

COMMONWEALTH of VIRGINIA

Karen Shelton, MD State Health Commissioner Department of Health
P O BOX 2448
RICHMOND, VA 23218

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

February 16, 2024

Mary E. Welch-Flores Program Manager, Business Intelligence Valley Health 220 Campus Boulevard, Suite 402 Winchester, Virginia 22601

RE: COPN Request No. VA-8724
Shenandoah Memorial Hospital
Planning District 7
Add One Fixed MRI Scanner

Dear Ms. Welch-Flores:

In accordance with Chapter 4, Article 1.1 of Title 32.1 of the Code of Virginia of 1950 (the Code), as amended, I reviewed the application and all supporting documents submitted by Shenandoah Memorial Hospital to expand magnetic resonance imaging (MRI) services through the addition of one fixed MRI scanner.

As required by Section 32.1-102.3B of the Code, I have considered all factors that must be taken into account in a determination of public need, and I have concluded that **conditional** approval of the request is warranted based on the following findings:

- 1. The proposal to expand MRI services through the conversion of one mobile MRI service to a fixed-site MRI service is generally consistent with the applicable standards and criteria of the State Medical Facilities Plan and the 8 Required Considerations of the Code of Virginia.
- 2. There does not appear to be any less costly alternative to the proposed project.
- 3. The capital costs of the proposed project are reasonable.
- 4. The proposed project is unlikely to have a significant negative impact upon the utilization, costs, or charges of other providers of MRI services in PD 7.
- 5. The proposed project appears to be financially viable in the immediate and long-term.

Ms. Mary E. Welch-Flores Shenandoah Memorial Hospital February 16, 2024 Page 2

6. There is no known opposition to the project.

This certificate is valid for the period February 16, 2024 through February 15, 2025. The total authorized capital cost of the project is \$4,996,000.

Please file two copies of the application for a certificate extension with the Department no later than 30 days before the expiration date of the certificate. Part VIII of the Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations identifies the filing requirements and review procedure for certificate extension requests.

Sincerely,

Karen Shelton, MD State Health Commissioner

Enclosure

cc: Allyson Tysinger, Senior Assistant Attorney General, Commonwealth of Virginia Erik Bodin, Director, Division of Certificate of Public Need Deborah K. Waite, Chief Operating Officer, Virginia Health Information Tara Blackley, BS, MBA, District Director, Lord Fairfax Health District



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

THIS CERTIFIES THAT Shenandoah Memorial Hospital is authorized to initiate the proposal as described below.

NAME OF FACILITY: Shenandoah Memorial Hospital

LOCATION: 759 South Main Street, Woodstock, Virginia 22664

OWNERSHIP AND CONTROL: Valley Health System

the addition of one fixed MRI scanner. Capital costs authorized for this project total \$4,996,000. The project is expected to be SCOPE OF PROJECT: Convert existing mobile magnetic resonance imaging (MRI) services to a fixed-site MRI service through completed by the second quarter of 2025. This certificate is issued with the condition that appears on its reverse.



Pursuant to Chapter 4, Article 1:1 of Title 32.1, Sections 32.1-102.1 through 32.1-102.12 of the Code of Virginia (1950), as amended and the 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 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

Certificate Number: VA-04872

Date of Issuance: February 16, 2024

Expiration Date: February 15, 2025

Karen Shelton, MD, State Health Commissioner

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persons in an aggregate amount equal to at least 1.92% of Shenandoah Memorial Hospital's total patient services revenue 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 Shenandoah Memorial Hospital will provide magnetic resonance imaging (MRI) services to all persons in need of this service, regardless of their ability to pay, and will provide as charity care to all indigent persons free services or rate reductions in services and facilitate the development and operation of primary care services to medically underserved derived from MRI services as 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. Compliance with this condition will be documented to the Division of Certificate of Public Need annually by providing audited or Shenandoah Memorial Hospital will accept a revised percentage based on the regional average after such time regional from Virginia Health Information. 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 otherwise appropriately certified financial statements documenting compliance with the preceding requirement. reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq.

U.S.C. § 1071 et seq. Additionally, Shenandoah Memorial Hospital will facilitate the development and operation of Shenandoah Memorial Hospital will provide MRI 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 primary and specialty medical care services in designated medically underserved areas of the applicant's service area.



