

# VIRGINIA DEPARTMENT OF HEALTH

## Office of Licensure and Certification

### Division of Certificate of Public Need

#### Staff Analysis

November 19, 2020

#### **COPN Request No. VA-8525**

Virginia Commonwealth University Health Systems Authority

Richmond, Virginia

Introduction of lung transplant services

#### **Applicants**

The Virginia Commonwealth University Health Systems Authority (VCUHS), doing business as VCU Medical Center, is a public body corporate and political subdivision of the Commonwealth of Virginia, governed by the Virginia Commonwealth University Health System Authority Act of 1996-Title 23, Chapter 6.2, 23-50.16:1 of the Code of Virginia. Subsidiaries of the applicant include MCV Associated Physicians, Crippled Children's Hospital, Community Memorial Hospital, University Health Services, Inc., Virginia Premier Health Plan, Inc., Rehab JV, LLC, and Virginia Children's Care Network, LLC. VCUHS proposes to introduce lung transplantation services at the VCUHS Transplant Center (VCUHS Transplant). VCUHS Transplant is located in Planning District (PD) 15, Health Planning Region (HPR) IV.

#### **Background**

VCUHS created one of the nation's first clinical organ transplantation programs in 1957 after performing its (and Virginia's) first kidney transplant in 1956. VCUHS added heart and liver transplantation services in 1968, and pancreas transplantation services in 2001. According to data from the Organ Procurement and Transplantation Network (OPTN), VCUHS performed 37% of all solid organ transplants in Virginia in 2019<sup>1</sup>. VCUHS' organ transplantation program relies on all disciplines and departments within VCUHS and is supported by:

- A transplant surgery team;
- Specialized transplant teams for each organ system;
- A transplant consultation team;
- A transplant administrative team (including transplant psychology, pharmacy lab, and research specialists);

---

<sup>1</sup> U.S. Department of Health and Human Services. Organ Procurement and Transplantation Network. State Data Reports: Transplants by Donor Type and Center. <https://optn.transplant.hrsa.gov/data/view-data-reports/state-data/#>. Accessed November 17, 2020.

- A transplant clinical team; and
- Other clinical and administrative team members, such as dedicated social workers, transplant dietitians, financial coordinators, and outreach coordinators.

VCUHS’ Division of Pulmonary and Critical Care Medicine operates nationally recognized centers of excellence in pulmonary hypertension, cystic fibrosis and sarcoidosis and has growing programs in interstitial lung diseases, chronic obstructive pulmonary disease (COPD) and lung cancer. VCUHS manages large cohorts of patients for whom lung transplantation could be a lifesaving option, including:

- 1,600 patients in the sarcoidosis program;
- More than 100 patients with cystic fibrosis; and
- Over 300 patients with pulmonary hypertension.

The applicant asserts that VCUHS’ proposal to augment its existing transplant program with lung transplantation services reflects the growth in VCUHS’ organ transplantation programs, the growth in VCUHS’ lung disease services and the growing demand for lung transplantation services in Central Virginia and HPR IV.

According to Virginia Health Information (VHI) data and DCOPN records, there are two lung transplant providers in Virginia, at the University of Virginia Medical Center (UVAMC) in HPR I, PD 10 and at Inova Fairfax Hospital (Inova Fairfax) in HPR II, PD 8 (**Table 1**).

**Table 1. COPN Authorized Lung Transplant Programs in Virginia**

Facility	PD	Lung Transplants						2012
		2018	2017	2016	2015	2014	2013	
University of Virginia	10	25	22	27	7	4	12	17
Inova Fairfax Hospital	8	25	24	20	17	21	26	23
<b>Total</b>		<b>50</b>	<b>46</b>	<b>47</b>	<b>24</b>	<b>25</b>	<b>38</b>	<b>40</b>

Source: VHI (2018) and DCOPN Records

**Proposed Project**

VCUHS proposes to add lung transplantation services to its existing solid organ transplantation services, which already include heart, liver, kidney and pancreas transplantation services. VCUHS Transplant is located at 1250 E. Marshall Street, Richmond, Virginia. The proposed lung transplantation services will be integrated with VCUHS’ existing organ transplantation services, infrastructure and resources. All spaces associated with the proposed project were constructed for inpatient hospital care and currently support solid organ transplantation services. Therefore, VCUHS will be able to quickly implement the requested addition of lung transplantation services without any physical modifications to the existing transplant center.

The projected capital costs of the proposed project are \$150,000 and include only the cost of purchasing an extracorporeal membrane oxygenation (ECMO) machine and related accessories (**Table 2**). Capital costs will be funded through the accumulated reserves of the applicant.

Accordingly, there are no financing costs associated with this project. The applicant asserts that the proposed project does not necessitate any construction or modifications to the existing spaces within VCUHS Transplant and thus no architectural planning or renovations are required for the proposed project. The applicant anticipates a target date of opening of Fall 2021.

