VIRGINIA DEPARTMENT OF HEALTH Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis

January 19, 2024

RE: COPN Request No. VA-8733

Scott Wagner Integrated Medicine, LLC Planning District 10 Establish a specialized center for MRI imaging

Applicant

Scott Wagner Integrated Medicine, LLC (SWIM) is a Virginia limited liability corporation. Dr. Wagner has been in practice for 20 years but SWIM was incorporated in 2020. SWIM is owned by Scott Wagner, DC. The facility is leased from S2KHoldings, LLC, also owned by Dr. Wagner. It is located in Charlottesville, Virginia, Planning District (PD) 10, Health Planning Region (HPR) I.

Background

Magnetic Resonance Imaging (MRI) is a powerful and critical diagnostic tool used to examine bones, joints and soft tissues such as muscles, tendons and cartilage to identify structural damage, defects and other musculoskeletal conditions. According to Virginia Health Information (VHI) data as reported for 2022, the latest year for which such data are available, there were 13 fixed MRI scanners at six sites in PD 10. Ten of the thirteen (77%) were owned by the University of Virginia (UVA) and three by Sentara Martha Jefferson Health Services. These scanners had a utilization of 76.9% of the State Medical Facilities Plan (SMFP) threshold of 5,000 procedures per scan (**Table 1**).

Facility Name	Total Stationary Units	MRI Procedures, Fixed MRIs	MRI Procedures per Fixed Scanner	Percent of SMFP Standard
Martha Jefferson Health Services - Proffit Road	1	1,498	1,498	30.0%
Sentara Martha Jefferson Hospital	2	8,767	4,384	87.7%
University of Virginia Medical Center	4	13,292	3,323	66.5%
UVA Imaging - Transitional Care Hospital (Northridge)	2	9,272	4,636	92.7%
UVA Imaging - Zion Crossroads	1	2,577	2,577	51.5%
UVA Imaging Center Fontaine (MOB 1)	3	14,566	4,855	97.1%
PD 10 Totals and Averages	13	49,972	3,844	76.9%

Table 1. Utilization, Fixed MRI Scanners, PD 10

Source: VHI 2022

Three MRI scanners have been authorized since the 2022 VHI report as UVA Imaging at UVA Health Orthopedic Center opened in July 2022 and University of Virginia added a fifth MRI in March of 2023, the latter a 0.064T portable scanner used for imaging the head and brain that can be wheeled to the patient's bedside. The current inventory of MRI scanners in PD 10 is shown in **Table 2**.

Facility	Total Diagnostic Scanners	
UVA Imaging - Ivy Mountain ¹ (UVA Health Orthopedic Center)	2	
UVA Imaging - Zion Crossroads	1	
Sentara Martha Jefferson Health Services - Proffit Road	1	
Sentara Martha Jefferson Hospital	2	
University of Virginia Medical Center ²	5	
UVA Imaging @ Transitional Care Hospital	2	
UVA Imaging Center Fontaine MOB 1	3	
PD 10 Total	16	

Table 2. Authorized MRI Scanners, PD 10

Source: DCOPN Records

SWIM offers integrated medical care for patients, looking at the body as a whole to determine the cause of pain or ailments. Its patients are primarily those with chronic pain and conditions such as fibromyalgia, arthritis, sciatica, and widespread joint pain. SWIM provides diagnostic and treatment options for back pain, headaches and migraines, joint pain and knee pain. Treatment includes manipulative therapies, physical rehabilitation, and other pain management techniques such as IV therapy, pain management, medial branch block, injections, radiofrequency facet ablation and

¹ COPN No. VA-04745 authorized UVA Imaging - Ivy Mountain, opened July 5, 2022, with 2 MRIs.

² COPN No. VA-04807 authorized the addition of a fifth MRI unit (portable) at UVA Medical Center, operational March 1, 2023.

sacroiliac joint fusion. Diagnostics include x-rays and ultrasounds. SWIM has three chiropractors on its medical staff, two advanced care providers and a licensed practical nurse. Its medical director is a doctor of osteopathy, board certified in physical medicine and rehabilitation and pain management.

