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SUPERIOR COURT OF NEW JERSEY
APPELLATE DIVISION
DOCKET NO. A-3852-10T3

NEW JERSEY ASSOCIATION OF
NURSE ANESTHETISTS, INC.,

Appellant,

v.

NEW JERSEY DEPARTMENT OF HEALTH
AND SENIOR SERVICES,[1]

Respondent.

Argued October 1, 2012 - Decided December 12, 2012

Before Judges Graves, Espinosa, and
Guadagno.

On appeal from the Department of Health and
Senior Services.

William P. Isele argued the cause for
appellant (Archer & Greiner, P.C.,
attorneys; Mr. Isele, of counsel and on the
brief).

Kimberly E. Jenkins argued the cause for
respondent (Jeffrey S. Chiesa, Attorney
General, attorney; Melissa H. Raksa,
Assistant Deputy Attorney General, of
counsel; Ms. Jenkins, on the brief).

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[1] The Department of Health and Senior Services (DHSS) was reorganized and renamed the Department of Health pursuant to L. 2012, c. 17, effective June 29, 2012. Since this matter was filed prior to June 29, 2012, we will use DHSS throughout.

Joseph M. Gorrell argued the cause for amicus curiae New Jersey State Society of Anesthesiologists (Brach Eichler, L.L.C., attorneys; Mr. Gorrell, of counsel and on the brief; John D. Fanburg, of counsel; Richard B. Robins, on the brief).

Mark J. Silberman (Duane Morris L.L.P.) of the Illinois bar, admitted pro hac vice, argued the cause for amicus curiae American Association of Nurse Anesthetists (Duane Morris L.L.P. and Mr. Silberman, attorneys; Erin M. Duffy, of counsel and on the brief).

Sokol, Behot & Fiorenzo, attorneys for amicus curiae Senator Joseph F. Vitale (Leon J. Sokol, of counsel and on the brief).

PER CURIAM

This appeal challenges the validity of regulations promulgated by the New Jersey Department of Health and Senior Services (DHSS or Department) requiring the physical presence of a collaborating anesthesiologist (CA) during induction, emergence and critical change in status when an Advanced Practice Nurse/Anesthesia (APN/A) administers general or major regional anesthesia, conscious sedation or minor regional blocks in a hospital. Appellant New Jersey Association of Nurse Anesthetists (NJANA) challenges the physical presence requirement, claiming DHSS exceeded its statutory authority; violated the Administrative Procedure Act (APA), N.J.S.A. 52:14B-1 to -15; and violated express and implied legislative intent. Because we conclude that DHSS was authorized to

promulgate the challenged rule and appellant has failed to overcome the presumption of validity of the regulation, we affirm.

I.

The Advance Practice Nurse (APN) was first recognized in this State in 1992 when the Legislature enacted the Advanced Practice Nurse Certification Act (APN Act), subsequently codified at N.J.S.A. 45:11-45 to -52. The APN Act permitted a wider range of functions for APNs than those previously performed by registered nurses. Some of these functions were done independently and others pursuant to joint protocols established with a collaborating physician. N.J.S.A. 45:11-49.

Amendments in 2004 further expanded the scope of practice for APNs, authorizing them to "manage preventive care services, and diagnose and manage deviations from wellness and long-term illnesses, consistent with the needs of the patient and within the scope of practice of the advanced practice nurse." Ibid.

A certified registered nurse anesthetist (CRNA) is a registered nurse who is certified to administer anesthesia under certain circumstances. In 2008, the New Jersey Board of Nursing (BON) promulgated rules codified at N.J.A.C. 13:37-7.1 to 7.2, that required CRNAs who wished to continue to administer anesthesia to meet requirements to be certified as an APN.

Those CRNAs who became certified as APNs became known as APN/As and the CRNA designation was no longer recognized.

At the time, respondent's licensure regulations for hospitals and ambulatory care facilities permitted CRNAs to administer and monitor general or major regional anesthesia under the supervision of an anesthesiologist and to administer minor regional blocks or anesthetic agents for conscious sedation under the supervision of an immediately available physician pursuant to medical staff bylaws. Adopted Amendments: N.J.A.C. 8:43G-6, 34 & 35, 35 N.J.R. 865, 870-71 (Feb. 3, 2003).