**Table 2. VCUHS' Projected Capital Costs**

Equipment Not Included in Construction Contract	\$150,000
<b>Total Capital Costs</b>	<b>\$150,000</b>

Source: COPN Request No. VA-8525

### **Project Definitions**

Section 32.1-102.1:3 of the Code of Virginia defines a project, in part as the, "Introduction into an existing medical care facility...of any organ or tissue transplant service...." A medical care facility, includes "[a]ny 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;**

Geographically, VCUHS Transplant is located at 1250 E. Marshall Street, Richmond, Virginia, in close proximity to Interstates 95 and 64. Additionally, the VCUHS campus is served by public transportation, including the GRTC Pulse system – a modern high quality, high-capacity rapid transit system that serves a 7.6-mile route along Broad Street and Main Street, two major thoroughfares in the city of Richmond.

**Table 3** shows projected population growth in PD 15 through 2030. As depicted in **Table 3**, at an average annual growth rate of 1.01%, PD 15's population growth rate from 2010-2020 is well above the state's average annual growth rate of 0.77%. Overall, the planning district is projected to add an estimated 108,937 people in the 10-year period ending in 2020—an approximate 11% increase with an average increase of 10,893 people annually. In the 10-year period ending in 2030, the planning district is projected to add an estimated 108,303 people – an approximate 10% increase with an average increase of 10,830 people annually.

Regarding the 65+ age group for PD 15, Weldon-Cooper projects a more rapid increase in population growth (an approximate 48% increase from 2010 to 2020 and approximately 30% from 2020 to 2030). Weldon-Cooper further projects that statewide, the 65+ age cohort population will increase at a rate of approximately 38% from 2010 to 2030 and approximately 27% from 2020 to 2030.

**Table 3. Population Projections for PD 15, 2010-2030**

Locality	2010	2020	2010 - 2020		2030	2020 - 2030	
			% Change	Avg Ann % Change		% Change	Avg Ann % Change
Charles City	7,256	6,982	-3.78%	-1.51%	6,941	-0.59%	0.06%
Chesterfield	316,236	353,841	11.89%	1.10%	396,647	12.10%	1.15%
Goochland	21,717	23,547	8.43%	0.79%	26,702	13.40%	1.27%
Hanover	99,863	109,244	9.39%	0.88%	119,360	9.26%	0.89%
Henrico	306,935	332,103	8.20%	0.77%	363,259	9.38%	0.90%
New Kent	18,429	23,474	27.38%	2.39%	28,104	19.72%	1.82%
Powhatan	28,046	29,909	6.64%	0.63%	33,440	11.81%	1.12%
Richmond city	204,214	232,533	13.87%	1.28%	245,483	5.57%	0.54%
<b>Total PD 15</b>	<b>1,002,696</b>	<b>1,111,633</b>	<b>10.86%</b>	<b>1.01%</b>	<b>1,219,936</b>	<b>9.74%</b>	<b>0.93%</b>
PD 15 65+	<b>116,609</b>	<b>172,249</b>	<b>47.72%</b>	<b>3.88%</b>	<b>224,417</b>	<b>30.29%</b>	<b>2.68%</b>
Virginia	8,001,024	8,655,021	9.30%	0.77%	9,331,666	7.82%	0.76%
Virginia 65+	976,937	1,352,448	38.44%	3.22%	1,723,382	27.43%	2.45%

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

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 IV facilities was 3.7% of all reported total gross patient revenues (**Table 4**). In that same year, VCUHS provided 6.28% of its gross patient revenue in the form of charity care. The Pro Forma Income Statement provided by the applicant includes the provision of charity care in the amount of 0.1% (**Table 6**). The applicant explains that charity care is limited due to the ability for transplant patients to qualify for insurance coverage under Medicare, Medicaid or commercial coverage. VCUHS asserts that it has provided charity care in its transplantation services that compares favorably to other transplant providers in Virginia. 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. 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 of 0.1% of total patient services revenue derived from lung transplantation services provided at VCU Medical Center

**Table 4. HPR IV 2018 Charity Care Contributions**

Hospital	Gross Patient Revenues	Adjusted Charity Care Contribution	Percent of Gross Patient Revenue
Bon Secours Richmond Community Hospital	\$674,969,731	\$42,666,943	6.32%
VCU Health System	\$5,621,665,960	\$352,825,510	6.28%
Southside Community Hospital	\$293,702,705	\$14,237,351	4.85%
Bon Secours St. Francis Medical Center	\$970,223,902	\$43,084,096	4.44%
Bon Secours Memorial Regional Medical Center	\$1,552,613,092	\$68,611,063	4.42%
Bon Secours St. Mary's Hospital	\$2,176,359,866	\$77,859,815	3.58%

