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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 PLAINTIFFS-PETITIONERS,	SUPREME COURT OF NEW JERSEY DOCKET NUMBER 084560 APPELLATE DIVISION DOCKET NO. A-1116-18T1 ON APPEAL FROM THE ORDER OF THE STATE OF NEW JERSEY DEPARTMENT OF LAW & PUBLIC SAFETY, DIVISION OF CONSUMER AFFAIRS, STATE BOARD OF PHARMACY Sat below: Hon. Richard S. Hoffman Hon. Heidi Willis Currier Hon. Lisa A. Firko

BRIEF ON BEHALF OF *AMICI CURIAE* MEDICAL SOCIETY OF NEW JERSEY AND AMERICAN MEDICAL ASSOCIATION

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COMBINED PROCEDURAL HISTORY AND BRIEF STATEMENT OF FACTS

On May 12, 2020, the Appellate Division affirmed the denial of a license application by the Summit Medical Group ("SMG") to operate a pharmacy. The per curiam opinion has not been approved for publication. In accordance with *R.*2:12-3, SMG submitted a timely petition for certification and review by this Court. [SCa1.][1] This Brief is filed on behalf of the Medical Society of New Jersey ("MSNJ") and the American Medical Association ("AMA") as *amici curiae* in support of reversal of that adverse decision.

SMG applied to the New Jersey State Board of Pharmacy ("Pharmacy Board" or "Board") on November 24, 2017 for a permit to operate a pharmacy. [Pa48.] In its Order of Denial of Registration dated October 24, 2018, the Pharmacy Board set forth the following background facts.

SMG is the largest and oldest physician-owned multi-specialty practice in New Jersey. It treats cancer patients. The oncology treatment protocols are often complex and require close clinical supervision to ensure optimal treatment outcomes, and SMG concluded that an on-site pharmacy would help provide oversight of

[1] The legend of "SCa" will be used to refer to the Appendix of the Petition for Certification. The legend "Pa" will be used to refer to the Appendix filed by Petitioner in the Appellate Division. The legend "Ma" will be used to refer to the Appendix of this Brief on behalf of the *Amici*.

its patients and assist in compliance with the drug regimes. [Pa8-9.]

The proposed specialty pharmacy would be owned by SMG. The pharmacists and staff will be employees of SMG. Billing would be done under the tax identification number ("TIN") of SMG. [Pa12.]

The SMG pharmacy would only provide services to the SMG oncology patients. Patients, however, would be free to select any pharmacy of their choosing to have their prescriptions filled. The pharmacy proposed to obtain from each patient a signed acknowledgment that they understood that they could direct that prescriptions be sent to the pharmacy of the patient's choice. SMG also offered to post a notice as well as obtaining an additional acknowledgment from the patient upon picking up and signing for a prescription that the patient was aware that the prescription may be filled at any pharmacy of the patient's choice. [Pa10-11.]

After several meetings, the Board voted to deny the application. The Board ruled that the proposed practice structure of the pharmacy would violate the so-called Codey Law, *N.J.S.A.* 45:9-22 et seq., generally restricting physician self-referrals. The Board started its analysis by noting that "pharmacy" was within the definition of "health care services" covered by the Codey Law. [Pa13-14.] But it concluded that a statutory exception to the restrictions for referral of 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" was inapplicable. It reasoned that "medical treatment or a procedure" as used in the Codey Law statute did not include the pharmacy services for which a permit was being requested. It reasoned:

> Pharmacies provide neither "medical treatments" nor "medical procedures" to patients. The dispensing of a medication by a pharmacist, pursuant to a validly written prescription, is neither a medical treatment nor a medical procedure. [Pa14.]

The Board declined to reach any conclusion as to the other requirements to the statutory exception, including whether or not the proposed SMG pharmacy provided "at the medical practitioner's office" and "a bill issued in the name of the practitioner[.]" [Pa15.]

