



## COMMONWEALTH of VIRGINIA

Colin M. Greene, MD, MPH  
State Health Commissioner

Department of Health  
P O BOX 2448  
RICHMOND, VA 23218

TTY 7-1-1 OR  
1-800-828-1120

September 27, 2022

### By Email

Erin S. Whaley, Esquire  
Troutman Pepper Hamilton Sanders LLP  
1001 Haxall Point  
Richmond, Virginia 23219

**Certificate of Public Need (COPN)**  
**Number VA-04807**  
**(Request Number VA-8630)**  
**University of Virginia Medical Center**  
**Addition of One Fixed Magnetic Resonance**  
**Imaging (MRI) Scanner**  
**At University Hospital**  
**Charlottesville, Virginia**  
**Health Planning Region II**  
**Planning District 10**

Dear Ms. Whaley:

In accordance with Article 1.1 of Chapter 4 of Title 32.1 (§ 32.1-102.1 *et seq.*) of the Code of Virginia (the "COPN law"), I have reviewed the application captioned above. As required by Subsection B of Virginia Code § 32.1-102.3, I have considered all matters, listed therein, in making this determination of public need under the COPN law.

I have reviewed and adopted the enclosed findings, conclusions and recommended decision of the adjudication officer that convened the informal fact-finding conference on this application in accordance with the Virginia Administrative Process Act, Virginia Code § 2.2-4000 *et seq.*


Erin S. Whaley, Esquire  
September 27, 2022  
Page 2 of 2

**Based on my review of this application and on the recommended decision of the adjudication officer, I am approving the application. The project proposed in the application (the “UVAMC project”) will meet a public need.**

The reasons for my decision include the following:

- (i) The UVAMC project is consistent with the State Medical Facilities Plan (SMFP), is in harmony or in general agreement with the SMFP or with the public policies, interests and purposes to which the SMFP and the COPN law are dedicated;
- (ii) The total costs of the UVAMC project are reasonable; and
- (iii) The UVAMC project would introduce an innovative application of MRI technology particularly beneficial in providing rapid, efficient screening vital in providing emergency medical care.

Sincerely,

DocuSigned by:  
  
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Colin M. Greene, MD, MPH  
State Health Commissioner

Encl.

cc (via email):  
Lilian Peake, MD, MPH  
Director, Blue Ridge Health District  
Deborah K. Waite  
Virginia Health Information, Inc.  
Allyson Tysinger, Esq.  
Senior Assistant Attorney General  
Douglas R. Harris, JD  
Adjudication Officer  
Erik O. Bodin, III  
Division of Certificate of Public Need

**COMMONWEALTH OF VIRGINIA**  
**DEPARTMENT OF HEALTH**  
**MEDICAL CARE FACILITIES CERTIFICATE OF PUBLIC NEED**

**THIS CERTIFIES THAT** University of Virginia Medical Center is authorized to initiate the proposal as described herein.

**NAME OF FACILITY:** University of Virginia Medical Center.

**LOCATION:** 1215 Lee St, Charlottesville, Virginia 22903.

**OWNERSHIP AND CONTROL:** University of Virginia Medical Center will own and control the approved resource.

**SCOPE OF PROJECT:** Introduction of one magnetic resonance imaging (MRI) scanner, *i.e.*, a portable MRI scanner capable of performing imaging at the point of care, in accordance with representations made during the course of review and adjudication. The portable MRI scanner shall not be replaced with a conventional fixed or mobile MRI. The total authorized capital cost of the project is \$467,190, to be defrayed using accumulated reserves. The project is scheduled to be completed by December 31, 2022.



Pursuant to Chapter 4, Article 1:1 of Title 32.1, Sections 32.1-102.1 through 32.1-102.11, Code of Virginia (1950), as amended and the policies and procedures promulgated thereunder, this Medical Care Facilities Certificate of Public Need is issued contingent upon substantial and continuing progress towards implementation of the proposal within twelve (12) months from the date of issuance. A progress report shall be submitted to the State Health Commissioner within twelve (12) months from the date of issuance along with adequate assurance of completion within a reasonable time period. The Commissioner reserves the right not to renew this Certificate in the event the applicant fails to fulfill these conditions. This Certificate is non-transferable and is limited to the location, ownership, control and scope of the project shown herein.

**Certificate Number:** VA-04807

**Date of Issuance:** September 27, 2022

**Expiration Date:** September 26, 2023

DocuSigned by:

Colin M. Greene

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**Colin M. Greene, MD, MPH**  
**State Health Commissioner**

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**Recommended Case Decision  
Certificate of Public Need (COPN)  
Request Number VA-8630  
University of Virginia Medical Center  
Addition of One Fixed Magnetic Resonance  
Imaging (MRI) Scanner  
At University Hospital  
Charlottesville, Virginia  
Health Planning Region II  
Planning District (PD) 10**

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**Introduction and Authority**

This document is a recommended decision submitted to the State Health Commissioner (“Commissioner”) for his consideration and adoption. It follows review of the application captioned above performed by the Department of Health professional health facilities planning staff and a separate review of the application that included the convening of an informal fact-finding conference (IFFC),<sup>1</sup> conducted in accordance with the Virginia Administrative Process Act (VAPA),<sup>2</sup> and preparation of this recommended decision.

