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SUPERIOR COURT OF NEW JERSEY
APPELLATE DIVISION
DOCKET NOS. A-1605-18T3
A-1606-18T3

IN THE MATTER OF THE CERTIFICATE OF NEED APPLICATION OF CENTRASTATE MEDICAL CENTER TO INITIATE FULL SERVICE ADULT CARDIAC CATHETERIZATIONS.

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IN THE MATTER OF THE CERTIFICATE OF NEED APPLICATION OF CENTRASTATE MEDICAL CENTER TO OFFER ON-SITE PRIMARY PERCUTANEOUS CORONARY INTERVENTION.

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Argued October 15, 2020 – Decided December 7, 2020

Before Judges Whipple, Rose and Firko.

On appeal from the New Jersey Department of Health, CN Nos. ER 0801-13-01 and ER 0802-13-01.

James A. Robertson argued the cause for appellant (Greenbaum Rowe Smith & Davis, LLP, attorneys;

James A. Robertson, of counsel and on the briefs; John W. Kaveney and Parampreet Singh, on the briefs).

Melissa H. Raksa, Assistant Attorney General, argued the cause for respondent (Gurbir S. Grewal, Attorney General, attorney; Melissa H. Raksa, of counsel; Mark D. McNally, Deputy Attorney General, on the briefs).

PER CURIAM

In these two appeals we calendared back-to-back and have consolidated for the purpose of writing one opinion, CentraState Medical Center appeals from two final agency decisions issued by the Department of Health (DOH): (1) denying its application for permission to expand its low-risk catheterization laboratory (low-risk cath lab) to include high-risk cardiac diagnostic services within a full-service adult diagnostic cardiac catheterization laboratory (full-service cath lab); and (2) denying its application for permission to expand its service line by offering on-site primary percutaneous coronary intervention (PCI) services, as a complement to those already offered in its low-risk cath lab.

The DOH refused to process CentraState's application in both matters because the hospital failed to meet the threshold eligibility and application review criteria set forth in the applicable regulations. CentraState appealed the rejection of both applications, emphasizing that the hospital demonstrated a special need to provide full-service cardiac care in the region due to its unique

location, its service to a predominantly elderly population, and the growth of its primary service area (PSA). We reject these arguments and affirm both decisions.

I.

A.

The material facts of each claim are generally undisputed and are gleaned from the record. In CentraState's matter filed under docket number A-1605-18, the hospital sought to expand its cardiac program to include a full-service cath lab. CentraState is a stand-alone community hospital located in Freehold and primarily serves residents from Monmouth, Middlesex, Mercer, Ocean, and Burlington Counties, the PSA. According to CentraState's application describing the PSA, the area recently underwent a transformation from farmland to residential developments, increasing the area's population, tourism, and need for modern conveniences.

Currently, CentraState's cardiology services include a cardiac diagnostic center, which performs electrocardiogram (EKG), echocardiogram, and stress testing, the low-risk cath lab, cardiac rehabilitation,[1] and a women's heart

[1] CentraState's cardiac rehabilitation program has been accredited by the American Association of Cardiovascular and Pulmonary Rehabilitation.

program. CentraState has operated its low-risk cath lab since April 20, 2005. In 2016, CentraState noted 692 patients who received or could have received low-risk cardiac catheterization services at its facility.[2] CentraState also cites 487 additional patients from its service area who went to other hospitals for these procedures, which it could have served if it had the proper facilities.

CentraState contends it has an active, award-winning endovascular program, which performed 4088 procedures at the time of its application. The program allows CentraState physicians to perform stent procedures "on every other area of the body except the heart," despite the general use of the same type of wire and stents and oftentimes, the performance of higher-risk procedures. Currently, the program has twenty-two physicians credentialed to perform low-risk catheterizations in CentraState's low-risk cath lab, and a minimum of three registered nurses or technologists available for each procedure.

According to an Outpatient Press Ganey report, CentraState scored a ninety-five percent patient satisfaction rating for the period commencing February 1, 2017 through April 30, 2017. William H. Matthai, Jr., M.D., FACC,

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[2] This number includes the 205 low-risk catheterizations performed at CentraState, the 127 patients admitted for these procedures but transferred elsewhere, and the 360 elective catheterizations that were scheduled by cardiologists elsewhere due to unavailability of PCI at the hospital.

FACP, FSCAI, conducted an external review of the low-risk cath lab specifically and found it to be "outstanding" in accordance with DOH requirements. Dr. Matthai was impressed that there had never been a procedure-related mortality in the low-risk cath lab and emphasized its safety initiatives. He concluded that the quality of care in CentraState's low-risk cath lab was "excellent and decision making appropriate," with proper patient selection and care, and an experienced physician and nursing staff.

On August 1, 2017, CentraState submitted a certificate of need (CN) application to the DOH seeking to expand its cardiac program to include a full-service cath lab. CentraState sought to expand its low-risk catheterization program to include invasive cardiac diagnostic services for adult patients within a full-service facility at the hospital. Doing so would permit CentraState to treat patients with conditions that are classified as high-risk.[3] Because there is no physical difference between a low-risk cath lab and a full-service cath lab, CentraState contends the program expansion would not require any construction

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[3] CentraState provided examples of high-risk conditions including: left main coronary syndrome, unstable myocardial infarction, acute myocardial infarction within three days, unstable angina with persistent angina, congestive heart failure, cardiogenic shock or severe hemodynamic instability, aortic stenosis, ejection fraction below thirty percent, or concomitant severe medical or vascular problems.

or renovation, or even the acquisition of additional equipment, other than minor supplies.