Hospital	Gross Patient Revenues	Adjusted Charity Care Contribution	Percent of Gross Patient Revenue
Sentara Halifax Regional Hospital	\$294,576,590	\$9,953,244	3.38%
Southside Regional Medical Center	\$1,956,522,794	\$63,281,154	3.23%
VCU Community Memorial Hospital	\$260,605,004	\$7,269,351	2.79%
CJW Medical Center	\$6,586,796,429	\$176,068,998	2.67%
Henrico Doctors' Hospital	\$4,501,141,313	\$97,784,217	2.17%
Southern Virginia Regional Medical Center	\$208,002,057	\$4,386,121	2.11%
John Randolph Medical Center	\$839,825,455	\$17,429,142	2.08%
Vibra Hospital of Richmond LLC	\$120,847,463	\$0	0.00%
Cumberland Hospital for Children and Adolescents	\$60,602,814	\$0	0.00%
Total Facilities			15
Median			3.2%
<b>Total \$ &amp; Mean %</b>	<b>\$26,118,455,175</b>	<b>\$975,457,005</b>	<b>3.7%</b>

Source: VHI (2018)

The applicant asserts that it accepts all patients, without regard to their ability to pay or other considerations. As one of the largest safety net hospitals in Virginia, VCUHS cares for medically challenging patient populations, including patients who are socioeconomically challenged, such as Medicaid enrollees, uninsured patients, and the prisoner population. DCOPN notes that according to the most recent U.S. Census data, the City of Richmond has a poverty rate of 24.5% - more than twice that of the statewide average (9.9%) and every other locality within PD 15 (**Table 5**). Additionally, and as will be discussed in greater detail later in this staff analysis report, approval of the proposed project will increase access for persons living in the southeastern portion of Virginia, including Norfolk, with a poverty rate of 19.7%, Portsmouth City, with a poverty rate of 17.2% and Franklin City, with a poverty rate of 16.2%.

**Table 5. Statewide and PD 15 Poverty Rates**

Locality	Poverty Rate
Virginia	9.9%
Charles City	12.3%
Chesterfield County	7.6%
Goochland County	6.7%
Hanover County	5.2%
Henrico County	9.0%
New Kent County	5.2%
Powhatan County	6.9%
Richmond City	24.5%

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

The applicant maintains that some patients in need of lung transplantation services, many of whom are Medicare or Medicaid beneficiaries with limited resources, decide to forego a life-saving transplant, intimidated by the extensive travel and non-medical costs. While the final tally for these

non-medical costs vary depending on the location of the procedure, the United Network for Organ Sharing (UNOS) details these non-medical costs<sup>2</sup> on its website, including:

- Food, lodging and long distance phone calls for the transplant recipient and his/her family
- Transportation, to and from the transplant center, before and after transplant
- Plane travel to get to the transplant hospital quickly
- Childcare
- Lost wages if the transplant recipient's employer does not pay for the time he/she spends away from work
- Lodging close to the center before and after surgery

Regarding the physical, logistical, economic and emotional toll that lung transplantation can have on a patient, the applicant explains:

Lung transplantation is not an episodic treatment, a fundamental concept underpinning the need for this proposal. Rather, it is a long-term process that commences long before the transplant surgery and continues for the remainder of the transplant patient's life. It is physically, mentally, emotionally, and financially taxing. It begins, often weeks, months, or even years before a donor lung becomes available, with a long and complicated evaluation process at a transplant facility, which may take place over several visits occurring over many weeks or even months. This process evaluates not only the condition of the patient's lungs but also his or her psychological make-up, other medical conditions, family and social support, and financial situation. A broad range of preliminary testing is necessary, including imaging studies, lab tests, and specialist consultations. Following this extensive evaluation, appropriate candidates are placed on a waiting list for an available organ. The transplant team then works with the local Organ Procurement Organization ("OPO") to find the most acceptable match for the patient. When a donor organ becomes available and is appropriately matched to the patient (by blood type, organ size, geographic location, and a range of other factors), the patient is notified and required to act quickly to get to the transplant center for surgery, typically within just a few hours.

Recovery after surgery can take several weeks or longer and includes administration of immunosuppressant medications to prevent the body's rejection of the new lung(s). For about three months following discharge, the patient must submit to close monitoring by the lung transplant care team to prevent, detect, and treat complications, assess lung function, and optimize immunosuppression. These first few weeks and months are critical to prevent infection and rejection, and patients must return to the transplant center frequently – possibly every day – for follow-up and therapy appointments. Typically, the patient is required to stay close to the transplant center during that time – ideally, less

---

<sup>2</sup> United Network for Organ Sharing. Transplant Living – Transplant Costs. <https://transplantliving.org/financing-a-transplant/transplant-costs/>. Accessed November 17, 2020.

than an hour away. Thereafter, follow-up visits continue, albeit at a less frequent rate, for the remainder of the patient's life and include immunosuppressant management, lab tests, chest x-rays, lung biopsies, and other tests and specialist check-ups.

