# COURT OF APPEALS OF VIRGINIA

Present: Judges Huff, Chafin and Decker Argued at Richmond, Virginia

LEWIS-GALE MEDICAL CENTER, LLC

v. Record No. 1289-13-3

# CYNTHIA C. ROMERO, M.D., STATE HEALTH COMMISSIONER, COMMONWEALTH OF VIRGINIA

# MEMORANDUM OPINION<sup>\*</sup> BY JUDGE MARLA GRAFF DECKER APRIL 29, 2014

# FROM THE CIRCUIT COURT OF THE CITY OF SALEM J. Michael Gamble, Judge Designate

Jeffrey D. McMahan, Jr. (Robert L. Hodges; Nathan A. Kottkamp; Thomas J. Stallings; McGuire Woods LLP, on briefs), for appellant.

Ishneila G. Moore, Assistant Attorney General (Kenneth T. Cuccinelli, II, Attorney General; Rita W. Beale, Deputy Attorney General; Allyson K. Tysinger, Senior Assistant Attorney General, on brief), for appellee.

Lewis-Gale Medical Center, LLC (Lewis-Gale), appeals from the circuit court's affirmance of the decision of the Commissioner of the Department of Health (Department) denying its application for a certificate of public need (COPN). Lewis-Gale contends that the circuit court erred in upholding the Commissioner's decision denying the COPN because the Commissioner: (1) deviated from prior agency decisions without explanation; (2) applied the wrong legal standard, thereby treating Lewis-Gale differently from other Virginia hospitals; (3) applied the public need calculation required under the State Medical Facilities Plan (SMFP) in an improper manner; and (4) reached a decision that was not supported by substantial evidence in the record. We hold that the record does not support these claims. Therefore, we affirm the circuit court's ruling.

<sup>&</sup>lt;sup>\*</sup> Pursuant to Code § 17.1-413, this opinion is not designated for publication.

# I. BACKGROUND

Lewis-Gale, a for-profit hospital owned by HCA, Inc., and located in Salem, sought a COPN to renovate space in its existing newborn nursery. At the time the July 1, 2010 application was filed, Lewis-Gale's nursery contained five general-level bassinets.<sup>1</sup> It was licensed for twenty-three obstetrics beds but was not staffing all of those beds due to low demand. In an effort to increase usage rates for its obstetrics beds, Lewis-Gale sought to create a neonatal intensive care unit (NICU) by adding eight specialty-level bassinets.<sup>2</sup> It indicated, as permitted by the applicable regulations, an intent to provide both specialty-level and intermediate-level services within those bassinets.<sup>3</sup>

Lewis-Gale averred that the only other hospital in the health planning region specifically licensed to provide specialty-level newborn care, Centra Virginia Baptist Hospital (CVBH), was located sixty miles away in Lynchburg, in a different planning district, and was not a realistic option for Lewis-Gale patients. It further noted that Carilion Roanoke Memorial Hospital (Carilion), located eight miles from Lewis-Gale in the same planning district, was the only facility in that district that was licensed to provide any level of NICU care. Carilion, as a licensed provider of subspecialty-level care, was also permitted to provide all lower levels of care in those bassinets,

<sup>&</sup>lt;sup>1</sup> The applicable regulations classify newborn infant bassinet space according to four levels of medical need: general, intermediate, specialty, and subspecialty care. <u>See</u> 12 VAC 5-410-443(B).

<sup>&</sup>lt;sup>2</sup> The term "[n]eonatal special care" encompasses care "in one or more of the higher service levels"— intermediate, specialty, and subspecialty care. 12 VAC 5-230-10. "[N]eonatal intensive care" refers to care at the specialty and subspecialty levels. <u>Compare</u> 12 VAC 5-410-443(B)(1), (B)(2) (stating that general-level and intermediate-level services "shall provide care [to newborns]" with specified lower-level medical needs), <u>with</u> 12 VAC 5-410-443(B)(3), (B)(4) (stating that specialty-level and subspecialty-level services "shall provide *intensive* care [to] *high-risk* [neonates]" with certain "neonatal illnesses" (emphases added)).

<sup>&</sup>lt;sup>3</sup> The regulations define the requirements for each level of care as including the ability to care for infants requiring all lesser levels of care. See 12 VAC 5-410-443(B)(1) to (4).

including specialty-level care. Because Carilion was the only provider of NICU services in the local planning district, Lewis-Gale asserted that no real competition existed for such services. Lewis-Gale suggested that an increasing need for specialized NICU services existed in the geographical area due to increasing maternal age and a high proportion of at-risk patients. Finally, Lewis-Gale offered evidence that its proposed project enjoyed significant public support as a means to avoid separating infants needing specialized care from their mothers.

The only public opposition to Lewis-Gale's COPN application came from Carilion, which was licensed for thirty intermediate-level and thirty subspecialty-level bassinets. Carilion contended the geographical market for NICU care was "oversupplied" and that the need for such care was "diminishing." It pointed to statistics showing downward trends in occupancy rates for Carilion's NICU bassinets over a period of years and noted studies showing "a high, positive correlation between larger size/volumes of NICU's and infants having a higher level of overall health and a significantly lower level of mortality."

The Department's Division of Certificate of Public Need (the DCOPN) reviewed Lewis-Gale's application and contacted Carilion for additional NICU occupancy data. Once it completed its review, the DCOPN issued a detailed report recommending denial of the application. It concluded that "reasonable availability and access to special care nursery services exists in the [health planning region], especially within the service areas of both [Lewis-Gale] and Carilion."

At the subsequent informal fact-finding conference, Lewis-Gale presented evidence challenging the DCOPN recommendation. The adjudication officer (AO), like the DCOPN, recommended denying Lewis-Gale's COPN application. The AO provided a detailed written analysis of the statutory and regulatory factors, including an assessment of the consistency of the application with the SMFP. He considered Carilion's declining occupancy statistics for its subspecialty-level bassinets in his analysis of both the SMFP and non-SMFP factors. Additionally,

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the AO observed that authorizing Lewis-Gale's requested eight additional specialty-level bassinets "pose[d] a risk of further reducing utilization" of existing specialty-level and subspecialty-level newborn services.

The Commissioner expressly adopted the findings, conclusions, and recommendation of the AO and denied the application. In doing so, she analyzed the administrative record pertaining to the proposed project and considered all the criteria in Code § 32.1-102.3 required to make a determination of public need. The Commissioner noted that she was "mindful of the emotional challenge created when a needful infant is separated from its family in order to receive special level nursery services at another hospital." However, she opined that such services "should not be allowed to be duplicated when evidence strongly shows that sufficient volume would not exist to support proficiency and quality in neonatal care delivery." She also opined that the addition of such services at Lewis-Gale would "stand[] to harm" the quality of care at Carilion, the facility then providing those services. The Commissioner further held that the proposed project was inconsistent with applicable provisions of the SMFP, including its 85% occupancy standard, as well as the "purposes to which that plan is devoted." She concluded that the project would "reduce the frequency and duration of medical transportation for only some infants in the Lewis-Gale system of hospitals"-those actually delivered at Lewis-Gale-and that the economic viability of the plan was "readily questionable." As a result, the Commissioner denied the COPN application despite her acknowledgement of "many expressions of community support for the project."