January 22, 2024

VIA EMAIL (Erik.Bodin@vdh.virginia.gov)
Erik Bodin, III, Director
Division of Certificate of Public Need
Virginia Department of Health
9960 Mayland Drive, Suite 401
Richmond, VA 23233

RE: COPN Request No. VA-8724

Shenandoah Memorial Hospital, Woodstock, VA

Add One Fixed MRI scanner

Dear Mr. Bodin:

Shenandoah Memorial Hospital, (the "Hospital") is in receipt of the Division of Certificate of Public Need (DCOPN) staff report for COPN Request No. VA-8724, dated January 19, 2024. The DCOPN recommended conditional approval of the above-referenced project, subject to the charity care condition outlined in the staff report. I am writing to confirm that the Hospital agrees to the DCOPN's recommended charity care condition of 1.9%.

With this condition, the Hospital accepts the DCOPNs recommendation in full. I appreciate your office's assistance with this project. If you have any questions or require additional information, please contact Mary Welch-Flores, Program Manager, at (540) 536-2504.

Sincerely,

N. Travis Clark

Vice President, Valley Health

N. Travis Clark

President, Shenandoah Memorial Hospital

cc: Mary Welch-Flores, Program Manager, Valley Health

NTC/mew



Karen Shelton, MD State Health Commissioner Office of Licensure and Certification

TYY 7-1-1 OR
1-800-828-1120

9960 Mayland Drive, Suite 401
Henrico, Virginia 23233-1485

Fax (804) 527-4502

January 19, 2024

Mary E. Welch-Flores Program Manager, Business Intelligence Valley Health 220 Campus Blvd., Suite 402 Winchester, Virginia 22601

RE: COPN Request No. VA-8724
Shenandoah Memorial Hospital
Planning District 7
Add One Fixed MRI Scanner

Dear Ms. Welch-Flores:

For your consideration, I enclose the Division of Certificate of Public Need (DCOPN) report and recommendation on the above referenced project. DCOPN is recommending conditional approval of this application for the reasons listed in the attached staff report.

If Shenandoah Memorial Hospital is willing to accept the recommendation for conditional approval of this project, please provide documentation of this acceptance no later than January 23, 2024. If not willing to accept, before the State Health Commissioner makes her decision on this project, the Department will convene an informal-fact-finding conference (IFFC) pursuant to Title 2.2 of the Code of Virginia. This IFFC has been scheduled for Friday, February 2, 2024 beginning at 10:00 a.m. in Board Room 4 of the Perimeter Center located at 9960 Mayland Drive in Henrico, Virginia. A copy of the procedures for conduct at IFFCs may be found at http://www.vdh.virginia.gov/OLC/copn/

Persons wishing to participate in an IFFC have four days from the date of this letter to submit written notification to the State Health Commissioner, DCOPN and the applicant stating a factual basis for good cause standing. If no person has submitted written notification stating grounds and providing a factual basis for good cause standing and Shenandoah Memorial Hospital accepts the conditional approval, DCOPN will then notify you of the cancellation of the scheduled IFFC. DCOPN would then anticipate action by the State Health Commissioner within a few weeks of transmission.

DIRECTOR (804) 367 2102 ACUTE CARE (804) 367 2104

COPN (804) 367-2126



COMPLAINTS 1-800-955-1819 LONG TERM CARE (804) 367-2100

Ms. Mary Welch-Flores COPN Request No. VA-8724 January 19, 2024 Page 2

Should you have questions or need further clarification of this report and/or its recommendations, please feel free to call me at (804) 367-1889 or email me at Erik.Bodin@VDH.Virginia.Gov.

Sincerely

Hik Bodin, Director

Division of Certificate of Public Need

Enclosures

cc: Vanessa MacLeod, J.D., Office of Adjudication, Virginia Department of Health

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-8724

Shenandoah Memorial Hospital

Woodstock, Virginia

Expand MRI Services through the addition of One Fixed MRI Scanner

Applicant

Shenandoah Memorial Hospital (SMH) is a 25-bed, critical access hospital located at 759 South Main Street, Woodstock, Virginia 22664, located within Planning District (PD) 7, further nested within Health Planning Region (HPR) I. SMH is a 501(c)3, not-for-profit hospital that is wholly owned by Valley Health System. SMH's only subsidiary is the Shenandoah Memorial Hospital Foundation.

Background

Population and Demographics

PD 7 is generally rural and is projected to make up 2.84% of the statewide population in 2030 (Table 1). Between 2020 and 2030, the PD 7 population is projected to grow by approximately 4.33%, slightly less than the statewide average growth of 5.30% anticipated for the same period (Table 1). Between 2020 and 2030 the aged 65+ cohort is anticipated to grow from 45,093 to 57,841 persons, or a growth rate of 20.43% (Table 1). The PD 7 65+ population growth is slightly less than the statewide projection of 21.52% (Table 1). Taking note of the 65+ cohort growth rate is pertinent as this population group typically uses health care resources, including magnetic resonance imaging (MRI) diagnostic services, at a rate much higher than those individuals under the age of 65.