Article 1 of Chapter 4 of Title 32.1 (§ 32.1-102.1 *et seq.*) of the Virginia Code (“COPN Law”) addresses medical care facilities and provides that “[n]o person shall undertake a project described in [this Article] or regulations of the [State] Board [of Health] at or on behalf of a medical care facility . . . without first obtaining a certificate [of public need] from the Commissioner.”<sup>3</sup> The endeavor proposed in this application falls within the statutory definition of “project” contained in the COPN Law, and, thereby, requires a certificate of public need (COPN, or “Certificate”) to be issued before the endeavor may be undertaken.<sup>4</sup>

**Factual Background**

1. The University of Virginia Medical Center (“UVAMC”) is an academic health care center operated under authority of the Rector and Visitors of the University of Virginia. UVAMC is a nationally-recognized, public-university teaching and research hospital

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<sup>1</sup> The IFFC was held in person on August 1, 2022.

<sup>2</sup> Va. Code § 2.2-4000 *et seq.*

<sup>3</sup> Va. Code § 32.1-102.1:2 (A).

<sup>4</sup> Va. Code § 32.1-102.1.

Adjudication Officer's  
Recommendation  
Page 2 of 6

licensed for 612 beds, and provides numerous medical and clinical services, including tertiary-quaternary and advanced medical services.

2. UVAMC proposes to add a specialized, limited-purpose MRI scanner. This scanner would be fixed, *i.e.*, it would operate within the physical plant of UVAMC's hospital. But this scanner, with *four percent of the strength of a 1.5T (Tesla) MRI scanner*, is housed in a portable device that can be wheeled within the hospital, to a patient's bedside. The intended scanner<sup>5</sup> can be wheeled about to allow *point-of-care screening to inform intracranial diagnoses using portable MRI technology*. The project's outward, attributable cost total less than \$0.5 million.

### **Summary of DCOPN Staff Report**

In a staff report dated July 19, 2022, prepared by the Department of Health's Division of Certificate of Public Need (DCOPN) on the RROC project (the "DCOPN staff report"), that division recommended that the Commissioner deny the project proposed by the applicants (the "UVAMC project"), relying, in substantial part, on the project's apparent inability to comply with the State Medical Facilities Plan.

### **Analysis and Conclusions Relating to the Proposed Project**

Salient analysis and conclusions regarding the UVAMC project and relating directly to the eight considerations of public need contained in the COPN law (the "statutory considerations"<sup>6</sup> appearing in bold type), are set forth in relation to each statutory consideration below.

**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.**

UVAMC is in the City of Charlottesville, located centrally in PD 10. The UVAMC project would increase a particular point access within a major provider of emergency medical care in HPR I. This access would allow the operationalization of a specifically-designed application of MRI technology. The project would allow quick imaging to screen for stroke, tumors, emergency injuries, and post-operative neurological complications.

The portable device comprising this iteration of MRI technology is on or within a wheeled frame, and can be wheeled, or "driven,"<sup>7</sup> to a patient's bedside where it can perform screening scans quickly, efficiently and without taking a patient to an MRI scanner located elsewhere in the hospital, if one is available. This project presents a novel

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<sup>5</sup> This manufactured iteration of MRI technology is known commercially as a "Swoop Hyperfine" scanner. DCOPN Staff Report at 2.

<sup>6</sup> See Subsection B of Virginia Code § 32.1-102.3.

<sup>7</sup> The 120-volt-powered unit is maneuvered via a keypad or physical control device.

Adjudication Officer's  
Recommendation  
Page 3 of 6

opportunity for health care, and promises to be an important, yet inexpensive, step forward in providing access to a potentially life-saving application of vital technology.

**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; (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; (iii) any recommendation or report of the regional health planning agency regarding an application for a certificate [*i.e.*, Certificate] that is required to be submitted to the Commissioner pursuant to subsection B of § 32.1-102.6;<sup>8</sup> (iv) any costs and benefits of the proposed project; (v) the financial accessibility of the proposed project to people in the area to be served, including indigent people; and (vi) at the discretion of the Commissioner, any other factors as may be relevant to the determination of public need for a proposed project.**

UVAMC provided DCOPN several letters of support. The only alternative to the project is maintaining the status quo. Denial of the project would close off an opportunity to provide rapid screening helpful in making quick decisions in treating medical emergencies. The costs of the project are reasonable. Regarding financial access, UVAMC is a major provider of charity care in Virginia. The project promises benefits and would meet a particular need.

**3. The extent to which the proposed project is consistent with the State Health Services Plan [*i.e.*, *de facto*, the SMFP].<sup>9</sup>**

The COPN law requires that “[a]ny decision to issue . . . a [COPN] shall be consistent with the most recent applicable provisions of the [SMFP]”<sup>10</sup> The SMFP, contained in the Virginia Administrative Code (VAC), includes provisions applicable to projects involving radiation therapy services MRI services.

DCOPN calculates that PD 10 has an inventory of 11 conventional MRI scanners and a surplus of six MRI scanners. The various provisions of the SMFP governing MRI technology are generally designed to promote the rational dispersal and location of MRI scanning capacity in a cost-effective manner that meets public need for general, often scheduled, diagnostic services. The SMFP does not appear directly useful in gauging the particular need, which has and does exist, for rapid, economical screening and diagnosis in the emergency medical care setting, which this recently-developed, innovative iteration of

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<sup>8</sup> No regional health planning agency currently exists to report on projects proposed in Health Planning Region (HPR) I, which includes PD 10.

