qualify as a so-called "in-house" exception because the restriction on the referral of patients does not apply to "medical treatment or a procedure that is provided at the practitioner's medical office for which a bill is issued directly in the name of the practitioner or the practitioner's medical office[.]" N.J.S.A. 45:9-22.5(c)(1). Amicus curiae, Regional Cancer Care Centers, urges us to reverse, asserting the Board "misinterpreted and overstepped its authority by invoking the Cody Law" as the basis for its decision.

The Board counters that under the plain language of the Codey Law, pharmacies do not provide "medical treatment." The Board further maintains our Legislature "intended that any self-referrals to a pharmacy would be a violation of the Codey Law."

Our review of a final decision of an administrative agency is limited. Russo v. Bd. of Trs., Police & Firemen's Ret. Sys., 206 N.J. 14, 27 (2011) (citing In re Herrmann, 192 N.J. 19, 27 (2007)). The agency's decision should be upheld "unless there is a clear showing that it is arbitrary, capricious, or unreasonable, or that it lacks fair support in the record." Ibid. (quoting Herrmann, 192 N.J. at 27-28). "The burden of demonstrating that the agency's action was arbitrary, capricious or unreasonable rests upon the [party] challenging the administrative action." In re Arenas, 385 N.J. Super. 440, 443-44 (App. Div. 2006) (citations omitted).

"We recognize that agencies have 'expertise and superior knowledge . . . in their specialized fields.'" Hemsey v. Bd. of Trs., Police & Firemen's Ret. Sys., 198 N.J. 215, 223 (2009) (alteration in original) (quoting In re License Issued to Zahl, 186 N.J. 341, 353 (2006)). We therefore accord deference to the "agency's interpretation of a statute" it is charged with enforcing. Thompson v. Bd. of Trs., Teachers' Pension & Annuity Fund, 449 N.J. Super. 478, 483 (App.

Div. 2017) (quoting Richardson v. Bd. of Trs., Police & Firemen's Ret. Sys., 192 N.J. 189, 196 (2007)).

"A reviewing court 'may not substitute its own judgment for the agency's, even though the court might have reached a different result.'" In re Stallworth, 208 N.J. 182, 194 (2011) (quoting In re Carter, 191 N.J. 474, 483 (2007)). Under the arbitrary, capricious, and unreasonable standard, our scope of review is guided by three major inquiries: (1) whether the agency's decision conforms with relevant law; (2) whether the decision is supported by substantial credible evidence in the record; and (3) whether, in applying the law to the facts, the administrative agency clearly erred in reaching its conclusion. Ibid.

Guided by these principles, we consider whether the Board's decision was arbitrary, capricious, unreasonable, or unsupported by substantial credible evidence in the record.

III

The Board is charged with enforcing the New Jersey Pharmacy Practice Act.³ N.J.S.A. 45:14-42. "The board may deny, suspend, revoke, restrict or refuse to renew a permit for a pharmacy practice site that does not comply with

³ N.J.S.A. 45:14-40 to -82.

the provisions of this act or any rule or regulation promulgated pursuant to this act." N.J.S.A. 45:14-69(g).

A "pharmacist" is "an individual currently licensed by this State to engage in the practice of pharmacy." N.J.S.A. 45:14-41. A "pharmacy practice site" is "any place in this State where drugs are dispensed or pharmaceutical care is provided by a licensed pharmacist, but shall not include a medical office under the control of a licensed physician." Ibid. "Dispensing" is "the procedure entailing the interpretation of a practitioner's prescription order for a drug, biological or device, and pursuant to that order the proper selection, measuring, compounding, labeling and packaging in a proper container for subsequent administration to, or use by, a patient." Ibid.

The Codey Law provides, in part, that "[a] practitioner shall not refer a patient or direct an employee of the practitioner to refer a patient to a health care service in which the practitioner, or the practitioner's immediate family, or the practitioner in combination with the practitioner's immediate family has a significant beneficial interest[.]" N.J.S.A. 45:9-22.5; see also N.J.A.C. 13:35-6.17(b). The statute's definition of "[h]ealth care service" expressly includes a pharmacy. N.J.S.A. 45:9-22.4. A "significant beneficial interest" is

any financial interest; but does not include ownership of a building wherein the space is leased to a person at

the prevailing rate under a straight lease agreement, payments made by a hospital to a physician pursuant to a hospital and physician incentive plan, or any interest held in publicly traded securities.

[N.J.S.A. 45:9-22.4.]

The so-called "in-house" exception to the Codey Law provides that the restrictions on referrals do not apply to a "medical treatment or a procedure that is provided at the practitioner's medical office and for which a bill is issued directly in the name of the practitioner or the practitioner's medical office." N.J.S.A. 45:9-22.5(c)(1).

We first note that SMG's specialty pharmacy structure is clearly prohibited under the plain language of the Codey Law. As proposed, SMG would exclusively refer its patients to a "health-care service" which its physicians wholly own. Therefore, SMG was required to demonstrate its proposed pharmacy met one of the statute's express exceptions.

With regard to the "in-house" exception, the Board concluded "[t]he dispensing of a medication by a pharmacist, pursuant to a validly written prescription, is neither a medical treatment nor a medical procedure." Given our deferential standard of review, we do not find the Board acted arbitrarily, capriciously, or unreasonably in reaching its conclusion.

While neither the statute nor its related regulations define "medical treatment," as used in N.J.S.A. 45:9-22.5(c)(1), the term has been defined in other contexts. See, e.g., Kemp v. State, Cty. of Burlington, 147 N.J. 294, 300 (1997); Kutten v. Sun Life Assur. Co. of Canada, 759 F.3d 942 (8th Cir. 2014). See also Webster's Ninth New Collegiate Dictionary 1257; Webster's II New Riverside University Dictionary 1230. Our Supreme Court has defined "treatment" to include "all the steps taken to effect a cure of an injury or disease; including examination and diagnosis as well as application of remedies." Kemp, 147 N.J. at 300-01.

In contrast, pharmacies are engaged in the practice of "compounding, dispensing and labeling . . . drugs." N.J.S.A. 45:14-41. SMG's proposed pharmacy would dispense drugs to patients of the oncology practice. Dispensing drugs involves interpreting a prescription and ensuring the drug is properly measured, packaged, and labeled. Ibid. Pharmacists do not examine patients, nor do they evaluate the symptoms of a patient's disease. Ibid. In other words, pharmacists and pharmacies are not involved in the "medical treatment" of a patient; rather, they are the means by which patients receive access to their treatment needs.

We find the agency record contains substantial credible evidence supporting the Board's conclusion that the proposed pharmacy would violate the restrictions of the Codey Law. The Board's decision to deny SMG's application was neither arbitrary, capricious, nor unreasonable.

Affirmed.

I hereby certify that the foregoing
is a true copy of the original on
file in my office.



CLERK OF THE APPELLATE DIVISION