



COMMONWEALTH of VIRGINIA

Department of Health

M. NORMAN OLIVER, MD, MA
STATE HEALTH COMMISSIONER

PO BOX 2448
RICHMOND, VA 23218

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

April 20, 2021

By Email

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

RE: Certificate of Public Need (COPN)
Number VA-04745 (Request Number VA-8530)
University of Virginia Imaging, LLC
City of Charlottesville, Planning District (PD) 10
Health Planning Region (HPR) I
Establishment of a Specialized Center for the
Provision of Computed Tomography (CT)
Services and Magnetic Resonance Imaging (MRI)
Services (with Relocation and New Inventory)

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 proposing the above-captioned project submitted by University of Virginia Imaging, LLC (the "UVAI project" or "project"). As required by Subsection B of Virginia Code § 32.1-102.3, I have considered all matters, listed therein, that must be taken into account in making a determination of public need under the COPN law.

I have reviewed and adopted the enclosed findings, conclusions and recommended decision of the adjudication officer who convened the informal fact-finding conference to discuss the UVAI project, and who reviewed the entire administrative record pertaining to the project.


Based on my review of the UVAI project and on the recommended decision of the adjudication officer, I am approving the project with a condition requiring an appropriate level of charity care. The project merits approval and will receive a Certificate. It is necessary to meet a public need.

Erin Whaley, Esq.
April 20, 2021
Page 2 of 2

The reasons for my decision include the following:

- (i) The UVAI project is consistent with the State Medical Facilities Plan (SMFP), 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) In light of the limited throughput, stemming from longer scanning times, that prevails with complex diagnostic cases, UVAI has demonstrated a unique, academic-based institutional need for the project, including the incremental MRI component, that diverges from typical instances of institutional need involving levels of prevailing utilization directly complying with the SMFP threshold, consistent with the applicable provision of the SMFP;
- (iii) Approval of the project, as proposed to meet a unique, academic-based institutional need, would not pose an adverse effect on any existing provider of CT or MRI services; and
- (iv) Following adjudication, a viable alternative to inclusion of the MRI component in the UVAI project does not exist.

Sincerely,

DocuSigned by:

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M. Norman Oliver, MD, MA
State Health Commissioner

Encl.

cc (via email):
Denise Bonds, MD, MPH
Director, Blue Ridge Health District
Vanessa MacLeod, Esq.
Assistant Attorney General
Erik O. Bodin, III
Director, Division of Certificate of Public Need
Douglas R. Harris, JD
Adjudication Officer

**Recommendation
to the State Health Commissioner
on Certificate of Public Need (COPN)
Request Number VA-8530
University of Virginia Imaging, LLC
City of Charlottesville, Planning District (PD) 10
Health Planning Region (HPR) I
Establishment of a Specialized Center for the
Provision of Computed Tomography (CT)
Services and Magnetic Resonance Imaging (MRI)
Services (with Relocation and New Inventory)**

Introduction and Authority

This recommended case decision is submitted to the State Health Commissioner (“Commissioner”) for his consideration and adoption. It follows review of the administrative record relating to the proposed project captioned above and an informal fact-finding conference (IFFC)¹ conducted in accordance with the Virginia Administrative Process Act (APA).²

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.”³ The endeavor proposed in the pending application, captioned above, falls within the statutory definition of “project” contained in the COPN law, and, thereby, requires a certificate of public need (COPN, or “certificate”).⁴

Factual and Procedural Background

1. University of Virginia Imaging, LLC (UVAI), is a Virginia limited liability company. Eighty percent of UVAI is owned by the Rectors and Visitors of the University of Virginia (UVA), and 20 percent is owned by OIA of Virginia, LLC, a subsidiary of Outpatient Imaging Affiliates, LLC (OIA), headquartered in Nashville, Tennessee. OIA develops, owns and manages outpatient imaging centers in partnership with local healthcare providers.

¹ The IFFC was convened and conducted virtually on February 4, 2021. A certified transcript of the IFFC is in the record.

² Va. Code § 2.2-4000 *et seq.*

³ Va. Code § 32.1-102.1:2 (A).

⁴ Va. Code § 32.1-102.1.

Adjudication Officer's
Recommendation
Page 2 of 9

2. UVA is a nationally-recognized public university. UVA operates a highly-ranked academic medical school, a teaching hospital that administers a comprehensive array of training programs and conducts various complex research initiatives, and a tertiary-quaternary health system that provides a vast array of medical and health care services, including numerous specialty and subspecialty services, to residents of the Commonwealth.

3. UVAI proposes to establish a specialized center, *i.e.*, a freestanding diagnostic imaging facility, for providing CT and MRI services deploying one CT scanner and two MRI scanners in the City of Charlottesville, PD 10 (the "UVAI project" or "project"). The project would include one incremental, specialty CT scanner (*i.e.*, one weight-bearing/extremity scanner that would be new to the PD 10 inventory) and two MRI scanners (a 1.5 Tesla unit and a 3.0 Tesla unit). One of the MRI scanners sought would be relocated from an existing site operated by UVAI in Charlottesville (and replaced through registration), and the other MRI scanner would be incremental, or new to the PD 10 inventory. Total capital costs of the project are \$5,821,660, to be defrayed by securing a seven-year conventional mortgage.

4. As proposed, the UVAI project would constitute an integral component of the UVA Orthopaedic Center at Ivy Mountain, provide scanning in concert with the treatment of orthopedic and non-orthopedic maladies and injuries, and promote various academic, tertiary-quaternary clinical and research-based operations at UVA. UVAI's plans for a complex at Ivy Mountain include additional outpatient services, such as physical therapy services, and business operations.

5. UVAI promotes the project, most prominently, as one that would meet a unique community and institutional need, *i.e.*, in this case, a need of an established corporate entity directly affiliated with and majority-owned by a teaching hospital associated with a public, academic, tertiary-quaternary medical center and health system that conducts medical research and serves an extended regional area and the Commonwealth at large with exacting and advanced diagnostic imaging capabilities in concert with the treatment of severe, complex and high-acuity cases.

6. UVAI represents that the sophisticated nature of its diagnostic operations requires average scanning times that are 66 percent longer than those presumed by drafters of the need analysis for MRI scanning contained in the State Medical Facilities Plan (SMFP),⁵ thereby precluding achievement of this regulatory throughput level by its existing scanners. UVAI states that a two-to-three week backlog, or wait time, prevails among its seven MRI scanners, allocated across three facilities. It argues that its existing scanners are at the limits of functional capacity due to the prolonged scanning time required for scanning in each patient's case.⁶

Summary and Incorporation of the DCOPN Staff Report

In a staff report dated January 19, 2021, prepared by the Virginia Department of Health, Division of Certificate of Public Need (DCOPN, or "division") on the UVAI project, that division recommended that the Commissioner give partial, conditional approval for the project,

⁵ IFFC Transcript at 13.

⁶ UVAI Proposed Findings and Conclusions at 11.

Adjudication Officer's
Recommendation
Page 3 of 9

finding public need for establishing the proposed center with the incremental CT scanner sought and the relocation of one MRI scanner, as sought, but not finding public need for the incremental MRI scanner sought.

More specifically, in relation to the UVAI project, DCOPN recommended in this report (the "DCOPN staff report") that the Commissioner:

- (i) Conditionally approve the establishment of a specialized center for CT and MRI services, with one specialty CT scanner, *i.e.*, a weight-bearing/extremity CT scanner, and one relocated (and replaced) MRI scanner because:
 - (a) These components of the proposed project are generally consistent with the SMFP and the COPN law;
 - (b) The capital costs of the project are reasonable;
 - (c) The project appears economically viable;
 - (d) No opposition to these components of the project is known to exist;
 - (e) The project is not likely to have a negative impact on existing providers of CT and MRI services in PD 10; and
- (ii) Deny the addition of one MRI scanner to the PD 10 inventory, *i.e.*, an incremental MRI scanner, because:
 - (a) This component of the proposed project is inconsistent with the SMFP and the COPN law;
 - (b) UVAI has not demonstrated a public need, including an institutional need, to add an incremental MRI scanner;
 - (c) A calculated surplus of MRI scanners exists in PD 10;
 - (d) This component of the project would have a significant negative impact on existing providers of MRI services in PD 10; and
 - (e) Reasonable alternatives to this component of the project exist.

By reference, the DCOPN staff report is incorporated into the present recommended decision for the purpose of establishing and corroborating facts and demonstrating analysis that, despite the recommended decision made herein diverging from the recommendation of DCOPN, together support and help constitute the evidentiary basis on which this recommended decision rests.

Adjudication Officer's
Recommendation
Page 4 of 9

Analysis and Conclusions Relating to the Proposed Project

Salient analysis and conclusions regarding the UVAI project and relating directly to the eight considerations of public need contained in the COPN law (the “statutory considerations”),⁷ appearing in bold type, are set forth below in relation to each statutory consideration. (The DCOPN staff report, incorporated herein, contains additional analysis and conclusions.)

In due recognition of and agreement with the DCOPN recommendation of partial approval of the UVAI project, *i.e.*, the division’s recommendation of (i) approval of the establishment of a specialized diagnostic center, (ii) approval of the new, or incremental, CT scanner to be located in that center, and (iii) approval of the MRI proposed for relocation to the center, the discussion herein will pertain mainly to the issue whether the remaining component of the proposed project, *i.e.*, the proposed addition of an incremental MRI scanner to be included at the center, should be included in an approval.

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 UVAI project, in its entirety, proposed for situating in a facility located at Ivy Mountain in Charlottesville, would be conveniently located on U.S. Route 250 (Business) at that route’s intersection of U.S. Route 29, and adjacent to Interstate 64 – all major thoroughfares serving the area. The site would be served by public transportation, connecting it to the core of the UVA academic medical resources and services, and other locations in the surrounding area. The project would collocate advanced diagnostic services with a range of orthopedic and musculoskeletal services offered by UVA, maximizing operational efficiencies and integrating varied services.

The incremental addition of an MRI, as proposed, would increase access to MRI services and expertise by combining, centralizing and coordinating sophisticated diagnostic services for patients who have limited access to such services elsewhere in PD 10, due to the uniqueness of their complex needs and the lack of additional functional service capacity at UVAI’s two existing facilities.

Due to UVAI’s existing MRI resources currently operating at the limits of their functional capacity, backlogs and long wait times exist for MRI services and appointments at UVAI. In this way, barriers to prompt, advanced MRI scanning, provided by an entity majority-owned by an academic medical center, exist for UVA’s and UVAI’s high-acuity, complex patients, many of whom originate beyond PD 10.