Before the Appellate Division, SMG advanced similar arguments. However, the court ignored the collaborative relationship of physician and pharmacist as constituting "medical treatment or procedure" and relied on a deferential standard of review applicable to an agency's interpretation of statute that it is charged with enforcing. [SCa13.] Like the Pharmacy Board, the court did not rule on the applicability or not of the "medical office" exception to the Codey Law restrictions. Finding that under the deferential standard of review, the Pharmacy Board's interpretation was not arbitrary, capricious, or unreasonable, it affirmed.

LEGAL ARGUMENT

THE APPELLATE DIVISION COMPOUNDED THE ERROR OF THE PHARMCY BOARD WITH ITS INCORRECT INTERPRETATION OF THE CODEY LAW BY FAILING TO CONSIDER THE REGULATIONS, RULINGS, AND GUIDANCE FROM THE BOARD OF MEDICAL EXAMINERS WHICH IS THE AGENCY ACTUALLY CHARGED WITH RESPONSIBILITY FOR ENFORCING THE CODEY STATUTE.

Concerns regarding and criticisms of physician ownership in healthcare facilities to which they make referrals received increasing scrutiny in the last 30 years. *See generally Thermographic Diagnostics, Inc. v. Allstate Insurance Co.*, 125 N.J. 491, 517-18 (1991). The potential for conflict of interest presents an abiding concern for the medical profession. Published articles in the professional literature urging caution and sensitivity to the ethical issues regularly appear. The AMA has repeatedly provided guidance to physicians as to such issues building on its long-standing Principles of Medical Ethics. [Ma1; Ma2-6.]

A. THE STATUTORY FRAMEWORK AND LEGISLATIVE HISTORY

The New Jersey legislative history of the laws concerning self-referrals by healthcare practitioners begins on January 27, 1989 with the passage of Senate Bills, which required physicians, chiropractors, and podiatrists to disclose their significant beneficial interests in health care services to patients. On February 6, 1989, Governor Kean conditionally vetoed the legislation and returned the bill for reconsideration

with certain clarifying amendments. Following the inclusion of those amendments, what has come to be known as the Codey Law was codified at *N.J.S.A.* 45:9-22.1 to 22.9.

The 1989 legislation supplemented Chapter 9 of Title 45 of the New Jersey statutes. The provisions of *N.J.S.A.* 45:9-1 et seq. are generally referred to as the Medical Practice Act ("MPA"). The MPA vests the Board of Medical Examiners ("BME") with the duty to regulate the practice of medicine and the power to promulgate rules and regulations to protect patients and licensees. *In re Zahl*, 186 N.J. 341, 352 (2006); *In re Kim*, 403 N.J. Super. 378, 385(App. Div. 2008). In *N.J.S.A.* 45:9-22.9 the Codey Act explicitly empowered the "State Board of Medical Examiners" to adopt rules and regulations necessary to carry out the purposes of the Act. As will be discussed further, the BME did adopt implementing regulations for the Codey Law found at *N.J.A.C.* 13:35-6.17.

The restrictions and requirements of the Codey Law apply only to a "practitioner" which is defined in *N.J.S.A.* 45:9-22.4 as "a physician, chiropractor or podiatrist." The implementing regulations adopted by the BME has a more expanded definition of "practitioner" to account for other healthcare professionals "within the jurisdiction of the Board of Medical Examiners." *N.J.A.C.* 13:35-6.17(a)(4). This does not include pharmacists.

The Codey Law was designed to prevent physicians from referring patients to a health care facility in which the physician or the physician's immediate family had a significant financial interest. The Codey Law encompassed a broad range of "health care service[s]" which was defined as meaning:

> [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, pharmacy, 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. [L. 1989, c. 19.]

At the Federal level, similar action was taken in 1990 with amendments to the Social Security Act enacted as the Physician's Self-Referral Law as part of the Omnibus Budget Reconciliation Act of 1990 and codified at 42 *U.S.C.* § 1395nn. This became known as the Stark Law. The Stark Law only applies to Medicare and Medicaid patients. The Stark Law was not a basis for the decision made by the Pharmacy Board or the Appellate Division in this matter.