Table 1. PD 7 Population Data

Geography Name	2010	2020	% Change 2010-2020	2030	% Change 2020-2030	2020 65+	2030 65+	% Change 2020-2030 65+
Clarke County	14,034	14,783	5.07%	15,309	3.44%	3,026	3,941	23.21%
Frederick County	78,305	91,419	14.34%	103,035	11.27%	15,622	21,735	28.12%
Page County	24,042	23,709	-1.40%	23,041	-2.90%	5,139	5,969	13.91%
Shenandoah County	41,993	44,186	4.96%	45,714	3.34%	10,198	11,893	14.25%
Warren County	37,575	40,727	7.74%	43,250	5.83%	6,596	8,795	25.01%
Winchester city	26,203	28,120	6.82%	29,606	5.02%	4,512	5,508	18.08%
PD 7 Totals/Averages	222,152	242,944	6.25%	259,956	4.33%	45,093	57,841	20.43%
Virginia, Statewide	8,001,024	8,644,727	7.45%	9,129,002	5.30%	1,352,448	1,723,382	21.52%

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

Table 2.	PD 7	Poverty	Rates	2022	&	Percentage	of	Total P	opulation
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Geography Name	Poverty Rate	% of Total PD 7 Population*
Clarke County	5.8%	5.9%
Frederick County	6.6%	39.6%
Page County	12.3%	8.6%
Shenandoah County	11.4%	17.6%
Warren County	10.9%	16.6%
Winchester city	13.3%	11.4%
PD 7 Totals/Averages	10.0%	100.0%
Virginia, Statewide	10.6%	N/A

Sources: U.S. Census Bureau

The average statewide poverty rate in Virginia is 10.6% (Table 2). The average PD 7 poverty rate is 10.0% (Table 2) and the weighted average (based on percentage of PD 7 population) for PD 7 is 9.4%. The PD 7 poverty rate, whether an average or weighted average, is similar to that of Virginia as a whole. SMH's primary service area is in Shenandoah County, and its secondary service areas include Warren and Page counties. All three of these counties have poverty rates greater than the PD 7 average and the statewide average (Table 2).

SMH is a critical access hospital (CAH); CAH is a federal designation to adjust Medicare reimbursement to assist rural hospitals in maintaining quality access to primary and emergency healthcare services, offering adequate healthcare services that meet the needs of the community citizens (such as radiology, laboratory services, outpatient rehab, and surgery), and assisting the financial viability of small rural hospitals through enhanced reimbursements.¹

Magnetic Resonance Imaging

An MRI is a noninvasive medical imaging test that produces detailed images of almost every internal structure in the human body, including organs, bones, muscles, and blood vessels; the images are created using a large magnet and radio waves, and no radiation is produced.² An MRI may be used instead of a CT scan when organs or soft tissue are being studied as MRI is better at distinguishing between types of soft tissues and normal and abnormal soft tissues.³

The procedure data in **Table 3** is derived from information reported to Virginia Health Information (VHI). The average utilization per scanner using the State Medical Facilities Plan (SMFP) threshold of 5,000 procedures per fixed scanner is 97.9% (**Table 3**); however, fixed utilization calculations are made using only the fixed-site units in the PD. Excluding the three mobile units during the 2021 reporting period, the average utilization per fixed-site scanner for 2021 was 136.4% per scanner in PD 7. The SMFP also provides a threshold of 3,000 procedures for a mobile unit to become a fixed site unit; SMH performed 1,381 procedures in 2021 (**Table 3**), or 46.0% of the 3,000-procedure threshold.

3 Ibid.

^{*2030} Projected

¹ https://www.vdh.virginia.gov/health-equity/critical-access-hospitals-cah/

² https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/magnetic-resonance-imaging-mri

Table 3. PD 7 MRIs and 2021 SMFP Utilization

Facility	Number of MRIs	Mobile/Fixed	Total Procedures	Utilization per Scanner
Valley Health Page Memorial Hospital	1	Mobile	690	13.8%
Valley Health Shenandoah Memorial Hospital	1	Mobile	1,381	27.6%
Valley Health Warren Memorial Hospital	1	Fixed ¹	2,982	59.6%
Valley Health Winchester Medical Center	3	Fixed	25,844	172.3%
Valley Open MRI – Medical Circle (Valley Health)	1 .	Fixed	1,671	33.4%
Winchester Imaging	1	Fixed	6,588	131.8%
Totals/Averages	8	2 Mobile, 6 Fixed	39,156	97.9%

Sources: DCOPN Records and VHI 2021 Data

¹During the 2021 reporting period, Valley Health Warren Memorial Hospital's MRI was a mobile unit. COPN No. VA-04726, issued November 20, 2020, and was completed on January 14, 2022.