A study released in 2023 by the National Institutes of Health³ was referenced by the applicant and stated:

"Overall, the study found that the rate of chronic pain and high-impact chronic pain (HICP) among adults is approximately 21% and 8%, respectively. Chronic pain is pain that is experienced on most days or every day in the past three months; and HICP is pain that limits life or work activities on most days or every day during the past three months."

Proposed Project

The applicant proposes to establish a specialized center for MRI imaging in its existing facility at 2109 India Road, Charlottesville, Virginia with one tilting MRI capable of isolating and scanning individual parts of the body in weight-bearing positions. The proposed unit requires a small amount of space and a room compatible with its specifications exists in the facility. The estimated capital costs for the proposed project are \$819,820 (**Table 3**) and these will be funded by a combination of accumulated reserves (11.3%), commercial loans (45.4%) and operating income (43.3%). If approved, the proposed project is expected to be operational two months after COPN approval.

Table 3: Capital Co	osts. MRI Imaging	at Scott Wagner	Integrated Medicine
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Equipment Not Included in Construction Contract	\$465,000
Site Acquisition Costs	\$354,820
Total Capital Costs	\$819,820

Source: COPN Request No. VA-8733

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 includes "[a]ny specialized center or clinic or that portion of a physician's office developed for the provision of ... 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.

³ https://www.nccih.nih.gov/news/press-releases/nih-study-finds-high-rates-of-persistent-chronic-pain-among-us-adults

1. The extent to which the proposed service or facility will provide or increase access to needed services for residents of the area to be served, and the effects that the proposed service or facility will have on access to needed services in areas having distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care.

The population of PD 10 is expected to be about 280,000 by 2030 and have 20,000 more people than it had in 2020, a 7.9% increase (**Table 4**). This is a slightly higher percentage of population growth than that of Virginia at 5.8%. Charlottesville, where the proposed project is located, is projected to grow more slowly than PD 10 or Virginia, at 5.1%, and have 2,367 more people in 2030 than it did in 2020.

Geography Name	2020	2030	Change in Population 2020 - 2030	% Change 2020-2030	2020 65+	2030 65+	Change in 65+ Population 2020 - 2030	% Change 2020-2030 65+
Albemarle County	112,395	124,016	11,621	10.3%	21,417	27,028	5,611	26.2%
Fluvanna County	27,249	28,394	1,145	4.2%	5,799	7,366	1,567	27.0%
Greene County	20,552	22,376	1,824	8.9%	3,836	5,442	1,606	41.9%
Louisa County	37,596	41,436	3,840	10.2%	7,826	10,691	2,865	36.6%
Nelson County	14,775	14,322	-453	-3.1%	4,124	4,525	401	9.7%
Charlottesville city	46,553	48,920	2,367	5.1%	4,711	6,306	1,595	33.9%
PD 10 Totals/Averages	259,120	279,464	20,344	7.9%	47,712	61,357	13,645	28.6%
Virginia, Statewide	8,631,393	9,129,002	497,609	5.8%	1,352,448	1,723,382	370,934	27.4%

Table 4. PD 10 Population Data

Source: Weldon-Cooper Data from the UVA Weldon-Cooper Center for Public Service, August 2023

The facility is accessible just off Seminole Trail (US Route 29) and near the US-250 Bypass on a major road near many businesses. Interstate 64 is a short drive, providing access to more distant areas of the PD. Public transportation is available and several bus stops are within a five-to-tenminute walk. Charlottesville Area Transit (CAT) buses are handicap-accessible and provide public transportation to the facility. In terms of socioeconomic barriers, **Table 5** shows that Charlottesville has a poverty rate of 23%, over twice the average statewide.

Geography Name	Poverty Rate
Albemarle County	9.00%
Fluvanna County	4.60%
Greene County	10.10%
Louisa County	10.80%
Nelson County	12.50%
Charlottesville city	23.10%
PD 10 Average/Total	11.70%
Virginia, Statewide	10.60%

Table 5. Poverty Rates, PD 10 Localities

Source: U.S. Census Bureau

The applicant states that Dr. Wagner has referred patients for MRI scans for many years and found that traditional MRI scans were not useful in accurately diagnosing and treating his patients. The proposal will increase access to MRI imaging of the cervical spine, lumbar spine, knees, hips and shoulders in the positions in which patients experience the pain in order to identify more specifically the source of pain.

