VIRGINIA DEPARTMENT OF HEALTH

Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis

May 20, 2024

COPN Request No. VA-8745
Carilion Medical Center (CMC) d/b/a Carilion Roanoke Memorial Hospital
Roanoke, Virginia
Introduction of kidney transplant services

Applicant

Carilion Medical Center (CMC) is a 501(c)(3) Virginia non-stock corporation. CMC is a tertiary care center located in Roanoke, Virginia, Planning District (PD) 5, Health Planning Region (HPR) III. CMC's campus has two hospitals – Carilion Roanoke Memorial Hospital (CRMH) and Carilion Roanoke Community Hospital (CRCH). CMC is a wholly owned subsidiary of Carilion Clinic, a 501(c)(3) Virginia non-stock corporation located in Roanoke, Virginia.

Background

Renal Transplant Services in Virginia
According to Virginia Health Information (VHI) data and DCOPN records, there are six renal transplant providers in the Commonwealth (**Table 1**).

Table 1. COPN Authorized Kidney Transplant Programs in Virginia

			Kidney Transplants						
Facility	**PD**	**HPR**	**2022**	**2021**	**2020**	**2019**	**2018**	**2017**	**2016**
Children's Hospital of The King's Daughters	20	V	3	4	7	7	5	4	5
Henrico Doctors' Hospital	15	IV	33	38	38	38	29	40	25
Inova Fairfax Hospital	8	II	117	129	98	111	99	87	88
Sentara Norfolk General Hospital	20	V	66	69	93	94	111	93	60
University of Virginia Medical Center	10	I	181	151	146	173	104	139	97
VCU Health System	15	IV	290	271	280	298	194	145	151
Total			**690**	**662**	**662**	**721**	**542**	**508**	**426**

Source: VHI (2016-2022) and DCOPN Records

Renal Transplant Services at CRMH

COPN No. VA-03086, issued January 6, 1993, authorized CRMH (at the time Roanoke Memorial Hospital) to establish a kidney transplant program. The program was cancelled and the COPN was surrendered in 1997 after the resignation of the transplant surgeon who was recruited to establish the program. No transplants were performed after August 31, 1997. According to the applicant, the program accomplished 73 transplants from 1993-1997. DCOPN records indicate that from 1993-1996, CRMH's kidney transplant program performed the lowest number of transplants in Virginia. Furthermore, the program's transplant volume was, on average, 60% lower than the next lowest center's volume for 1993-1996.

Organ Transplantation

The Organ Procurement and Transplantation Network (OPTN) is "a unique public-private partnership that links all professionals involved in the U.S. donation and transplantation system."[1] There are seven types of members of the OPTN : Transplant Centers, Organ Procurement Organizations (OPO), Histocompatibility Laboratories, Public Organizations, such as the National Kidney Foundation, Individual Members, Medical Scientific Organizations, such as the American Society of Transplant Surgeons, and Business Members.[2]

The OPTN works "to improve the U.S. system so that more life-saving organs are available for transplant…. [t]he OPTN acts through its Board of Directors and committees, who bring a wealth of commitment and technical knowledge to guide us. Committees address issues of concern in the transplant community. The board establishes and maintains transplant policies (operational rules) and bylaws (membership requirements) that govern the OPTN."[3] The OPTN defines a transplant hospital as "any hospital that performs organ transplants and has current approval as a designated transplant program for at least one organ.[4]" The OPTN requires transplant hospitals to agree to comply with all OPTN obligations.[5]

The "United Network for Organ Sharing (UNOS) is the private, non-profit organization that serves as the nation's organ transplant system - [OPTN] – under contract with and oversight by the federal government.[6]" UNOS has administered the OPTN since September 30, 1986.

According the UNOS' website, "[o]rgan matching policies are developed by volunteer committees of donation and transplant professionals, recipients, donor families and other members of the community, and approved by the OPTN Board of Directors."[7] UNOS uses these policies and computerized network to match donated organs with transplant candidates. UNOS describes the organ transplant process as follows:

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[1] Organ Procurement and Transplantation Network. About. https://optn.transplant.hrsa.gov/about/ .
[2] Id.
[3] Id.
[4] Organ Procurement Bylaws, Appendix D. Membership Requirements for Transplant Hospitals and Transplant Programs. https://optn.transplant.hrsa.gov/media/lgbbmahi/optn_bylaws.pdf.
[5] Id.
[6] United Network for Organ Sharing. About: the national organ transplant system. https://unos.org/about/national-organ-transplant-system/#WorkingTogether.
[7] United Network for Organ Sharing. How We Match Organs. https://transplantliving.org/before-the-transplant/about-organ-allocation/.

> 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[8].

Kidney Transplantation

According to OPTN, in Virginia, 791 kidney transplants were performed in 2022 and 698 kidney transplants were performed in 2023.[9] Also, according to OPTN, at the time of this writing, there were 2,599 candidates on the Virginia kidney transplant recipient wait list, representing approximately 86% of all organ transplant waitlist registrations.[10]

Proposed Project

CMC proposes to establish a renal transplantation program on the CRMH campus located at 1906 Belleview Avenue SE, Roanoke, Virginia. The applicant explains that no construction or modification to the existing surgical suite is required. If the proposed project is approved, renal transplants will be performed in an existing general purpose operating room. Outpatient clinics will be located a three-minute drive from the hospital at Building Riverside 3, located at 3 Riverside Circle, Roanoke, Virginia.

The projected capital costs of the proposed project are $150,000 and include the cost of the slush machine, which is used to keep organs fresh during transplant surgery, 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. The applicant anticipates a target date of opening in September 2024.

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[8] United Network for Organ Sharing. How We Match Organs. https://transplantliving.org/before-the-transplant/about-organ-allocation/.

[9] 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/

[10] 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 May 13, 2024

Table 2. CMC's Projected Capital Costs

Equipment Not Included in Construction Contract	$150,000
Total Capital Costs	**$150,000**

Source: COPN Request No. VA-85745

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 described in subsection A …of any organ or tissue transplant service…." A medical care facility, includes "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;**

Geographically, the CMC campus is located off Interstate 581. According to the applicant, "the hospital campus and surrounding outpatient clinics [are] easily accessed by residents of the broad geographic and health planning region that consists of Southwest Virginia and surrounding communities." Additionally, the CRMH campus is accessible by Valley Metro, the public transportation provider for the Roanoke Valley and the SmartWay bus, which links the Roanoke Valley and the New River Valley. Furthermore, the Star Line-Trolley Services has a stop at CRMH.

The population of PD 5 is projected to be 284,571 by 2030 and it is projected to grow by 1% during the 2020 to 2030 decade, a significantly lower rate of growth than the projected growth for Virginia which is 5.8% during the same period (**Table 3**). The population over age 65 is projected to grow faster than the overall population, about 45%, in PD 5 during the same decade, compared with 26.3% across Virginia (**Table 3**).

Table 3. Population by Locality, PD 5

Locality	2020 Population	2030 Projected Population	Projected Growth 2020-2030	Percent Growth 2020-2030	65+ 2020 Population	Projected 65+ 2030 Population	Projected Growth 65+	Percent Growth 65+
Alleghany	15,223	13,993	(1,230)	-8.08%	3,933	5,271	1,338	34.02%
Botetourt	33,596	33,556	(40)	-0.12%	7,882	11,786	3,904	49.53%
Craig	4,892	4,528	(364)	-7.44%	1,124	1,652	528	46.95%
Roanoke County	96,929	100,027	3,098	3.20%	21,449	31,009	9,560	44.57%
Covington city	5,737	5,434	(303)	-5.28%	1,201	1,688	487	40.54%
Roanoke city	100,011	101,514	1,503	1.50%	17,899	26,059	8,160	45.59%
Salem city	25,346	25,519	173	0.68%	5,328	7,653	2,325	43.64%
PD 5	**281,734**	**284,571**	**2,837**	**1.01%**	**58,816**	**85,118**	**26,302**	**44.72%**
Virginia	**8,631,393**	**9,129,002**	**497,609**	**5.8%**	**1,395,291**	**1,762,641**	**367,350**	**26.3%**

Source: United States Census Bureau at https://data.census.gov/ and Weldon Cooper Center for Public Service, August 2023.

