

VIRGINIA DEPARTMENT OF HEALTH

Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis

January 19, 2022

COPN Request No. VA-8600

Carilion Medical Center (CMC) d/b/a Carilion Roanoke Memorial Hospital and Carilion Roanoke Community Hospital
Roanoke, Virginia
Add one MRI scanner

COPN Request No. VA-8601

Carilion Medical Center (CMC) d/b/a Carilion Roanoke Memorial Hospital
Roanoke, Virginia
Add one special-use MRI scanner for specialized therapeutics

Applicants

COPN Request No. VA-8600: Carilion Medical Center (CMC) d/b/a Carilion Roanoke Memorial Hospital (CRMH) and Carilion Roanoke Community Hospital (CRCH)

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.

COPN Request No. VA-8601: Carilion Medical Center (CMC) d/b/a Carilion Roanoke Memorial Hospital (CRMH)

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

Background

According to Division of Certificate of Public Need (DCOPN) records, there are 11 certificate of public need (COPN) authorized fixed site magnetic resonance imaging (MRI) scanners in PD 5 (**Table 1**).

Table 1. PD 5 COPN Authorized Fixed Site MRI Units

Facility	Units
Carilion Roanoke Memorial Hospital	5
Insight Imaging - Roanoke	2
LewisGale Imaging at Brambleton	1
LewisGale Hospital - Alleghany	1
LewisGale Medical Center	2
Total	11

Source: DCOPN records

Proposed Projects

COPN Request No. VA-8600: Carilion Medical Center (CMC) d/b/a Carilion Roanoke Memorial Hospital (CRMH) and Carilion Roanoke Community Hospital (CRCH)

CMC proposes to expand its existing MRI services through the addition of one MRI unit. CMC’s campus has two acute care hospitals, CRMH and CRCH, as well as several medical office buildings that house physician practices, imaging, lab and other services. The applicant proposes to add the requested MRI unit in the 3 Riverside Building in existing outpatient imaging space adjacent to two other MRI units. The applicant states that it needs to add an MRI unit to CMC’s existing complement of five MRI units in order to enable most routine inpatient MRI scans to be performed outside of the hospital setting, freeing the units at CRMH for the more complex, lengthier and specialized MRI procedures, inpatient or emergent procedures, and procedures requiring anesthesia. The applicant states that, in addition to inpatients, outpatients, and emergency room patients, MRI services include several special categories of studies that are not done elsewhere in the region including, MR-enterography for diagnosis of patients with Crohn’s disease, colitis or ulcerative colitis; cardiac MRIs intracranial ablations to treat epilepsy and Deep Brain Stimulation (DBS) for Parkinson’s disease; scans on patients with pacemakers, fetal MRIs; MRIs requiring anesthesia; and pediatric MRIs. The applicant further asserts that all of these studies consume significantly more time than routine studies, making the units at CRMH unavailable to other patients for extended periods of time. The applicant reports that a routine MRI takes about 45 minutes for contrast studies and 30 minutes for non-contrast studies. In comparison, DBS procedures take four to six hours to perform, and five to eight routine studies could be performed during that time. Additionally, MR enterography, cardiac studies and MRI-guided breast biopsy take the time of two routine studies. Finally, pediatric sedation studies take the time of two routine studies and adult sedation studies take one and a half time slots.

If the proposed project is approved, CMC will have a resulting complement of six MRI units. The projected capital costs of the proposed project are \$3,570,434, 32.5% of which are attributed to direct construction costs (**Table 2**). Capital costs will be funded entirely using the accumulated resources of the applicant. Accordingly, there are no financing costs associated with the proposed project. Construction on the proposed project is anticipated to begin on May 15, 2022 and is expected to be completed by January 15, 2023. The target date of opening is March 30, 2023.

Table 2. COPN Request No. VA-8600 Projected Capital Costs

Direct Construction Costs	\$1,160,434
Equipment Not Included in Construction Contract	\$2,410,000
Total Capital Costs	\$3,570,434

Source: COPN Request No. VA-8600

COPN Request No. VA-8601: Carilion Medical Center (CMC) d/b/a Carilion Roanoke Memorial Hospital (CRMH)

CMC proposes to expand its existing MRI services through the addition of one part-time special use MRI unit that will be used only to guide focused ultrasound therapy – Magnetic Resonance Imaging Guided Focused Ultrasound (MRgFUS) and not for diagnostic imaging purposes. The applicant explains:

MRgFUS is an incisionless treatment option for medication-refractory essential tremor (ET) and tremor-dominant Parkinson’s disease patients. Anatomical locations of the brain responsible for the tremors are identified using MR imaging. Using a special focused ultrasound system installed in the MR scanner, ultrasound waves are focused on the small spot in the brain identified from the MR images. These ultrasound waves pass safely through the skull without incisions and create a small lesion in the targeted brain locations. For many patients, the result is immediate tremor improvement in their treated hand with minimal complications. The predominant current treatment for tremor patients that would be appropriate for MRgFUS is DBS. DBS requires two procedures and an overnight hospital stay. Recovery time is approximately one to two weeks compared with minimal recovery for MRgFUS. Results of DBS are inferior to MRgFUS and are not immediate. Eliminating hospital stays with a four-hour MRgFUS treatment is a more efficient way to treat patients and certainly more convenient and advantageous for patients than an implanted device. If approved, CMC will be able to provide MRgFUS to patients with essential tremor and tremor-dominant Parkinson’s disease in a non-hospital free-standing physician office setting.

The applicant further explains:

The Virginia Tech Carilion School of Medicine (VTC), a college of Virginia Polytechnic Institute and State University, is a public medical school located in Roanoke, Virginia on the CMC campus. The medical school is associated with a university-level research institute called the Fralin Biomedical Research Institute at VTC (FBRI). FBRI is a division of Virginia Tech Health Sciences and Technology at Virginia Polytechnic and State University. FBRI has an MR-Guided Focused Ultrasound Unit (MRgFUS) that it uses for animal research. The MR component of the unit has not been COPN-regulated because it has been used in a research capacity only and not for the treatment of patients. FBRI is relocating its MRgFUS to its new research building (Riverside 4) on CMC’s campus. That is the location of the proposed project where Carilion will lease from Virginia Tech the equipment and space to be used in connection with the MRgFUS.

The projected capital costs of the proposed project are \$550,000 (**Table 3**). Capital costs will be funded entirely using the operational revenue of the applicant. Accordingly, there are no financing

costs associated with the proposed project. No construction is required. The target date of opening is 120 days after COPN issuance.

Table 3. COPN Request No. VA-8601 Projected Capital Costs

Equipment Not Included in Construction Contract	\$550,000
Total Capital Costs	\$550,000

Source: COPN Request No. VA-8601

Project Definitions

Section 32.1-102.1:3 of the Code of Virginia defines a project, in part as the, “The addition by an existing medical care facility described in subsection A of any new medical equipment for the provision of...magnetic resonance imaging (MRI)...” A medical care facility includes “[a]ny facility licensed as a hospital, as defined in Section 32.1 – 123.”

