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SUPERIOR COURT OF NEW JERSEY APPELLATE DIVISION DOCKET NO. A-2080-19

IN THE MATTER OF THE APPLICATION OF ONCOLOGY AND HEMATOLOGY SPECIALISTS, P.A., d/b/a OHS PHARMACY TO OPERATE A PHARMACY IN THE STATE OF NEW JERSEY.

Argued October 20, 2021 – Decided December 22, 2021

Before Judges Hoffman, Geiger, and Susswein.

On appeal from the New Jersey Board of Pharmacy, Division of Community Affairs, Department of Law and Public Safety.

Richard B. Robins argued the cause for appellant Oncology and Hematology Specialists, P.A. (Mandelbaum Salsburg, PC, attorneys; Richard B. Robins, of counsel and on the briefs; Mohamed H. Nabulsi, on the briefs).

Jodi C. Krugman, Deputy Attorney General, argued the cause for respondent New Jersey Board of Pharmacy (Andrew J. Bruck, Acting Attorney General, attorney; Sookie Bae-Park, Assistant Attorney General, of counsel; Jodi C. Krugman, on the brief).

PER CURIAM

Petitioner Oncology and Hematology Specialists, P.A. appeals from the final agency decision of the New Jersey State Board of Pharmacy (the Board), entered on December 11, 2019, denying petitioner's application to register, open, and operate a pharmacy within its medical practice.

Petitioner, a medical practice wholly owned by four medical doctors, sought to open a "closed door clinic pharmacy" within its practice location, exclusively for the patients of its physicians. The Board denied petitioner's pharmacy application, concluding that such a pharmacy would violate the Codey Law, N.J.S.A. 45:9-22.5(a), which prohibits physicians from referring patients to health care services owned by them. The Board further concluded the proposed pharmacy did not fit within an exception to the Codey Law that states: "The restrictions on referral of patients . . . shall not apply to . . . medical treatment or a procedure that is provided at the provide medical office[,]" N.J.S.A. 45:9-22.5(b), because pharmacies do not provide medical treatment.

On appeal, petitioner argues the Board erred by failing to recognize that pharmacies provide medical treatment and by acting beyond the scope of its authority in considering the Codey Law, which falls under the authority of the Board of Medical Examiners. Petitioner further contends the Board's denial of the application amounted to impermissible anti-competitive conduct, and the doctrine of equitable estoppel required the Board to approve petitioner's application. We reject these arguments and affirm.

I.

In May 2018, petitioner, an oncology and hematology medical practice in Mountain Lakes wholly owned by four physicians, submitted a pharmacy permit application to the Board, seeking to open a new "closed door clinic pharmacy" that would only be accessed by – and fill prescriptions for – petitioner's patients. The proposed pharmacy would be located at petitioner's practice in Mountain Lakes. An affidavit attached to its application specified that the pharmacy would be operated "in compliance with the 'Same Practice' Exception to New Jersey Codey Law" Thereafter, petitioner's counsel submitted a letter and certification, dated February 11, 2019, setting forth legal arguments and attaching documents in support of the subject application.

On April 24, 2019, the Board considered petitioner's application and voted to deny the application, concluding "the practice structure would create a violation of the Codey Law." On December 11, 2019, the Board issued an order memorializing the denial of petitioner's application, which included a sevenpage written explanation of its decision.

The Board explained the Codey Law bars medical practitioners from referring patients to health care services where the practitioners hold "a significant beneficial interest." N.J.S.A. 45:9-22.5(a). Because "[t]he definition of '[h]ealth care service' set forth in N.J.S.A. 45:9-22.4 expressly includes a pharmacy," the Board stated, "any referral by a physician to a pharmacy, in which the physician has a beneficial interest, would violate the Codey Law, unless an exception to the law applies." <u>Ibid.</u> (second alteration in original). Such an unlawful arrangement would exist if the Board approved petitioner's application because petitioner's physicians would have a beneficial interest in the pharmacy, which would only fill prescriptions for patients referred exclusively by the petitioner's physicians.

