VIRGINIA DEPARTMENT OF HEALTH

Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis

April 21, 2021

RE: COPN Request No. VA-8545
LewisGale Medical Center, LLC d/b/a LewisGale Medical Center
Salem, Virginia
Introduce Neonatal Special Care Services at the Intermediate Level with 6 Bassinets

Applicant

LewisGale Medical Center, LLC, doing business as LewisGale Medical Center (LGMC), is a Delaware domiciled, for-profit, Limited Liability Company. LGMC was organized in November 1998 and its sole member is LewisGale Hospital, Inc. The ultimate parent of LewisGale Hospital, Inc. is HCA Healthcare, Inc. (HCA). LGMC's sole subsidiary is Daleville Imaging Manager, LLC. LGMC is located in the independent city of Salem, in Planning District (PD) 5, within Health Planning Region (HPR) III.

Background

LGMC is a 506-bed acute care hospital located in Salem, Virginia. LGMC provides a full array of diagnostic, therapeutic, surgical, and palliative care services. LGMC serves as the regional referral center for the LewisGale Regional Health System (LG Health System), which is a comprehensive healthcare network that stretches from the Alleghany Highlands and Rockbridge County to the Roanoke and New River Valleys and includes four hospitals, two regional cancer centers, six outpatient centers, and a freestanding emergency department.

As **Table 1** demonstrates, within HPR III, there are five neonatal special care providers with services ranging from intermediate, to specialty, to subspecialty levels of care. In total, these service providers reported a 2019 inventory of 82 bassinets to Virginia Health Information (VHI).

The Division of Certificate of Public Need (DCOPN) notes that bassinets within certificate of public need (COPN) approved special care nurseries may be utilized interchangeably at their approved level or at a lower level, but not at a higher level than approved within that facility. Bassinets are not licensed beds and authorized facilities can change the number of bassinets at will.

As may be observed in **Table 1** below, special care nursery utilization has been consistently high at Centra Virginia Baptist Hospital and moderate at Carilion Roanoke Memorial Hospital (CRMH).

With regard to intermediate-level special care services, utilization has historically been moderate at Carilion New River Valley, but significantly lower at LewisGale Hospital Montgomery and Johnston Memorial Hospital. DCOPN observes that while the collective occupancy percentage of all the neonatal special care facilities within HPR III exhibited an increase from 2015 to 2018, occupancy percentages dropped at every HPR III facilities but LewisGale Hospital Montgomery in 2019 and 2019.

Table 1. Special Care Nursery Inventory and Utilization: HPR III 2015-2019

Facility (COPN Approved Bassinet Level)	Staffed Bassinets	2015	2016	2017	2018	2019	Facility Average
Johnston Memorial Hospital (Intermediate)	4	9.7%	12.6%	14.0%	8.0%	4.0%	9.6%
Carilion New River Valley dba St. Albans (Intermediate)	4	67.2%	67.1%	88.6%	82.1%	63.7%	73.7%
LewisGale Hospital Montgomery (Intermediate)	1	3.6%	13.1%	12.3%	6.6%	11.0%	9.3%
Carilion Roanoke Memorial Hospital (Subspecialty)	60	67.0%	69.3%	67.1%	75.3%	61.3%	68.2%
Centra Virginia Baptist Hospital (Specialty)	13	87.5%	80.7%	87.0%	84.7%	67.4%	81.5%
Total and Average	**82**	**66.7%**	**67.5%**	**68.0%**	**73.0%**	**59.0%**	**66.9%**

Source: VHI Data (2015-2019)

As demonstrated in **Table 2**, LGMC is among the top four providers of obstetric services in HPR III (based on facility averages for 2015-2019), and is the second largest provider in PD 5. LGMC and CRMH are presently the only providers of obstetric services in PD 5.

Table 2. HPR III Births: 2015-2019

Facility	PD	2015	2016	2017	2018	2019	Facility Average
Norton Community Hospital	1	220	216	156	161	154	**181**
Wellmont Lonesome Pine Mt. View Hospital	1	255	253	234	146	161	**210**
Clinch Valley Medical Center	2	336	300	291	282	259	**294**
Johnston Memorial Hospital	3	543	527	452	462	411	**479**
Twin County Regional Hospital	3	279	246	190	193	225	**227**
Wythe County Community Hospital	3	301	316	353	365	339	**335**
Carilion New River Valley dba St. Albans	4	1,186	1,189	1,095	998	844	**1,062**
LewisGale Hospital Montgomery	4	434	445	508	521	523	**486**
Carilion Medical Center	5	3,117	3,159	3,056	3,117	3,186	**3,127**
LewisGale Medical Center	5	994	954	922	901	975	**949**
Centra Health	11	2,671	2,613	2,693	2,679	1,961	**2,523**
Sovah Health-Danville	12	772	689	687	669	632	**690**
Sovah Health-Martinsville	12	401	370	324	293	320	**342**
Total		**11,509**	**11,277**	**10,961**	**10,787**	**9,990**	
Average		**885**	**867**	**843**	**830**	**768**	

Source: VHI Data 2015-2019

As **Table 3** demonstrates, LGMC is an existing provider of obstetrical services and is licensed to operate 23 obstetric beds, but reported staffing only seven obstetric beds in 2019.[1] In 2019, LGMC reported 975 births, which is approximately a 2% decrease from what the facility reported in 2015, but an approximate 8% increase from what the facility reported in 2018 (901 births). The occupancy data from 2015-2019 demonstrates a consistently poor obstetric occupancy rate at LGMC.

Table 3. LGMC Obstetric Occupancy: 2015-2019

	2015	2016	2017	2018	2019
Births	994	954	922	901	975
OB Patient Days	2,486	2,553	2,360	2,356	2,573
OB Occupancy	29.6%	30.3%	28.1%	28.1%	30.7%

Source: VHI Data 2015-2019

Proposed Project

LGMC proposes to expand on its existing obstetric service through the introduction of intermediate-level neonatal special care services with six intermediate-level bassinets. LGMC currently operates a general newborn level nursery with six bassinets. The applicant states that the project is a "low-cost, modest proposal to expand on an existing service: newborn care." The applicant further states that "The benefits [of this project] will be enormous: the addition of neonatal special care will promote

[1] VHI bed usage data, 2019.

continuity of care, create better patient outcomes, reduce costs due to transfer, and help keep new families together during an already challenging time."