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

(i) The level of community support for the project demonstrated by citizens, businesses, and governmental leaders representing the area to be served.

DCOPN received two letters of commitment, one from medical director Scott D. Chirichetti, D.O. and one from the Chief Operating Officer of NationalRad. DCOPN also received thirty-two letters of support for the proposed project from providers affiliated with SWIM and its patients. These letters, in aggregate, expressed the following:

- The most effective treatment plan starts with the most accurate diagnosis.
- An upright MRI provides a more accurate diagnosis for (my) patients with pain.
- My patients experience pain when standing, walking, weight-bearing.
- The information gained by evaluating a joint or the spine in a weight-bearing stance can be of immense diagnostic value.
- An upright MRI is needed to provide the best possible care and assure the best outcomes for patients.
- NationalRad, a team of fellowship trained musculoskeletal radiologists, commits to providing highest quality MRI interpretations for the proposed scanner.
- Dr. Wagner has always provided the latest technology and services to treat patients' chronic pain and injuries effectively.
- Dr. Wagner has helped me and a lot of my family members.
- He has one of the best medical offices I have ever been to.

- It is challenging to diagnose and treat some conditions due to difficulty identifying the source of pain.
- A traditional MRI scan does not help because the pain is gone when lying flat at rest.
- The proposed project would offer new technology that could be used to help Dr. Wagner treat patients experiencing ongoing, chronic pain more effectively.
- Patients like me would greatly benefit from this service.
- Dr. Wagner's office is easy to access.
- The new MRI would offer better insight into what patients' bodies are experiencing in active or weight-bearing stance. This would allow Dr. Wagner to create a more efficient treatment plan that could address and alleviate pain.
- This treatment would be more cost-efficient in the long run, avoiding treatments that are ineffective and developing the best treatment plan more quickly.
- I believe this project is needed for greater, comprehensive care for patients with chronic pain and other injuries.
- If Dr. Wagner had an MRI, it would decrease time for patients to get help.
- The MRI would be beneficial and a necessary service.

DCOPN also received a letter of opposition from the University of Virginia Medical Center (UVAMC) in opposition to the proposed project, with an addendum letter signed by the Executive Vice Chair, Department of Radiology and Medical Imaging and the Director of Musculoskeletal Imaging and Intervention at UVA Health. These letters made the following points:

- The establishment of MRI services at SWIM would not meet a public need.
- A low-powered MRI will not meaningfully improve access to MRI services in PD 10.
- It will produce lower quality scans.
- It will frustrate physicians who find the scan results are not adequate for diagnoses of many orthopedic diseases.
- It will confuse and frustrate patients when lower quality scans lead to delayed or incorrect diagnosis and result in additional scans and costs.
- It will lead to underutilization of existing capacity in PD 10, to the detriment of existing providers.
- PD 10 has a wide array of high powered (1.5T and 3T) MRIs operated by UVA and Sentara Martha Jefferson.
- The UVA MRIs provide high quality imaging under the direction of radiologists and faculty of the UVA School of Medicine.
- UVAMC and UVA Imaging performed 4,147 orthopedics and musculoskeletal studies in 2023.
- Maintaining strong volumes at UVA's academic medical center is vitally important to UVA's mission and helps ensure it can provide clinical care, research and training.
- The applicant stated in error that several of UVA's MRIs did not report volumes to VHI, skewing utilization data. UVA reported its imaging facilities as required by VHI.
- The application does not demonstrate the proposed project will meaningfully increase access to MRI services in PD 10 or address barriers to access to care.
- Magnet strength matters in the diagnosis and treatment of orthopedic diseases.