Moreover, the Board determined the "so-called 'in-office' exception" did not apply because "the proposed pharmacy would have to provide a 'medical treatment or a procedure'" in petitioner's office, but "a pharmacy provides neither 'medical treatments' nor 'medical procedures' to patients." The Board also noted that its decision was consistent with the several advisory opinions rendered by the Board of Medical Examiners, providing "that although physicians may own pharmacies, the Codey Law would prohibit a physician from referring the physician's own patients to the pharmacy in which he or she held an ownership interest."

Before the Board issued its order and accompanying explanation, the Deputy Director of Consumer Affairs, assisted by the Supervising Management Improvement Specialist and the Executive Officer and Chief Investigator of the Legalized Games of Chance Commission, reviewed the Board's then-proposed order and the relevant documentation "to determine whether the denial of a pharmacy permit to a physician-owned medical practice constitutes anticompetitive conduct by the Board" In a memorandum dated December 10, 2019, the Deputy Director stated, "[w]e unanimously determined the Board's proposed action would not displace competition" because the denial

> in no way suggests that licensed physicians cannot become owners of a pharmacy. The Board's action does not limit ownership of a pharmacy to only licensed pharmacists. Non-licensees, including physicians, may own a pharmacy. The Board's determination to deny the application for a permit was based on the fact that the proposed pharmacy would only have filled prescriptions written by the same physicians who were owners of the pharmacy.

Petitioner now appeals from the December 11, 2019 order that denied its application to register, open, and operate a pharmacy within its medical practice.

Petitioner presents the following points of argument:

POINT I

THE BOARD ERRONEOUSLY ACTED BEYOND ITS LAWFUL SCOPE OF AUTHORITY BY SEEKING TO INTERPRET AND APPLY THE CODEY LAW, WHICH DOES NOT GOVERN PHARMACIES, AND WHICH THE BOARD LACKS POWER TO ENFORCE.

POINT II

THE BOARD ERRONEOUSLY FOUND THAT THE IN-OFFICE EXCEPTION TO THE CODEY LAW IS INAPPLICABLE TO THE PRACTICE OF PHARMACY.

POINT III

THE BOARD'S DENIAL OF APPELLANT'S PERMIT APPLICATION WAS PRECLUDED BASED ON THE DOCTRINE OF EQUITABLE ESTOPPEL AND OTHER EQUITABLE GROUNDS.

POINT IV

THE BOARD ERRED BY ENGAGING IN ANTI-COMPETITIVE CONDUCT.

II.

Appellate review of a final agency decision is limited, Russo v. Bd. of

Trs., 206 N.J. 14, 27 (2011), in recognition "that agencies have 'expertise and

superior knowledge . . . in their specialized fields.'" <u>Hemsey v. Bd. of Trs.</u>, 198 N.J. 215, 223 (2009) (alteration in original) (quoting <u>In re License Issued to</u> <u>Zahl</u>, 186 N.J. 341, 353 (2006)). Thus, an 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." <u>Russo</u>, 206 N.J. at 27 (quoting <u>In re</u> <u>Herrmann</u>, 192 N.J. 19, 27-28 (2007)).

Likewise, on appeal, appellate courts accord deference to the "agency's interpretation of a statute" it is charged with enforcing. Thompson v. Bd. of Trs., 449 N.J. Super. 478, 483 (App. Div. 2017) (quoting Richardson v. Bd. of Trs., 192 N.J. 189, 196 (2007)). "Deference to agency interpretation of a statute is appropriate as long as that interpretation is reasonable, and does not conflict with the express or implied intent of the legislature" Gilliland v. Bd. of Rev., 298 N.J. Super. 349, 354 (App. Div. 1997) (citations omitted). However, an agency's "interpretation of the law outside of its charge is entitled to 'no special deference." Comm. Workers of Am., Local 1034 v. N.J. State Policemen's Benevolent Ass'n, Local 203, 413 N.J. Super. 286, 291 (App. Div. 2010) (quoting In re Camden Cnty. Prosecutor, 394 N.J. Super. 15, 23 (App. Div. 2007)). See also Teeters v. Div. of Youth and Fam. Servs., 387 N.J. Super. 423, 428 (App. Div. 2006) (citations omitted) ("Although we are enjoined to

accord respect to an agency's interpretation of the statute it is assigned to administer, we are not bound by an agency's interpretation of law, any more than we are bound by the legal rulings of lower courts").