<sup>9</sup> 12 Virginia Administrative Code (VAC) 5-230-10 *et seq.* While Senate Bill 764 (Acts of Assembly, c. 1271, 2020) calls for promulgation and adoption of a State Health Services Plan (SHSP) to replace the SMFP, the process for developing the SHSP has not been completed. Therefore, the SMFP remains in effect as regulatory guidance in reviewing applications for a COPN.

<sup>10</sup> Va. Code § 32.1-102.3 (B).

Adjudication Officer's  
Recommendation  
Page 4 of 6

MRI technology would address. Approval of the UVAMC project would provide valuable, flexible availability of a powerful screening diagnostic ability *within* UVAMC's emergency department – an innovation in itself.

Past decisions in COPN cases have demonstrated the Commissioner's ability to find, in his discretion, a new, novel or particularly-beneficial proposed project to be consistent with the SMFP. When doing so, the adjudicated recommended decisions were prepared after reviewing applicable case law from Virginia courts in order to find reliable terms and concepts that faithfully carry through on making a rational and defensible case decision under the COPN Law. Judicial case law, providing agency guidance, informs the exercise of administrative discretion, serving to substantiate and justify approvable projects under the COPN Law more reasonably, reliably and judicially-defensibly, to the public benefit.

Despite inability to show compliance with certain quantitative provisions and standards set forth in the SMFP, a worthy project may still be approved. As noted in past recommended decisions, the SMFP has never been intended to obstruct or prevent the operationalization of innovative resources, their "devolution," or "roll-out," to the service of residents of the Commonwealth.

The UVAMC project is consistent with the SMFP, is in harmony or in general agreement with the SMFP or with the public policies, interests and purposes to which the SMFP and the COPN Law are dedicated.<sup>11</sup>

**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.**

Not applicable, without prejudice to the applicant.

**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.**

The UVAMC project would augment the system of health care resources in the area to be served by placing a particularly-beneficial, non-conventional iteration of MRI technology in a medical center that provides a substantial amount of emergency medical care. The project would have an appropriate relationship to the existing health care system.

When a particular iteration of a regulated technology would not be fungible or interchangeable with conventional iterations of that technology, approval of such a project carries little ability to disrupt the operation, utilization or sustainability of past projects, comprising existing iterations together forming a system to meet public need for the technology.

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<sup>11</sup> See *Roanoke Mem. Hosp. v. Kenley*, 3 Va. App. 599, 352 S.E.2d 525 (1987).

Adjudication Officer's  
Recommendation  
Page 5 of 6

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

The UVAMC project is feasible in relation to all particulars specified.

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

The UVAMC project would provide and introduce a distinct innovation in the delivery of health care services by introducing a new means of applying a vital technology that promotes screening and diagnosis, quality and effectiveness.

**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.**

UVAMC is a teaching hospital associated with a public institution of higher education that includes a medical school. UVAMC has demonstrated having a research, training and clinical mission dedicated to promoting the general delivery of health care services and generally helpful innovation in the application of medical technology. Approval of the project would allow research scientists at UVAMC to work with this portable technology, and improve and develop its usefulness.<sup>12</sup> The project would assist in the promotion of rapid, effective screening and diagnosis in treating medical emergencies, thereby improving services for citizens of the Commonwealth.

### **Conclusion and Recommendation**

In light of all eight statutory considerations and upon review of the administrative record compiled in relation to the UVAMC project, I conclude that the project would meet a public need and merits approval. I recommend that the UVAMC project be approved, as it will meet a public need.<sup>13</sup>

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<sup>12</sup> UVAMC Closing Statement at 1-2.

<sup>13</sup> The resulting COPN should demonstrate in clear terms that the approval therein is for a portable iteration of MRI technology to facilitate point-of-care screening, and that this portable MRI scanner cannot be replaced with a conventional fixed or mobile MRI scanner without further approval from the Commissioner. UVAMC has proposed specific language to serve this purpose; this language is acceptable and could be adopted. *See* UVAMC Closing Statement at 2.



Adjudication Officer's  
Recommendation  
Page 6 of 6

Specific reasons supporting this recommendation include:

- (i) The UVAMC project is consistent with the SMFP, is in harmony or in general agreement with the SMFP or with the public policies, interests and purposes to which the SMFP and the COPN law are dedicated;
- (ii) The total costs of the project are reasonable; and
- (iii) The UVAMC project would introduce an innovative application of MRI technology particularly beneficial in providing rapid, efficient screening vital in providing emergency medical care.

Respectfully submitted,

A handwritten signature in blue ink, appearing to read "D. Harris", with a stylized flourish extending to the right.

September 23, 2022

Douglas R. Harris, JD  
Adjudication Officer

# VIRGINIA DEPARTMENT OF HEALTH

## Office of Licensure and Certification

### Division of Certificate of Public Need

#### Staff Analysis

July 19, 2022

#### **COPN Request No. VA-8630**

University of Virginia Medical Center

Charlottesville, Virginia

Add one fixed MRI scanner at University Hospital

#### Applicant

The University of Virginia Medical Center (UVAMC) is a state-owned, academic health care center operated under the authority of The Rector and Visitors of the University of Virginia. UVAMC is located in Charlottesville, Virginia, Planning District (PD) 10, Health Planning Region (HPR) I.