Illustrated in Figure 1 are the VHI data from years 2013-2021, and the applicant-reported data for 2022 and 2023; the 2023 data was annualized by the applicant from procedure volumes between January 2023 and June 2023. Following the Covid-19 pandemic between 2021 and 2022, SMH experienced an increase of procedures from 1,386 to 2,353; this is a 59% increase in procedure volumes in one year. In 2023, SMH has seen another increase in procedure volumes to 2,588 procedures. The orange line in Figure 1 shows the anticipated procedure volumes forecast using the past 10 years' data. The yellow and grey lines in Figure 1 represent the upper and lower confidence intervals (within 95% confidence). While 2024 may see a decrease in volumes, it is reasonable to expect the volumes to continue to increase over the long-term. The Pro Forma included in the application projects a total MRI volume of 6,687 by 2033.

Figure 1. SMH 2013-2023 (Annualized) Procedure Data and Forecasting



Source: DCOPN Data, VHI Data, and COPN Request No. VA-8724

Final- 2nd Quarter 2023

Proposed Project

SMH is proposing to convert its existing mobile MRI to a fixed unit at the SMH facility. The site is presently zoned for healthcare use and is connected to operable and adequate utilities. The project will require an addition and renovation of 5,900 square feet of space adjacent to the laboratory suite in SMH. The total capital cost is projected to be \$4,996,000, 100% of which is to be paid through SMH cash reserves. Of the total capital cost, 53% (or \$2,643,000) is allocated to direct construction costs and 40% (or \$2,000,000) is allocated to equipment not included in the construction contract.

The following timeframes are projected for the project:

Date of Drawings: Preliminary- 1st Quarter 2023

Date of Construction: Begin-3rd Quarter 2024 Completion-1st Quarter 2025

Target Opening: 2nd Quarter 2025

Project Definition

Section 32.1-102.1:3 of the Code of Virginia defines a project, in part, as the "addition by an existing medical care facility described in subsection A[, to include a]ny facility licensed as a hospital[,] of ... magnetic resonance imaging (MRI) ..."

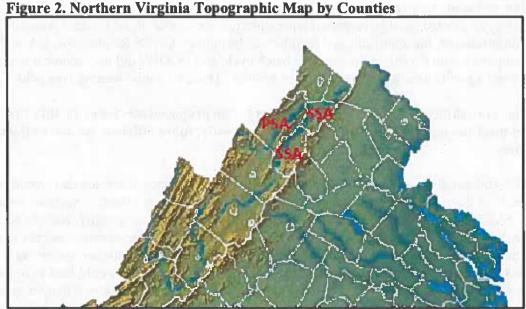
Required Considerations - § 32.1-102.3, of the Code of Virginia

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

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 hospital site is accessible by Interstate 81 and Route 11. The location provides adequate access for patients, visitors, staff, and emergency medical vehicles. Additionally, SMH has a helipad located near the emergency department for receiving and dispatching emergency air transports. Many of the SMH patients reside in rural, mountainous communities where the topography and smaller roadways can make transportation difficult for older adults and during times of inclement weather.

Depicted in Figure 2 is a segment of northern Virginia's topography and county lines. SMH's primary service area (PSA) is Shenandoah County, while its secondary service areas (SSA) are Warren and Page Counties (top SSA and bottom SSA, respectively) (Figure 2). While not as mountainous as the Appalachian range to the western portion of the map, SMH's PSA and SSAs are located in the Shenandoah Valley, which has mountainous areas with more difficult terrain and severe impacts during weather (such as heavier snow, icing, and flash flooding). As a CAH, having a fixed site MRI unit with more study capabilities would reduce the need for patients residing in these counties to drive even farther through the more difficult terrain to seek services.



Sources: geology.com & COPN Request No. VA-8724

- 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 no letters of opposition and 16 letters of support for the proposed project from local residents, community leaders (to include the Woodstock, Virginia mayor), and the Valley Health medical community. Collectively, these letters articulate several benefits of the project, including:

- The population is growing, increasing the demand for imaging services.
- Local residents have been driving to other cities for care due to the long wait times, which is not convenient or efficient. The project would allow residents to receive MRI imaging needs in their home community.
- Residents depend on this community hospital for care.
- SMH has been "... a vital asset to [the] community for nearly seven decades and this area depends on the excellent services provided at SMH for their healthcare needs. Their presence and the services they provide enhance the quality of life for [the] residents and make [Shenandoah County] a more attractive community when attracting additional businesses and industry in Shenandoah County."