Additionally, in PD 10, Nelson County and the City of Charlottesville both have poverty levels exceeding ten percent of the population – the statewide average among localities. UVAI represents that recent charity care data indicate it currently provides a level of charity care approximating nine percent of its gross patient revenue, exceeding even the level provided by

⁷ See Subsection B of Virginia Code § 32.1-102.3.

Adjudication Officer's
Recommendation
Page 5 of 9

UVA, as a whole, which provided an amount of such care equivalent to 5.88 percent of patient revenues in 2018 – the highest level of any acute care facility in PD 10.

Approval of the incremental MRI component, indeed, approval of the remainder of the proposed project, would position UVA and UVAI to continue providing a considerable amount of charity care and access to advanced diagnostic expertise, and thereby, addressing prevailing socioeconomic barriers to care. The incremental MRI component of the UVAI project would increase access to advanced diagnostic imaging for residents of PD 10 in an appropriate and necessary manner.

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 that is required to be submitted to the Commissioner pursuant to subsection B of § 32.1-102.6; (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.

In advancing its project, UVAI has provided numerous letters of support, which are summarized in the DCOPN staff report. Sentara Martha Jefferson Hospital (SMJH) submitted a letter expressing concern over the addition of one component of the project – an incremental MRI scanner – while voicing no opposition to the remainder of the proposed project. SMJH states that PD 10 has a surplus of general-purpose MRI scanners, which would be exacerbated by approval of the incremental MRI scanner, and that approval of the incremental MRI component would be premature. SMJH's letter, along with UVAI's response, is comprehensively summarized in the DCOPN staff report.⁸ Since the intended deployment and role of the incremental MRI scanner would directly address a unique institutional need and is in concert with the overall academic, tertiary-quaternary purpose of UVA and UVAI, unlike the typical deployment of a general-purpose MRI scanner, SMJH's assertions appear to be of limited concern.

Regarding alternatives, DCOPN suggests that the UVAI project is premature, and that UVAI should wait and reapply for a certificate authorizing an incremental MRI scanner when utilization data for the MRI scanner proposed for relocation is available and able to show a compelling need for additional resourcing. DCOPN notes that no MRI scanner in PD 10 has met the 5,000-annual scan threshold for adding an MRI scanner to a PD-wide inventory. DCOPN also suggests consideration of the relocation of a separate MRI scanner from among the seven operated by UVAI at two existing sites.

⁸ See DCOPN Staff Report at 8-12.

Adjudication Officer's
Recommendation
Page 6 of 9

I do not believe additional delay is necessary to recognize the unique institutional need of a tertiary-quaternary, academic health care system for the proposed additional MRI. Prevailing utilization of unrelated facilities in PD 10 is of limited relevance to the availability of the advanced nature of scanning associated with the UVAI project, and UVAI's operating scanners do not appear available for relocation; UVAI represents that UVA has experienced a 25 percent increase in outpatient visits, alone, since 2015.⁹

DCOPN concludes that the costs of the project, as proposed to include a new CT scanner, a relocated MRI scanner *and* a new MRI scanner (the project component in contention), are reasonable and in line with previously-approved projects similar in clinical scope. The benefits posed by the project revolve mainly around appropriately resourcing, coordinating and collocating services, and strategically situating a set of advanced diagnostic resources to serve a regional, academic, tertiary-quaternary health system.

Regarding financial accessibility, UVA and UVAI provide an exemplary level of charity care and are committed to continued assistance for patients with limited financial resources. UVA serves as a safety-net provider of health care services for the region. UVAI is willing to agree to the issuance of certificate with a routinely-devised charity care condition.

3. The extent to which the proposed project is consistent with the State Health Services Plan [i.e., the SMFP].¹⁰

The COPN law requires that “[a]ny decision to issue . . . a [COPN] shall be consistent with the most recent applicable provisions of the [SMFP]”¹¹ The SMFP, contained in the Virginia Administrative Code (VAC), includes several provisions applicable to a project proposing the establishment of specialized center for providing CT and MRI services and proposing the addition of incremental CT and MRI scanners.¹²

DCOPN contends the components of the UVAI project that propose the establishment of a specialized center for diagnostic services, the addition of an incremental CT scanner to the PD 10 inventory and the relocation of an MRI scanner warrant approval. I agree.

Zeroing in on the remaining issue whether an additional, incremental MRI scanner is warranted, a specific type of institutional need exists in this case. The conditions and requirements of providing advanced, exacting MRI imaging for a large, regional, academic, tertiary-quaternary health system are unique. The inability of an MRI scanner serving such a system to perform procedures rapidly enough to satisfy the SMFP utilization threshold is apparent. This would be true regardless of the prevailing surplus of MRI scanners in PD 10,

⁹ UVAI Proposed Findings and Conclusions at 3-4.

¹⁰ While Senate Bill 763 (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. The SMFP remains in effect as guidance in reviewing applications for a COPN.

¹¹ Va. Code § 32.1-102.3 (B).

¹² 12 Virginia Administrative Code (VAC) 5-230-90 *et seq.*, 12 VAC 5-230-140 *et seq.* For the sake of brevity, the SMFP provisions revealing the most salient features of the project are discussed in this document.

Adjudication Officer's
Recommendation
Page 7 of 9

which DCOPN calculates to total 5.1 scanners (within a combined inventory of 14 scanners), although UVAI argues that a “functional surplus” of only 2.1 scanners exists.¹³

UVAI marshals several points to justify a finding, based in the prevalence of a unique academic, teaching, tertiary-quaternary environment, of institutional need in conformance with the applicable SFMP provision.¹⁴ UVA's patients originate from across the Commonwealth, and beyond, often after conventional treatments have failed; many seek participation in clinical trials or to avail themselves of state-of-the-art technologies and treatments at UVA. Patients travel great distances to receive orthopedic and non-orthopedic care from physicians at UVA offering specialized expertise in treating complex diseases and disorders. Receiving scanning services on the same day as receiving clinical evaluations and consultations is a matter of particular convenience for traveling patients who have complex ailments needing detailed imaging that limits scanner throughput. Aging among Virginia's population will likely increase the need for specialty and subspecialty care. The additional MRI scanner sought would serve UVA's well-established, clinical, scientific and teaching environment, which is constantly evolving, making projection of demand for undiscovered applications of services based on historical demand difficult.¹⁵ A unique institutional need for the incremental MRI scanner exists, as well as a more general need for the other components of the UVAI project, as proposed.

Upon consideration of all salient matters, I conclude that sufficient data and information weigh in favor of and substantiate a determination that the UVAI project is consistent with the SMFP, or 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.¹⁶

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.

UVAI's justification for the incremental MRI scanner component of its project is based on a unique institutional need. Indeed, UVA provides a wide array of services that range beyond that of any nearby community hospital, including SMJH. Potential to foster institutional competition is not normally a matter to keep foremost in mind when reviewing a project arguably justified based on institutional need, as the justification for the project lies in addressing an organization's own operational exigencies rather than meeting a more general market demand or community-based need.

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.

In regard to the incremental MRI component of the UVAI project – the main matter in adjudication – the existing health care system in PD 10 has a surplus of MRI scanners; this surplus is a major component behind DCOPN's reasoning that this component of the project be

¹³ UVAI Proposed Findings and Conclusions at 7.

¹⁴ 12 VAC 5-230-80.

¹⁵ UVAI Proposed Findings and Conclusions at 9-10.

¹⁶ See *Roanoke Mem. Hosp. v. Kenley*, 3 Va. App. 599, 352 S.E.2d 525.

Adjudication Officer's
Recommendation
Page 8 of 9

denied. But an overall surplus is not primarily consequential when reviewing a project alleged to address an institutional need. Additionally, the MRI component of the project poses little potential to affect the utilization of MRI services in PD 10.

Approval of the incremental MRI is unlikely to result in the ill effects of over-resourcing PD-wide capacity because such action would be based on a unique academic-based institutional need. Rather, approval of the project would enhance the Commonwealth's armamentarium of health care resources and advanced academic, clinical and research-based operations ongoing and evolving at UVA.

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 UVAI project appears, and is likely, feasible. If successful, it would provide benefits to UVAI, the applicant, and UVA, by extension. As DCOPN suggests, the attendant construction costs of the project are reasonable.

Indeed, focusing only on costs relating to the project component in contention, UVAI estimates that the cost of building a second MRI suite during initial construction of the facility, *i.e.*, finishing off specific space necessary to house the incremental MRI scanner (and not including the cost of the scanner), is \$255,000. If such a suite is needed later, UVAI estimates its costs would be "at least \$500,000 – \$600,000," without knowing the effects of inflation.¹⁷ So, allowing inclusion of the incremental MRI component as part of the proposed project carries economy of scale and savings in construction costs.

Financial and human resources required to implement and operate the project are or appear readily available. The cost of capital, as that matter is conventionally understood under this statutory consideration, does not appear to be an issue.

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 UVAI project may provide improvements or innovations in the delivery of health care services by deploying advanced diagnostic technology in concert with the provision of sophisticated academic, specialty, clinical and research-based services that are continually evolving to address complex maladies, including orthopedic conditions.

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

¹⁷ UVAI Supplemental Exhibit, Cover Letter at 2.

Adjudication Officer's
Recommendation
Page 9 of 9

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.

UVAI contends that the research, training and clinical care that would occur in conjunction with the proposed services, including MRI scanning, would lead to innovation in the delivery and provision of healthcare, in furtherance of UVA's tripartite mission to provide medical research, academic training and clinical care to the benefit of citizens of the Commonwealth. I agree that the project, with the incremental MRI scanner component, offers promise in fulfilling this goal.

Conclusion and Recommendation

In relation to all eight statutory considerations and upon analytical review of the administrative record compiled in relation to the UVAI project, I conclude that the project merits approval. I recommend that the application for authorization to initiate the UVAI project, as proposed, be approved. UVAI should receive a certificate authorizing the project because it is necessary to meet a demonstrated public need.

- Specific reasons supporting this recommendation include:
- (i) The UVAI project is consistent with the SMFP, 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) In light of the limited throughput, stemming from longer scanning times, that prevails with complex diagnostic cases, UVAI has demonstrated a unique, academic-based institutional need for the project, including the incremental MRI component, that diverges from typical instances of institutional need involving levels of prevailing utilization directly complying with the SMFP threshold, consistent with the applicable provision of the SMFP;
 - (iii) Approval of the project, as proposed to meet a unique, academic-based institutional need, would not pose an adverse effect on any existing provider of CT or MRI services; and
 - (iv) Following adjudication, a viable alternative to inclusion of the MRI component in the UVAI project does not appear to exist.