- "While low field/weight bearing MRI has occasional advantages, high field MRI is the widespread standard in the United States for good reason: it is more likely that subtle and relevant diagnoses would be missed on low field devices, even if the scan is conducted while the patient is in a weight-bearing position."
- "Weight bearing MRI does have potential to show some findings to greater advantage if the findings are obvious enough at low field strength and would be significantly influenced by axial load (weight bearing)..." but lower field strength scanners do not reveal more findings with greater sensitivity than conventional high field scanners that are not weight bearing.
- There is no question some patient fear conventional MRIs, but most patients aren't aware of variability in quality due to variances in magnet strength.
- Low strength MRIs are not new and are more likely to be associated with missed diagnosis or misdiagnosis.
- Lower strength magnets were commonplace years ago but were abandoned by many hospitals and providers because of the inferior diagnostic results; UVAMC had a 0.7T open magnet many years ago and replaced it with a stronger device. Orthopedic surgeons did not want their patients' studies performed on the lower strength device due to inferior quality.
- SWIM's proposal has garnered support, but such support does not override responsible health planning.
- The status quo is a reasonable alternative. SWIM has provided no evidence of access barriers beyond anecdotal claims that patients encounter delays in getting MRI scans in PD 10.
- While acquisition costs are low, there is a tradeoff in quality, outcomes and potential for overutilization resulting from self-referrals.
- The project will not improve financial accessibility. There is no indication in SWIM's "Practice Statistics" that it historically has provided charity care.
- The project is generally inconsistent with relevant provisions of the SMFP. The application fails to identify the existing inventory in PD 10.
- The project will not foster institutional competition that benefits the area; to the contrary, it will provide inferior quality and frustrate providers.
- Half of anticipated volumes would be for patients of SWIM, creating potential for overreferral.
- SWIM could replace the magnet later with a stronger magnet, which would adversely impact existing providers.
- The proposed technology is not new or innovative and would provide neither improvement in financing nor the delivery of health care services.
- Innovation in MRI continues to trend toward stronger magnets, 5T to 9T.
- There is no public need for the low powered MRI that SWIM has requested.

DCOPN received a letter in response to UVAMC's opposition letter. It made the following key points:

• UVAMC is incorrect about the basis for SWIM's weight-bearing MRI unit and the need for the project.

- UVAMC misrepresents or otherwise attributes certain positions to SWIM that were not made in its application.
- The project is necessary to meet an identified need for SWIM's patients seeking comprehensive chiropractic care for resolutions of ongoing concerns not resolved through traditional means.
- UVAMC's letter primarily focuses on magnet strength and claims that lower magnet strength will result in lower quality results.
- UVAMC overlooks that the project is proposed to treat a specific patient population with a demonstrated need.
- SWIM does not intend to perform MRI scans on the general public to view concerns that might benefit from the more precise imaging of a stronger magnet.
- The project is intended for the unique patients who have chronic orthopedic issues that have not been solved by traditional methods
- A significant portion of SWIM's patients have already undergone previous scans and surgical intervention and are in need of different options.
- The proposed scanner would provide additional information to be used in formulating treatment plans because of its weight-bearing capability not available currently.
- Exhibits are provided confirming that weight-bearing scans are useful and rebutting UVAMC's claim that these images are of "dubious diagnostic value."
- SWIM has not represented that this is new technology but recognized that the project would improve access to technology in demand for pain management patients.
- UVA's past experience with a 0.7T open magnet was different technology and older technology.
- Significant technological improvements have made low-field strength MRI more comparable diagnostically.
- Documentation is provided that imaging techniques and software enhancements optimize image quality, even at lower field strengths.⁴
- Documentation also discusses unique benefits of a weight-bearing MRI and improvements in the efficacy of these units.
- The weight-bearing nature of the scan is suited to identify chronic, hard to diagnose issues.
- UVAMC's letter acknowledges that weight bearing MRI has "occasional advantages" and SWIM submits that the weight bearing scanner will result in more useful scans to its practice's patient base.
- The claim that the project will frustrate providers or lead to unnecessary scans is without merit.
- The majority of SWIM's patients who will use the scanner have already received scans and have undergone treatment that did not succeed.
- Most providers who see a patient for treatment are going to perform an updated MRI scan regardless of the patient's previous scans (not due to lower quality image).
- Low field strength does not equal low quality images. They are clinically effective and "purpose built" to support clinical decision making in scenarios where high-field MRIs are ill-suited.