Under this limited standard of review, "[a] reviewing court 'may not substitute its own judgment for the agency's, even though the court may have reached a different result.'" In re Stallworth, 208 N.J. 182, 192 (2011) (quoting In re Carter, 191 N.J. 474, 483 (2007)). Rather, an appellate court focuses on 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. Id. at 192.

Petitioner's principal claim of agency error asserts that the Board erroneously interpreted the Codey Law. We disagree. The Codey Law provides, "[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(a). "'Practitioner' means a physician, chiropractor or

podiatrist licensed pursuant to Title 45 of the Revised Statutes." N.J.S.A. 45:9-

22.4; see also N.J.S.A. 45:9-18.

"Health care service" means a business entity which provides on an inpatient or outpatient basis: testing for or diagnosis or treatment of human disease or dysfunction; or dispensing of drugs or medical devices for the treatment of human disease or dysfunction. Health care service includes, but is not limited to, a bioanalytical laboratory, <u>pharmacy</u>, home health care agency, rehabilitation facility, nursing home, hospital, or a facility which provides radiological or other diagnostic imagery services, physical therapy, ambulatory surgery, or ophthalmic services.

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"Significant beneficial interest" means 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 (emphasis added).]

The Codey Law includes the following relevant exception to the above

rule:

"The restrictions on referral of patients established in this section shall not apply

to . . . 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). Neither the statutes governing physicians, nor the Board of Medical Examiners' regulations, define "medical treatment" or "medical procedure."

Petitioner argues the Board's determination that "the 'practice of pharmacy' does not involve 'medical treatment or procedure' . . . was totally erroneous." Petitioner contends a pharmacy's activities fit within "the generally accepted meaning of the language 'medical treatment or procedure,"' which, citing medical and legal dictionaries, OSHA regulations, and New Jersey case law, petitioner asserts "is defined as 'a <u>broad term covering all the steps taken</u> to effect a cure of an injury or disease; including examination and diagnosis as well as application of remedies[.]'" Petitioner argues a pharmacy's activities of

dispensing medication, ... "interpreting and evaluating prescriptions"; "administering and distributing drugs"; "advising and consulting on the therapeutic values, contents, hazards and uses of drugs"; "collecting, analyzing and monitoring patient data"; "providing pharmaceutical care and education"; "collaborative drug therapy management including modifying, continuing or discontinuing drug or device therapy"; "ordering or performing of laboratory tests under collaborative drug therapy management"; and "ordering clinical tests"

[N.J.S.A. 45:14-41.]

constitute medical treatment as steps taken to combat illness and the application of remedies. Petitioner also emphasizes the significant training and qualifications of pharmacists to show they administer medical treatment.

The Board's interpretation that pharmacies do not provide medical treatment is also supported by the professional and statutory distinction between medical doctors and pharmacists. Physicians and pharmacists undergo different education and training, and pharmacists are not medical doctors. Moreover, the statutes governing medical practice and those governing pharmaceutical practice occupy two different chapters of New Jersey's Revised Statutes – Chapter 9 governs medical practice, and Chapter 14 governs pharmacy practice.

Physicians are persons "licensed or permitted to practice medicine or surgery in this State[,]" N.J.S.A. 45:9-27.5(a), whereas pharmacists are persons "licensed by this State to engage in the practice of pharmacy[,]" N.J.S.A. 45:14-41. These distinctions suggest that only physicians (or those under their supervision) provide medical care while pharmacists provide pharmaceutical care.

Whereas Chapter 9 states that, "'the practice of medicine or surgery' . . . include[s] the practice of any branch of medicine and/or surgery, and any method of treatment of human ailment, disease, pain, injury, deformity, mental

A-2080-19

or physical condition," N.J.S.A. 45:9-5.1, Chapter 14 describes the "practice

of pharmacy" in terms of the provision of services, not treatment.