Respectfully submitted,



April 15, 2021

Douglas R. Harris, JD
Adjudication Officer

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

THIS CERTIFIES THAT University of Virginia Imaging, LLC, is authorized to initiate the proposal as described herein.

NAME OF FACILITY: University of Virginia Imaging.

LOCATION: 2280 Ivy Road, Charlottesville, VA., Charlottesville, Virginia 22903.

OWNERSHIP AND CONTROL: The approved resources will be owned and operated by University of Virginia Imaging, LLC, members of which are the Rector and Visitors of the University of Virginia and OIA of Virginia, LLC.

SCOPE OF PROJECT: Establishment of a specialized center for the provision of computed tomography (CT) and magnetic resonance imaging services, consisting of the addition of one (1) CT scanner, the addition of one (1) MRI scanner and the relocation of one (1) MRI scanner, in accordance with specifications and representations made during the course of review. The total authorized capital cost of the project is \$5,821,660. The project is scheduled to be completed by May 1, 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-04745
Date of Issuance: April 20, 2021
Expiration Date: April 19, 2022

DocuSigned by:
M. Norman Oliver, MD
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M. Norman Oliver, MD, MA
State Health Commissioner

Condition Placed on the Issuance of this Certificate:

UVA Imaging, LLC shall provide MRI and CT services to all persons in need of this service, regardless of their ability to pay, and shall facilitate the development and operation of primary medical care services to medically underserved persons in Planning District (PD) 10 in an aggregate amount equal to at least **4.5% of UVA Imaging, LLC's gross patient revenue derived from MRI and CT services at UVA Orthopedic Center at Ivy Mountain.**

Compliance with this condition shall 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. UVA Imaging, LLC 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, Inc. The value of charity care provided to individuals pursuant to this condition shall be based on the provider reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.*

UVA Imaging, LLC shall provide MRI and CT services 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 UVA Imaging, LLC, shall facilitate the development and operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area.

VIRGINIA DEPARTMENT OF HEALTH

Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis

January 19, 2021

COPN Request No. VA-8530

UVA Imaging, LLC

Charlottesville, Virginia

Establish a Specialized Center for CT and MRI Services at the UVA Orthopedic Center at Ivy Mountain, Charlottesville, Virginia, PD 10 via Relocation and Replacement of an Existing MRI Currently Located at Fontaine Research Park and the Addition of One MRI and One CT to the PD 10 Inventory

Applicant

University of Virginia Imaging, LLC (“UVAI”) is a Virginia limited liability company established on March 26, 2002. The applicant is 100% owned by UVAI. The members are the Rector and Visitors of the University of Virginia (80% owner) and OIA of Virginia, LLC (20% owner). OIA of Virginia, LLC is a subsidiary of Outpatient Imaging Affiliates, LLC, a Nashville, Tennessee based healthcare company that develops, owns and manages outpatient imaging centers in partnership with local healthcare providers. The applicant has no subsidiaries. The proposed project would be located at the new UVA Orthopedic Center at Ivy Mountain (“Ivy Mountain”), located in Charlottesville within Planning District (“PD”) 10, Health Planning Region (“HPR”) I.

Background

Fontaine Research Park

In 2002, the UVA Health System formed UVAI and initiated imaging services in the Fontaine Research Park (“Fontaine”), located south and just outside of the City of Charlottesville. The goal of this effort was to provide a more positive alternative for patients requiring outpatient radiology services whose access to such services was compromised by inpatient radiology services demand and space limitations at the nearby University of Virginia Medical Center (“UVAMC”). Within the Fontaine Campus there are two imaging centers operated by UVAI, which are located immediately adjacent and contiguous to one another: 415 Ray C. Hunt Drive (“415 Facility”) and 545 Ray C. Hunt Drive (“545 Facility”). Today, UVAI operates three magnetic resonance imaging scanners (“MRIs”) and two computed tomography scanners (“CTs”) at the 415 Facility and one MRI at the 545 Facility. These two sites each address the imaging needs of the outpatients seeking care at the numerous UVA specialty clinics located at Fontaine.

COPN Request No. VA-8530
DCOPN Staff Report

January 19, 2021
Page 2 of 26

Computed Tomography (CT) Scanners and Utilization in PD 10

According to 2018 Virginia Health Information (VHI) data, the most recent year for which such data is available, there were 12 COPN authorized fixed-site CT scanners in PD 10 (**Table 1**). Eight of the scanners were located in acute care hospitals and operated at a collective utilization of 84.1%. Four of the scanners were located in freestanding facilities and operated at a collective utilization of 61.5%. The collective PD 10 fixed-site CT inventory (freestanding and hospital-based) operated at a collective utilization of 76.6% based on the State Medical Facilities Plan (“SMFP”) expansion threshold of 7,400 procedures per scanner per year. There were no mobile CT scanners in operation in PD 10 in 2018. DCOPN notes that as of the date of this report, four additional CT scanners (all fixed-site) have been added to the CT inventory, totaling 16 authorized CT scanners in the planning district.

Table 1. PD 10 Authorized CT Scanners and Utilization: 2018

Hospital Based Facility	Units	Procedures	Procedures/Unit	% Utilization
Sentara Martha Jefferson	3	23,311	11,656	157.5%
UVA Medical Center	9	26,478	4,413	59.6%
Hospital Based TOTAL and Average	12¹	49,789	6,224	84.1%
Freestanding Facility	Units	Procedures	Procedures/Unit	% Utilization
Martha Jefferson Health Services-Proffit	1	4,372	4,372	59.1%
UVA Imaging-Transitional Care Hospital	1	2,608	2,608	35.2%
UVA Imaging Center-Fontaine	2	11,219	5,610	75.8%
Freestanding TOTAL and Average	4	18,199	4,550	61.5%
GRAND TOTAL and Average	16²	67,988	5,666	76.6%

Source: VHI (2018) and DCOPN Records

Magnetic Resonance Imaging (MRI) Scanners and Utilization in PD 10

According to 2018 VHI data, the most recent year for which such data is available, and DCOPN records, there were 11 COPN authorized fixed-site MRI scanners in PD 10 (**Table 2**). Five of the scanners were located in acute care hospitals and operated at a collective utilization of 87.5%. Six of the scanners were located in freestanding facilities and operated at a collective utilization of 75.8%. The collective fixed-site MRI inventory operated at a cumulative utilization of 81.1% based on the SMFP expansion threshold of 5,000 procedures per scanner per year. There was one operational mobile MRI unit in PD 10 that operated at 72.6% utilization based on the SMFP mobile MRI expansion threshold of 2,400 scans per unit per year. DCOPN notes that subsequent to 2018, two additional fixed-site MRI scanners were added to the PD 10 inventory and the existing mobile site received authorization to convert to a fixed-site service. As of the date of this report, there are 14 authorized MRI scanners in the planning district.

¹ Reflects additions to PD 10 hospital-based CT inventory not included in 2018 VHI data. (COPN Nos. VA-04643, 4620, 4550 and 4551)

² Though not included in calculations for utilization, this number reflects additions to the total PD 10 CT inventory not included in 2018 VHI data. (COPN Nos. VA-04643, 4620, 4550 and 4551)

COPN Request No. VA-8530
DCOPN Staff Report

January 19, 2021
Page 3 of 26

The four MRI scanners at Fontaine, the facility from which the applicant proposes to transfer one of the requested MRIs, operated at a collective utilization of 71.2% in 2018. DCOPN has calculated that if the number of procedures performed at Fontaine in 2018 remains consistent, removal of one MRI scanner would result in utilization of approximately 94.9% at that facility. However, the applicant expects orthopaedic scans currently performed at Fontaine to shift to Ivy Mountain upon completion of the proposed project, and thus, utilization of the remaining Fontaine scanners will likely be lower than the previously stated 94.9%.

Table 2. PD 10 Authorized MRI Scanners and Utilization: 2018

Fixed MRI Units				
Hospital Based Facility	Units	Procedures	Procedures/Unit	% Utilization
Sentara Martha Jefferson	2	8,139	4,070	81.4%
UVA Medical Center	5	13,736	4,579	91.6%
Hospital Based TOTAL and Average	7³	21,875	4,375	87.5%
Freestanding Facility	Units	Procedures	Procedures/Unit	% Utilization
UVA Imaging-Transitional Care Hospital	2	8,502	4,251	85.0%
UVA Imaging Center-Fontaine	4 ⁴	14,242	3,561	71.2%
Freestanding TOTAL and Average	7⁵	22,744	3,791	75.8%
Fixed MRI GRAND TOTAL/Average	14⁶	44,619	4,056	81.1%
Mobile MRI Sites	Sites	Procedures	Procedures/Unit	% Utilization
Martha Jefferson Health Services-Profit	0 ⁷	1,743	1,743	72.6%

Source: VHI (2018) and DCOPN Records

Proposed Project

UVAI proposes to establish a specialized center for CT and MRI services at Ivy Mountain by relocating and simultaneously replacing one MRI scanner, currently located at Fontaine in the 545 Facility, and adding one new MRI and one new specialty CT scanner for orthopaedic patients. Building design for the Ivy Mountain facility includes an internal access road network, structured parking, loading and waste docks, a central utility plant, new sewer main lines, and a pumping station. The vacated space at the 545 Facility will be used in the short-term for expansion of

³ This number reflects changes and additions to the PD 10 hospital-based, fixed-site MRI inventory not included in 2018 VHI data. (COPN No. VA-04695)

⁴ VHI reports three MRIs at Fontaine, however this number is in error. DCOPN has confirmed with the applicant that to date, there are four authorized MRI scanners in operation at this facility. Occupancy calculations for this facility have been adjusted to reflect the correct number of authorized MRI scanners.

⁵ This number reflects changes and additions to the PD 10 freestanding, fixed-site MRI inventory not included in 2018 VHI data. (COPN No. VA-04637)

⁶ Though not included in calculations for occupancy, this number reflects all changes and additions to the PD 10 fixed-site MRI inventory that are not included in 2018 VHI data. (COPN Nos. VA-04695 and 04637)

⁷ Authorized for conversion to a fixed-site service. Accordingly, this scanner is reflected in the freestanding fixed-site inventory as well as the total fixed-site inventory. (COPN No. VA-04637)

COPN Request No. VA-8530
DCOPN Staff Report

January 19, 2021
Page 4 of 26

UVAMC's ambulatory clinical services. Long-term options for the space will be dependent on plans for the future expansion of Fontaine. When the relocation of the equipment is complete and the new equipment is operational, imaging services provided at the 545 Facility will cease. The 545 unit will then be decommissioned, removed from the location, and returned to Siemens. UVAI will continue to provide imaging services at Fontaine with three MRIs and two CTs at the 415 Facility. The applicant cites an institutional need for the additional MRI.

