VIRGINIA DEPARTMENT OF HEALTH

Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis

April 21, 2021

COPN Request No. VA-8483
Sentara RMH Medical Center
Harrisonburg, Virginia
Introduce neonatal special care nursery services

Applicant

Sentara RMH Medical Center (SRMH) is a wholly owned subsidiary of Sentara Blue Ridge, LLC, which is a wholly owned subsidiary of Sentara Hospitals, which is a wholly owned subsidiary of Sentara Healthcare (Sentara), a non-stock, not-for-profit Section 501(c)(3) corporation headquartered in Norfolk, Virginia. SRMH is in Planning District (PD) 6, Health Planning Region (HPR) I.

Background

SRMH is a 238-bed community hospital in Harrisonburg, Virginia. As a full-service acute care facility, SRMH provides inpatient medical/surgical, intensive care, cardiac, pediatric, obstetric, cancer, and psychiatric services. SRMH also provides a wide-range of diagnostic and imaging technologies, outpatient surgery, and emergency care.

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 **Table 1** demonstrates, within HPR I, there are nine special care level neonatal intensive care (NICU) providers with services ranging from intermediate, to specialty, to subspecialty levels of care. In total, these service providers reported a 2019 inventory of 124 bassinets to Virginia Health Information (VHI).

DCOPN further notes that the applicant provided corrected utilization data for 2015-2019 and explained "starting in 2015, VHI data do not correctly reflect the utilization of SRMH's licensed intermediate level nursery….VHI does not accept corrections after data submission; however, corrected utilization data…are used in this application." and "[d]ue to a transition in the hospital's electronic medical record platform, the 2017 and 2018 utilization data submitted in the application … was incorrect. Following extensive record review, SRMH reassessed the

historical and projected utilization data submitted in the application." While DCOPN cannot independently verify this data, it is included in **Table 1** below, recognizing that the applicant provided assurances with its application that the information provided is correct to the best of its knowledge.

As may be observed in **Table 1**, special care nursery utilization has been consistently high at University of Virginia Medical Center (UVAMC) and Mary Washington Hospital, moderate at Spotsylvania Regional Medical Center, Sentara Martha Jefferson Hospital, SRMH and Valley Health Winchester Medical Center, but has been significantly lower within the intermediate level services at Stafford Hospital Center and Sentara Martha Jefferson Hospital.

Table 1. Special Care Nursery Inventory and Utilization in HPR I: 201-2019

Facility (COPN Approved Bassinet Level)	**2019 Staffed Bassinets**	**2015**	**2016**	**2017**	**2018**	**2019**	**Average**
Augusta Health (Intermediate)	0	N/A	N/A	N/A	N/A	N/A	N/A
Fauquier Hospital (Intermediate)	6	N/A	30%	41%	30%	19%	30%
Mary Washington Hospital (Specialty)	17	70%	65%	61%	68%	67%	66%
Sentara Martha Jefferson Hospital (Intermediate)	4	46%	41%	0%	0%	0%	17%
Sentara RMH Medical Center (Intermediate)[1]	6	48%	60%	42%	66%	46%	52%
Spotsylvania Regional Medical Center (Intermediate)	4	53%	44%	36%	41%	27%	40%
Stafford Hospital Center (Intermediate)	6	11%	17%	15%	15%	23%	16%
University of Virginia Medical Center (Sub-specialty)	51	82%*	90%*	84%	87%	87%	86%
Valley Health Winchester Medical Center (Specialty)	30	49%**	48%	51%	51%	52%	51%
Total and Average	**124**	**63%**	**64%**	**60%**	**64%**	**63%**	**63%**

Source: VHI Data 2015-2019
*Based on 45 bassinets reported in 2015 - 2017
** Based on 33 bassinets reported in 2015

[1] The applicant provided corrected utilization data for 2015-2019 and explained "starting in 2015, VHI data do not correctly reflect the utilization of SRMH's licensed intermediate level nursery….VHI does not accept corrections after data submission; however, corrected utilization data…are used in this application." And "[d]ue to a transition in the hospital's electronic medical record platform, the 2017 and 2018 utilization data submitted in the application … was incorrect. Following extensive record review, SRMH reassessed the historical and projected utilization data submitted in the application." VHI reports show zero utilization of SSRMH's intermediate level nursery from 2016-2019 and <1% utilization for 2015.

As demonstrated by **Table 2**, SRMH is among the top four providers of obstetric services in HPR I, and is the largest provider in PD 6. In 2019, SRMH reported 1,853 live births. SRMH and Augusta Health are presently the only providers of obstetric services in PD 6.

Table 2. HPR I Births: 2015-2019

Facility	PD	2015	2016	2017	2018	2019	Facility Average
Augusta Health	6	1,216	1,186	1,149	1,098	1,015	1,133
Sentara RMH Medical Center	6	1,709	1,809	1,767	1,888	1,853	1,805
Valley Health Warren Memorial Hospital*	7	355	373	375	127	N/A	308
Valley Health Winchester Medical Center	7	2,268	2,268	2,167	2,532	2,541	2,355
Fauquier Hospital	9	763	739	686	765	506	692
Novant Health UVA Health System Culpeper Hospital	9	405	393	496	448	491	447
Sentara Martha Jefferson Hospital	10	1,662	1,553	1,529	1,491	1,407	1,528
University of Virginia Medical Center	10	1,668	1,754	1,758	1,817	1,787	1,757
Mary Washington Hospital	16	2,865	2,769	2,618	2,055	1,755	2,412
Spotsylvania Regional Medical Center	16	581	615	587	608	675	613
Stafford Hospital Center	16	1,085	1,125	1,191	915	827	1,029
Total		**14,577**	**14,584**	**14,323**	**13,744**	**12,857**	
Average		**1,325**	**1,326**	**1,302**	**1,249**	**1,286**	

Source: VHI Data 2015-2019
*Valley Health Warren Memorial Hospital discontinued obstetrics services in 2018.

As **Table 3** demonstrates, SRMH is an existing provider of obstetrical services and is licensed to operate 22 obstetric beds, and reported staffing 22 obstetric beds from 2015-2019. In 2019, SRMH reported 1,853 births, which is a 35-birth decrease from what the facility reported in 2018 (1,888 births). The occupancy data from 2015-2019 demonstrates a consistently moderate obstetrical bed occupancy rate at SRMH. DCOPN notes both PD 6 and HPR I are showing an overall downward trend in births (2015-2019).