The applicant asserts that they accept all patients, without regard to socioeconomic capabilities or insured or non-insured status. Regarding socioeconomic barriers to access to the applicant's services, according to regional and statewide data regularly collected by VHI, for 2021, the most recent year for which such data is available, the average amount of charity care provided by HPR III facilities was 0.51% of all reported total gross patient revenues (**Table 4**). Pursuant to § 32.1-102.4B of the Code of Virginia DCOPN must now place a charity care condition on every applicant seeking a COPN. Accordingly, should the Commissioner approve the proposed project, DCOPN recommends a charity care condition of no less than the 0.51% HPR III average, in addition to any new requirements as found in the revised § 32.1-102.4B of the Code of Virginia.

Table 4. HPR III Charity Care Contributions

2021 Charity Care Contributions at or below 200% of Federal Poverty Level			
Hospital	**Gross Patient Revenues**	**Adjusted Charity Care Contribution**	**% of Gross Patient Revenue:**
Ridgeview Pavilion (Bristol Region)	$7,039,355	$202,287	2.87%
Rehabilitation Hospital of Bristol, LLC	$17,924,164	$425,516	2.37%
Norton Community Hospital	$192,721,442	$4,326,681	2.25%
Centra Specialty Hospital	$54,375,383	$1,209,721	2.22%
Carilion Franklin Memorial Hospital	$183,022,650	$3,710,846	2.03%
Russell County Medical Center	$114,418,556	$1,817,173	1.59%
Carilion Tazewell Community Hospital	$72,052,309	$931,102	1.29%
Smyth County Community Hospital	$197,730,692	$2,394,391	1.21%
Johnston Memorial Hospital	$793,700,215	$9,589,955	1.21%
Carilion Medical Center	$4,573,096,613	$47,142,780	1.03%
Carilion New River Valley Medical Center	$850,387,927	$7,838,754	0.92%
Carilion Giles Memorial Hospital	$164,758,336	$1,138,319	0.69%
Lewis-Gale Medical Center	$2,622,575,795	$16,278,026	0.62%
Wellmont Lonesome Pine Mountain View Hospital	$439,099,646	$2,474,748	0.56%

Table 4. HPR III Charity Care Contributions

2021 Charity Care Contributions at or below 200% of Federal Poverty Level			
LewisGale Hospital-Montgomery	$843,161,635	$4,517,613	0.54%
LewisGale Hospital - Alleghany	$228,965,488	$1,212,396	0.53%
LewisGale Hospital Pulaski	$412,765,905	$1,669,986	0.40%
Centra Health	$3,059,619,663	$9,930,233	0.32%
Bedford Memorial Hospital	$154,732,192	$413,141	0.27%
Buchanan General Hospital	$97,833,827	$149,944	0.15%
Sovah Health-Danville	$970,752,775	$(26,593,700)	-2.74%
Twin County Regional Hospital	$253,554,954	$140,601	0.06%
Sovah Health-Martinsville	$716,672,616	$265,419	0.04%
Clinch Valley Medical Center	$630,716,254	$149,413	0.02%
Wythe County Community Hospital	$262,553,121	$14,433	0.01%
Total Facilities Reporting			25
Median			0.6%
Total $ & Mean %	**$17,914,231,513**	**$91,349,778**	**0.51%**

Source: VHI (2021)

Regarding the difficulties kidney transplant patients encounter, the applicant explains:

> As with any patient and particularly at this level of complexity, follow-up monitoring, testing, self-care training will be an ongoing process with medically trained and appropriate staffing to promote full recovery with an enhanced survival rate leading to a longer healthier and fulfilling life. Renal transplantation is not an episodic treatment but rather a longer-term process that commences long before the actual surgery and continues for the remainder of the transplant patient's life. It is a process that is enormously taxing physically, emotionally, and financially. The barrier of distance is yet one more stressor on both patient and family, particularly when it comes to the pre and post transplant visits that will ensue… With approval of the proposed renal transplant program, the current gap in geographic access with less patient travel and expense, and less upheaval to an already physically taxing process.

As will be discussed in greater detail later in this staff analysis report, UVA Medical Center, a well-established transplant center with a large kidney transplant program has opposed the proposed project. In its opposition letter, UVA Medical Center explains the outpatient care it provides for for kidney transplant patients in HPR III as follows:

> Outpatient services in particular are important to kidney transplant candidates because 90% of the care related to kidney transplantation is provided on an outpatient basis. Recognizing the need for community-based care, UVA operates three kidney patient-focused outpatient clinics in HPR III – one in Martinsville, another in Roanoke, and another in Lynchburg – ensuring care close to home for the care patients most frequently need. Resources and services provided in those outpatient clinics include patient evaluations, education classes reviewing all aspects of kidney transplant, lab work, and individual meetings with the transplant surgeon, transplant nephrologist, nurse coordinator, financial coordinator, social worker, and nutritionist.

> UVA has for nearly 30 years operated outpatient clinics in HPR III, bringing the care patients most often need closer to their homes. Those clinics were established after Carilion approached UVA in 1997 with notice of the closure of its program. UVA quickly became the regional provider of renal transplant services in HPR III. But UVA also knew, from decades of experience as a provider of the full spectrum of healthcare to the indigent and underserved throughout HPR III and other rural parts of Virginia, that it needed to offer outpatient services that were both geographically and financially accessible. It also knew that it would offer the full range of pre- and post-transplant care that transplant patients would need far more frequently than inpatient care. It has done so and continues to do so, operating clinics in Martinsville, Roanoke, and Lynchburg (with a fourth clinic in Marion in the planning stages).

Transplant patients face significant costs related to the transplant process and related treatment. UNOS details these costs on its website[11], including:

Medical Costs:

- Insurance deductibles;
- Insurance co-pays;
- Pre-transplant evaluation and testing;
- Fees for surgeons, physicians, radiologist, anesthesiologist and lab tests;
- Fees for the recovery of the organ from the donor;
- Surgery;
- Follow-up care and testing;
- Additional hospital stays for complications;
- Anti-rejection[12] and other drugs, which can easily exceed $2,500 per month; and
- Rehabilitation.

Non-Medical Costs:

- 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; and
- Lodging close to the center before and after surgery.

[11] United Network for Organ Sharing. Transplant Living – Transplant Costs. https://transplantliving.org/financing-a-transplant/transplant-costs/.

[12] According to UNOS, Kidney transplant patients who are 36 months post-kidney transplant, who receive Medicare benefits because of End Stage Renal Disease and who are not enrolled in other healthcare coverage may be eligible for a Medicare Part B Immunosuppressive Drug benefit that would help cover the costs of immunosuppressive medications. United Network for Organ Sharing. Transplant Living – Transplant Costs. https://transplantliving.org/news/medicare-part-b-benefit-available-for-kidney-recipients/.

DCOPN notes that according to the most recent U.S. Census data, the City of Roanoke has a poverty rate of 19.9% - almost twice that of the statewide average (10.6%) and more than every other locality within PD 5 (**Table 5**). Additionally, the applicant includes Craig County, with a poverty rate of 11.8%, Salem City, with a poverty rate of 10.9%, Roanoke County, with a poverty rate of 7.5% and Botetourt County, with a poverty rate of 7% in its primary service area.

Table 5. Statewide and PD 5 Poverty Rates

Locality	Poverty Rate
Virginia	10.6%
Alleghany County	13.5%
Botetourt County	7%
Craig County	11.8%
Roanoke County	7.5%
Covington City	16.2%
Roanoke City	19.9%
Salem City	10.9%

Source: U.S. Census Small Area Income and Poverty Estimates Data (Census.gov)

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

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

DCOPN received eight letters of support for the proposed project from members of the Carilion medical community, one letter from Marlon Levy, MD, MBA, Chief Executive Officer of VCU Health System Authority, one letter from David A. Bruno, MD Interim Chairman, Division of Transplantation, Virginia Commonwealth University School of Medicine, and one letter from LifeNet Health. Collectively, these letters articulate numerous benefits of the project, such as:

- CRMH is a Level 1 Trauma and tertiary care center located in Roanoke, offering a range of complex services and procedures.

- CRMH would become a transplant center located in Southwest Virginia, where transplant services are currently unavailable to Carilion patients and the surrounding communities.

- Improving access to transplant services would be life-changing for the end-stage renal patients who are members of the CRMH community.

- Because transplant services are unavailable in HPR III, residents of HPR III must travel beyond the SMFP's two-hour guideline to access renal transplant services. Approval of CRMH's project will address the geographic barrier many Virginians face with end-stage renal disease.

- Improving access to transplant services would be life-changing for the end-stage renal patients who are member of [the] community.