12VAC5-410-443 B.2 designates that an intermediate level newborn service "…shall provide care as specified within the service's medical protocol to moderately ill neonates or stable-growing low birthweight neonates who require only a weight increase to be ready for discharge. In addition to the capabilities required of the general level newborn nursery, the intermediate level nursery shall have the equipment and staff capabilities to provide controlled temperature environments for each neonate, the insertion and maintenance of umbilical arterial lines, hood oxygen to 40%, continuous monitoring of blood oxygen, and assisted ventilation of a neonate in preparation for transport utilizing a mechanical ventilator or an ambu bag."

The applicant anticipates construction for the proposed project to begin within seven months of COPN issuance and to be complete within 18 months of COPN issuance. The applicant projects a target date of opening within 19 months of COPN issuance. The projected capital costs for the proposed project total $1,369,262 (**Table 4)**, the entirety of which will be funded using the accumulated reserves of the applicant. Accordingly, there are no financing costs associated with this project.

Table 4. Capital and Financing Costs

Direct Construction	$845,000
Equipment Not Included in Construction Contract	$416,262
Off-site Costs	$32,000
Architectural and Engineering Fees	$76,000
Total Capital Costs	**$1,369,262**

Source: COPN Request No. VA-8545

Project Definition

§32.1-102.1:3 of the Code of Virginia (the Code) defines a project, in part, as the... "Introduction into an existing medical care facility described in subsection A of any new…neonatal special care." Medical care facilities are further defined, in part, as "Any facility licensed as a hospital, as defined in § 32.1-123."

Required Considerations -- § 32.1-102.3, of the Code of Virginia

In determining whether a public need exists for a proposed project, the following factors shall be taken into account when applicable.

1. The extent to which the proposed project will provide or increase access to health care services for people in the area to be served and the effects that the proposed project will have on access to health care services in areas having distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to health care;

As displayed in **Tables 2 and 3**, LGMC is an existing provider of obstetrical services with 23 obstetric beds. The applicant requests to expand on this existing service through the introduction of intermediate-level neonatal special care services with six intermediate-level bassinets.

Geographically, LGMC is located at 1900 Electric Road in Salem, Virginia and is readily accessible to residents of PD 5. LGMC is accessible from the Valley Metro Bus Line and by area cab companies. These carriers connect to the area's major train, bus, and airline routes. The hospital is also accessible via highway from Interstate 81 and Route 220 via Route 419. LGMC also has an FAA-listed heliport pad on site to receive patients via helicopter transport in emergencies. As will be discussed in more detail later in this staff analysis report, DCOPN concludes that intermediate-level neonatal services currently exist within 30 minutes driving time one way under normal conditions of hospitals providing general level new born services. Accordingly, DCOPN contends that approval of the proposed project will not improve geographic access to intermediate-level neonatal services for the residents of HPR III or PD 5 in any meaningful way. However, the applicant states that notwithstanding this geographical accessibility, the availability of neonatal special care services for many of LGMC's patients is dependent on the availability of specialized transport services offered by other providers.

Table 5 shows projected population growth in PD 5 through the year 2030. Overall, the planning district was projected to add only an estimated 139 people in the 10-year period ending in 2020. However, in the 10-year period ending in 2030, the planning district is projected to add an estimated 4,096 people – an approximate 1.5% increase over the ten-year period. Salem, the location of the proposed project, is expected to experience a population increase of approximately 4.6% from 2010 to 2020, and an additional 0.7% from 2020 to 2020 –a rate significantly lower than the statewide average.

Table 5. PD 5 - Population Projections for PD 5, 2010-2030

Locality	2010	2020	% Change 2010-2020	2030	% Change 2020-2030	% Change 2010-2030
Alleghany	16,250	14,950	(8.0%)	13,620	(8.9%)	(16.2%)
Botetourt	33,148	33,387	0.7%	34,484	3.3%	4.0%
Craig	10,380	5,084	(51.0%)	5,020	(1.3%)	(51.6%)
Roanoke County	92,376	94,145	1.9%	97,249	3.3%	5.3%
Covington City	5,961	5,677	(4.8%)	5,281	(7.0%)	(11.4%)
Roanoke City	97,032	100,891	4.0%	102,388	1.5%	5.5%
Salem City	24,802	25,953	4.6%	26,141	0.7%	5.4%
Total PD 5	**279,949**	**280,088**	**0.0%**	**284,184**	**1.5%**	**1.5%**
Virginia	8,001,024	8,655,021	8.2%	9,331,666	7.8%	16.6%

Source: U.S. Census, Weldon Cooper Center Projections (June 2019) and DCOPN (interpolations)

Regarding socioeconomic barriers to access to services, the applicant has provided assurances that it would accept all patients in need of the proposed service without regard to ability to pay or payment source. However, the Pro Forma Income Statement provided by the applicant did not anticipate a projected charity care contribution. DCOPN notes that according to regional and statewide data regularly collected by VHI, for 2019, the most recent year for which such data is available, the average amount of charity care provided by HPR III facilities was 1.6% of all reported total gross patient revenues (**Table 6**). In that same year, LGMC provided 1.0% of its gross patient revenue in the form of charity care—a rate lower than the HPR III average. Furthermore, pursuant to the recent change to §32.1-102.4B of the Code of Virginia, DCOPN is now required to place a charity care condition on all applicants seeking a COPN. Accordingly, should the Virginia State Health Commissioner (Commissioner) approve the proposed project, DCOPN recommends a charity care condition consistent with 1.6% HPR III average. DCOPN notes that its recommendation includes a provision allowing for the reassessment of the charity rate when more reliable data becomes available regarding the full impact of Medicaid expansion in the Commonwealth.