#### Background

UVAMC is a comprehensive tertiary teaching hospital. The medical center is composed of an integrated network of primary and specialty services that include the Emily Couric Clinical Cancer Center, the UVA Children's Hospital, the Heart and Vascular Center, the Digestive Health Center of Excellence, a Level I Trauma Center, the Blue Ridge Poison Center, and more than 60 outpatient clinics located on the main hospital campus and in surrounding Albemarle County. Currently, UVAMC is authorized to utilize four fixed magnetic resonance imaging (MRI) scanners. As demonstrated in **Table 1** below, there are currently 15 authorized fixed diagnostic MRI scanners in PD 10. For 2020, the most recent year for which utilization data is available from Virginia Health Information (VHI), the collective utilization of the then 11 operational fixed diagnostic MRI scanners in PD 10 amounted to 74.8% of the SMFP fixed MRI expansion threshold (Table 8). UVAMC controls 12 of the 15 (80%) MRIs authorized in PD 10.

**Table 1. PD 10 COPN Authorized Fixed Site Diagnostic MRI Units**

Facility	Number of MRI Scanners
UVA Imaging -- Ivy Mountain	2
UVA Imaging - Zion Crossroads	1
Sentara Martha Jefferson Health Services - Proffit Road	1
Sentara Martha Jefferson Hospital	2
University of Virginia Medical Center	4
UVA Imaging Transitional Care Hospital	2
UVA Imaging Center Fontaine MOB 1	3
<b>TOTAL</b>	<b>15</b>

Source: DCOPN records

### **Proposed Project**

UVAMC proposes to expand its existing MRI services through the addition of one Swoop Hyperfine fixed MRI unit – a portable scanner that is only used for imaging the head and brain. The magnet for this 0.064T scanner is only 4% of the strength of a 1.5T MRI. The MRI scanner in question is a highly specialized, limited use scanner, specifically designed to facilitate the diagnosis and treatment of several health issues relating to strokes, brain tumors, and post-operative neurological complications. The Hyperfine MRI unit is distinguishable from a traditional fixed MRI unit in several ways. For example, while it is fixed, meaning it permanently remains on the hospital site, the Hyperfine is portable, so that it can be wheeled directly to a patient’s bed. Moreover, as described above, the Hyperfine unit magnet operates at a fraction of the strength of a traditional 1.5T MRI fixed site unit.

UVAMC currently has an inventory of four fixed MRI scanners, and, based on 2020 utilization data from VHI, the most recent year such data is available, the four MRI scanners at UVAMC performed at 66.3% of the SMFP threshold for expansion of fixed site MRI services. The applicant states that it needs to add an MRI unit to UVAMC’s existing complement of four fixed MRI units in order to meet a unique medical need.

If the proposed project is approved, UVAMC will have a resulting complement of five fixed MRI units. The projected capital costs of the proposed project are \$467,190, all of which are attributed to the purchase of the Hyperfine MRI scanner (**Table 2**). The proposed specialized MRI is approximately a quarter of the cost of a more conventional, full service MRI. Capital costs will be funded entirely using the accumulated resources of the applicant. Accordingly, there are no financing costs associated with the proposed project. If approved, the new MRI scanner will be operational within six months of COPN issuance.

**Table 2. COPN Request No. VA-8627 Projected Capital Costs**

Equipment Not Included in Construction Contract	\$467,190
<b>Total Capital Costs</b>	<b>\$467,190</b>

Source: COPN Request No. VA-8630

### **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...” A medical care facility includes “[a]ny facility licensed as a hospital, as defined in Section 32.1 – 123.” UVAMC is specifically exempted from the requirement to be licensed by Va Code § 32.1-124.

### **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;**

**COPN Request Nos. VA-8630**  
**DCOPN Staff Report**

**July 19, 2022**  
**Page 3 of 13**

The applicant proposes to add one MRI unit for diagnostic imaging at UVAMC in order to meet a unique medical need. Approval of a fifth MRI scanner will allow the provision of MRI services without requiring patients and providers to wait lengthy time periods for scheduling, diagnosis and treatment. Specifically, approval of the Hyperfine portable scanner would facilitate the diagnosis and treatment of strokes, brain tumors, and post-operative neurological complications, without the need to tie up one of UVAMC's existing fixed scanners.

Geographically, UVAMC is readily accessible from I-64, US-29 and US-250. Additionally, public transportation is readily available via a Charlottesville Transit Service and Jefferson Area United Transit, Inc. Finally, the applicant states that there is ample public parking at UVAMC in hospital owned parking garages.

The most recent Weldon-Cooper data projects a total PD 10 population of 287,829 residents by 2030 (**Table 3**). This represents an approximate 22.6% increase in total population from 2010 to 2030. Comparatively, Weldon-Cooper projects the total population of Virginia to increase by approximately 16.6% for the same period. With regard to the City of Charlottesville specifically, Weldon-Cooper projects a total population increase of approximately 20.5% from 2010 to 2030. With regard to the 65 and older age cohort, Weldon-Cooper projects a much more rapid increase among PD 10 as a whole than for the City of Charlottesville. Specifically, Weldon-Cooper projects an increase of approximately 90% in residents age 65 and over for PD 10 as a whole from 2010 to 2030, while an increase of only 57% is projected among the same age cohort for the City of Charlottesville (**Table 4**).