"Practice of pharmacy" means a health care service by a pharmacist that includes: compounding, dispensing and biologicals, labeling of drugs. radio pharmaceuticals or devices; overseeing automated medication systems; interpreting and evaluating prescriptions; administering and distributing drugs, biologicals and devices; maintaining prescription drug records; advising and consulting on the therapeutic values, content, hazards and uses of drugs, biologicals and devices; managing and monitoring drug therapy; collecting, analyzing and monitoring patient data; performing drug utilization reviews: storing prescription drugs devices; supervising and technicians, interns and externs; and such other acts, services, operations or transactions necessary, or incidental to, providing pharmaceutical care and education. In accordance with written guidelines or protocols established with a licensed physician, the "practice of pharmacy" also includes collaborative drug therapy management including modifying, continuing or discontinuing drug or device therapy; ordering or performing of laboratory tests under collaborative drug therapy management; and ordering clinical tests, excluding laboratory tests, unless those tests are part of collaborative drug therapy management.

[N.J.S.A. 45:14-41.]

Chapter 14 further provides:

"Pharmaceutical care" means the provision by a pharmacist of drug therapy review and other related patient care services intended to achieve positive outcomes <u>related to</u> the treatment, cure or prevention of

a disease; control, elimination or reduction of a patient's symptoms; or arresting or slowing of a disease process as defined by the rules and regulations of the board.

[N.J.S.A. 45:14-41 (emphasis added).]

Notably, under Chapter 9, the practice of medicine involves "any method of treatment of human ailment[,]" N.J.S.A. 45:9-5.1, whereas under Chapter 14, pharmaceutical care involves "patient care services intended to achieve positive outcomes <u>related to</u> the treatment[,]" N.J.S.A. 45:14-41 (emphasis added). Pharmaceutical care being related to treatment, but not treatment itself, reflects that pharmacists and pharmacies do not render medical treatment to patients; rather, they are the means by which patients receive access to their treatment needs.

Even where the practice of pharmacy involves working "in conjunction with . . . physicians" to provide "collaborative drug therapy management[,]" N.J.A.C. 13:39-13.2(a), a pharmacist may perform "[o]nly those activities that have been approved by the collaborating physician," N.J.A.C. 13:39-13.1, which

> shall only include the collecting, analyzing and monitoring of patient data; ordering or performing of laboratory tests based on the standing orders of a physician as set forth in the written protocol; ordering of clinical tests based on the standing orders of a physician as set forth in the written protocol, . . . modifying, continuing or discontinuing drug or device

therapy; and therapeutic drug monitoring with appropriate modification to dose, dosage regimen, dosage forms or route of administration.

[N.J.S.A. 45:14-41.]

These activities do not obviously constitute medical treatment and are akin to the others "related to" treatment. Furthermore, to engage in collaborative practice with a physician, a pharmacist must "be pre-approved by the Board." N.J.A.C. 13:39-13.3. Petitioner does not indicate that it planned to engage in collaborative practice or would seek permission from the Board to do so.

We acknowledge that in <u>Kemp</u>, our Supreme Court interpreted the word "treatment"¹ and held, "[t]he plain meaning of "treatment" encompasses the administration of a vaccine." 147 N.J. at 300-01 (citing various legal and medical dictionaries for the proposition that "treatment" encompasses prevention of diseases). Later in its opinion, the Court explicitly stated, "[t]he introduction of the vaccine into [one]'s body, . . . to cause the body to react in a certain way, falls within the definition of <u>medical</u> treatment." <u>Id.</u> at 303-04

¹ <u>Kemp</u> involved the issue of whether a State entity enjoyed immunity from liability under the Tort Claims Act, N.J.S.A. 59:6-4. 147 N.J. at 297, 299. The statute provided public entities with "absolute immunity for the failure to perform an adequate examination 'for the purpose of determining whether [a] person has a disease or physical or mental condition that would constitute a hazard to the health or safety of himself or others'" unless "the examination is 'for the purpose of treatment."' <u>Id.</u> at 300.