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

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

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

The applicant proposes to add one MRI unit for diagnostic imaging at CMC. The purpose of the proposed project is to enable most routine outpatient MRI scans to be performed outside of the hospital setting, freeing the units in the hospital for the more complex, lengthier and specialized MRI procedures, emergent procedures and procedures requiring anesthesia. The applicant explains that CMC provides the only tertiary-level services available to rural Southwest Virginia in many specialties, including the only Level One Trauma Center in the region, a stroke center, a NICU, a cancer center, an Inflammatory Bowel Disease Center (IBD), a Children’s Hospital with pediatric subspecialties not otherwise offered in the region, fetal MRIs and specialized orthopaedic, neurosurgical, and gastroenterological services. According to the applicant, these services require specialized imaging to support diagnosis and treatment. Importantly, the specialized MRI studies take much longer to perform than routine studies and CMC’s MRI volumes do not fully reflect the time required to complete the specialized studies.

The applicant asserts that it currently has a wait time of three weeks for MR-enterographies, which is used as a crucial staging tool for patients with IBD. According to the applicant, this delay causes many patients with IBD to be admitted to the hospital. The applicant additionally asserts that it currently has a wait time of five weeks for pediatric MRI studies, which usually require anesthesia and that CRMH is the only facility in the area that performs MRI studies with anesthesia on children. Finally, the applicant explains that CRMH is one of only two facilities in the area performing cardiac MRIs, and the wait time for those studies is six weeks. The applicant’s primary goal in operationalizing the proposed project is to reduce these wait times, as many of these patients are unable to receive treatment until they receive an MRI scan. Based on the information provided

by the applicant above, DCOPN concludes that approval of the project would significantly increase access to MRI services for patients requiring these specialized MRI studies in PD 5.

Table 4 shows projected population growth in PD 5 through 2030. As depicted in **Table 4**, at an average annual growth rate of 0.19%, PD 5's growth rate from 2010-2020 is below the state's average annual growth rate of 0.77%. Overall, the planning district is projected to add an estimated 5,329 people in the 10-year period ending in 2020—an approximate 1.94% increase with an average increase of 533 people annually. In the 10-year period ending in 2030, the planning district is projected to add an estimated 4,096 people – an approximate 1.46% increase with an average increase of 410 people annually.

Regarding the 65+ age group for PD 5, Weldon-Cooper projects a more rapid increase in population growth (an approximate 24% increase from 2010 to 2020 and approximately 14% 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. This is significant, as this age group typically uses health care services, including diagnostic imaging services, at a rate much higher than those under the age 65.

Table 4. Population Projections for PD 5, 2010-2030

Locality			2010 - 2020		2020 - 2030		
	2010	2020	% Change	Avg Ann % Change	2030	% Change	Avg Ann % Change
Alleghany	16,250	14,950	-8.00%	-0.81%	13,620	-8.90%	-0.93%
Botetourt	33,148	33,387	0.72%	0.07%	34,484	3.29%	0.32%
Craig	10,380	5,084	-51.02%	-6.73%	5,020	-1.26%	-0.13%
Roanoke County	92,376	94,145	1.91%	0.19%	97,249	3.30%	0.32%
Covington city	5,961	5,677	-4.76%	-0.47%	5,281	-6.98%	-0.72%
Roanoke city	97,032	100,891	3.98%	0.38%	102,388	1.48%	0.15%
Salem city	24,802	25,953	4.64%	0.44%	26,141	0.72%	0.07%
Total PD 5	274,759	280,088	1.94%	0.19%	284,184	1.46%	0.15%
PD 5 65+	44,720	55,442	23.98%	2.12%	63,434	14.42%	1.36%
Virginia	8,001,024	8,655,021	8.17%	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)

Regarding socioeconomic barriers to access to the applicant's services, according to regional and statewide data regularly collected by VHI, for 2019, the most recent year for which such data is available, the average amount of charity care provided by HPR III facilities was 1.6% (**Table 5**).

Table 5. 2019 HPR III Charity Care Contributions

2019 Charity Care Contributions at or below 200% of Federal Poverty Level			
Hospital	Gross Patient Revenues	Adjusted Charity Care Contribution	Percent of Gross Patient Revenue:
Carilion Franklin Memorial Hospital	\$151,201,325	\$6,677,672	4.42%
Dickenson Community Hospital	\$25,351,508	\$928,420	3.66%
Wellmont Lonesome Pine Mt. View Hospital	\$390,073,389	\$13,498,881	3.46%
Carilion Tazewell Community Hospital	\$62,008,894	\$2,071,457	3.34%
Carilion New River Valley Medical Center	\$738,306,843	\$20,469,127	2.77%
Carilion Medical Center	\$4,068,259,340	\$105,984,180	2.61%
Carilion Giles Memorial Hospital	\$102,107,168	\$2,603,534	2.55%
Russell County Medical Center	\$124,033,055	\$2,964,704	2.39%
Norton Community Hospital	\$319,225,076	\$6,779,613	2.12%
Smyth County Community Hospital	\$213,627,381	\$4,308,217	2.02%
Johnston Memorial Hospital	\$889,740,579	\$17,870,544	2.01%
Bedford Memorial Hospital	\$129,289,507	\$2,513,096	1.94%
Centra Health	\$2,600,865,348	\$41,780,244	1.61%
Lewis-Gale Medical Center	\$2,121,321,310	\$21,145,842	1.00%
LewisGale Hospital -- Montgomery	\$658,786,131	\$5,276,155	0.80%
LewisGale Hospital -- Pulaski	\$339,877,654	\$2,029,419	0.60%
Clinch Valley Medical Center	\$547,087,883	\$3,000,603	0.55%
LewisGale Hospital -- Alleghany	\$212,218,793	\$1,046,051	0.49%
Twin County Regional Hospital	\$257,431,228	\$1,068,667	0.42%
Buchanan General Hospital	\$101,667,920	\$403,430	0.40%
Wythe County Community Hospital	\$257,623,709	\$406,156	0.16%
Memorial Hospital of Martinsville & Henry County	\$736,050,736	\$1,113,236	0.15%
Danville Regional Medical Center	\$965,570,236	-\$15,516,656	-1.61%
Total Facilities Reporting			23
Median			1.9%
Total \$ & Mean %	\$16,011,725,013	\$248,422,592	1.6%

Source: VHI (2019)

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Geographically, the 3 Riverside building on CMC’s campus is located approximately two miles from Interstate 581, which connects to Interstate 81. 3 Riverside building is also accessible by public transportation, on the bus routes of Valley Metro, serving the greater Roanoke area. Furthermore, the Star Line Trolley, a service of Valley Metro, provides free, convenient transportation along Jefferson Street between downtown Roanoke and CRMH.