Table 3. SRMH OB Occupancy: 2015-2019

	2015	2016	2017	2018	2019	Average
Births	1,709	1,809	1,767	1,888	1,853	1,805
OB Patient Days	3,691	3,819	3,676	3,984	4,007	3,793
OB Occupancy	46.0%	47.4%	45.8%	49.6%	49.9%	47.7%

Source: VHI Data 2015-2019

Proposed Project

SRMH proposes to introduce specialty level NICU services and to add an additional five bassinets, for a total of 11 bassinets that could be used to provide specialty level nursery care. SRMH currently operates an intermediate level nursery with six bassinets complementing its general newborn level nursery with 16 bassinets. The applicant observes that SRMH is one of only two hospitals in Virginia that has birthing volumes greater than 1,700 but lacks a specialty level nursery (the other hospital is Sentara Leigh Hospital, which is located nine miles from Sentara Norfolk General). The applicant asserts that the primary purpose of its proposal is to increase access to higher-level nursery services for patients residing in its vast, mostly rural service area. The proposed increase in acuity level of the existing intermediate level nursery will accommodate infants needing specialty level services, including premature newborns with conditions requiring isolation, increased airway management or additional clinical attention. The specialty level nursery space will provide parents with the ability to stay with their infant throughout the entirety of the infant's NICU stay, with sleeping arrangements and access to a parent lounge with separate shower and bathroom facilities. To accomplish the NICU expansion, SRMH will relocate and consolidate storage and utility space currently serving SRMH's existing nursery, without having to demolish any exterior hospital walls.

12VAC5-410-443 B.3 designates that "[a] specialty level newborn service shall provide intensive care to high-risk neonates with neonatal illnesses as specified in the service's medical protocol. In addition to the capabilities required of the lower level nurseries, the specialty level nursery shall have the equipment and staff capabilities to provide the following: maintenance of central arterial umbilical catheters or peripheral arterial lines with constant pressure monitoring, insertion and maintenance of chest tubes for drainage, administration of total parenteral nutrition (TPN), the maintenance of pressor medications, the administration of surfactant and respiratory support to include the maintenance of hood oxygen, continuous positive airway pressure (CPAP), and neonatal mechanical ventilation beyond the immediate stabilization period."

The projected capital costs of the proposed project total $3,474,200, approximately 42% of which represents direct construction costs (**Table 4**). The project will be funded through a combination of accumulated reserves and support from the RMH Foundation. Accordingly, there are no financing costs associated with this project. The applicant expects to begin construction upon COPN approval, and for the project to be completed 18 months after COPN approval. The applicant anticipates a target date of opening one month after construction is complete.

Table 4. Sentara RMH Projected Capital Costs

Direct Construction	$1,450,000
Equipment Not Included in Construction Contract	$2,024,200
Total	**$3,474,200**

Source: COPN Request No. VA-8483

Project Definition

§32.1-102.1:3 of the Code of Virginia defines a project, in part, as "Introduction into an existing medical care facility described in subsection A of any… neonatal special care…."

§32.1-123 defines a medical care facility as "Any facility licensed as a hospital."

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 **Table 3**, SRMH is an existing provider of obstetrical services with 22 obstetric beds and an intermediate level nursery. The applicant requests to expand on this existing service through the introduction of specialty level neonatal special care services and the addition of five bassinets. Geographically, SRMH is located at 2010 Health Campus Drive, Harrisonburg, Virginia and is readily accessible to residents of the greater Harrisonburg/Rockingham area. SRMH is located on the corner of two public roads, Port Republic Road (Virginia Route 253) and Stone Spring Road (Virginia Route 280) in Rockingham County. Interstate 81 is located 2.2 miles from the SRMH campus via Port Republic Road. Additionally, the City of Harrisonburg runs a bus line with two stops along Health Campus Drive.

SRMH asserts that the primary purpose of its proposal is to increase access to higher-level nursery services for patients residing in its vast, mostly rural service area, which it has identified as the Cities of Harrisonburg, Waynesboro and Staunton, and the Counties of Page, Augusta, Shenandoah and Rockingham. Among the geographic access concerns cited by the applicant are: (1) the majority of roads in PD 6 are secondary roads and byways; (2) frequent inclement weather, including fog, ice and snow; (3) traveling Afton Mountain, often beset by fog and other conditions that lengthen travel times beyond those in ideal conditions; and (4) Anabaptist residents (according to the applicant, approximately 20,000 residents) of Rockingham and Augusta Counties rely solely on traditional means of transportation, such as horse and buggy.

Table 5 shows projected population growth in PD 6 through 2030. As depicted in **Table 5**, at an average annual growth rate of 0.62%, PD 6's population growth rate from 2010-2020 is in line with the state's average annual growth rate of 0.77%. Overall, the planning district was projected to add an estimated 18,611 people in the 10-year period ending in 2020—an approximate 7% increase with an average increase of 1,861 people annually. In the 10-year period ending in 2030, the planning district is projected to add an estimated 19,442 people – an approximate 21% increase with an average increase of 1,944 people annually. Harrisonburg, the location of the

proposed project, is expected to experience a population increase of approximately 1.3% from 2010-2020 and 1.2% from 2020-2030.

Table 5. PD 6 - Population Projections for PD 6, 2010-2030

Locality	2010	2020	% Change 2010-2020	Avg Ann % Change 2010 - 2020	2030	% Change 2020-2030	Avg Ann % Change 2020-2030
Augusta	73,750	75,734	2.69%	0.26%	80,035	5.68%	0.55%
Bath	4,731	4,377	-7.49%	-0.76%	3,980	-9.06%	-0.94%
Highland	2,321	2,258	-2.72%	-0.27%	2,080	-7.88%	-0.82%
Rockbridge	22,307	22,636	1.47%	0.14%	23,290	2.89%	0.29%
Rockingham	76,314	82,720	8.39%	0.79%	89,156	7.78%	0.75%
Buena Vista City	6,650	6,302	-5.23%	-0.52%	6,222	-1.28%	-0.13%
Harrisonburg City	48,914	56,012	14.51%	1.33%	63,037	12.54%	1.19%
Lexington City	7,042	7,447	5.75%	0.55%	7,622	2.34%	0.23%
Staunton City	23,746	25,293	6.51%	0.62%	25,577	1.13%	0.11%
Waynesboro City	21,006	22,613	7.65%	0.72%	23,835	5.40%	0.53%
Total PD 6	**286,781**	**305,392**	**6.49%**	**0.62%**	**324,834**	**6.37%**	**0.62%**
Virginia	8,001,024	8,655,021	8.17%	0.77%	9,331,666	7.82%	0.76%

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

Regarding socioeconomic barriers to access to the applicant's services, according to regional and statewide data regularly collected by VHI, for 2018, the most recent year for which such data is available, the average amount of charity care provided by HPR I facilities was 3.0% of all reported total gross patient revenues (**Table 6**). In that same year, SRMH provided 3.21% of its gross patient revenue in the form of charity care. Pursuant to Section 32.1 – 102.4 of the Code of Virginia, should the State Health Commissioner (Commissioner) approve the proposed project, DCOPN recommends a charity care condition no less than the 3.0% HPR I average.