DCOPN did not identify any additional geographic, socioeconomic, cultural, transportation, and other barriers to access to care.

**Table 3. PD 10 and Statewide Total Population Projections, 2010-2030**

Locality	2010	2020	% Change	2030	% Change	2010-2030 % Change
Albemarle	98,970	111,039	12.2%	125,718	13.2%	27%
Charlottesville City	43,475	50,714	16.7%	52,376	3.3%	20.5%
Fluvanna	25,691	26,965	5.0%	30,258	12.2%	17.8%
Greene	18,403	20,348	10.6%	22,669	11.4%	23.2%
Louisa	33,153	36,737	10.8%	41,959	14.2%	26.6%
Nelson	15,020	14,828	-1.3%	14,850	0.1%	-1.1%
<b>Total PD 10</b>	<b>234,712</b>	<b>260,631</b>	<b>11.0%</b>	<b>287,829</b>	<b>10.4%</b>	<b>22.6%</b>
Virginia	8,001,024	8,655,021	8.2%	9,331,666	7.8%	16.6%

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

**Table 4. PD 10 Population Projections for 65+ Age Cohort, 2010-2030**

Locality	2010	2020	% Change	2030	% Change	2010-2030 % Change
Albemarle	14,124	21,417	51.6%	27,028	26.2%	91.4%
Charlottesville City	4,017	4,711	17.3%	6,306	33.9%	57%
Fluvanna	4,022	5,799	44.2%	7,366	27%	83.1%
Greene	2,345	3,836	63.6%	5,442	41.9%	132.1%
Louisa	4,796	7,826	63.2%	10,691	36.6%	122.9%
Nelson	2,988	4,124	38%	4,525	9.7%	51.4%

**COPN Request Nos. VA-8630**  
**DCOPN Staff Report**

**July 19, 2022**  
**Page 4 of 13**

<b>Total PD 10</b>	<b>32,292</b>	<b>47,712</b>	<b>47.8%</b>	<b>61,357</b>	<b>28.6%</b>	<b>90%</b>
Virginia	976,937	1,352,448	38.4%	1,723,382	27.4%	76.4%

**Source:** U.S. Census, Weldon Cooper Center Projections (August 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 2020, the most recent year for which such data is available, the average amount of charity care provided by HPR I facilities was 2.1% (**Table 5**).

**Table 5. 2020 HPR I Charity Care Contributions**

<b>Health Planning Region I</b>			
<b>2020 Charity Care Contributions at or below 200% of Federal Poverty Level</b>			
<b>Hospital</b>	<b>Gross Patient Revenues</b>	<b>Adjusted Charity Care Contribution</b>	<b>Percent of Gross Patient Revenue:</b>
Culpeper Regional Hospital	\$359,182,141	\$12,102,933	3.37%
University of Virginia Medical Center	\$5,962,089,202	\$186,745,010	3.13%
UVA Transitional Care Hospital	\$66,296,097	\$2,047,513	3.09%
Sentara RMH Medical Center	\$918,098,298	\$22,656,844	2.47%
Carilion Stonewall Jackson Hospital	\$137,363,522	\$2,944,339	2.14%
Martha Jefferson Hospital	\$731,733,007	\$11,500,103	1.57%
Page Memorial Hospital	\$63,530,998	\$792,862	1.25%
Augusta Medical Center	\$1,059,370,204	\$12,042,914	1.14%
Shenandoah Memorial Hospital	\$121,946,999	\$1,321,088	1.08%
Warren Memorial Hospital	\$150,609,573	\$1,621,917	1.08%
Stafford Hospital Center	\$287,238,184	\$3,044,975	1.06%
Winchester Medical Center	\$1,433,802,000	\$14,305,992	1.00%
Spotsylvania Regional Medical Center	\$589,741,098	\$5,843,457	0.99%
Mary Washington Hospital	\$1,429,424,065	\$13,513,637	0.95%
Bath Community Hospital	\$23,228,689	\$145,250	0.63%
Fauquier Hospital	\$412,365,921	\$1,528,892	0.37%
Total Facilities			16
<b>Total \$ &amp; Mean %</b>	<b>\$13,386,837,857</b>	<b>\$280,054,793</b>	<b>2.1%</b>

**Source:** VHI (2020)

Geographically, UVAMC is located 2.5 miles from the U.S. 29 and U.S. 250 bypass and approximately 3 miles east of the I-64 exit on U.S. 29. Additionally, public transport is readily available by a public bus stop located across the street from the emergency department. DCOPN is not aware of any geographic, socioeconomic, cultural, or transportation barriers to access to care.

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

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

The applicant provided several letters of support for the proposed project from current UVA Health employees. Collectively, these letters articulated the unique benefits of the Hyperfine

MRI unit, particularly as it relates to the highly complex cases UVAMC sees as an academic hospital.

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

#### Public Hearing

DCOPN provided notice to the public regarding this project on May 10, 2022. The public comment period closed on June 24, 2022. 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 Virginia State Health Commissioner, the applicant, or a member of the public. The proposed project is not competing, and no public hearing was requested by the applicant, the Commissioner, an interested party, or member of the public. As such, no public hearing was held.

**(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;**

Maintaining the status quo is a reasonable alternative. Currently, based on 2021 data provided by the applicant, UVAMC's four existing MRI scanners performed at an overall utilization rate of 70.8%, which is considerably short of the SMFP expansion threshold. Consequently, DCOPN finds that there is ample capacity within UVAMC's existing inventory, and no additional MRI scanners are needed.