Section 32.1-102.6 B of the Code of Virginia directs DCOPN to hold one public hearing on each application in a location in the county or city in which the project is proposed or a

⁴ Support Letter from Director of Tourism & Economic Development, Chair of the SMH Hospital Foundation, Jenna French

contiguous county or city in the case of competing applications, or in response to a written request by an elected local government representative, a member of the General Assembly, the Commissioner, the applicant, or a member of the public. COPN Request No. VA-8724 is not competing with another project in this batch cycle and DCOPN did not receive a request to conduct a public hearing for the proposed project. Thus, no public hearing was held.

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

DCOPN did not discover any reasonable alternatives to the proposed service that would meet the needs of the population in a less costly, more efficient, or more effective manner. As a CAH, SMH is a fundamental medical care hub for the rural PD 7 community. Having access to a wider range of MRI study capabilities as well as the potential for emergent access to an MRI unit can potentially lead to reduced costs for patients and the healthcare system as a whole as the care and transportation to care would be less fragmented, would lead to more efficient delivery of care involving MRI imaging needs, and would be more effective as the study capabilities would be greater than that of the currently implemented mobile MRI unit.

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

(iv) Any costs and benefits of the project.

The total capital cost of the project is \$4,996,000, 100% of which is to be paid through SMH's cash reserves. An 0.9 full time equivalent (FTE) staffing addition will result from the project for an MRI technician; no other staffing needs will result from the project. The applicant asserts that the MRI scanner being chosen will be able to perform additional imaging studies that the mobile MRI they are contracted with can perform. Moreover, the project will benefit timeliness and ease of access for patients in the local community as the hours of availability will be increased and the need to travel for special studies or faster procedures will not be necessary.

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

The applicant has provided assurances that MRI services will be accessible to all patients, regardless of financial considerations. In 2021, the most recent data available, SMH reports 0.78% of their gross revenues to be charity, which is less than the average of HPR I of 1.92%, and is slightly less than the inpatient hospital mean for HPR I of 0.90%. Recent changes to §32.16-102.4B of the Code of Virginia now require DCOPN to place a charity

care condition on all applicants seeking a COPN. For this reason, DCOPN recommends that the proposed project, if approved, be subject to a 1.92% charity care condition, to be derived from total MRI gross patient services revenues, consistent with the HPR I average. DCOPN's recommendation includes a provision allowing for the reassessment of the charity care rate at such time as more reliable data becomes available regarding the full impact of Medicaid expansion in the Commonwealth.

Health Planning Region I 2021 Charity Care Contributions at or below 200% of Federal Poverty Level							
UVA Transitional Care Hospital	\$	53,021,859	\$3,256,725	6.14%			
Encompass Health Rehab Hosp of Fredericksburg	\$	42,215,195	\$1,984,765	4.70%			
Culpeper Regional Hospital	\$	445,240,580	\$15,076,533	3.39%			
University of Virginia Medical Center	\$	6,669,433,774	\$198,965,329	2.98%			
Sentara RMH Medical Center	\$	993,414,446	\$18,657,804	1.88%			
Carilion Rockbridge Community Hospital	\$	180,498,750	\$2,600,213	1.44%			
Sentara Martha Jefferson Hospital	\$	825,488,467	\$11,009,327	1.33%			
UVA Encompass Health Rehabilitation Hospital	S	36,000,152	\$373,808	1.04%			
Stafford Hospital Center	S	337,420,833	\$3,079,852	0.91%			
Augusta Health	\$	1,232,396,858	\$10,863,652	0.88%			
Page Memorial Hospital	\$	75,441,642	\$592,000	0.78%			
Shenandoah Memorial Hospital	\$	150,943,059	\$1,183,240	0.78%			
Mary Washington Hospital	\$	1,548,595,215	\$11,288,574	0.73%			
Winchester Medical Center	\$	1,541,736,262	\$10,319,447	0.67%			
Spotsylvania Regional Medical Center	\$	681,942,940	\$4,520,886	0.66%			
Fauquier Hospital	\$	462,729,762	\$2,463,787	0.53%			
Warren Memorial Hospital	\$	196,713,548	\$977,784	0.50%			
Bath Community Hospital	\$	25,547,880	\$73,591	0.29%			
Total Inpatient Hospitals:				18			
HPR I Inpatient Hospital Median		X - 1 - 2 -		0.90%			
HPR I Total Inpatient \$ & Mean %	\$	15,498,781,222	\$ 297,287,317	1.92%			

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

DCOPN did not identify any other discretionary factors, not discussed elsewhere in this staff analysis report, to bring to the attention of the Commissioner as may be relevant in determining a public need for the proposed 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, by November 1, 2022, recommendations for a comprehensive State Health Services Plan (SHSP). In the interim, these regulations provide the best available criteria and DCOPN will consider the consistency of the proposed project with the predecessor of the SHSP, the State Medical Facilities Plan (SMFP).