⁴ https://pubmed.ncbi.nlm.nih.gov/37345725/

- In response to UVAMC's alleged concerns that patient will be confused by the introduction of this unit, SWIM will continue to educate patient fully on capabilities and limitations of the unit, as relevant.
- UVAMC fails to acknowledge in its letter that the patient that SWIM anticipates will be proper candidates for this weight-bearing MRI, and are those patients who have already undergone scans and surgical and other treatments without pain resolution.
- To the extent that patient are not appropriate candidates for SWIM's services, SWIM has historically referred patients elsewhere, including to UVA's facilities.
- This project will meaningfully improve access to weight-bearing MRI in PD 10, and to SWIM's knowledge, in Virginia.
- The proposed unit is not intended to serve the general population, but the identified subset who have not had orthopedic pain issues resolved through traditional surgical options.
- Contrary to UVAMC's assertions, SWIM works with all patients regardless of their ability to pay and is committed to providing a level of charity care as a condition of COPN approval.
- SWIM will adopt policies and protocols to ensure that patients are appropriate candidates for scans on the proposed unit.
- SWIM has no intention to replace a weight-bearing MRI scanner with a stronger MRI unit, despite UVAMC's speculative concerns.
- UVAMC's motives in opposing this project seem less designed to control proliferation of services and instead focus on protecting its significant control of imaging services in PD 10.
- UVAMC conjectures that the SWIM unit will significantly impact its services and limit its ability to fulfill its mission, but also acknowledges that it operates 13 of the 16 MRI units in PD 10.
- SWIM does not intend or anticipate diverting patients from existing providers, but to treat a specific group of patients with a specific imaging need.
- Utilization of existing traditional MRIs that treat the general population is not particularly relevant to the need for this specific scanner.
- Some patients who are post-surgical with hardware could benefit from this unit which can scan at lower magnetic level and isolate certain portions of the body at each time.
- The type of patients UVAMC's letter of opposition says weight bearing MRI has potential to image with greater advantage are exactly the patients SWIM intents to serve with the proposed MRI.
- The unit is not anticipated to be used by orthopedic surgeons or other providers who might require higher field strength contrast MRI scans.
- It intends to service the orthopedic/pain management space in a chiropractic practice and reach the root cause of patients' chronic pain.

Public Hearing

§32.1-102.6B of the Code of Virginia directs DCOPN to hold one public hearing on each application in the case of competing applications; or in response to a written request by an elected local government representative, a member of the General Assembly, the Commissioner, the applicant, or a member of the public. COPN Request No. VA-8733 is not competing with another project and DCOPN did not receive a request to conduct a public hearing for the proposed project. Thus, no public hearing was held.

DCOPN provided notice to the public on May 10, 2024 regarding this project inviting public comment. The public comment period closed on June 24, 2024. Other than the letters of support and opposition referenced above, no members of the public commented.

(ii) The availability of reasonable alternatives to the proposed service or facility that would meet the needs of the population in a less costly, more efficient, or more effective manner.

The status quo is a reasonable alternative to the proposal, though it leaves a subset of the PD 10 population without a local weight-bearing MRI imaging option that the applicant believes is necessary for proper diagnosis of chronic pain patients. DCOPN records indicate that there is (at least) one authorized and confirmed MRI in Virginia that is an open, multi-positional scanner capable of weight-bearing images. It was authorized in 2004 and located at Hampton Roads Orthopaedics and Sports Medicine, 141 miles and just over 2 hours away from SWIM. It has been well-utilized at 75% to 93% over the past five years.

(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 project.

Total projected capital costs for the proposed project are \$819,820, with additional conventional loan financing costs, not provided. The estimated costs are less than other recently approved projects to establish MRI services at existing facilities, for example COPN No. VA-04831 was authorized at \$1.9 million and COPN No. VA-04800 at \$3.2 million.

The applicant has described benefits to the proposed project, primarily access to weight-bearing MRI technology, not available elsewhere in PD 10 that would allow for better identification of the sources of chronic pain in its patients, specifically those with unresolved pain. According to literature for the Esaote G-scan Brio MRI scanner proposed, "the forces of gravity generate bio-mechanical changes in the human anatomy, so MRI imaging in the natural, standing position allows you to obtain extra details which would not normally be seen." This type of scanner allows imaging of patients in the same position as when they experience their pain and problematic symptoms, allowing for clearer identification of the cause and affecting diagnoses and treatments. SWIM proposes a practice-based MRI scanner that would have lower charges than hospital-based imaging.

