COMMONWEALTH of VIRGINIA

Department of Health

Office of Licensure and Certification

M. Norman Oliver, MD, MA
State Health Commissioner

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July 20, 2020

Ms. Mary Welch-Flores
Business Development Manager
Valley Health
220 Campus Boulevard, Suite 210
Winchester, Virginia 22601

RE: **COPN Request No. VA-8502**
Warren Memorial Hospital, Front Royal, Virginia
Add one fixed MRI scanner and one fixed CT Scanner

Dear Ms. Welch-Flores:

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

If Warren Memorial Hospital is willing to accept the recommendation of conditional approval regarding the addition of a CT unit portion of this project, please provide documentation of this acceptance *no later than* **July 24, 2020**.

Irrespective of Warren Memorial Hospital's acceptance of the recommendation of conditional approval regarding the addition of a CT unit portion of this project, because a recommendation of denial was made regarding the converstion of a mobile MRI service to a fixed site serice portion, Warren Memorial Hospital is a party to the informal-fact-finding-conference (IFFC) scheduled pursuant to Section 2.2 of the Code of Virginia. This IFFC is scheduled for Monday, August 3, 2020 beginning at 1:00 p.m. in Board Room 3 of the Perimeter Center located at 9960 Mayland Drive in Henrico, Virginia.

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. 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,

Erik Bodin, Director
Division of Certificate of Public Need

Enclosures

cc: Douglas R. Harris, 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

July 20, 2020

RE: COPN Request No. VA-8502
Warren Memorial Hospital
Front Royal, Virginia
Add one fixed MRI scanner and one fixed CT scanner

Applicant

Warren Memorial Hospital, Inc., (WMH) is a 501(C)(3) nonstock corporation. The hospital is located in the town of Front Royal in Warren County, Virginia Planning District (PD) 7, Health Planning Region (HPR) I. WMH is wholly owned by Valley Health System (VHS), a Virginia nonstock, not-for-profit corporation located in Winchester, Virginia.

Background

WMH operates a 68-bed inpatient acute care hospital in Front Royal, Virginia. WMH offers a comprehensive range of medical services and care including advanced surgical services, elderly care, diagnostic services, rehabilitation services, and skilled nursing assistance. In early 2021, WMH will open its new replacement hospital pursuant to COPN No. VA-04602. With regard to diagnostic services specifically, WMH currently offers Computed Tomography (CT) services using one fixed-site CT unit and Magnetic Resonance Imaging (MRI) services using one mobile MRI unit.

Computed Tomography (CT) Scanners at WMH and in PD 7
According to the 2018 Virginia Health Information (VHI) data, the most recent year for which such data is available, there were eight COPN authorized CT units in PD 7 in 2018 (**Table 1**). More specifically, WMH operated one CT unit for this period. DCOPN notes that in addition to the eight CT scanners reported by VHI, an additional two CT units were added to the PD 7 inventory subsequent to 2018. COPN No. VA-04699 authorized the addition of one intraoperative CT unit at Winchester Medical Center and is expected to become operational on September 30, 2020. COPN No. VA-04594 authorized the addition of a fifth CT unit at Winchester Medical Center and is expected to become operational on March 3, 2021. DCOPN notes that the volume for the additional machines is not included in **Table 1** below, as the units are not yet operational and this data is not available.

Table 1. COPN Authorized CT Units in PD 7: 2018

Hospital Based Facility	Units	Procedures	Procedures/ Unit	Utilization
Valley Health Page Memorial Hospital	1	3,592	3,592	48.5%
Valley Health Shenandoah Memorial Hospital	1	7,542	7,542	101.9%
Valley Health Warren Memorial Hospital	1	8,365	8,365	113.0%
Valley Health Winchester Medical Center*	4	41,455	10,361	140.0%
Hospital Based TOTAL and Average	**9**[1]	**60,954**	**8,708**	**117.7%**
Freestanding Facility				
Winchester Imaging	1	6,648	6,648	89.8%
Grand TOTAL and Average	**10**[2]	**67,602**	**8,450**	**114.2%**

Source: VHI (2018) and DCOPN records
Note: Italics denotes critical access hospital
*One intraoperative CT unit added pursuant to COPN No. VA-04699, issued on February 18, 2020; Fifth CT unit added pursuant to COPN No. VA-04594, issued on March 6, 2018.

Magnetic Resonance Imaging (MRI) Scanners at WMH and in PD 7

COPN No. VA-03715, issued in 2002, authorized the introduction of MRI services by use of a shared mobile service at WMH. The applicant's original mobile MRI vendor serviced WMH on Mondays and Thursdays from 8:00 a.m. until 11:00 p.m. and on every third Saturday with one-hour time slots available between 8:00 a.m. and 4:00 p.m. However, over the past year, WMH has added a second mobile MRI unit in an effort to alleviate some of the scheduling constraints it currently experiences. At this time, WMH patients have access to a mobile MRI five days per week (Monday through Friday). However, the applicant states that due to the nature of a mobile MRI, the service currently is not available 24/7; therefore, limitations still exist for patients that may arrive in the emergency room requiring MRI services. In the event that a patient arrives to the emergency room and needs an MRI scan after hours, they are transferred to Winchester Medical Center. The applicant states that this delays services to the patient and creates additional costs. Accordingly, the applicant asserts that maintaining the status quo is not practical, operationally efficient, or consistent with the industry standard of care. The applicant also states that despite adding a second mobile MRI service schedule, patient demand is not being met.