On November 13, 2009, appellant filed a petition for rulemaking with DHSS, seeking to amend the hospital and ambulatory care facility licensure regulations to allow APN/As "to provide anesthesia services without anesthesiologist supervision." DHSS scheduled the matter for a hearing before the Health Care Administration Board (HCAB).[2] Respondent proposed to delete the "requirement that a certified registered nurse anesthetist administer and monitor general or major regional anesthesia only under the supervision of a privileged

[2] The HCAB is comprised of thirteen members: the Commissioner of the Department of Health and Senior Services together with the Commissioner of Insurance, "or their designated representatives," and eleven "representative[s] of medical and health care facilities and services, labor, industry and the public at large" who are "appointed by the Governor with the advice and consent of the Senate." N.J.S.A. 26:2H-4.

physician" and replace it with a provision that would include APN/As "within the list of professionals authorized to administer general, major regional anesthesia, conscious sedation or minor regional blocks, provided that this is done in accordance with a joint protocol established in accordance with N.J.A.C. 13:37-6.3." Memorandum of Agenda from John A. Calabria to Health Care Admin. Bd. Members, p.4 (undated) (on file w/ DHSS).

Following a hearing, HCAB published a notice of proposed regulation to amend N.J.A.C. 8:43G-6.3 as follows:

> The Department proposes to add new N.J.A.C. 8:43G-6.3(e)3 to include APNs/anesthesia within the list of professionals authorized to administer general or major regional anesthesia, provided that this is done in accordance with a joint protocol established in accordance with N.J.A.C. 13:37-6.3, Standards for joint protocols between advanced practice nurses and collaborating anesthesiologists. This protocol would need to include sections governing the availability of an anesthesiologist to consult with the APN/anesthesia on site, on-call or by electronic means.
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> [Proposed Readoption with Amendments: N.J.A.C. 8:43G, 42 N.J.R. 1774, 1776 (Aug. 16, 2010).]

Over four hundred comments were received regarding the required level of supervision for APN/As, prompting respondent to extend the public comment period to November 15, 2010, and schedule another hearing before HCAB.

Respondent determined that the original proposal had been subject to misinterpretation, as the joint protocols did not specifically provide for the availability and presence of an anesthesiologist and many who submitted comments viewed the proposed amendment as relaxing or removing the supervision requirement.

On January 13, 2011, the HCAB held a second public hearing. Respondent's representative explained that DHSS proposed replacing the term "address" with "require" to clarify the intent of DHSS:

> The intent of the Department in this case is that we didn't want to have protocols that were void of discussing the availability and the presence. And it is also the intent - - when we discussed presence, it is - - it's some sort of physical presence, whereas the anesthesiologist can be made available physically in cases of emergency situations, especially, rather than being available or present by electronic means or by phone. The Commissioner for public safety purposes, is concerned that an anesthesiologist not be off site and just make the recommendations, especially in extreme cases.

After some discussion, the HCAB chairman summarized his understanding:

> [I]t is not the Commissioner's intent to require the presence of an anesthesiologist in all procedures, just that on procedures where the protocols indicate the presence is required, that that presence be somewhere in the facility, and that this does not -- is not the intention of the Department to

require this in emergent situations, and that it's the protocols that will control that.

HCAB approved the proposal. The final rule provides that:

> (e) General or major regional anesthesia shall be administered and monitored only by the following:
>
> 1. An anesthesiologist;
>
> . . .
>
> 3. An APN/anesthesia, in accordance with a joint protocol established in accordance with N.J.A.C. 13:37-6.3, which joint protocol shall require sections governing:
>
> i. The availability of an anesthesiologist to consult with the APN/anesthesia on site, on-call or by electronic means; and
>
> ii. The presence of an anesthesiologist during induction, emergence and critical change in status . . . .
>
> [N.J.A.C. 8:43G-6.3(e).]

In response to public comments, respondent explained:

> This change on adoption would ensure that the rule is understood to mean that the required joint protocol governing anesthesia services would require the presence of an anesthesiologist during induction of and emergence from anesthesia and during critical changes in status. The level of presence (such as in the room where the procedure is being performed, in the operating suite or merely in the building) would be determined in the joint protocol depending on the type of procedure and related risk factors, including any exigent circumstances. Contrary to the issue of

> consultation, presence is understood to mean physical presence rather than by electronic or other means.
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> [Readoption with Amendments: N.J.A.C. 8:43G, 43 N.J.R. 401, 415 (Feb. 22, 2011).]