In making these applications, CentraState cited a special need for basic, essential cardiac care among the disproportionately elderly populations living within its PSA, specifically in Monroe and Jackson Townships. CentraState emphasized that the hospital's patients are on average sixty-eight years old, and Monmouth County, in particular, accounts for 7.3% more residents over the age of sixty-five than the average for the entire State of New Jersey. Truven Health Analytics projections indicate that the number of people aged sixty-five and older living within CentraState's PSA would increase 16% by 2021. Further, CentraState cited that the percentage of Monmouth County residents with some form of cardiovascular disease was 9% higher than the national average and were more likely than others in the nation to have at least one cardiovascular risk factor, like high blood pressure, high cholesterol, or diabetes.

Currently, residents living within CentraState's PSA must travel farther to receive basic cardiac services than those living within close proximity to other hospitals that offer those services. Freehold is located within a triangle of highways, with no fluid access through the middle of Monmouth County. There is no train service that runs from east to west in Monmouth County, leaving the

heart of the county unserved by that form of public transportation, and it can also take up to an hour-and-a-half for a patient to arrive by bus from certain parts of CentraState's PSA.

Therefore, if a patient who is admitted at CentraState must be transferred to another hospital to receive services not offered at its hospital, the transfer could involve up to four patient hand-offs,[4] which is inconsistent with coordinated patient care and patient risk. And, it adds at least an additional hour of travel time to the small window patients have to receive life-saving cardiac procedures, which is approximately ninety minutes.

Based on this information, in its application, CentraState asserted a substantial need for cardiac services in its PSA. While CentraState failed to meet the DOH's 400-low-risk case volume requirement and precondition for a full-service cath lab, it argued that the DOH was still required to address this substantial need and to relax its regulatory requirements.

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[4] A patient who first appears at CentraState's emergency room is first transferred to the CentraState cardiac team. If the cardiac services cannot be provided at CentraState, the patient must be transferred to emergency medical personnel for transport in an ambulance to another hospital. The emergency transporters then hand-off the patient to the other hospital's emergency personnel, and finally to the receiving hospital's catheterization lab staff.

On November 2, 2018, the DOH Director, Certificate of Need and Healthcare Facility Licensure Program, issued a written final decision. In his decision, the Director refused to process CentraState's application to expand its low-risk cath lab to include high-risk cardiac diagnostic services because it "failed to document full unconditional compliance with the eligibility and application review criteria set forth at N.J.S.A. 8:33E-1.3 [to] -1.10." For a low-risk cath lab to apply for expansion, it must demonstrate compliance with a minimum annual volume of 400 cases, which CentraState failed to do. Because of CentraState's inability to meet that requirement for submission of its application the DOH refused to review the substance of the request.

On appeal, CentraState claims that because the DOH "flatly refused to process" the application instead of addressing it on the merits, the DOH did not learn of the special need for services presented by "the uniqueness of CentraState's geographic location, the extensive population growth across Monmouth and other surrounding counties, and in particular, the elderly populations residing in Jackson and Monroe Townships . . . ." Instead of analyzing the merits of the application, CentraState claims the DOH flatly refused to process it, and did not properly consider the special needs it identified in its rejection.

B.

Turning to CentraState's matter filed under docket number A-1606-18, the hospital sought to expand its service line by offering on-site PCI services, as a complement to those already offered in its low-risk cath lab. Primary PCI is a non-surgical procedure which uses a catheter to place a stent into the heart for the purpose of opening blood vessels that have been narrowed by plaque buildup. CentraState intended these expansions to its low-risk catheterization program to offer a broader range of life-saving cardiac services to adult patients within a full-service facility at the hospital. Doing so would permit CentraState to treat patients with conditions that are classified as high-risk.

Because there is no physical difference between a low-risk cath lab and a full-service cath lab, the program and service expansion would not require physical construction or renovation, or even the acquisition of additional equipment, other than minor supplies. Additionally, all of the physicians on CentraState's medical staff who would be responsible for performing primary PCI procedures are already qualified to do so, and perform them frequently at other facilities. The cardiologists and nursing staff also regularly conduct stent and balloon procedures on every other part of the body in CentraState's

Endovascular Division. Given this information, CentraState claims to be staffed, equipped, and prepared to offer primary PCI services.

In making this application, CentraState made the same demographic and statistical arguments as in the other matter under docket number A-1605-18. The DOH refused to process CentraState's application for the provision of PCI services because it must first operate as a full-service adult diagnostic cardiac catheterization program for a period of six months. Because Centra-State was not licensed to operate as a full-service cardiac facility at the time it submitted its application, the DOH refused to consider it.

In a November 2, 2018 letter, the Director denied processing CentraState's CN application regarding PCI services because the hospital "failed to document full unconditional compliance with the eligibility and application review criteria set forth in [the administrative code]." Specifically, CentraState's:

> eligibility to initiate primary angioplasty (PCI) without on-site cardiac surgery backup is limited to any general hospital having a full[-]service adult diagnostic cardiac catheterization program that has been licensed for at least six months . . . prior to the application submission date and has documented, to the satisfaction of the [DOH], licensure and full compliance with all cardiac catherization program and facility utilization for the most recent four quarters.