According to VHI data for 2018, there were eight COPN authorized MRI units in PD 7 in 2018. These MRI units include five fixed-site MRI units and three mobile MRI unit sites (**Table 2**). DCOPN notes that no additional MRI units have been added to the PD 7 inventory subsequent to 2018.

[1] Though not included in the overall calculations for occupancy, this number reflects the CT scanner and intraoperative CT scanner added at Winchester Medical Center pursuant to COPN Nos. VA-04594 and 04699.
[2] This number also reflects the CT scanner and intraoperative CT scanner added pursuant to COPN Nos. VA-04594 and 04699.

Table 2. COPN Authorized MRI Scanners in PD 7: 2018

Fixed MRI Units				
Hospital Based Facility	**Units**	**Procedures**	**Procedures/Unit**	**Utilization**
Valley Health Winchester Medical Center	3	12,663	4,221	84.4%
Freestanding Facility				
Valley Open MRI (Valley Health)	1	1,252	1,252	25.0%
Winchester Imaging	1	6,047	6,047	120.9%
Freestanding TOTAL and Average	**2**	**7,299**	**3,650**	**73.0%**
Fixed MRI TOTAL and Average	**5**	**19,962**	**3,992**	**79.8%**
Mobile MRI Sites				
Facility	**Sites**	**Procedures**	**Procedures/Unit**	**Utilization**
Valley Health Page Memorial Hospital	1	678	678	**28.2%**
Valley Health Shenandoah Memorial Hospital	1	1,114	1,114	**46.4%**
Valley Health Warren Memorial Hospital	1	1,081	1,081	**45.0%**
Mobile MRI TOTAL and Average	**3**	**2,873**	**2,873**	**39.9%**

Source: VHI (2018) and DCOPN records
Note: Italics denotes critical access hospital

DCOPN notes that WMH applied to convert its one mobile MRI to a fixed-site MRI in 2018 as part of its application to establish a replacement hospital (COPN Request No. VA-8349). DCOPN recommended, and the Commissioner upheld, denial regarding the MRI portion of that project, stating the following:

> "DCOPN finds that the proposed project is not consistent with the applicable criteria and standards of the State Medical Facilities Plan and the 8 Required Considerations of the Code of Virginia. 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 in question—WMH's mobile scanner utilization data falls well short of this minimum threshold. To clarify this point further, the sum total of mobile scans performed for the entirety of PD 7 in 2016 does not surpass the 3,000 procedure threshold, indicating that both the demand for, and utilization of mobile MRI scans, is quite low. In short, the projected utilization for WMH's fixed site scanner would approximate nearly one third of the suggested SMFP threshold for fixed MRI utilization. Furthermore, DCOPN acknowledges that reasonable alternatives, such as the status quo, do exist."

Proposed Project

WMH seeks approval to add one fixed CT unit to its existing inventory and to establish a fixed site MRI service through conversion of the existing mobile MRI service. If approved, both units will be located on the campus of WMH's new replacement hospital located at 351 Valley Health Way, Front Royal, Virginia.[3] The applicant anticipates that the new replacement hospital will open its

doors to patients in early 2021. The applicant anticipates construction for the proposed project to commence in July 2020 and to be complete by January 21, 2021. The applicant anticipates a target opening date of April 30, 2021. The projected capital costs of the proposed project total $3,771,844, the entirety of which will be funded using the accumulated reserves of the applicant. Accordingly, there are no financing costs associated with this project.

Table 3. WMH Projected Capital Costs

Direct Construction Costs	$1,276,000
Equipment Not Included in Contract	$2,311,644
Architectural and Engineering Fees	$139,200
Other Consultant Fees	$45,000
TOTAL Capital Costs	**$3,771,844**

Source: COPN Request No. VA-8502

Project Definition

Section 32.1-102.1:3 of the Code of Virginia defines a project, in new part, as the "addition by an existing medical are facility described in subsection A of any medical equipment for the provision of…computed tomographic (CT) scanning…magnetic resonance imaging (MRI)…" A medical care facility is defined, in part, as "Any facility licensed as a hospital, as defined in § 32.1-123…"

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

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

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

The proposed project will be located at the new replacement hospital located at 351 Valley Health Way in Front Royal. The applicant states that the location of the replacement hospital is "an ideal site, which will improve overall access to hospital services for residents in the WMH community." The replacement hospital site is easily accessible by Interstates 66 and 81, Routes 522 and 340, and by public bus transportation through the Front Royal Trolley. WMH also has a helipad for receiving and dispatching emergency air transports. Even though there is adequate and suitable highway access to the replacement hospital site, many of WMH's patients reside in rural areas located throughout the service area. The topography and two-lane highways that connect these communities to the major highways make travel more difficult and hazardous, and thus, lengthens commute times during periods of inclement weather. As will be discussed in more detail later in this staff analysis report, DCOPN concludes that at least 95% of the population of PD 7 is within 30 minutes' drive time, one way, under normal driving conditions of existing CT and MRI services. However, the applicant states that because the existing CT service operates at

[3] Replacement hospital authorized pursuant to COPN No. VA-04602.

maximum capacity, and because the existing mobile MRI schedule is insufficient to allow for the proper care of their patient population, patients frequently are required to receive CT and MRI scans elsewhere. The applicant states that in 2019, 118 patients were transferred to Winchester Medical Center to receive MRI scans and that accordingly, geographic access is not the factor that prevents residents in PD 7 from access to quality care. While DCOPN cannot quantifiably confirm this data, it notes that 118 patients is still a relatively small percentage (approximately 10%) of the total number of patients which received MRI scans at WMH in 2018.