Appellant filed a notice of appeal on April 8, 2011. On August 12, 2011, we denied a motion to intervene by the New Jersey State Society of Anesthesiologists (NJSSA), but granted it permission to appear as an amicus curiae. On March 12, 2012, we granted applications by the American Association of Nurse Anesthetists (AANA) and State Senator Joseph Vitale to appear as amici, as well. We also denied appellant's motion for a stay of the regulations, but ordered that disposition of the matter be accelerated.

Appellant argues that respondent lacked the statutory authority to expand the minimum requirements for a joint protocol or to restrict the scope of practice for APN/As. Even if respondent did have such authority, appellant claims the regulations conflict with the APN Act and implementing regulations, and are therefore invalid.

Senator Vitale filed a brief, concurring with appellant's arguments and emphasizing, as the first prime sponsor of the relevant amendments to the APN Act, that the regulations were contrary to the statute's legislative intent to broaden the

scope of practice for APNs as a means to reduce healthcare costs.

In its brief, amicus AANA argues that when respondent replaced the term "address" with "require," it substantially changed the scope of the Rule in violation of the APA. AANA also argues that respondent's arguments for requiring supervision by a CA are meritless.

NJSSA maintains the regulations do not conflict with the APN Law or exceed respondent's jurisdiction.

II.

We begin our analysis by noting the relevant principles of law that guide our review. When considering the actions of an administrative agency, our role is "severely limited." Mazza v. Bd. of Trs., 143 N.J. 22, 25 (1995) (citing Gloucester Cnty. Welfare Bd. v. N.J. Civil Serv. Comm'n, 93 N.J. 384, 390 (1983)). We grant administrative agency action a "strong presumption of reasonableness," Newark v. Natural Res. Council, 82 N.J. 530, 539 (1980), and we "must defer to an agency's expertise and superior knowledge of a particular field." Greenwood v. State Police Training Ctr., 127 N.J. 500, 513 (1992).

That deference is not without limit, and where an agency exceeds its delegated power in promulgating a regulation, its

action is arbitrary and capricious and therefore invalid. In re N.J. Individual Health Coverage Program's Readoption of N.J.A.C. 11:20-1, 179 N.J. 570, 580 (2004).

Appellant bears the burden of proving that the challenged regulation is arbitrary, capricious or unreasonable. In re Amendment of N.J.A.C. 8:31B-3.31, 119 N.J. 531, 543-44 (1990). Our Supreme Court has defined arbitrary and capricious actions in this context as those that are "unreasonable or irrational." Bergen Pines Cnty. Hospital v. N.J. Dep't of Human Services, 96 N.J. 456, 477 (1984).

Appellant concedes that DHSS enjoys authority to promulgate rules governing health care facility utilization and costs, but claims it had no authority to set standards for joint protocols between CAs and APNs, which is the exclusive province of the Division of Consumer Affairs (DCA). This position is inconsistent with appellant's several petitions to DHSS for rulemaking to amend these regulations. In appellant's initial petition, it acknowledged seeking clarification from DHSS regarding the supervision requirements "on numerous occasions." Appellant also conceded in that petition that "DHSS establishes licensure regulations governing who may provide anesthesia as well as other standards for the administration of general anesthesia, conscious sedation and local anesthesia."

In 1971, the Legislature enacted the Health Care Facilities Planning Act (HCFPA), N.J.S.A. 26:2H-1 to -26. The HCFPA gives DHSS "central responsibility for the development and administration of the State's policy with respect to health planning, hospital and related health care services and health care facilities cost containment programs[.]" N.J.S.A. 26:2H-1.

The Legislature has authorized DHSS to promulgate rules and regulations to effectuate the provisions of the HCFPA. N.J.S.A. 26:2H-5(b). However, those regulations must be promulgated in accordance with the APA and require approval of the HCAB. N.J.S.A. 26:2H-5(b); N.J.S.A. 26:2H-2(d). In furtherance of this policy, DHSS promulgated rules and standards "intended to assure the high quality of care delivered in hospital facilities throughout New Jersey." N.J.A.C. 8:43G-1.1. Anesthesia is but one of several areas of practice specifically regulated under this section. N.J.A.C. 8:43G-6.2. Staffing, qualifications, training and supervision are addressed for anesthesia services just as they are for other areas of hospital services. See, e.g., N.J.A.C. 8:43G-7.3 (cardiac surgery); N.J.A.C. 8:43G-7.15 (cardiac catheterization); N.J.A.C. 8:43G-7.29 (coronary angioplasty); N.J.A.C. 8:43G-7.32 (electrophysiology); N.J.A.C. 8:43G-7.37 (pediatric cardiac services); N.J.A.C. 8:43G-7A.4 (primary stroke center); N.J.A.C. 8:43G-9.5 (critical care);

N.J.A.C. 8:43G-12.3 (emergency rooms); and N.J.A.C. 8:43G-12.16 (trauma services).