As originally enacted, the Codey Law regulated physician self-referrals through the mechanism of written disclosure and notices. However, the statute was amended in 1991 and self-referrals were restricted even with disclosure of the ownership interest. While physicians or their family members who held a significant beneficial interest in "health care services" as of

July 1, 1999 were "grandfathered in" and could continue making referrals provided the disclosure was made, a more restrictive standard essentially prohibiting such referrals applied to any physician acquiring a financial interest after that date.

The restrictions on referrals had a statutory exception that the prohibitions did not apply to "**a health care service that is provided at the practitioner's medical office and for which the patient is billed directly by the practitioner**." L. 1991 c. 187 (emphasis added). This provision is commonly referred to as "the In-Office exception" and sometimes as "the Medical Office extension." The statute did not define a "practitioner's medical office" in any way for permitted referrals. The language that was originally enacted in this 1991 amendment is different than the text of the statute as it presently exists. Amendments to the statute adopted in 2009 replaced the phrase "a health care service" with "medical treatment or a procedure" provided at the practitioner's office.

The 2009 amendments were largely the result of disputes that had arisen in the context of reimbursement for services provided at free-standing ambulatory surgery centers by surgeons who shared in the ownership of these facilities but belonged to separate practices. *See generally* EG Litten & JZ Jackson, "New Jersey's New Codey Law – New Limits on Physician Ownership and Referrals," 56 *GARDEN STATE FOCUS* 21 (March/April 2009). [Ma35=37.]

The 2009 statutory amendments added an exception for medical treatment or procedures performed at a "surgical practice" registered with the Department of Health or at an ambulatory surgery center licensed by the Department of Health subject to a variety of conditions. L. 2009, c. 24. The Assembly Committee Statement on the bill noted that the amendment "**updates language** concerning medical treatment provided at a practitioner's medical office to specify that the medical office **includes, but is not limited to**, a surgical practice." *Statement to Assembly No. 1933* (June 19, 2008) (emphasis added). This language change does not suggest a narrowing of any exception. *Cf. NL Indus., Inc. v. State,* 228 N.J. 280, 299 (2017).

Amendments in 2013 and 2016 recognized additional exceptions concerning referrals for lithotripsy services and medically-necessary intraoperative monitoring services during a procedure performed in a hospital. L. 2013, c. 178; L 2016, c. 20. An amendment in 2017 included referrals to a health care service that participated in an alternative payment model registered with the Department of Health. L. 2017, c. 111. Additional amendments in 2012 and 2017 are not germane to the issues in this matter. L. 2012, c.17; L. 2017, c. 283.

B. REGULATIONS AND REGULATORY GUIDANCE

The BME had first proposed Codey Law regulations in 1991. 23 *N.J.R.* 161, 164-65 (Jan. 22, 1991). Consistent with the statute as

it then existed, these only set forth the notice and disclosure requirement. This was before the broader restrictions went into effect. After the 1991 statutory amendment, revised regulations were issued. 24 *N.J.R.* 626 (February 18, 1992). The new provisions codified at *N.J.A.C.* 13:35-6.17(b)(4) stated:

> The restrictions on referral of patients established in this subsection shall not apply to:
> I. **A health care service that is provided at the practitioner's medical office** for which the patient is billed directly by and in the practitioner's name; or
> Il. Radiation therapy pursuant to an oncological protocol, or lithotripsy or renal dialysis treatment, provided that there is disclosure of the financial interest. [24 *N.J.R.* at 640 (emphasis added).]

Like the statute, "the practitioner's medical office" is not defined. The regulation provided no guidance concerning the scope of the In-Office exception.