Regarding socioeconomic barriers to access to services, the applicant has provided assurances that it would accept all patients in need of care without regard to ability to pay or payment source. Additionally, the Pro Forma Income Statement provided by the applicant proffered a charity care contribution equal to approximately 1% of gross patient services revenue derived from each CT and MRI services (reflected in the "Deductions from Revenue" line) (**Table 4**). DCOPN notes that this amount is significantly lower than both the 4.5% HPR I average reported by VHI for 2018 and the 3.77% contribution made by WMH for the same period (**Table 5**). Furthermore, DCOPN notes that pursuant to the recent changes 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 HPR I average, and equal to at least 4/5% of gross patient services revenue derived from CT and MRI services at WMH. DCOPN notes that its recommendation includes a provision allowing for the reassessment of the charity rate when ore reliable data becomes available regarding the full impact of Medicaid expansion in the Commonwealth.

Table 4. WMH Pro Forma Income Statement

CT	**2022**	**2023**
Gross Patient Services Revenue	$21,651,942	$22,209,239
Deductions from Revenue	$12,999,989	$13,334,595
Net Revenue	**$8,651,953**	**$8,874,644**
Operating Expenses	$1,828,384	$1,872,986
Net Income	**$6,823,568**	**$7,001,657**
MRI	**2022**	**2023**
Gross Patient Services Revenue	$7,352,280	$7,682,190
Deductions from Revenue	$3,886,654	$4,028,684
Net Revenue	**$3,465,626**	**$3,653,506**
Operating Expenses	$1,052,231	$1,078,157
Net Income	**$2,413,395**	**$2,575,349**

Source: COPN Request No. VA-8502

Table 5. HPR I Charity Care Contributions: 2018

Health Planning Region I 2018 Charity Care Contributions at or below 200% of Federal Poverty Level			
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, two localities within PD 7 (Page County and the City of Winchester) had poverty rates higher than the 10.7% statewide average (**Table 6**).

Table 6. Statewide and PD 7 Poverty Rates

Locality	Poverty Rate
Virginia	10.7%
Clarke	6.5%
Frederick	7.0%
Page	13.9%
Shenandoah	10.4%
Warren	10.3%
Winchester City	15.0%

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

The most recent Weldon-Cooper data projects a total PD 7 population of 265,817 persons by 2030 (**Table 7**). This represents an approximate 19.66% increase in total population from 2010 to 2030. Comparatively, Weldon-Cooper projects the total population of Virginia to increase by approximately 16.63% for the same period. With regard to the 65 and older age cohort in PD 7, Weldon-Cooper projects a much more rapid increase. Weldon-Cooper projects a PD 7 increase of approximately 76.81% among this age cohort from 2010-2030 (**Table 8**). With regard to Warren County specifically, a 17.24% increase in expected, the third largest in PD 7. This is significant,

as this age group typically uses health care services, including diagnostic imaging services, at a rate much higher than those under the age of 65.

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

Locality	2010	2020	% Change	2030	% Change	2010-2030 % Change
Virginia	8,001,024	8,655,021	8.17%	9,331,666	7.82%	16.63%
Clarke	14,034	14,509	3.38%	15,279	5.31%	8.87%
Frederick	78,305	90,115	15.08%	104,608	16.08%	33.59%
Page	24,042	23,838	(0.85%)	23,888	0.21%	(0.64%)
Shenandoah	41,993	43,233	2.95%	46,984	8.68%	11.89%
Warren	37,575	40,164	6.89%	44,053	9.68%	17.24%
Winchester City	26,203	28,804	9.92%	31,005	7.64%	18.32%
Total PD 19	**222,152**	**240,663**	**8.33%**	**265,817**	**10.45%**	**19.66%**

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

Table 8. PD 7 Population Projections for 65+ Age Cohort, 2010-2030

Locality	2010	2020	% Change	2030	% Change	2010-2030 % Change
Clarke	2,287	3,026	32.31%	3,941	30.24%	72.32%
Frederick	9,954	15,622	56.94%	21,735	39.13%	118.35%
Page	4,248	5,139	20.97%	5,969	16.15%	40.51%
Shenandoah	7,768	10,198	31.28%	11,893	16.62%	53.10%
Warren	4,780	6,596	37.99%	8,795	33.34%	84.00%
Winchester City	3,676	4,512	2.74%	5,508	22.07%	49.84%
Total PD 19	**32,713**	**45,093**	**37.84%**	**57,841**	**28.27%**	**76.81%**

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

2. The extent to which the 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 from medical professionals associated with Valley Health, local businesses, and the Warren County Department of Fire and Rescue Services. Collectively, these letters addressed the following:

- With the increased patient demand and expansion of the professional medical community, patients have experienced extended wait times and disruptions in care when seeking either MRI or CT scans. Additional capacity at WMH would alleviate these issues and allow patients to obtain comprehensive care in their home community.
- The addition of both MRI and CT equipment will enhance access and contribute to the broad complement of services available at WMH's replacement hospital.