On appeal in this matter, CentraState argues: (1) the DOH's failure to accept CentraState's CN application for processing and grant a CN to provide primary PCI services violates our holding in Irvington General Hosp. v. Department of Health;[5] (2) the DOH's regulation imposing a requirement that CentraState operate a full service diagnostic catheterization laboratory for six months as a precondition to applying for a CN to offer primary PCI services is arbitrary and inconsistent with the 400-case volume requirement regulation, which is undermined by modern science; and (3) the DOH failed to make any findings of fact or conclusions of law as to CentraState's contention that special need for cardiac services exists among the over sixty-five populations in Monroe and Jackson townships warranting a remand.

II.

Our review of an agency's decision is limited. In re Stallworth, 208 N.J. 182, 194 (2011) (citing Henry v. Rahway State Prison, 81 N.J. 571, 579 (1980)). A reviewing court "should not disturb an administrative agency's determinations or findings unless there is a clear showing that (1) the agency did not follow the law; (2) the decision was arbitrary, capricious, or unreasonable; or (3) the decision was not supported by substantial evidence." In re Virtua-West Jersey

[5] 149 N.J. Super. 461 (App. Div. 1977).

Hosp. Voorhees for a Certificate of Need, 194 N.J. 413, 422 (2008) (citing In re Herrmann, 192 N.J. 19, 28 (2007)); see also Bergen Pines Cty. Hosp. v. N.J. Dep't of Human Servs., 96 N.J. 456, 477 (1984).

CentraState argues that the DOH improperly disqualified the hospital's CN application for a full-service cath lab on the grounds that CentraState has not demonstrated compliance with the minimum annual facility volume requirement of 400 cases. CentraState contends the decision ignored the factors enumerated in the CN statute, as well as the clear mandate of Irvington General, 149 N.J. Super. at 461.

Establishment of health care facilities in New Jersey is governed by the Health Care Facilities Planning Act (HCFPA), N.J.S.A. 26:2H-1 to -26, which allows the State to supervise changes in the statewide delivery of health care. In re Virtua-West, 194 N.J. at 416. The government oversight includes the construction, expansion, modernization, and addition of health care facilities, services, and plans. Desai v. St. Barnabas Med. Ctr., 103 N.J. 79, 88-89 (1986). The legislative intent of the HCFPA is "to provide state residents with high quality health care services at a contained cost." In re Virtua-West, 194 N.J. at 423 (citing N.J.S.A. 26:2H-1).

In furtherance of that objective, the HCFPA implemented the CN process, which requires health care providers to submit proposals to the DOH before any new health care facility is constructed or expanded. N.J.S.A. 26:2H-7. The HCFPA dictates that no CN shall be issued unless the action proposed in the application is

> necessary to provide required health care in the area to be served, can be economically accomplished and maintained, will not have an adverse economic or financial impact on the delivery of health care services in the region or Statewide, and will contribute to the orderly development of adequate and effective health care services.
>
> [N.J.S.A. 26:2H-8.]

Specifically, in assessing a CN, the Commissioner of Health must consider:

> (a) the availability of facilities or services which may serve as alternatives or substitutes,
>
> (b) the need for special equipment and services in the area,
>
> (c) the possible economies and improvement in services to be anticipated from the operation of joint central services,
>
> (d) the adequacy of financial resources and sources of present and future revenues,
>
> (e) the availability of sufficient manpower in the several professional disciplines, and
>
> (f) such other factors as may be established by regulation.

> The State Health Plan may also be considered in determining whether to approve a certificate of need application.
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> [N.J.S.A. 26:2H-8.]

The DOH is required to consider this criterion in determining whether to grant a CN. The process may be done on an "expedited" basis, which dispenses with the otherwise necessary secondary review by the State Health Planning Board and leaves it entirely in the hands of the DOH. N.J.A.C. 8:33-4.1(b).

Regulations adopted under the HCFPA "establish standards and general criteria for the planning of cardiac diagnostic facilities and for the preparation of an application for a [CN] for such a facility." N.J.A.C. 8:33E-1.1(a). Invasive cardiac diagnostic facilities must meet the minimum standards and criteria set forth in N.J.A.C. 8:33E-1.1(d). Because "[t]he American College of Cardiology/American Heart Association Task Force supports the position that the safety and efficacy of laboratory performance requires a caseload of adequate size to maintain the skills and efficacy of the staff[,]" N.J.A.C. 8:33E-1.1(c), "[u]tilization criteria for all invasive cardiac diagnostic facilities are based on the number of patients upon whom invasive cardiac diagnostic procedures . . . are performed." N.J.A.C. 8:33E-1.4(a).

Specifically, all facilities licensed to provide invasive cardiac diagnostic services pursuant to low-risk catheterization facility standards must maintain a minimum of 200 adult cardiac catheterization patients per year. N.J.A.C. 8:33E-1.4(c)(1). All facilities licensed to provide full-service invasive cardiac diagnostic services must maintain a minimum of 400 adult cardiac catheterization patients per year. N.J.A.C. 8:33E-1.4(b)(1). The volume requirements are calculated based on the last four quarters of operation prior to the facility's licensure anniversary date. N.J.A.C. 8:33E-1.4(b)(1). Applications to provide new full-service invasive cardiac diagnostic services are limited to

> [l]icensed providers of low-risk cardiac catheterization services that have demonstrated full unconditional compliance with State licensure requirements that includes . . . compliance with the minimum annual facility volume requirement for full[-]service cardiac catheterization (that is, 400 cases) . . . throughout their . . . most recent four quarters of operation . . . .
>
> [N.J.A.C. 8:33E-1.15(a)(1).]