Regarding socioeconomic barriers to access to the applicant’s services, according to regional and statewide data regularly collected by VHI, for 2019, the most recent year for which such data is

available, the average amount of charity care provided by HPR III facilities was 1.6% of all reported total gross patient revenues (**Table 5**). For that same year, CMC provided 2.61% of its gross patient revenue in charity care (**Table 5**). Pursuant to Section 32.1 – 102.4 of the Code of Virginia, should the State Health Commissioner (Commissioner) approve the proposed project, CMC should be subject to a charity care condition no less than the 1.6% HPR III average, in addition to any new requirements as found in the revised § 32.1-102.4B of the Code of Virginia.

DCOPN is not aware of any other distinct and unique geographic, socioeconomic, cultural, transportation, or other barriers to care that this project would address.

COPN Request No. VA-8601: Carilion Medical Center (CMC) d/b/a Carilion Roanoke Memorial Hospital (CRMH)

Geographically, the 4 Riverside building on CMC’s campus is located approximately two miles from Interstate 581, which connects to Interstate 81. The 4 Riverside building is also accessible by public transportation, on the bus routes of Valley Metro, serving the greater Roanoke area. Furthermore, the Star Line Trolley, a service of Valley Metro, provides free, convenient transportation along Jefferson Street between downtown Roanoke and CRMH.

Regarding socioeconomic barriers to access to the applicant’s services, according to regional and statewide data regularly collected by VHI, for 2019, the most recent year for which such data is available, the average amount of charity care provided by HPR III facilities was 1.6% of all reported total gross patient revenues (**Table 5**). For that same year, CMC provided 2.61% of its gross patient revenue in charity care (**Table 5**). Pursuant to Section 32.1 – 102.4 of the Code of Virginia, should the Commissioner approve the proposed project, CMC should be subject to a charity care condition no less than the 1.6% HPR III average, in addition to any new requirements as found in the revised § 32.1-102.4B of the Code of Virginia.

DCOPN is not aware of any other distinct and unique geographic, socioeconomic, cultural, transportation, or other barriers to care that this project would address.

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;**

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The applicant provided six letters of support for the proposed project from the local medical community. Collectively, these items addressed the following:

- Current wait times for outpatient MRI services at CMC are approximately three weeks, despite two MRI units at CRMH operating 24/7/365, the three outpatient MRI units operating from 7 a.m. to 11 p.m. five days a week, and one outpatient MRI unit also operating from 7 a.m. to 7 p.m. on Saturdays and Sundays.

- Prolonged wait times can cause delays in diagnosis and treatment for patients with serious medical conditions, including cancer, cardiovascular/pulmonary disease, neurological disorders, orthopedic injuries/conditions and disorders of the abdomen and pelvis.
- CMC offers procedures that utilize extended periods of time on its current MRI units, like MR-directed treatments, advanced cardiac MRI, breast MRI, MRI enterographies, brain spectroscopy and tractography, and sedated MRIs. Many of these subspecialized MRIs are not offered at other facilities in the planning district.
- Newer, more effective therapies and increased cancer rates have led to a markedly increased patient population requiring diagnostic and follow up imaging. For many of these patients, MRI is the required imaging study to diagnose malignancy, plan for treatment and ensure control of their disease.
- This increase in volume has led to a delay in diagnosis and treatment for many. For example, appointments for sedation MRI, required for pediatric patients, is commonly a month delayed.
- MRI remains one of the most effective and safe form of evaluation for cancer patients as it does not confer a secondary risk of cancer like CT or PET imaging can.

DCOPN did not receive any letters in opposition to the proposed project.

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-8600 is competing with COPN Request No. VA-8601 in this batch cycle. DCOPN conducted a public hearing on December 8, 2021 by teleconference. A total of eight individuals attended the teleconference. The project was presented by Dr. Daniel Karolyi, Chair of Radiology at Carilion Clinic, who discussed:

- The long wait times for diagnostic procedures at CMC.
- An overview of the hours of CMC's current MRI units, including 24/7 for the two MRI units in CRMH, 7:00 a.m. -11: 00 p.m. for all of the outpatient units, and from 7:00 a.m. – 7:00 p.m. on Saturdays and Sundays for the MRI unit at 3 Riverside.
- The five MRI units at CMC currently performed enough exams to meet 85% of the state threshold for additional COPN with our two inpatient MRI systems exceeding 91% of the state threshold.

COPN Request No. VA-8601: Carilion Medical Center (CMC) d/b/a Carilion Roanoke Memorial Hospital (CRMH)

The applicant provided three letters of support for the proposed project from the local medical community. Collectively, these items addressed the following:

- Focused ultrasound is a non-invasive technology that promises to alleviate tremors in patients with specific conditions without an incision or hospital stay and with minimal recovery time.
- The focused ultrasound technology requires an MRI unit to identify and precisely target tremor-inducing points in the brain. Making MRgFUS available by utilizing excess capacity on the research equipment at the Fralin Biomedical Research Institute at VTC is an efficient, low-cost way to offer these treatments to patients in Southwestern Virginia.
- Offering MRgFUS procedures in southwest Virginia will have significant positive impact for patients with essential tremor and Parkinson's related tremors. This non-invasive procedure can be life altering for these patients, many of whom cannot complete simple tasks of daily living due to severe tremors.
- There are no other providers of MRgFUS in the Health Planning Region and the nearest site offering the technology is University of Virginia, located two hours away from CMC.

DCOPN did not receive any letters in opposition to the proposed project.

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-8601 is competing with COPN Request No. VA-8600 in this batch cycle. DCOPN conducted a public hearing on December 8, 2021 by teleconference. A total of eight individuals attended the teleconference. The project was presented by Dr. Mark Witcher, Assistant Professor, Neurosurgery and Functional Neurosurgeon at Carilion Clinic, who discussed:

- It is CMC's position that the MRgFUS will not add to the inventory of MRIs, similar to a CT simulator.
- CMC is seeking COPN approval to use the MRgFUS for treatment of Essential Tremor and Parkinson's Disease. For many patients, this treatment results in immediate symptom improvement with minimal complications.
- Currently, the closest site where patients can access MRgFUS is UVA.
- This project would create access to life-changing procedures for patients with essential tremor and tremor-dominant Parkinson's in our area.

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

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As discussed throughout this staff report, there is currently a scheduling backlog of three weeks for MR-enterographies, five weeks for pediatric MRI studies, and six weeks for cardiac MRI studies. Moreover, as previously discussed, the applicant is the only provider of many of these subspecialty services in PD 5. Therefore, maintenance of the status quo is very likely to exacerbate an already unacceptable delay in diagnosis and treatment of conditions for these patient populations.