- As the local population as continued to grow, the demand for imaging services has increased.
- Because of the growth in the area and the increased demand, patients often face extended wait times for imaging services and often address this by seeking care in other locales. While this is an inconvenience for the patient, travel can become a barrier for lesser socioeconomic groups in finding sufficient transportation. This is not only a potential roadblock to sufficient resources, but is disruptive to efficient delivery of care onsite.
- Approval of the proposed project will save resources in the Fire and Rescue Department from making unnecessary inter-facility transports out of county to Winchester Medical Center for these services.

DCOPN received no letters in opposition to the proposed project.

DCOPN conducted the required public hearing on June 25, 2020. A total of 13 individuals signed in, seven of which elected to speak in support of the proposed project. No individual indicated opposition to the proposed project.

(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, DCOPN calculated a net deficit of 0.14 (1) CT scanner in PD 7.[4] Additionally, as **Table 1** demonstrates, the sole CT unit at WMH operated at 113% occupancy (8,365 procedures) in 2018, well above the SMFP threshold for expansion. Accordingly, maintaining the status quo is not a viable option. Furthermore, only one PD 7 Valley Health facility, Winchester Medical Center, operates more than one CT unit. The four units at Winchester Medical Center operated at a collective utilization of 140% in 2018. Even when the additional fifth scanner becomes operational, DCOPN calculates that the Winchester Medical Center CT inventory will operate well above capacity (112%).[5] Accordingly, DCOPN concludes that no available capacity exists within the Valley Health System for transfer and that the applicant has adequately demonstrated an institutional need with regard to the requested additional CT unit.

With respect to the applicant's request to convert the existing mobile MRI to a fixed site MRI service, the applicant did not identify an alternative means to meet their projected increase in demand. However, given the low utilization rate of the applicant's current mobile service (45.0% or 1,081 procedures (**Table 2**)), it is arguable that the status quo is an adequate alternative. As the VHI data and the applicant's own projections (**Table 9**) demonstrate, even with the applicants projected increase in need for MRI's taken into consideration, the applicant's current mobile MRI service is sufficient to meet the need, especially given that the ability to add additional mobile capacity is entirely within the applicant's control.

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[4] DCOPN notes that the intraoperative CT unit, while included in the PD 7 inventory count in **Table 1**, was not included in DCOPN's calculations for a determination of need, as it is not utilized in the same diagnostic capacity as the other CT units in PD 7.

[5] Calculated by maintaining the same number of procedures reported to VHI in 2018, while adjusting the number scanners to reflect the addition of the fifth CT 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 this project.

(iv) Any costs and benefits of the project;

The total projected capital cost of the proposed project is $3,771,844, the entirety of which will be funded using the accumulated reserves of the applicant (**Table 3**). Accordingly, there are no financing costs associated with the proposed project. DCOPN concludes that the costs for the proposed project are reasonable when compared to previously approved projects similar in scope.[6] The applicant identified the following benefits of the proposed project:

- Approval of the proposed project will provide access to fixed MRI services for patients within the community, especially those patients citing lack of transportation as a barrier to care.
- With a fixed MRI located at the replacement hospital, emergency room patients will no longer need to travel to Winchester Medical Center for services.
- A fixed MRI until will provide more opportunity to schedule patients for same-day testing.

With regard to the benefits of the requested additional CT unit, DCOPN concludes that the unit is needed in order to meet a unique institutional need and address the overutilization currently experienced by the existing service.

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

The applicant provided assurances that its services would be available to all patients in need of those services, without regard to ability to pay or payment source. DCOPN again notes that the applicant's proffered charity care contribution of approximately 1% of gross patient services revenue derived from CT and MRI services is significantly lower than both the 4.5% HPR I average and the 3.77% contribution made by WMH in 2018 (**Tables 4 and 5**). Furthermore, DCOPN again notes that according to the most recent U.S. Census data, two PD 7 localities had poverty rates higher than the 10.7% statewide average (**Table 6**). Furthermore, DCOPN again notes that pursuant to the recent changes 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. For the preceding reasons, should the Commissioner approve the proposed project, DCOPN recommends a charity care condition consistent with the HPR I average, and equal to at least 4.5% of gross

[6] COPN No. VA-04637, which authorized the conversion of one mobile MRI to a fixed MRI and had a capital cost of $2,228,785; COPN No. VA-04698, which authorized the addition of one CT scanner and had a capital cost of $2,884,526.

patient services revenue derived from CT and MRI services at WMH. 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.

(vi) At the discretion of the Commissioner, any other factors as may be relevant to the determination of public need for a 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 application is consistent with the State Health Services Plan;