Table 6. HPR III Charity Care Contributions: 2019

Hospital	Gross Patient Revenues	Adjusted Charity Care Contribution	Percent of Gross Patient Revenue:
Carilion Franklin Memorial Hospital	$151,201,325	$6,677,672	4.42%
Dickenson Community Hospital	$25,351,508	$928,420	3.66%
Wellmont Lonesome Pine Mt. View Hospital	$390,073,389	$13,498,881	3.46%
Carilion Tazewell Community Hospital	$62,008,894	$2,071,457	3.34%
Carilion New River Valley Medical Center	$738,306,843	$20,469,127	2.77%
Carilion Medical Center	$4,068,259,340	$105,984,180	2.61%
Carilion Giles Memorial Hospital	$102,107,168	$2,603,534	2.55%
Russell County Medical Center	$124,033,055	$2,964,704	2.39%
Norton Community Hospital	$319,225,076	$6,779,613	2.12%
Smyth County Community Hospital	$213,627,381	$4,308,217	2.02%
Johnston Memorial Hospital	$889,740,579	$17,870,544	2.01%
Bedford Memorial Hospital	$129,289,507	$2,513,096	1.94%
Centra Health	$2,600,865,348	$41,780,244	1.61%
Lewis-Gale Medical Center	$2,121,321,310	$21,145,842	1.00%
LewisGale Hospital -- Montgomery	$658,786,131	$5,276,155	0.80%
LewisGale Hospital -- Pulaski	$339,877,654	$2,029,419	0.60%
Clinch Valley Medical Center	$547,087,883	$3,000,603	0.55%
LewisGale Hospital -- Alleghany	$212,218,793	$1,046,051	0.49%
Twin County Regional Hospital	$257,431,228	$1,068,667	0.42%
Buchanan General Hospital	$101,667,920	$403,430	0.40%
Wythe County Community Hospital	$257,623,709	$406,156	0.16%
Memorial Hospital of Martinsville & Henry County	$736,050,736	$1,113,236	0.15%
Danville Regional Medical Center	$965,570,236	-$15,516,656	-1.61%
Total Facilities Reporting			23
Median			1.9%
Total $ & Mean %	**$16,011,725,013**	**$248,422,592**	**1.6%**

Source: VHI (2019)

Also with regard to socioeconomic barriers to access to services, DCOPN notes that, according to the most recent U.S. Census data, only three localities in PD 5, Botetourt, Roanoke County and the City of Salem, had poverty rates lower than the 10.7% statewide average (**Table 7**). DCOPN notes that nearby Roanoke City, a city within the applicant's primary service area has a poverty rate nearly double that of the statewide average.

Table 7. Statewide and PD 5 Poverty Rates

Locality	Poverty Rate
Virginia	10.7%
Alleghany	11.5%
Botetourt	5.7%
Craig	11.2%
Roanoke County	6.5%
Covington City	13.2%
Roanoke City	20.8%
Salem City	9.1%

Source: U.S. Census Data (census.gov)

2. The extent to which the proposed project will meet the needs of people in the area to be served, as demonstrated by each of the following:

(i) The level of community support for the proposed project demonstrated by people, businesses, and governmental leaders representing the area to be served;

The applicant provided numerous letters of support for the proposed project from medical professionals, elected officials, and members of the public. Collectively, these letters addressed the following:

- While LGMC is a high quality, tertiary-care hospital, it lacks the ability to care for some of its most fragile patients. Infants who require intermediate NICU services must be transferred to another facility. These transfers involve clinical risks and have high emotional costs for new families. The approval of this project would help mitigate additional emotional strains and financial costs for families experiencing what is already an exhausting, stressful, and costly situation. In additional, clinical outcomes are usually improved by keeping new families together.

- The addition of on-site neonatal special care services will improve continuity of care for patients who learn that they have at-risk pregnancies and who might otherwise need to transfer to a different patient care team after several months of pre-natal care with their physicians and nurses.

- Approval of this project would give mothers the option to receive prenatal care at LewisGale and deliver their babies with teams of physicians and other healthcare providers with whom they have an existing relationship, even if their pregnancies are deemed at-risk.

- Approving this project is an essential step toward improving [Salem's] healthcare infrastructure, and would greatly benefit the entire region. Patients and hospitals waste time and money under the current system through costly transports for fragile infants, coordinating the transfer of medical records between facilities, and forcing families to spend time traveling back and forth the different facilities where mother and baby are receiving their care. Patients are, at times, unable to take advantage of negotiated insurance rates by being forced outside of their coverage plans. Ultimately, this economic waste needlessly increases the cost of healthcare for patients, and is not good for the financial health of the Roanoke valley.

- Expectant mothers should be able to rest assured that they and their child can be taken care of in the same facility by the same care team with whom they have developed a relationship. However, expectant mothers who seek care at LGMC are forced to choose between delivering at a facility that cannot provide the basic care their infants might need in an emergency and delivering with a care team that they may not know or want. Families should not be forced to make that choice.

- From a business perspective, approving this application would help to improve the healthcare infrastructure in the region, drawing in more families and quality employees. This would, in turn, help to drive positive economic growth in the entire region.

- Approval of this project would create another point of referral and is expected to increase inter-system efficiency for referrals among the HCA Virginia community hospitals. Quality healthcare is essential to the economic growth of communities in southwestern Virginia.

DCOPN did not receive any letters expressing opposition to the proposed project, nor is it aware of any opposition to the proposed project. DCOPN further notes that the applicant did not request a public hearing for this project, nor did any member of the public or elected official, and accordingly, no public hearing was held.

(ii) The availability of reasonable alternatives to the proposed project that would meet the needs of the people in the area to be served in a less costly, more efficient, or more effective manner;

The applicant has not identified any reasonable alternatives to introducing intermediate-level neonatal special care services at LGMC. The applicant has demonstrated that Perinatal Region 1, which encompasses southwest Virginia, consists of one subspecialty-level, one specialty-level, and three intermediate-level providers of neonatal special care services.

However, as will be discussed in greater detail throughout this staff analysis report, the State Medical Facilities Plan (SMFP) directs that intermediate level neonatal special-care services should be located within 30-minutes driving time, one way, under normal conditions, of hospitals providing general level newborn services. As demonstrated in **Table 8** and **Figure 1**, Carilion Roanoke Memorial Hospital (subspecialty-level) is the only facility within a 30-minute drive of

LGMC that provides intermediate-level neonatal special-care services. With a drive time of 16 minutes, Carilion Roanoke Memorial Hospital is a reasonable alternative to the proposed project per the drive-time standard of the SMFP.