Regarding increasing hours on CMC's existing ambulatory machines to absorb appropriate cases from the hospital, the applicant asserts that there are no available hours for Crystal Spring and Riverside to perform additional MRIs. These locations are already imaging from 7 a.m. to 11 p.m. (16 hours per day) Monday through Friday. These sites are also open on Saturdays and Sundays, including 2nd shift hours staffed by employed and traveling technologists. Moreover, the two units in the hospital are open 24 hours a day and also include outpatient studies on Saturdays and Sundays. Despite these extensive operating hours, wait times are weeks or even months.

For these reasons, DCOPN concludes that there does not appear to be reasonable alternatives to the proposed project that would meet the needs of the population in a less costly, more efficient, or more effective manner.

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Neither DCOPN nor the applicant is aware of any reasonable alternatives to the proposed project that would meet the needs of the population in a less costly, more efficient, or more effective manner. Currently, tremor patients are treated with Deep Brain Stimulation (DBS). DBS requires two procedures and an overnight stay in the hospital. Recovery time for DBS is from one to two weeks. Approval of the proposed project would allow many of these patients to be treated with MRgFUS, which is completed in four hours and requires no hospital stay. Additionally, for many patients, the results are immediate. Finally, because the closest facility that offers MRgFUS is the University of Virginia Medical Center, 119 miles and two hours away, approval of the proposed project would provide access for patients residing in southwestern Virginia.

Regarding the costs of the proposed project, the applicant explains that if it were to purchase a dedicated MRI unit to support the MRgFUS treatments, it would cost approximately \$4.5 million. In comparison, using excess capacity of existing research equipment on CMC's campus will cost significantly less, at \$550,000 (**Table 3**).

For these reasons, DCOPN concludes that there does not appear to be a reasonable alternative to the proposed project that would meet the needs of the population in a less costly, more efficient, or more effective manner.

(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;

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As demonstrated by **Table 2**, the projected capital costs of the proposed project are \$3,570,434, 32.5% of which are attributed to direct construction costs. 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 the costs for the proposed project are reasonable when compared with previously approved projects similar in clinical scope. For example, COPN No. VA-04753 issued to Chippenham & Johnston-Willis Hospitals, Inc. to add one MRI unit is projected to cost approximately \$3,701,138.

The applicant identified the following benefits of the proposed project:

- As MRI services on the campus of CMC are threatened by high utilization and expanding wait times for appointments, patients needing CMC's services experience delays in diagnosis, and therefore, delays in treatment. This project is necessary to the continued, high-level, quality care of patients in the region.
- The proposed project would locate an additional MRI unit in a space already used for MRI services, therefore, already designed and approved for the service. By co-locating three MRI scanners, CMC will realize increased efficiencies due to scale.
- Technologists can work on adjacent MRI systems preventing delays or downtime. They can help with patient screening/scanning/throughput and move patients between the three scanners if delays occur. A single provider will be able to perform IV contrast reaction coverage during evening hours and weekends because MRI units will be located in adjacent spaces.
- Support spaces, reception areas, personnel, etc., can be shared with the existing MRI services.
- Location on the campus of CMC would immediately decompress the current MRI units, especially the scanners within CRMH that are experiencing weeks of wait times for appointments due to the unique and lengthy MRI studies provided there.

- It is important to be able to shift MRI studies that do not have to be conducted at CRMH to CMC's outpatient MRI sites so that the hospital-based scanners are available for emergencies.
- This important project makes it possible for patients in rural Southwest Virginia to have timely access to life-altering diagnostics and procedures without traveling to another academic, tertiary care facility a hundred-plus miles from home.

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As demonstrated by **Table 3**, the projected capital costs of the proposed project are \$550,000. Capital costs will be funded through the operational revenue of the applicant. Accordingly, there are no financing costs associated with this project. DCOPN is unable to compare the costs for the proposed project to previously approved projects because it has not reviewed such a project. However, DCOPN notes that the project does not require the purchase of new equipment and will use excess capacity of existing research equipment on CMC's campus.

The applicant identified the following benefits of the proposed project:

- The proposed project would utilize excess capacity of a research MRgFUS for the special use of offering life-changing procedures to patients in Southwest Virginia.
- The proposed project would utilize excess capacity of an existing research MRgFUS that is not currently subject to COPN review. CMC would not need to purchase equipment.
- There are no other providers of MRgFUS in HPR III.
- The proposed project would allow eligible patients to receive treatment sooner with less travel, less recovery time and avoid hospital stays.
- The MRgFUS procedures will be performed by the neurosurgeons caring for the patients, assuring complete continuity of care.

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

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The Pro Forma Income Statement provided by the applicant includes the provision of charity care in the amount of 1.6% (**Table 6**). DCOPN notes that, according to VHI data from 2019, the most recent year for which such data is available, the average amount of charity care provided by HPR III facilities was 1.6% of all reported total gross patient revenues (**Table 5**). 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 no less than the 1.6% HPR III average.

Table 6. COPN Request No. VA-8600 Pro Forma Income Statement

	Year 1	Year 2
Gross Patient Revenue	\$80,123,000	\$84,129,000
Contractual Allowances and Provision for Bad Debts	(\$65,714,000)	(\$69,394,000)
Charity Allowances	(\$1,282,000)	(\$1,346,000)
Net Revenue	\$13,127,000	\$13,390,000
Total Expenses	(\$5,409,000)	(\$5,694,000)
Net Operating Income	\$7,718,000	\$7,695,000

Source: COPN Request No. VA-8600

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The Pro Forma Income Statement provided by the applicant includes the provision of charity care in the amount of 1.6% (Table 7). DCOPN notes that, according to VHI data from 2019, the most recent year for which such data is available, the average amount of charity care provided by HPR III facilities was 1.6% of all reported total gross patient revenues (Table 5). 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 no less than the 1.6% HPR III average.

Table 7. COPN Request No. VA-8601 Pro Forma Income Statement

	Year 1	Year 2
Gross Patient Revenue	\$1,837,000	\$2,249,000
Contractual Allowances and Provision for Bad Debts	(\$1,176,000)	(\$1,439,000)
Charity Allowances	(\$29,000)	(\$36,000)
Net Revenue	\$632,000	\$774,000
Total Expenses	(\$723,000)	(\$746,000)
Net Income	(\$91,000)	\$28,000

Source: COPN Request No. VA-8601

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

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Section 12VAC5-230-160 of the SMFP does not differentiate between general MRI scans and those subspecialty scans, such as sedation MRIs, MR enterography, cardiac MRIs and MR guided breast biopsies, which take two to three times longer than routine studies. This is especially important in cases such as the current application, where one facility is the sole provider of several subspecialty MRI imaging services in the region. The applicant reports that of the 21,003 MRI studies it performed in 2021, 1,430 were sedation MRIs, MR enterography studies, cardiac MRIs, or MR guided breast biopsies, which if weighted according to the time required to perform the study, would

be the equivalent of 2,563 studies. While the applicant does not meet the level of utilization necessary to establish institutional need in 2019 (**Table 8**), or based on the numbers reported in their application (**Table 9**), were DCOPN to weigh the subspecialty scans based on the additional time required, the applicant would be much closer to meeting this standard, at 88.7%. DCOPN is not suggesting the use of this weighted approach to calculate utilization, either generally or specifically in this case, but rather merely seeks to show additional evidence of the demonstrable burden on CMC's existing machines because of the specialty scans. Penalizing CMC for providing a necessary service that would otherwise be unavailable in the region runs contrary to the guiding principles of the SMFP found in 12VAC5-230-30, which states that "[t]he COPN program seeks to promote the development and maintenance of services and access to those services by every person who needs them..." As such, solely in this current application, DCOPN recommends that the Commissioner not permit the SMFP utilization threshold to be an obstacle to reducing the overutilization of an extremely important and time consuming specialty MRI imaging service.