- VCU intends to enter into a Histocompatibility Laboratory Affiliation with CRMH. Under this agreement, CRMH will access VCU's OPTN approved Histocompatibility and Immunogenetics Laboratory to perform necessary testing for solid organ transplant services.

On April 24, 2024, DCOPN received one letter of opposition from the University of Virginia Medical Center (UVA Opposition Letter). The UVA Opposition Letter addressed:

- UVA has significant concerns about Carilion's proposal. In brief, the application does not demonstrate that Carilion is prepared to provide the wide range of clinical services and subspecialty care needed for a successful transplant program.

- Although some transplant patients from the service area may elect to receive transplant care from Carilion, it is likely that the program would remain on the smaller side compared to the average size of kidney transplant programs (about 116 transplants annually). In UVA's experience, smaller programs can correlate with worse outcomes because – as UVA again suspects would be the case with Carilion – smaller programs simply cannot sustain the range and redundancy of complex clinical support services required by transplant patients.

- Even if Carilion's program is small, it portends significant risk to UVA, given the extensive overlap in UVA's and Carilion's service areas and the realities of the kidney allocation system. That overlap means that Carilion's program would rely on diverting patients from UVA. That diversion will threaten quality staffing, UVA's training missions and research initiatives, and the viability of many of the transplant-adjacent services that UVA provides, many of them specifically focused on HPR III residents and in HPR III communities.

- The diversion of patients also seems poised to focus on better-insured patients, at risk to the financial sustainability of UVA's services. While UVA's experience indicates that substantial portions of kidney transplant patients from southwestern Virginia require financial assistance from UVA's indigent care funds, Carilion's pro forma indicates a surprisingly low charity care percentage of 0.51%.

- Carilion's application appears to misapprehend the current organ allocation process, which actually diminishes the import of geography as compared to the prior methodology on which Carilion seems to rely. Carilion's program would not, in the end, improve access to kidney transplant services but rather would undermine it.

- Outpatient services in particular are important to kidney transplant candidates because 90% of the care related to kidney transplantation is provided on an outpatient basis. Recognizing the need for community-based care, UVA operates three kidney patient-focused outpatient clinics in HPR III – one in Martinsville, another in Roanoke, and another in Lynchburg – ensuring care close to home for the care patients most frequently need. Resources and services provided in those outpatient clinics include patient evaluations, education classes reviewing all aspects of kidney transplant, lab work, and individual meetings with the transplant surgeon, transplant nephrologist, nurse coordinator, financial coordinator, social worker, and nutritionist.

- UVA started the first outpatient clinic in Roanoke following the closure of Carilion's briefly operational kidney transplant program in the mid-1990s to ensure the appropriate transition of care for transplant patients. In the 27 years since UVA assumed the full range of kidney transplant care for the region, UVA has performed more than 1,100 transplants on patients from HPR III.

- Carilion's proposal, quite simply, fails to meet a public need. It would not meaningfully improve geographic or financial access to quality transplant procedures or to pre- and post-transplant services. It would not increase the number of transplantable kidneys available to residents of HPR III. And it is not more reasonable, efficient, or effective than maintaining the status quo.

- The percentage of kidney transplant patients – from all regions, but especially HPR III – who require indigent care financial assistance from UVA dwarfs the overall average of patients who require charity care in other services. In short, these are patients who rely heavily on indigent care financial assistance. In that context, Carilion's estimate of 0.51% charity care for its kidney transplant program is puzzling, representing either an uninformed view of the needs of kidney transplant patients or an intent to focus care on the minority of kidney transplant patients who have robust commercial coverage (and lower charity care needs).

- Contrary to what seems to be the fulcrum of Carilion's proposal, distance to a transplant center is not the primary barrier to organ transplant surgery, but rather the availability of appropriately matched, transplantable organs. Carilion's proposal would not increase the number of transplantable organs or increase the number of kidney transplants. Kidneys are allocated based on several factors, including a patient's length of time on dialysis, a patient's length of time on the waiting list, a patient's blood type, medical complexity of the patient, and characteristics of the donor. Carilion seems to rely on an outdated understanding of organ allocation which, decades ago, emphasized proximity to a transplant center….In short, a patient's proximity to a transplant canter neither shortens nor prolongs how long they might wait for a kidney.

- [M]uch of the HPR III population already has two-hour access to strong transplant programs, including UVA's. Carilion's program would merely bring another program to large swaths of the population that already has such access. The population that would gain two-hour access anew thanks to Carilion's program is quite small and historically does not have high demand for kidney transplant services.

- The Carilion application, with its emphasis on the geographic need for a transplant center at Carilion, provides no detail concerning Carilion's plans for providing outpatient services for kidney transplant patients. It merely notes that there will be one clinic located close to the hospital in Roanoke once transplant services are approved and initiated, and future sites as yet undetermined.

- The SMFP threshold of 30 transplants is unattainable without directing volumes away from other providers, particularly UVA, which provides the bulk of kidney transplant services in HPR III and for HPR III patients.

- UVA is concerned that Carilion may again not reach those one-year survival levels, simply because Carilion's program does not seem poised to have the very features that make UVA's program so successful – volumes to ensure proficiency, redundancy in experienced surgeons, complementary subspecialists, and extensive community-based outpatient programs. While some small programs can have good outcomes, UVA is concerned that Carilion's program – which would be the only transplant service offered by Carilion – is not well positioned for good outcomes.

- UVA has significant concerns with the staffing of Carilion's program based on the information provided in the application. HRSA/OPTN Bylaws require a Program Director, a Primary Surgeon, and a Primary Physician for each transplant facility, and, under OPTN Bylaws, a Transplant Center Program Director must be a member of the hospital's transplant staff. At present, there does not appear to be a transplant surgeon on the staff of Carilion based on the hospital's website. Nonetheless, the application provides assurances that a "transplant surgeon/program director [is] already on site and fully invested in the program concept and strategy." Yet according to the Curriculum Vitae ("CV") for that surgeon, as attached to the application, the surgeon's last experience as a transplant surgeon was in 2009 when he was "Attending Transplant Surgeon, Sentara Medical Group, Abdominal Transplant Surgery." Further troubling is the apparent lack of faculty physicians at Carilion with any expertise in transplantation.

- Aside from those requirements, the operation of a successful high-quality kidney transplant program requires significant ancillary staffing and other resources, including financial advisors, pharmacy, social workers, nursing staff, surgery, nephrology, infectious disease, same-day access to dialysis, histocompatibility lab, operating room time, night coverage, transplant-dedicated beds, and infusion rooms. Despite replete assurances and timelines throughout the application touting Carilion's readiness to stand up the kidney transplant program by the end of the year, it seems unlikely that Carilion can meet all OPTN, CMS, and SMFP requirements and possess sufficient experience and expertise to perform safe, high-quality kidney transplant procedures.

- A documented affiliation with an OPTN-approved histocompatibility lab must be demonstrated in any OPTN application for kidney transplant center approval. Yet the application fails to specify, in Section III.E or elsewhere, that Carilion will have on site, or available via contract, an OPTN-approved histocompatibility lab. Failure to have a contract with an OPTN-approved histocompatibility service would make any OPTN approval of a kidney transplant program at Carilion impossible.

- UVA encourages the Commissioner to consider the real limitation on kidney transplants – the availability of compatible organs. Carilion states, without attribution, that "the primary barrier to transplant is distance." That is simply not the case. The primary barrier to transplant is access to compatible organs.

- As a small program, Carilion is unlikely to have redundancies in experienced surgeons, proficient clinical staff teams, transplant-focused subspecialists or ancillary services such as a specialized laboratory or outpatient clinics. Rather, Carilion would likely be a small program

that provides a closer transplant location to a minute number of patients, focused on less complex cases, in a way that harms UVA and potentially patients.

- The addition of Carilion's proposed kidney transplant program duplicates UVA's efforts in the area to be served, in ways that will harm UVA's utilization (as well as proficiency, training, and research that are correlated with utilization) and that will reduce the efficiency of delivering high quality comprehensive kidney care.

- In an apparent attempt to minimize Carilion's reliance on patient diversion, Carilion provides statistics on various kidney-related ailments. In large part, though, these statistics are irrelevant; the conditions cited by Carilion often do not lead to kidney transplants.