Table 8. Travel Time and Distance from LGMC

Facility (COPN Approved Bassinet Level)	Travel Time (Minutes)	Travel Distance (Miles)
Carilion Roanoke Memorial Hospital (Subspecialty)	16	6.6
LewisGale Hospital Montgomery (Intermediate)	41	31.9
Carilion New River Valley d/b/a St. Albans (Intermediate)	42	34.1
Centra Virginia Baptist Hospital (Specialty)	92	57.5
Johnston Memorial Hospital (Intermediate)	127	122
Average	**63.6**	**50.4**

Source: MapQuest

Regarding available capacity, as demonstrated in **Table 1**, the 60 bassinets at Carilion Roanoke Memorial Hospital operated at 68.2% capacity in 2019, indicating that ample capacity exists at that facility to accommodate any transfers that may need to come from LGMC. Consequently, it can be argued that the status quo suffices as an alternative to the proposed project. However, the applicant asserts that maintaining the status quo is an unreasonable alternative to the proposed project and provided the following:

> "The current system is inadequate. Currently, many mothers who would prefer to deliver at LGMC are forced to deliver elsewhere because LGMC does not offer neonatal special care. Many at-risk mothers are directed elsewhere during their pregnancy by their obstetricians or simply choose not to take the chance delivering at a hospital without a NICU. As a result, the well-known and well-publicized lack of neonatal special care continues to artificially depress deliveries at LGMC…
>
> "…The presence of neonatal special care at other facilities does not alleviate LGMC's issues of continuity of care, nor does it address the reasonable expectation of patients and physicians that a tertiary hospital, such as LGMC, should have some level of neonatal special care on-site. Indeed, the on-site availability of neonatal special care is necessary to enable skin-to-skin contact of mothers and babies who are born at LGMC with special care needs. Further, by eliminating the inherent delays in care involved with transfers, infants with certain health problems born at LGMC will be able to receive the neonatal special care they need immediately. All of these factors have real clinical benefits on outcomes."

(iii) Any recommendation or report of the regional health planning agency regarding an application for a certificate that is required to be submitted to the Commissioner pursuant to subsection B of § 32.1-102.6;

Currently, there is no organization in HPR III designated by the Virginia Department of Health to serve as the Health Planning Agency for PD 5. Therefore, this consideration is not applicable to the review of the proposed project.

(iv) Any costs and benefits of the proposed project;

As illustrated in **Table 4**, the total projected capital cost of the proposed project is $1,369,262, the entirety of which will be funded using the accumulated reserves of the applicant. Accordingly, there are no financing costs associated with this project. DCOPN contends that the projected cost of the proposed project is reasonable and consistent with previously approved projects similar in clinical scope.[2]

The applicant provided the following summarization of the benefits of the proposed project:

> "This project is a natural extension of LGMC's tradition of excellence and is consistent with, and necessary to, achieving LGMC's guiding objective of providing appropriate care and services to its patients. This project is a low-cost, modest proposal to expand on an existing service: newborn care. The benefits will be enormous: the addition of neonatal special care will promote continuity of care, create better patient outcomes, reduce costs due to transfer, and help keep new families together during an already challenging time."

(v) The financial accessibility of the proposed project to people in the area to be served, including indigent people; and

As already discussed, the applicant has provided assurances that intermediate-level specialty care neonatal services will be made available to all persons in need of this service, regardless of financial considerations. However, as discussed, recent changes to §32.1-102.4B of the Code of Virginia now require DCOPN to place a charity care condition on every applicant seeking a COPN. While the applicant's Pro Forma Income statement does not address the provision of charity care, DCOPN again notes that in 2019, the most recent year for which VHI charity care contribution data is available, the average amount of charity care provided by HPR III facilities was 1.6% of all reported total gross patient revenues (**Table 6**). In that same year, LGMC provided 1.0% of its gross patient revenue in the form of charity care—a rate lower than the HPR III average. Accordingly, should the Commissioner approve the proposed project, DCOPN recommends a charity care condition no less than the 1.6% HPR III average.

[2] COPN No. VA-04537 authorized StoneSprings Hospital to introduce intermediate-level specialty care services with six newborn stations, and cost approximately $4,867,000; COPN No. VA-04536 authorized Novant Health UVA Health System to introduce intermediate-level specialty care services, and cost approximately $91,200; COPN No. VA-04515 authorized Sentara CarePlex Hospital to introduce obstetrical and intermediate special-care services, and cost approximately $3,659,660.

(vi) At the discretion of the Commissioner, any other factors as may be relevant to the determination of public need for a proposed project;

The applicant previously submitted COPN Request Nos. VA-7783 (2010), VA-7892 (2012), VA-8082 (2014), and VA-8391 (2018) to introduce specialty-level newborn services. DCOPN recommended denial of all four proposed projects. With regard to COPN Request Nos. VA-7783 and 7892, the adjudication officer recommended denial of each project following informal fact-finding conferences, a recommendation ultimately upheld by the State Health Commissioner (Commissioner). The IFFC regarding COPN Request No. VA-8082 was deferred indefinitely, and the project subsequently withdrawn. With regard to LGMC's most recent application, COPN Request No. VA-8391, the adjudication officer recommended approval of the proposed project. However, the Commissioner declined to adopt the adjudication officer's recommendation of approval, and instead denied LGMC's request to introduce specialty-level newborn services. The applicant formally requested the Commissioner reconsider the decision, to which the Commissioner agreed. However, upon reconsideration, the Commissioner upheld the denial on the following grounds:

1. The project was 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.

Furthermore, the Commissioner found:

> "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."

DCOPN notes that the application at hand differs from the previously denied applications in that presently, LGMC is requesting to introduce intermediate-level services, and not specialty-level services as has been requested in the past. However, DCOPN nonetheless concludes that the Commissioner's reasons for denial of LGMC's prior request are equally applicable to the current project request.