Lewis-Gale sought circuit court review of the Commissioner's decision. The circuit court, in affirming the decision, found that the Commissioner had "complied with her duty to thoroughly consider the factors under Code §32.1-102.3(B)[,] . . . includ[ing] . . . the regulations adopted pursuant to the [SMFP]." The circuit court held that Lewis-Gale had not established an error of

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law subject to review under Code § 2.2-4027. The court further held that the agency record contained "substantial evidence . . . with respect to issues of fact upon which the Commissioner could deny the COPN." The court concluded that it could not "find that the Commissioner's factual findings should [have] be[en] rejected."

Lewis-Gale appeals the circuit court's ruling affirming the denial of the COPN.

# II. ANALYSIS

### A. STATUTORY AND REGULATORY FRAMEWORK

Code § 32.1-102.3(A) provides that "[n]o person shall commence any [medical care facilities] project without first obtaining a [COPN] issued by the Commissioner." It further provides that "[n]o [COPN] may be issued unless the Commissioner has determined that a public need for the project has been demonstrated." Code § 32.1-102.3(A). That statute also requires that "[a]ny decision to issue or approve the issuance of a [COPN] shall be consistent with the most recent applicable provisions of the [SMFP]." <u>Id.</u> As relevant to the instant case, the SMFP sets out certain size and occupancy standards, based on the level of neonatal care to be provided, for use in determining whether a COPN for additional neonatal bassinet space should issue. <u>See</u> 12 VAC 5-410-443 (levels of care); 12 VAC 5-230-940, -960 to -980 (standards for determining additional need).

Consistency with the SMFP, however, is only one of eight statutory factors for consideration. Code § 32.1-102.3(B). The Commissioner is not required to award a COPN if the evidence supports a finding that the applicant has failed to demonstrate a public need based on *any* of the enumerated factors. <u>See State Health Comm'r v. Sentara Norfolk Gen. Hosp.</u>, 260 Va. 267, 273, 534 S.E.2d 325, 329 (2000). The other seven factors are whether the project: improves access to needed health care services, enjoys community support, fosters institutional competition, improves utilization and efficiency of existing services, is feasible in financial and human resources terms, provides improvements or innovations in health care financing and delivery, and positively impacts a teaching hospital or medical school. Code § 32.1-102.3(B).

Further, when denying a COPN application, the Commissioner is not required to make specific findings with respect to the SMFP and the seven other statutory criteria. <u>See, e.g., Va.</u> <u>Ret. Sys. v. Cirillo</u>, 54 Va. App. 193, 199, 676 S.E.2d 368, 371 (2009). She needs only to notify the parties "briefly and generally in writing[] of the factual basis for an adverse decision." <u>Id.</u> (quoting Code § 2.2-4019(A)(v)).

### **B. STANDARDS OF REVIEW**

On appeal of an administrative agency's decision, "the party complaining . . . has the burden of demonstrating an error of law subject to review." <u>Hilliards v. Jackson</u>, 28 Va. App. 475, 479, 506 S.E.2d 547, 549 (1998). Reviewable issues of law include determining whether the agency: (1) acted in accordance with the law; (2) committed a procedural error that was not harmless; and (3) had sufficient evidential support for its findings of fact. <u>Johnston-Willis, Ltd.</u> <u>v. Kenley</u>, 6 Va. App. 231, 241-42, 369 S.E.2d 1, 6-7 (1988); see Code § 2.2-4027.

In the face of a challenge to the Commissioner's findings of fact, a reviewing court must defer to the exercise of her expert discretion as long as substantial evidence supports those findings. Loudoun Hosp. Ctr. v. Stroube, 50 Va. App. 478, 491, 650 S.E.2d 879, 885-86 (2007). Substantial evidence is "more than a mere scintilla." Johnson v. Va. Ret. Sys., 30 Va. App. 104, 110, 515 S.E.2d 784, 787 (1999) (quoting Consol. Edison Co. v. NLRB, 305 U.S. 197, 229 (1938)). "Under the substantial evidence standard, the reviewing 'court may reject the agency's findings of fact only if, considering the record as a whole, a reasonable mind would *necessarily* come to a different conclusion." Loudoun Hosp., 50 Va. App. at 491, 650 S.E.2d at 885-86 (quoting <u>Va. Real Estate Comm'n v. Bias</u>, 226 Va. 264, 269, 308 S.E.2d 123, 125 (1983)) (internal quotation marks omitted). Further, when an agency has accepted witness testimony, a

court reviewing the agency's action may not set aside the hearing officer's credibility determination unless the testimony is "inherently incredible." <u>Va. Real Est. Bd. v. Kline</u>, 17 Va. App. 173, 177, 435 S.E.2d 596, 599 (1993) (quoting <u>Gamble-Skogmo, Inc. v. FTC</u>, 211 F.2d 106, 115 (8th Cir. 1954)); <u>see Comm'r v. Fulton</u>, 55 Va. App. 69, 80, 683 S.E.2d 837, 842 (2009).

Where an issue is purely one of statutory interpretation, this Court, like the circuit court, reviews the issue de novo. Va. Dep't of Health v. NRV Real Estate, LLC, 278 Va. 181, 185, 677 S.E.2d 276, 278 (2009). However, "an agency's interpretation of its governing statutes, as reflected in its regulations, is entitled to great weight." Manassas Autocars, Inc. v. Couch, 274 Va. 82, 87, 645 S.E.2d 443, 445-46 (2007) (emphasis added). ""[A]n agency's interpretation of its own regulations is controlling unless plainly erroneous or inconsistent with the regulations being interpreted." Mathews v. PHH Mortg. Corp., 283 Va. 723, 738, 724 S.E.2d 196, 204 (2012) (alteration in original) (quoting Long Island Care at Home, Ltd. v. Coke, 551 U.S. 158, 171 (2007)). "The General Assembly has granted the Commissioner broad discretion in rendering case decisions. The Commissioner's determination [of what is] relevant to understanding public need lies within an area of [her] experience and specialized competence and[,] therefore, is entitled to great deference." Doctors' Hosp. of Williamsburg, LLC v. Stroube, 52 Va. App. 599, 609-10, 665 S.E.2d 862, 867 (2008) (citation omitted). When an agency decision is challenged as arbitrary, "judicial interference is permissible only for relief against arbitrary or capricious action that constitutes a clear abuse of the discretion delegated to the agency." NRV Real Estate, 278 Va. at 188, 677 S.E.2d at 280. "The reviewing judicial authority may not exercise anew the jurisdiction of the administrative agency and merely substitute its own independent judgment for that of the body entrusted by the Legislature with

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the administrative function." <u>Doctors' Hosp.</u>, 52 Va. App. at 607, 665 S.E.2d at 866 (quoting <u>Johnston-Willis</u>, 6 Va. App. at 244, 369 S.E.2d at 8) (internal quotation marks omitted).

This Court reviews this case under these well-established standards.

# C. DENIAL OF LEWIS-GALE'S COPN APPLICATION

#### 1. Explanation for Decision and Legal Standard Applied to Lewis-Gale

Lewis-Gale contends in its first and second assignments of error that the Commissioner erred in deviating from prior agency decisions without explanation and in arbitrarily treating Lewis-Gale differently by applying the outdated regionalized model of care to assess its application. The record, however, refutes these claims.