On May 8, 2024, CMC replied to the UVA Opposition Letter (CMC Response Letter). The CMC Response Letter discussed:

- UVA argues "establishing a kidney transplant program at Carilion will not meaningfully improve geographic. . . access to transplant procedures or to pre- and post-transplant services." To support its argument, UVA performed a ZIP code analysis to show that "only 7,864 HPR III residents currently live in ZIP codes that are fully more than two hours away from an existing transplant center. . ." UVA's analysis considers out-of-state kidney transplant programs, such as Wake Forest University. However, under established Virginia COPN statutory and case law, the Commissioner cannot consider the availability of out-of-state facilities in determining whether a need for a new service, such as a kidney transplant service, exists in Virginia. With this in mind, the DCOPN should disregard UVA's ZIP code analysis.

- Under the State Medical Facilities Plan ("SMFP"), "organ transplantation services should be accessible within two hours driving time one way under normal conditions of 95% of Virginia's population. . ." [Attachments to CMC Response Letter] demonstrate that a significant portion of southwest Virginia cannot access existing Virginia kidney transplant programs within a 2-hour drive. The [Attachment to CMC Response Letter] shows that approximately 878,757 people reside in HPR III localities more than a 2-hour drive from existing Virginia kidney transplant programs. This constitutes 65.6% of the total HPR III population. Many HPR III residents without 2-hour drive access to kidney transplant services are elderly (approximately 192,640) and reside in communities with very high poverty rates. See [Attachment to CMC Response Letter]. These patients must drive significant distances to access kidney transplant services. Some must access kidney transplantation services outside of Virginia.

- Requiring patients to travel more than 2 hours to access kidney transplant services places a significant burden on patients and their family members. Some patients in need of kidney transplant services, many of whom are elderly or indigent, decide to forego a life-saving transplant because they are intimidated by the extensive travel and non-medical expenses involved.

- Throughout its letter, UVA states that "ninety percent of the care needed by those patients will be provided on an outpatient basis" and explains that UVA has set up "kidney patient-focused outpatient clinics" in HPR III. However, these "kidney patient-focused outpatient clinics" do not replace the services and resources available to patients at a kidney transplant center. Immediately before and after the kidney transplant, patients cannot access all required care at these clinics. Instead, they must travel to the transplant center for multiple pre- and post-operative appointments. Typically, kidney transplant patients (and their caregivers) have several pre-operative appointments at a transplant center. Assuming the patient does not experience complications, the patient (and the patient's caregivers) can expect to make at least 4 to 6 weekly post-operative visits to the transplant center. After that, the patient must visit the transplant center every two weeks for testing. Eventually, patient visits to the transplant center occur every three months.

- Approval of CMC's project would significantly reduce the distance between HPR III residents and the nearest kidney transplant center, providing a much-needed lifeline. For this reason, residents of HPR III, particularly elderly and indigent residents, would undoubtedly disagree with UVA arguing to maintain the status quo instead of the Commissioner approving CMC's project.

- UVA incorrectly assumes that CMC's proforma shows CMC's projected revenues and expenses for all services, including inpatient and outpatient, delivered to transplant patients throughout each patient's lifetime. This approach would be impractical and inconsistent with COPN requirements and previous transplant program COPN application submissions. To be clear, CMC's proforma projects the revenues and expenses for inpatient kidney transplant services during the first two years of the kidney transplant program's operation at CMC…. The opportunity to provide inpatient kidney transplant services as charity care will be limited because most kidney transplant patients qualify for coverage under Medicare or commercial pay contracts. CMC's projected charity care for its kidney transplant program is consistent with charity care projected in previous transplant service COPN applications.

- Carilion Clinic is acutely aware of the financial needs of the population it serves and has a long history of meeting the healthcare needs of indigent patients in HPR III. In FY 2022, the system provided $68 million in charity care.

- In 1997, CMC discontinued its kidney transplant program after the resignation of its transplant surgeon. UVA references the 1997 program closure to raise doubt as to the viability of Carilion's proposed project. UVA explains "[c]ircumstances have not changed since Carilion's program closed in 1997 such that its proposed program would be any more successful than the first go-round." This statement is incorrect and should be dismissed by the DCOPN.

- UVA's concerns are unfounded. CMC is prepared "to provide the wide range of clinical services and subspecialty care needed for a successful transplant program." As a Level I Trauma Center and the region's primary tertiary care hospital, CMC-Carilion Roanoke Memorial Hospital receives patients from a 150-mile radius. It is the flagship hospital of a

seven-hospital network serving a 20-county area in southwest Virginia and parts of West Virginia. CMC is the ideal site for the only transplant center in HPR III.

- It is important to note that Virginia COPN law does not require COPN applicants for kidney transplant services to address the Organ Procurement and Transplantation Network ("OPTN") guidelines or to provide this level of detail in its COPN application. For this reason, it is inappropriate for UVA to raise concerns about the "breadth and qualifications of [CMC] staff under the OPTN guidelines based solely on CMC's COPN application….. On the contrary, CMC will recruit additional physicians to join its transplant program and has already recruited a second transplant surgeon, Dr. David Cronin. Dr. Cronin completed a fellowship in transplant surgery at the University of Chicago Hospitals and Clinics and has extensive experience performing organ transplant surgeries.
- Eager to bring kidney transplant services back to its community, CMC has already invested resources and laid the groundwork for project implementation immediately following COPN authorization. By way of example, CMC has taken the following steps:
    - Histocompatibility Laboratory Affiliation: CMC plans to enter a Histocompatibility Laboratory Affiliation with VCU Health System.
    - Transplant Program Consultant: CMC has identified a consulting company to facilitate transplant program start-up. With over two decades of experience, the company is a leading consulting firm in transplantation services.
    - Contract with Organ Procurement Organization: CMC has contracted with LifeNet Health, a member of OPTN and an independent Organ Procurement Organization designated by CMS to provide organ donation and recovery services to transplant centers in Virginia and neighboring states.
- UVA argues that if CMC's kidney transplant program is approved, it will be a "smaller program" unable to "sustain the range and redundancy of complex clinical support services required by transplant patients…. With at least 30 kidney transplants annually, CMC meets the SMFP's volume standard for maintaining service proficiency (12 VAC 5-230-720). CMC's projected kidney transplant volumes also meet OPTN Bylaws, which require kidney transplant programs to remain functionally active by performing a minimum of 1 transplant in 3 consecutive months.
- While it is reasonable to conclude that some portion of patients receiving kidney transplantation services at UVA may seek this care at CMC, UVA will still be able to meet, if not exceed, the SMFP's annual kidney transplant volume standard if CMC's project is approved….In FY 2022, UVA performed 147 kidney transplants.27 Of those transplants, 58 originated from HPR III.28 However, not all HPR III cases originated from CMC's service area. According to Sg2 data, 34 of the 147 total kidney transplants performed by UVA originated from CMC's service area in FY 2022.

- UVA has already demonstrated an ability to sustain a robust, high-quality kidney transplant program with nearby competition. Both Henrico Doctors' Hospital and VCU Medical Center operate kidney transplant programs within a 1-hour drive of UVA.

- If CMC's project is approved, HPR III patients currently traveling more than 2 hours to access kidney transplants will have nearby access. Furthermore, HPR III residents will no longer be required to travel out of state to access kidney transplant services.

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-8745 is not competing with another project in this batch cycle and DCOPN did not receive a request to conduct a public hearing for the proposed project. Thus, no public hearing was held.

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

The status quo is a viable alternative to the proposed project. As will be discussed in greater detail later in this staff analysis report, the proposed project will increase geographic access to kidney transplantation services for a portion of the population that does not currently have access within two hours driving time. However, as will be discussed in greater detail later in this staff analysis report, DCOPN has concerns with the recency with which the applicant has implemented corrective actions with regard to serious issues with its surgical instrument sterilization processes. Additionally, DCOPN received extensive opposition from UVA, the closest Virginia transplant hospital to CRMH, with the second largest kidney transplant program in Virginia. Furthermore, comparing the number of patients on the waitlist to the number of transplants performed, it can be argued that the availability of organs is the highest barrier to care for patients requiring kidney transplants, and not geographic access. These reasons contribute to DCOPN's conclusion that the status quo is more advantageous than the proposed project.

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

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

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

As demonstrated by **Table 2**, the projected capital costs of the proposed project are $150,000 and include the cost of the slush machine, which is used to keep organs fresh during transplant surgery, 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 would authorize CMC to conduct renal transplants on the CRMH campus with no construction, modifications or any related construction costs.

- The location of the renal transplantation surgical program in CRMH will be central to all services on CRMH's campus.