Table 6. HPR I 2018 Charity Care Contributions

2019 Charity Care Contributions at or below 200% of Federal Poverty Level			
Hospital	**Gross Patient Revenues**	**Adjusted Charity Care Contribution**	**Percent of Gross Patient Revenue:**
University of Virginia Medical Center	$5,908,975,470	$281,698,729	4.77%
Culpeper Regional Hospital	$380,434,774	$13,782,293	3.62%
Sentara RMH Medical Center	$990,510,384	$31,826,597	3.21%
Carilion Stonewall Jackson Hospital	$128,681,326	$4,054,332	3.15%
Martha Jefferson Hospital	$738,572,393	$16,357,090	2.21%
Shenandoah Memorial Hospital	$138,346,148	$2,949,504	2.13%
Page Memorial Hospital	$67,252,269	$1,411,441	2.10%
Warren Memorial Hospital	$159,448,610	$2,896,105	1.82%
Augusta Medical Center	$1,084,003,117	$17,664,291	1.63%
Spotsylvania Regional Medical Center	$593,173,888	$9,003,897	1.52%
Winchester Medical Center	$1,547,423,083	$22,313,262	1.44%
UVA Transitional Care Hospital	$62,823,527	$851,414	1.36%
Bath Community Hospital	$25,106,383	$268,755	1.07%
Mary Washington Hospital	$1,504,703,712	$12,119,248	0.81%
Stafford Hospital Center	$321,401,662	$2,151,628	0.67%
Fauquier Hospital	$448,588,022	$2,715,780	0.61%
Total Facilities			16
Median			1.7%
Total $ & Mean %	**$14,099,444,768**	**$422,064,366**	**3.0%**

Source: VHI Data (2019)

DCOPN notes that according to the most recent U.S. Census data, the City of Harrisonburg, the location of the proposed project, has a poverty rate of 28.3% - more than twice that of the statewide average (9.9%) and higher than every other locality within PD 6 (**Table 7**). Additionally, the applicant has indicated that its service area includes Waynesboro, with a poverty rate of 16.8%, Staunton, with a poverty rate of 11.1%, Augusta County, with a poverty rate of 7.3%, and Rockingham County, with a poverty rate of 8.1%.

Table 7. Statewide and PD 6 Poverty Rates

Locality	Poverty Rate
Virginia	9.9%
Augusta	7.3%
Bath	9.9%
Highland	12.4%
Rockbridge	11.5%
Rockingham	8.1%
Buena Vista City	25.5%
Harrisonburg City	28.3%
Lexington City	27.4%
Staunton City	11.1%
Waynesboro City	16.8%

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

Regarding the economic toll that families with a newborn in a NICU experience, the applicant explains:

- Parents and other family members can expect to travel long distances and incur related expenses, such as gas, parking, overnight accommodations and food costs.
- Many families have a loss of income due to missed days of work.
- Medical transport costs are very expensive, with air travel costing between $20,000 and $50,000, and ground transport costing between $3,000 and $5,000.

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;

DCOPN received 63 letters of support for the proposed project from members of the local medical community, patients of SRMH and citizens of SRMH's service area, including the Original Virginia Old Order Mennonite Conference. Collectively, the letters of support addressed:

- Eliminating or reducing the need to transfer newborns outside of SRMH would provide multiple benefits for the mother and child, including:
  - Lowering the stress that families are already coping with the anxiety of a sick child;
  - Eliminating the expense of a transfer for infants who are in need of more complex neonatal services than SRMH currently offers;
  - Reducing the cost for families with newborns in NICUs further away; and

- Reducing the risk of having to make the transfer of a sick infant in dangerous weather conditions through the Blue Ridge Mountains, which can be treacherous terrain when the weather is bad;

- The inconvenience of the distance of the nearest specialty-level NICU at UVAMC. A NICU in Harrisonburg would be at a midpoint in the Shenandoah Valley.

- The number of deliveries at SRMH is increasing year over year, with approximately 2,000 births in 2019. A higher acuity NICU would allow parents to stay overnight with their infants.

- The projected growth of the population of women of childbearing years throughout SRMH's service area.

- The high utilization of the NICU at UVAMC, which often causes the need to transfer infants to Roanoke, Lynchburg or Richmond.

- How emotionally draining and stressful traveling to visit a newborn in a NIUC over an hour away is on families.
- Keeping families close to home can aid in the healing process after birth.

- In addition to the cost and inconveniences that affect all families, accessing higher-level services for babies in need is exceedingly challenging for members of the Old Order Mennonites, who do not rely on forms of modern technology or transportation. SRMH is located centrally to the Old Order Mennonite community.

DCOPN received a letter of opposition for the proposed project from Chris Ghaemmaghami, M.D., UVA Medical Center's Interim Chief Executive Officer. Dr. Ghaemmaghami's March 26, 2020 letter outlined UVAMC's objections, including:

- There is no public need for an additional NICU in HPR I.

  - UVAMC has not diverted 150-200 neonates originating in the SRMH primary service area. Very few infants or mothers are diverted and UVAMC's capacity is adequate to meet the needs of those seeking care at the hospital. After examining data from several sources, UVAMC found that it diverted no more than 6 babies from SRMH from 2017-2019.
  - SRMH appears to have misstated the number of patients from its PSA being transferred to other hospitals for neonatal intensive care services.
  - SRMH's projected utilization of its requested services is unsubstantiated.

- SRMH's project does not meet the requirements of the SMFP.

  - There are existing specialty level services in HPR I within 90 minutes of SRMH.
  - Specialty level services in the region have not achieved an average annual occupancy of 85%.

  - The SMFP requires new specialty services to have a minimum of 18 bassinets, while SRMH seeks to add only 5.
  - SRMH fails to show that service volumes of existing specialty level newborn services providers located within 90 minutes of SRMH will not be significantly reduced. UVAMC does foresee an adverse impact on its service volumes if SRMH's project is approved, constituting roughly 10% of its volume.

- UVAMC has robust medical transport capabilities, which mitigate the risks associated with transporting critically ill infants, including a Newborn Emergency Transport System and Pegasus for ground and air transport.

- UVAMC has partnered with the Yellow Door Foundation and Ronald McDonald to provide lodging for families undergoing treatment at UVAMC. UVAMC's NICU also has several "rooming- in" rooms.

- The addition of a low volume NICU at SRMH fails to meet either the letter or the spirit of the SMFP, and it will not enhance care or alleviate stresses on families. Instead, it will have a deleterious effect on the quality of neonatal specialty services in the region.

On January 26, 2021, the applicant responded to UVAMC's opposition letter. The applicant's letter addressed:

- If the proposed project is approved, SRMH will continue to rely on its partnership with UVAMC to treat babies who require resources not available at SRMH.

- This application (COPN Request No. VA-8483) is about treating babies whom SRMH is capable of treating and whom do not need to travel, or have their families travel, at least an hour for the standard of care in hospitals like SRMH.

- SRMH does not agree with UVAMC's position that there is no public need for a NICU at SRMH.