It is well established that "in its ordinarily accepted meaning, the doctrine of *stare decisis* is inapplicable . . . to the decisions of an administrative agency." <u>Courtesy Motors, Inc. v. Ford</u> <u>Motor Co.</u>, 9 Va. App. 102, 106, 384 S.E.2d 118, 120 (1989). "Erroneous statutory interpretations an administrative agency may have adopted in the past can never cause the subsequent adoption of a correct application of the law to be arbitrary and capricious. If an agency has acted in error, it has no obligation to continue to err in perpetuity." <u>NRV Real Estate</u>, 278 Va. at 188, 677 S.E.2d at 280. Instead, "'[a]n agency may refuse to follow its own precedent [as long as] it [does] not act arbitrarily in doing so." <u>Courtesy Motors</u>, 9 Va. App. at 106, 384 S.E.2d at 120 (quoting 1 Charles H. Koch, Jr., <u>Administrative Law and Practice</u> § 6.57 (1985)). The issue, therefore, is "whether [the decision] is a departure and indistinguishable from [prior] decisions . . . and, if so, whether the commissioner acted arbitrarily in disregarding the precedent." <u>Id.</u> at 106, 384 S.E.2d at 121.

The decision of the Commissioner, viewed in context of the evidence before her and applying the appropriate legal standard, is distinguishable from the prior decisions upon which Lewis-Gale relies. All but two of those decisions were rendered prior to the amendments to the

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SMFP that became effective February 15, 2009. Lewis-Gale argues that the regulatory changes make no difference here. However, the previous version of the SMFP, in assessing various size, volume, and occupancy standards, required the aggregation of statistics for all levels of neonatal special care within a health planning region. <u>See</u> 12 VAC 5-250-90 (repealed). The current regulations, by contrast, provide for separate consideration of such statistics for bassinets of the same classification level. <u>See</u> 12 VAC 5-230-960 to -980. Thus, for example, under the previous regulations, high occupancy rates for one level of neonatal care could inflate overall bassinet occupancy rates and justify the addition of bassinet space at another level even though the occupancy rates for that level were significantly lower than 85%. Such a skewing of occupancy rates is less likely to occur under the new regulatory scheme, and this fact provides a legitimate basis for distinguishing between pre-amendment and post-amendment case decisions.

Only two of the projects relied upon by Lewis-Gale involved review under current SMFP standards, and both are readily distinguishable. The first COPN application involved merely relocating eight existing specialty-level bassinets by moving them from Sentara Virginia Beach General Hospital to Sentara's new Princess Anne Hospital, located nine miles away in an underserved part of the same city.<sup>4</sup> The second application—the request of Stafford Hospital,

<sup>&</sup>lt;sup>4</sup> Lewis-Gale offered the related DCOPN report into evidence. <u>See</u> Sentara Hosps., Inc., COPN Applic., No. VA-7787, at 1-2 (Va. Dep't of Health Oct. 19, 2010). The report noted that although Virginia Beach's population was concentrated in the southern portion of the city, no acute care hospital was located there. It concluded that moving these specialty-level bassinets to Princess Anne would improve access without harming other facilities. Id. at 1-4, 7-8.

Lewis-Gale contends that an earlier phase of Sentara's project involved significant deviation from current SMFP bassinet standards. The record does not support this claim. Sentara's 2008 COPN for construction of the hospital included authorization for more than one hundred beds and four intermediate-level bassinets. <u>See</u> Sentara Hosps. COPN Applic., No. VA-7535, at 4, 9 (Va. Dep't of Health Feb. 18, 2009) (DCOPN staff rep.) (citing COPN No. VA-04138 (issued Mar. 21, 2008)). Sentara later sought authorization for a larger number of beds and agreed, as part of that proposal, to surrender its 2008 COPN. <u>Id.</u> In reviewing Sentara's second proposal in 2009, the DCOPN applied the amended SMFP. <u>Id.</u> at 4. However, Lewis-Gale's evidence shows that the Department reviewed only the new components of the application and does not indicate that it revisited the licensing of the bassinets. <u>Id.</u> at 4, 9, 27.

LLC, to introduce intermediate-level services with six bassinets—is also readily distinguishable from Lewis-Gale's application because the regulations as revised in 2009 require the Commissioner to evaluate considerations for intermediate-level and specialty-level bassinets that overlap but are not identical.<sup>5</sup> The regulations, which suggest a minimum of six bassinets for intermediate-level care and a much higher minimum of eighteen bassinets for specialty-level and subspecialty-level care, reflect the Department's recognition that NICU-level treatment is more volume sensitive than intermediate-level nursery care. <u>Compare</u> 12 VAC 5-230-960(B), <u>with</u> 12 VAC 5-230-970(B), and -980(B). As the Department has observed,

> [a] well-trained and experienced staff is critical to the success of [specialty-level and subspecialty-level NICU] programs. Regionalization of this service concentrates patients at the most appropriate sites, which in turn creates the most experienced staff. The American Academy of Pediatrics advocates the regionalization of neonatal care in order to optimize the care and outcomes of all newborn infants.

Dep't of Health, <u>Ann. Rep. on the Status of Va.'s Med. Care Facilities COPN Pgm.</u> 17 (2010). Further reflecting these principles, the regulations also require that an applicant for specialty-level or subspecialty-level care "shall demonstrate that service volumes of existing . . . providers" of the same type within the same area will not be "significantly reduced." <u>See</u> 12 VAC 5-230-970(D), -980(D). No such requirement applies to applications for intermediate-level care. 12 VAC 5-230-960. Thus, for these reasons, we hold the Commissioner did not act arbitrarily to the extent that her denial of Lewis-Gale's application resulted in treating it differently from applicants seeking intermediate-level bassinets.

Lewis-Gale argues next that the Commissioner has acknowledged that specialty-level NICU services are a "safe and reasonable expectation of patients and physicians," i.e., the

<sup>&</sup>lt;sup>5</sup> Lewis-Gale offered the DCOPN report regarding the Stafford Hospital COPN application into evidence. <u>See</u> Stafford Hosp., LLC, COPN Applic., No. VA-7718 (Va. Dep't of Health Apr. 27, 2010) (DCOPN staff rep.).

standard of care, for all hospitals that provide obstetrics services. However, as the AO pointed out, the Commissioner has not held that such services *are* the standard of care. Instead, as recognized by the Commissioner here, a previous Commissioner, in a case involving Chesapeake General Hospital, held only that "[a]ccess to some level of on-site specialty care . . . *appears to be becoming* the standard of care for hospitals providing *substantial* [volumes of] newborn care as safety has improved and technology and expectations have evolved." Chesapeake Gen'l Hosp. COPN Applic., No. VA-7376 [hereinafter CGH Applic.], at 8, 10 (Va. Dep't of Health Apr. 2, 2007) (recommended dec. of adjud. officer) (emphases added), <u>adopted by</u> CGH Applic., at 1 (Va. Dep't of Health Apr. 3, 2007) (dec. of comm'r).

Further, as the AO held here with regard to that prior case decision:

Th[at] language does not establish a standard of care[;] it only recognizes that, . . . in an appropriate setting *where need can be observed and volumes can be sustained*, special care nursery services may be approved while preserving the proficiency and quality of care across an area's hospitals. [Therefore,] [r]eliance on this language for determinative effect in the present case is misplaced.