- With efficiencies and added benefit of no construction costs, overall operations will save both time and money and CRMH will have the ability to quickly implement the new service.

- Approval of a renal transplantation program at CRMH will create new opportunities for participation in clinical research and medical professional training programs that can only further enhance the outreach of a renal transplantation center located at CRMH.

- With the Carilion Clinic reputation, collaboration with nephrologists around the broader region, and a transplant surgeon/program director already on-site and fully invested in the program concept and strategy, the new program will have every opportunity to meet all requirements.

- As a tertiary care hospital, basic infrastructure is already in place, including a close working relationship with nephrologists in the valley, operating room access, specialized post-operative inpatient units, social workers and case manager for discharge planning and clinic space.

- By filling the current gap of this service in the broader area, the renal transplantation program can dramatically increase awareness and geographic access for the increasingly urgent and growing set of patients from the region being referred/sent elsewhere beyond the accepted two-hour drive time. With this awareness also comes the potential for the expansion and availability of donor kidneys, optimizing the procurement process.

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

The applicant provided assurances that its renal transplant services will be available to all those in need, without regard to their ability to pay. As previously discussed, according to regional and statewide data regularly collected by VHI, for 2021, the most recent year for which such data is available, the average amount of charity care provided by HPR III facilities was 0.51% of all

reported total gross patient revenues (**Table 4**). Pursuant to § 32.1–102.4 of the Code of Virginia, should the Commissioner approve the proposed project, the applicant should be subject to a charity care condition no less than the 0.51% HPR III average, in addition to any new requirements as found in the revised § 32.1-102.4B of the Code of Virginia.

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

Surveys at CRMH

Unannounced Medicare/Medicaid complaint surveys were completed at CRMH ending on September 26, 2023 and November 24, 2023. As directed by the Centers for Medicare and Medicaid Services (CMS), the Medical Facilities Inspectors (MFI) from the Virginia Department of Health (VDH) reviewed the Conditions of Participation for Hospitals related to the complaint allegations, conducted observations, interviews, medical record review, and document review and determined that the facility was not in compliance with the applicable parts of the Medicare Conditions of Participation[13]. Based on the report of the survey, CMS determined that conditions within CRMH posed an Immediate Jeopardy to the health and safety of patients. During this survey, VDH MFIs verified that the Immediate Jeopardy had been removed. Accordingly, CMS concluded that the conditions no longer posed an Immediate Jeopardy to the health and safety of patients effective September 26, 2023 (for the survey ending September 26, 2023) and effective November 24, 2023 (for the survey ending November 24, 2023). After the survey ending September 26, 2023, substantial noncompliance (i.e., Condition-level noncompliance) remained with the following Medicare Conditions of Participation:

- 42 CFR § 482.12- Governing Body – The facility Governing Body failed to ensure oversight and immediate action was taken when the facility became aware of the concerns regarding the proper decontamination and sterilization of surgical instruments brought forward by staff on July 13, 2023. Based on observation, staff interview, clinical record review, facility document review and during the course of the complaint investigation, the Governing Body failed to ensure that the medical staff were evaluating the quality of services and care provided. For example, numerous interviews conducted during the survey ending September 26, 2023 evidenced staff's concerns related to continuing problems with surgical instrument contamination.

- 42 CFR § 482.13- Patient Rights – A hospital must protect and promote each patient's rights. Based on observation, clinical record reviews, staff interviews, facility document review and during the course of the complaint investigation, the facility staff failed to ensure the patient's right to receive safe care and the safety of all patients. The facility failed to ensure the proper cleaning of surgical instruments which resulted in patients having their surgical procedures canceled, the patients having to be transferred to another facility or rescheduled. According to interviews and document reviews, the facility had been aware of the concerns since July 13, 2023.

[13] 42 C.F.R. § 482

- 42 CFR § 482.21- QAPI – A hospital must develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement [QAPI] plan. The facility failed to adequately address and correct known issues related to ineffective cleaning and sterilization of surgical instruments. Staff interviews and document review revealed the hospital's quality program failed to act on reports of increasing problems with contamination of surgical trays by bioburden (blood, bone tissue, unidentified debris, hair, etc.) and other contaminates.

- 42 CFR § 482.42- Infection Control – The hospital must have active hospital-wide programs for the surveillance, prevention, and control of hospital acquired infections and other infectious diseases, and for the optimization of antibiotic use through stewardship. Based on observation, staff interview, facility document review and during the course of a complaint investigation, the facility staff failed to ensure the prevention and potential spread of infectious diseases. For example, the survey team observed three of four surgical instrument trays processed on September 20, 2023, which were identified as sterile and ready for use. The trays were inspected and found to be contaminated with unknow brownish red substance, spots, staining and a candy wrapper was found inside a sterile tray.

- 42 CFR § 482.51- Surgical Services – If a hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. Based on observation, clinical record review, the facility failed to ensure the proper cleaning of surgical instruments which interfered with the ability to provide quality of care for surgical services.

After the survey ending September 26, 2023, substantial noncompliance (i.e., Condition-level noncompliance) remained with the following Medicare Conditions of Participation:

- 42 CFR § 482.12- Governing Body – The Governing Body must ensure that the medical staff is accountable to the governing body for the quality of care provided to patients. Based on observation, staff interview, facility document review and during the course of the complaint investigation, the Governing Body failed to provide oversight to ensure patient safety and infection control concerns were fully addressed and mitigate. For example, numerous interviews conducted during the survey ending November 24, 2023 evidenced staff's concerns related to continuing problems with surgical instrument contamination.

- 42 CFR § 482.21- QAPI – A hospital must develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement [QAPI] plan. For example, the survey team reviewed a total of 544 reports submitted from September 30, 2023 through November 20, 2023 which identified multiple trays of instruments that were rejected for use by the OR scrub team due to potential contamination.

- 42 CFR § 482.42- Infection Control – The hospital must have active hospital-wide programs for the surveillance, prevention, and control of hospital acquired infections and other infectious diseases, and for the optimization of antibiotic use through stewardship. Based on observation, staff interview, facility document review and during the course of a complaint investigation, the facility staff failed to ensure the prevention and potential spread of

infectious diseases by monitoring and ensuring the proper decontamination and sterilization of surgical instruments. For example, the survey team randomly selected four surgical instrument trays that were sterilized and ready for use. Two of the trays were processed by an outside vendor and two of the trays were identified as being process in-house. Four of the four trays had visibly contaminated instruments with spots that were easily removed with a gloved finger, dark and light areas of staining, numerous instruments with a pitted surface and instruments with a reddish discoloration.

The deficiencies were determined to be of such character as to substantially limit the hospital's capacity to furnish adequate care and/or as to adversely affect the health and safety of patients. In accordance with the federal regulation at 42 C.F.R. § 488.9, CMS determined that CRMH was no longer deemed to meet the Medicare Conditions of Participation and will be subject to the federal requirements applied to unaccredited hospital. Consequently, CRMH was under the jurisdiction of the State Survey Agency and was required to submit an acceptable Plan of Correction (PoC) regarding these deficiencies. After the approved Plan of Correction is implemented, and CMS finds that all Medicare Conditions of Participation for Hospitals are met, CMS will discontinue the State Agency's survey jurisdiction.

As it was required to do, CRMH submitted a PoC which included:

- An intensive investigation and analysis with subject matter experts including Hospital Infection Prevention and Control Surgical Services, and Sterile Processing (SPD) staff.

- Change to policy to ensure that SafeWatch reports are completed within 24 hours of occurrence. When instrument sterilization issues are identified, the affected instruments are removed and the SafeWatch report is completed. Events related to instruments are reviewed by the Surgical Quality team within 72 hours.

- The sterile field policy was updated on November 14, 2023, with a reference guide for staff. 100% of the OR staff received education on this change.

- All trays, at the point of assembly and before sterilization, are inspected by the Sterile Processing Department (SPD) Charge or Team Lead to ensure standards compliance. The tray card is initialed by the staff members and the photos of the instrument trays are audited by the Surgical Services Vice President. At least 25 of these audits are completed each week.

- Infection Prevention and Control audits following the decontamination but prior to sterilization were performed with high levels of scrutiny on instrument condition and cleanliness. Based on some of the findings, action items have included: instrument refurbishing, purchase and replacement of instruments and immediate feedback for human factor issues.

- Case cancellations are monitored by the Senior Director of CVI Quality and the Senior Director of Surgical Services to identify trends and reasons for cancellations.