- SRMH does not dispute the fact that its application does not strictly comply with each SMFP criterion. However, it does dispute the suggestion that a lack of strict compliance precludes a finding of public need for SRMH's application, particularly when the Commissioner has found these standards to be "meaningless" and "unworkable." Indeed, the COPN statute, COPN regulations and precedent support approval here.

- With regard to the perceived data discrepancies, SRMH believes, that in part, SRMH and UVAMC are relying on different data sources and thus not comparing like data sets.

DCOPN received a letter of continued opposition and additional comments from Wendy Horton, CEO of UVAMC dated April 7, 2021. Ms. Horton's letter outlined:

- UVAMC's continued belief that there is no public need for an additional specialty NICU in HPR I, that the proposed NICU at SRMH would negatively impact other providers in the region, and that an additional specialty level NICU would have a deleterious effect on the quality of neonatal specialty services.

- Sentara's EMTALA records are very close to UVAMC's internal records regarding infant and maternal transfers and confirm that UVAMC could not have diverted 150-200 infants per year.

- With its clarification of the total infant transfers, Sentara's response corrects portions of the application with respect to projected utilization and volumes. Even the revised numbers set forth in Sentara's response cannot be relied upon to establish a need for specialty NICU at SRMH because the response only shows aggregated transfers to both specialty and subspecialty NICUs.

- Volumes are critically important to NICU outcomes. Unfortunately, such care is not always accessible in the family's community. But the solution is not placing a specialty level NICU at SRMH with only five bassinets, and by definition, low volumes.

- The affidavit from Dr. Ann Heerens, says that SRMH plans to have two full time neonatologist for its 11 bassinets. For comparison, UVAMC's 52 bassinets, it has 12 neonatologists on staff and six neonatal-perinatal fellows.

- Contrary to SRMH's assertions, the retention of 90 mothers and infants at SRMH would, in all likelihood, impact UVAMC most significantly, as this represents 17% of its total NICU discharges in 2019.

- The desire to provide CPAP services to neonates, while understandable, does not justify the creation of a specialty level NICU.

DCOPN received a letter from Robert A. Sinkin, M.D., Division Head of Neonatology at UVAMC, on April 14, 2021. Dr. Sinkin's letter addressed:

- His agreement with and reiteration of UVAMC's opposition.

- His appreciation of the stresses and burdens expressed by the NICU parents

- His concern that establishing a Level III NICU at SRMH for the convenience of the parents will jeopardize the care of the patients – the vulnerable neonates who require teams of highly trained and experienced physicians and other supportive care providers, which UVA and other facilities already offer to SRMH patients.

- Neonatologists and pediatric hospitalists alone cannot address the needs of infants who require specialized neonatal intensive care. For example, Necrotizing Enterocolitis (NEC) is not uncommon in premature infants; as UVA pointed out in its March 26, 2020 letter, it is estimated that approximately 10% of neonates weighing less than 1500 grams or less than 32 weeks' gestation can be expected to develop this often fatal condition, and 27-52% require diagnostic imaging and surgical intervention with anesthesia.

  - Special skills and expertise and optimally, board certification in pediatric radiology, is needed to provide the highest quality diagnostic findings and determinations.

  - Administering anesthesia to a premature infant is not the same as anesthetizing an adult or older child. Similarly, performing surgery on a premature infant is not the same as operating on a child or adult.

- SRMH does not have any pediatric radiologist, pediatric anesthesiologist, or pediatric surgeon on its medical staff. Nor is there a pediatric neurosurgeon.

- Addressing the needs of a child with NEC or other life threatening conditions requires immediate attention from highly trained and experienced support personnel—pharmacists, respiratory therapists, phlebotomists, and dietitians-- with specific expertise in neonatal and pediatric care. SRMH has yet to demonstrate that any of these specialized services are or would be made available to these very vulnerable patients.

- High volumes are needed to attract and retain the specialists and support services personnel needed to provide Level III services, and SRMH's anticipated Level III volumes are low.

- At the public hearing, Doug Moyer, CEO of SRMH, stated that neonates may wait 2-3 hours before receiving care if they require transfer. That is simply not accurate. Mr. Moyer failed to acknowledge that infants being transported to UVA are essentially receiving state of the art neonatal care as soon as our Neonatal Emergency Transport System (NETS) Team, composed of highly trained specialists, sets foot in the RMH facility in a mobile ICU capable of providing the necessary services as they safely bring the baby to Charlottesville.

On April 16, 2021, Jordan Leonard, M.D., Medical Director and neonatologist at SRMH, responded to UVAMC's continued opposition and additional comments, and Dr. Sinkin's letter. Dr. Leonard's letter addressed:

- SRMH is disappointed that UVAMC continues to oppose this important community need. At best, UVAMC's continued opposition seems to be rooted in confusion about (i) the scope of nursery services to be provided, and the types of babies to be treated, by SRMH in the proposed NICU (as compared to those babies who will continue to be transferred to UVAMC for subspecialty-level care), and (ii) the utility of precisely quantifying historical transfer data, which SRMH, and effectively even UVAMC, has acknowledged are inherently imprecise given the number and variability of data sources and metrics.

- SRMH disagrees with UVAMC's position that data in the record do not establish a need for a NICU at SRMH or that the proposed NICU will somehow be both too small to yield high-quality outcomes and yet too large to operate without negatively impacting one of the state's busiest subspecialty nurseries.

- Given SRMH's uncontested status as the busiest labor and delivery program in PD 6, and the significant distance to the closest NICU, it strains credulity to think that SRMH does not have the birthing volumes to support a successful NICU while, at the same time, UVAMC continues to fulfill its role as the region's only Level IV subspecialty nursery.

- Throughout the course of this review, and as summarized most recently in its letter dated January 26, 2021, SRMH has undertaken significant efforts to locate and analyze relevant data to help quantify the need for this project and to support its conservative request. SRMH has reviewed and re-reviewed its internal EMTALA transfer log, APCD information, VHI reports, and even UVAMC's own internal data submitted with its letters. Based on this review, there appear to be two clear takeaways:

    - As UVAMC acknowledges, data differences are inevitable. Data sources are voluminous and metrics are imperfect and variable.

    - Notwithstanding data discrepancies, the record is replete with data and information establishing numerous uncontested indicia of public need for a NICU at SRMH.

- SRMH is similar in size based on birthing volumes to two other large birthing facilities in Virginia that operate successful Level III nurseries and are located approximately one hour from the closest Level IV nursery – Mary Washington Hospital in PD 16 (located about an hour from Inova Fairfax Hospital in PD 8 and six Level IV nurseries in PD 15), which reported 1,755 births in 2019 (compared to 1,853 reported births at SRMH), and Virginia Baptist Hospital in Lynchburg in PD 11 (located about an hour from Carilion Roanoke Memorial Hospital in PD 5), which reported 1,961 births.

- Acutely aware of the variability of data and data sources, SRMH has proposed a conservatively sized NICU that will bring the much-needed standard of neonatal care to the communities it serves.