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As previously discussed, FBRI has an MRgFUS unit that it uses for animal research on the campus of CMC, and CMC will lease the equipment and space on a part-time basis. The applicant explained that the FBRI will continue to use the equipment for animal research, but on the days that CMC uses the equipment, only human patients will utilize the equipment. CMC will follow protocols from the National Institute of Health on how to clean the equipment between animal and human patients. If the proposed project is approved, CMC's Infection Control department will establish appropriate policies for patient safety.

3. The extent to which the proposed project 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).

The SMFP contains criteria/standards for the establishment or expansion of MRI services. They are as follows:

Part II Diagnostic Imaging Services
Article 2. Criteria and Standards for Magnetic Resonance Imaging

12VAC5-230-140. Travel Time.

MRI services should be within 30 minutes driving time one way under normal conditions of 95% of the population of the health planning district using a mapping software as determined by the commissioner.

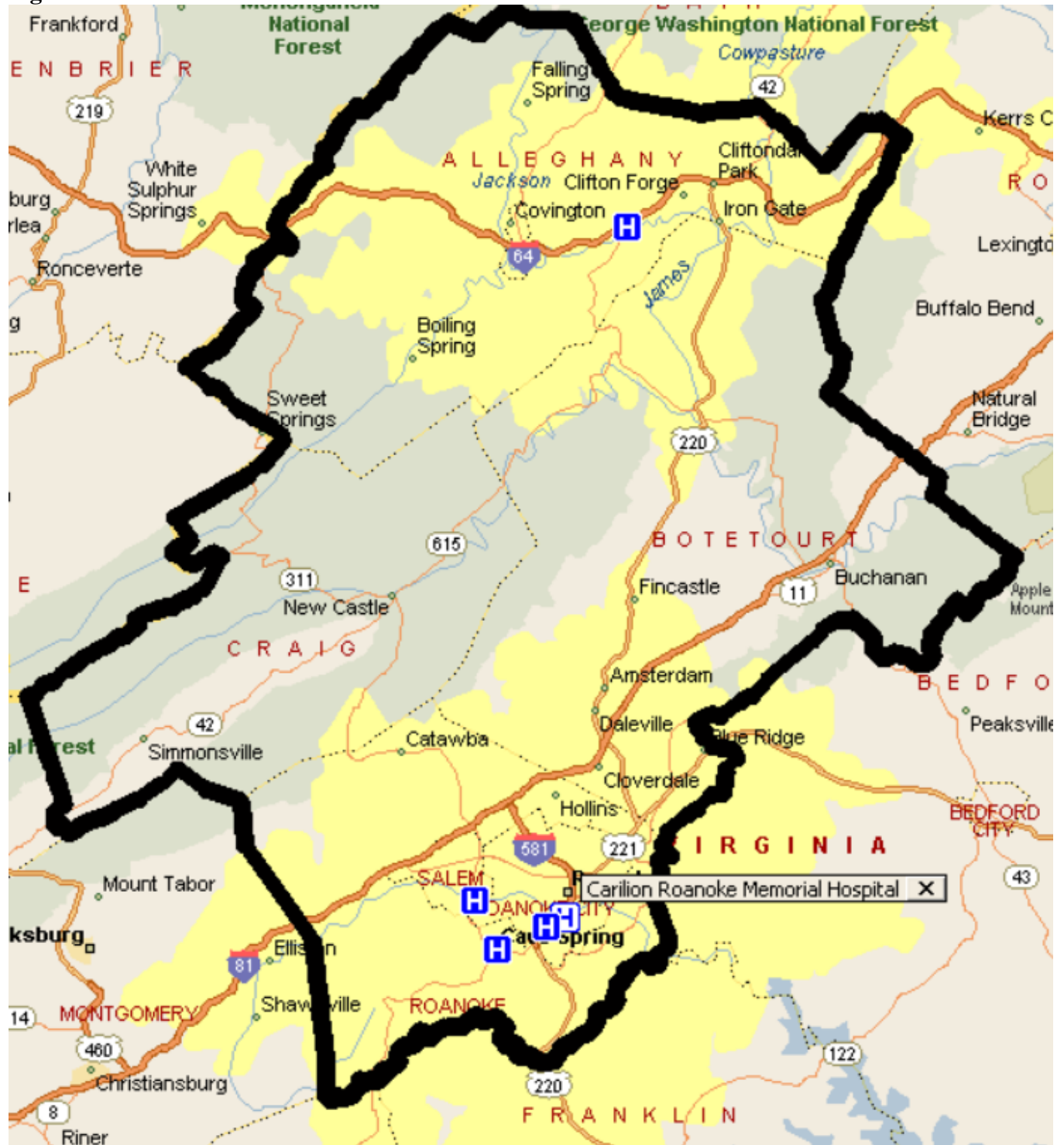
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The heavy black line in **Figure 1** is the boundary of PD 5. The blue “H” symbols mark the locations of existing MRI providers in PD 5. The white “H” symbol marks the location of the proposed projects. The yellow shaded area includes all locations that are within 30 minutes driving time one-way under normal conditions of MRI services in PD 5. As the proposed project would be located in a facility that already offers MRI services, it would not improve geographic access to this service in any meaningful way.

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The project does not include a diagnostic MRI and will not improve access to diagnostic MRI services.

Figure 1.



12VAC5-230-150. Need for New Fixed Site Service.

No new fixed site MRI services should be approved unless fixed site MRI services in the health planning district performed an average of 5,000 procedures per existing and approved fixed site MRI scanner during the relevant reporting period and the proposed new service would not significantly reduce the utilization of existing fixed site MRI providers in the health planning district. The utilization of existing scanners operated by a hospital and serving an area distinct from the proposed new service site may be disregarded in computing the average utilization of MRI scanners in such health planning district.

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The applicant is not proposing to establish a new fixed site MRI service, but rather to expand an existing service. Accordingly, this standard is not applicable to the review at hand. However, in the interest of completeness, DCOPN will address this standard.