- Conducted water quality assessments and reviewed water treatment processes supporting SPD. Made changes including: Repaired dichlorination equipment; Converted SPD water source to city water source to mitigate further potential for instrument damage and galvanic corrosion, and increased frequency of professional cleaning of autoclave chambers to twice per year.

- Add new role of Quality Facilitator in SPD.

An unannounced Medicare/Medicaid revisit survey to the complaint validation surveys that concluded on September 26, 2023, and November 24,2023, was conducted on April 16, 2024, by two MFIs from the VDH, Office of Licensure and Certification (OLC). At the time of the revisit survey, CRMH was reviewed for compliance with the Conditions and Standards of 42 CFR Part 482, Condition of Participation for Hospitals and found to be in substantial compliance with the following Medicare Conditions of Participations for Hospitals:

- 42 CFR § 482.12- Governing Body;
- 42 CFR § 482.13- Patient Rights;
- 42 CFR § 482.21 Quality Assessment and Performance Improvement Program;
- 42 CFR § 482. 42 – Infection Prevention and Control and Antibiotic Stewardship Programs; and
- 42 CFR § 482.51- Surgical Services**.**

CRMH received notification that based on these findings CRMH will continue to be a Medicare/Medicaid certified provider and to continue to be "deemed" to meet applicable Medicare conditions on May 8, 2024.

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 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 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 kidney transplantation services in Virginia. The blue “H” symbol marks the location of CMC’s proposed kidney transplant program. The white “H” symbols mark

the locations of other existing kidney transplantation providers in Virginia. The yellow shaded area represents the area of Virginia that is within two hours driving time of existing kidney transplantation services. The light blue shading represents the area within two hours driving 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 yellow and light blue shaded area, there is a portion of the population of Virginia that is not currently served by kidney transplantation services within two hours driving time that would be served by the addition of kidney transplantation services at CRMH. This area includes the counties of Bland, Carroll, Craig, Floyd, Franklin, Giles, Grayson, Henry, Montgomery, Patrick, Pittsylvania, Pulaski, Smyth and Wythe, with a total population of 463,058 (**Table 6**).

Additionally, as can be observed from the area without shading, there is a portion of the population of Virginia that is not currently served by kidney transplantation services within two hours' drive time that would continue to not be served, even with the addition of a kidney transplant program at CRMH. This area includes the counties of Buchanon, Dickenson, Lee, Russell, Scott, Tazewell, Washington and Wise, with a total population of 234,503 (**Table 6**).
Currently, considering a total population of Virginia of 8,631,393 and a total population of the counties without access within two hours driving time in **Table 6** of 697,561, DCOPN observes that 91.92% of the population of Virginia has access to kidney transplant services within two hours driving time. Approval of the proposed project would increase this percentage to 97.28%. Accordingly, DCOPN concludes that approval of the proposed project would improve geographic access to kidney transplantation services for persons in Virginia, such that the SMFP drive time standard of two hours would be met. However, a portion of Virginia would remain without access to kidney transplant services.

Table 6. Access to Kidney Transplantation Services[14]

Locality	**Population**
Virginia	**8,631,393**
Counties to be Covered by CRMH Program	
Bland	6,270
Carroll	29,155
Craig	4,892
Floyd	15,476
Franklin	54,477
Giles	16,787
Grayson	15,333
Henry	50,948
Montgomery	99,721
Patrick	17,608
Pittsylvania	60,501
Pulaski	33,800
Smyth	29,800
Wythe	28,290
Total	**463,058**

[14] 2020 Decennial Census Counts by Total, Age and Sex for Virginia and its Localities. https://data.census.gov/

Counties Remaining Uncovered (Even with CRMH Program)	
Buchanon	20,355
Dickenson	14,124
Lee	22,173
Russell	25,781
Scott	21,576
Tazewell	40,429
Washington	53,935
Wise	36,130
Total	**234,503**
Grand Total	**697,561**

Source: Census.gov

Figure 1: Kidney 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 be establishing parttime satellite clinics.

The applicant plans to establish outpatient satellite clinics in Roanoke, Christiansburg and Galax. With regard to this standard, the applicant stated:

> The proposed Renal Transplant service will be operationally located on CMC's campus at Carilion Roanoke Memorial Hospital. 1906 Belleview Avenue SE, Roanoke, VA 24014,

with clinic space at Building Riverside 3, 3 Riverside Circle Roanoke, VA 24016 (3 minutes from hospital property); however, the plan to reach Virginia residents within our service area and the Health Planning Region III includes proposed satellite clinics in and around rural areas of Southwest Virginia.

CMC plans to establish outpatient satellite clinics in Roanoke, Christiansburg, and Galax. New patients will receive education at these clinic locations (describing the transplant process/procedure), lab-blood testing and will be introduced to the interdisciplinary team that will be involved in the patient's care. Certain post-operation appointments and labs will also be available to patients at these locations.

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 renal transplantation services available in HPR III, since CRMH closed its kidney transplant program in 1997 after four years of operation. There are six providers of kidney transplantation services in Virginia – UVA Medical Center in HPR I, PD 10, Inova Fairfax in HPR II, PD 8, Henrico Doctors Hospital and VCU Health System in HPR IV, PD 15, and Children's Hospital of the King's Daughters and Sentara Norfolk General Hospital in HPR V, PD 20.

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:

Kidney	**30**
Pancreas or kidney/pancreas	**12**
Heart	**17**
Heart/Lung	**12**
Lung	**12**
Liver	**21**
Intestine	**2**

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.

The pro forma income statement (**Table 7**) provided by the applicant projects that it will perform 10 kidney transplants in the first year of operations and 30 kidney transplants in the second year of operation. The applicant asserts that its projections are reasonable and conservative. According to its data analytics provider, the applicant reports that a total of 76 kidney transplants originated from HPR III in 2022 and 45 of those were from CMC's PSA and SSA. The applicant also explains that Carilion Clinic and its affiliate providers have not tracked the number of Carilion Clinic patients referred to transplant centers. However, the applicant reports that in 2022, Carilion Clinic had a market share of 34% for end stage renal disease services in HPR III. **Figure 2** below contains that applicant's estimated number of Carilion Clinic patients receiving kidney transplants.

Figure 2: Estimated Carilion Clinic Patients Receiving Kidney Transplants

	FY 2020	FY 2021	FY 2022	FY 2023*
Kidney Transplant Cases Originating from HPR III (Sg2 Data)	89	92	76	62
Estimated Number of Carilion Clinic Patients Receiving Kidney Transplants (Assume 34% market share in HPR III).	30	31	26	21

**Annualized from 2 quarters*
Source: COPN Request No. VA-8745

As shown in **Table 1**, in 2022, the six existing providers of kidney transplant services provided 690 transplants, with a low of three pediatric transplants at Children's Hospital of the King's Daughters, followed by 33 transplants at Henrico Doctors Hospital, and a high of 290 transplants at VCU Health System. Considering that, with the exception of Children's Hospital of the King's Daughters (which is limited to pediatric transplants), all of the providers of kidney transplant services met or far exceeded the SMFP threshold in 2022 (**Table 1**), it is reasonable to conclude that if CMC's request to add kidney transplantation services is approved by the Commissioner, each facility would still be able to meet, if not exceed, the SMFP's kidney transplant standard of 30 transplants from a numerical perspective.

As previously discussed, UVA has expressed opposition to the proposed project and contends that losing any capacity, despite its program exceeding the SMFP threshold, would have a negative effect on its program. With regard to this, the UVA Opposition Letter says:

> Even if Carilion's program is small, it portends significant risk to UVA, given the extensive overlap in UVA's and Carilion's service areas and the realities of the kidney allocation system. That overlap means that Carilion's program would rely on diverting patients from UVA. That diversion will threaten quality staffing, UVA's training missions and research initiatives, and the viability of many of the transplant-adjacent services that UVA provides, many of them specifically focused on HPR III residents and in HPR III communities…. The diversion of patients also seems poised to focus on better-insured patients, at risk to the financial sustainability of UVA's services.

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:

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

The applicant has stated its understanding of this standard and has expressed an intention to "comply by transparently reporting all survival, complications, and outcomes data to the Scientific Registry of Transplant Recipients per standard UNOS and American Society of Transplant Surgery guidelines. We intend to pursue Organ Procurement and Transplant Network Quality Committee evaluation through regular outcomes assessments."

