State of New York
Supreme Court, Appellate Division
Third Judicial Department

Decided and Entered: March 3, 2022 531877

In the Matter of NEUROLOGICAL SURGERY, P.C.,
Appellant,
v MEMORANDUM AND ORDER

NEW YORK STATE DEPARTMENT OF HEALTH et al.,
Respondents.

Calendar Date: January 12, 2022

Before: Lynch, J.P., Clark, Aarons and Reynolds Fitzgerald, JJ.

Harris Beach PLLC, Uniondale (Roy W. Breitenbach of counsel), for appellant.

Letitia James, Attorney General, Albany (Kate H. Nepveu of counsel), for respondents.

Reynolds Fitzgerald, J.

Appeal from a judgment of the Supreme Court (Corcoran, J.), entered July 22, 2020 in Albany County, which dismissed petitioner's application, in a proceeding pursuant to CPLR article 78, to review a certain regulation promulgated by respondents.

Respondent Department of Health (hereinafter DOH) has broad authority to implement regulations establishing standards in health care facilities for the prevention, diagnosis and treatment of disease (see Matter of Spence v Shah, 136 AD3d

1242, 1245 [2016], lv denied 27 NY3d 908 [2016]; Public Health Law § 2800). Since 2004, DOH has designated certain hospitals as stroke centers, denoting that these facilities have a degree of expertise in providing care to patients presenting with stroke symptoms. In 2019, respondents promulgated 10 NYCRR 405.34 establishing a voluntary program where facilities could apply for designation as one of three increasingly specialized tiers of stroke centers. The purpose of the program was to create a tiered system of facilities independently certified as meeting the latest evidence-based standards, thus providing the highest quality of care. In ascending order of expertise, the three tiers of stroke centers consist of primary, thrombectomy capable and comprehensive. To qualify as a designated stroke center, facilities must first be certified by "an accredited organization approved by the Centers for Medicare and Medicaid Services."[1] Once certified, a facility may then apply to DOH for designation as a stroke center (see 10 NYCRR 405.34 [d] [2]; [e]).

In connection with the regulation, a guidance document was issued entitled "New York State Stroke Services Guidance Document for Hospital and Health Systems Version 19.3." This document sets forth, as a prerequisite to designation as a thrombectomy capable stroke center, that the hospital must have the capability to perform mechanical thrombectomies on a 24-hour, seven day a week basis, as well as perform thrombectomies on at least 15 patients over the prior 12 months, or 30 patients over a 24-month term. Additionally, the document requires that all primary neurointerventionists[2] must have performed, as the primary operator, an average of 15 mechanical thrombectomies over the past 12 months or 30 over the past 24 months. The volume criteria are applicable to each neurointerventionist.

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[1] The four approved certifying organizations are the Joint Commission, the Center for Improvement in Healthcare Quality, Det Norske Veritas and Healthcare Facilities Accreditation.

[2] Neuorinterventionists are "those [physicians] who routinely take call[s] to perform [an] emergency mechanical thrombectomy."

Petitioner, a neurosurgical group consisting of physicians, neurosurgeons, endovascular neurosurgeons, neurophysiologist and neurointerventional radiologists, commenced this CPLR article 78 proceeding seeking to annul the volume requirement for individual physicians as arbitrary and capricious. Specifically, petitioner asserted that, with the volume standard in place, few hospitals will be able to qualify as a second tier thrombectomy capable stroke center. Petitioner asserts, among other things, that this will result in compromised patient care due to the lack of said facilities and the increased transport time for patients to reach one of the few select hospitals.[3] Additionally, it contends that the individual volume standard will so limit the supply of physicians qualified to perform thrombectomies that, in many instances, those doctors who do meet the standard will not be able to endure the rigorous on-call schedule, and this will lead to a dearth of qualified physicians in the field. Following joinder of issue, Supreme Court dismissed the petition finding that respondents had rationally determined that the volume requirement would elevate the standard of medical care given to stroke patients thereby improving patient outcomes. Petitioner appeals.