(Emphasis added). The DCOPN also concluded that Lewis-Gale "does not operate a 'busy' obstetrical service," one of the factors considered relevant by the Commissioner in the prior case decision.

Here, after independent review, the AO adopted the findings in the DCOPN report, and the Commissioner, after her own review, adopted the findings in the AO's report. Substantial evidence in the record supports these findings. The Chesapeake General proceeding involved evidence that the hospital performed over 3,000 deliveries per year, more than any other non-military hospital in its perinatal region. CGH Applic., <u>supra</u>, at 7-8 (recommended dec. of adjud. officer). Chesapeake General also offered evidence that at the time of its 2007 application, "'there [were] no other hospitals in Virginia that deliver[ed] more than 2,500 babies

per year that [were] not also authorized to provide at least specialty[-]level care.'" <u>Id.</u> at 8. Lewis-Gale, by contrast, delivered 497 babies in 2009; calculated an annualized delivery rate of 780 babies in 2010 based on figures for nine months of that year; and "conservatively" predicted deliveries of 1,035 babies per year by 2013. Although Lewis-Gale's application demonstrated it had experienced some increase in obstetrical cases and hoped to achieve a greater increase, the record, viewed under the proper standard, supports a finding that even its projected volume of 1,035 was not high as compared to Chesapeake General's 3,000 annual deliveries. Under the standard for reviewing an agency's interpretation and application of its regulations, we defer to the Commissioner's exercise of her specialized competence in this area. <u>See Doctors Hosp.</u>, 52 Va. App. at 609-10, 665 S.E.2d at 867.

Lewis-Gale further challenges the Commissioner's decision, contending that this outcome upholds "the [previously favored] regionalized model of neonatal care" in the health planning region. Lewis-Gale contends that this finding contradicts circumstances elsewhere in Virginia which reflect an effort to move away from the regionalized model. To the contrary, as a previous Commissioner recognized in 2007, although "protecting a regionalized model for subspecialty-level neonatal care is important," it must be balanced against the need for "specialty-level care . . . [within] a busy obstetrics program." CGH Applic., <u>supra</u>, at 8 (recommended dec. of adjud. officer), <u>adopted by</u> CGH Applic., at 1 (dec. of comm'r). Similarly here, the Commissioner's ruling indicates a need to *balance* these interests rather than to uphold the regionalized model at any cost. It is true that the SMFP no longer provides for a single regional perinatal center in each geographical area. <u>See</u> 12 VAC 5-250-80 (repealed). Nevertheless, for all facilities authorized to provide subspecialty-level NICU care, the regulations continue to require staff members with the same qualifications previously required of such perinatal centers. <u>Compare</u> 12 VAC 5-410-443(B)(4) (eff. Feb. 14, 2005), <u>with</u> 12 VAC

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5-410-440(D)(2)(a)(4) (2004) (repealed). Further, as Lewis-Gale concedes, research shows better outcomes at the subspecialty level if treatment is provided in a higher-volume setting because staff are more experienced in dealing with infants needing such high levels of care. <u>See,</u> <u>e.g., Ann. Rep., supra</u>, at 17. This research supports the Commissioner's effort to achieve a balance between these interests, a determination that falls within her expert discretion.

Consequently, we hold that Lewis-Gale has failed to prove the Commissioner committed an error of law by applying the wrong legal standard to assess its application or abused her discretion by arbitrarily or capriciously deviating from prior agency decisions.

#### 2. Application of the SMFP Need Calculation

Lewis-Gale contends in its third assignment of error that its COPN application was consistent with the SMFP's various standards for assessing the need for additional NICU bassinets. Evaluating this assignment of error involves interpreting the SMFP, which is contained in the Department's regulations. Therefore, the Department's interpretation of the SMFP "is entitled to great weight." <u>Couch</u>, 274 Va. at 87, 645 S.E.2d at 445-46; <u>see also</u> <u>Roanoke Mem. Hosps. v. Kenley</u>, 3 Va. App. 599, 605-06, 352 S.E.2d 525, 529 (1987) (holding that the word "should" as used in the COPN regulations at issue "confer[red] an appropriate amount of discretionary authority" on the Commissioner). We hold that the Commissioner's construction of the applicable regulations was not "plainly erroneous or inconsistent with the regulations being interpreted." <u>See Mathews</u>, 283 Va. at 738, 724 S.E.2d at 204 (quoting <u>Coke</u>, 551 U.S. at 171).

## a. Subsection (A): 85% Minimum Annual Occupancy Standard

Lewis-Gale correctly asserts that the only bassinets in the health planning region that are formally classified as specialty-level bassinets are the thirteen located at CVBH. Lewis-Gale points to CVBH's reported occupancy level for 2009 of approximately 87%. Because this rate

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exceeded the SMFP's recommended minimum occupancy standard of 85%, Lewis-Gale contends that it proved its proposed project was consistent with this provision of the SMFP.<sup>6</sup> These facts, standing alone, do not establish that the Commissioner's application of the 85% occupancy guideline was erroneous. The record shows that the Commissioner considered other occupancy data in addition to CVBH's occupancy rate. By adopting the AO's recommendation, the Commissioner interpreted the 85% minimum annual occupancy standard as permitting consideration of the occupancy rate for bassinets of the higher subspecialty-level because, consistent with the regulations, these bassinets were available to provide lower specialty-level NICU care. Lewis-Gale avers that the Commissioner's consideration of these subspecialty-level bassinets in assessing the consistency of the project with the 85% occupancy standard was error. We disagree.

The Commissioner's interpretation of the regulations in this fashion is entitled to deference. <u>See Couch</u>, 274 Va. at 87, 645 S.E.2d at 445-46. In addition, the evidence supports the finding that Carilion was using its subspecialty bassinets to provide specialty-level care and still was not achieving an 85% occupancy rate. Data from Carilion, which the evidence established was "the primary site for NICU transfers from Lewis-Gale," showed a subspecialty-level bassinet occupancy rate of 61.52% for Carilion's fiscal year 2010.<sup>7</sup>

<sup>&</sup>lt;sup>6</sup> Lewis-Gale argues that the Commissioner erred in ruling that the 85% standard was "problematic" and in rejecting the project for that reason. The record shows, however, that the AO ultimately concluded that "[r]egardless" of any problems with this standard, "reasonable availability and access to special care nursery services exists in [the health planning region], especially within the service areas of both [Lewis-Gale] and Carilion." Thus, the record demonstrates that no such error occurred.

<sup>&</sup>lt;sup>7</sup> Data that Carilion provided on October 1, 2010, covered the period of October 1, 2009, to August 31, 2010, eleven-twelfths of Carilion's fiscal year 2010. Although Carilion had reported a 2009 occupancy rate of 93% to Virginia Health Information (VHI), the body charged with compiling and disseminating health care data, <u>see</u> Code § 32.1-276.4; 12 VAC 5-230-10, Lewis-Gale conceded that this figure was for "staffed" bassinets, and the evidence showed that Carilion, due to low occupancy rates, was not staffing all of its bassinets.