- SRMH does not dispute that complications arise in caring for preterm babies. With a NICU at SRMH, though, the vast majority of preterm babies currently sent to UVAMC for Level III care will be able to receive Level III services closer to home. SRMH is fully aware of what the law requires of a Level III nursery, and, importantly, what best practices dictate above and beyond regulatory requirements. SRMH has the specialists, experience, volumes, and institutional knowledge of two busy and successful NICUs – Sentara Norfolk General Hospital and Sentara Princess Anne Hospital – to meet demand for Level III nursery care at SRMH in a safe, high quality manner.

    - In general, very low birth weight babies are born prior to 30 weeks' gestation and require a variety of intensive, subspecialized nursery care. As SRMH repeatedly has clarified in

this review, these are not the babies whom SRMH primarily is trying to serve with this proposal, but rather the very type of neonate whom SRMH will continue to send to UVAMC for subspecialty nursery care. With a NICU, SRMH aims to treat primarily moderate or late preterm babies who need only, for example, intravenous support or minimal respiratory support – services that SRMH is fully capable of providing but that Virginia regulations permit only in a Level III or higher nursery.

  - SRMH would staff its proposed NICU with three pediatric hospitalists, at least two neonatologists, and either an additional neonatologist or two advance practice providers to permit 24-hour in-house coverage. Comparing UVAMC and SRMH in this regard is unproductive and immaterial to a determination of public need.

  - The vast majority of Level III nurseries in Virginia do not staff the subspecialty service lines identified in Dr. Sinkin's letter such as pediatric radiology, surgery, or neurosurgery because they are not required to do so to operate safe, successful NICUs.

- To the extent that a NICU at SRMH would impact UVAMC, such an impact would be marginal at best and significantly outweighed by the immense benefits to access and patient care for SRMH patients.

- SRMH patients experience the very type of unique challenges accessing care from their rural communities that the COPN law calls on the Commissioner to consider in assessing need, and which the Commissioner indeed has considered in finding public need for other services at SRMH.

Public Hearing

Section 32.1-102.6 B of the Code of Virginia directs DCOPN to hold one public hearing on each application in a location in the county or city in which the project is proposed or a contiguous county or city in the case of competing applications; or in response to a written request by an elected local government representative, a member of the General Assembly, the Commissioner, the applicant, or a member of the public. COPN Request No. VA-8483 is not competing with another project in this batch cycle, but DCOPN received a request from the applicant to conduct a public hearing. DCOPN conducted a public hearing on April 7, 2021 by video conference. A total of 81 individuals attended the video conference, including 12 who spoke. 74 individuals expressed support for the proposed project, five individuals expressed opposition to the proposed project and two individuals took no position. The project was presented by representatives of SRMH. Members of the public and the SRMH medical community spoke in support of the project, discussing:

- The Old Order Mennonite Community's support of the project.

- The distance to the NICU at UVAMC and the treacherous conditions of Afton Mountain in bad weather.

- The SRMH project is about improving access to NICU services for SRMH's patients.

- The difficulties experienced by families with sick newborns who have to travel to UVAMC or other area NICUs, including the emotional toll, expense, difficulties of leaving other children at home, pain of not being able to see your newborn every day, and inconvenience of traveling while recovering from birth.

(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 asserts that there are no reasonable alternatives to the proposed project. Regarding maintenance of the status quo, the applicant states:

> The status quo is not a viable option. SRMH is one of only two hospitals in Virginia that has annual birthing volumes higher than 1,700 but lacks a specialty level nursery. At the same time, it is the only intermediate-level nursery in Virginia supporting an L&D program that delivers more than 1,000 babies annually and is located more than 60 minutes from the closest NICU. In short, SRMH operates a robust L&D program, serves patients residing in a vast, mostly rural service area, is the birthing hospital of choice for those patients, yet cannot provide much-needed nursery care to patients in need of NICU services. Instead, those patients are transferred – or mothers are redirected prior to birth – to distant hospitals outside of PD 6.
>
> Those facilities are not ideally accessible to SRMH's patients, and transfer to those facilities entails a host of financial, emotional and clinical burdens. UVAMC, the closest provider of higher-acuity (specialty and sub-specialty level) NICU services and thus the most frequent destination for NICU transfers from SRMH, is more than 60 minutes away in ideal travel conditions and further for many residents of SRMH's mostly rural service area.
>
> In addition to being geographically challenging to access for SRMH patients, UVAMC can be practically challenging to access due to high occupancy of its NICU…. In the past, UVAMC's high occupancy levels have prevented it from accepting all transfer requests from SRMH, requiring patients and mothers to seek care at more distance facilities…

However, as will be discussed in greater detail later in this staff analysis report, the SMFP directs that 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. As demonstrated in **Table 8** and **Figure 1**, UVAMC (sub-specialty level) and Valley Health Winchester Medical Center (specialty level) are located within a 90-minute drive from SRMH. With a drive time of 62 and 70 minutes respectively, UVAMC or Valley Health Winchester Medical Center are reasonable alternatives per the drive time standard of the SMFP.

Regarding available capacity, as demonstrated in **Table 1**, in 2019, UVAMC operated at 87% capacity and Valley Health Winchester Medical Center operated at 52% capacity. As previously discussed, in response to the applicant's assertion that UVAMC's high occupancy levels have prevented it from accepting all transfer requests from SRMH, UVAMC stated: "[v]ery few

infants or mothers are diverted and our capacity is adequate to meet the needs of those seeking care at our hospital…. and "[i]n 2017-2019, UVAMC diverted no more than 6 babies from SRMH...." Furthermore, UVAMC explained that it is adding five additional specialty/subspecialty bassinets, available in July 2020, to meet the community need for NICU services. Finally, at 52% occupancy, Winchester Medical Center has available capacity to serve newborns needing specialty level nursery services. For these reasons, it can be argued that the status quo is a reasonable alternative to the proposed project.

Table 8. Travel Time and Distance from SRMH

Facility (COPN Approved Bassinet Level)	Travel Time (Minutes)	Travel Distance (Miles)
Mary Washington Hospital (Specialty)	117	88.5
Spotsylvania Regional Medical Center (Specialty)	124	91.6
University of Virginia Medical Center (Sub-specialty)	62	60.5
Valley Health Winchester Medical Center (Specialty)	70	72.7

Source: Google Maps (4/12/2021)

(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 I designated by the Virginia Department of Health to serve as the Health Planning Agency for the northwestern Virginia region. Accordingly, this consideration is not applicable to this review.

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

As demonstrated by **Table 4** above, the projected capital costs of the proposed project are $3,474,200. The project will be funded through a combination of accumulated reserves and support from the RMH Foundation. Accordingly, there are no financing costs associated with this project. DCOPN concludes these costs are considerable, but are consistent with previously approved projects to introduce NICU services. For example, COPN VA-04537 issued to StoneSprings Hospital Center to introduce intermediate level NICU services with six newborn stations, which cost approximately $2,313,184, but was projected to cost $4,867,000.