However, the BME has issued advisory opinions that have recognized the In-Office exception for referrals. By statute, the BME is authorized to make declaratory rulings and issue advisory opinions. *N.J.S.A.* 52:14B-8. Although these Board opinions are by their terms confined to the facts presented in them, they have been relied upon by healthcare law practitioners in counseling and planning with clients and by the Office of Administrative Law in considering disciplinary charges against physicians.

The BME has provided express written approval of differing scenarios involving the In-Office exception. In the absence of a statutory definition of "office," these advisory rulings reflect

a recognition that a physician's practice is not inherently limited to a particular room or suite. It may also include a nearby suite across the hall or on a different floor two stories below in the same building or another physician-owned and controlled location two blocks or two miles away.

Starting in 1994, the BME Executive Director or other representatives of the BME provided letters approving the ownership interest and referral by surgeons to ambulatory surgical facilities under the circumstances described. [Ma7-12; Ma16-17.] These are perhaps more appropriately referred to as the Medical Office extension rather than In-House exception. Most germane to this matter, however, is the BME's determination in 2000 that referrals by a pulmonologist, an ear-nose-and-throat specialist, or an anesthesiologist to a separately located sleep-study service facility in which the referring physicians held an interest was not an impermissible self-referral because the scenario is akin to the surgeon's referral of his or her own patients to an ambulatory surgical center in which the surgeon has an interest:

> The Committee concurred with your analysis that, in the specific matter you describe, the referral by a pulmonologist, ear, nose and throat specialist or anesthesiologist to a sleep study service in which the referring physician holds an interest is **not an impermissible self-referral**. This scenario is akin to the surgeon's referral and performance of surgery of his patient to an ambulatory surgical center in which he holds an interest. **The Board's rationale is based on its view that the service, in this instance, the diagnostic sleep study, is integral to the licensee's provision of care and overall practice.**

> Additionally, but for space and conduciveness concerns, the sleep studies would be conducted within the confines of the licensee's office and comes within the exemption of *N.J.S.A.* 49:9-22.5(c) and *N.J.A.C.* 13:35-6.17(b)(4). [Letter from Board of Medical Examiners dated August 15, 2000(emphasis added) Ma13.]

The application of the exception in the context of ambulatory surgery was impacted by court decisions that were not officially reported. *See generally Garcia v. Health Net of New Jersey, Inc.*, 2009 WL 3849685 (App. Div. Nov. 17, 2009), *certif. denied,* 201 N.J. 442 (2010); *Endo Surgi Center v. Liberty Mutual,* 2010 WL 4067156 (App. Div. Aug.17, 2010).[2] This led to regulatory and legislative action with the new exception for ambulatory surgery facilities adopted in 2009.

The appropriateness of the proposed SMG structure is more directly – although inferentially – supported by a May 3, 2005 BME advisory opinion regarding a pharmacy. While accepting the propriety of physician ownership of a pharmacy that had an approved permit from the Pharmacy Board, the BME rejected any waiver of the self-referral prohibition. The BME noted that "the Pharmacy permit granted by the Board of Pharmacy was not a specialized permit **specific [] to a doctor's office, and situated within the confines of that office**." [Ma18 (emphasis added).] Without question the BME is referring to the "Medical Office exception" and implicitly

[2] Pursuant to *R.*1:36-3 copies of these unpublished opinions are included in the Appendix to this Brief.

concluding that if the pharmacy permit were specific to a particular medical practice and the pharmacy were situated within the confines of that office it would not constitute a prohibited self-referral. This is the situation presented here concerning SMG.

The sleep study ruling invokes not only the "Medical Office extension" aspect of the exception but also implicates the "medical treatment or procedure" terms that now exist. The sleep study under consideration manifestly did not require the personal presence of the referring physician or any "touching" of the patient so to treat. The services were rendered by others but under the supervision of the physician. The key concept is the "integral" nature of the service to the licensee's provision of care to a patient. The SMG proposal presents an integrated approach with physician and pharmacist working together for the best interests of the patient. In contrast to the situation presented in the adverse 2005 BME ruling regarding a physician-owned pharmacy that had received a permit from the Board of Pharmacy, the proposed SMG pharmacy is in the SMG physician-owned office location, all the physicians and the pharmacists are employed by the same entity, and the patient is billed under a single TIN. The requirements for the In-Office exception are present here if one concludes that under physician supervision the oncological pharmacist is providing "medical treatment or procedure" to the patient.