In addition to the outpatient imaging space that is the subject of this application, long-term plans for the Ivy Mountain facility include space for outpatient clinics, outpatient orthopaedic surgery, physical therapy and patient support. Non-clinical spaces for faculty offices, administration and training/education will also be included.

The applicant anticipates construction for the proposed project to begin March 15, 2021 and to be complete by July 15, 2021. The applicant anticipates a March 2022 date of opening. The projected capital costs for the proposed project total \$4,991,703, the entirety of which will be financed using a seven-year conventional mortgage loan (**Table 3**). The applicant anticipates capital and financing costs together to total approximately \$5,821,660.

Table 3. Projected Capital Costs

Direct Construction Costs	\$514,063
Equipment Not Included in Construction Contract	\$3,499,265
Site Acquisition Costs	\$817,866
Site Preparation Costs	\$92,848
Architectural and Engineering Fees	\$48,119
Other Consultant Fees	\$19,542
TOTAL Capital Cost	\$4,991,703
Dollar Amount of Long-Term Mortgage	\$4,991,703
Total Interest Cost on Long-Term Financing	\$829,957
TOTAL Capital and Financing Costs	\$5,821,660

Source: COPN Request No. VA-8530

The proposed project, if approved, would add one specialty fixed-site CT scanner and one fixed-site MRI scanner to the PD 10 inventory.

Project Definition

Section 32.1-102.1:3 of the Code of Virginia defines a project, in part, as the "Establishment of a medical care facility described in subsection A." A medical care facility is defined, in part, as "any specialized center...developed for the provision of...computed tomographic (CT) scanning, magnetic resonance imaging (MRI)..."

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 Ivy Mountain facility is conveniently located on Route 250, a well-traveled and accessible roadway. The facility is located at the intersection of Routes 29 and 250, which are two major thoroughfares in Charlottesville/Albemarle County. The site is adjacent to I-64 and is within two miles of UVA's Fontaine Research Park. Both JAUNT, an 85-vehicle public transportation fleet, and the UVA Bus system, which will connect to University Grounds, including the Medical Center Complex, will serve the site. As will be discussed in more detail later in this staff analysis report, DCOPN concludes that at least 95% of the population of PD 10 is within 30 minutes' drive time, one way, under normal driving conditions of existing CT and MRI services. Accordingly, DCOPN concludes that the proposed project is not likely to improve geographic access to CT or MRI services in any meaningful way.

Regarding socioeconomic barriers to access to services, the applicant has provided assurances that it would accept all patients in need of CT and MRI services without regard to ability to pay or payment source. Additionally, the Pro Forma Income Statement provided by the applicant projects a charity care contribution equal to 9% of gross patient services revenue (reflected in the "Deductions from Revenue" line)(**Table 4**). DCOPN notes that this amount is significantly higher than the 5.88% contributed by UVAMC in 2018 as well as the 4.5% HPR I average (**Table 5**). Furthermore, pursuant to the recent change to §32.1-102.4B of the Code of Virginia, DCOPN is now required to place a charity care condition on all applicants seeking a COPN. Accordingly, should the Commissioner approve the proposed project, DCOPN recommends a charity care condition consistent with the 4.5% HPR I average, to be derived from gross MRI and CT patient services revenue at Ivy Mountain. DCOPN notes that its recommendation includes a provision allowing for the reassessment of the charity rate when more reliable data becomes available regarding the full impact of Medicaid expansion in the Commonwealth.

Table 4. Ivy Mountain Pro Forma Income Statement

	Year 1	Year 2
Gross Patient Service Revenue	\$30,642,068	\$36,419,502
Deductions from Revenue	\$25,963,650	\$30,874,947
Net Patient Services Revenue	\$4,678,418	\$5,544,560
Total Expenses	\$2,049,152	\$2,702,346
Net Income	\$2,629,266	\$2,842,215

Source: COPN Request No. VA-8530

Table 5. HPR I Charity Care Contributions: 2018

Hospital	Gross Patient Revenues	Adjusted Charity Care Contribution	Percent of Gross Patient Revenue:
University of Virginia Medical Center	\$5,458,582,571	\$320,837,238	5.88%
Culpeper Regional Hospital	\$353,170,660	\$20,212,457	5.72%
Carilion Stonewall Jackson Hospital	\$111,421,225	\$6,377,158	5.72%
Sentara RMH Medical Center	\$936,446,646	\$49,668,275	5.30%
Augusta Medical Center	\$950,090,570	\$43,074,941	4.53%
Shenandoah Memorial Hospital	\$133,239,115	\$5,104,392	3.83%
Warren Memorial Hospital	\$144,458,311	\$5,453,245	3.77%
Martha Jefferson Hospital	\$680,999,557	\$24,602,596	3.61%
Page Memorial Hospital	\$61,523,920	\$2,121,843	3.45%
Spotsylvania Regional Medical Center	\$509,827,047	\$16,733,022	3.28%
Mary Washington Hospital	\$1,395,008,159	\$41,522,514	3.03%
Stafford Hospital Center	\$295,274,352	\$8,357,218	2.83%
Winchester Medical Center	\$1,489,750,189	\$37,306,401	2.50%
Fauquier Hospital	\$444,728,304	\$10,241,560	2.30%
Bath Community Hospital	\$22,027,611	\$471,192	2.14%
UVA Transitional Care Hospital	\$72,568,503	\$1,273,051	1.80%
Total Facilities			16
Median			3.5%
Total \$ & Mean %	\$12,986,548,237	\$592,084,052	4.5%

Source: VHI (2018)

Also with regard to socioeconomic barriers to access to services, DCOPN notes that, according to the most recent U.S. Census data, only two localities in PD 10, Nelson County and Charlottesville City, had poverty rates higher than the 10.7% statewide average (Table 6). Charlottesville City, where the proposed project will be located, is more than double that of the statewide average.

Table 6. Statewide and PD 10 Poverty Rates

Locality	Poverty Rate
Virginia	10.7%
Albemarle	6.7%
Fluvanna	7.3%
Greene	7.6%
Louisa	9.5%
Nelson	11.8%
Charlottesville City	24.1%

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

The most recent Weldon-Cooper data projects a total PD 10 population of 287,829 persons by 2030 (Table 7). This represents an approximate 22.6% increase in total population from 2010-2030. Comparatively, Weldon-Cooper projects the population of Virginia as a whole to increase by only 16.6% for the same period. With regard to Charlottesville specifically, Weldon-Cooper projects a total population increase of approximately 20.5% from 2010-2030. With regard to the 65 and older age cohort, Weldon-Cooper projects a much more rapid increase (Table 8). Specifically, Weldon-Cooper projects an increase of approximately 90% among PD 10's collective 65 and older age cohort, while an increase of approximately 57% is expected among

this cohort in Charlottesville. This is important as this age group uses medical care resources, including diagnostic imaging services, at a rate much higher than the rest of the population.

Table 7. Statewide and PD 10 Total Population Projections: 2010-2030

Locality	2010	2020	% Change	2030	% Change	2010-2030 % Change
Virginia	8,001,024	8,655,021	8.2%	9,331,666	7.8%	16.6%
Albemarle	98,970	111,039	12.2%	125,718	13.2%	27.0%
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%)
Charlottesville	43,475	50,714	16.7%	52,376	3.3%	20.5%
TOTAL PD 10	234,712	260,631	11.0%	287,829	10.4%	22.6%

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

Table 8. 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%
Fluvanna	4,022	5,799	44.2%	7,366	27.0%	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	38.0%	4,525	9.7%	51.4%
Charlottesville	4,017	4,711	17.3%	6,306	33.9%	57.0%
TOTAL PD 10	32,292	47,712	47.8%	61,357	28.6%	90.0%

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

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 numerous letters of support for the proposed project. Collectively, these letters addressed the following:

- The proposed project will be highly beneficial for orthopaedic patients while creating much needed additional capacity for MRI services that will benefit all of UVA Health.
- Ivy Mountain will co-locate a broad range of musculoskeletal services offered by UVA Health, thereby maximizing operational efficiencies while providing a truly integrated and streamlined patient experience and the best orthopedic care that academic medicine can offer.
- Programming for the new building features the full spectrum of orthopedic services, including joint replacement, sports medicine, hand and upper extremity, foot and

ankle, spine, prosthetics and orthotics, and physical therapy as well as outpatient surgery. Ancillary support services such as pharmacy and labs will also be available onsite.

- An extremity CT with its capacity for weight-bearing imaging of the lower extremities is a particularly important tool in the diagnosis and treatment of patients with small bone and joint fracture, especially compound fracture. A dedicated weight bearing extremity CT scanner will create views of the lower extremities in weight bearing position to better define injury, anatomy, and orthopedic hardware during physiologic loading. This capability is not available in the Charlottesville area today, although this new technology has significant potential to guide treatment decisions, including surgical planning.
- Currently, many patients seeking care at UVA outpatient clinics at Fontaine experience delays in receiving MRI scans. Optimally, such scans are coordinated with clinic visits. The need for imaging services has only increase at Fontaine with the growth in demand for UVA services across the board. However, because of backlogs, it is becoming increasingly difficult for UVA Imaging to coordinate same day appointments. Additional MRI capacity would significantly help UVA imaging to address this issue.
- It is a reality unique to academic medicine that, because of the severity of patients' conditions—and the complexities of their diagnoses—MRI scans take, on average, more than 50 minutes to complete; this is significantly longer than scans performed in community hospitals or free standing imaging centers. The complexity and duration of the scans, while unquestionably vital to the care of patients, greatly impacts UVA Imaging's daily throughput and the their ability to provide access to necessary services.
- An imaging center at Ivy Mountain will also enhance research and teaching missions by providing new opportunities for students to learn in a truly integrated care environment where they can explore and develop new treatment options for orthopedic conditions.