Lewis-Gale conceded that Carilion's NICU was the only realistic option for its newborn patients needing special care services. Carilion's 2010 occupancy figure of 61.52% was more than twenty percentage points lower than the 85% regulatory minimum that the SMFP suggested each level of existing specialized neonatal care should achieve before new space at the same level should be added. It was also the lowest subspecialty-level bassinet occupancy rate that Carilion had recorded for the five-year period of 2006 to 2010.<sup>8</sup> The report further showed that 2010 was the year with the lowest average length of stay over the five-year period. The DCOPN inferred from these figures, which did not separately account for specialty-level and subspecialty-level use, that Carilion "proportionally provided care to fewer sub[]specialty-level] bassinets than in 2009." This evidence supports a finding that the demand for specialty-level NICU bassinet space within a reasonable distance from Carilion and Lewis-Gale was well below the 85% occupancy level recommended for approving a COPN for new services.

Using figures for 2009, the last year for which occupancy rates for both Carilion and CVBH are contained in the record, yields similar results. Carilion's thirty subspecialty bassinets

<sup>&</sup>lt;sup>8</sup> The report showed a rate meeting the 85% regulatory minimum during only two of those five years, 86.59% in 2006 and 85.60% in 2008, adjusted downward to compensate for a temporary unavailability of NICU bassinet space when Carilion, in 2008, moved its NICU services from one location to another. During 2007 and 2009, Carilion's rates were 78.64% and 75.21% respectively. The chair of pediatrics at Carilion, Dr. Alice Ackerman, noted recent demographic data suggested "that the birth rate within the [health planning region] is falling despite the expansion in obstetrics services by hospitals in the region," pointing to an 11% decline in the region's birth rate from 2007 to 2009. She also noted the fact that the region "ha[d] fewer annual live births than any other region in the state." She further pointed out a decrease in the rate of infants born prematurely, a figure considered predictive of the number of infants likely to need neonatal special care. Dr. Ackerman posited that these trends "suggest that the demand for NICU services in the Health Planning Region will be significantly lower in coming years and [that] NICU [bassinets] may be oversupplied even at the levels currently licensed." Finally, she noted the quantity of medical research recognizing a "high, positive correlation between larger size/volume NICU's and infants having a higher level of overall health and a significantly lower level of mortality."

had an occupancy rate of 75.2% which, combined with CVBH's 2009 rate of 86.8% for its thirteen specialty bassinets, yields a functional occupancy rate of 78.7% for the health planning region for 2009, also below the 85% floor set out by the SMFP.

Lewis-Gale contends that a comparison of the regulations before and after the 2009 amendments makes clear that the Commissioner erred by considering occupancy rates for *subspecialty* bassinets in applying the SMFP's 85% standard to its COPN request for *specialty-level* bassinets. The purpose of the 2009 amendment, it argues, was to assure sufficient bassinet space for each separate level of care and the Commissioner's conflation of the data for specialty-level and subspecialty-level bassinets defeats that purpose, "effectively . . . undo[ing] the amendment" and creating a new regulation. We hold, however, based on the record, that the Commissioner's interpretation of the regulations was not plain error.

When reviewing a claim of regulatory interpretive error, the court "'[must] accept only those agency interpretations that are reasonable in light of the principles of [statutory] construction courts normally employ." <u>Bd. of Supers. v. State Bldg. Code Tech. Rev. Bd.</u>, 52 Va. App. 460, 466, 663 S.E.2d 571, 574 (2008) (quoting <u>EEOC v. Arabian Am. Oil Co.</u>, 499 U.S. 244, 260 (1991) (Scalia, J., concurring)). Consequently, in interpreting the relevant regulations, we apply the same principles of construction applied to interpreting ambiguous statutes. <u>See Avalon Assisted Living Facilities, Inc. v. Zager</u>, 39 Va. App. 484, 503, 574 S.E.2d 298, 307 (2002). One of those principles directs that "an amendment to an existing [regulation]" carries "a presumption that a substantive change in law was intended." <u>Dale v. City of Newport News</u>, 243 Va. 48, 51, 412 S.E.2d 701, 702 (1992). A second counsels that regulations "on the same subject matter, i.e., those standing *in pari materia*, must be considered together and harmonized if possible." <u>Avalon</u>, 39 Va. App. at 503, 574 S.E.2d at 307.

Lewis-Gale averred in its COPN application that its specialty-level bassinets would serve roughly equal numbers of intermediate-level and specialty-level patients. Inherent in this claim is the admission that the SMFP permits a facility to care for infants needing a lower level of neonatal care in bassinets officially classified as capable of providing a higher level of such care. This practice is supported by the text of the SMFP, which expressly defines each successive level of neonatal care space as including equipment and treatment capabilities in addition to the equipment and treatment capabilities required of the next lowest level of neonatal care. See 12 VAC 5-410-443(B). Allowing for such care without also permitting the Department to consider that provision of care in the calculation of need would defeat the purposes of the SMFP. Thus, the Commissioner's application of the regulations in a way that permitted her to consider the functional use of all existing bassinet space rather than merely its formal classification best achieved the SMFP's purpose.

For example, under the pre-2009 regulations, evaluating the need for specialty-level bassinets required consideration of occupancy rates not only for existing subspecialty-level bassinets but also for intermediate-level bassinets. <u>See</u> 12 VAC 5-250-90 (repealed). Such consideration was required in spite of the fact that the regulations do not permit the use of intermediate-level bassinets to provide higher specialty-level care. <u>See</u> 12 VAC 5-410-443. Under this prior regulatory scheme, the existence of an excess of intermediate-level bassinets could make it difficult to remedy a shortage of specialty-level bassinets.<sup>9</sup> The 2009 revisions to the regulations provide for separate consideration of the occupancy statistics for

<sup>&</sup>lt;sup>9</sup> If existing intermediate-level bassinets were not achieving the recommended minimum occupancy of 85%, this fact could cause aggregate occupancy statistics for all bassinet levels to fall below 85%. Under this scenario, even if specialty and subspecialty bassinets had occupancy rates significantly in excess of 85%, thereby tending to indicate a need for additional bassinets of those classifications, a strict application of the prior regulations would nevertheless have counseled against the issuance of a COPN for such bassinets because of the low occupancy rate for intermediate-level bassinets.

intermediate-level, specialty-level, and subspecialty-level bassinets, thereby remedying this problem. See 12 VAC 5-230-960 to -980.

Lewis-Gale concedes that, as a practical matter, patients needing specialty-level care may receive that care in subspecialty-level bassinets, but it would simultaneously require the Commissioner to ignore this functional capacity of existing subspecialty-level bassinets in assessing the need for additional specialty-level bassinets. The regulatory structure and evidence in this case support the Commissioner's conclusion that such an approach is unwise for two reasons. First, such an expansion is not necessary to ensure adequate bassinet space because, as Lewis-Gale concedes, "[n]eonatal special care bassinets are generally not licensed as beds in Virginia . . . . [T]herefore[, existing] capacity can be expanded . . . , within the authorized level of care, as needed without [additional] COPN or license authorization." <u>Ann. Rep.</u>, supra, at 19. Second, allowing the unnecessary proliferation of specialty-level bassinet space could cause a corresponding decrease in the quality of care. <u>Id.</u> at 17.