The challenged regulation is part of a comprehensive group of licensing standards enacted pursuant to N.J.S.A. 26:2H-5(b). Respondent clearly has statutory authority to regulate the licensure of hospitals and ambulatory care facilities and, in the course of that regulation, may mandate staffing requirements for those facilities that impact the practice of APN/As. Respondent did not exceed its authority in enacting the challenged rule.

Appellant also argues that the challenged rule is in conflict with rules adopted by the BON and the APN Act. While the APN Act expanded the permitted duties of APNs, their ability to prescribe and order medications is limited. N.J.S.A. 45:11-49 (b)-(c). When recognizing APN/As, the BON did not purport to overrule or question the propriety of any supervisory requirements already duly adopted by other agencies. Certification of Advanced Practice Nurses, 40 N.J.R. 3729, 3731 (June 16, 2008).

The APN Act did not grant APNs authority to administer anesthesia without supervision. We have held "the administration of anesthesia is, in fact, the 'practice of medicine' since it is used in the treatment of 'human ailment,

disease, pain, injury, [or] deformity.' N.J.S.A. 45:9-5.1." N.J. State Ass'n of Nurse Anesthetists, Inc. v. N.J. State Bd. of Medical Examiners, 372 N.J. Super. 554, 566 (App. Div. 2004), aff'd, 183 N.J. 605 (2005). In Nurse Anesthetists, the NJANA challenged a regulation proposed by the New Jersey State Board of Medical Examiners (BME) and subsequently codified at N.J.A.C. 13:35-4A.1 to -4A.18, that set forth standards for the administration of anesthesia by CRNAs in physicians' offices during non-minor surgeries and procedures. Id. at 557-58. The regulation required doctors who performed procedures necessitating anesthesia in their offices, as opposed to hospitals or ambulatory care sites, to meet certain requirements if they chose to employ CRNAs to administer the anesthesia. Id. at 558-59. One such requirement was that the CRNA be supervised during the administration of general and regional anesthesia by a "supervising physician" who must "be physically present and available to immediately diagnose and treat the patient in an emergency without concurrent responsibilities to administer anesthesia or perform surgery . . . ." N.J.A.C. 13:35-4A.8(c); N.J.A.C. 13:35-4A.9(c).

In upholding the regulation, we recognized that, pursuant to N.J.S.A. 45:9-6, "[t]he BME is responsible for issuing licenses to individuals engaged in the practice of medicine" and

"we have recognized that the BME has been delegated the authority to draw a line 'between services which nonprofessionals could perform and those which must be limited to licensed health care providers.'" Nurse Anesthetists, supra, 372 N.J. Super. at 562. We also noted that "[a]nesthesiologists receive more training to administer anesthesia and handle other medical problems that may arise during a surgery or the administration of anesthesia." Ibid. We concluded that "the BME is doing exactly what it is authorized to do: promulgate reasonable licensing standards for its physicians" and "it should be left to the BME to promulgate who should supervise CRNAs and how such supervision should take shape." Id. 564-65.

The Supreme Court affirmed, finding that "the challenged rule fell within the legal authority of the BME." N.J. Ass'n of Nurse Anesthetists, Inc. v. N.J. State Bd. of Med. Exam'rs, 183 N.J. 605, 611 (2005). As to our conclusion that "the challenged regulation falls squarely in the BME's core jurisdiction, the licensing and qualifications of physicians and how they perform their professional services," the Court found "no principled basis upon which [to] disagree with those conclusions." Ibid.

We therefore conclude that DHSS acted within its jurisdiction in enacting the challenged regulations. It is not regulating the practice of APN/As or the nursing profession.

Rather, it is regulating the practice of administering anesthesia in a hospital setting. It is fundamentally reasonable for DHSS to recognize the differences in education, training and skill of APN/As and anesthesiologists in establishing hospital anesthesia staffing regulations. Requiring the availability of an anesthesiologist to handle complications beyond the expertise of APN/As is a reasonable exercise of DHSS's regulatory authority and will better protect patients. Further, the challenged rule does not conflict with rules adopted by BON and the APN Act. Accordingly, appellants have failed to overcome the presumption of validity to which the regulation is entitled.

Affirmed.