The applicant identified numerous benefits of the proposed project, including:

- SRMH will be able to retain and care for neonates born at 24-weeks' gestation or who would otherwise require higher-level nursery care and must currently be transferred to other facilities.

- Transferring newborns to other facilities significantly disrupts care delivery and continuity and creates clinical risks for the babies. Separating babies from their mothers for purposes of

treatment also increases stress levels for newborns and disrupts the parent-newborn bonding process. Decreasing the number of transfers to distant facilities for neonatal intensive care nursery services will alleviate the associated financial, emotional and clinical concerns.

- The proposed project will significantly improve access to care for mothers and babies, enhance care delivery and clinical outcomes, minimize delays and access burdens, reduce costs and improve patients' experience.

- The proposed project will allow SRMH to provide enhanced respiratory services, including CPAP airway support and ventilators for more serious respiratory needs.

- The project will reduce the cost of care for patients and the healthcare system overall. The cost of transferring a neonate from SRMH to the closest NICU can run between $20,000 and $50,000 by air and between $3,000 and $5,000 by ground.

- Enabling mothers to deliver at the hospital of their choice promotes continuity of care.

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

The Pro Forma Income Statement (**Table 9**) provided by the applicant does not address the provision of charity care. However, DCOPN notes that according to regional and statewide data regularly collected by VHI, for 2018, the most recent year for which such data is available, the average amount of charity care provided by HPR I facilities was 3.0% of all reported total gross patient revenues (**Table 6**). In that same year, SRMH provided 3.21% of its gross patient revenue in the form of charity care. Pursuant to Section 32.1 – 102.4 of the Code of Virginia, should the Commissioner approve the proposed project, DCOPN recommends a charity care condition no less than the 3.0% HPR I average.

Table 9. SRMH Pro Forma Income Statement

	Year 1	**Year 2**
Gross Revenue	$8,380,136	$9,090,414
Contractuals & Bad Debt	($5,568,531)	($6,155,138)
Net Revenue	$2,811,605	$2,935,276
Variable Expenses	$2,292,463	$2,437,808
Fixed Expenses	$261,382	$243,144
Excess (deficit) of Revenue Over Expenses	**($39,010)**	**($42,446)**

Source: COPN Request No. VA-8483

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

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. [2]

Furthermore, 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 to introduce neonatal specialty care services at LewisGale Medical Center in Salem, Virginia. Regarding this specific provision of the SMFP, the Commissioner said:

> 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.

As previously discussed, the applicant is proposing to add five bassinets to its existing six bassinet intermediate level nursery, for a total of 11 bassinets that could be used to provide specialty level nursery care. DCOPN again notes that 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. SRMH has projected a volume of 2,654 patient days by Year 1, and a volume of 2,709 patient days by Year 2 for its requested specialty level service. With respect to the average daily census, this amounts to an average of 7.3 and 7.4 specialty level NICU patients per day. This projection falls considerably short of the 15 patient average daily census threshold recommended by the American Academy of Pediatrics, in addition to the 44.6 average daily census accomplished by UVAMC, and the 15.7 average daily census accomplished by Valley Health Winchester Medical Center in 2019.

[2] 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.

3. The extent to which the application is consistent with the State Medical Facilities Plan.

Section 32.1-102.2:1 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, these regulations provide the best available criteria and DCOPN will consider the consistency of the proposed project with the predecessor of the SHSP, the State Medical Facilities Plan (SMFP).

The SMFP contains criteria/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 driving conditions of hospitals providing general level newborn services using mapping software as determined by the commissioner.

Not applicable. The applicant is not requesting to introduce intermediate level special care services. However, if the proposed project is approved, DCOPN expects that an undetermined portion of the utilization of the specialty level bassinets will be utilized for intermediate level care.

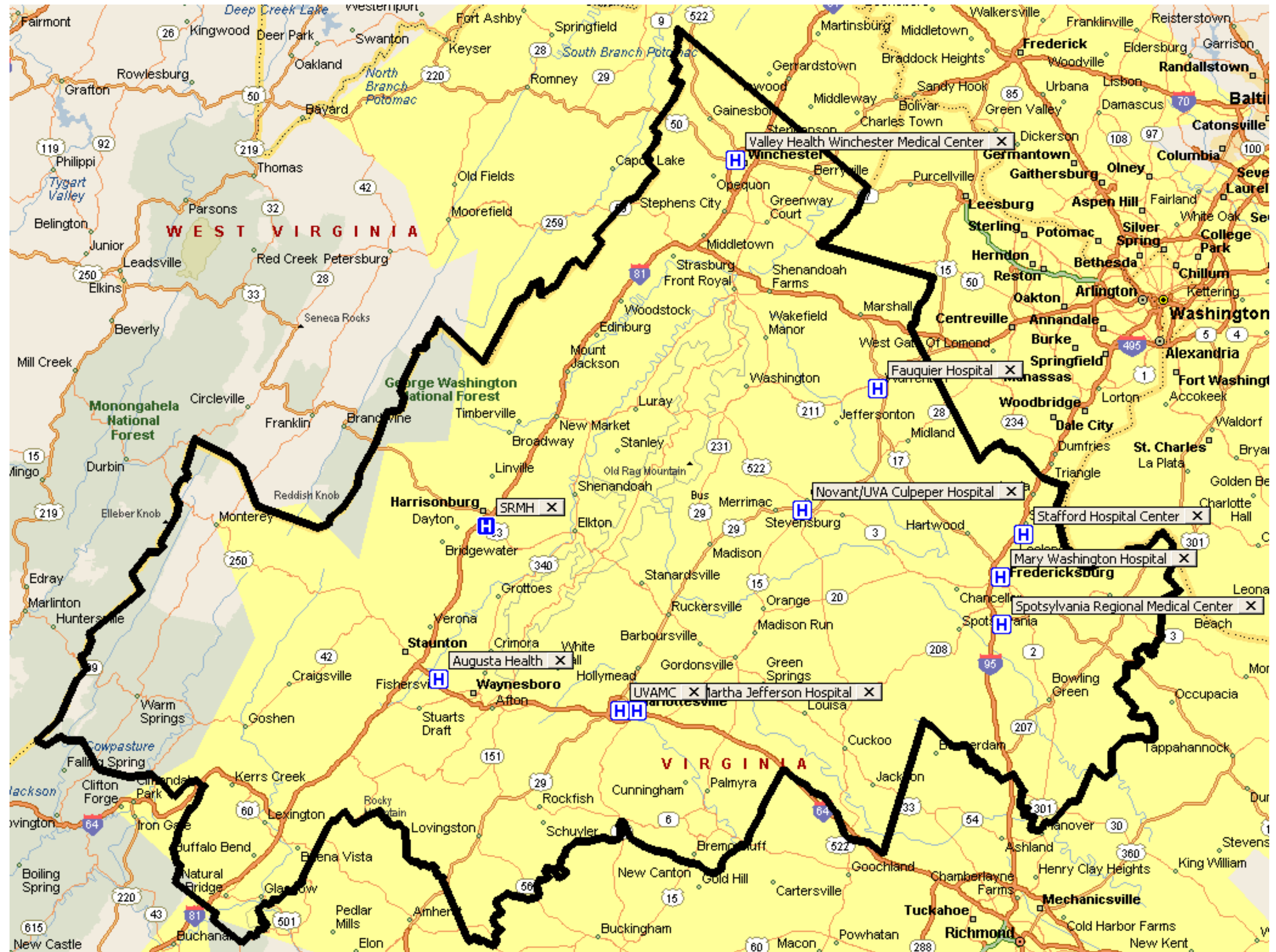
B. Specialty and subspecialty neonatal special care services should be located within 90 minutes driving time under normal conditions of hospitals providing general or intermediate level newborn services using mapping software as determined by the commissioner.