DCOPN received one letter in opposition to the proposed project. In his letter of concern, Johnathan Davis, President of Sentara Martha Jefferson Hospital ("SMJH"), provided the following points:

- SMJH does not oppose UVAI's request to relocate and replace an MRI unit from Fontaine, to be used to meet orthopaedic imaging needs at the new orthopaedic center. SMJH likewise does not oppose UVAI's request to add a limited-use, weight-bearing extremity CT unit at that center.
- SMJH has significant health planning concerns about adding another general-purpose MRI unit to PD 10 at this time. PD 10 has significant MRI capacity as measured by the SMFP. PD 10 already has the second-highest number of operational MRI units per capita

among all 22 PDs in Virginia—behind only the much more rural PD 2 in southwest Virginia. With 12 operational fixed MRI units in PD 10, and a population of approximately 255,000, there are approximately 4.7 MRI units per 100,000 residents as compared to 2.6 in Virginia. Based on 14 authorized fixed MRI units in PD 10, that ratio increases to 5.5.

- To the extent that UVAI believes that its current supply and distribution of MRI units does not meet patient needs, there appears to be more reasonable, efficient, and effective alternatives to adding a 12th unit to the UVA-affiliated facilities—and a 15th unit to PD 10. For example, UVAI could operationalize the one MRI unit requested to be relocated from Fontaine to Ivy Mountain, assess utilization of that unit and the remaining three MRI units at Fontaine after shifting orthopaedic scans, and then, to the extent demonstrated capacity constraints exist, request an additional unit at that time. Alternatively, UVAI could relocate two of its seven existing MRI units to Ivy Mountain. Either way, adding a general-purpose MRI unit now, given the nascency of the Ivy Mountain facility and the unknowns relating to utilization of the to-be-relocated unit, seems premature. From a reasonable health planning perspective, it seems more prudent to wait until operationalization of the orthopaedic center and the relocated MRI unit before adding capacity anew.
- Relying solely on scan times to create the appearance of need is misleading. UVAI—an outpatient-only provider—proposes an outpatient imaging center. Unlike UVA and SMJH, UVAI will not be performing MRI scans that require coordination with intensive care units, managing patients on multiple intravenous drips during their scans, overseeing high-acuity sedation of patients on ventilators while being scanned, or performing other high-acuity cases that entail the longest scan times. Rather, consistent with UVAI's relocation request, UVAI scanners likely do and will continue to perform a high volume of orthopaedic scans, which generally last no more than 30 minutes, assuming that scanning protocols are configured to reasonable benchmarks to achieve quality and efficiency. Although SMJH certainly does not contest UVAI's reported scan times, it does question how much weight they should carry in an application by a freestanding, outpatient imaging center that is not seeking to decant outpatient volumes from a hospital, where longer scans on high-acuity patients indeed can frustrate scheduling for outpatients.
- To the extent that UVAI experiences a surge in demand on the Ivy Mountain scanner, there still are two UVAI facilities within two miles—Fontaine and Northridge (located within the Transitional Hospital)—with a combined five MRI units. Additionally, one MRI unit at Zion Crossroads (PD 9) has capacity available to address any overflow demand.
- If DCOPN finds that UVAI has demonstrated a need for two MRI units at Ivy Mountain, prudent health planning militates towards relocating two of its seven MRI units instead of adding incremental capacity. Although UVAI's application does not detail how orthopaedic scans are distributed among UVAI's existing MRI units, presumably they are performed on more than one or two scanners. If UVAI were to relocate two units to Ivy Mountain, and all 5,900 orthopaedic scans were performed at Ivy Mountain, those units would be operating at only 59% capacity.

COPN Request No. VA-8530
DCOPN Staff Report

January 19, 2021
Page 10 of 26

In its response to the letter of concern submitted by SMJH, the applicant provided the following points (summarized):

- While the UVAI application is for a freestanding, outpatient imaging center, UVAI's facilities support an academic medical center providing tertiary/quaternary care to patients from central Virginia and regions beyond HPR I. As part of an academic medical center, there are many factors that impact and lengthen UVAI's imaging times including:
 - Complex patients come to UVA Health to access a continuum of care available only at an academic medical center, and are often imaged at UVAI before and after receiving treatment at UVAMC.
 - Many patients come from great distances to receive their care at UVA Health and benefit from coordinated same day imaging services. Because many patients travel long distances and have multiple coordinated appointments during their visit, they are often late for their scans, decreasing efficiencies of MRI scanning throughput.
 - Unlike community hospitals and freestanding imaging centers, UVAI scans are considerably longer than 30 minutes. There are many reasons for this, including: (1) Complex presentations which may lead to additional problem-solving MRI sequences; (2) Fewer than 50% of MRI scans in community practice are abnormal, whereas 80-90% of MRI scans done at UVA are abnormal; and (3) Many scans done at community hospitals are done to "eliminate" a diagnosis, whereas patients are referred to UVA Health to find the reason for a patient's symptoms or problem that could not be solved by the community providers.
 - Patient volumes at UVA Health are growing, and as they grow, additional capacity is needed. Outpatient clinic volumes have increased by 25% in the five years since UVAI last requested additional capacity. Consistent with the growth in outpatient volumes, imaging volumes rose by 20.7% between 2015 and 2019 for the Charlottesville locations.
 - Social determinants and financial disparities result in many more "no shows" or "late shows" which also affects volume and throughput efficiencies.
 - The vast majority of outpatient imaging procedures conducted at UVAI cannot be completed in 30 minutes, including those performed on orthopedic patients. In fact, only 2% of scans performed at UVAI can be done in 20 minutes. At UVAI, 71% of MRI scans take 40 minutes, 21% take 60 minutes or longer, 4% take 80 minutes or longer, and 2% take more than 100 minutes.
- Actual scan times are critically important in determining whether UVAI has capacity to meet its institutional need or requires an additional MRI scanner to be able to serve its patients in a timely and efficient manner. The SMFP standard of 5,000 procedures per scanner assumes that scans will take approximately 30 minutes or less to complete (5,000/50 weeks per year per machine = 100 scans per week, or 20 per day for an imaging center that is open five days per week, 10 hours per day). If the same assumptions—10

COPN Request No. VA-8530
DCOPN Staff Report

January 19, 2021
Page 11 of 26

hours per day, 5 days per week, 50 weeks per year—are applied to UVAI’s actual imaging times (50 minutes per scan), UVAI’s functional capacity should be 12 scans per day or 3,000 scans per year. Using this standard, UVAI is significantly exceeding its functional capacity, which explains the MRI backlog, and demonstrates UVAI’s institutional need for another scanner.

- UVAI operates Fontaine 415 for 15 hours per day during the week and 10 hours per day on the weekends, which allows the facility to exceed its standard functional capacity and come close to meeting the SMFP standard. This pace is unsustainable, but UVAI will continue this schedule as long as the need and backlog demand it. By adding a second scanner at Ivy Mountain and operating both scanners at that location 12 hours per day, 5 days per week, UVAI seeks to decant volumes from its other outpatient facilities while shortening, if not eliminating, the backlog for MRI imaging services. If necessary to meet the needs of its patients, UVAI may expand Ivy Mountain’s schedule to include weekends.
- There are no reasonable alternatives to the addition of a second MRI at Ivy Mountain. Each of Sentara’s suggested alternatives ignores critically important facts and circumstance stated in the application and previously recognized by DCOPN as germane to analysis of institutional and public need.
- Relevant precedents strongly support approval of UVAI’s application. DCOPN has determined in prior UVAI applications that the analysis of need for imaging services at UVAI requires consideration of the challenges inherent in caring for a population needing complex tertiary and quaternary services and, in many instances, coming to UVA for those services from locations far beyond PD 10. In decisions on UVAI applications submitted in 2012 and 2015, DCOPN recognized UVAI’s institutional need for additional capacity notwithstanding utilization standards in the SMFP.
 - In 2012, UVAI sought to establish an imaging center at Zion Crossroads (COPN Request No. VA-7966, resulting in the issuance of COPN No. VA-04370). At that time, DCOPN noted a 2.2 unit surplus of MRIs in PD10 based on 5,000 MRI procedures per existing and authorized MRI unit.
 - In 2015, UVAI applied for and was granted approval to add a fixed MRI at Fontaine in the 545 Facility (COPN Request No. VA-8188, resulting in the issuance of COPN No. VA-04503). At that time, DCOPN noted a 2.7 unit surplus of MRIs in PD 10. Additionally, DCOPN determined that it was not practical to reallocate patients stating:

“The existing MRI scanners at the applicant’s Northridge and Zion Crossroads facilities are well utilized and it is not prudent to reallocate any of these MRI scanners to the Fontaine campus.”

DCOPN notes that, as will be discussed in more detail elsewhere in this staff analysis report, the proposal at hand differs from the 2012 and 2015 requests in that the calculated surplus of MRI

COPN Request No. VA-8530
DCOPN Staff Report**January 19, 2021**
Page 12 of 26

scanners in PD 10 is considerably larger today. In fact, the 5.1 unit surplus calculated as of the date of this report is more than double that of the surplus reported in the 2015 application. Furthermore, DCOPN notes that the 2015 application relied on 2014 VHI data that demonstrated an 84.0% collective UVA Health System MRI utilization rate. Comparatively, the UVA Health System collective utilization rate relied upon for purposes of this staff analysis report is lower—81.1% (based on 2018 VHI data). For reasons already discussed and for reasons that will be discussed in more detail throughout this report, DCOPN maintains that currently, existing capacity exists within the UVA Health System MRI inventory to properly care for its patient population.

(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;

As will be discussed in more detail later in this staff analysis report, with regard to the requested specialty use CT scanner, DCOPN contends that approval is warranted despite the applicant failing to satisfy the 7,400 procedure per scanner per year expansion threshold found in the SMFP. The weight-bearing/extremity CT would provide a service not currently available in PD 10 and due to the specialized nature of the scanner, approval is not likely to negatively impact the utilization of existing PD 10 CT providers. With regard to the CT portion of the proposed project, DCOPN contends that no reasonable alternatives to the proposed project exist.

With regard to the requested relocation of an existing MRI scanner, DCOPN contends that no reasonable alternative exists. However, with regard to the requested additional MRI scanner, DCOPN contends that the request is premature. First, as will be discussed in more detail later in this staff analysis report, no facility within PD 10 or the UVA Health System met the 5,000 procedure per unit per year expansion threshold in 2018, indicating that ample capacity exists both within the health system and the planning district to care for Ivy Mountain's future patient population. DCOPN contends that should the applicant wish to operate a second MRI at the proposed new facility, reallocating a second MRI from an existing facility within the health system would be preferable from a health planning perspective. This would provide the applicant with the requested second scanner at Ivy Mountain while avoiding the unnecessary duplication of services within a planning district that already has a large surplus of MRI scanners. Alternatively, DCOPN maintains that a second alternative is to simply operationalize the MRI the applicant proposes to relocate from Fontaine, and request an additional MRI if and when occupancy at Ivy Mountain deems it appropriate to do so.