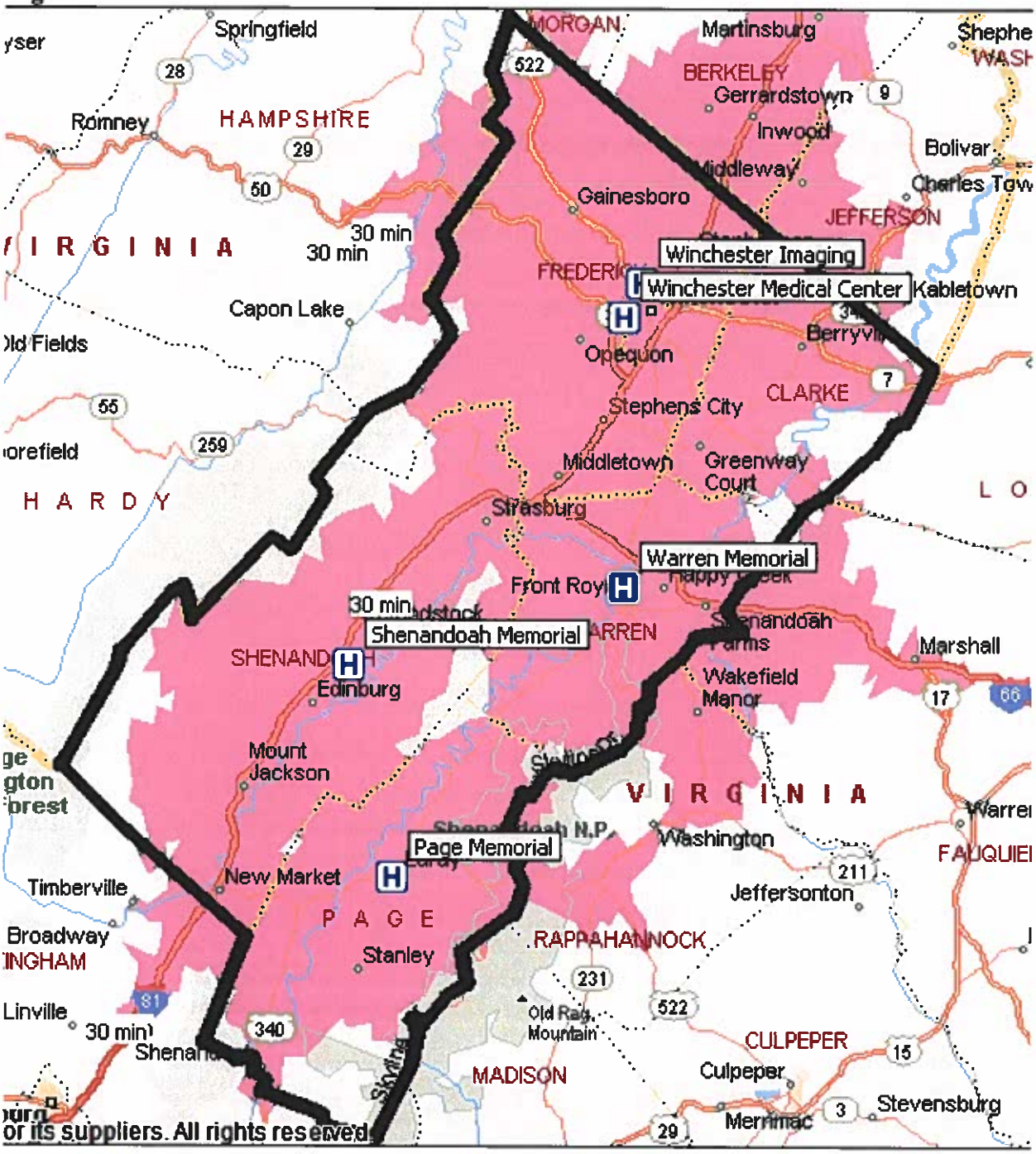
The State Medical Facilities Plan (SMFP) contains the criteria and standards for the expansion of diagnostic services at an existing medical facility. They are as follows:

Part II. Diagnostic Imaging Services
Article 1. Criteria and Standards for 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 7. The blue "H" sign marks the location of Warren Memorial Hospital. The white "H" signs mark the locations of all other existing CT services in PD 7. The pink shaded area represents the area of PD 7 and surrounding areas that are within 30 minutes' drive time of existing PD 7 CT services. Given the amount and location of the shaded area, it is evident that CT services are already well within a 30 minute drive for at least 95% of the population of PD 7. As the proposed project would be located in a facility that already offers CT services, it would not improve geographical access in any meaningful way. However, DCOPN contends that due to the high utilization of existing CT services at WMH, as well as among the collective PD 7 CT inventory, approval of the proposed project would nonetheless improve access to CT services for residents of PD 7.

Figure 1.


Springfield
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Winchester Medical Center
Capon Lake
Kabletown
Opequon
Stephens City
CLARKE
Middletown
Greenway Court
Strasburg
Warren Memorial
Front Royal
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Shenandoah Memorial
Edinburg
Marshall
Wakefield Manor
Mount Jackson
VIRGINIA
Page Memorial
New Market
Timberville
Washington
Jeffersonton
PAGE
Broadway
Stanley
RAPPAHANNOCK
Linville
30 min
Old Rag Mountain
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Culpeper
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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.

Not applicable. The applicant is not proposing to establish a new fixed site CT service. Rather, the applicant is proposing to add one additional CT unit to its existing inventory.

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.

In 2018, the eight operational CT units in PD 7 had a cumulative utilization of 114.2% based on the SMFP expansion threshold of 7,400 CT procedures per CT unit per year (**Table 1**). DCOPN observes that utilization of hospital-based CT units varies from that of CT units at freestanding facilities. Specifically, hospital-based CT units in PD 7 operated at a collective utilization of 117.7% in 2018, while CT units at freestanding facilities operated at a collective utilization of 89.8% for the same period. With regard to WMH specifically, the sole CT unit operated at 113% occupancy in 2018, well above the State Medical Facilities Plan (SMFP) threshold for expansion.