At the public hearing for the proposed project, one patient with cystic fibrosis detailed her experience, which included:

- Receiving healthcare at the cystic fibrosis center at VCUHS, but having to relocate to within 30 minutes of Duke University in Durham, North Carolina to begin the lung transplant process there;
  - The significant expenses her family incurred to pay for her relocation expenses, recognizing that this would likely be impossible for socioeconomic challenged patients;
  - The challenge of attending frequent doctor appointments and coordinating the availability of enough supplemental oxygen when traveling; and
  - The difficulties of coordinating care between a cystic fibrosis center and lung transplant center that are not within the same hospital network, including transferring medical and imaging records and facilitating physician communications, especially in urgent care situations.
- 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 16 letters of support for the proposed project from members of the medical community and patients of VCUHS. Collectively, these letters articulate numerous benefits of the project, such as:

- Lung transplantation is a natural addition to VCUHS' top-tier, busy transplant center;
- The infrastructure that supports the transplantation of other organs overlaps substantially with the needs of a lung transplant program;
- Lung disease rates in Virginia, particularly for vulnerable populations and the socio-economically underserved, have been rising;
- Central Virginia is underserved in the area of management of advanced lung disorders and lung transplant;

- VCUHS has significant existing expertise in pulmonary hypertension, interstitial lung disease, COPD, cystic fibrosis and others – addition of lung transplant services will allow patients to gain the full benefit of a comprehensive program;
- VCUHS is an important part of the State safety net;
- VCUHS has key relationships with Veterans Health System and the lung transplant program will benefit the needs of the veterans;
- The lung transplant program will also benefit patients who do not require lung transplant but require complex lung care that is associated with lung transplant services;
- VCUHS has referred 60 patients for lung transplant evaluation in the last two years. Lung transplant requires patients to remain geographically close to the transplant center. This is not feasible for many of the patients that VCUHS serves, who do not have the financial or social resources to move to another city for several months;
- Having lung transplant services at VCUHS will benefit the fellowship program by expanding the breadth of pulmonary diseases for which the fellows will help care and would increase the research efforts and interests in varied lung diseases;
- Patients with cystic fibrosis require care at a cystic fibrosis center after transplant, which can be difficult when the cystic fibrosis center and the lung transplant center are not at the same hospital;
- The excellent standard of care at VCUHS and the professionalism and expertise of the transplant team.

### Public Hearing

Section 32.1-102.6 B of the Code of Virginia requires 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. DCOPN received a request to conduct a public hearing for COPN Request No. VA-8525 from the applicant.

DCOPN conducted the public hearing on October 7, 2020. A representative for the applicant presented the proposed project. Additionally, three physicians from VCUHS and several members of the public spoke. They highlighted the benefits of the proposed project, including:

- Adding lung transplantation services is a natural addition to the other solid organ transplantation services at VCUHS because of the shared infrastructure that already exists.



- Patients who receive lung transplants require lifelong visits. Traveling is inconvenient financially and logistically. Adding lung transplantation services at VCUHS will increase access.
- Several of VCUHS' programs related to lung health have been recognized as excellent, including the COPD program and cystic fibrosis program.
- VCUHS would be able to treat the over 60 patients it referred for lung transplantation to other facilities.

**(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 status quo could be a viable alternative to the proposed project. However, as will be discussed in greater detail later in this staff analysis report, the proposed project will increase geographic access to lung transplantation services for a portion of the population that does not currently have access within two hours driving time. Furthermore, the proposed project is complementary to VCUHS' existing solid organ transplantation services, the needed infrastructure already exists at VCUHS, and the proposed project requires only a modest capital investment to operationalize. Finally, VCUHS' patient base includes patients from areas with poverty rates that far exceed Virginia's statewide rate and who present unique socioeconomic challenges when facing the economic and logistical burdens involved with lung transplant services. For these reasons, DCOPN concludes that the proposed project is more advantageous than the status quo.

**(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 IV designated by the Virginia Department of Health to serve as the Health Planning Agency for PD 15. Therefore, this consideration is not applicable to the review of the proposed project.

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

As demonstrated by **Table 2**, projected capital costs of the proposed project are \$150,000 and include only the cost of purchasing an ECMO machine and related accessories. Capital costs will be funded through the accumulated reserves of the applicant. Accordingly, there are no financing costs associated with this project. DCOPN concludes that these capital costs are modest.

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

- The proposal will significantly improve access to lung transplantation services for patients in need;
- The proposal will reduce the physical, emotional, logistical and financial toll associated with lung transplantation;
- The proposal will promote continuity of care;
- The proposal will support VCUHS’ academic center functions, expanding opportunities for participation in important clinical research and trials; and
- The proposal will leverage the existing clinical and operational expertise within the VCUHS Transplant Center, the VCU Pauley Heart Center, and VCUHS Pulmonary and Critical Care Division.

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

The applicant is considered one of the largest safety net hospitals in the region and asserts that it treats all patients regardless of ability to pay or payment source. The Pro Forma Income Statement provided by the applicant includes the provision of charity care in the amount of 0.1% (**Table 6**). As previously discussed, the applicant explains that charity care is limited due to the ability for transplant patients to qualify for insurance coverage. DCOPN notes that, according to VHI data from 2018, the most recent year for which such data is available, the average amount of charity care provided by HPR IV facilities was 3.7% of all reported total gross patient revenues (**Table 4**). In that same year, VCUHS provided 6.28% 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 of 0.1% of the total patient services revenue derived from lung transplantation services provided at VCU Medical Center.