(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 PD 10. Therefore, this consideration is not applicable to the review of the proposed project.

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

As illustrated in **Table 3**, the total projected capital cost of the proposed project is \$4,991,703, the entirety of which will be financed using a seven-year conventional mortgage loan. The applicant anticipates capital and financing costs together will total approximately \$5,821,660. DCOPN contends that the costs for the proposed project are reasonable and consistent with previously approved projects similar in clinical scope.⁸

The applicant provided the following with regard to benefits of the proposed project:

“Because UVAI’s current MRI units are already over capacity, one of the most significant benefits of adding an additional MRI scanner at Ivy Mountain is the increased efficiency in procedure turn-around and access to care for additional patients. Approval of the relocation of one MRI scanner and addition of a specialty CT at Ivy Mountain will be particularly advantageous to orthopaedic patients whose physicians and ancillary support services will also be accessible at Ivy Mountain.

“Additionally, because UVA is committed to treating patients regardless of their ability to pay, the increased access to this specialized care also increases opportunities for those patients with financial needs so that they too can obtain the healthcare services they require.

“The new imaging center will also provide enhanced opportunities for medical education and clinical research at UVA. It is important for UVAMC to deliver cutting edge technology that enables more precise treatments. The long-term benefits from more precise diagnostic procedures will drive down long-term costs associated with such care.”

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

As already discussed, the applicant has provided assurances that CT and MRI services at Ivy Mountain will be accessible to all patients, regardless of financial considerations. However, recent changes to §32.1-102.4B of the Code of Virginia now require DCOPN to place a charity care condition on every applicant seeking a COPN. Accordingly, should the Commissioner approve the proposed project, DCOPN recommends a charity care condition consistent with the HPR I average, to be derived from CT and MRI gross patient services revenue at Ivy Mountain.

⁸ COPN No. VA-04719 authorized the establishment of a specialized center for diagnostic imaging with one CT and one MRI and had a capital cost of \$5,398,637; COPN No. VA-04729 authorized the establishment of a specialized center for diagnostic imaging with one CT and one MRI and had a capital cost of \$8,000,161; COPN No. VA-04700 authorized the establishment of a specialized center for CT and MRI imaging and had a capital cost of \$12,895,042.

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

Section 32.1-102:1 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, DCOPN will consider the consistency of the proposed project with the predecessor of the SHSP, the SMFP.

3. The extent to which the proposed project is consistent with the State Health Services Plan;

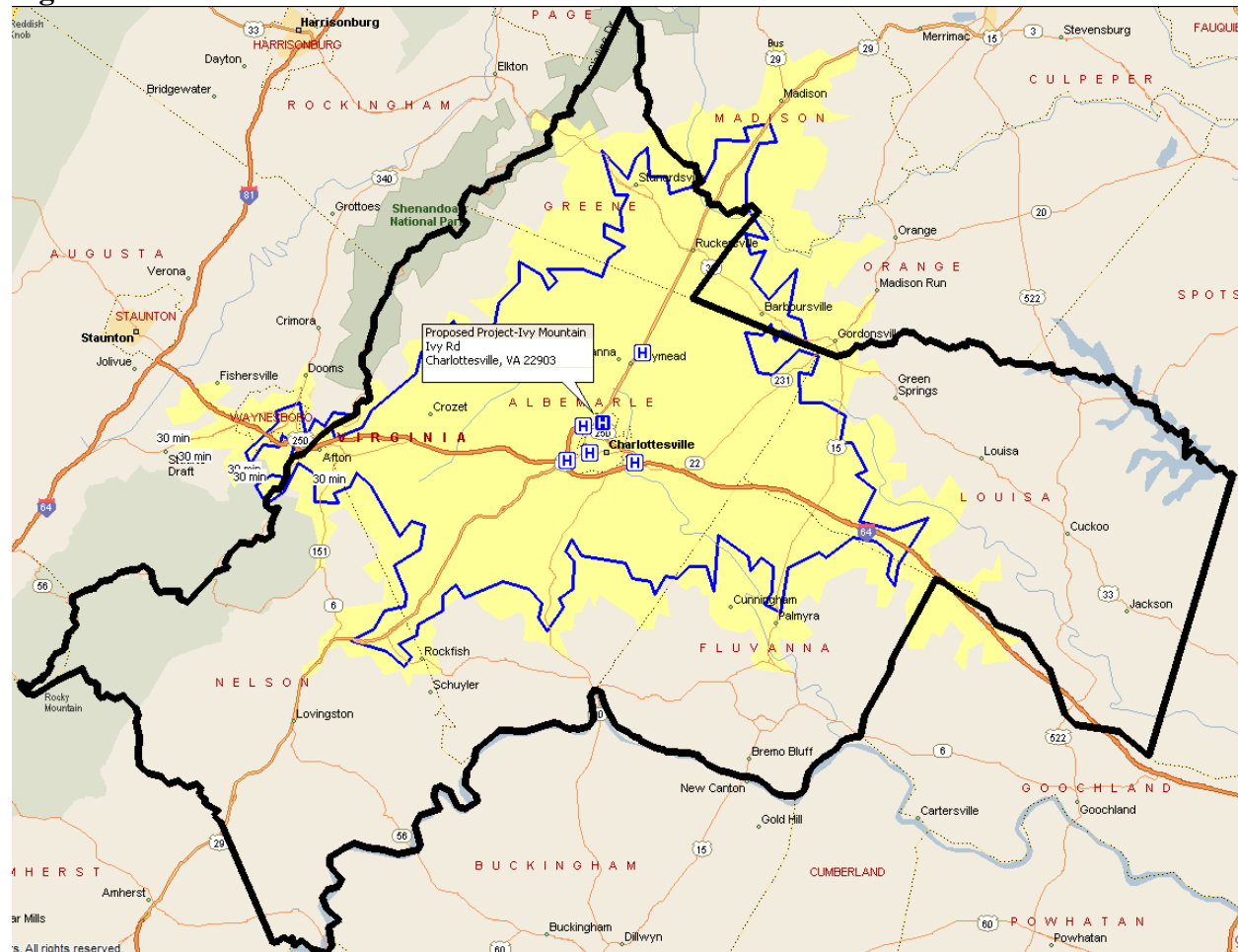
Part II of the SMFP contains criteria and standards for the addition of Diagnostic Imaging Services. They are as follows:

Part II. Diagnostic Imaging Services
Article 1. Computed Tomography

12VAC5-230-90. Travel Time.

CT 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** represents the boundary of PD 10. The blue “H” sign marks the location of Ivy Mountain. The white “H” signs mark the locations of all other existing CT services in PD 10. The yellow shaded area represents the area of PD 10 and surrounding areas that are within 30 minutes’ drive time of existing PD 10 CT services. The thin blue line represents the area within a 30 minutes’ drive time of the proposed project. Given the amount and location of shaded area, it is evident that CT services currently exist within a 30-minute drive for at least 95% of the population of PD 10. Accordingly, DCOPN concludes that approval of the proposed project would not improve geographic access to CT services for residents of PD 10 in any meaningful way.

Figure 1.**12VAC5-230-100. Need for New Fixed Site or Mobile Service.**

- A. No new fixed site or mobile CT service should be approved unless fixed site CT services in the health planning district performed an average of 7,400 procedures per existing and approved CT scanner during the relevant reporting period and the proposed new service would not significantly reduce the utilization of existing 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 CT scanners in such health planning district.**
- B. Existing CT scanners used solely for simulation with radiation therapy treatment shall be exempt from the utilization criteria of this article when applying for a COPN. In addition, existing CT scanners used solely for simulation with radiation therapy treatment may be disregarded in computing the average utilization of CT scanners in such health planning district.**

As **Table 1** above illustrates, VHI reports that authorized fixed-site CT scanners in PD 10 performed an average of 5,666 procedures per unit in 2018 (approximately 76.6% utilization), falling well short of the 7,400 procedures per unit per year expansion threshold. However, the applicant provided the following with regard to this standard:

COPN Request No. VA-8530
DCOPN Staff Report

January 19, 2021
Page 16 of 26

“In preparing this application, it came to UVAI’s attention that in 2018, University Hospital erroneously reported its CT volumes to VHI. The error was not corrected before VHI issued its annual data report. The error apparently occurred because of confusion surrounding VHI instructions for how CT volumes occurring in the ED (emergency department) should be reported, as well as EMR (electronic medical records) system changes at UVAMC. As a result, University Hospital did not report ED volumes for CT services that year, and only 26,478 total procedures were reported to VHI. When the unreported ED volume is added, actual CT utilization in 2018 at University Hospital was 45,421 procedures.”

DCOPN notes that while it cannot quantifiably confirm the unreported ED CT data provided by the applicant, UVAMC is required to report the corrected data to VHI and accordingly, DCOPN has relied upon it for purposes of analyzing PD 10’s collective CT utilization. When the additional ED procedures are considered, DCOPN calculates that PD 10 CT scanners performed, on average, 7,244 procedures per unit (approximately 97.9% utilization), falling only marginally beneath the 7,400 procedures per unit expansion threshold. Furthermore, DCOPN notes that this number includes PD 10s two CT scanners used in simulation with radiation therapy treatment (one located at UVAMC and the other at SMJH) and that when these scanners are removed, the average number of scans performed by the remaining scanners would likely surpass this threshold.

Using 2018 VHI data and the data submitted by the applicant above, based on the twelve authorized CT units in PD 10 and CT volume of 86,931 procedures (7,244 procedures per scanner), there is a calculated surplus of 0.3 CT units in PD 10 as follows:

COPN authorized CT units per VHI data = 12

Needed CT units = $86,931 \text{ total scans} \div 7,400 \text{ scans per CT standard} = 11.7$ (12 scanners)

Utilization Percentage = $\text{Actual scans/CT} (89,931 \text{ total scans} \div 12 \text{ scanners}) \div 7,400 \text{ scans per CT standard} = 97.9\% \text{ utilization.}$

CT unit surplus = 0.3

However, when the four CT units added to the PD 10 inventory subsequent to 2018 (for which we have no utilization figures, or figures on the impact they had on existing scanners) are considered, the result is a calculated **surplus of 4.3 (4) CT scanners.**⁹

Nonetheless, DCOPN contends that the CT portion of this project warrants approval despite the applicant’s failure to satisfy this standard. The requested scanner is a weight bearing/extremity CT scanner not currently available elsewhere in PD 10. Additionally, the requested scanner will have a utility limited to orthopaedic patients and will not be used to diagnose other kinds of disease or injuries. It will therefore have limited impact on overall CT utilization in PD 10, and is unlikely to have a significant impact existing PD 10 providers of CT services. DCOPN again notes that SMJH,

⁹ DCOPN again notes that PD 10s two CT scanners used in simulation with radiation therapy treatment (one located at UVAMC and the other at SMJH) are included in DCOPN’s calculations for determination of need.

the only party to submit opposition to this project, explicitly stated that it did not oppose the CT portion of the proposed project.

