COMMONWEALTH of VIRGINIA
Department of Health
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M. Norman Oliver, MD, MA
State Health Commissioner

TTY 7-1-1 OR
1-800-828-1120

January 6, 2020

Thomas J. Stallings, Esquire
McGuire Woods, LLP
800 East Canal Street
Richmond, Virginia 23219

RE: Request for Reconsideration of December 13, 2019, Case Decision
REQUEST NUMBER VA-8391
LewisGale Medical Center, LLC
Salem, Planning District (PD) 5
Introduction of Neonatal Special Care Services

Dear Mr. Stallings:

As indicated in my December 20, 2019, letter to you, I have reconsidered the above matter in response to your request. In accordance with Article 1.1 of Chapter 4 of Title 32.1 (§ 32.1-102.1 *et. seq.*) of the Code of Virginia, I have reviewed the application captioned above and the record compiled in relation to the project proposed in that application. As required by Subsection B of Virginia Code § 32.1-102.3, I have considered all matters that must be taken into account in making a determination of public need.

I have received and reviewed the findings, conclusions, and recommended decision of the adjudication officer who convened the informal fact-finding conference to discuss the application and who reviewed the administrative record pertaining to the proposed project. I also have reviewed the staff recommendations of the Division of Certificate of Public Need (DCOPN). I decline to adopt either recommendation in its entirety. Instead, I find that a public need for the project has not been demonstrated for the reasons stated below.

I. The project is not consistent with the State Medical Facilities Plan ("SMFP").

In order for a project to be approved, it must be consistent with the most recent applicable provisions of the SMFP. Va. Code § 32.1-102.3(A). After review of the record, including your December 18, 2019, letter, I find that the proposed project is not consistent with the SMFP.

A. Driving Time

Pursuant to 12VAC-230-940(B), specialty and subspecialty neonatal special care services should be located within 90 minutes driving time one way under normal conditions of hospitals providing general or intermediate level newborn services using mapping software as determined by the Commissioner. This standard is already met. Approval of the proposed project would not significantly increase access in this manner.

B. Need for New Services

Pursuant to 12VAC5-230-970(A), existing specialty level newborn services as designated in 12VAC5-410-443 should achieve 85% average annual occupancy before new specialty level newborn services can be added to the health planning region. I acknowledge that the definition of "beds" in the SMFP excludes bassinets, that bassinets are not COPN-approved or otherwise licensed as to the number of bassinets, that hospitals may increase or decrease the number of bassinets at will, and that the availability and occupancy of existing bassinets may often be arbitrary. I do not agree necessarily that this renders the SMFP provisions meaningless, but I agree with the general consensus of the DCOPN staff report and the adjudication officer's recommendation that this provision is not instructive in this case.

C. Minimum Size of Unit

The SMFP states that specialty level newborn services as designated in 12VAC5-410-443 should contain a minimum of 18 bassinets. 12VAC-230-970(B). This standard is not met. LewisGale is requesting approval for only an 8-bassinet unit, less than half the required number of bassinets under this provision.

Evidence of record demonstrates that all but 3 of Virginia's 14 existing specialty level units have fewer than 18 bassinets. While true that other projects have been approved with less than 18 bassinets, those projects are distinguishable from the current application. Specifically, the projects at St. Francis and Chesapeake were approved in 2006 and 2007 before the COPN laws underwent significant change in 2009. The Sentara Princess Anne project, approved in 2010, was a relocation of an existing service at Sentara Virginia Beach General Hospital.

Moreover, the creation of a small, specialty level neonatal service, when established specialty and sub-specialty neonatal services are located just 15 minutes away, tends to cut against the quality-based benefits of the services at that location. Notably, those nearby services have available an average of 18 specialty care bassinets on a daily basis. Neonatal services, as they progress in acuity and level, are highly utilization sensitive. Unnecessary addition of services, despite any other benefits the project may have, could have a harmful effect on the quality of services available and provided.

D. Effect on Existing Services

The SMFP states that proposals to establish specialty level services as designated in 12VAC5-410-443 shall demonstrate that service volumes of existing specialty level newborn service providers located within the travel time listed in 12VAC5-230-940 will not be reduced significantly. 12VAC-230-970(D). I find that the record demonstrates there will be some reduction in both obstetrical and neonatal admissions. The DCOPN staff report noted concerns that utilization at Carilion Roanoke Memorial Hospital would be impacted negatively, such that it will experience a decline in both specialty and intermediate level admissions.

For the reasons discussed, I find that the proposed project is not consistent with the guiding principles of the SMFP; and, therefore, the application for the proposed project must be denied. Va. Code § 32.1-102.3(A). It is not necessary to address the remaining statutory factors; but for the sake of clarity, I will address the other reasons I find that a public need does not exist for the proposed project.

II. There is no public need for the proposed project.

A. The project will not increase access to needed services.[1]

Carilion Roanoke Memorial Hospital is recognized as the regional perinatal center in southwestern Virginia and is equipped, staffed, and organized to provide 60 subspecialty level nursery bassinets. It has available an average of 18 specialty care bassinets on a daily basis. It is located just 15 minutes from LewisGale Medical Center.

Approval of the project would increase the number of women with high-risk pregnancies who could be admitted to their facility. These women, however, have access to a facility 15 minutes away that can provide both high-risk obstetrical and subspecialty neonatal care. The argument that health outcomes would improve with approval of the project is not substantiated with objective data. The studies and reports cited by LewisGale, as well as the anecdotal evidence of record, is not persuasive enough to rebut the fact that sufficient services exist only 15 minutes from the site of the proposed project. Additionally, while approval of the project could decrease transfers for some LewisGale Medical Center patients, it could increase transfers for patients at other hospitals. A nearby hospital without specialty services could transfer its patient to LewisGale Medical Center but then require a second transport to Carilion Roanoke Memorial Hospital should the patient's condition deteriorate.