**Table 6. VCUHS’ Pro Forma Income Statement\***

	<b>Year 1 (2022)</b>	<b>Year 2 (2023)</b>
<b>Total Gross Charges</b>	<b>\$230,824, 817</b>	<b>\$262,915,017</b>
Contractual Adjustments	(\$142,568,981)	(\$160,788,134)
Bad Debt	(\$9,694,642)	(\$11,042,431)
Charity Care	(\$289,897)	(\$330,199)
<b>Net Patient Revenue</b>	<b>\$78,271,296</b>	<b>\$90,754,253</b>
Total Operating Expenses	(\$76,994,293)	(\$88,882,264)
<b>Excess Revenue</b>	<b>\$1,277,003</b>	<b>\$1,871,989</b>

Source: COPN Request No. VA-8525

\*Covers solid organ transplant services excluding heart transplantation.

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

UNOS uses its policies and computerized network to match donated organs with transplant candidates. In addition to blood type and other medical factors, UNOS lists survival benefit, medical urgency, waiting time, distance from donor hospital and pediatric status factor into the lung distribution policy. UNOS describes the organ transplant process as follows:

When a transplant hospital accepts a person as a transplant candidate, it enters medical data—information such as the person’s blood type and medical urgency and the location of the transplant hospital—about that candidate into UNOS’ computerized network. When an organ procurement organization gets consent for an organ donor, it also enters medical data—information such as the donor’s blood type and body size and the location of the donor hospital—into UNOS’ network. Using the combination of donor and candidate information, the UNOS computer system generates a “match run,” a rank-order list of candidates to be offered each organ. This match is unique to each donor and each organ. The candidates who will appear highest in the ranking are those who are in most urgent need of the transplant, and/or those most likely to have the best chance of survival if transplanted. The UNOS Organ Center helps place donated organs for transplantation 24 hours a day, 365 days a year<sup>3</sup>.

According to OPTN, in 2018, there were 60 donor lungs available in Virginia and in 2019, there were 70 donor lungs available<sup>4</sup>. Also according to OPTN, there are 29<sup>5</sup> candidates on the current Virginia lung transplant recipient wait list.

**3. The extent to which the application is consistent with the State Health Services 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).

---

<sup>3</sup> United Network for Organ Sharing. How We Match Organs. <https://unos.org/transplant/how-we-match-organs/>. Accessed November 17, 2020.

<sup>4</sup> U.S. Department of Health and Human Services. Organ Procurement and Transplantation Network. State Data Reports: Transplants by Donor Type and Center. <https://optn.transplant.hrsa.gov/data/view-data-reports/state-data/#>. Accessed November 17, 2020.

<sup>5</sup> U.S. Department of Health and Human Services. Organ Procurement and Transplantation Network. State Data Reports: Overall by Organ. <https://optn.transplant.hrsa.gov/data/view-data-reports/state-data/#>. Accessed November 17, 2020.

The SMFP contains criteria/standards for organ transplant services. They are as follows:

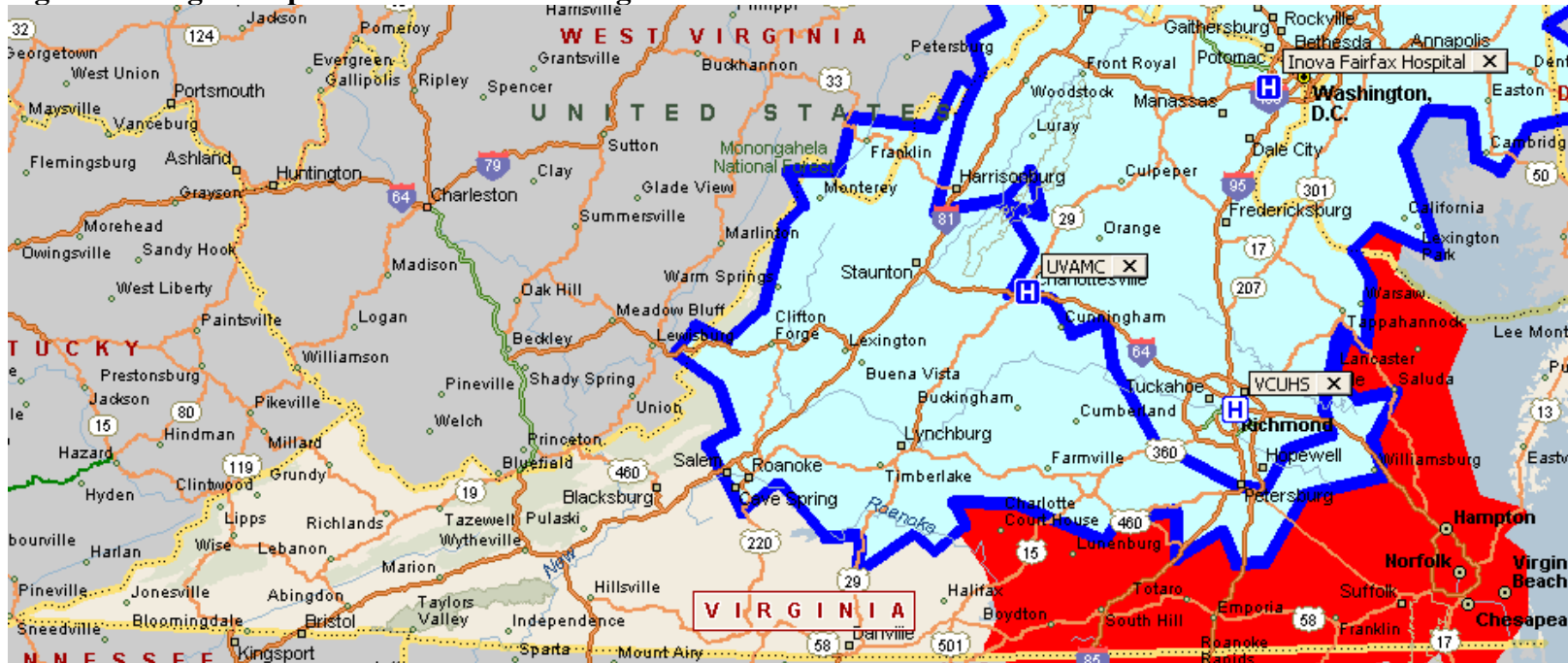
### Part IX Organ Transplant

#### 12VAC5-230-700. Travel time.

- A. Organ transplantation services should be accessible within two hours driving time one way under normal conditions of 95% of Virginia's population using mapping software as determined by the commissioner.

**Figure 1** displays the existing lung transplantation services in Virginia. The white “H” symbol marks the proposed location of VCUHS’ lung transplantation services. The blue “H” symbols mark the locations of other existing lung transplantation providers in Virginia - UVAMC and Inova Fairfax. The light blue shaded area with the dark blue outline represents the area of Virginia that is within 120 minutes’ drive time of existing lung transplantation services. The red shading represents the area within 120 minutes’ drive time of the proposed project that is not already within 120 minutes of an existing transplant center. As can be observed from the contrast between the dark blue outlines and the red shaded area, there is a portion of the population of Virginia that is not currently served by lung transplantation services within two hours driving time and would be served by the addition of lung transplantation services at VCUHS, including the population dense Tidewater Virginia region. Accordingly, DCOPN concludes that approval of the proposed project would improve geographical access to lung transplantation services for persons in Virginia.

**Figure 1: Lung Transplantation Services in Virginia**



**B. Providers of organ transplantation services should facilitate access to pre and post transplantation services needed by patients residing in rural locations by establishing parttime satellite clinics.**

VCUHS' transplant center currently has multiple satellite locations for heart, liver, kidney and pancreas patients located in South Richmond, Williamsburg and Newport News. Furthermore, VCUHS is in the process of establishing a satellite clinic in Fredericksburg. According to the applicant, these clinics are strategically positioned to promote access to patients who live in rural communities by providing appropriate care closer to patients' home communities. The applicant also explains that it plans to develop lung-focused clinics in those same communities and is in the discussion stage of establishing satellite clinics in more rural areas of central and southern Virginia. Finally, VCUHS' telehealth services are available, when clinically appropriate, for patients who are unable to travel to downtown Richmond.

**12VAC5-230-710. Need for New Service.**

**A. There should be no more than one program for each transplantable organ in a health planning region.**

**B. Performance of minimum transplantation volumes as cited in 12VAC5-230-720 does not indicate a need for additional transplantation capacity or programs.**

There are currently no lung transplantation services available in HPR IV. There are two providers of lung transplantation services in Virginia – UVAMC in HPR I, PD 10 and Inova Fairfax in HPR II, PD 8.

**12VAC5-230-720. Transplant Volumes; Survival Rates; Service Proficiency; Systems Operations**

**A. Proposals to establish organ transplantation services should demonstrate that the minimum number of transplants would be performed annually. The minimum number transplants of required by organ system is:**

<b>Kidney</b>	<b>30</b>
<b>Pancreas or kidney/pancreas</b>	<b>12</b>
<b>Heart</b>	<b>17</b>
<b>Heart/Lung</b>	<b>12</b>
<b>Lung</b>	<b>12</b>
<b>Liver</b>	<b>21</b>
<b>Intestine</b>	<b>2</b>

**Note: Any proposed pancreas transplant program must be a part of a kidney transplant program that has achieved a minimum volume standard of 30 cases per year for kidney transplants as well as the minimum transplant survival rates stated in subsection B of this section.**

VCUHS projects that it will perform 10-15 lung transplants in each of the first two years of operation, with higher volumes expected in the second year of operation. As previously discussed, in 2018, UVAMC and Inova Fairfax performed 25 lung transplants each. Considering that there were 60 donor lungs available for that same year, it is reasonable to conclude that if VCUHS’ request to add lung transplantation services is approved by the Commissioner, each facility would still be able to meet, if not exceed, the SMFP’s lung transplant standard by performing, at minimum, 12 lung transplants each and VCUHS’ projection is reasonable.