(emphasis added). Chapter 14 provides, the "[p]ractice of pharmacy . . . includes . . . administering a distributing drugs" N.J.S.A. 45:14-41. It further provides:

"Administer" means the direct application of a drug to the body of a patient or research subject by subcutaneous, intramuscular or intradermal injection, inhalation or ingestion by a pharmacist engaged in collaborative practice or in accordance with regulations jointly promulgated by the board and the State Board of Medical Examiners.

[<u>Ibid.</u>]

While pharmacists provide medical treatment when they administer vaccines, most referrals from physicians to a pharmacy are not for vaccination, but rather for the dispensing of drugs and the other services encompassing the "practice of pharmacy" under N.J.S.A. 45:14-41, which do not constitute medical treatment or procedures. Petitioner does not claim its pharmacy would only be administering vaccines. Since the primary functions of a pharmacy do not include medical treatment, the Board did not err by finding the "in-office" exception to the Codey Law inapplicable.

Petitioner also highlights the Board of Medical Examiners' regulations that "permit[] physicians to refer their own patients for bioanalytical tests to laboratories in which the physicians have a financial interest, and which are located at the physicians' offices" and "permit[] physicians to dispense prescription drugs to their own patients in their offices." N.J.A.C. 13:35-6.16(i)(1); N.J.A.C. 13:35-7.5(a). Petitioner argues that if physicians are allowed to provide these services without violating the Codey Law, then they also can lawfully operate a pharmacy within their practice. We disagree.

First, bioanalytical testing may constitute medical treatment and fit within the above-discussed exception to the Codey Law. More importantly, N.J.S.A. 45:14-41 provides: "Pharmacy practice site' means any place in this State where drugs are dispensed or pharmaceutical care is provided by a licensed pharmacist, <u>but shall not include a medical office under the control of a licensed physician</u>." N.J.S.A. 45:14-41 (emphasis added). Accordingly, when physicians dispense medication directly to patients per N.J.A.C. 13:35-7.5, they do not act as pharmacists or a separate pharmaceutical entity. There is thus no "refer[ral]" ... to a health care service" that would violate the Codey Law; instead, the dispensing falls within the scope of the doctor's medical practice.

Petitioner maintains the Board exceeded the scope of its authority by interpreting, applying, and enforcing the Codey Law. Petitioner also contends the Pharmacy Practice Act (PPA), N.J.S.A. 45:14-40 to -82, only empowers the Board to regulate the practice of pharmacy, and thus the Board was not

authorized to enforce the Codey Law, which regulates the profession of physicians; instead, the New Jersey State Board of Medical Examiners has sole and exclusive authority to regulate the conduct of physicians in New Jersey. Citing Newcomb Sales v. Bd. of Pharmacy, 218 N.J. Super. 69, 71 (App. Div. 1987), petitioner further argues the Board deviated from the PPA's directives, which "mandates issuance of a pharmacy permit," upon an applicant's satisfaction of the applicable statutory requirements to receive a permit, none of which prohibit physician ownership of pharmacies. Petitioner contends that "the Board may deny an application only for one or more of the eleven grounds specifically enumerated in the PPA." Thus, because it "satisfied each of the enumerated statutory and regulatory permit requirements," petitioner asserts "the Board lacked lawful power to deny the permit application based on a reason that was not enumerated in the controlling statute." We disagree.

N.J.S.A. 45:14-42 provides:

The [B]oard shall enforce the provisions of this act. The [B]oard shall have all of the duties, powers and authority specifically granted by or necessary for the enforcement of this act, as well as such other duties, powers and authority as it may be granted from time to time by applicable law.

The statute delineating the Board's responsibilities and powers authorizes the Board to "deny . . . the permit of any pharmacy practice site" if the Board

finds "that any conduct of the . . . applicant is violative of <u>any</u> federal, State or local laws or regulations relating to the practice of pharmacy" N.J.S.A. 45:14-75(b)(1) (emphasis added). The Codey Law reasonably relates to the practice of pharmacy, as it explicitly defines pharmacies as a health care service, N.J.S.A. 45:9-22.4, to which physicians are barred from referring their patients if they hold a beneficial interest in said pharmacy, N.J.S.A. 45:9-22.5(a). Thus, we conclude the Board acted within the scope of its authority under N.J.S.A. 45:14-75(b) in denying petitioner's application because petitioner, a group of physicians, would violate a state law relating to the practice of pharmacy if permitted to operate the pharmacy.