The functional approach applied by the Commissioner did not nullify the change in the regulations and was well within the parameters of her authority to exercise her expert discretion. The prior regulation allowed occupancy rates of lower levels of care to impact the ability to approve the addition of bassinets to provide higher levels of care. Under the functional approach applied here, only bassinets *capable* of providing the level of service for which a COPN is being sought may be considered under the SMFP in assessing need for those new bassinets.<sup>10</sup> Requiring the Commissioner to blindly ignore the apparent oversupply of subspecialty-level bassinet space at Carilion, which the Commissioner found was available and actually being used

<sup>&</sup>lt;sup>10</sup> We need not determine whether the Department could appropriately consider the expected functional use of the *proposed* bassinets, i.e., Lewis-Gale's estimation that the eight specialty-level bassinets it sought would routinely treat a roughly equal number of specialty-level and intermediate-level patients. Lewis-Gale has not made this argument.

to care for infants needing specialty-level treatment, would contravene the purposes of the SMFP to assure both adequate capacity and quality of care. <u>See id.</u> at 17, 19. Deferring to the Commissioner's interpretation of the regulations, as required by the applicable standard of review, we conclude that the Commissioner's consideration of the functional use of the bassinets at issue was not plain error.<sup>11</sup> <u>See Mathews</u>, 283 Va. at 738, 724 S.E.2d at 204.

Lewis-Gale further contends that the Commissioner erred by considering Carilion's 2010 occupancy figures because they were not for the "[r]elevant reporting period," 12 VAC 5-230-10, and were received from Carilion rather than Virginia Health Information (VHI), the body charged with compiling and disseminating health care data, <u>see</u> Code § 32.1-276.4; 12 VAC 5-230-10. The regulations, however, do not support Lewis-Gale's contention.

The SMFP defines the "[r]elevant reporting period," "*when used in this chapter*," as "the most recent 12-month period, prior to the beginning of the applicable batch review cycle, for which data is available from VHI or a demographic entity as determined by the commissioner." 12 VAC 5-230-10 (emphasis added). However, no regulation pertaining to determining whether a COPN for neonatal bassinet space should be issued requires the Commissioner to use data from the "[r]elevant reporting period."<sup>12</sup> Consequently, this definition of "relevant reporting period"

<sup>&</sup>lt;sup>11</sup> Lewis-Gale contends this conflation was error with regard to all four SMFP standards for specialty-level care in 12 VAC 5-230-970. To the extent this argument is relevant to the standards in subsections (B), (C) or (D), we hold the Commissioner did not err in considering the functional capacity of Carilion's subspecialty-level beds under these subsections for the same reasons she did not err in considering them under subsection (A).

<sup>&</sup>lt;sup>12</sup> The neonatal bassinet regulations do not use this term. <u>Compare</u> 12 VAC 5-230-10, 12 VAC 5-230-940 to -1000, <u>and</u> 12 VAC 5-410-443 (establishing definitions and usage standards for issuing COPNs for neonatal special care services without mentioning the "[r]elevant reporting period"), <u>with, e.g.</u>, 25 Va. Reg. Regs. 1706, 1711, 1714-22, 1724-25, 1727, 1729, 1736-37 (Jan. 5, 2009) (revising and re-enacting the SMFP) (directing the use of data for the "relevant reporting period," "when used in this chapter," to provide usage standards for a variety of other types of equipment, services, and beds), <u>and</u> 12 VAC 5-230-10 (defining "bed" as "includ[ing] cribs and bassinets used for pediatric patients" but expressly "[excluding] cribs and bassinets in the newborn nursery or neonatal special care setting").

does not limit the time period for which the Commissioner may consider occupancy data. It also does not limit the Department to considering data only from VHI or a demographic entity as determined by the Commissioner. Finally, no other provision of the SMFP relating to neonatal special care requires reliance on statistics solely from VHI.<sup>13</sup> As a result, the agency had the discretion to rely on the statistical evidence received directly from Carilion. <u>See Fulton</u>, 55 Va. App. at 80, 683 S.E.2d at 842; Loudoun Hosp., 50 Va. App. at 490-91, 650 S.E.2d at 885-86.

In sum, based on the deference owed to the agency's interpretation and application of its regulations, here the SMFP, we hold that the Commissioner did not abuse her discretion by including in her analysis the occupancy rates for both CVBH's specialty-level bassinets and Carilion's subspecialty-level bassinets. This interpretation is consistent with the 2009 amendments to the SMFP because Carilion's subspecialty bassinets were functionally able to provide specialty-level care. Further, we hold that the Commissioner's consideration of data covering multiple years and received from sources other than VHI, some of which was provided directly by Carilion, was not plain error. Finally, we hold that substantial evidence supports the Commissioner's finding that these existing bassinets had occupancy rates significantly below the recommended level of 85%.

# b. Subsection (B): Eighteen-Bassinet Minimum Standard

Lewis-Gale proposed a NICU of eight specialty-level bassinets, despite the fact that the SMFP provides that the minimum number of bassinets for specialty-level or subspecialty-level care should be eighteen. Lewis-Gale's justification for asking the Commissioner to disregard

<sup>&</sup>lt;sup>13</sup> The only parts of the SMFP requiring the use of VHI statistics relate to: surgical operating rooms, 12 VAC 5-230-500; medical/surgical beds, 12 VAC 5-230-540; pediatric beds, 12 VAC 5-230-550; intensive care beds, 12 VAC 5-230-660; nursing home beds, 12 VAC 5-230-610, -620; and rehabilitation beds, 12 VAC-230-810. As stated *supra* in footnote 12, the SMFP's definition of "bed" expressly excludes "cribs and bassinets in the newborn nursery or neonatal special care setting." 12 VAC 5-230-10.

this requirement is that "no specialty-level NICUs in Virginia... meet this standard" because the Commissioner has not previously enforced it. As already discussed, however, the Commissioner's prior deviation from the SMFP does not require her to deviate in this instance as long as that action is not arbitrary or capricious. See NRV Real Estate, 278 Va. at 188, 677 S.E.2d at 280. As the AO concluded, the creation of "yet another" small specialty-level NICU, in close proximity to a subspecialty-level NICU, "would tend to cut against the quality-based benefits of a larger, well-utilized service." The 2009 amendments to the SMFP, which increased the recommended minimum number of neonatal bassinets operated by a particular facility from fifteen bassinets of all levels combined to eighteen bassinets of either the specialty or subspecialty category, follow this same theory that a larger number of NICU bassinets in a single facility supports proficiency and quality of care. See Ann. Rep., supra, at 17 (noting that "[a] well-trained and experienced staff is critical to the success of [specialty-level and subspecialty-level NICU] programs"). The Commissioner opined that "sufficient volume would not exist to support proficiency and quality [of care at Lewis-Gale]." She also concluded that granting the application would "stand[] to harm" the quality of such care at Carilion, the only regional provider of subspecialty care, which was already experiencing a sharp decline in occupancy due to a decrease in premature births in the region. Given the demonstrated lack of need for additional bassinets and the potential for harm that authorizing such bassinets could cause, the record does not support deviation below the eighteen-bassinet minimum. Therefore, the Commissioner's refusal to deviate from this minimum requirement, despite having done so in earlier cases, was not arbitrary or capricious.