However, given the applicant's arguments regarding the innovation in technology presented by the Hyperfine MRI unit, in addition to its portability and low cost, the DCOPN posits that one possible alternative to the proposed project would be for UVAMC to simply replace one of its existing hospital-based fixed MRI scanners with the Hyperfine unit. This alternative would be more beneficial than both the status quo, and the proposed project, for several reasons:

- (1) Replacement of an existing unit would not exacerbate the current surplus of fixed MRI units in PD 10.
- (2) Based on data provided by the applicant, even with the replacement of one of the existing MRI units with the Hyperfine unit, UVAMC would still have ample capacity to meet its current and future need. For example, based on 2021 data provided by the applicant, along with the applicant's assertion that the Hyperfine unit would perform 1,200 scans in Year 1, the remaining three fixed MRI scanners would perform approximately 12,875 scans, which amounts to a utilization rate of 85.8% for the three remaining fixed scanners, which would still be short of the SMFP threshold for expansion, and leave sufficient capacity within UVAMC's inventory to accommodate future demand. UVAMC makes the claim that demand for MRI usage will continue to rise in the near future, as neurological cases affecting the head and brain continue to increase. However, as discussed above, even with the replacement of one of the four existing fixed site units

with the Hyperfine unit, the three traditional fixed MRI units would still operate well below peak utilization. Moreover, if the applicant's assertion is correct, that head and brain cases will continue to rise, then the applicant would be well-positioned to demonstrate the efficacy and utility of the Hyperfine, as the sole provider in the Commonwealth. However, as the data demonstrates, currently, there is no need for added capacity as it pertains to fixed site MRI units in PD 10.

- (3) Moreover, it is arguable that the reduction in existing fixed units would likely encourage more utilization of the Hyperfine unit, which, as highlighted by the applicant, has the added benefits of portability, comfortability, as well as reduced costs for patients.

It is also notable that, among the four UVA Health System outpatient facilities in PD 10 that are providing MRI services, there are currently eight authorized MRI scanners – three of which were not in service in 2020, or did not report utilization data. Based on 2020 data, the five functioning fixed MRI scanners performed at a collective utilization rate of 77.8%, demonstrating that UVA Health System has additional outpatient capacity within the health system should it need to offload cases to decompress demand at UVAMC. For these reasons, DCOPN concludes that there are reasonable alternatives to the proposed project that would meet the needs of the population in a less costly, more efficient, or more effective manner.

**Table 6. UVA Health System MRI Utilization 2020**

Facility	Number of MRI Scanners	Number of MRI Scans	Utilization Rate
UVA Imaging - Transitional Care Hospital (Northridge)	2	8,314	83.1%
UVA Imaging Center Fontaine (MOB 1)	3	11,149	74.3%
<b>TOTAL and Average</b>	<b>5</b>	<b>19,463</b>	<b>77.8%</b>

Source: VHI (2020)

Note:

\*COPN VA-04745 authorized the establishment of a diagnostic imaging center with two MRI and one CT by UVA Imaging. Not yet operational.

\*\*COPN VA-04370 authorized the establishment of a diagnostic imaging center with one MRI and one CT by University of Virginia Imaging, LLC. Not included in 2020 VHI data.

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

Currently there is no organization in HPR I designated by the Virginia Department of Health to serve as the Health Planning Agency for HPR I. 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 \$467,190. 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

**COPN Request Nos. VA-8630**  
**DCOPN Staff Report**

**July 19, 2022**  
**Page 7 of 13**

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:

- Approval of a fifth MRI scanner will allow the provision of MRI services without requiring patients and providers to wait lengthy time periods for scheduling, diagnosis and treatment.
- Additionally, UVAMC argues that, as a teaching hospital, it has a particular responsibility to introduce new technology that will safely advance patient care throughout the commonwealth.
- The portability of the new MRI unit would allow it to be wheeled into the emergency room or ICU, and placed right alongside a patient's bed, without jeopardizing breathing tube or IV connections during transport.
- The 0.064T is very affordable, and does not require shielding, cooling, or screening for ferromagnetic objects normally necessary with higher field-strength MRIs.
- In addition to the significant clinical value, the Hyperfine MRI will also have important research and teaching implications.

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

DCOPN notes that, according to VHI data from 2020, the most recent year for which such data is available, the average amount of charity care provided by HPR I facilities was 2.1% 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 2.1% HPR I average.

**Table 7. COPN Request No. VA-8630 Pro Forma Income Statement**

	<b>Year 1</b>	<b>Year 2</b>
<b>Gross Patient Revenue</b>	<b>\$8,842,210</b>	<b>\$9,019,054</b>
Contractual Allowances and Provision for Bad Debts	(\$6,973,519)	(\$7,112,989)
Charity Allowances	(\$61,613)	(\$62,846)
<b>Net Revenue</b>	<b>\$1,807,078</b>	<b>\$1,843,219</b>
Total Expenses	(\$1,393,469)	(\$1,459,223)
<b>Net Operating Income</b>	<b>(\$413,609)</b>	<b>(\$383,996)</b>

Source: COPN Request No. VA-8630



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

DCOPN notes that, while there are alternatives that are more advantageous than the proposed project, there are unique benefits associated with implementation of the Hyperfine unit, namely, its portability and utility in an ER setting. For example, because of its lower strength magnet, the Hyperfine unit does not require shielding or cooling, making it very efficient in an emergency setting. Moreover, the Hyperfine unit's size and portability make it ideal for rapid deployment on patients presenting symptoms of possible stroke.