12VAC5-230-110. Expansion of Fixed Site Service.

Proposals to expand an existing medical care facility's CT service through the addition of a CT scanner should be approved when the existing services performed an average of 7,400 procedures per scanner for the relevant reporting period. The Commissioner may authorize placement of a new unit at the applicant's existing medical care facility or at a separate location within the applicant's primary service area for CT services, provided the proposed expansion is not likely to significantly reduce the utilization of existing providers in the health planning district.

Not applicable. The applicant is not proposing to expand an existing fixed-site service, but rather is proposing to establish a new fixed-site service.

12VAC5-230-120. Adding or Expanding Mobile CT Services.

- A. Proposals for mobile CT scanners shall demonstrate that, for the relevant reporting period, at least 4,800 procedures were performed and that the proposed mobile unit will not significantly reduce the utilization of existing CT providers in the health planning district.**
- B. Proposals to convert authorized mobile CT scanners to fixed site scanners shall demonstrate that, for the relevant reporting period, at least 6,000 procedures were performed by the mobile scanner and that the proposed conversion will not significantly reduce the utilization of existing CT providers in the health planning district.**

The applicant is not proposing to add or expand mobile CT services. Accordingly, this standard is not applicable to the proposed project.

12VAC5-230-130. Staffing.

CT services should be under the direction or supervision of one or more qualified physicians.

The applicant provided assurances that all CT services provided at Ivy Mountain will be provided under the supervision of members of the clinical staff who are appropriately trained and credentialed to direct and supervise these services.

Article 2. Magnetic Resonance Imaging

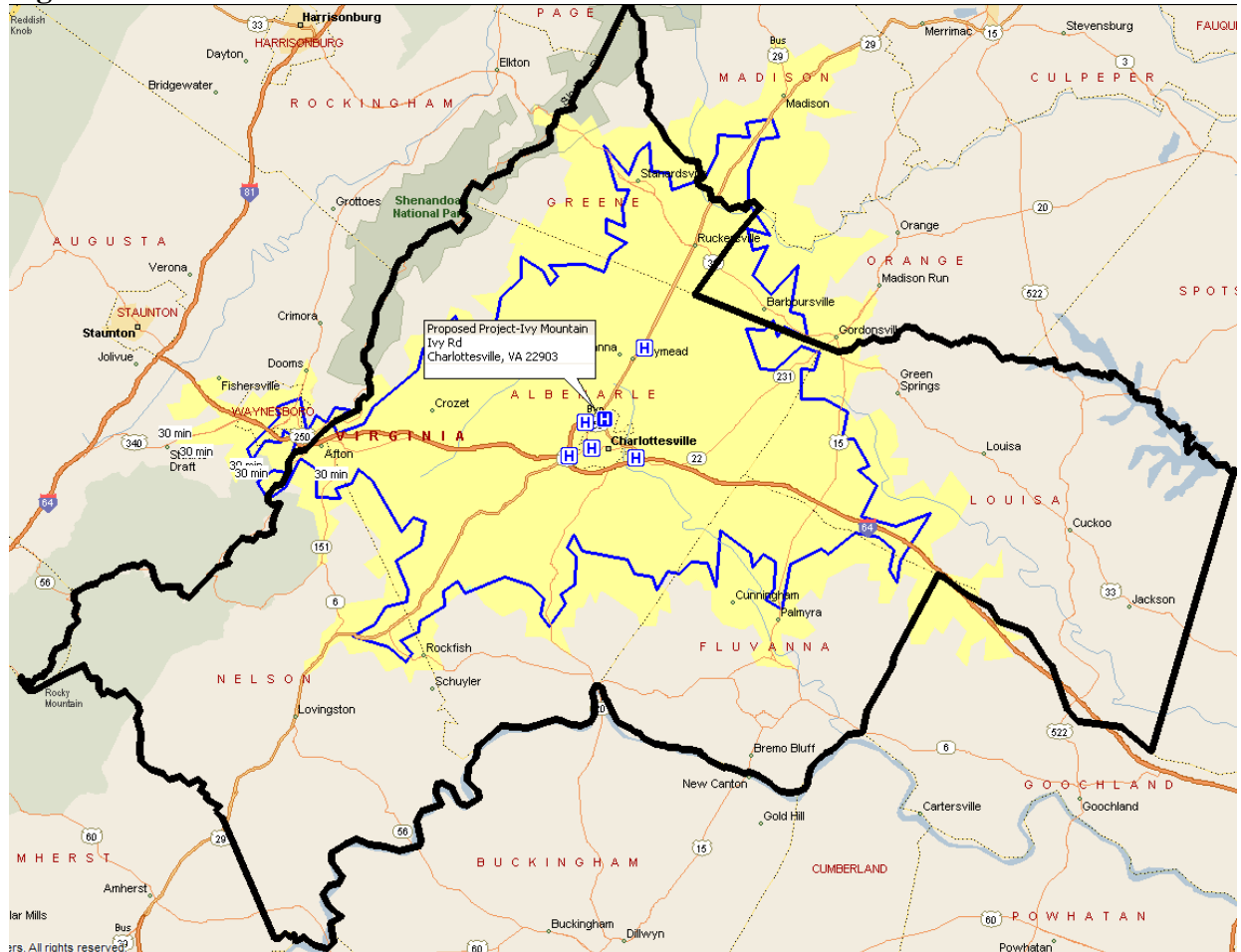
12VAC5-230-140. Travel Time.

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 2** represents the boundary of PD 10. The blue "H" sign marks the location of Ivy Mountain. The white "H" signs mark the locations of all other existing MRI services in PD 10. The yellow shaded area represents the area of PD 10 and surrounding areas that are within 30 minutes' drive time of existing PD 10 MRI services. The thin blue line represents the area within a 30 minutes' drive time of the proposed project. Given the amount and

location of shaded area, it is evident that MRI services currently exist within a 30-minute drive for at least 95% of the population of PD 10. Accordingly, DCOPN concludes that approval of the proposed project would not improve geographic access to MRI services for residents of PD 10 in any meaningful way.

Figure 2.



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.

As **Table 2** above illustrates, VHI reports that authorized fixed-site MRI scanners in PD 10 performed an average of 4,056 procedures per unit in 2018 (approximately 81.1% utilization), falling well short of the 5,000 procedures per unit per year expansion threshold. Using 2018 VHI data, based on 11

COPN Request No. VA-8530
DCOPN Staff Report

January 19, 2021
Page 19 of 26

authorized MRI units in PD 10 with a reported fixed MRI volume of 44,619 MRI procedures (4,056 procedures per unit), there is a calculated surplus of 2.1 fixed MRI scanners in PD 10 as follows:

COPN authorized fixed MRI units per VHI data = 11

Needed MRI units = 44,619 total scans ÷ 5,000 scans per MRI standard = 8.9 (9 scanners)

Utilization Percentage = Actual scans/MRI (44,619 total scans ÷ 11 scanners) ÷ 5,000 scans
 Per MRI standard = 81.1% utilization

MRI unit surplus = 2.1

However, when the three fixed-site MRI units added to the PD 10 inventory subsequent to 2018 are considered, the result is a calculated **surplus of 5.1 (5) MRI scanners**

With regard to the UVA Health System MRI inventory specifically, as demonstrated in **Table 9** below, the collective PD 10 UVA Health System MRI inventory operated at 81.1% utilization in 2018. This demonstrates that ample capacity exists within the health system to care for its existing patient population. More specifically, no individual facility within the PD 10 UVA Health System met the 5,000 procedures per scanner per year expansion threshold. Accordingly, DCOPN contends that the request for an additional MRI unit is premature, and the approval of an additional MRI scanner would unnecessarily duplicate services for which there is not an immediate need. As already discussed elsewhere in this staff analysis report, DCOPN contends that with regard to the requested additional MRI scanner, more efficient alternatives exist.

Table 9. PD 10 UVA Health System Authorized MRI Scanners and Utilization: 2018

Facility	Units	Procedures	Procedures/Unit	% Utilization
UVA Medical Center	5	13,736	4,579	91.6%
UVA Imaging-Transitional Care Hospital	2	8,502	4,251	85.0%
UVA Imaging Center-Fontaine	4	14,242	3,561	71.2% ¹⁰
UVA Health System TOTAL/Average	11¹¹	36,480	4,053	81.1%

Source: VHI (2018) and DCOPN Records

¹⁰ As previously discussed, VHI incorrectly reported the number of MRI scanners for this facility in 2018. DCOPN has recalculated occupancy by adjusting the number of scanners while maintaining the same number of procedures.

¹¹ Though not included in calculations for occupancy, this number reflects additions to the VCU Health System PD 10 MRI inventory made subsequent to 2018.

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 to 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.

The applicant is not proposing to expand a fixed site service, but rather is proposing to establish a new fixed-site service. Accordingly, this standard is not applicable to the proposed project.

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 to add or expand Mobile MRI Services.

12VAC5-230-180. Staffing.

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

The applicant has provided assurances that all MRI Services at Ivy Mountain will be provided under the supervision of the UVA clinical staff who are appropriately trained and credentialed to direct and supervise these services.