According to VHI data for 2018, VCUHS’ existing solid organ transplant services well exceeded the SMFP’s minimum thresholds, with the exception of pancreas transplant volume (**Table 7**). The applicant reports that the volume of pancreas/kidney transplants increased to 12 in 2019.

**Table 7. VCUHS’ Solid Organ Transplant Volumes - 2018**

Organ	VCUHS Volume	SMFP Standard
Heart	23	17
Kidney	194	30
Liver	73	21
Pancreas/Kidney	3	12

Source: VHI (2018) and SMFP

**B. Applicants shall demonstrate that they will achieve and maintain at least the minimum transplant patient survival rates. Minimum one-year survival rates listed by organ system are:**

<b>Kidney</b>	<b>95%</b>
<b>Pancreas or kidney/pancreas</b>	<b>90%</b>
<b>Heart</b>	<b>85%</b>
<b>Heart/Lung</b>	<b>70%</b>
<b>Lung</b>	<b>77%</b>
<b>Liver</b>	<b>86%</b>
<b>Intestine</b>	<b>77%</b>

According to VHI data for 2018, VCUHS’ existing solid organ transplant services met or exceeded the SMFP’s minimum thresholds for that year (**Table 8**). The applicant offers assurances that the proposed lung organ transplantation services would quickly meet and exceed the SMFP’s minimum one-year survival rate of 77%. Given VCUHS’ survival rate history with other organs, it is reasonable for VCUHS to project that it will be successful with lung transplant survivability as well.

**Table 8. VCUHS' Solid Organ Transplant Patient Survival Rates - 2018**

Organ	VCUHS	SMFP Standard
Heart	96%	85%
Kidney	95%	95%
Liver	91%	86%
Pancreas/Kidney	90%	90%

Source: VHI (2018) and SMFP

**12VAC5-230-730. Expansion of Transplant Services.**

**A. Proposals to expand organ transplantation services shall demonstrate at least two years successful experience with all existing organ transplantation systems at the hospital.**

As previously discussed, VCUHS' existing solid organ transplant services met or exceeded the SMFP's minimum thresholds for 2018.

**B. Preference may be given to a project expanding the number of organ systems being transplanted at a successful existing service rather than developing new programs that could reduce existing program volumes.**

As previously discussed, VCUHS' existing solid organ transplant services met or exceeded the SMFP's minimum patient survival rates for 2018. The proposed project is meant to further complement the existing programs and increase access to lung transplantation services for VCUHS' patients who may otherwise forego lung transplants because of the economic and/or logistical burdens of traveling to Charlottesville or Northern Virginia. As previously discussed, in 2018, UVAMC and Inova Fairfax performed 25 lung transplants each. Considering that there were 60 donor lungs available for that same year, it is reasonable to conclude that if VCUHS' request to add lung transplantation services is approved by the Commissioner, each facility would still be able to meet, if not exceed, the SMFP's lung transplant standard.

**12VAC5-230-740. Staffing.**

**Organ transplant services should be under the direction or supervision of one or more qualified physicians.**

The applicant is an established provider of solid organ transplant services. VCUHS currently has a team of surgeons capable of performing lung transplant services led by Dr. Benjamin Medalion. Dr. Medalion is VCUHS' chair of cardiothoracic surgery. Dr. Medalion comes from University Hospitals in Cleveland where he established a lung transplant program and served as a transplant surgeon and attending surgeon in the Division of Cardiac Surgery. Prior to his work at University Hospitals in Cleveland, Dr. Medalion was the director of the largest lung transplant program in Israel at the Rabin Medical Center.

### 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;**

As previously discussed, there are no providers of lung transplantation services in HPR IV and VCUHS' proposal would increase geographic access to lung transplantation services for Virginians who do not currently have access to these services within a two-hour drive time. While it is reasonable to conclude that some portion of patients receiving lung transplantation services at UVAMC or Inova Fairfax may seek this care at VCUHS, it is likely that each facility would still be able to meet, if not exceed, the SMFP's lung transplant standard if VCUHS' request is approved..

**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 already discussed, VCUHS' existing transplantation services include solid organ transplant for heart, kidney, liver and pancreas. Furthermore, VCUHS' existing solid organ transplant services met or exceeded the SMFP's minimum patient survival rates in 2018. The proposed project is meant to further complement the existing programs and increase access to lung transplantation services for VCUHS' patients who may otherwise forego lung transplants because of the economic and/or logistical burdens of traveling to Charlottesville or Northern Virginia. As previously discussed, these costs can be considerable and may include relocation, lodging, food, transportation to and from surgery center, childcare and lost wages.

**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 modest. The applicant will fund the proposed project using accumulated reserves. Accordingly, there are no financing costs associated with this project. Furthermore, the Pro Forma Income Statement provided by the applicant projects excess revenue of \$1,277,003 in the first year of operation and of \$1,871,989 in the second year of operation

The applicant anticipates the need to hire 11 additional full-time equivalent personnel (FTE) to staff the proposed project. These FTEs are as follows:

- Two administration – business office;
- Two Registered Nurses
- One Nurses' Aides, Orderlies and Attendants;
- One Medical Social Worker;
- Two Perfusionists; and
- Three All Other Personnel.