(v) The financial accessibility of the project to the residents of the area to be served, including indigent residents.

SWIM treats all patients regardless of their ability to pay for services or of their payor source and the proforma provided with COPN Request No. VA-8733 proffers 4.5% charity care as a percentage of

gross patient revenues. This is well above the HPR I average of 1.9% for inpatient hospitals in 2022 (**Table 6**).

		Total Charity		
		Care Provided	Adjusted	
HPR I	Gross Pt Rev	Below 200%	Charity Care	%
Encompass Health Rehab Hosp of Fredericksburg	\$44,295,730	\$2,229,009	\$2,229,009	5.0%
UVA Health Culpeper Medical Center	\$240,048,159	\$7,421,653	\$7,421,653	3.1%
University of Virginia Medical Center	\$7,848,317,103	\$221,917,841	\$221,917,841	2.8%
UVA Transitional Care Hospital	\$33,698,098	\$949,912	\$949,912	2.8%
Sentara RMH Medical Center	\$1,071,307,453	\$23,829,680	\$23,829,680	2.2%
Sentara Martha Jefferson Hospital	\$859,138,273	\$13,611,074	\$13,611,074	1.6%
Carilion Rockbridge Community Hospital	\$198,916,994	\$2,991,170	\$2,991,170	1.5%
Valley Health Winchester Medical Center	\$1,626,765,087	\$15,114,509	\$15,114,509	0.9%
Fauquier Hospital	\$403,961,455	\$3,743,617	\$3,743,617	0.9%
Valley Health Page Memorial Hospital	\$86,671,293	\$784,764	\$784,764	0.9%
Valley Health Shenandoah Memorial Hospital	\$172,624,855	\$1,427,262	\$1,427,262	0.8%
Stafford Hospital Center	\$325,489,642	\$2,667,241	\$2,667,241	0.8%
Valley Health Warren Memorial Hospital	\$214,875,231	\$1,602,856	\$1,602,856	0.7%
Augusta Health	\$1,319,446,005	\$9,441,322	\$9,441,322	0.7%
Spotsylvania Regional Medical Center	\$767,734,481	\$5,368,645	\$5,368,645	0.7%
Mary Washington Hospital	\$1,489,676,899	\$7,943,769	\$7,943,769	0.5%
Bath Community Hospital	\$27,995,987	\$81,827	\$81,827	0.3%
UVA Encompass Health Rehabilitation Hospital	\$35,912,204	\$11,443	\$11,443	0.0%
Total Inpatient Hospitals:				18
HPR I Total Inpatient \$ & Mean %	\$16,766,874,949	\$321,137,594	\$321,137,594	1.9%

Table 6. Charity Care, PD 10 Facilities, 2022

Source: VHI 2022

In accordance with section 32.1-102.4.B of the Code of Virginia, should the proposed project receive approval, the project would be conditioned to provide a level of charity care based on gross patient revenues derived from MRI imaging that is no less than the equivalent average for charity care contributions in HPR I. Pursuant to Code of Virginia language any COPN issued for this project will also be conditioned on the applicant's agreement to accept patients who are the recipients of Medicare and Medicaid.

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

There are no other factors, not addressed elsewhere in the analysis, relevant to the determination of a public need for either project.

3. The extent to which the application is consistent with the State Medical Facilities Plan.

Section 32.1-102.2:1 of the Code of Virginia calls for the State Health Services Plan Task Force to develop recommendations for a comprehensive State Health Services Plan (SHSP). In the interim,

DCOPN will consider the consistency of the proposed project with the predecessor of the SHSP, the State Medical Facilities Plan (SMFP).