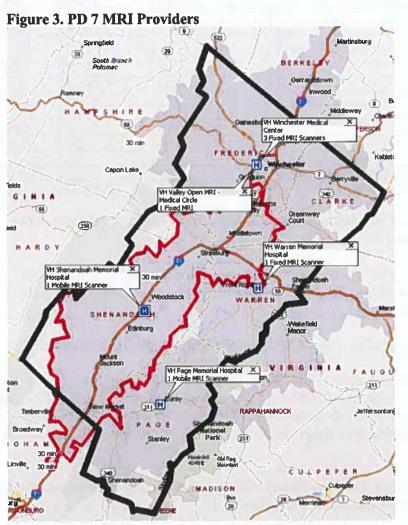
Part II, Article 2 of the State Medical Facilities Plan (SMFP) contains the standards and criteria for the establishment of diagnostic services. They are as follows:

Part II. Diagnostic Imaging Services Article 2. Criteria and Standards for Magnetic Resonance Imaging 12VAC5-230-140. Travel time.

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

The vast majority of the PD 7 population clusters around the towns and major thoroughfares, all of which have access to MRI services within a 30-minute driving distance as depicted by the shaded grey area of the map in Figure 3. Considering the areas uncovered by the grey shading in Figure 3 are very rural and not densely populated, it is reasonable to assume that approximately 95% of the PD 7 population is within the 30-minute driving distance threshold delineated by the SMFP.

The red outline in Figure 3 illustrates the 30-minute driving distance radius from SMH. The project will not add coverage for patients within the red boundary; however, it would increase the amount of time MRI services are available and the types of studies that can be done within this boundary.



Sources: DCOPN Records, Google Maps, and Microsoft Streets & Trips

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.

While the applicant is not proposing a new fixed site service, but rather a conversion of a mobile site to a fixed site, DCOPN has conducted the following calculations to provide the Commissioner with an overall picture of MRIs and their utilization within PD 7.

In the <u>Background</u>, <u>Magnetic Resonance Imaging</u> section of the staff report, DCOPN provided the following information:

- Using the 2021 VHI data and all MRIs, the average utilization in PD 7 is 97.9% per MRI scanner with regard to the 5,000 procedures per scanner threshold (**Table 3**).
- Considering only the five units that were fixed-site scanners during the 2021 reporting period, the average utilization was 136.4% per scanner with regard to the 5,000 procedures per scanner threshold (**Table 3**).
- The fixed unit at Valley Health Warren Memorial Hospital (WMH) was a mobile unit during the 2021 reporting period; however, as of January 14, 2022, this unit has been operating as a fixed unit (Table 3).
- Using the WMH data provided in 2021 and the six fixed units at present (**Table 3**), calculating the fixed unit utilization yields a rate of 123.6%.

With a total of 39,156 MRI procedures in PD 7 in 2021 and a 5,000 MRI procedure threshold per the SMFP, PD 7 needs 8 fixed MRI scanners. Using 2021 data, PD 7 has access to 8 scanners, 6 of which are fixed units and 2 of which are mobile units.

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.

This provision of the SMFP is not applicable as the applicant is not proposing to expand an existing fixed-site 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.

This provision is not applicable as the applicant is not proposing to add or expand a mobile MRI site.

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.

The relevant reporting period consists of data from 2021, whereby SMH performed 1,386 procedures (much less than the 3,000 SMFP dictated threshold) (**Table 3, Figure 1**). However, in 2022, the applicant reports performing 2,353 MRI procedures and anticipates performing 2,588 MRI procedures in 2023 (**Figure 1**). **Figure 1** illustrates a forecast where SMH would perform roughly 3,000 procedures between 2027-2028 (but this could occur sooner or later).

Although the applicant does not presently meet the 3,000 procedures threshold, SMH being a CAH in a rural community with no fixed units within the 30-minute driving distance radius, the forecasted increase in procedure volume at SMH, and the capabilities of the proposed fixed unit compared to the presently utilized mobile unit are all important considerations when addressing this provision.

12VAC5-230-180. Staffing.

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

The applicant provides assurances that the MRI services will be under the direct supervision of one or more qualified physicians.

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.