Using 2018 VHI data, based on the eight authorized CT units in PD 7 and reported CT volume of 67,602 CT procedures (8,450 procedures per unit), there is a calculated deficit of 1.14 CT units in PD 7 as follows:

COPN authorized CT units per VHI data = 8
Needed CT units = 67,602 ÷ 7,400 = 9.14
Utilization Percentage = 114.2%
CT unit deficit per VHI data = 1.14

However, when the CT unit added pursuant to COPN No. VA-04594 is considered, the result is a calculated **deficit of 0.14 (1) CT scanner.**[7]

As **Table 1** clearly demonstrates, the existing CT scanner at WMH performed 8,365 procedures (113.5% occupancy) in 2018, well above the SMFP threshold for expansion of 7,400 procedures per scanner per year. Furthermore, as already discussed, DCOPN concludes that no available capacity exists within the PD 7 Valley Health System for transfer. DCOPN concludes that approval of the CT portion of the proposed project would address the overutilization experienced by WMH's single scanner, while also addressing the calculated deficit within PD 7. DCOPN concludes that the applicant satisfies this standard.

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 has provided assurances that CT services at WMH will be under the direct supervision of one or more qualified physicians.

Article 2. Criteria and Standards for Magnetic Resonance Imaging

12VAC5-230-140. Travel time.

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

The heavy black line in **Figure 2** represents the boundary of PD 7. The blue "H" sign marks the location of Warren Memorial Hospital. The white "H" signs mark the locations of all other existing MRI services in PD 7. The pink shaded area represents the area of PD 7 and surrounding areas that are within 30 minutes' drive time of existing PD 7 MRI services. Given the amount and location of the shaded area, it is evident that MRI services are already well within a 30 minute drive for at least 95% of the population of PD 7. As the proposed project would be located in a facility that already offers mobile services, it would not improve geographical access in any meaningful way.

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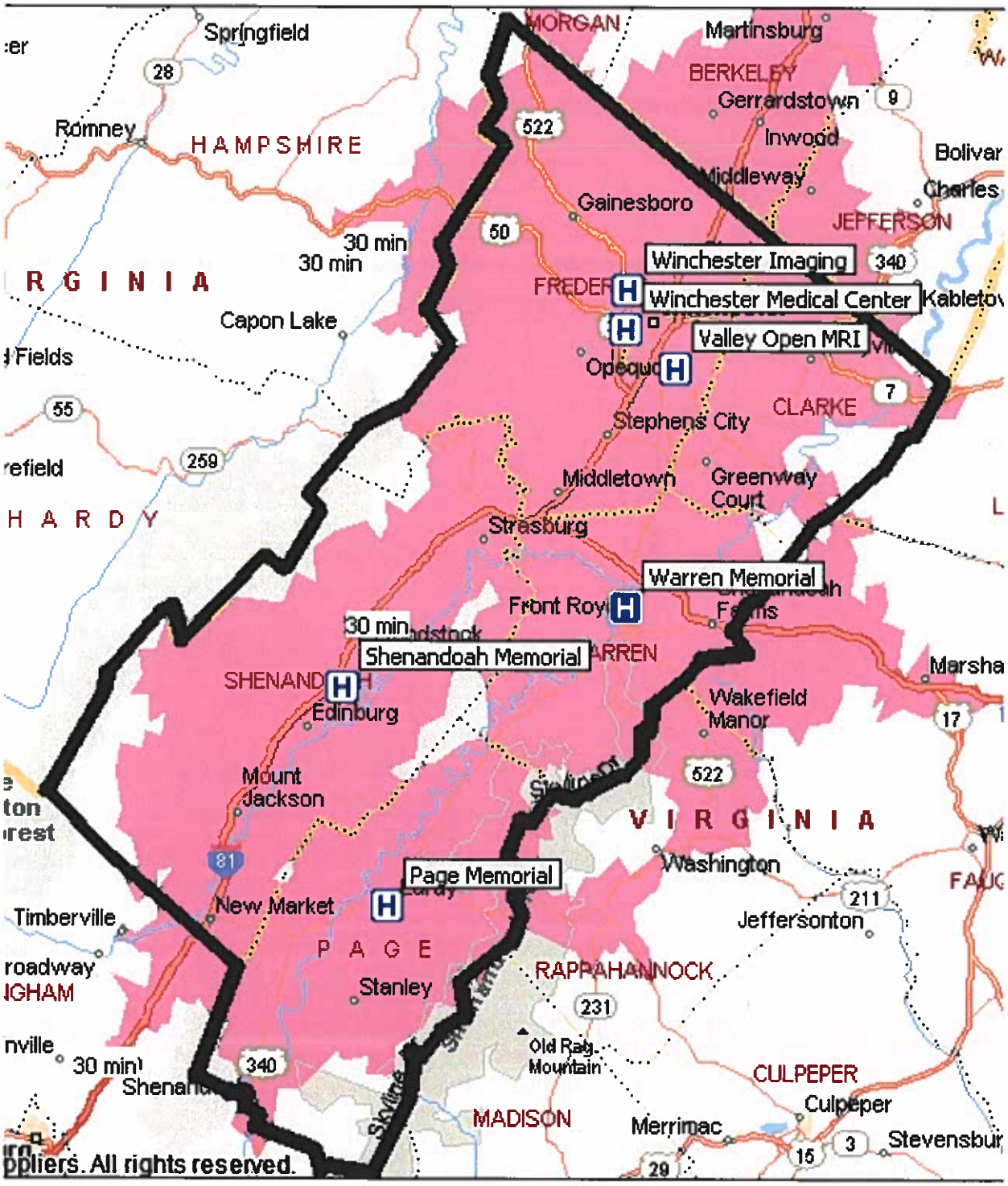
[7] DCOPN again notes that the intraoperative CT unit added pursuant to COPN No. VA-04699, while included in the PD 7 inventory count in Table 1, was not included in DCOPN's calculations for determination of need, as it is not utilized in the same diagnostic capacity as other CT units in PD 7.