As shown in **Table 8** below, the then-existing PD 5 fixed MRI inventory performed a collective MRI volume of 37,783 MRI procedures in 2019. Based on this data, DCOPN has calculated a current surplus of three fixed MRI scanners in PD 5 as follows:

2019 COPN authorized fixed MRI units = 11
Calculated Need = 37,783 (2019 MRI procedures) ÷ 5,000 = 7.56
(8) MRI units needed
2021 COPN authorized MRI units = 11
PD 5 Calculated Surplus = 3

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The applicant is not proposing to establish a new fixed site MRI service, but rather to expand an existing service with an MRI unit to be used solely in conjunction with MRgFUS procedures.

12VAC5-230-160. Expansion of Fixed Site Service.

Proposals to expand an existing medical care facility's MRI services through the addition of an MRI scanner may be approved when the existing service performed an average of 5,000 MRI procedures per scanner during the relevant reporting period. The commissioner may authorize placement of the new unit at the applicant's existing medical care facility, or at a separate location within the applicant's primary service area for MRI services, provided the proposed expansion is not likely to significantly reduce the utilization of existing providers in the health planning district.

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CMC has cited an institutional specific need to expand its current MRI services. As noted in **Table 6** below, for 2019, the most recent year for which VHI data is available, CMC's five MRI units performed 19,146 MRI procedures with a utilization rate of 76.6%, below the SMFP expansion standard of 5,000 procedures per scanner per year.

Table 8. PD 5 COPN Authorized Fixed MRI Units and Utilization: 2019

Facility	Number of Scanners	Number of Scans	Utilization Rate
Carilion Roanoke Memorial Hospital	5	19,146	76.6%
Insight Imaging - Roanoke	2	7,896	79.0%
Lewis Gale Imaging at Brambleton	1	1,316	26.3%
LewisGale Hospital - Alleghany	1	1,927	38.5%
LewisGale Medical Center	2	7,498	75.0%
Total and Average	11	37,783	68.7%

Source: VHI Data (2019)

Table 9 displays the 2019-2021 utilization of CMC’s MRI units by location. As shown in **Table 9**, the hospital based units operated at 100% utilization in 2019, at 81.4% utilization in 2020 and at 91.3% utilization in 2021. According to the applicant, the 2019 MRI volume for the MRI unit at the Crystal Springs building represents only four months of operation. The MRI unit was replaced that year due to age and quality (COPN Registration No. VA-R-006-19). The replacement required reconfiguration of the MRI suite and the MRI unit was not operating during that time. DCOPN notes that Crystal Spring’s utilization appears to have recovered and grown, displaying utilization of 45.9% in 2020 and 72.1% in 2021 (**Table 9**).

Regarding the drop in MRI utilization in 2020, the applicant gave the following reason:

- Cancellation of elective procedures in 202 while complying with state/federal mandates during the Covid-19 pandemic.
- Restrictions on sedation, which was only allowed for emergency procedures.
- Covid-19 testing pre-procedure.
- Terminal-style cleaning that is required after any case that is a known-Covid-19 patient.

As shown in **Table 9**, MRI volumes at CMC have rebounded. In 2021, MRI volumes are up 21% from 2020. Comparing 2021 to 2019, CMC’s MRI volumes are up 8.6%.

The applicant explains that it must reduce the burden on the hospital based machines by adding another MRI unit in the Riverside medical office building. In support of this request, the applicant asserts:

As the only Level One Trauma Center in the region, CRMH’s MRI unit must be available for urgent diagnoses of incoming trauma patients that must be scanned prior to emergency surgeries or other treatment. These traumatic injuries have a short turn-around, and all other scans must wait for these. In addition, CRMH is a primary stroke center. Patients with possible stroke and other patients coming through CRMH’s emergency room requiring MRIs are priority as well. There is no alternative site for these studies. They must be done on CRMH’s hospital-based MRI units. Obviously, the MRI scanners located in the hospital

must operate 24 hours a day, 7 days per week. CMC’s five MRI units in aggregate operated at 85% of the State Health Services Plan (SHSP) threshold in FY21; the two hospital based units have volumes that put them at 91% of the SHSP threshold, even with the very lengthy studies they support. It is important to be able to shift MRI studies that do not have to be conducted at CRMH to CMC’s outpatients. MRI sites so that the hospital-based scanners are available for emergencies.

Table 9. CMC MRI Units and Utilization: 2019-2021

Facility	Number of Scanners	2019 Scans	2019 Utilization	2020 Scans	2020 Utilization	2021 Scans	2021 Utilization
CRMH	2	9,998	100.0%	8,144	81.4%	9,130	91.3%
Crystal Springs ¹	1	941	18.8%	2,297	45.9%	3,605	72.1%
Riverside	2	8,403	84.0%	6,896	69.0%	8,268	82.7%
Total and Average	5	21,224	77.4%	17,337	69.3%	21,003	84.0%

Source: COPN Request No. VA-8600

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The applicant is not proposing to establish a new fixed site diagnostic MRI service, but rather to expand an existing service with an MRI unit to be used solely in conjunction with MRgFUS procedures.

I12VAC5-230-170. Adding or Expanding Mobile MRI Services.

- A. Proposals for mobile MRI scanners shall demonstrate that, for the relevant reporting period, at least 2,400 procedures were performed and that the proposed mobile unit will not significantly reduce the utilization of existing MRI providers in the health planning district.**
- B. Proposals to convert authorized mobile MRI scanners to fixed site scanners shall demonstrate that, for the relevant reporting period, 3,000 procedures were performed by the mobile scanner and that the proposed conversion will not significantly reduce the utilization of existing MRI providers in the health planning district.**

Not applicable. The applicant is not proposing the addition or expansion of a mobile MRI service, nor is the applicant proposing the conversion of a mobile MRI service to a fixed site scanner.

¹ According to the applicant, the 2019 MRI volume for the MRI unit at the Crystal Springs building represents only four months of operation. The MRI unit was replaced that year due to age and quality (COPN Registration No. VA-R-006-19). The replacement required reconfiguration of the MRI suite and the MRI unit was not operating during that time.

12VAC5-230-180. Staffing.

MRI services should be under the direct supervision of one or more qualified physicians.

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The applicant has provided assurances that the MRI services will continue to be under the direction or supervision of one or more qualified physicians.

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The applicant has provided assurances that the MRI services would be under the direction or supervision of one or more qualified physicians. According to the applicant, existing staff from CMC's diagnostic MRI services will shift hours or work extra hours to operate the part-time special use MRI unit. Mark Witcher, MD, PhD, FAANS will perform the MRgFUS procedures. Dr. Witcher is the Associate Program Director, Neurosurgery at Carilion Clinic and Assistant Professor, Department of Surgery at the Virginia Tech Carilion School of Medicine and Assistant Professor, School of Neuroscience at Virginia Polytechnic Institute and State University.

The SMFP also contains criteria/standards for when institutional expansion is needed. They are as follows:

12VAC5-230-80. When Institutional Expansion is Needed.