The State Medical Facilities Plan (SMFP) contains the criteria and standards for MRI services. They are as follows:

12VAC5-230 Part I, Article 2

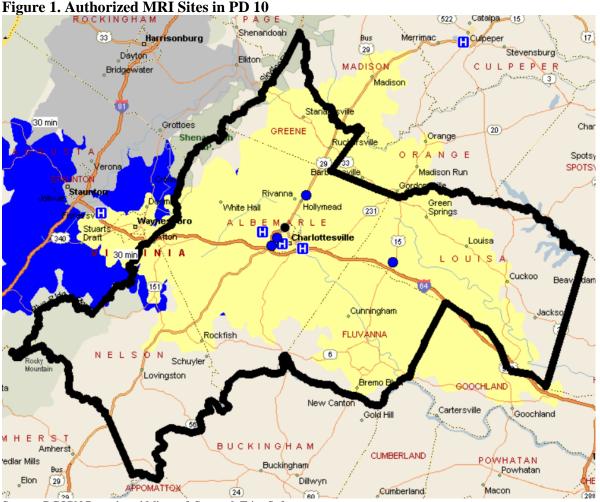
Criteria and Standards for Magnetic Resonance Imaging

12VAC5-230-140. Travel time.

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

The black line in **Figure 1** shows the boundary of PD 10. The yellow shaded area illustrates the area within 30 minutes driving distance of a PD 10 MRI service. The dark blue illustrates MRI coverage within 30 minutes from providers outside of PD 10. The H icons locate authorized hospital-based MRI services while the blue dots locate authorized outpatient MRI sites. The black dot shows the location of the proposed project.

The areas not within the shaded area include Lovingston (population 584 per 2020 Census), Schuyler (population 349 per 2020 Census), and Jackson (population 1,964 per 2020 Census). The total PD 10 population was 259,120 in 2020, so these localities include only 1.1% of the population of PD 10. Though there appear to be large areas of PD 10 outside of 30 minutes' drive from MRI services, these are the more rural areas of the PD, so it is likely 95% of the population is within 30 minutes' drive of an MRI service. The proposed project will not increase geographical access to MRI services in PD 10.



Source: DCOPN Records and Microsoft Streets & Trips Software

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.

According to VHI, a total of 49,972 MRI scans were performed in PD 10 in 2022 (**Table 1**) on 13 fixed site scanners, for an average of 3,844 procedures per MRI scanner (76.8%) of the SMFP threshold of 5,000 procedures. These 49,972 MRI scans represent full utilization (at the 5,000-procedure standard) of ten MRI scanners:

MRI Scanners Needed: 49,972/5,000 = 9.99 (10) There are currently 16 authorized MRI scanners in PD 10, so there is a surplus of six MRI scanners in PD 10: 16 Authorized MRI Scanners – 10 MRI Scanners Needed = Surplus of 6 MRI Scanners

SWIM proposes to introduce a unique type of MRI scanner for a particular patient population and it is not likely that the proposed project would impact existing MRI providers significantly.

12VAC5-230-160. Expansion of fixed site service.

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

Not applicable. The proposed project is not an expansion of an existing MRI service.

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.

This provision is not applicable as 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 stated that the project will be overseen by "qualified and trained professionals." SWIM states that, "due to the low 1.5 MHz of the proposed unit and the fact that the unit does not use ionizing radiation, it does not require a certified radiologic technician to operate. SWIM will partner with NationalRad to contract qualified, certified radiologists to read the MRI scans. Though the medical director at SWIM is a board-certified physician, it is unclear that the proposal meets this staffing standard.

Required Considerations Continued

4. The extent to which the proposed service or facility fosters institutional competition that benefits the area to be served while improving access to essential health care services for all persons in the area to be served.

UVA Health owns and operates 13 of the 16 authorized MRI scanners in PD 10 (81%) and Sentara Martha Jefferson owns and operates the other 3. There is a high degree of market concentration of MRI services with UVA Health in PD 10. Though the proposed project introduces a new owner into the MRI market, it has been stated by both UVAMC and the applicant that the unique offering of a low-field strength weight-bearing MRI would not directly compete with existing providers.

5. The relationship of the project to the existing health care system of the area to be served, including the utilization and efficiency of existing services or facilities.

SWIM is a stand-alone chiropractic practice with, notably, a medical director who is a physician, board-certified in physical medicine and rehabilitation, and pain management. The applicant does not currently offer COPN-regulated services. MRI scanners are highly concentrated with UVA Health. Utilization in PD 10 was 77% in 2022, the latest year for which such data are available from VHI.