"Pursuant to the Planning Act, and specifically N.J.S.A. 26:2H-7, no health care facility, including a hospital, may construct new facilities, expand existing ones, or initiate a new health care service, unless a CN has been applied for by the facility and granted by the Commissioner." In re Certificate of Need for the Mem. Hosp. of Salem Cnty., 464 N.J. Super. 236, 247 (App. Div. 2020).

"The ultimate policy goals of the Planning act are to 'protect and promote the health of the inhabitants of the State' and to 'guard against the closing of important institutions and the transfer of services from facilities in a manner that is harmful to the public interest.'" Id. at 247-48 (quoting N.J.A.C. 8:33-1.1(a)). Further, the Planning Act states that the Commissioner shall not grant a CN unless the proposal:

> is necessary to provide required health care in the area to be served, can be economically accomplished and maintained, will not have an adverse economic or financial impact on the delivery of health care services in the region or [s]tatewide, and will contribute to the orderly development of adequate and effective health care services.
>
> [N.J.S.A. 26:2H-8.]

In determining whether to grant a CN, the Commissioner shall consider:

> (a) the availability of facilities or services which may serve as alternatives or substitutes, (b) the need for special equipment and services in the area; (c) the possible economies and improvement in services to be anticipated from the operation of joint central services, (d) the adequacy of financial resources and sources of present and future revenues (e) the availability of sufficient manpower in the several professional disciplines, and (f) such other factors as may be established by regulation.
>
> [Ibid.; see also N.J.A.C. 8:33-4.9(a)(1)-(5); N.J.A.C. 8:33-4.10(b).]

The application and review process regarding CNs is further outlined in N.J.A.C. 8:33-1.1 to -6.2. In this regard, the applicable regulations provide for either a full or expedited review of a CN application. N.J.A.C. 8:33-4.1(a) to (b). As defined by N.J.A.C. 8:33-1.3, a full review includes "the review of an application by the . . . Planning Board, as well as the Department," while an expedited review "means the review by the Department of a [CN] application meeting certain specified criteria" without a Planning Board review.

On November 2, 2018, the DOH refused to accept CentraState's CN application for processing because the department found "the [a]pplicant failed to document full unconditional compliance with the eligibility and application review criteria set forth in [the regulations]." Specifically, the DOH explained:

> In accordance with N.J.A.C. 8:33E1.15(a)[(1)] eligibility to initiate full[-]service cardiac catheterization services is limited to licensed providers of low[-]risk cardiac catherization services that have demonstrated full unconditional compliance with state licensure requirements that includes, but is not limited to, compliance with the minimum annual facility volume requirement for full[-]service cardiac catheterization of 400 cases with the most recent data available to the [DOH]. The [a]pplicant has not met the eligibility criteria in that the most recent licensure of its low[-]risk cardiac catheterization program is conditional (effective May 1, 2018) and the [a]pplicant's low[-]risk cardiac catheterization program performed only 154 adult diagnostic cardiac

> catheterization cases for the four quarters ended March 31, 2018.

The DOH refused to process the application because CentraState did not meet the threshold eligibility criteria. CentraState's licensure of its low-risk cath lab was conditional, effective May 1, 2018, and it performed only 154 adult diagnostic cardiac catheterization cases for the four quarters ending March 31, 2018, making it ineligible to apply for a full-service cath lab. <u>See</u> N.J.A.C. 8:33E-1.15(a)(1) (limiting applications for new full-service cath labs to "[l]icensed providers of low-risk cardiac catheterization services that have demonstrated full unconditional compliance with State licensure requirements [including], . . . compliance with the minimum annual facility volume requirement" of 400 cases).

CentraState does not contend that the DOH should have considered its application because it met the regulatory requirements, but instead, that those requirements should be disregarded. CentraState cites <u>Irvington General</u> for the principle that the DOH erroneously relied on the case volume requirement in its refusal to process the application and it should have instead relaxed its standards in order to ensure the special need cited in its application was met.

In <u>Irvington General</u>, the hospital submitted an application for a CN seeking to construct an addition to its building and to add two surgical beds, six

intensive care units, and seventeen intermediate care beds, which are essentially the equivalent of surgical beds. 149 N.J. Super. at 464. While the application was pending, the Health Care Administration Board reclassified 150 long-term care beds at another hospital to surgical beds, thereby creating an excess of the type in Essex County. Id. at 465. The hearing officer then recommended the application be denied solely on that ground. Ibid.

On appeal, we held that while the hearing officer "was permitted to consider the latest statistics on bed need at the time of the remand hearing[,]" it did not mean "those figures [could] be the sole determinative factor." Id. at 466. We cited N.J.S.A. 26:2H-8, emphasizing that certificates are issued upon a showing that the action "is necessary to provide required health care in the area to be served, can be economically accomplished and maintained, and will contribute to the orderly development of adequate and effective health care services[,]" taking into account the several enumerated factors. Ibid.

In that case, we concluded the hearing officer erroneously rejected the application as not "necessary" to provide health care services to the area, only citing "the availability of facilities or services which may serve as alternatives or substitutes" as a factor in the decision, without reference to the others. Id. at 467 (citing N.J.S.A. 26:2H-8). We remanded for consideration of all the factors

set out in N.J.S.A. 26:2H-8, specifically, "the need for special . . . services in the area" for the Township of Irvington's large density of citizens over the age of sixty-five. Id. at 467-68.