Petitioner next argues "the doctrine of equitable estoppel precludes the Board from lawfully denying [petitioner]'s application" because petitioner relied on the Board's previous grant and multiple renewals of a pharmacy permit to a similarly-structured in-house physician-owned pharmacy. The Board granted this application to Regional Cancer Care Associates LLC (RCCA) in 2014 and renewed it as recently as May 2019. Petitioner argues it "reasonably expected" its pharmacy permit would be granted, relying on the Board allowing RCCA to operate a physician-owned pharmacy. Based on this assumption, petitioner asserts it has incurred costs in excess of \$512,000 relating to its pharmacy application.

Equitable estoppel "is designed to prevent injustice by not permitting a party to repudiate a course of action on which another party has relied to his detriment." Knorr v. Smeal, 178 N.J. 169, 178 (2003). This equitable doctrine is "founded in the fundamental duty of fair dealing imposed by law" and "is invoked in 'the interests of justice, morality and common fairness.'" Ibid. (first quoting Casamasino v. City of Jersey City, 158 N.J. 333, 354 (1999); and then quoting Palatine I v. Plan. Bd., 133 N.J. 546, 560 (1993)). "[T]o establish equitable estoppel, plaintiffs must show that defendant engaged in conduct, either intentionally or under circumstances that induced reliance, and that plaintiffs acted or changed their position to their detriment." Ibid. (citing Miller v. Miller, 97 N.J. 154, 163 (1984)). However, "[s]ubstantial detrimental reliance is not enough, 'only justified and reasonable reliance warrant the application of equitable estoppel[.]" Gen. Accident Ins. Co. v. N.Y. Marine and Gen. Ins. Co., 320 N.J. Super. 546, 557 (App. Div. 1999) (quoting Palatine I v. Plan. Bd., 133 N.J. 546, 563 (1993)).

"Equitable estoppel is rarely invoked against a governmental entity. However, equitable estoppel will be applied in the appropriate circumstances

19

unless the application would prejudice essential governmental functions." <u>Middletown Twp. Policemen's Benevolent Ass'n Local No. 124 v. Twp. of</u> <u>Middletown</u>, 162 N.J. 361, 367 (2000) (internal citations and quotation marks omitted) (quoting <u>Wood v. Borough of Wildwood Crest</u>, 319 N.J. Super. 650, 656 (App. Div. 1999)). We recently stated that "equitable considerations are relevant to assessing governmental conduct, and may be invoked to prevent manifest injustice." <u>Tasa v. Bd. of Trs.</u>, 458 N.J. Super. 47, 60 (App. Div. 2019) (quoting <u>In re Johnson</u>, 215 N.J. 366, 378-79 (2013)).

We reject petitioner's equitable estoppel argument. The Board has conceded that it made a mistake when it granted the permit to RCCA and has filed an action for the rescission of RCCA's permit. We agree with the Board that "if approval of RCCA's application was in error, it was not required to repeat that error as to [petitioner]."

Additionally, within four months of submitting its application to the Board, petitioner received notice the Board would likely reject its pharmacy application to avoid violating the Codey Law. In May 2018, petitioner submitted the application under review, and in September 2018, the Board denied the application for a physician-owned-pharmacy permit submitted by Summit Medical Group (SMG).²

Finally, petitioner has not shown the Board reversing its position on physician-owned pharmacies to be unjust. <u>See Johnson</u>, 215 N.J. at 379-80 ("Equitable estoppel is designed to prevent disavowal of prior conduct if a change of course would be unjust."). "[A]dministrative agencies generally have the inherent power to reopen or to modify and rehear prior decisions[,]" including "decision[s] involving the same parties and the identical subject matter" <u>In re Trantino</u>, 89 N.J. 347, 364 (1982).