Additionally, DCOPN encourages the Commissioner to give consideration to the issue of newborn safety and the difficulties faced by NICU providers operating with a limited average daily census. The American Academy of Pediatrics has articulated some degree of correlation between patient volume and the quality of care:

> "In addition to level of care, patient volume in the NICU seems to influence outcome. However, it must be acknowledged that the relationship between volume and outcome tends to be true on the average, and considerable variability exists among individual hospitals and physicians. In a study of hospitals in California in 1990, risk-adjusted neonatal mortality based on linked birth and death certificate data were significantly lower for births that occurred in hospitals with level III NICUs that had an average daily census of at least 15 patients, compared with lower-volume centers."[3]

LGMC has projected a volume of 652 patient days by Year 1, and a volume of 710 patient days by Year 2 for its requested Level II service (**Table 9**). With respect to the average daily census, this amounts to an average of 1.8 and 1.9 NICU patients per day. This projection falls considerably short of the 15 patient average daily census threshold recommended by the American Academy of Pediatrics. The applicant's projections also fall well-beneath the daily average census accomplished by CRMH (subspecialty), located only a few miles away, and Virginia Baptist Hospital (specialty) (**Table 10**). However, DCOPN notes that the applicant's projections do align line with the 2019 average daily census accomplished by HPR III's existing providers of intermediate-level neonatal care. More specifically, the applicant's projections fall only marginally beneath that of Carilion New River Valley dba St. Albans and are higher than the average daily census accomplished by Johnston Memorial Hospital and Lewis Gale Hospital Montgomery.

Table 9. LGMC Pro Forma Income Statement

	Year 1	**Year 2**
Patient Days	652	710
Gross Revenue	$2,433,816	$2,726,705
Deductions from Revenue	$1,514,124	$1,739,267
Net Patient Services Revenue	**$919,693**	**$987,438**
Total Expenses	$871,781	$925,814
Net Income	**$47,912**	**$61,623**

Source: COPN Request No. VA-8530

Table 10. HPR III Average Daily Census: 2019

Facility (COPN Approved Bassinet Level)	**Patient Days**	**Avg. Daily Census**
Carilion New River Valley dba St. Albans (Intermediate)	930	2.5
Carilion Roanoke Memorial Hospital (Subspecialty)	13,435	36.8
Johnston Memorial Hospital (Intermediate)	58	0.2
Lewis Gale Hospital Montgomery (Intermediate)	40	0.1
Virginia Baptist Hospital (Specialty)	3,197	8.8
Avg.	**3532**	**9.7**

Source: VHI (2019)

[3] American Academy of Pediatrics, "Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of All Children", PEDIATRICS Volume 114, November 5, 2004.

Section 32.1-102:1 of the Code of Virginia calls for the State Health Services Plan Task Force to develop, by November 1, 2022, recommendations for a comprehensive State Health Services Plan (SHSP). In the interim, DCOPN will consider the consistency of the proposed project with the predecessor of the SHSP, the SMFP.

3. The extent to which the proposed project is consistent with the State Health Services Plan;

Part XIII, Article 2 of the SMFP contains criteria and standards for the addition of Neonatal Special Care Services. They are as follows:

Part XIII
Perinatal and Obstetrical Services
Article 2
Neonatal Special Care Services

12VAC5-230-940. Travel time.

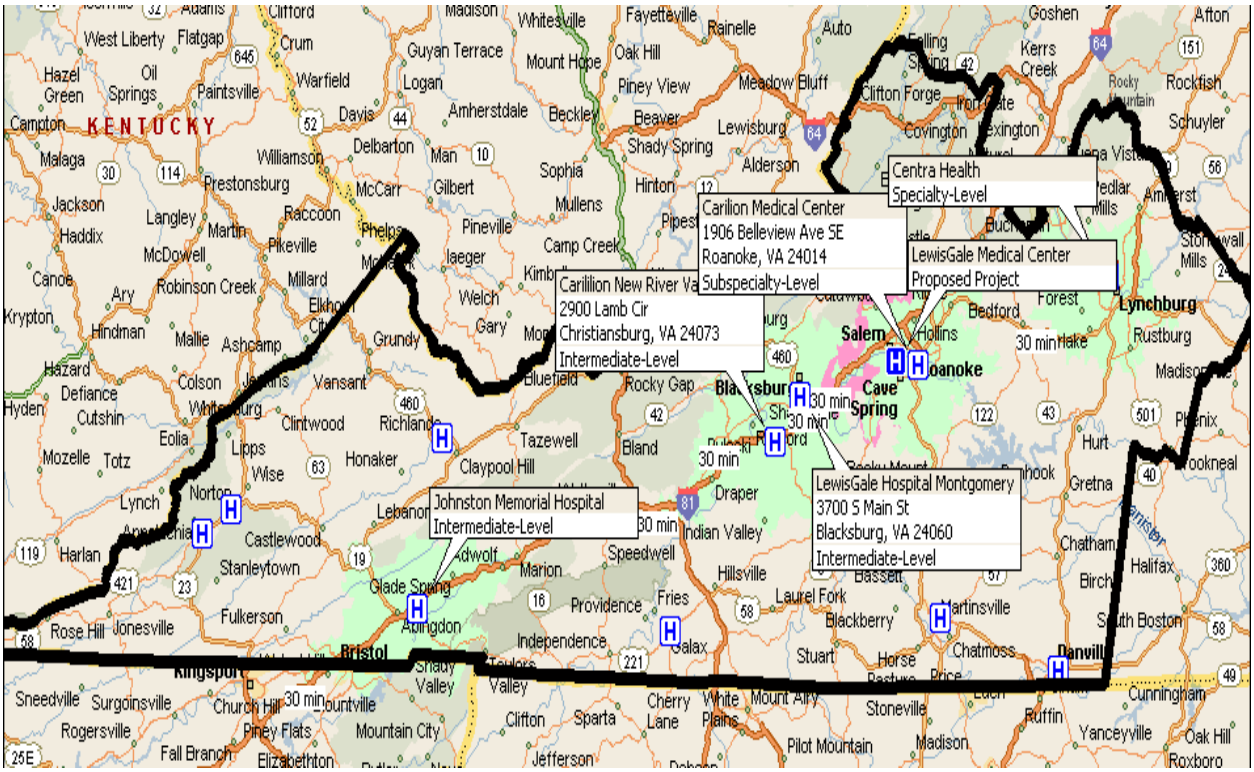
A. Intermediate level neonatal special care services should be located within 30 minutes driving time one way under normal conditions of hospitals providing general level newborn services using mapping software as determined by the commissioner.