CentraState argues the holding in Irvington General requires this court to reverse the DOH decision in this case because the DOH wrongly relied exclusively on the 400-case volume requirement to the exclusion of other CN factors and because the DOH failed to recognize the special need for full services among the residents aged sixty-five and older living within the hospital's PSA.

First, CentraState argues that the DOH's sole reliance on the 400-case volume requirement is the equivalent of its erroneous reliance on bed statistics in Irvington General because the decision similarly ignores the remaining CN statutory factors. CentraState contends the DOH reached its decision by only considering the sixth statutory factor, "such other factors as may be established by regulation[,]" to the exclusion of the others, including "the need for special equipment and services in the area" when it refused to process the application citing N.J.A.C. 8:33E-1.15(a)(1). And, CentraState claims the DOH's neglect of the remaining factors was at odds with the statute and the holding of Irvington General, and therefore, constituted improper ultra vires action.

CentraState cites the 487 patients from its PSA who had to inconveniently undergo low-risk cardiac catheterizations at other hospitals because of CentraState's limited services, as well as the rapidly growing elderly population in the area, as support for its argument that the CN is "necessary to provide required health care in the area to be served." N.J.S.A. 26:2H-8. CentraState also emphasizes that it requires no additional construction or improvement to its facilities if the CN is granted, showing that the action can easily be "economically accomplished and maintained." Ibid.

CentraState additionally notes that there is no indication there will be "an adverse economic or financial impact on the delivery of health care services in the region or Statewide" if the CN is granted and argues that its history of highly-rated service will translate to the "orderly development of adequate and effective health care services" in the full-service cath lab. Ibid. CentraState maintains that the DOH erroneously ignored its satisfaction of all of the elements of N.J.S.A. 26:2H-8 and relied solely on the outdated case volume requirement to deny its application.

Whether CentraState made a showing under the statutory factors is irrelevant and the holding of Irvington General is inapplicable here. CentraState's argument focuses on N.J.S.A. 26:2H-8, and emphasizes that it has

met the requirements for a CN to be issued by the DOH. Even if that is true, however, CentraState failed to meet N.J.A.C. 8:33E-1.15(a)(1), which outlines the requirements to submit a CN application in the first place.

The regulatory requirements were intended to "establish standards and general criteria for the planning of cardiac diagnostic facilities and for the preparation of an application for a [CN] for such a facility." N.J.A.C. 8:33E-1.1(a). The requirement for submission of a CN application to provide full-service invasive cardiac diagnostic services, relevant to the issue in this case, includes the applicant be a "[l]icensed provider[] of low-risk cardiac catheterization services" that has complied with the State's licensure requirements, including "with the minimum annual facility volume requirement for full[-]service cardiac catheterization (that is, 400 cases) as set forth at N.J.A.C. 8:33E-1.4(b)(1) . . . ." N.J.A.C. 8:33E-1.15(a)(1). The reason this requirement is important is because "the safety and efficacy of laboratory performance requires a caseload of adequate size to maintain the skills and efficiency of the staff." N.J.A.C. 8:33E-1.1(c).

Here, the record is clear that CentraState's low-risk cardiac catheterization program was conditional, effective May 1, 2018, and performed only 154 adult diagnostic cardiac catheterization cases in the relevant period, plainly failing to

satisfy the 400-case requirement. Because CentraState did not meet the "[e]ligibility for submission of [CN] applications[,]" the content of its application was immaterial. The question of whether a CN should be granted only arises when an application is properly submitted. See N.J.A.C. 8:33E-1.15(a)(1). Therefore, whether CentraState met the statutory factors of N.J.S.A. 26:2H-8 is not germane to our analysis.

In Irvington General, the hospital's application was submitted to the DOH and accepted for consideration. See id. at 464-65. Upon evaluation of the application, the hearing officer recommended the request be denied and the Board agreed based on the bed statistics in the county. Id. at 465. We remanded the matter because the DOH focused entirely on "the availability of facilities . . . which . . . serve[d] as alternatives or substitutes" in the area, and ignored the remaining factors of N.J.S.A. 26:2H-8, including "the need for special equipment and services in the area." Id. at 468.

The holding of Irvington General is inapplicable here because, in that case, the application was properly before the DOH and the issue centered on whether the DOH should have issued the CN, not on whether the application should have been submitted at all. Because the application was accepted for processing, it presumably met the threshold requirements that CentraState failed

to overcome here, inviting argument on the N.J.S.A. 26:2H-8 factors. Therefore, Irvington General simply does not and cannot stand for the principle that the DOH has an obligation to address the statutory factors, including a special need for services, when the applicant has not demonstrated a threshold eligibility to apply.

Because the volume requirement is not one of the factors the DOH must consider when issuing a CN, but instead, a threshold consideration for submission of the application, the DOH did not wrongly rely on it to the exclusion of any N.J.S.A. 26:2H-8 factors. Instead, the DOH's refusal to process CentraState's CN application was consistent with the regulatory requirements adopted under the HCFPA and the principles articulated in Irvington General.

CentraState also argues that, like in Irvington General, the DOH failed to adequately consider the CN factors, including "the need for special . . . services in the area." N.J.S.A. 26:2H-8(b). It argues that the DOH in this case similarly ignored the large density of elderly citizens in the area and the lack of adequate transportation to other hospitals in the county. Because the DOH failed to account for the special unmet need for cardiac services in its PSA, CentraState contends the DOH refusal of its application was in error.