# c. Subsection (C): Four Specialty-Level Bassinets Per 1,000 Births Standard

Subsection (C) of the regulation states that "[n]o more than four bassinets for specialty[-]level newborn services . . . per 1,000 live births should be established in each health

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planning region." 12 VAC 5-230-970(C) (emphasis added). The subsection, through its plain language, provides a maximum rather than a minimum figure. Therefore, even assuming that Lewis-Gale's COPN application was consistent with this subsection in that it would not result in more than four specialty-level bassinets per 1,000 live births, such consistency is only one component of the SMFP analysis and does not compel the issuance of the requested COPN.

Lewis-Gale argues that if the Commissioner properly considered Carilion's thirty existing subspecialty-level bassinets along with CVBH's specialty-level bassinets, which we have held was not error, these figures still permit the addition of seven specialty-level bassinets. Lewis-Gale's application, however, requested eight bassinets. The request for eight bassinets, therefore, is inconsistent not only with the subsection (B) requirement that specialty-level newborn services should contain a minimum of eighteen bassinets but also with the capacity of seven bassinets under subsection (C). See Mathews, 283 Va. at 738, 724 S.E.2d at 204.

Consequently, the finding that Lewis-Gale's application was inconsistent with subsection (C) requirements was not plain error.

### d. Subsection (D): No Significant Reduction in Service Volumes of Existing Providers

Subsection (D) of the regulation provides that "[p]roposals to establish specialty[-]level services . . . shall demonstrate that service volumes of existing specialty[-]level newborn service providers located within ['90 minutes driving time one way under normal conditions'] will not be significantly reduced." 12 VAC 5-230-970(D); <u>see</u> 12 VAC 5-230-940(B) (ninety-minute travel time limit incorporated by reference). This subsection places the burden of proof squarely upon the applicant. In addition, it requires that the applicant "*shall* demonstrate" that no significant reduction in existing specialty-level service volumes will result. 12 VAC 5-230-970(D) (emphasis added). This language stands in marked contrast to the permissive

language "should achieve," "should contain," and "should be established," as used in subsections (A), (B), and (C) of the regulation, respectively. 12 VAC 5-230-970.

Lewis-Gale avers that the Commissioner "grossly exaggerates the potential impact" of its proposed eight NICU bassinets on Carilion. It contends, based on its own occupancy projections, that Carilion would continue to be the third-largest provider of NICU services in the state "even in the unlikely event that Lewis-Gale's NICU volume [was] taken entirely from Carilion." It also points to the DCOPN's statement that it is "unable to quantify the negative impact" that granting Lewis-Gale's application would have on Carilion.

Lewis-Gale, in making these claims, fails to acknowledge key facts in the record. The vast majority of Lewis-Gale's patients needing neonatal special care services are transferred to Carilion, and no competition exists for Carilion's specialty-level NICU services because the next closest specialty-level provider is located sixty miles away.<sup>14</sup> Lewis-Gale's COPN application projects an increase in obstetrical admissions and deliveries. The DCOPN observed, however, that "[s]ince the applicant has presented no *new* source of obstetric admissions, this increase could only come at the expense of existing providers." (Emphasis added). The reasonable inference from this evidence is that Lewis-Gale would obtain the specialty-level infants it would treat entirely at the expense of Carilion.

Lewis-Gale's claim that Carilion would continue to remain the third largest provider of NICU services in Virginia, if accurate, nevertheless is not dispositive of the subsection (D) requirement that Lewis-Gale "shall demonstrate" that service volumes at Carilion "will not be significantly reduced" by its project. Lewis-Gale posits that its projected numbers would take no

<sup>&</sup>lt;sup>14</sup> The DCOPN report indicates that, of the fifty-four infants requiring transfers from Lewis-Gale between 2007 and June 2010, fifty-two of them, or 96.3%, were transferred to Carilion. During that same period of time, infants from three other HCA network hospitals in the same health planning region transferred fifty-seven infants for special care, and fifty-three of them, or 93%, were transferred to Carilion. No infants were transferred to Lynchburg's CVBH.

more than 5% of Carilion's neonatal special care patients. The evidence in the record, however, supports the finding, made by the DCOPN and adopted by the AO and the Commissioner, that approving Lewis-Gale's project would adversely affect Carilion's "[sub]specialty [and] specialty[-]level nursery program." The DCOPN noted that Carilion's program "has seen a significant decline in census since 2008 (85.6%) to 61.5% projected in 2010." It also noted that Lewis-Gale's proposed addition of eight specialty-level bassinets of its own "poses a risk of further reducing utilization of existing [NICU] services" at Carilion. The DCOPN further opined that allowing Lewis-Gale to introduce specialty-level bassinets "at this time would compromise [Carilion's] role and major investment" in being the regional perinatal center or, in post-2009 amendment language, the sole provider of subspecialty-level services in the health planning region.

Consequently, because subsection (D) places the burden on Lewis-Gale to demonstrate that its project will not significantly reduce the number of patients receiving specialty-level services at Carilion, the DCOPN's inability to quantify the impact on Carilion with precision is not determinative of the Commissioner's assessment of the project for consistency with subsection (D). Instead, this evidence supports the Commissioner's finding that Lewis-Gale failed to prove that its proposed NICU would not significantly reduce Carilion's volume of specialty-level care. Thus, the evidence also supports her finding that the COPN application was inconsistent with this provision of the SMFP.<sup>15</sup>

<sup>&</sup>lt;sup>15</sup> The Commissioner suggested that Lewis-Gale apply instead for a COPN to offer intermediate-level neonatal care, for which the regulations permitted a minimum of six bassinets and did not require proof of a lack of significant impact on existing area providers of the same level of service. <u>See</u> 12 VAC 5-230-960. The Commissioner avers on brief that if Lewis-Gale operated a "busy" intermediate-level neonatal program, this fact could provide a reasonable basis for her to conclude that an advancement in service level was appropriate. Lewis-Gale concluded this suggestion was "not viable" and declined to follow it.

## 3. Substantial Evidence to Support the Denial

Lewis-Gale contends in its final assignment of error that the record contains substantial evidence compelling the Commissioner to issue the requested COPN and that the circuit court erred in holding to the contrary. Code § 32.1-102.3(B) requires consideration of whether the project: (1) increases access to needed services; (2) meets community needs as demonstrated by factors such as community support, reasonable alternatives, costs and benefits, and financial accessibility to residents; (3) is consistent with the SMFP; (4) fosters institutional competition while improving health care access; (5) improves utilization and efficiency of existing services; (6) is feasible in financial and human resources terms; (7) provides improvements or innovations in financing and delivering health care; and (8) positively impacts a teaching hospital or medical school or is positively impacted by the hospital or school in terms of the delivery of health care. The Commissioner is not required to award a COPN if the applicant has failed to demonstrate a public need based on any of these factors. See Sentara Norfolk Gen. Hosp., 260 Va. at 273, 534 S.E.2d at 329. Contrary to Lewis-Gale's assessment, we conclude that the record contains substantial evidence to support the Commissioner's decision to deny the COPN. This conclusion is based on the lack of consistency with the SMFP and several of the remaining statutory factors.