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

- A. Notwithstanding any other provisions of this chapter, the Commissioner may grant approval for the expansion of services at an existing medical care 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.**
- B. 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 the 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.**
- C. This section is not applicable to nursing facilities pursuant to § 32.1-102.3:2 of the Code of Virginia.**
- D. Applicants shall not use this section to justify a need to establish new services.**

While the applicant asserts it has an institutional need to add additional CT and MRI scanners at the proposed new facility, DCOPN contends that because the applicant proposes to establish a new specialized center for diagnostic imaging, i.e. establish a new service, this section is not applicable to the project at hand (pursuant to Section D of this provision). Nonetheless, DCOPN contends that even if this provision *were* applicable to the proposed project, the applicant has not adequately demonstrated an institutional need with respect to the requested additional MRI scanner. To reiterate, no facility within the PD 10 UVA Health System met the SMFP 5,000 procedure per unit per year expansion threshold in 2018, indicating that ample capacity exists within the health system to care for Ivy Mountain's future patient population. While the applicant has proposed to transfer one MRI from Fontaine to service the proposed project, DCOPN contends that should it wish to operate a second MRI at the proposed new facility, reallocating a second MRI from an existing facility within the health system would be preferable from a health planning perspective. This would provide the applicant with the requested second scanner at Ivy Mountain while avoiding the unnecessary duplication of services within a planning district that already has a moderate surplus of MRI scanners. Alternatively, as already discussed, DCOPN maintains that a second alternative is to simply operationalize the MRI the applicant proposes to relocate from Fontaine, and request an additional MRI if and when occupancy at Ivy Mountain deems it appropriate to do so.

With regard to the requested CT scanner, as already discussed, DCOPN contends that approval is warranted despite the applicant failing to satisfy the 7,400 procedure per scanner per year expansion threshold found in the SMFP.

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;**

With regard to the CT portion of the proposed project, the requested weight-bearing/extremity CT unit will be the first of its kind in PD 10. Accordingly, DCOPN contends that the CT portion

of the project will not foster institutional competition, as the applicant will be the sole provider of this service. DCOPN concludes that approval the requested specialty CT unit will not likely have a significant negative impact on existing PD 10 providers of CT services.

With regard to the MRI portion of the project, the applicant bases its request on institutional need, indicating that the request is not intended to foster institutional competition, but rather is intended to ensure its patients access to MRI services in a timely manner. However, as already discussed, DCOPN contends that the applicant has not adequately demonstrated an institutional need for the requested additional scanner and that approval of the request would likely prove detrimental to utilization of existing PD 10 providers. Also as discussed, DCOPN contends that the applicant's request for an additional MRI is premature and that reasonable alternatives to the request exist.

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;

For reasons already discussed throughout this staff analysis report, DCOPN contends that approval of the CT portion of the project is warranted despite the calculated surplus of CT units in PD 10 and that approval would not likely negatively impact existing PD 10 providers of CT services. Similarly, DCOPN concludes that the applicant's request to relocate and replace an MRI scanner currently in operation at Fontaine is not likely to negatively impact existing providers, as ultimately, this portion of the project is inventory neutral.

With regard to the requested additional MRI scanner, DCOPN again notes that no unit in PD 10 operated at or above the SMFP expansion threshold of 5,000 procedures per unit per year, indicating that ample capacity exists both with the planning district and the UVA Health System to adequately care for Ivy Mountain's patient population. Accordingly, DCOPN contends that the applicant has not adequately demonstrated an institutional need for the requested additional MRI scanner and that this portion of the proposed project is premature. Approval of this portion of the project would result in the unnecessary duplication of services in a planning district that already has a large surplus of MRI scanners, thereby potentially negatively impacting existing providers of the service. DCOPN again notes that reallocating a second MRI from within the existing UVA Health System inventory or alternatively, operationalizing the one scanner, with the intention of reassessing utilization at a later date, are reasonable alternatives to the proposed project.

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

As already discussed, DCOPN contends that the projected costs for the proposed project are reasonable when compared to previously authorized projects similar in clinical scope. The project will be financed entirely using a seven-year conventional mortgage loan. Furthermore, the Pro Forma Income Statement provided by the applicant anticipates a net profit of \$2,629,266 in the first year of operation and \$2,842,215 by year two, illustrating that the proposed project is financially feasible both in the immediate and the long-term (**Table 4**).

With regard to staffing, the applicant anticipates the need to hire 6.5 additional full-time employees in order to staff the proposed project. The applicant stated that in order to hire additional technologists, UVAI will first look to graduates of the UVA-affiliated educational programs in medical imaging technologies. The applicant is a current provider of CT and 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 10 facilities.

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 proposed project would provide PD 10 with its first weight-bearing/extremity CT unit, thereby providing improvements and innovations in the delivery of health services as demonstrated by the introduction of new technology. Additionally, approval of the proposed project would introduce an additional outpatient diagnostic imaging facility to the planning district. Regarding cooperative efforts to meet the regional health care needs, the applicant provided the following:

“UVAI is a component of UVA and 80% of this joint venture is owned by the Rector and Visitors of the University of Virginia. UVA is engaged in many cooperative efforts throughout the region to meet healthcare needs of the citizens of the Commonwealth. The joint venture between UVAMC and Novant Health is but one example of two systems cooperating with one another to improve patient care. Recently, OIA, which owns 20% of UVAI, entered into a joint venture with Novant Health UVA Health Culpeper Regional Medical Center to provide imaging services in a new facility in Culpeper. One purpose of this partnership is to connect patients in Northern Virginia with subspecialty care and clinical trials at UVAMC.”

DCOPN did not identify any other factors, not discussed elsewhere in this staff analysis report, to bring to the attention of the Commissioner.

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.

The applicant provided the following with regard to this standard:

“UVA has a tripartite mission to provide research, training, and clinical care to benefit the citizens of the Commonwealth. The Rector and Visitors of the University of Virginia

owns 80% of UVAI. While the University is not the applicant here, there is no question that UVAI is an integrated, integral party of the Health System, lending vital support to the University's teaching and research missions. We thereby enhance the delivery, innovation, and improvement of healthcare throughout the Commonwealth. The new Ivy Mountain facility is essential to fulfillment of UVA's commitment to providing all patients with access to high quality services, regardless of ability to pay. MRI and CT services to be offered at Ivy Mountain will reach the indigent and underserved populations—who are often the patients most in need of the kind of care that only academic medicine can provide.

“Finally, the imaging services to be provided to Ivy Mountain will continue to enrich UVA's existing environment for the training of residents, nurses, and other healthcare providers, in state-of-the-art specialty and subspecialty care, better preparing all who train at UVA to serve across the Commonwealth and elsewhere. The research and training that will occur at Ivy Mountain, which UVAI will facilitate, and the ancillary services that UVAI will provide, will undoubtedly lead to innovation in the delivery and provision of healthcare to all citizens of the Commonwealth.

DCOPN Staff Findings and Conclusions

UVAI is requesting authorization to establish a specialized center for CT and MRI services at Ivy Mountain by relocating and simultaneously replacing one MRI scanner, currently located at Fontaine in the 545 Facility, and adding one MRI and one specialty CT scanner for orthopaedic patients. The projected capital costs for the proposed project total \$4,991,703, the entirety of which will be financed using a seven-year conventional mortgage loan. The applicant anticipates capital and financing costs together to total approximately \$5,821,660. DCOPN concludes that this cost is reasonable and consistent with previously approved projects similar in clinical scope. Furthermore, DCOPN concludes that the proposed project appears to be economically feasible both in the immediate and in the long-term.

With regard to the CT portion of the proposed project, DCOPN concludes that due to the specialized nature of the weight-bearing/extremity CT unit, approval is not likely to have a significant negative impact on the staffing or utilization of existing PD 10 providers of CT services. Accordingly, DCOPN contends that this portion of the project warrants approval despite the calculated surplus of CT scanners in PD 10.

DCOPN concludes that the applicant's request to relocate an existing MRI scanner from Fontaine to Ivy Mountain is ultimately inventory neutral and would not negatively impact existing PD 10 providers of MRI services. Accordingly, DCOPN concludes that this portion of the proposed project warrants approval.

With regard to the applicants' request for an additional MRI scanner, DCOPN contends that the applicant has failed to adequately demonstrate a unique institutional need. To reiterate, no MRI scanner within PD 10 operated at or above the 5,000 procedure per scanner per year SMFP expansion threshold, indicating that ample capacity exists both within PD 10 and the UVA Health System to adequately care for the Ivy Mountain patient population. Furthermore, DCOPN calculated

COPN Request No. VA-8530
DCOPN Staff Report**January 19, 2021**
Page 25 of 26

a large surplus of MRI scanners within the planning district. Accordingly, DCOPN maintains that approval of this portion of the project would have a significant negative impact on existing PD 10 providers of MRI services and would unnecessarily duplicate services for which there is not an immediate need. DCOPN further concludes that reasonable alternatives to the requested additional MRI scanner exist. One option is for the applicant to reallocate the second scanner from an existing, underutilized facility within the PD 10 UVA Health System. Alternatively, a second option would be to operationalize the one scanner to be relocated from Fontaine, with the intention of assessing occupancy and applying for an additional scanner if and when the occupancy at Ivy Mountain deems doing so appropriate.

DCOPN Staff Recommendation

The Division of Certificate of Public Need recommends the **denial** of UVA Imaging, LLC's request to add one MRI scanner to the PD 10 inventory for the following reasons:

1. The proposed project is generally inconsistent with the applicable criteria and standards of the State Medical Facilities Plan and the Eight Required Considerations of the Code of Virginia.
2. The applicant has not demonstrated a public need, nor has it adequately demonstrated a unique institutional need, to add one MRI scanner to the PD 10 inventory.
3. There is a calculated surplus of MRI scanners in PD 10.
4. Approval of the proposed project would have a significant negative impact on existing providers of MRI services in PD 10.
5. Reasonable alternatives to the proposed project exist.

The Division of Certificate of Public Need recommends **conditional approval** of UVA Imaging, LLC's request to establish a specialized center for CT and MRI Services at the UVA Orthopedic Center at Ivy Mountain with one weight-bearing/extremity CT and one MRI relocated and replaced from Fontaine Research Park for the following reasons:

1. The proposed 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 capital costs of the proposed project are reasonable.
3. The proposed project appears economically viable in the immediate and the long-term.
4. There is no known opposition to this portion of the proposed project.
5. The proposed project is not likely to have a negative impact on existing PD 10 providers of CT and MRI services.

COPN Request No. VA-8530
DCOPN Staff Report**January 19, 2021**
Page 26 of 26

DCOPN's recommendation is contingent on UVA Imaging, LLC's agreement to the following charity care condition: UVA Imaging, LLC will provide MRI and CT services to all persons in need of this service, regardless of their ability to pay, and will facilitate the development and operation of primary medical care services to medically underserved persons in PD 10 in an aggregate amount equal to at least 4.5% of UVA Imaging, LLC's gross patient revenue derived from MRI and CT services at UVA Orthopedic Center at Ivy Mountain. 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. UVA Imaging, LLC 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.

UVA Imaging, LLC will provide MRI and CT 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 UVA Imaging, LLC will facilitate the development and operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area.