While in the Irvington General matter we faulted the DOH for relying solely on bed need statistics and not the special need articulated in the hospital's application when evaluating its expansion request, the DOH in the matter under review was not required to consider the substance of the application because the requirements for submitting the application were not met. While CentraState argues the DOH overlooked its articulated "special need," which it identifies as a large density of elderly persons within its PSA and lack of public transportation to and from the area, the DOH had no obligation to consider that factor or any other in its determination of whether CentraState could submit a CN application at all.

Moreover, the facility volume requirement for submission of a CN application in N.J.A.C. 8:33E-1.15 is clearly a threshold issue in respect of the DOH's consideration of whether to issue the requested relief in that application. Accordingly, the DOH did not improperly ignore the special need asserted by CentraState, but instead, properly refused to process its application for a different reason entirely – that the hospital failed to maintain a caseload of adequate size to demonstrate the skills and efficiency of its staff, necessary to sustain a full-service cath lab. We conclude that the DOH complied with express

legislative policies and did not act in an arbitrary, capricious, or unreasonable manner. In re Herrmann, 192 N.J. 19, 27-28 (2007).

CentraState next contends that the applicable DOH regulations impose two different, incongruent volume requirements and are therefore, internally inconsistent. Further, CentraState claims that those same regulations are contrary to law and modern science and should not be arbitrarily used to summarily reject its application. Specifically, CentraState challenges the DOH's interpretation of the regulation, calling it unreasonable and unsupported by the record, because it: (1) creates volume prerequisites for CN applicants that newly-licensed full-service cath labs do not need to demonstrate until their second year of operations; (2) doubles the number of annual low-risk cases a low-risk cath lab must perform; and (3) ignores modern science, including DOH expert recommendations.

CentraState identifies the interplay between N.J.A.C. 8:33E-1.15 and N.J.A.C. 8:33E-1.4 as problematic. The former sets forth the prerequisites for the DOH to consider a CN application by a low-risk cath lab seeking to operate as a full-service cath lab. The relevant language of N.J.A.C. 8:33E-1.15 includes:

> Eligibility for the submission of such applications will be limited to the following:

> Licensed providers of low-risk cardiac catheterization services that have demonstrated full unconditional compliance with State licensure requirements that includes, but is not limited to, compliance with the minimum annual facility volume requirement for full[-]service cardiac catheterization (that is, 400 cases) as set forth at N.J.A.C. 8:33E-1.4(b)[(1)] throughout their second year of operation or their most recent four quarters of operation, whichever is later . . . .

The latter regulation, incorporated by N.J.A.C. 8:33E-1.15(a)(1), more thoroughly outlines the existing volume requirement:

> [F]acilities licensed to provide full[-]service invasive cardiac diagnostic services shall, as a condition of continued licensure, be required to maintain the following basic utilization criteria:
>
> . . . The minimum acceptable number of adult cardiac catheterization patients per full[-]service cardiac laboratory is 400 per year. New full[-]service providers (those previously operating as low[-]risk cardiac catheterization laboratories) must provide documentation of full compliance with the minimum utilization level during their second year of operation or their most recent four quarters of operation, whichever is later and fully documented by the Department using audited data. Existing full[-]service invasive cardiac diagnostic providers (with or without cardiac surgery on site) must achieve minimum utilization levels each year. Compliance with minimum annual facility volume requirements will be calculated on the basis of the last four quarters of operation prior to the facility's licensure anniversary date.
>
> [N.J.A.C. 8:33E-1.4(b)(1).]

CentraState contends that when both regulations are considered together, they require only that CentraState demonstrate at the time it applies for a CN, compliance with a 200-case volume and the ability to comply with a 400-case volume by its second year of operation as a new full-service cath lab. CentraState supports that position by arguing that a regulation requiring a new facility to artificially meet the 400-case requirement of only low-risk catheterizations is arbitrary and capricious, serving no logical objective. Because CentraState identified over 400 patients it served or would have served if it had the capacity of a full-service cath lab, CentraState claims to have met the proper interpretation of the requirement.

We interpret regulations de novo. US Bank, N.A. v. Hough, 210 N.J. 187, 198-99 (2012) (citing Bedford v. Riello, 195 N.J. 210, 221-22 (2008)). In doing so, we review the intent of the drafter as the paramount goal, which is generally "found in the actual language of the enactment." Id. at 199. It is not the court's function to "rewrite a plainly-written enactment" or "presume that the drafter intended a meaning other than the one 'expressed by way of the plain language.'" Ibid. (quoting DiProspero v. Penn, 183 N.J. 477, 492 (2005)). We simply construe the regulation as written. Ibid.

N.J.A.C. 8:33E-1.4(c)(1) is clear, and CentraState agrees, that all low-risk catheterization facilities are required to meet the acceptable volume number of 200 cases per year. CentraState also concedes that it is evident from the regulation's language that a full-service cath lab is required to maintain a volume of 400 cases per year under N.J.A.C. 8:33E-1.4(b)(1). However, CentraState contends the error in the DOH interpretation was that new full-service providers are not required to maintain a 400-case volume before applying for a CN like already operating full-service cath labs, but must alternatively show a compliance with the 200-case volume requirement and an ability to comply with the 400-case volume requirement by the second year of operation. We disagree.