### **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:

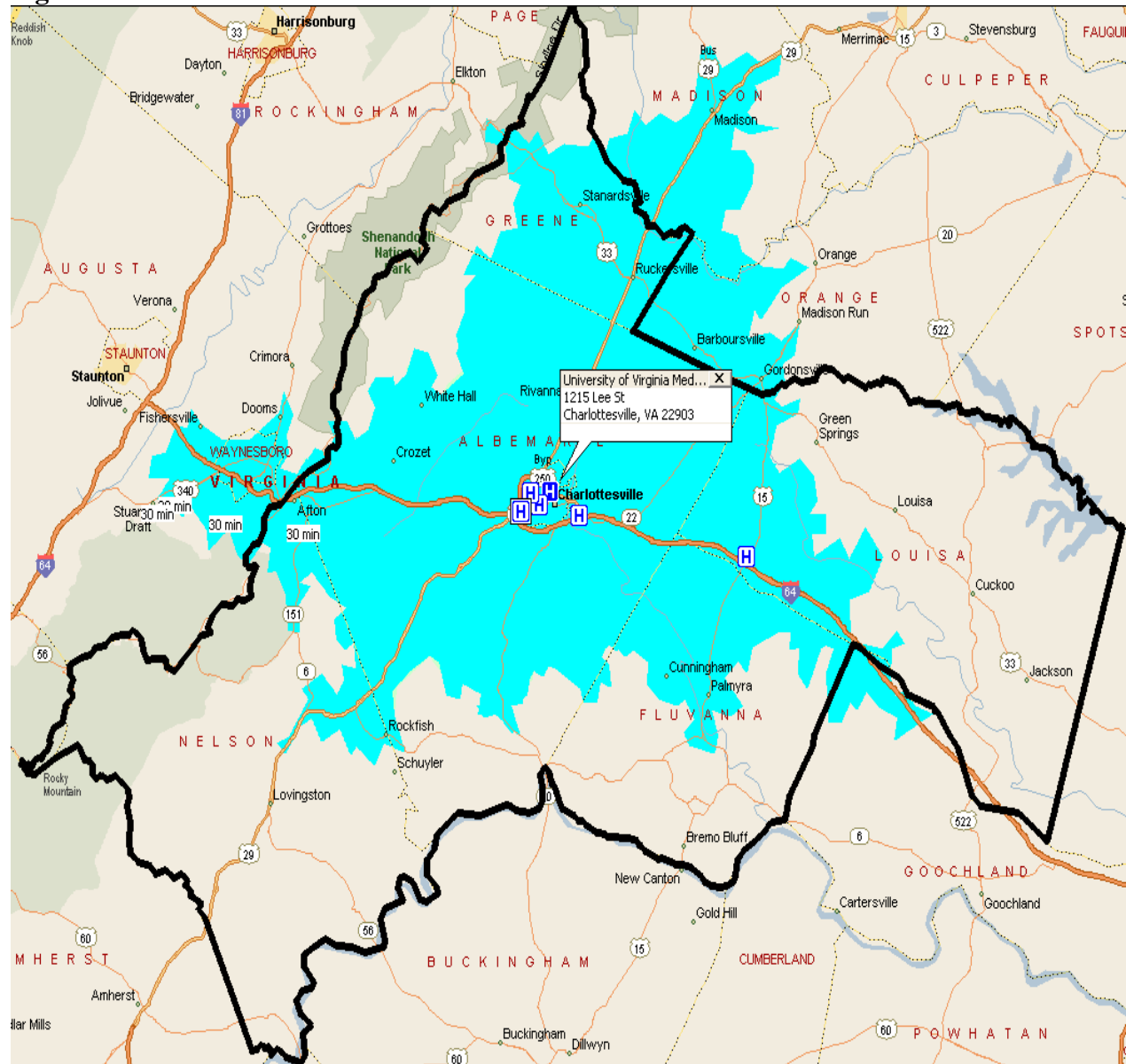
## **Part II Diagnostic Imaging Services**

### **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.**

The heavy black line in **Figure 1** is the boundary of PD 10. The white "H" symbols mark the locations of existing MRI providers in PD 10. The blue "H" symbol marks the location of UVAMC. The blue shaded area includes all locations that are within 30 minutes driving time one-way under normal conditions of MRI services in PD 10. 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.

**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.

**COPN Request Nos. VA-8630**  
**DCOPN Staff Report**

**July 19, 2022**  
**Page 10 of 13**

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, in 2020, the existing PD 10 fixed MRI inventory performed a collective MRI volume of 41,144 MRI procedures in 2020. Based on this data, DCOPN has calculated a current surplus of six fixed MRI scanners in PD 10 as follows:

2022 COPN authorized fixed MRI units = 15

Needed MRI units = 41,144 (2020 MRI procedures) ÷ 5,000 = 8.22 (9)

**Fixed MRI unit surplus = 6**

**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.**

As noted in **Table 8** below, for 2020, the most recent year for which VHI data is available, UVAMC's four MRI units performed 13,254 MRI procedures with a utilization rate of 66.3%, well below the SMFP expansion standard of 5,000 procedures per scanner per year. However, based on data provided by the applicant, in 2021, UVAMC's four MRI scanners performed 14,075 scans, at a utilization rate of 70.8%, which still falls considerably short of the SMFP standard (**Table 9**).