There are three intermediate-level nurseries in HPR III: Johnston Memorial Hospital, Carilion New River Valley dba St. Albans, and LewisGale Hospital Montgomery. Additionally, there is one specialty-level nursery (Centra Virginia Baptist Hospital) and one subspecialty-level nursery (CRMH) in HPR III, which also offer intermediate-level neonatal special care. An additional eight facilities provide general-level newborn services, but do not currently offer neonatal special care services.

The heavy dark line in **Figure 1** is the boundary of HPR III. The white "H" symbols mark the locations of all existing nurseries in HPR III. The blue "H" symbol marks the location of the proposed project. The green shading illustrates the area of HPR III that is currently within 30 minutes driving time from an existing HPR III facility that offers intermediate-level (or above) neonatal special care services. The pink shaded area represents the area that is within a 30 minutes' drive of the proposed project and not otherwise covered by an existing provider.

As demonstrated by the map below, intermediate-level neonatal special care services are readily available in the central and northeastern portions of the planning region, but are not available to those living in the far western and southeastern parts of the planning region. However, the proposed project does not address this maldistribution of services. Rather, the proposed project would be located within a 16-minute drive of an existing provider of subspecialty-level neonatal special care services. Accordingly, DCOPN contends that approval of the proposed project would not significantly increase geographic access to intermediate-level neonatal special care for residents of HPR III.

Figure 1.



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.

Not applicable. The applicant is not requesting to introduce specialty or subspecialty level special care services.

12VAC5-230-950. Need for new service.
No new level of neonatal service shall be offered by a hospital unless that hospital has first obtained a COPN granting approval to provide each level of service.

It is the express intent of the applicant to obtain COPN approval for the proposed project.

12VAC5-230-960. Intermediate level newborn services.
A. Existing intermediate level newborn services as designated in 12VAC5-410-443 should achieve 85% average annual occupancy before new intermediate level newborn services can be added to the health planning region.

The definition of "bed" in the SMFP excludes bassinets and, regardless of the service level, bassinets are neither COPN approved nor licensed as to the number of bassinets. COPN authorization and licensing relate *only to the level* of neonatal special care, i.e. intermediate, specialty or subspecialty level. Therefore, the available number of such bassinets, either in total

or at any specific level, is not a fixed number for any period of time. Because hospitals may increase or decrease the number of bassinets without COPN authorization or notice, the availability and occupancy of existing bassinets reported to VHI by hospitals with special care nursery services may often be arbitrary. Furthermore, in the adjudication officer's good cause standing report for COPN Request No. VA-7283 (Bon Secours St. Francis Medical Center's request to introduce specialty level nursery services), in which Chippenham and Johnston-Willis Hospitals, Inc. were found to have good cause standing, the adjudication officer reached the conclusion that this standard is "meaningless" and "unworkable."

However, on January 6, 2020, the Commissioner issued a decision in response to Lewis Gale Medical Center's request for Reconsideration of the December 13, 2019 denial of COPN Request No. VA-8391, which sought to introduce neonatal specialty care services at Lewis-Gale Medical Center in Salem, Virginia. The Commissioner found that a public need for the [Lewis Gale] project had not been demonstrated and that the [Lewis Gale] project was not consistent with the SMFP. Regarding this specific provision of the SMFP, the Commissioner stated the following:

> "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 an occupancy of existing bassinets may often be arbitrary. I do not agree necessarily that this renders the SMFP provisions meaningless…"

DCOPN notes that the average utilization of all intermediate, specialty, and subspecialty level nurseries (which may also be used to provide intermediate level care) in HPR III in 2019, was far below 85% at only 59% (**Table 1**).

B. Intermediate level newborn services as designated in 12VAC5-410-443 should contain a minimum of six bassinets.

LGMC proposes to introduce neonatal special care services with six intermediate-level bassinets. DCOPN concludes that the applicant has satisfied this standard.

C. No more than four bassinets for intermediate level newborn services as designated in 12VAC5-410-443 per 1,000 live births should be established in each health planning region.

As previously discussed, because bassinets are neither COPN-approved nor licensed and hospitals may increase or decrease the number of bassinets without COPN authorization or notice, the availability and occupancy of existing bassinets reported to VHI by special care nurseries may often be arbitrary, thus this standard is considered to be "meaningless" and "unworkable" by DCOPN.

However, DCOPN notes that according to VHI data for 2019, the most recent year for which such data is available, there were 9,990 live births in HPR III (**Table 2**), representing a maximum of 40 intermediate-level bassinets in HPR III. While there are only nine bassinets currently

existing in HPR III that are specifically designated as "intermediate-level," as previously discussed, bassinets within COPN approved special care nurseries may be utilized interchangeably at their approved level or at a lower level, but not at a higher level than approved within that facility. Therefore, the subspecialty and specialty level nurseries in HPR III may also provide intermediate level care. DCOPN notes that 82 bassinets are authorized for intermediate, specialty or subspecialty care in HPR III. Thus, it could be argued that a large surplus of special care bassinets already exists in HPR III, and that the approval of the proposed project would result in the unnecessary duplication of existing services. To reiterate, in a December 13, 2019 decision, the Commissioner found:

> "…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."

12VAC5-230-970. Specialty level newborn services.

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.
B. Specialty level newborn services as designated in 12VAC-410-443 should contain a minimum of 18 bassinets.
C. No more than four bassinets for specialty level newborn services as designated in 12VAC5-410-443 per 1,000 live births should be established in each health planning region.
D. 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 significantly reduced.

Not applicable. The applicant is not proposing to introduce specialty level newborn services.

12VAC5-230-980. Subspecialty level newborn services.

A. Existing subspecialty level newborn services as designated in 12VAC5-410-443 should achieve 85% average annual occupancy before new subspecialty level newborn services can be added to the health planning region.
B. Subspecialty level newborn services as designated in 12VAC5-410-443 should contain a minimum of 18 bassinets.
C. No more than four bassinets for subspecialty level newborn services as designated in 12VAC-410-443, per 1,000 live births should be established in each health planning region.
D. Proposals to establish subspecialty level newborn services as designated in 12VAC5-410-443 shall demonstrate that service volumes of existing subspecialty level newborn providers located within the travel time listed in 12VAC-230-940 will not be significantly reduced.