N.J.A.C. 8:33E-1.15(a)(1) clearly requires that low-risk cath labs seeking to submit a CN application to become full-service cath labs must demonstrate a compliance with all State licensure requirements including "compliance with the minimum annual facility volume requirement for full-service cardiac catheterization (that is, 400 cases)" as set forth at N.J.A.C. 8:33E-1.4(b)(1). The language clearly indicates that for a low-risk cath lab to become a full-service cath lab, the low-risk cath lab must not simply show that it can comply with the minimum annual facility volume requirement for a full-service cath lab, but

actually comply with that requirement. To hold otherwise would ignore the plain language of the regulation.

Instead, when read in conjunction with other regulatory provisions, it is apparent the regulation's intent was to impose a more stringent standard on low-risk cath labs seeking to provide full cardiac catheterization services, as opposed to low-risk cath labs simply seeking to comply with their current 200-case minimum to maintain low-risk licensure. See N.J.A.C. 8:33E-1.1(c) ("[T]he safety and efficacy of laboratory performance requires a caseload of adequate size to maintain the skills and efficiency of the staff."); N.J.A.C. 8:33E-1.4(a) ("Utilization criteria for all invasive cardiac diagnostic facilities are based on the number of patients upon whom invasive cardiac diagnostic procedures (cardiac catheterization) are performed."). CentraState's proposed interpretation of the regulation is inconsistent with the statute's clear language and common sense.

It is beyond cavil that a reading of the two regulatory requirements makes clear CentraState had to maintain a 400-case volume throughout its second year of operation or its most recent four quarters of operation, whichever was later, in order to meet the requirements for submission of the CN application for a full-service cath lab. The low-risk lab was required to demonstrate an ability of

its staff and facilities to meet and maintain a 400-case volume, which would become its new minimum if approved for full-service, before requesting that the DOH consider making that number permanent. Therefore, we reject CentraState's statutory argument to the contrary as it is unsupported by the statute's language and clear intent to test the efficacy of the lab's performance before considering its application for expansion.

CentraState also challenges the notion that the 400-case volume requirement serves as a necessary means of maintaining quality of full-service cath labs, calling it contrary to undisputed scientific evidence. In support of this argument, CentraState points to the Cardiovascular Health Advisory Panel (CHAP), a group created by N.J.A.C. 8:33E-1.14 to provide the Commissioner with expert clinical and technical advice related to cardiovascular health policy, which opined against the volume requirement in favor of more relaxed standards to increase cardiac care providers in 2011. Specifically, CentraState highlights CHAP's recommendations to abandon low-risk cath lab designations altogether, to require low-risk facilities transitioning to full-service cath labs to perform a minimum of 250 cases in the second year after transition to the new level of service, and to permit the Commissioner to waive annual volume requirements under certain circumstances.

More recently, CentraState highlights the current legislative undertakings to update the medical regulatory standards. CentraState contends pending legislation focuses on eliminating distinctions between low-risk and full-service cath labs, reducing the 400-case volume requirement to 250 cases, providing a two-year transition periods for new full-service cath labs to meet volume requirements, and codifying the Commissioner's waiver authority. See S. 2427/A. 3769 (2018). However, CentraState explains that, after a decade of governmental inaction and the stall of the relevant bill before the July 2019 recess, it has no confidence a legislative solution is forthcoming and requests a favorable decision by this court. CentraState contends that the CHAP recommendations and pending bill reflect the scientific advancements in cardiovascular services, lessening the need for strict regulatory oversight.

Saliently, CHAP's 2011 recommendations have not been implemented and the pending legislation has not been signed into law. Therefore, the adopted regulations remain unchanged and serve as the governing law in this case. See Johnson v. Roselle EZ Quick LLC, 226 N.J. 370, 389 (2016) (alterations in original) (quoting James v. N.J. Mfrs. Ins. Co, 216 N.J. 552, 573 (2014)) ("For example, a party may not rely on pending legislation because '[t]he possibility that a bill might become law is an expectation built on uncertainty until it

happens.'"); Cty. of Hudson v. Dep't of Corr., 152 N.J. 60, 71 (1997) ("[A]lthough an administrative agency may change its regulations, so long as they are in force the agency is bound by them."). Because the regulations are clear and consistent, and it is not the court's function to "rewrite a plainly-written enactment," Hough, 210 N.J. at 199, we see no basis to reverse the DOH denial of CentraState's CN application.

CentraState next argues that the DOH failed to properly assess and acknowledge all the CN factors as required, and instead, mechanically applied the regulatory standard. CentraState contends the DOH was responsible for considering its "special need" argument on the merits, and since the DOH chose to reject the application, it was responsible for providing a reasoned explanation for why the DOH believed that need was not established. In the alternative to granting a full-service cath lab, CentraState seeks to have the matter remanded to the DOH with instructions that it: (1) accept the application for processing; (2) review the evidence within the application regarding the articulated need; (3) grant or deny the CN based on those facts; and (4) issue findings and conclusions of law on the merits. CentraState further requests that the DOH complete its review within thirty days of remand. We reject CentraState's arguments.

Here, the DOH was not obligated to address CentraState's "special need" argument on the merits because the CN application was not accepted for processing for failing to satisfy the eligibility and application review criteria of the regulations. The application did not even make it to the point of the process where the DOH was supposed to review its substance. Without that review, there can be no findings.

A CN application will only be accepted for review when a "[l]icensed provider[] of low-risk cardiac catheterization services . . . ha[s] demonstrated full unconditional compliance with State licensure requirements that includes . . . compliance with the minimum annual facility volume requirement for full[-]service cardiac catheterization (that is, 400 cases) . . . " at the designated time. N.J.A.C. 8:33E-1.15(a)(1). Here, CentraState's most recent licensure was conditional, effective May 1, 2018, and the low-risk cath lab only performed 154 adult diagnostic cardiac catheterizations for the most recent four quarters ending March 31, 2018.