[1] Va. Code § 32.1-102.3(B)(1).

B. The needs of the residents are met already.[2]

The proposed project has ample public support and no known opposition. The record includes letters of support from constituents, Virginia Senate members, Virginia House of Delegates members, and other local leaders. The neonatologists who currently staff Carilion Roanoke Memorial Hospital's subspecialty level services also support the project. These facts, while helpful in gauging public opinion, are not dispositive of a public need determination.

The adjudication officer noted that legislation was introduced recently to the General Assembly regarding specialty level neonatal care services in Planning District 5.[3] The Commissioner notes the proposed legislation; but it, too, is not dispositive in the public need determination.

A reasonable alternative exists to the proposed project. Despite a history of a recent bad outcome, the status quo is a reasonable alternative. Carilion Roanoke Memorial Hospital is only 15 minutes away and offers both specialty and subspecialty level services.

The applicant argues that offering specialty level at its facility would avoid the stress of transport to Carilion Roanoke Memorial Hospital. The applicant submitted evidence that infants often suffer both long- and short-term effects from separation from their mothers and neonatal handling and that infants have better outcomes due in part to skin-to-skin contact with the mother immediately after birth. It is true that an infant in an in-house neonatal intensive care unit has an increased chance of bonding opportunities with the mother. These benefits, however, would apply only to patients born at LewisGale Medical Center if the project is approved.

Evidence of record demonstrates that the LewisGale Medical Center's amount of charity care was just 1.10% in 2016, less than half the regional average of 2.8%. It appears that the applicant would agree to a charity care condition.

I also note the shift in position of the regional perinatal care center at Carilion Roanoke Memorial Hospital. The applicant has sought the introduction of specialty care services for several years, and each time the application has been opposed by that group. Carilion Roanoke Memorial Hospital does not, however, oppose the current proposal; and it also would staff the unit at LewisGale Medical Center, if approved. As stated previously, this fact is helpful in gauging public opinion but is not dispositive to the public need determination. Overall, I do not find any other factors remarkable enough to warrant using my discretion to grant the COPN.

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[2] Va. Code § 32.1-102.3(B)(2).

[3] The adjudication officer stated that the bill was passed by the House of Delegates and continued into 2019. For clarity, the Commissioner notes that the bill did not pass, but was "passed by," i.e., continued to the next session.

C. The project does not provide any cooperative efforts to meet regional health care needs.[4]

The fact that LewisGale Medical Center would contract with the same third-party company as Carilion to obtain neonatologists does not signify cooperative efforts to meet regional health care needs.

D. Overall, any benefits of the project are insufficient to demonstrate a public need for the project.

I generally agree with the adjudication officer's findings as to statutory factors 4, 5, 6, and 8. Va. Code § 32.1-102.3(B). Approval of the project would introduce institutional competition between LewisGale Medical Center and Carilion Roanoke Memorial Hospital.[5] The proposed project would reduce somewhat the number of admissions to Carilion Roanoke Memorial Hospital, but this would not reduce staff proficiency because the newborns would be cared for by the same neonatology physicians group.[6] The cost of the project is reasonable.[7] The project could present a site for educational opportunities because a member of the neonatology physician group is an assistant professor at Virginia Tech Carilion School of Medicine.[8]

Despite these benefits, the applicant does not demonstrate a public need for the project. These benefits do not outweigh the concerns regarding consistency with the SMFP, whether services are needed, and reasonable alternatives to the project.

III. Conclusion

Based on my review of the project, I am denying the project proposed by LewisGale Medical Center, LLC. The applicant has not demonstrated a public need for the project:

1. The proposed project is not consistent with the SMFP;
2. The project would enhance the applicant's ability to increase its obstetrical admissions; however, this fact is not equivalent to increasing accessibility to specialty care for either women with high-risk pregnancies or their infants; and
3. The status quo is a reasonable alternative.

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[4] Va. Code § 32.1-102.3(B)(7).
[5] Va. Code § 32.1-102.3(B)(4).
[6] Va. Code § 32.1-102.3(B)(5).
[7] Va. Code § 32.1-102.3(B)(6).
[8] Va. Code § 32.1-102.3(B)(8).

In accordance with Rule 2A:2 of the Rules of the Supreme Court of Virginia, any aggrieved party to an administrative proceeding choosing to appeal a case decision[9] shall file, within 30 days after service of the case decision, a signed notice of appeal with "the agency secretary." I would consider such a notice sufficiently filed if it were addressed and sent to the Office of the State Health Commissioner, and timely received by that office, at the James Madison Building, Thirteenth Floor, 109 Governor Street, Richmond, Virginia 23219. Under the rule, when service of a decision is "accomplished by mail," 3 days are added to the 30-day period.

Sincerely,

M. Norman Oliver MD

M. Norman Oliver, MD, MA
State Health Commissioner

cc: Stephanie Harper, MD, MPP, Director, Alleghany Health District
Vanessa MacLeod, Esq., Assistant Attorney General
Deborah Waite, Virginia Health Information
Erik O. Bodin, III, Director, Division of COPN
Douglas R. Harris, JD, Adjudication Officer

[9] In accordance with Va. Code § 2.2-4023, the signed original of these final agency case decisions "shall remain in the custody" of the Department, while the applicants receive a photocopy of the original case decision letter.