The applicant also provided the following information with respect to this standard: "[t]he proposed renal transplant service would be seamlessly integrated into our overall operational infrastructure of [CRMH]. We are reviewing the transplant documentation model available in our electronic health record developed for enhanced transparency, targeted data mining and reporting."

The applicant is not an existing provider of organ transplant services. Therefore, DCOPN is unable to review the survival rates of its existing programs to determine if these assurances are reasonable.

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.

Not applicable. The applicant is proposing to establish a kidney transplantation program, not to expand organ transplantation services.

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.

The applicant is proposing to establish a kidney transplantation program, not to expand organ transplantation services. Thus, no preference should be given with regard to the proposed project.

12VAC5-230-740. Staffing.
Organ transplant services should be under the direction or supervision of one or more qualified physicians.

As previously discussed, UVA Medical Center, a well-established transplant center with a large kidney transplant program has opposed the proposed project. According to the UVA Opposition Letter:

> Based on the projected staffing as described in the application, it would seem rather challenging for Carilion to meet criteria for approval under this SMFP standard, much less the HRSA/OPTN staffing requirements for transplantation programs. HRSA/OPTN Bylaws require a Program Director, a Primary Surgeon, and a Primary Physician for each transplant facility, and, under OPTN Bylaws, a Transplant Center Program Director must be a member of the hospital's transplant staff. At present, there does not appear to be a transplant surgeon on the staff of Carilion based on the hospital's website.
>
> Nonetheless, the application provides assurances that a "transplant surgeon/program director [is] already on site and fully invested in the program concept and strategy." Yet according to the Curriculum Vitae ("CV") for that surgeon, as attached to the application, the surgeon's last experience as a transplant surgeon was in 2009 when he was "Attending Transplant Surgeon, Sentara Medical Group, Abdominal Transplant Surgery." Since then, he has specialized in bariatric surgery. It is unclear whether he has "maintained a current working knowledge of kidney transplantation" as required by the OPTN guidelines.

DCOPN independently verified that the OPTN bylaws require a transplant hospital to have a transplant team including a Transplant Program Director, qualified Primary Surgeon and Primary Physician.[15] DCOPN further confirmed that the OPTN bylaws require the Primary Surgeon to have:

> [M]aintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care in the last 2 years. This includes the management of patients with end stage renal disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long term outpatient care.[16]

DCOPN observes that the applicant indicated in the application that it is recruiting for Primary Physician and Program Director. However, the applicant also indicates that "[t]he Renal Transplant Program will be implemented under the directorship of Arnold D. Salzberg, Physician and Surgeon…" The applicant provided Dr. Salzberg's curriculum vitae (CV). DCOPN

[15] [15] Organ Procurement Bylaws, Appendix D. Membership Requirements for Transplant Hospitals and Transplant Programs. https://optn.transplant.hrsa.gov/media/lgbbmahi/optn_bylaws.pdf.
[16] Id.

similarly observes that the CV does not appear to have the requisite direct involvement in kidney transplant patient care in the last two years, as required by OPTN.

The applicant provided the following in response to UVA's opposition with regarding to the qualifications of CMC's staff:

> It is important to note that Virginia COPN law does not require COPN applicants for kidney transplant services to address the Organ Procurement and Transplantation Network ("OPTN") guidelines or to provide this level of detail in its COPN application. For this reason, it is inappropriate for UVA to raise concerns about the "breadth and qualifications of [CMC] staff under the OPTN guidelines based solely on CMC's COPN application. For example, the Virginia COPN application requires an applicant to demonstrate that the transplant program will be under the supervision of a qualified physician. To address this COPN requirement, CMC provided the curriculum vitae ("CV") for its kidney transplant program director (Dr. Arnold Salzberg), who completed his abdominal transplant surgery fellowship at VCU's Hume-Lee Transplant Center. Based on this information alone, UVA raises concerns about whether CMC's future kidney transplant program will meet OPTN physician staffing requirements. UVA's speculative comments wrongly assume that Dr. Salzberg will be CMC's only transplant surgeon on staff. On the contrary, CMC will recruit additional physicians to join its transplant program and has already recruited a second transplant surgeon, Dr. David Cronin. Dr. Cronin completed a fellowship in transplant surgery at the University of Chicago Hospitals and Clinics and has extensive experience performing organ transplant surgeries.

The applicant did not indicate whether Dr. Cronin would be named Primary Surgeon. DCOPN observes that Dr. Cronin has been the Chief of Surgery at Salem Veterans Administration Medical Center since March, 2021.

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 kidney transplantation services in HPR III, and the proposed project would increase geographic access to kidney transplantation services for Virginians who do not currently have access to these services within a two-hour drive time. However, it can be argued that competition in the area of organ transplantation can have a negative impact on quality and cost. There is also the possibility that a low-volume transplant center will not be able to care for the sickest individuals in need of a kidney transplant, and that those sickest patients will still need to travel out of the HPR for a kidney transplant.

As previously discussed, UVA Medical Center, a well-established transplant center with a large kidney transplant program has opposed the proposed project. According to the UVA Opposition Letter:

> A kidney transplant service at Carilion will not foster institutional competition that benefits the area or improves access to essential healthcare services. High-acuity services are rarely positively influenced by proliferation. While more commoditized services might engage in pricing strategies, operational schedules (such as weekend/evening hours), convenient suburban locations, or facility design elements with an eye toward "competing" with other providers, those market factors are far less relevant in high-acuity services such as kidney transplants…. Losing measurable volumes to Carilion, as Carilion seems to contemplate given its utilization projections and service area aspirations, would have a deleterious impact on UVA's kidney transplant program. Given the organ shortage and organ allocation system, the loss of volumes at UVA would not be readily reconstituted with transplant patients from other parts of Virginia. This has significant adverse implications for UVA's ability to meet its tripartite mission to provide clinical, research, and teaching services to the citizens of the Commonwealth.
>
> The viability of the program that UVA has built in HPR III is dependent upon sustainable volumes of transplants. Increasing kidney transplant services in HPR III will not increase institutional competition while improving access to transplant services. In fact, the very opposite will occur: should Carilion establish a kidney transplant service and succeed in capturing UVA's considerable transplant volumes from HPR III (and possibly some from HPR I), UVA may have to shutter or curtail its HPR III operations. In short, Carilion's proposal does not improve access to essential healthcare services but rather threatens it.

As previously discussed, DCOPN notes that According to OPTN, in Virginia, 791 kidney transplants were performed in 2022 and 698 kidney transplants were performed in 2023.[17] Also, according to OPTN at the time of this writing, there were 2,599 candidates on the current Virginia kidney transplant recipient wait list, representing approximately 86% of all organ transplant waitlist registrations.[18] Comparing the number of patients on the waitlist to the number of transplants performed, it can be argued that the availability of organs is the highest barrier to care for patients requiring kidney transplants, and not geographic access.

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 shown in **Table 1**, there are six providers of kidney transplantation services in Virginia – UVA Medical Center in HPR I, PD 10, Inova Fairfax in HPR II, PD 8, Henrico Doctors Hospital and VCU Health System in HPR IV, PD 15, and Children's Hospital of the King's Daughters and Sentara Norfolk General Hospital in HPR V, PD 20. The three busiest kidney transplant programs are located at VCU, UVAMC and Inova Fairfax Hospital, which all have multiple organ transplant programs allowing for efficient use of specially trained staff and ancillary resources.

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[17] 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/
[18] 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 May 13, 2024.

UVA Medical Center is the closest transplant hospital to CRMH at 119 miles away and it has expressed significant opposition to the proposed project. According to the UVA Opposition Letter:

> Even if Carilion's program is small, it portends significant risk to UVA, given the extensive overlap in UVA's and Carilion's service areas and the realities of the kidney allocation system. That overlap means that Carilion's program would rely on diverting patients from UVA. That diversion will threaten quality staffing, UVA's training missions and research initiatives, and the viability of many of the transplant-adjacent services that UVA provides, many of them specifically focused on HPR III residents and in HPR III communities. The diversion of patients also seems poised to focus on better-insured patients, at risk to the financial sustainability of UVA's services.
>
> In 2022 alone, UVA performed 66 kidney transplants for residents of Southwest Virginia, representing approximately 35% of UVA's total kidney transplant volume, and 80% of [Carilion's data analytics provider] Sg2's projected volume for the region (as cited by Carilion). Indeed, southwestern Virginia is a key part of UVA's service area not only for kidney transplants but for many other services as well. On the one hand, that fact reflects simple geography: while UVA technically is in HPR I, it is in the southwest quadrant of that expansive HPR and is closer to many communities in HPR III than to those in HPR I. On the other hand, as an academic medical center and Level I trauma center, UVA draws patients from vast swaths of rural Virginia regardless of HPR designation. Accordingly, to achieve the minimum volume of 30 kidney transplants, Carilion would inevitably have to divert patients from UVA. Thirty transplants represent more than half of UVA's 2022 kidney transplants for HPR III patients, or about 16% of UVA's total kidney transplant volume.
>
> Losing measurable volumes to Carilion, as Carilion seems to contemplate given its utilization projections and service area aspirations, would have a deleterious impact on UVA's kidney transplant program. Given the organ shortage and organ allocation system, the loss of volumes at UVA would not be readily reconstituted with transplant patients from other parts of Virginia. This has significant adverse implications for UVA's ability to meet its tripartite mission to provide clinical, research, and teaching services to the citizens of the Commonwealth.