We reiterate that CentraState failed to meet the eligibility criteria to even apply for the full-service cath lab, which was the basis of the DOH's rejection. The DOH explained in its rejection letter:

> Please be advised that the above-referenced [CN] application to initiate full[-]service adult cardiac

> catheterization, submitted for consideration on August 1, 2017, cannot be accepted for processing . . . . The [DOH] approved [CentraState's] requested six-month deferral of the above noted CN application . . . effective January 8, 2018 through July 8, 2018. Upon the [a]pplicant's decision to reactivate the CN application, the [DOH] finds the [a]pplicant has failed to document full unconditional compliance with the eligibility and application review criteria set forth at N.J.A.C. 8:33E-1.3 through 1.10.
>
> In accordance with N.J.A.C. 8:33E-1.15(a)[(1)] eligibility to initiate full[-]service cardiac catherization services is limited to licensed providers of low[-]risk cardiac catheterization services that have demonstrated full unconditional compliance with state licensure requirements that includes, but is not limited to, compliance with the minimum annual facility volume requirement for full[-]service cardiac catherization of 400 cases with the most recent data available to the [DOH]. The [a]pplicant has not met the eligibility criteria in that the most recent licensure of its low[-]risk cardiac catheterization program is conditional (effective May 1, 2018) and the [a]pplicant's low[-]risk cardiac catheterization program performed only 154 adult diagnostic cardiac catheterization cases for the four quarters ended March 31, 2018.

We are satisfied the DOH provided a reasoned explanation for its rejection of the application according to the regulatory guidelines and was not required to address the substance of the application at that time. The findings of fact and conclusions of law on the "special need" issue were irrelevant to the DOH's

decision at this point, and not required in its initial rejection of the CN application.

III.

Applying the same considerations to the matter under docket number A-1606-18, we similarly reject CentraState's argument that the DOH improvidently disqualified its application for primary PCI services summarily because the hospital did not operate a full-service adult diagnostic cardiac cath lab for at least six months. Again, we conclude that the DOH properly refused to process CentraState's application because it did not meet the threshold eligibility criteria.

On November 2, 2018, the DOH refused to accept CentraState's CN application for processing because the department found "the [a]pplicant failed to document full unconditional compliance with the eligibility and application review criteria set forth in N.J.A.C. 8:33E-2.16." Specifically, the DOH explained:

> In accordance with N.J.A.C. 8:33E-2.16(a)[(1)] eligibility to initiate primary angioplasty (PCI) without on-site cardiac surgery backup is limited to any general hospital having a full[-]service adult diagnostic cardiac catheterization program that has been licensed for at least six months as a full[-]service adult diagnostic cardiac catheterization program prior to the application submission date and has documented, to the satisfaction

> of the [DOH], licensure and full compliance with all cardiac catheterization program and facility utilization for the more recent four quarters. The [a]pplicant has not met this eligibility criteria in that it is not currently licensed as a full[-]service adult diagnostic cardiac catheterization program.

At the time of its application for primary PCI services, CentraState only operated a low-risk cath lab, and therefore, could not have operated a full-service cath lab for the requisite six-month period. We agree with the DOH that CentraState's application was not subject to consideration on that ground. It is undisputed that at the time it submitted its CN application to provide primary PCI services, CentraState did not operate as a full-service adult diagnostic cardiac catheterization program. Indeed, CentraState submitted a simultaneous application on the same date to become a full-service facility. We are unpersuaded by the timing of the applications. Again, because CentraState did not meet the threshold requirement to submit its CN application, the content of its application was immaterial. And, whether CentraState met the statutory factors of N.J.S.A. 26:2H-8 is unavailing.

In DOH's rejection letter relative to PCI services, it aptly stated:

> Please be advised that the above-referenced [CN] application to initiate primary angioplasty (PCI) without on-site cardiac surgery backup, submitted for consideration on August 1, 2017, cannot be accepted for processing . . . . The [DOH] approved

> [CentraState's] requested six-month deferral of the above noted CN application . . . effective January 8, 2018 through July 8, 2018. Upon the [a]pplicant's decision to reactivate the CN application, the [DOH] finds the [a]pplicant has failed to document full unconditional compliance with the eligibility and application review criteria set forth at N.J.A.C. 8:33E-2.16.
>
> In accordance with N.J.A.C. 8:33E-2.16(a)[(1)] eligibility to initiate primary angioplasty (PCI) without on-site cardiac surgery backup is limited to any general hospital having a full[-]service adult diagnostic cardiac catheterization program that has been licensed for at least six months as a full[-]service adult diagnostic cardiac catheterization program prior to the application submission date and has documented, to the satisfaction of the [DOH], licensure and full compliance with all cardiac catheterization program and facility utilization for the more recent four quarters. The [a]pplicant has not met this eligibility criteria in that it is not currently licensed as a full[-]service adult diagnostic cardiac catheterization program.

We are not persuaded by CentraState's argument that the DOH wrongfully failed to process its application for permission to expand its service line to include PCI services. CentraState's remaining arguments are without sufficient merit to warrant discussion in a written opinion. R. 2:11-3(e)(1)(D).

Affirmed.

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

CLERK OF THE APPELLATE DIVISION