There are three specialty level nurseries in HPR I: Mary Washington Hospital (Specialty), University of Virginia Medical Center (Sub-specialty), and Valley Health Winchester Medical Center (Specialty). Additionally, there are six hospitals offering general or intermediate level newborn services in HPR I: Augusta Health (Intermediate), Fauquier Hospital (Intermediate), Novant Health UVA Health System Culpeper Hospital (General), Spotsylvania Regional Medical Center (Intermediate), SRMH (Intermediate), and Stafford Hospital Center (Intermediate).

The heavy dark line in **Figure 1** is the boundary of HPR I. The white “H” symbols mark the locations of existing nurseries in HPR I. The blue “H” symbol marks the location of the proposed project. The yellow shading illustrates the area that is within 90 minutes driving time from the HPR I facilities that offer specialty or sub-specialty level nursery series. As demonstrated by **Figure 1**, all of the facilities in HPR I that provide general or intermediate level newborn services are within 90 minutes driving time from a facility that provides specialty or sub-specialty neonatal special care services. Therefore, approval of the proposed project would

not significantly increase geographic access to specialty neonatal special care for residents of HPR I.

Figure 1



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 region.

Not applicable. The applicant is not requesting to introduce intermediate level newborn services.

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

Not applicable. The applicant is not requesting to introduce intermediate level newborn services.

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 health planning region.

Not applicable. The applicant is not requesting to introduce intermediate level newborn services.

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 any new specialty 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 level, specialty level and 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.

On January 6, 2020, the Commissioner issued a decision in response to LewisGale Medical Center's request for Reconsideration of the December 13, 2019 denial of COPN Request No. VA-8391 to introduce neonatal specialty care services at LewisGale 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 found:

> 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 intermediate and specialty level nurseries (which may also be used to provide intermediate level care) in HPR I, in 2019, was far below 85%, at only 63% (**Table 1**).

B. Specialty level newborn services as designated in 12VAC5-410-443 should contain a minimum of 18 bassinets.

This standard is not met. The applicant is proposing to add five bassinets to its existing six bassinet intermediate level nursery, for a total of 11 bassinets that could be used to provide

specialty level nursery care. 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.

As previously discussed, on January 6, 2020, the Commissioner issued a decision in response to LewisGale Medical Center's request for Reconsideration of the December 13, 2019 denial of COPN Request No. VA-8391 to introduce neonatal specialty care services at LewisGale Medical Center in Salem, Virginia. Regarding this specific provision of the SMFP, the Commissioner found:

> This condition is not met. LewisGale is requesting approval for only an 8-bassinet unit, less than half the required 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 [Lewis Gale] application. Specifically, the projects at St. Francis and Chesapeake were approved in 2006 and 2007 before the COPN law underwent significant change in 2009…
>
> 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.

Furthermore, in his December 13, 2019 decision, the Commissioner found:

> But the fact that providers have decreased the number of bassinets in their specialty level newborn service after obtaining their COPN does not change the SMFP requirement. Although I acknowledge that the number of bassinets can change at will, LewisGale Medical Center is requesting less than half the required number of bassinets under this provision. 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.

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.

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 nursery hospitals may often be arbitrary.

However, DCOPN notes that according to VHI data for 2019, the most recent year for which such data is available, there were 12,857 live births in HPR I (**Table 2**), representing a maximum of 51.4 specialty level bassinets in HPR I. 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 sub- specialty level nurseries in HPR I may also provide specialty (and intermediate) level care. DCOPN notes that there are 102 bassinets that are approved for a maximum care level of specialty or sub-specialty. Thus, it can be argued that there already exists a surplus of bassinets in HPR I.

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.

If the proposed project is approved, it is expected that most, if not all, of the newborns born at SRMH who require specialty level care will stay at SRMH, instead of going to UVAMC or Valley Health Winchester Medical Center, as they would currently. It is also expected that UVAMC and Valley Health Winchester Medical Center will experience a decline in both specialty admissions resulting from patients and/or their physicians choosing to seek obstetrical services at SRMH because it offers specialty level newborn services. Although the applicant asserts "it is nearly impossible to know with certainty the number of babies transferred from SRMH, or mothers redirected to birth, for higher-level nursery care due to volume and variability of data sources," based on its clinical data, in combination with its EMTALA logs, the applicant estimates that with a specialty level NICU, it could have retained 57 mothers and babies in 2017, 90 mothers and babies in 2018, and 79 mothers and babies in 2019, which would assuredly have some negative impact on the utilization at UVAMC or Valley Health Winchester Medical Center. At the very least, approval of the proposed project could reduce Winchester Medical Center's average daily census, which at 15.7, is barely meeting the threshold recommended by the American Academy of Pediatrics.

Accordingly, DCOPN considers the proposed project to be an unnecessary duplication of existing special care nursery services that will improve access only for those patients who would prefer to receive services at SRMH with a detrimental impact on UVAMC's and Valley Health Winchester Medical Center's special care nursery programs.

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 any new subspecialty level newborn services can be added to the health planning region.

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

B. Subspecialty level newborn bassinets as designated in 12VAC5-410-443 should contain a minimum of 18 bassinets.

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

C. No more than four bassinets for subspecialty level newborn services as designated in 12VAC50410-443 per 1,000 live births should be established in each health planning region.

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

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 times listed in 12VAC5-230-940 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. The applicant indicates that SRMH's service area for neonatal services covers a vast geographic region, including the cities of Harrisonburg, Staunton and Waynesboro and the counties of Page, Rockingham, Shenandoah and Augusta. The applicant also asserts that all counties in SRMH's Virginia-based service area are mostly rural. Furthermore, the applicant explains that the service area includes Augusta Medical Center (intermediate level neonatal service), Valley Health Page Memorial Hospital (no neonatal service) and Valley Health Shenandoah Memorial Hospital (no neonatal service).