- 1. Notwithstanding any other provisions of this chapter, the commissioner may grant approval for the expansion of services at an existing medical facility in a health planning district with an excess supply of such services when the proposed expansion can be justified on the basis of a facility's need having exceeded its current service capacity to provide such service or on the geographic remoteness of the facility.**
- 2. If a facility with an institutional need to expand is part of a health system, the underutilized services at other facilities within the health system should be reallocated, when appropriate, to the facility with the institutional need to expand before additional services are approved for the applicant. However, underutilized services located at a health system's geographically remote facility may be disregarded when determining institutional need for the proposed project.**
- 3. This section is not applicable to nursing facilities pursuant to §32.1-102.3:2 of the Code of Virginia.**
- 4. Applicants shall not use this section to justify a need to establish new services.**

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The applicant states that it has an institutional need for one additional diagnostic MRI unit. As detailed in **Table 8** above, CMC's five MRI units performed 19,146 scans, in 2019, the most recent year for which VHI data is available. This is only 76.6% of the SMFP standard required to establish institutional need to expand. Moreover, the total scans provided by the applicant for 2020 and 2021 (**Table 9**) do not exceed this threshold either. Although 2021 does show an increase in overall utilization to 84% (**Table 9**). As such, DCOPN concludes that the applicant has failed to demonstrate an institutional need to expand its MRI services. As noted above, however, DCOPN

has, for this application only, recommended that the Commissioner not permit the SMFP utilization threshold to be an obstacle to reducing the overutilization of extremely important and time-consuming MRI imaging services with low potential for detrimental effect for existing service providers in the region.

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The applicant has not asserted an institutional need to expand MRI services. As such, this provision is not applicable to the proposed project.

Eight Required Considerations Continued

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

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As the sole provider of many subspecialty MRI services, it is unlikely that the proposed project would foster institutional competition that benefits the area to be served. However, given the excessive wait times currently experienced by patients needing these scans, as discussed above, DCOPN finds approval of the proposed project would improve access to essential health care services for people in PD 5.

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This MRI unit will be used solely in conjunction with MRgFUS procedures. As the MRI unit will not be used for diagnostic MRI services, this project will not foster institutional competition with regard to MRI services.

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;

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The applicant asserts, and DCOPN agrees, that approval of the project is unlikely to impact existing services or facilities. As previously discussed, the primary purpose of the proposed MRI scanner would be to lessen the wait times for the subspecialty MRI services that are only supplied in HPR III by CMC.

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As previously discussed, the requested MRI unit will be used solely in conjunction with MRgFUS procedures. As the MRI unit will not be used for diagnostic MRI services, this project will have no effect on utilization and efficiency of existing services or facilities.

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;

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As previously discussed, the projected capital costs of the proposed project are \$3,570,434, 32.5% of which are attributed to direct construction costs. Capital costs will be funded through the accumulated reserves of the applicant. Accordingly, there are no financing costs associated with this project. As previously discussed, DCOPN concludes that when compared to similar projects, these costs are reasonable. Furthermore, the Pro Forma Income Statement provided by the applicant projects income of \$7,718 in the first year of operation and \$7,695 by year two (Table 6).

The applicant anticipates the need to hire 11.9 full-time equivalent personnel (FTE) to staff the proposed project. These FTEs include:

- One administration – business office employee
- One Registered Nurse
- Six Radiological Technologists
- 0.9 Radiological Technologist Assistant
- Two HAA employees
- One PACS support employee

However, the applicant is a current provider of MRI services with a robust employee recruitment and retention program. Accordingly, DCOPN does not anticipate that the applicant will have difficulty staffing the proposed project or that doing so will have a significant negative impact on other PD 5 facilities.

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As previously discussed, the projected capital costs of the proposed project are \$550,000, which represents the costs to lease the equipment and space. Capital costs will be funded through the operational revenue of the applicant. Accordingly, there are no financing costs associated with this project. DCOPN is unable to compare the costs for the proposed project to previously approved projects because it has not reviewed such a project. However, DCOPN notes that the project does not require the purchase of new equipment and will use excess capacity of existing research equipment on CMC's campus. Finally, the Pro Forma Income Statement provided by the applicant projects income of \$2,384,221 in the first year of operation and \$2,753,518 by year two.

The applicant does not anticipate the need to hire any additional personnel to staff the proposed project. As previously discussed, existing staff from CMC's diagnostic MRI services will shift hours or work extra hours to operate the part-time special use MRI unit. Mark Witcher, MD, PhD, FAANS will perform the MRgFUS procedures. Dr. Witcher is the Associate Program Director, Neurosurgery at Carilion Clinic and Assistant Professor, Department of Surgery at the Virginia Tech

Carilion School of Medicine and Assistant Professor, School of Neuroscience at Virginia Polytechnic Institute and State University.

- 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 bases; (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**

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The proposed project does not offer the introduction of new technology that promotes quality, cost effectiveness, or both in the delivery of health care services. However, the proposed project will increase the provision of services on an outpatient basis because the requested MRI unit will be housed in a medical office building and not in the hospital. DCOPN did not identify any other relevant factors to bring to the Commissioner's attention.

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Approval of the proposed project would offer the introduction of new technology that promotes quality, cost effectiveness, or both in the delivery of health care services. As previously discussed, CMC proposes to expand its existing MRI services through the addition of one part-time special use MRI unit that will be used only for MRgFUS, an incisionless treatment option for patients with essential tremor and Parkinson's disease. Currently, patients with essential tremor are treated with DBS. DBS requires two procedures and an overnight stay in the hospital. Recovery time for DBS is from one to two weeks. Approval of the proposed project would allow many of these patients to be treated with MRgFUS, which is completed in four hours and requires no hospital stay. Additionally, for many patients, the results are immediate. Finally, because the closest facility that offers MRgFUS is the University of Virginia Medical Center, 119 miles and two hours away, approval of the proposed project would provide access for patients residing in southwestern Virginia.