Not applicable. The applicant is not proposing to introduce subspecialty level newborn services.

12VAC5-230-990. Neonatal services.
The application shall identify the service area and the levels of service of all the hospitals to be served by the proposed service.

The applicant identified the service area and the levels of service of all hospitals to be served by the proposed service.

12VAC5-230-100. Staffing.
All levels of neonatal special care services should be under the direction or supervision of one or more qualified physicians as described in 12VAC5-410-443.

The applicant has provided assurances that the neonatal special care services provided at LGMC will be provided under the direction or supervision of one or more qualified physicians.

Eight Required Considerations Continued

4. The extent to which the proposed project fosters institutional competition that benefits the area to be served while improving access to essential health care services for all people in the area to be served;

Given that LGMC does not currently offer the requested service, the proposed project would theoretically introduce institutional competition between LGMC and Carilion Roanoke Memorial Hospital with respect to intermediate-level special care nursery services and would also increase existing competition with respect to obstetrical services. However, DCOPN does not consider such competition beneficial.

DCOPN notes that the number of births at LGMC has decreased slightly in recent years-- from 994 births in 2015 to 975 in 2019—a 1.9% overall decline (**Table 2**). DCOPN notes however, that births at LGMC increased by 8.2% from 2018 to 2019. With regard to HPR III as a whole, the overall number of deliveries has declined more rapidly from 2015 to 2019—by approximately 13%. This decline in the birth rate is also reflected in the most recent population data provided by Weldon Cooper regarding PD 5, which projects a decline of approximately 1.95% between 2010 and 2030 for children less than five years of age. Based on this data, DCOPN contends that approval of the proposed project is likely to result in a low-volume program at LGMC, while also reducing utilization at other special care nurseries in HPR III, a service where there is a direct correlation between higher volumes and favorable clinical outcomes.

On the other hand, DCOPN notes that one of the goals of the proposed project is to continue to grow LGMC's obstetrical program by removing a barrier to the decision by expectant woman, who may be knowingly or unknowingly at risk for birth complications, to selecting LGMC rather than nearby Carilion Roanoke Memorial Hospital. Similarly, obstetricians affiliated with LGMC, who may have been reluctant to deliver obstetrical patients with risk factors at LGMC, may be more confident to do so if the proposed project is approved. In 2019, LGMC staffed only seven of its 23 licensed obstetric beds and had an occupancy rate of only 30.7%. Approval of the proposed project would introduce a greater level of choice and would likely reduce the number of expensive ambulance transports required for infants born at LGMC which require intermediate-

level neonatal special care. However, it is reasonable to also conclude that the number of subspecialty and specialty ambulance transports form LGMC to Carilion Roanoke Memorial Hospital may increase as a result of more high risk patients choosing to deliver at LGMC. Moreover, approval of the proposed project would not reduce the number of neonatal transports from other HCA facilities in southwestern Virginia requiring subspecialty, specialty or intermediate level nursery services, as they will still need to be transported to LGMC, Carilion Roanoke Memorial Hospital, or another provider with the necessary level of service. Finally, it is plausible that many neonates transported to LGMC from other HCA facilities may incur the additional cost of a second ambulance transport to a subspecialty or specialty level care provider at a later date—a transport which could be avoided if the neonate was initially transported the additional 6.6 miles to Carilion Roanoke Memorial Hospital, as is the current practice.

5. The relationship of the proposed project to the existing health area system of the area to be served, including the utilization and efficiency of existing serves or facilities;

As already discussed, approval of the proposed project would not improve geographic access to intermediate-level neonatal special care for residents of HPR III, but is likely to reduce utilization at CRMH. Similarly, the number of obstetrical admissions to CRMH, both for expected uncomplicated and those to be determined to be at moderate or high risk, will likely be reduced. In recent years, CRMH has seen a steady decline in patient days in its special care nursery. Its cumulative special care occupancy percentage has dropped from 67.0% in 2015 to 61.3% in 2019 (**Table 1**). This is due, in part, to a significant decline in the regional birth rate, a reduction in teenage deliveries, and a shorter length of stay due to sustained efforts to improve patient care.

Furthermore, for reasons already discussed in this report, approval of this project will likely lead to a low volume NICU program at LGMC. The applicant's own projections anticipate an average daily census of only 1.8 NICU patients per day in the first year of operation, and 1.9 NICU patients per day by year two (**Table 9**). These projections fall considerably short of the 15 patient average daily census threshold recommended by the American Academy of Pediatrics. The applicant's projections also fall well-beneath the daily average census accomplished by CRMH (subspecialty), located only a few miles away, and Virginia Baptist Hospital (specialty) (**Table 10**). However, DCOPN notes that the applicant's projections are in line with the 2019 average daily census accomplished by HPR III's existing providers of intermediate-level neonatal care. More specifically, the applicant's projections fall only marginally beneath that of Carilion New River Valley dba St. Albans and are higher than the average daily census accomplished by Johnston Memorial Hospital and Lewis Gale Hospital Montgomery. Nonetheless, DCOPN maintains that approval of the proposed project would likely contribute to the continued decrease in utilization among HPR IIIs existing special care nursery services. To reiterate, as the Commissioner observed in his January 6, 2020 response to LewisGale Medical Center's request for Reconsideration of the December 13, 2019 denial of COPN Request No. VA-8391,

> "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."

6. The feasibility of the proposed project, including the financial benefits of the proposed project to the applicant, the cost of construction, the availability of financial and human resources, and the cost of capital;

As already discussed, DCOPN contends that the projected costs for the proposed project are reasonable and consistent with previously authorized projects similar in clinical scope. The project will be funded entirely using the accumulated reserves of the applicant. Similarly, there are no financing costs associated with this project. Furthermore, the Pro Forma Income Statement provided by the applicant anticipates a net profit of $47,912 in the first year of operation and $61,623 by year two, illustrating that the proposed project is financially feasible both in the immediate and the long-term (**Table 9**).