Figure 2.



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

No new fixed site MRI service 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.

DCOPN notes that the proposed project does not seek to establish a new MRI service where none previously existed, but rather is proposing to convert an existing mobile MRI service to a fixed site service. As such, the data here is presented merely to provide an overview of the number of MRI scanners currently required by the planning district.

In 2018, the five fixed MRI units had a cumulative utilization of 79.8% based on the SMFP expansion threshold of 5,000 MRI procedures per MRI unit per year. DCOPN observes that utilization of hospital-based fixed MRI units varies from that of fixed MRI units at freestanding facilities. Specifically, the three fixed MRI units located in a hospital setting operated at a collective utilization of 84.4%, while the two fixed MRI units located at freestanding facilities operated at a cumulative occupancy of 73%. For the same period, the three mobile MRI sites displayed a cumulative utilization of 39.9% based on the SMFP mobile scanner threshold of 2,400 MRI procedures per mobile MRI unit per year (**Table 2**). With regard to WMH specifically, 2018 VHI data indicates that WMH's mobile MRI service performed only 1,081 procedures with a utilization rate of 36% based on the SMFP conversion threshold of 3,000 MRI procedures per unit per year (**Table 2**).

Using 2018 VHI data, based on eight authorized MRI units in PD 7 (**Table 2**) with a reported fixed MRI volume of 19,962 fixed MRI procedures (3,992 procedures per unit), and mobile MRI volume of 2,873 mobile MRI procedures (957.6 procedures per unit) there is a calculated surplus of 2 MRI scanners in PD 7 as follows:

COPN authorized Fixed MRI units = 5
Needed Fixed MRI units = 19,962 ÷ 5,000 = 3.99
Fixed MRI Unit Utilization Percentage = 79.8%

COPN authorized Mobile MRI units = 3
Needed Mobile MRI units = 2,873 ÷ 2,400 = 1.19
Mobile MRI Unit Utilization Percentage = 39.9%

Number of MRIs Needed = 3.99 + 1.19 = 5.18 (6)

MRI Surplus: 8-6 = 2 MRI 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 are 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 applicant is not proposing to expand an existing fixed 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.

Not applicable. The applicant is not proposing to add or expand mobile MRI services, but rather, is proposing to convert an existing mobile service to a fixed service.

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.

As displayed in **Table 2**, according to VHI data for 2018, the most recent year for which such data is available, the existing mobile scanner at WMH performed 1,081 MRI procedures which, when evaluated according to the SMFP conversion standard of 3,000 scans per authorized scanner, demonstrates a 36.0% utilization rate, falling well short of the SMFP conversion standard. The applicant contends that MRI volumes at WMH have increased steadily in recent years, and provided its projections for MRI services through 2021 (**Table 9**). While DCOPN cannot quantifiably confirm the applicant's projections, VHI data indicates that utilization of the existing mobile service has increased from 24.4% in 2014 to 36% in 2018 (using the SMFP conversion standard of 3,000 procedures per scanner per year). This represents an average increase of 70 procedures per year, a rate at which if maintained, would result in max capacity in approximately 27 years. Furthermore, DCOPN notes that the applicant's own projections anticipate only 2,445 procedures by the year 2023, well short of the 3,000 procedures required for conversion under the SMFP. To clarify this point further, the sum total of mobile scans performed for the entirety of PD 7 in 2018 does not surpass the 3,000 procedure threshold, indicating that both the demand for, and utilization of mobile MRI scans, is quite low. DCOPN further notes that the applicant's projections for the proposed fixed site MRI service vary considerably from the projections provided 2018 in the application for COPN Request No. VA-8349 (**Table 10**), which ultimately was denied by the Commissioner. In fact, projections provided for this application amount to almost double the anticipated volume as projected in COPN Request No. VA-8349. Accordingly, DCOPN contends that the applicant's projections are not reasonable and concludes that the applicant has failed to satisfy this standard.

Table 9. Historical and Projected Mobile MRI Utilization[8]—WMH

Year	Procedures	Mobile Utilization
2023 (Projected)	2,445	81.5%
2022 (Projected)	2,340	78.0%
2021 (Projected)	2,240	74.7%
2020 (Projected)	2,078	69.2%
2020 (annualized)	2,008	67.0%
2019	1,752	58.4%
2018	1,081	36.0%
2017	837	27.9%
2016	855	28.5%
2015	812	27.1%
2014	733	24.4%

Source: VHI (2013-2018) and COPN Request No. VA-8502

Table 10. WMH Projected Fixed Site Scans: COPN Request No. VA-8349 (2018)

Year	Number of Scans	Utilization Percentage
2016	855	28.5%
2017	871	29.0%
2018	888	29.6%
2019	904	30.1%
2021	975	32.5%
2021	1,046	34.9%
2022	1,118	37.3%
2023	1,190	39.7%
2024	1,263	42.1%

Source: DCOPN Staff Report for COPN Request No. VA-8349, at 16

The applicant cites to past decisions in which the Commissioner has "acknowledged that it has become the industry standard of care for an around-the-clock ED (emergency department) to be supported by a full-time fixed MRI service."[9] However, DCOPN notes that an important distinction to be made is that in each case cited by the applicant, an existing fixed-site MRI scanner was relocated, whereas in the case at hand, the conversion standard must be applied. Furthermore, DCOPN again notes that due to the low utilization of the existing mobile MRI service at WMH, it is arguable that maintaining the status quo is a viable option.