Additionally, an agency may revise its interpretation of a statute after testing the "wisdom of its policy" and to meet "the demands of changed circumstances" <u>Glukowsky v. Equity One, Inc.</u>, 180 N.J. 49, 65-66 (2004) (citations omitted). Thus, the Board changing course to accord its policy with the Codey Law and the Board of Medical Examiners' position on physician-owned pharmacies did not amount to a "manifest injustice."

We further agree with the Board arguments regarding petitioner's desire to open a pharmacy rather operate a dispensary:

 $^{^2}$ The Board voted to deny SMG's application for a specialty pharmacy license at the conclusion of its September 27, 2018 meeting and explained the denial in an October 24, 2018 order and decision.

Most telling, however, is [petitioner's] admission that there is a direct financial incentive for its desire to open a pharmacy rather operate a dispensary. [Petitioner] admits that operating a dispensary "would present a serious payment issue" because pharmacy benefit managers "deter payment by seeking to restrict patient access to physician dispensaries." [Petitioner] thus admits to a direct financial incentive for [its] physicians to prescribe medications to be filled at the proposed pharmacy, where they will obtain additional profit from owning that pharmacy. Nothing would prevent an [petitioner's] physician[s] from choosing to prescribe a drug that will provide a higher profit margin for the pharmacy than a lower cost drug, assuming both would provide a similar benefit for patient treatment, or worse, choosing to prescribe a drug that would be less efficacious but produce a higher profit for the pharmacy and its physician-owners. This potential financial gain should not[,] either actually or potentially[,] influence a treatment decision. This concern is the precise ill the Codey Law was intended to prevent.

Lastly, petitioner argues the Board engaged in anti-competitive conduct by changing its position on physician owned pharmacies and denying petitioner's pharmacy application. Petitioner claims the Board, which is "controlled by active market participants, i.e., practicing pharmacists[,]" denied petitioner (and SMG's) application "to protect its members' financial interests[] by prohibiting non-pharmacists from competing against them in the free market." Petitioner relies on <u>N.C. State Bd. of Dental Exam'rs v. Fed. Trade</u> <u>Comm'n</u>, 574 U.S. 494 (2015). In that case, the United States Supreme Court allowed the Federal Trade Commission (FTC) to bring a complaint against a dentist-run state dentistry board which, "after dentists complained to the Board that non-dentists were charging lower prices for certain services than dentists, "issued cease-and-desist letters to non-dentist teeth whitening service providers and product manufacturers, often warning that the unlicensed practice of dentistry is a crime." <u>Id.</u> at 494.

The Court considered whether the Board could claim state-action immunity, not the merits of the FTC's claims alleging "anticompetitive and unfair method of competition." <u>Id.</u> at 501. Ultimately, the Court held that "a state board on which a controlling number of decisionmakers are active market participants in the occupation the board regulates" cannot "invoke state-action antitrust immunity" unless the state actively supervises the board for anti-competitive conduct. <u>Id.</u> at 511-12. Because the State did not exercise active supervision over the dentistry board, the Court found the board was not immune from suit and affirmed the decision disciplining the board for violating antitrust law. <u>See Id.</u> at 515.

Petitioner's reliance on this case is unpersuasive. Petitioner did not assert an anti-trust claim against the Board. Moreover, petitioner presents no evidence the Board acted improperly, but instead asks this court to "infer" the Board acted with an anti-competitive motive based on the Board's change-of-position on physician owned pharmacies after a large medical practice, SMG, applied to open a pharmacy.

Furthermore, the State proactively screened the Board's denial of petitioner's pharmacy application for anti-competitive conduct and concluded the denial did not displace competition. Nothing suggests the State's review of the Board's decision was deficient. <u>See N.C. State Bd. of Dental Exam'rs</u>, 574 U.S. at 515 (discussing state supervision over regulatory boards, which requires the supervisor review "the substance of the anticompetitive decision, not merely the procedures followed to produce it"; "the supervisor must have the power to veto or modify particular decisions to ensure they accord with state policy"; and "the state supervisor may not itself be an active market participant").

In sum, petitioner fails to convincingly show the Board acted with an improper motive or arbitrarily, capriciously, or unreasonably.

Affirmed.

I hereby certify that the foregoing is a true copy of the original on file in my office. CLERK OF THE APPELLATE DIVISION