The BME issued amendments to its Codey regulations after the statutory language of the Codey Law was modified in 2009 to refer to "medical treatment or procedure" in connection with a referral to a surgical practice or ambulatory surgery center being regulated by the Department of Health following the November 2007 trial court's decision in *Garcia v. Health Net of New Jersey*, *supra*, which was affirmed in 2009 WL 3849685 (App. Div. Nov. 17, 2009). But it made no textual change to the regulations. 42 *N.J.R.* 1310 (July 6, 2010). Indeed, to the present the BME regulations have continued to state that "[t]he restrictions on referral of patients established in this subsection shall not apply to: … **[a] health care service** that is provided at the practitioner's medical office for which the patient is billed directly by and in the practitioner's name." It has not used the terminology of "a medical treatment or procedure" for the exception.

Thus, it would seem from the perspective of the agency charged with the responsibility for enforcing the Codey Law, the terms "health care service" and "a medical treatment or procedure" are interchangeable. And "health care service" by definition includes "pharmacy." Under the Board of Medical Examiners' regulations, SMG's pharmacy complies with the Codey Law.

Neither the Pharmacy Board nor the Appellate Division made any reference to the BME regulations in the analysis of this matter. Apart from the specific Codey Law issue, those regulations

show a clear recognition that pharmacists working in direct collaboration with physicians can have a role in the "medical treatment and procedures" Given to a patient. Plainly stated, "pharmacy" is much more than counting out pills to be put into a plastic bottle.

To begin with, under the BME regulation found at *N.J.A.C.* 13:35-6.26, a pharmacist is authorized to administer the "treatment" of immunization subject to the supervision of a physician.

More pertinent to the setting of this matter, pursuant to *N.J.A.C.* 13:35-6.27(b), a licensed physician "may enter into a collaborative practice agreement with one or more licensed pharmacists."[3] Collaborative drug therapy management is defined in this regulation as "the cooperative **management of a patient's drug**, biological, and device-related health care **needs**, pursuant to a written protocol directed on a voluntary basis by a patient's physician with the patient's informed consent, **by the patient's physician and a pharmacist** who has signed a collaborative practice agreement with the physician." Id. Under the BME regulation, the interpretation of clinical or laboratory test procedures in the setting of a written collaborative practice protocol "shall be

[3] The Pharmacy Board has a corresponding set of regulations found at *N.J.A.C.* 13:39-1 et seq. permitting pharmacists to enter into such agreements.

performed by a pharmacist only in direct consultation with a physician." *N.J.A.C.* 13:35-6.27(l).

Curiously, the Appellate Division referred to the statutory definition of "practice of pharmacy" found in *N.J.S.A.* 45:14-41. But it only quoted the reference to "compounding, dispensing and labeling of drugs." It left out a substantial portion of the statute including the role of a pharmacist in "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." Also omitted was that the "practice of pharmacy" 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…"[4]

The Pharmacy Board's own regulations recognize the important role a pharmacist can play in the "medical treatment or procedure" being given to a patient. According to *N.J.A.C.* 13:39-1.2, the term "pharmaceutical services" includes all patient-oriented