The project would provide a fixed MRI service for patients within a 30-minute driving distance that would otherwise only have access to a mobile unit within that driving distance (Figure 3). While the additional study capabilities may reduce volumes slightly from other locations in the PD that offer them, SMH having the ability to perform these studies increases access in relatively isolated area that is not likely to have detrimental effects on other locations in the PD. Also of importance to note, Valley Health System is the owner of all the MRI service providers in PD 7; the addition of the proposed scanner is not likely to have an impact on institutional competition. Moreover, as a CAH, SMH having the ability to provide MRI services in a setting where patients on stretchers and those who have ambulation difficulties in an indoor setting would improve access and safety for the patients in the area to be served.

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.

Using the 5,000 procedures SMFP threshold, the average utilization per MRI scanner in PD 7 in 2021 was 97.9% (Table 3). Although the utilization is less than 100% including the mobile

scanners, using only the fixed scanners during 2021, the utilization was at 136.4% (**Table 3**). SMH is part of Valley Health System, which is the ultimate parent of the MRI service providers in PD 7. The utilization in the PD and the efficiency for providing services in a rural CAH both support approval of the proposed conversion of SMH's mobile MRI to a fixed site MRI service.

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.

The project would require a modest staffing need of 0.9 FTE. The total capital cost of the project is \$4,996,000, 100% of which is to be paid through accumulated reserves (**Table 4**). Of the total capital cost, 52.9% is allocated to the direct construction cost and 40.0% is allocated for the equipment not included in the construction contract (**Table 4**). The total capital cost is slightly higher than the following two projects of similar size and scope (adjusted for inflation):

- COPN No. VA-04801, authorizing Riverside Hospital, Inc. to add one MRI with a total capital cost of \$4,583,647 (\$4,761,626⁵ when adjusted for inflation) on August 22, 2022.
- COPN No. VA-04753, authorizing Chippenham & Johnston-Willis Hospitals, Inc. to add one MRI with a total capital cost of \$3,701,138 (\$4,162,5386 when adjusted for inflation) on August 16, 2021.

Although the total capital cost is higher than the projects described above, the cost of construction has been increasing substantially since the COVID-19 pandemic started and following the aftermath of the pandemic. With this in mind, the total capital cost of the project, which includes an addition for the MRI to be housed, appear reasonable.

⁵ Calculated using the Consumer Price Index (CPI) calculator available by the Bureau of Labor Statistics. The most recent calculations available at the time of the writing of this staff report are for October 2023.

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⁷ Alsharef, Abdullah, Siddharth Banerjee, S M Jamil Uddin, Alex Albert, and Edward Jaselskis. 2021. "Early Impacts of the COVID-19 Pandemic on the United States Construction Industry" International Journal of Environmental Research and Public Health 18, no. 4: 1559. https://doi.org/10.3390/ijerph18041559

Table 4. Total Capital Cost Summary

Direct Construction Costs Sub-total Equipment included in the construction contract	\$2,643,000 \$2,643,000
Equipment Not Included in the Construction Contract Sub-total	\$2,000,000
Major Medical Equipment	\$1,727,000
Information Systems	\$237,000
Furniture	\$36,000
Architectural and Engineering Fees Sub-total	\$237,000
Architect's Design Fees	\$237,000
Other Consultant Fees Sub-total	\$56,000
Legal Fees/Insurance	\$12,000
COPN Application Fee	\$20,000
Testing & Commissioning	\$24,000
Total Capital Cost	\$4,996,000

Source: COPN Request No. VA-8724

While the first year of operation (of the incremental addition of MRI scans) is anticipated to yield a loss of \$244,173, the second year of operation is expected to result in a profit of \$55,992, and the third year is projected to see a profit of \$483,897 (**Table 5**). The overall MRI services program is anticipated to see a gain of \$5,157,899 in 2033 (**Table 5**). The project appears to be financially viable of the short and long-term.

Table 5. Pro Forma Summary

	Current MRI Program FY2023 Projected	Incremental MRI 2026	Incremental MRI 2027	Incremental MRI 2028	Projected MRI Program 2033
MRI Procedures	4,077	148	1,094	1,570	6,687
Total Operating Revenue	\$4,070,872	\$126,649	\$1,190,342	\$1,773,750	\$7,511,997
Total Operating Expenses	\$727,068	\$370,821	\$1,134,351	\$1,289,853	\$2,254,098
Income from Operations	\$3,343,804	(\$244,173)	\$55,992	\$483,897	\$5,157,899