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

Projected capital costs of the proposed project are reasonable, far less than recent projects that authorized the establishment of an MRI service in an existing facility. The proposal is projected to lose money the first year of operation but produce income in year two, according to the proforma provided (**Table 8**). No additional staffing is needed to operationalize the proposed project as SWIM states its existing staff will be trained in the proper use of the equipment and qualified and certified radiology services will be contracted through NationalRad.

	Year 1			Year 2		
Gross Revenue	\$	4,065,755	\$	4,914,906		
Charity Care	\$	182,958	\$	221,170		
Net Revenue	\$	3,882,797	\$	4,693,736		
Expenses	\$	3,924,965	\$	4,673,929		
Income/Loss	\$	(42,168)	\$	19,807		

Table 8. Proforma MRI, Scott Wagner Integrated Medicine

Source: COPN Request No. VA-8733

7. The extent to which the project provides improvements or innovations in the financing and delivery of health 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 services on an outpatient basis. (iii) Any cooperative efforts to meet regional health care needs. (iv) At the discretion of the Commissioner, any other factors as may be appropriate. The proposed MRI would be the only MRI in PD 10 capable of producing images of body parts in weight-bearing positions. This is the basis of SWIM's need for the proposed project. SWIM has not identified any other MRI scanners in Virginia, and certainly not in PD 10, that are capable of the weight-bearing images needed to identify the sources of pain in patients. DCOPN has identified one other scanner authorized in Virginia that will produce images in weight-bearing positions, but this MRI is over two hours away. It is unknown whether that MRI accepts referrals from outside the practice that owns and operates it.

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. (ii) Any contribution the teaching hospital or medical school may provide in the delivery, innovation, and improvement of health care for citizens of the Commonwealth, including indigent or underserved populations.

Not applicable. The applicant is not a teaching hospital associated with a public institution of higher education or a medical school in the area to be served.

DCOPN Staff Findings and Conclusions

The proposed project is the establishment of an MRI service with one MRI scanner in an existing chiropractic practice with a physician medical director. The proposed MRI is intended to take images of patients in weight-bearing positions for better visualization of the source of chronic pain. The proposal would improve access for a small segment of chronic pain and orthopedic patients in PD 10 that require this specific type of MRI imaging. DCOPN is satisfied that improved technology in lower field strength MRIs makes the proposed MRI capable of producing quality MRI scans for the purpose intended in the proposed project.

Projected capital costs of the proposed project are relatively low and the proposal is financially feasible in the long-term. The applicant states that the proposal requires no additional staffing but it is unclear whether the proposal meets the SMFP staffing requirement for physician oversight. The applicant proffers charity care at 4.5% of patient revenues, higher than the mean level of charity care provided in HPR I in 2022, the latest year for which an average has been calculated.

There is community support for the proposal as well as opposition from UVA Health. Provision of MRI imaging in PD 10 is highly concentrated with UVA Health, but the proposed project would not contribute in a meaningful way to alleviating this situation. The proposal is unlikely to impact MRI providers in PD 10 significantly. The proposal is not consistent with applicable standards and criteria of the State Medical Facilities Plan and the 8 Required Considerations of the Code of Virginia as there is a surplus of six MRI scanners in PD 10. The status quo is a reasonable alternative to the proposed project, though it unfortunately leaves a segment of patients with chronic pain without access to weight-bearing MRI imaging within PD 10.

DCOPN Staff Recommendations

The Division of Certificate of Public Need recommends **denial** of Scott Wagner Integrated Medicine, LLC's COPN Request No. VA-8733 to establish an MRI service with one MRI scanner capable of weight bearing imaging, located in its facility in Charlottesville, Virginia for the following reasons:

- The proposal to establish a specialized center for MRI imaging at Scott Wagner Integrated Medicine, LLC is not consistent with the applicable standards and criteria of the State Medical Facilities Plan and the 8 Required Considerations of the Code of Virginia as there is a surplus of six MRIs in PD 10.
- 2. It is unclear whether the proposal meets the staffing requirements of the SMFP.
- 3. The status quo is a reasonable alternative to the proposal.
- 4. There is documented opposition to the project.