[4] In the context of the Coronavirus public health emergency, however, the Division of Consumer Affairs and the Attorney General have sufficient trust in the skill of pharmacists to do a "procedure" that these licensees have been authorized to assess individuals and administer tests for the presence of the Covid-19 virus. https://www.nj.gov/oag/newsreleases20/pr20200519b.html

services provided by a pharmacist specific to their scope of practice such as but not limited to: the monitoring of drug therapy; the reporting and recording of adverse drug reactions and the provision of appropriate drug information; and teaching and counseling on the proper and safe use of drugs and medications. Somewhat relatedly, the regulations set forth in some detail the obligation of a pharmacist to provide patient counseling concerning the "medical treatment or procedure" that is being provided by the physician such as adverse or severe side effects or interactions and contraindications that may be encountered, including how to avoid such side effects, interactions and contraindications, and the action required if they occur and techniques for self-monitoring of drug therapy. *N.J.A.C.* 13:39-7.21. Furthermore, the "medical treatment or procedure" being given is subject to a pharmacist's utilization review under *N.J.A.C.* 13:39-7.20 which can include consultation with the medical practitioner.

C. MEDICAL LITERATURE AND CLINICAL PRACTICE

SMG is well-positioned to utilize the collaborative practice agreement concept in connection with its oncology practice as permitted by the BME regulations. Members of the MSNJ have experienced the benefits and enhancement of patient safety resulting from in-house presence at hospitals of an oncological pharmacist especially regarding the high toxicity of cancer

medications and the complex protocols under which they are administered. The multi-disciplinary approach of the collaborative practice has substantial support as a best practice in the oncological literature. Representative articles from the scientific and professional literature are included in the Appendix to this Brief and additional literature can be provided. [Ma38-119.]

The use of collaborative drug therapy management agreements is supported by the American College of Physicians as well as in reports from the Centers for Disease Control and Prevention. *Compare* RB Doherty & RA Crowley, "Principles Supporting Dynamic Clinical Care Teams: An American College of Physicians Position Paper," 159 *Ann. Intern. Med.* 620, 627 (2013) *with* Centers for Disease Control & Prevention, "Collaborative Practice Agreements and Pharmacists' Patient Care Services" (2013). [Ma104; Ma112.] Some of the benefits of this approach are summarized in LM Holle & LB Michaud, "Oncology Pharmacists in Health Care Delivery: Vital Members of the Cancer Care Team," 10 *J Oncol Prac* e142 (2014):

> Oncology pharmacists are viewed as cancer medication experts based on their training, expertise, and knowledge, and they function best in a collaborative environment with other health care professionals whose expertise complements their own. The knowledge and skills of an oncology pharmacist support a wide variety of functions in all aspects of patient care-from the bedside to implementing policies and from primary research to influencing other clinicians in the selection and management of anticancer therapies. [Ma100, 102.]

The literature shows that there are positive consequences in terms of quality of care and patient safety from the presence of an in-house pharmacist working directly in collaboration with a physician. Notably absent from the Board's decision and the Appellate Division opinion is any discussion or consideration of the negative impact on the treatment of oncology patients from denial of the integrated pharmacy.

Consistent with the regulatory approach to the sleep study that had been approved as not being a banned self-referral and the implicit approval of a pharmacy in a physician's office in a different BME advisory opinion, the involvement of a pharmacist and on-site pharmacy is "integral" to the care of cancer patients undergoing chemotherapy.

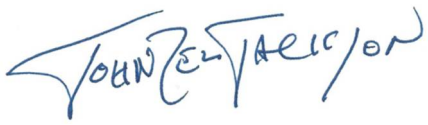
CONCLUSION

The physician and pharmacist share a unique relationship. After years of study and training, it is the doctor who identifies and treats illness or injury through surgery, therapy, or the prescription of medications. In tandem, the pharmacist has studied at length, learning about the chemistry, pharmacology, and pharmaceutics of each drug that to be compounded and dispensed. The doctor orders medications for the patient and the pharmacist, in addition to interpreting and preparing the order, can fulfill a role in the administration of the treatment with education, assessment of interactions, and monitoring for and handling

toxicity. The integrated and combined multidisciplinary effort works to serve the best interests of the patient. None of the problems presented by a self-referral conflict of interest situation can be found here.

The petition for certification should be granted and after review, the decision below should be corrected and reversed.

Respectfully submitted,



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