Source: COPN Request No. VA-8724

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 project would not bring new technology to the PD, but it would introduce an indoor, easily accessible by stretcher and patients with mobility difficulties, setting for MRI services to a CAH in rural PD 7. The MRI services would be in an acute care setting, making the cost-effectiveness for procedures the same, but the benefit to patients in the area who rely on the CAH for their healthcare needs is paramount. The services would also continue to be provided on an outpatient basis. The quality and ability for additional studies to be performed

closer to their homes (reducing travel in an area where travel can be difficult) would be increased. The proposed unit will be able to scan patients needing a higher level of monitoring, such as pulse/oxygen, heart rate, etc. that they are not able to provide on the mobile unit currently in use. Additionally, the new unit would be able to scan patients with breast implants that must currently be transferred (which creates higher costs for patients and the healthcare system). DCOPN did not identify any other discretionary factors, not discussed elsewhere in this staff analysis report, to bring to the attention of the Commissioner as may be relevant in determining the extent to which the project provides improvements or innovations in the financing and delivery of health services.

- 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 affiliated with a teaching hospital associated with a public institution of higher education or a medical school in the area to be served.

DCOPN Staff Summary and Findings

The PD 7 population and the 65+ portion of the population between 2020 and 2030 are growing at a rate slightly less than the statewide averages, but they are still growing (**Table 1**). The 65+ population in PD 7 is growing nearly five times faster than the overall PD 7 rate between 2020 and 2030 (**Table 1**). The PSA and SSA for SMH are all experiencing poverty at a higher rate than the PD 7 and statewide averages (**Table 2**).

SMH is a CAH providing critical healthcare services for residents of a rural community. Despite providing services in a rural community, the 2023 annualized SMH MRI volumes are 86.3% of the SMFP threshold of 3,000 scans per unit for conversion of a mobile to a fixed unit (Figure 1). Furthermore, projections by both the applicant and Excel Forecasting indicate a reasonable increaser in MRI procedures in the future at SMH (Figure 1).

In 2021, the average utilization per scanner was 97.9% based upon the SMFP 5,000 procedures per scanner threshold (**Table 3**). The utilization per fixed scanner in 2021 was 136.4%, while the utilization per fixed scanner available in 2023 using the 2021 procedure volumes was 123.6% (**Table 3**).

The total capital cost is slightly higher than the inflation-corrected total capital cost for two projects of similar size and scope; however, the COVID-19 pandemic has created an exponential increase in construction costs. The total capital cost for the project considering inflation is reasonable. Additionally, 0.9 FTE staff is needed for the project; this is not likely to have a substantial effect on other area MRI service providers.

There was no opposition to the project and 16 letters of support from residents, community leaders, and the Valley Health medical community. DCOPN did not identify any reasonable alternatives to the proposed project that would meet the needs of this rural, relatively geographically isolated community in a less costly, more efficient, or more effective manner.

Approximately 95% or more of the PD 7 population has access to MRI services; the proposed project would not increase access to MRI services in general, but it would increase fixed-site, indoor, easily accessible by stretcher and those with mobility difficulties, MRI services for those in a 30-minute driving distance radius of SMH (Figure 3). The project would not add additional MRI services, but rather would convert one mobile service to a fixed-site service.

DCOPN Staff Recommendations

COPN Request No. VA-8724 - Shenandoah Memorial Hospital

The Division of Certificate of Public Need recommends the **conditional approval** of this project for the following reasons:

- 1. The proposal to expand MRI services through the conversion of one mobile MRI service to a fixed-site MRI service is generally consistent with the applicable standards and criteria of the State Medical Facilities Plan and the 8 Required Considerations of the Code of Virginia.
- 2. There does not appear to be any less costly alternative to the proposed project.
- 3. The capital costs of the proposed project are reasonable.
- 4. The proposed project is unlikely to have a significant negative impact upon the utilization, costs, or charges of other providers of MRI services in PD 7.
- 5. The proposed project appears to be financially viable in the immediate and long-term.
- 6. There is no known opposition to the project.

Charity Conditions

DCOPN's recommendation is contingent upon Shenandoah Memorial Hospital's agreement to the following charity care condition:

Shenandoah Memorial Hospital will provide magnetic resonance imaging (MRI) services to all persons in need of this service, regardless of their ability to pay, and will provide as charity care to all indigent persons free services or rate reductions in services and facilitate the development and operation of primary care services to medically underserved persons in an aggregate amount equal to at least 1.92% of Shenandoah Memorial Hospital's total patient services revenue derived from MRI services as 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. 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. Shenandoah Memorial Hospital 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 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.

Shenandoah Memorial Hospital will provide MRI 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, Shenandoah Memorial Hospital will facilitate the development and operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area.