With regard to staffing, the applicant anticipates the need to hire 3.6 additional full-time employees (all registered nursing positions) to staff the proposed project. While this is a relatively small number of staff to hire, DCOPN notes that this is *in addition to* the 206 positions currently vacant at LGMC (most of which are also registered nursing positions). The applicant provided the following with regard to this standard:

> "Given the growing number of students actively enrolled and reported waiting lists within the community college systems across the state, LGMC anticipates adequate staffing with minimal impact on health care facilities. Furthermore, LGMC's current neonatal care staff is anticipated to train at existing HCA facilities providing neonatal special care prior to the opening of the new unit at LGMC. Accordingly, LGMC's special care neonatal care staff can be anticipated to deliver the same level of outstanding care that is provided at other HCA facilities within the Commonwealth and beyond…
>
> "Furthermore, HCA has a multi-faceted approach to staff development, which places particular emphasis on expanding the pool of new staff….
>
> "To address short-term fluctuations in staffing or to provide interim staffing solutions for its facilities, HCA hospitals develop per diem staff and certified "float" pools, which are hospital-based reserve staff for peaks in volume. This provides hospitals with a group of highly trained health workers that can be accessed in periods of high demand. Beyond allowing hospitals to accommodate fluctuating patient volumes with appropriate staffing levels, this approach also serves to reduce costs…"

The applicant is a current provider of obstetric and general-level nursery services and has a robust employee recruitment and retention plan. Furthermore, while the total number of vacant positions at LGMC is considerable, DCOPN notes that as the fifth largest employer in the Commonwealth, HCA facilities consistently have a large number of vacant positions. DCOPN does not anticipate that the applicant will have any difficulty staffing the proposed project, or that doing so would have a significant negative impact on existing providers of special care nursery services.

7. The extent to which the proposed project provides improvements or innovations in the financing and delivery of health care services, as demonstrated by (i) the introduction of new technology that promotes quality, cost effectiveness, or both in the delivery of health care services; (ii) the potential for provision of health care services on an outpatient basis; (iii) any cooperative efforts to meet regional health care needs; and (iv) at the discretion of the Commissioner, any other factors as may be appropriate; and

The proposal would not introduce new technology that would promote quality or cost effectiveness in the delivery of neonatal special care services, nor could these services be offered on an outpatient basis. The applicant currently has a transfer agreement in place with Carilion Roanoke Memorial Hospital, and anticipates continuing this longstanding relationship by transferring neonates in need of specialty and subspecialty nursery services to CRMH, while keeping babies in need of intermediate-level nursery services at LGMC. DCOPN did not identify any other factors, not discussed elsewhere in this staff analysis report, to bring to the attention of the Commissioner.

8. In the case of a project proposed by or affecting a teaching hospital associated with a public institution of higher education or medical school in the area to be served, (i) the unique research, training, and clinical mission of the teaching hospital or medical school and (ii) any contribution the teaching hospital or medical school may provide in the delivery, innovation, and improvement of health care services for citizens of the Commonwealth, including indigent or underserved populations.

Not applicable. The applicant is not a teaching hospital or affiliated with a public institution of higher education or medical school in the area to be served. However, DCOPN notes that HCA sponsors and endorses statewide education and outreach programs intended to attract current student enrollees in state nursing schools by offering on-site preceptor clinical training to support student nursing education. Furthermore, HCA provides support through clinical rotation sites and provides adjunct faculty in area health service programs.

DCOPN Staff Findings and Conclusions

DCOPN finds that the applicant's proposal to introduce intermediate-level NICU services with six intermediate-level bassinets is not consistent with the applicable criteria and standards of the State Medical Facilities Plan and the eight Required Considerations of the Code of Virginia. Existing intermediate, specialty, and subspecialty services in HPR III operated at only 59.0% occupancy in 2019. Accordingly, DCOPN concludes that the project does not comply with 12VAC5-230-960A, which requires existing intermediate-level newborn services to achieve 85% average annual occupancy before new intermediate-level newborn services are added to the health planning region. Additionally, the project does not comply with 12VAC5-230-960C, which directs that there should be no more than four bassinets for intermediate level newborn services per 1,000 live births in the HPR. There were 9,990 live births in HPR III in 2019, representing a maximum of 40 intermediate-level bassinets in HPR III. At present, 82 bassinets are approved for intermediate, specialty, and subspecialty level nursery care. Thus, it can be argued that a large surplus of bassinets already exists in HPR III.

DCOPN finds that the projected capital cost of the proposed project is reasonable and consistent with previously approved projects similar in clinical scope. However, DCOPN further finds that maintaining the status quo is preferable to the proposed project. While intermediate-level neonatal care services are not presently located within 30 minutes of every facility providing general nursery care, DCOPN notes that the proposed project, if approved, would not address this maldistribution of services. Rather, the proposed project would be located within a short drive to CRMH, and would likely further reduce the utilization of NICU services at that facility. As CRMH's collective NICU program operated at only 68.2% in 2019, it is clear that ample capacity exists at CRMH for it to continue providing adequate care for all neonates that might need transferred from LGMC.

As discussed, DCOPN reiterates that approval of the proposed project would likely have a detrimental impact on CRMH's special care nursery programs. Finally, approval of the proposed project would likely lead to a low volume NICU program at LGMC. The applicant's own projections predict an anticipated daily average daily census of only 1.8 NICU patients per day by the end of the first full year of operation, and only 1.9 NICU days by year two. This projection falls considerably short of the 15 patient average daily census threshold recommended by the American Academy of Pediatrics, in addition to the average daily census accomplished by CRMH. As the Commissioner observed, "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."

DCOPN Staff Recommendation

The Division of Certificate of Public Need recommends **denial** of Lewis Gale Medical Center's proposed project to introduce intermediate-level neonatal special care services with six intermediate-level bassinets for the following reasons:

1. The proposed project is not consistent with the applicable criteria and standards of the State Medical Facilities Plan and the Eight Required Considerations of the Code of Virginia.

2. Maintenance of the status quo is more advantageous than the proposed project.

3. Neonatal special care services are already sufficiently available in HPR III and within a 30-minute drive time from LGMC.

4. The proposed project will create an adverse impact on the utilization and quality of the system of existing neonatal special care services.