12VAC5-230-1000. 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 SRMH will be under the direction and supervision of board-certified neonatologists. The applicant reports that the proposed NICU will incorporate a sleeping in room to ensure that a provider is available at all times. The applicant also provided an affidavit from Dr. Ann T. Heerens, Corporate Medical Director at Pediatrix Medical Group. Pediatrix Medical Group has partnered with SRMH to provide neonatology care in SRMH's intermediate level nursery. Dr. Heerens attests that Pediatrix Medical Group has "the training, experience, and expertise to care for mothers and babies in need of specialty level nursery services" and that its goal is to have two full-time neonatologists on staff at SRMH full time.

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 SRMH does not currently offer specialty level nursery services, approval of the proposed project would foster institutional competition. However, DCOPN does not consider such competition beneficial. As previously discussed, and by the applicant's own admission, approval of the proposed project will result in a low-volume program at SRMH, with an average daily census that is less than half of the daily census recommended by the American Academy of Pediatrics, and is highly likely to have a deleterious impact on the utilization of other specialty level nurseries in HPR I, a service where there is a direct correlation between higher volumes and favorable clinical outcomes.

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

As previously discussed, approval of the proposed project would not significantly increase geographic access to specialty neonatal special care for residents of HPR I but is likely to reduce utilization at other specialty level nurseries in HPR I.

Furthermore, approval of this project will likely lead to a low volume NICU program at SRMH. As previously discussed, the applicant is proposing to add five bassinets to its existing six bassinet intermediate level nursery, for a total of 11 bassinets that could be used to provide specialty level nursery care. DCOPN again notes that 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. SRMH has projected a volume of 2,654 patient days by Year 1, and a volume of 2,709 patient days by Year 2 for its requested specialty level service. With respect to the average daily census, this amounts to an average of 7.3 and 7.4 specialty level NICU patients per day. This projection falls considerably short of the 15 patient average daily census threshold recommended by the American Academy of Pediatrics[3], in addition to the 44.6 average daily census accomplished by UVAMC and the 15.7 average daily census accomplished by Valley Health Winchester Medical Center in 2019. 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."

[3] See Footnote 2

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;

The Pro Forma Income Statement (**Table 9**) provided by the applicant projects a net deficit of $39,010 by the end of the first year of operation and a net deficit of $42,446 by the end of year two. As previously discussed, the projected capital costs of the proposed project total $3,474,200. The project will be funded through a combination of accumulated reserves and support from the RMH Foundation. Accordingly, there are no financing costs associated with this project. As previously discussed, the costs for the project are considerable, but consistent with previously approved projects to introduce NICU services. Because the project will be funded through a combination of accumulated reserves and support from the RMH Foundation, and there are no financing costs associated with it, the proposed project can be considered financially feasible despite the initial losses in Years 1 and 2.

The applicant anticipates the need to hire 12 registered nurses to staff the proposed project. While this number is relatively few staff to hire, this is *in addition to* the over 50 registered nursing positions currently vacant at SRMH. DCOPN notes that the applicant is an established provider of obstetrical services and will use a variety of methods to recruit additional personnel, such as advertising online and in newspapers and utilizing career fair. Additionally, SRMH is a teaching hospital and works closely with the nursing programs at James Madison University, Blue Ridge Community College and Eastern Mennonite University. As such, DCOPN concludes that the applicant will not have difficulty filling the required registered nurse positions.

As previously discussed, the applicant provided an affidavit from Dr. Ann T. Heerens, Corporate Medical Director at Pediatrix Medical Group. Pediatrix Medical Group has partnered with SRMH to provide neonatology care in SRMH's intermediate level nursery. Dr. Heerens attests that Pediatrix Medical Group has "the training, experience, and expertise to care for mothers and babies in need of specialty level nursery services" and that its goal is to have two full-time neonatologists on staff at SRMH full time.

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 introduce no 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.

SRMH has a longstanding cooperation and transfer agreement with UVAMC, under which SRMH transfers neonates in need of higher-level nursery services to UVAMC. If the Commissioner approves the proposed project, SRMH anticipates continuing this longstanding

relationship by transferring neonates in need of subspecialty nursery services to UVAMC, while keeping babies in need of specialty level nursery services at SRMH, closer to home.

DCOPN did not identify any other discretionary factors to bring to the Commissioner's attention.

8. In the case of a project proposed by or affecting a teaching hospital associated with a public institution of higher education or a 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 for citizens of the Commonwealth, including indigent or underserved populations.

SRMH serves as a teaching hospital for nurses from area schools of nursing, including James Madison University, Eastern Mennonite University, Blue Ridge Community College, and plans to work with Bridgewater College for recruitment of non-clinical staffing.

DCOPN Findings and Conclusions

DCOPN finds that the proposed project to introduce specialty level NICU services with the addition of five 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.

The proposed project does not comply with 12VAC5-230-970B, which requires that specialty level newborn services contain a minimum of 18 bassinets. The applicant is proposing to add five bassinets to its existing six bassinet intermediate level nursery, for a total of 11 bassinets that could be used to provide specialty level nursery care. The proposed project also does not comply with 12VAC5-230-970C, which directs that there should be no more than four bassinets for specialty level newborn services per 1,000 live birth in the HPR. There were 12,857 live births in HPR I in 2019 (**Table 2**), representing a maximum of 51.4 specialty level bassinets in HPR I. At present, 102 bassinets are approved for a maximum care level of specialty or sub-specialty. Thus, it can be argued that there already exists a surplus of bassinets in HPR I.

DCOPN finds that the total projected capital cost of $3,474,200 are considerable but are consistent with previously approved projects to introduce NICU services. However, DCOPN further finds that the status quo is preferable to the proposed project. Specialty level neonatal care services are currently within 90 minutes drive time of hospitals offering general or intermediate level nursery services in HPR I and approval of the proposed project would not significantly increase geographic access for residents of HPR I. With drive times of 62 and 70 minutes, respectively, UVAMC or Valley Health Winchester Medical Center are reasonable alternatives to the proposed project, and both facilities had available capacity in 2019. Additionally, UVAMC stated in its letter of opposition that it is adding five additional specialty/subspecialty bassinets, available in July 2020, to meet the community need for NICU services.

Moreover, DCOPN finds that approval of the proposed project would have a detrimental impact on UVAMC's and Valley Health Winchester Medical Center's special care nursery programs.

Finally, approval of this project will likely lead to a low volume NICU program at SRMH, with an anticipated average daily census of 7.3 and 7.4 NICU patients per day. This projection falls considerably short of the 15 patient average daily census threshold recommended by the American Academy of Pediatrics[4], in addition to the 44.6 average daily census accomplished by UVAMC and the 15.7 average daily census accomplished by Valley Health Winchester Medical Center in 2019. 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 Sentara RMH Medical Center's proposed project to introduce specialty level neonatal special care services with up to five bassinets.

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 I and within a 90-minute drive time from SRMH.

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

[4] See Footnote 2