VCU is farther away at 199 miles but has provided support for the proposed project. As noted in one of VCU's support letters, the applicant plans to enter a Histocompatibility Laboratory Affiliation with VCU Health System. Through this affiliation, the applicant will have access to VCU's OPTN-approved Histocompatibility and Immunogenetics Laboratory to perform necessary testing for its kidney transplant service.

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. DCOPN notes that the Pro Forma Income Statement provided by the applicant projects a loss of $1,357,203 in the first year of operation and a loss of $160,392 in the second year of operation.

Table 7. CMC Pro Forma Income Statement

	Year 1	**Year 2**
Projected Case Volume	10	30
Patient Services Revenue (net of contractual allowances)	**$695,310**	**$2,127,649**
Charity Care	($3,546)	($10,851)
Net Patient Revenue	**$691,764**	**$2,116,798**
Total Operating Expenses	($2,048,967)	($2,277,190)
Income	**-$1,357,203**	**-$160,392**

Source: COPN Request No. VA-8745.

The applicant anticipates the need to hire 12 additional full-time equivalent personnel (FTE) to staff the proposed project. These FTEs are as follows:

- Four administration – business office;
- Two Registered Nurses
- One Registered Pharmacist;
- One Psychologist;
- One Medical Social Worker;
- One Program Director;
- One Coordinator and
- One Registrar.

According to the applicant, "Carilion Clinic has a robust talent acquisition team that uses their resources (posting sites internal and external, etc.) to post and recruit internal and external applicants to these positions. As needed, outside recruiting agencies are used for key positions that are difficult to recruit."

As previously discussed, the applicant has not yet identified a Primary Physician or Transplant Program Coordinator but is still recruiting. Additionally, the CV for the Primary Surgeon does not appear to have the requisite direct involvement in kidney transplant patient care in the last two years, as required by OPTN.

DCOPN notes that transplant teams require highly specialized and experienced individuals. With regard to facilitation of the transplant program start-up, the applicant indicates that it has hired a "leading consulting firm in transplantation services." The consulting firm will partner with the applicant to "(1) recruit and train transplant program staff and support clinical currency initiatives; (2) develop and/or contract for complementary ancillary services and resources; (3) create policies and procedures; (4) establish internal quality control protocols; and (5) obtain OPTN/UNOS approvals and CMS certification."

Other than indicating that it is hiring a consulting firm in transplant services, the applicant did not specifically discuss its recruitment efforts with regard to the ancillary services needed to stand up a transplant program. Furthermore, because of the unique needs of a transplant program and the previously discussed specific OPTN requirements, DCOPN is concerned that the applicant may have difficulty filling the required positions with appropriately qualified individuals.

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;
The proposed project would not introduce new technology that would promote quality or cost effectiveness in the delivery of inpatient acute care.

(ii) the potential for provision of health care services on an outpatient basis;
Nor would the proposed project increase the potential for provision of services on an outpatient basis.

(iii) any cooperative efforts to meet regional health care needs; and
The applicant has contracted with LifeNet Health, a member of the OPTN and the independent Organ Procurement Organization (OPO) designated by the CMS to provide organ donation and recovery services within most of Virginia.

(iv) at the discretion of the Commissioner, any other factors as may be appropriate; and
While the applicant correctly points out in the CMC Response Letter that there is no specific language in the SMFP or statutory considerations that requires compliance with organ procurement organization requirements, it is imperative that, in making her determination of need for a requested transplant service project, the Commissioner consider the practicality and viability of the requested project. To that end, an applicant's ability to successfully implement a project authorized under COPN is a substantial factor for her consideration. For that reason this analysis has included the discussion of the OPTN requirements.

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.

The applicant provided the following with regard to this standard:

> Medical school affiliations include not only the Virginia Tech Carilion School of Medicine with 28 accredited training programs, but also VCOM, Virginia College of Osteopathic Medicine. Approval of the renal transplantation program at CRMH will create new opportunities for participation in clinical research and medical professional training programs that can only further enhance the outreach of a renal transplantation center located at Carilion Roanoke Memorial Hospital.

As previously discussed, UVA Medical Center has expressed significant opposition to the proposed project. According to the UVA Opposition Letter:

> …Carilion's proposal will jeopardize UVA's well established and highly respected training programs. UVA conducts cutting-edge, transformative clinical and translational research. After years of effort and continued growth, its transplant teams and its patients have participated in some of the largest and most important kidney transplant-related national clinical studies. This work can change the direction of the field of transplant and helps make UVA a national destination program for patients. To maintain its ability to participate in large and complex studies, UVA needs to maintain a diverse population of patients, specialized research infrastructure, and faculty familiar with conducting such trials. Reducing the diversification and size of UVA's kidney transplant services would constrict its ability to be successful, limit recruitment of research-trained faculty, and imperil its future participation in these pivotal national trials.
>
> The loss of volumes could also impact Carilion's ACGME-accredited surgical program. Carilion sends one third-year surgical resident each month to UVA for a four-week transplant rotation. While at UVA, these residents have access to hundreds of multi-organ transplant specialists that can only be provided by a large, comprehensive transplant center. Loss of renal transplant volumes at UVA could thus adversely impact the training experience of Carilion's residents as well.

DCOPN Findings and Conclusions

DCOPN finds that Carilion Medical Center (CMC) d/b/a Carilion Roanoke Memorial Hospital's COPN request to establish kidney transplant services is generally inconsistent with the applicable criteria and standards of the SMFP and the Eight Required Considerations of the Code of Virginia. Although the proposed project could improve geographic access for some patients, comparing the number of patients on the waitlist to the number of transplants performed, it can be argued that the availability of organs is the highest barrier to care for patients requiring kidney

transplants, and not geographic access. Furthermore, as described at length in Required Consideration 2 (vi), CRMH recently had numerous and serious issues with its surgical instruments and sterilization processes. Although the facility is back in regulatory compliance, DCOPN concludes that it is too soon to embark on an undertaking as critical and sensitive to infection control as a transplant program. Therefore, DCOPN must recommend denial because the proposed project is premature, among other reasons outlined in this staff analysis report.

Additionally, as previously discussed, DCOPN observes that the status quo is preferable to the proposed project. Finally, DCOPN received written opposition to the proposed project from UVA Medical Center, which operates the second-busiest kidney transplant program in Virginia. The opposition cited significant concerns with the proposed project, including: (1) The program's significant risk to UVA, given the extensive overlap in UVA's and Carilion's service areas; (2) Diversion of patients could threaten UVA's staffing, training missions, research initiatives, the viability of transplant-adjacent services that UVA provides focused on HPR II and HPR III residents, and the financial sustainability of UVA's services; (3) The requested program will not increase the number of transplantable kidneys available to resident of HPR III; and (4) The status quo is preferable to the proposed project.

DCOPN Staff Recommendations

The Division of Certificate of Public Need recommends the **denial** of Carilion Medical Center (CMC) d/b/a Carilion Roanoke Memorial Hospital's COPN request to establish kidney transplant services for the following reasons:

1. The project is inconsistent with the applicable criteria and standards of the State Medical Facilities Plan and the Eight Required Considerations of the Code of Virginia.

2. There are reasonable alternatives to the proposed project, including the status quo.

3. The proposed project is premature with regard to CRMH's issues with instrument sterilization and infection control.

4. The proposed project appears to have issues with regard to financial feasibility and staffing.

5. The proposed project could negatively impact existing providers of kidney transplant services.

6. There is documented opposition to the proposed project.