Petitioner contends that Supreme Court erred in dismissing the petition because respondents' determination was arbitrary and capricious as it lacked a rational basis for instituting a volume requirement for individual physicians. "The standard for judicial review of an administrative regulation is whether the regulation has a rational basis and is not unreasonable, arbitrary or capricious" (Matter of Consolation Nursing Home v Commissioner of N.Y. State Dept. of Health, 85 NY2d 326, 331 [1995]). "An administrative agency's exercise of its rule-making powers is accorded a high degree of judicial deference, especially when the agency acts in the area of its particular expertise" (Matter of Spence v Shah, 136 AD3d at 1246 [internal

[3] Inherent in this second concern is the fear that emergency medical transports will bypass capable but non-designated hospitals in favor of the designated centers, and that patients will suffer due to the time expended between the onset of their strokes and treatment.

quotation marks and citations omitted]). "[T]he party seeking to nullify such a regulation has the heavy burden of showing that the regulation is unreasonable and unsupported by any evidence" (Matter of Consolation Nursing Home v Commissioner of N.Y. State Dept. of Health, 85 NY2d at 331-332). Further, "[w]e may not substitute our judgment for that of the agency responsible for making the [regulation]" (Matter of Adirondack Wild: Friends of the Forest Preserve v New York State Adirondack Park Agency, 161 AD3d 169, 176 [2018], affd 34 NY3d 184 [2019]).

Contrary to petitioner's contention, the record reveals that the regulation has a rational basis and is supported by medical and factual evidence. Respondents reasoned that designated stroke centers will deliver better patient outcomes by lowering the mortality rates associated with stroke and decreasing the disabilities associated with circulation deprivation to the brain caused by stroke, and that the volume requirements increase the facilities' training and experience, resulting in physicians developing, honing, and refining their skills based on the number of procedures that he or she performs. Prior to developing the regulation, respondents consulted with a stroke advisory group consisting of experts in the field of neurology, neurosurgery, neuroendovascular surgery and emergency medicine. Respondents also considered numerous medical publications[4] and studies, including support for the volume requirements in a 2007 article published electronically on Neurology.org. Additionally, DOH performed its own comprehensive analysis using data from the Statewide Planning and Research Cooperative System to determine what hospitals were performing endovascular procedures in the state, such as mechanical thrombectomy and how many were performed between July 2016 and June 2017, and it determined that the current volume of endovascular procedures performed in the state would be sufficient to support the proposed volume requirements.

[4] One of the publications relied on was the February 2019 bulletin from the Joint Commission explaining that mechanical thrombectomies were being performed at an increased rate, thereby ameliorating the concern that the individual physician would not have the opportunity to perform the required number of procedures within the time frame.

Moreover, the regulation's requirements were aligned with nationwide standards for accreditation as a stroke center in various states, and the four nationally recognized certifying organizations have similar volume requirements. Finally, the record reveals established procedures governing when stroke patients are taken to a designated center instead of a closer, non-designated hospital. Petitioners' contentions are not baseless, and, in fact, this Court shares these concerns. However, as the record demonstrates that the regulation has a rational basis and is not arbitrary and capricious, it must be sustained, even if this Court may have reached a different result (see Matter of Beer v New York State Dept. of Envtl. Conservation, 189 AD3d 1916, 1919 [2020]; Matter of Mallick v New York State Div. of Homeland Sec. & Emergency Servs., 145 AD3d 1172, 1175 [2016]; Matter of Dugan v Liggan, 121 AD3d 1471, 1474 [2014]).

Lynch, J.P., Clark and Aarons, JJ., concur.

ORDERED that the judgment is affirmed, without costs.

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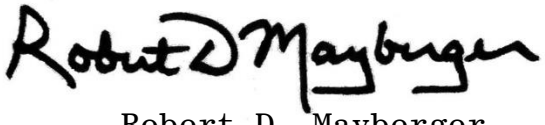

Robert D. Mayberger
Clerk of the Court