- 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 services for citizens of the Commonwealth, including indigent or underserved populations.**

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The applicant provided the following information regarding this consideration:

Carilion Clinic is a teaching hospital with the Virginia Tech Carilion School of Medicine (VTCSOM). As a result, the Radiologists practicing and reading studies for clinical

patients at Carilion Clinic are also teaching faculty for rotating medical students through Carilion Clinic's Department of Radiology. Radiology is a core Clerkship rotation for medical students. The Assistant Dean for Clinical Service, (Years 3-4) for VTCSOM, Tracey Criss, MD, also practicing clinical psychiatrist, cites Radiology Clerkship's experience as vital. Further, the experience with Magnetic Resonance Imaging (MRI) is one that provides excellence and value specific to clinical application and appropriateness of ordering-- to assure the educational experience informs both the clinical application and the importance of appropriate ordering and utilization. As this is key to appropriate clinical use and application of MRI for diagnosis, it improves health care for our citizens, as well as benefiting underserved populations. The rotation and exposure to MRI for the medical school educates medical students regarding application of American College of Radiology (ACR) appropriateness criteria and appropriate ordering of studies for clinical impact for patients; other clinical experience in MRI exposure side-by-side with Carilion Clinic Radiologists include:

- Neuro-vascular, use MRI images to demonstrate normal and pathological
- anatomy of the cerebral vasculature.
- Determining staging for hepatic, renal, pancreatic, colorectal, and
- uterine/ovarian malignancy.
- Demonstrate the significant clinical impact of multi-parametric MR
- imaging for prostate cancer staging and treatment.
- Advantage of MRI for musculoskeletal (MSK) trauma.
- Evaluation of orthopedic ligament injuries.
- Understanding MRI T1 and T2 weighting; and
- Understanding MRI safety issues

These experiences for VTCSOM medical students provide a solid foundation in clinical learning for clinical Radiology and diagnosis and evaluation with MRI, as a core component of that education, which also emphasizes the appropriate utilization of MRI.

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The applicant provided the following information regarding this consideration:

Carilion Clinic is the primary teaching hospital aligned with the Virginia Tech Carilion School of Medicine (VTC). The Virginia Tech Carilion School of Medicine is located on CMC's campus. It is a public medical school of Virginia Polytechnic Institute and State. The medical school is associated with a university-level research institute called the Fralin Biomedical Research Institute at VTC (FBRI). FBRI has an MR-Guided Focused Ultrasound Unit (MRgFUS) that is not COPN-regulated because FBRI is not a provider of treatment for patients. Its MRgFUS is utilized only for research purposes. CMC proposes to utilize the MRgFUS at FBRI for the treatment of patients. The primary neurosurgeon that plans to provide the treatments initially is an assistant professor at the VTC and Associate Residency Program Director. The proposed project is an example of a teaching hospital and medical school providing delivery, innovation and improvement of health care for citizens of the Commonwealth.

DCOPN Staff Findings and Conclusion

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DCOPN finds that the proposed project to add one fixed MRI unit at CMC is generally consistent with the applicable criteria and standards of the State Medical Facilities Plan and the eight Required Considerations of the Code of Virginia. As previously discussed, the applicant's five MRI units operated at 76.6% utilization in 2019, below the SMFP threshold for expansion. While DCOPN did not find that CMC has demonstrated an institutional need to expand MRI imaging services based on its 2019 utilization, for the reasons discussed, the status quo is not a preferable alternative to the proposed project. As discussed throughout this staff report, there is currently a scheduling backlog of three weeks to six weeks for specialized studies, some of which are only provided at CMC. Moreover, as previously discussed, the applicant is the only provider of many of these subspecialty services in PD 5. Therefore, maintenance of the status quo is very likely to exacerbate an already unacceptable delay in diagnosis and treatment of conditions for these patient populations.

DCOPN notes that there is no known opposition to the proposed project. DCOPN maintains that the projected capital costs of the proposed project are reasonable and consistent with previously approved projects similar in clinical scope; and notes that because the costs will be funded using accumulated reserves of the applicant, no financing fees are associated with this project. Finally, DCOPN finds that the proposed project will prove financially feasible both in the immediate and in the long-term.

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DCOPN finds that the proposed project to expand CMC's existing MRI services through the addition of one part-time special use MRI unit that will be used only to guide focused ultrasound therapy – Magnetic Resonance Imaging Guided Focused Ultrasound and not for diagnostic imaging purposes is generally consistent with the applicable criteria and standards of the State Medical Facilities Plan and the eight Required Considerations of the Code of Virginia. The proposed project is more favorable than maintaining the status quo because MRgFUS offers treatment for tremor in four hours, and requires no hospital stay, as opposed to the current treatment, which requires two procedures and an overnight stay in the hospital. Furthermore, because the closest facility that offers MRgFUS is the University of Virginia Medical Center, 119 miles and two hours away, approval of the proposed project would provide access for patients residing in southwestern Virginia.

DCOPN notes that there is no known opposition to the proposed project. DCOPN maintains that it is unable to compare the costs for the proposed project to previously approved projects because it has not reviewed such a project. However, DCOPN notes that the project does not require the purchase of new equipment and will use excess capacity of existing research equipment on CMC's campus. If the applicant purchased a dedicated MRI unit to support the MRgFUS treatments, it would cost approximately \$4.5 million. In comparison, using excess capacity of existing research equipment on CMC's campus will cost significantly less, at \$550,000. DCOPN also notes that because the costs will be funded using accumulated reserves of the

applicant, no financing is associated with this project. Finally, DCOPN finds that the proposed project will prove financially feasible both in the immediate and in the long-term.

DCOPN Staff Recommendation

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The Division of Certificate of Public Need recommends **conditional approval** of Carilion Medical Center's request to add one MRI unit for the following reasons:

1. The proposed project is consistent with the applicable criteria and standards of the State Medical Facilities Plan, or is in harmony or general agreement with the SMFP, and the Eight Required Considerations of the Code of Virginia.
2. The project is more favorable than the alternative of the status quo.
3. There is no known opposition to the project.
4. The capital costs associated with this project are reasonable.
5. The proposed project appears economically viable in the immediate and in the long-term.

DCOPN's recommendation is contingent upon Carilion Medical Center's agreement to the following charity care condition:

Carilion Medical Center will provide MRI services to all persons in need of these services, regardless of their ability to pay, and will provide as charity care to all indigent persons free services or rate reductions in services and will facilitate the development and operation of primary medical care services to medically underserved persons in PD 5 in an aggregate amount equal to at least 1.6% of Carilion Medical Center's gross patient revenue derived from MRI services. 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. Carilion 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 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.

Carilion Medical Center will provide MRI 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 Carilion 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.

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The Division of Certificate of Public Need recommends **conditional approval** of Carilion Medical Center's request to expand its existing MRI services through the addition of one part-time special use MRI unit that will be used only to guide focused ultrasound therapy – Magnetic Resonance Imaging Guided Focused Ultrasound and not for diagnostic imaging purposes, for the following reasons:

1. The project is generally consistent with the applicable criteria and standards of the State Medical Facilities Plan and the eight Required Considerations of the Code of Virginia.
2. The project is more favorable than the alternative of the status quo.
3. The proposed project appears economically viable in the immediate and in the long-term.
4. There is no known opposition to the project.

DCOPN's recommendation is contingent upon Carilion Medical Center's agreement to the following charity care condition:

Carilion Medical Center will provide MRI services to all persons in need of these services, regardless of their ability to pay, and will provide as charity care to all indigent persons free services or rate reductions in services and will facilitate the development and operation of primary medical care services to medically underserved persons in PD 5 in an aggregate amount equal to at least 1.6% of Carilion Medical Center's gross patient revenue derived from MRI services. 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. Carilion 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 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.

Carilion Medical Center will provide MRI 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 Carilion 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.