VCUHS is an established provider of solid organ transplantation services and has a well-developed and effective recruitment and employee retention program. Furthermore, VCUHS is an academic medical center with partnerships with Virginia Commonwealth University and area schools of nursing. Finally, VCUHS currently has a team of surgeons, led by its chair of cardiothoracic surgery, Dr. Benjamin Medalion, and other health care clinicians capable of providing lung transplantation services. For any additional staff, VCUHS will use its existing recruitment and training processes to fill the positions. For these reasons, DCOPN finds that the applicant will not have difficulty filling the required positions or that doing so will have a negative impact upon other area healthcare providers.

- 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**

According to the applicant, VCUHS leads and participates in a broad range of clinical research and trial programs aimed at enhancing the quality of transplant services, including researching the utilization of new technologies and techniques to expand the availability of organs and improve clinical outcomes. The applicant is currently participating in several clinical research and trial programs.

VCUHS and LifeNet Health, the organ procurement organization designated by the Centers for Medicare and Medicaid Services to provide organ donation and recovery services within VCUHS' donation service area, are members of the OPTN. VCUHS is also a member transplant center of UNOS, the non-profit organization that manages the nation's organ transplant system and OPTN under contract with the federal government.

- 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.**

VCUHS is a public research university and academic health center dedicated to preserving and restoring health for all people through innovation in services, research and education, along with Virginia Commonwealth University. VCUHS' clinical trials give patients access to advanced diagnostics and medical treatments and technologies before they are widely available. The researchers at VCUHS Transplant Center have actively participated in numerous national and international collaborative studies and have successfully introduced their own researcher-initiated studies.

The applicant asserts that the proposed project will significantly enhance access to clinical services and will create new opportunities for participation in important research and clinical trials for pulmonary medicine and lung disease patients. The applicant also explains that the project will offer new learning opportunities to the many medical students, interns, residents and fellows who are in training programs at Virginia Commonwealth University.

### **DCOPN Findings and Conclusions**

DCOPN finds that the proposed project to introduce lung transplantation services is generally consistent with the applicable criteria and standards of the SMFP and the Eight Required Considerations of the Code of Virginia. As previously discussed, DCOPN finds that the proposed project is more advantageous than the status quo because it will increase geographic access to lung transplantation services for a portion of the population that does not currently have access within two hours driving time. Furthermore, the proposed project is complementary to VCUHS' existing solid organ transplantation services and infrastructure and requires only a modest investment to operationalize. Moreover, there is no known opposition to the proposed project. Finally, DCOPN finds that the total capital and financing costs for the project of \$150,000 (**Table 2**) are modest and reasonable.

### **DCOPN Staff Recommendations**

The Division of Certificate of Public Need recommends the **conditional approval** of Virginia Commonwealth University Health Systems Authority, doing business as VCU Medical Center's, request to introduce lung transplantation services. DCOPN's recommendation is based on the following findings.

1. The proposed project is generally consistent with the applicable standards and criteria of the State Medical Facilities Plan and the Eight Required Considerations of the Code of Virginia.
2. The proposed project is more advantageous than maintaining the status quo.
3. There is no known opposition to the project.
4. The capital costs are reasonable.
5. The proposed project appears economically viable both in the immediate and in the long-term.

DCOPN's recommendation is contingent upon Virginia Commonwealth University Health Systems Authority, doing business as VCU Medical Center's, agreement to the following charity care condition:

Virginia Commonwealth University Health Systems Authority (doing business as VCU Medical Center) will provide lung transplantation services to all persons in need of this service, regardless of their ability to pay, and will provide as charity care to all indigent persons free

services or rate reductions in services and facilitate lung transplantation services to medically underserved persons in an aggregate amount equal to at least 0.1% of Virginia Commonwealth University Health Systems Authority's (doing business as VCU Medical Center) total patient services revenue derived from lung transplantation services provided at VCU Medical Center, as valued under the provider reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. Compliance with this condition will be documented to the Division of Certificate of Public Need annually by providing audited or otherwise appropriately certified financial statements documenting compliance with the preceding requirement. Virginia Commonwealth University Health Systems Authority (doing business as VCU Medical Center) will accept a revised percentage based on the regional average after such time regional charity care data valued under the provider reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. is available from Virginia Health Information. The value of charity care provided to individuals pursuant to this condition shall be based on the provider reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq.

Virginia Commonwealth University Health Systems Authority (doing business as VCU Medical Center) will provide lung transplantation care to individuals who are eligible for benefits under Title XVIII of the Social Security Act (42 U.S.C. § 1395 et seq.), Title XIX of the Social Security Act (42 U.S.C. § 1396 et seq.), and 10 U.S.C. § 1071 et seq. Additionally Virginia Commonwealth University Health Systems Authority (doing business as VCU Medical Center) will facilitate the development and operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area.