**Table 8. PD 10 COPN Authorized Fixed MRI Units and Utilization: 2020**

<b>Facility</b>	<b>Number of MRI Scanners</b>	<b>Number of MRI Scans</b>	<b>Utilization Rate</b>
Sentara Martha Jefferson Hospital	2	8,427	84.3%
University of Virginia Medical Center	4	13,254	66.3%
UVA Imaging - Transitional Care Hospital (Northridge)	2	8,314	83.1%
UVA Imaging Center Fontaine (MOB 1)	3	11,149	74.3%
<b>TOTAL and Average</b>	<b>11</b>	<b>41,144</b>	<b>74.8%</b>

Source: VHI Data (2020)

**Table 9. UVAMC COPN Authorized Fixed MRI Units and Utilization: 2021**

<b>Facility</b>	<b>Number of MRI Scanners</b>	<b>Number of MRI Scans</b>	<b>Utilization Rate</b>
University of Virginia Medical Center	4	14,075	70.8%

Source: COPN Request No. VA-8630

**12VAC5-230-170. 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.

**12VAC5-230-180. Staffing.**

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

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, the addition of a fixed MRI scanner will require minimal additional staff. Given current staffing levels, and UVAMC's existing recruiting strategies and resources, there is no impact anticipated for the staffing at UVAMC, or other area providers.

**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;**

As an existing MRI service provider, and the most-heavily utilized MRI provider in PD 10, it is unlikely that the proposed project would foster institutional competition that benefits the area to be served. It will, to the contrary, further solidify UVAMC's dominance in the PD 10 MRI market.

- 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;**

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 introduce a technological innovation in the field of diagnostic imaging, as well as lessening the wait times for patients already seeking care from UVAMC.

- 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 previously discussed, the projected capital costs of the proposed project are \$467,190. 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.

- 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**

One of the main benefits of the proposed project is that would offer the introduction of new technology that promotes quality and cost effectiveness in the delivery of health care services. Outside of these improvements, DCOPN finds approval of the proposed project would only marginally improve access to essential health care services for people in PD 10. DCOPN did not identify any other relevant factors to bring to the Commissioner's attention.

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

UVAMC is a state owned academic medical center. UVAMC asserts that they have a tripartite mission to provide research, training, and clinical care to benefit the citizens of the Commonwealth. The applicant additionally asserts that approval of the project inherently enhance their ability to carry out their clinical mission. Moreover, UVAMC asserts that their research and teaching missions will be aided and enhanced. Finally, the applicant states that innovations in inpatient services are intended to reach indigent and underserved populations and that the research, training, and clinical care at UVAMC will undoubtedly lead to innovation in the provision of healthcare for all citizens of the Commonwealth.

### **DCOPN Staff Findings and Conclusion**

DCOPN finds that the proposed project to expand UVAMC's existing MRI services through the addition of one fixed MRI is not 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 discussed, based on the current inventory of authorized MRI scanners in PD 10, there is an existing surplus of six MRI scanners.

Moreover, there are reasonable alternatives that are as advantageous, or more advantageous, than the proposed project. Namely, UVAMC could simply replace one of its existing fixed MRI

**COPN Request Nos. VA-8630**  
**DCOPN Staff Report****July 19, 2022**  
**Page 13 of 13**

scanners with the Hyperfine unit. This alternative would be more beneficial than both the status quo, and the proposed project, for several reasons:

- (1) Replacement of an existing unit would not exacerbate the current surplus of fixed MRI units in PD 10.
- (2) Based on data provided by the applicant, even with the replacement of one of the existing MRI units with the Hyperfine unit, UVAMC would still have ample capacity to meet its current and future need. For example, based on 2021 data provided by the applicant, along with the applicant's assertion that the Hyperfine unit would perform 1,200 scans in Year 1, the remaining three fixed MRI scanners would perform approximately 12,875 scans, which amounts to a utilization rate of 85.8% for the three remaining fixed scans, which would still be well short of the SMFP threshold for expansion.
- (3) Moreover, it is arguable that the reduction in existing fixed units would likely encourage more utilization of the Hyperfine unit, which, as highlighted by the applicant, has the added benefits of portability, comfortability, as well as reduced costs for patients.

It is also notable that, among the four UVA Health System outpatient facilities in PD 10 that are providing MRI services, there are currently eight authorized MRI scanners. Based on 2020 data, the five functioning fixed MRI scanners performed at a collective utilization rate of 77.8%, demonstrating that UVA Health System has additional capacity within the health system should it need to offload cases to decompress demand at UVAMC. For these reasons, DCOPN concludes that there are reasonable alternatives to the proposed project that would meet the needs of the population in a less costly, more efficient, or more effective manner.

**DCOPN Staff Recommendation**

The Division of Certificate of Public Need recommends **denial** of the University of Virginia Medical Center's request to expand its existing MRI services through the addition of one fixed MRI unit, for the following reasons:

1. The project is not 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. There is an existing surplus of fixed MRI scanners in PD 10.
3. There are reasonable alternatives that are as advantageous, or more advantageous, than the proposed project.