## a. Factor (3): Consistency with the SMFP

The Commissioner did not err in concluding that the proposed project is not consistent with the SMFP. As previously discussed, <u>see supra</u> Part II.C.2, substantial evidence supports the finding that "reasonable availability and access to special care nursery services exists in the [health planning region], especially within the service areas of both [Lewis-Gale] and Carilion" as judged under the standards of 12 VAC 5-230-970(A) to (D).

First, despite Lewis-Gale's claim that existing specialty-level bassinets met the 85% minimum occupancy standard which, if substantiated, could support the claim of need for

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additional bassinet space, the record supports the finding that the availability of subspecialty-level bassinet space met the region's *functional need* for specialty-level space. This evidence, in turn, supports the finding that granting Lewis-Gale's application to add specialty-level bassinet space would be inconsistent with subsection (A).

Second, Lewis-Gale concedes that its application for eight bassinets was inconsistent with the subsection (B) requirement that specialty-level newborn services should contain a minimum of eighteen bassinets. Although Lewis-Gale contended that "no specialty-level NICUs in Virginia . . . meet this standard," all specialty-level NICUs were licensed prior to the 2009 amendments.<sup>16</sup> Further, the AO concluded that "[r]egardless, the creation of yet another small special[ty-]level NICU, in close proximity to a subspecial[ty-]level NICU, would tend to cut against the quality-based benefits of a larger, well-utilized service." The evidence supports this finding that Lewis-Gale failed to meet the subsection (B) requirement in both fact and spirit.

Third, the evidence supports a finding that Lewis-Gale's application was also inconsistent with the subsection (C) provision that a health planning region should have no more than four bassinets per 1,000 live births for each level of care. Lewis-Gale concedes that considering the functional use of Carilion's subspecialty-level bassinets in this calculation supports a need for no more than seven additional specialty-level bassinets. Given that Lewis-Gale's application is for eight and that the SMFP suggests a minimum of eighteen bassinets for the creation of a neonatal special care nursery, substantial evidence supports a finding that Lewis-Gale's application was also inconsistent with this standard of the SMFP.

<sup>&</sup>lt;sup>16</sup> Sentara's Princess Anne Hospital in Virginia Beach received a COPN for eight specialty-level bassinets in 2010. However, this COPN merely permitted the relocation of eight existing bassinets from another of Sentara's hospitals in Virginia Beach. <u>See supra</u> note 4 and accompanying text.

Fourth, the evidence supports a finding that Lewis-Gale failed to prove under subsection (D) that no significant reduction in existing specialty-level services would result from its proposal. The evidence showed that Carilion provided both specialty-level and subspecialty-level care in its subspecialty bassinets. The DCOPN found that the number of specialty-level patients at Carilion was increasing in proportion to the subspecialty patients. Statistics also showed that virtually all of Lewis-Gale's patients in need of neonatal special care were then being referred to Carilion for treatment. Despite this dual usage of Carilion's subspecialty bassinets and the number of referrals received from Lewis-Gale, occupancy rates for Carilion's subspecialty bassinets had dropped more than twenty percentage points below the SMFP's 85% mark. Lewis-Gale's plan to retain all but its subspecialty-level infants and to attract additional obstetrics patients without identifying any new source for them virtually assured a negative impact on Carilion's already declining statistics.

# b. Factors (1), (2), and (4) to (8): Broader Assessment of the Existence of Public Need

In addition to the statutory criterion requiring consistency with the SMFP, the Commissioner determined that several of the seven remaining factors in Code § 32.1-102.3(B) also weighed against a finding of public need. Substantial evidence in the record supports that determination. Although the Commissioner was not required to make specific findings with regard to the eight statutory criteria for assessing public need, she adopted the detailed discussion and findings of the AO and, in addition, provided a summary of the basis for her decision.

The Commissioner found that "[d]espite many expressions of community support," the project would "unnecessarily duplicate existing services, such as those at Carilion." Although this duplication would introduce competition and provide parents with a choice of providers, she determined that the negative effects of duplication would outweigh its benefits. She found that both services "depend on sufficient volume in order to maintain [the] clinical proficiency"

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necessary to provide "exacting clinical care . . . to frail infants." As a result, she concluded that duplication would "exert[] an adverse impact on the utilization and quality" of both the existing services at Carilion and the proposed services at Lewis-Gale. These findings are supported by evidence in the record. That evidence includes scholarly studies regarding proficiency in subspecialty-level care, which the Department has also applied to specialty-level care. <u>See Ann.</u> <u>Rep.</u>, <u>supra</u>, at 17. It also includes statistics showing a decline in the need for NICU care (specialty and subspecialty) in the health planning region. This decline reduced Carilion's subspecialty-level bassinet occupancy by twenty-five percentage points from previous years and more than twenty percentage points below the level recommended by the SMFP for introducing new special care services. This evidence negates a finding of public need under factors (1), (2), (4), and (5).

The Commissioner also found that the project would reduce the frequency and duration of medical transportation for only some of the infants in the Lewis-Gale system of hospitals those actually delivered at Lewis-Gale—and the record shows this would likely be fewer than half the total number of infants delivered at HCA hospitals who needed neonatal special care.<sup>17</sup> These findings contribute to the determination of lack of public need under factors (1), (2), and (5).

Additionally, in keeping with Lewis-Gale's representations in its application, the Commissioner found that the project would result in a financial loss for at least two years. The Commissioner also questioned whether it would ever be economically viable or capable of

<sup>&</sup>lt;sup>17</sup> The evidence showed that over the forty-two-month period prior to Lewis-Gale's application, it transferred almost exactly the same number of patients to Carilion as HCA's other three regional hospitals did in combination. If Lewis-Gale's COPN application were granted, the infants delivered at the other HCA hospitals would still require transfer, as would all infants delivered at Lewis-Gale needing subspecialty-level care. Therefore, the number of infants needing transfer would still be greater than half those delivered at HCA's four area hospitals.

maintaining a sufficiently skilled staff. The evidence in the record supports these concerns. As the Commissioner observed, Lewis-Gale provided no evidence of any new source of obstetric admissions, and the Commissioner concluded that it was "evident from the applicant's projections . . . of obstetrical discharges . . . that it anticipate[d] that approval of the proposed project [would] increase its obstetrical market share, primarily by reallocating admissions from Carilion . . . to [Lewis-Gale]." The Commissioner's concerns regarding economic viability and skill proficiency are supported by the record and demonstrate a lack of public need under factors (2) and (6).

The record shows that the Commissioner, in addition to considering consistency with the SMFP as required by subsection (3) of Code § 32.1-102.3(B), also considered the other statutory factors. Substantial evidence in the record supports the Commissioner's determination, made in the exercise of her expert discretion, that the application was inconsistent with both the SMFP and non-SMFP factors. Accordingly, the Commissioner did not err in her application of the law or abuse her discretion in concluding that Lewis-Gale failed to demonstrate a public need for its proposed project.

#### III.

For these reasons, we hold that the circuit court did not err in rejecting Lewis-Gale's claims and concluding that the Commissioner (1) adequately explained her deviations from prior agency decisions; (2) applied proper legal standards and did not arbitrarily treat Lewis-Gale differently from other hospitals in the Commonwealth; (3) properly applied the SMFP calculations; and (4) reached a decision regarding the existence of public need that was supported by substantial evidence in the record. Therefore, we affirm the circuit court's ruling.

### Affirmed.