12VAC5-230-180. Staffing.

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[8] DCOPN calculated utilization for years 2014 through 2019 using the SMFP mobile to fixed conversion standard of 3,000 procedures per scanner per year. Utilization for years 2020 through 2023 were calculated using the SMFP fixed unit expansion standard of 5,000 procedures per scanner per year.

[9] COPN No. VA-044223 authorized the relocation of a fixed MRI unit to an ambulatory care campus, including a freestanding emergency department, 2014; COPN No. VA-04483 authorized the establishment of a specialized center for MRI services by relocating a fixed MRI unit within the planning district (to an ambulatory campus where a freestanding ED was constructed), 2015; COPN No. VA-04495 authorized the establishment of a specialized center for CT and MRI Imaging at New Kent Surgery Center, 2015.

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

The applicant provided assurances that the MRI services at WMH are under the direct supervision of one or more qualified physicians.

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

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

With a utilization rate of 113% in 2018, the most recently available VHI data confirms that WMH's current CT capacity demonstrates an institutional need for expansion. Additionally, as already discussed, no existing capacity exists within the PD 7 Valley Health System for transfer to WMH. Consequently, it can be inferred that approval of the additional CT unit at WMH can be justified on the facility's need having exceeded its current service capacity. DCOPN contends that with regard to the CT portion of the proposed project, the applicant has adequately demonstrated an institutional need for expansion.

With regard to the MRI portion of the proposed project, DCOPN again notes that due to the low utilization of the existing mobile MRI service, DCOPN contends that maintaining the status quo is a viable alternative.

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 applicant bases its application on an institutional need to expand its existing inventory due to the overutilization of its sole existing scanner.

With regard to the MRI portion, DCOPN notes that when the applicant must transfer a patient due to the unavailability of its mobile MRI service, the patient is taken to Winchester Medical Center, a

facility within the Valley Health System. For this reason, the sole provider of diagnostic services in PD 7 not part of the Valley Health System, Winchester Imaging, is not likely to be impacted in a significantly negative way by the approval of either portion of the applicant's request. DCOPN contends that the project is not intended to foster institutional competition within PD 7, but rather to meet a need at WMH. Furthermore, as the applicant is an established provider of both CT and MRI services, DCOPN concludes that the project will not improve geographic access to underserved members of the population of PD 7 in any meaningful way.

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;

As previously discussed, approval of the CT portion of the proposed project would address the calculated deficit of CT scanners in PD 7 while simultaneously addressing the institutional need adequately demonstrated by the applicant. Accordingly, DCOPN contends that while approval may have some impact on PD 7's sole provider of CT services not within the Valley Health System, that impact is not likely to be destabilizing. With regard to the MRI portion of the proposed project, approval would add to the calculated surplus of MRI scanners in PD 7. Furthermore, DCOPN again notes that the applicant's own projections for 2023 fall short of the conversion threshold of 3,000 procedures per unit per year. Additionally, DCOPN again notes that the sum total of mobile MRI scans performed for the entirety of PD 7 in 2018 did not surpass the 3,000 procedure threshold, indicating that both the demand for, and utilization of MRI scans, is quite low.

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 scope. Furthermore, with regard to the CT service at WMH, the Pro Forma Income Statement provided by the applicant projects a net profit of $8,651,953 in the first year of operation and $8,874,644 by year two. With regard to the MRI service at WMH, the Pro Forma Income Statement projects a net profit of $2,413,395 in the first year of operation and $2,575,349 by year two. The applicant will fund the proposed project entirely with accumulated reserves. Accordingly, there are no financing costs associated with this project.

The applicant requests authorization to establish the fixed MRI service before construction is complete on the replacement hospital in order to allow the replacement hospital to be designed and constructed to accommodate the fixed MRI scanner. The applicant asserts that if WMH is required to wait to introduce fixed MRI services until after the replacement hospital opens, future renovations will likely be required and will result in unnecessary costs to WMH and VHS.

With regard to staffing, the applicant anticipates the need to hire an additional two full-time employees (FTEs) in order to staff the proposed project. These two employees are in addition to the 14.7 positions currently vacant. The applicant states that in the event any new positions become vacant, WMH will utilize newspaper and journal advertisements (locally, statewide and nationally), internet advertising and recruitment efforts across the country. Due to the small

number of employees needed to staff this project, DCOPN does not anticipate that staffing of the proposed project will have a significant negative impact on the staffing of other PD 7 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 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; and**

The applicant does not propose to provide improvements or innovations in the financing of CT or MRI services, nor does it propose to introduce new technology that promotes quality and/or cost effectiveness in the delivery of health care services. However, the CT portion of the proposed project would improve the delivery of health care services at WMH by addressing the overutilization of its existing CT scanner while simultaneously addressing the calculated deficit in PD 7.

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. WMH is not a teaching hospital associated with a public institution of higher education or a medical school in the area to be served by the project.

DCOPN Staff Findings and Conclusions

The proposed project enjoys broad support from area healthcare providers and business owners. Additionally, there is no known opposition to the project. DCOPN finds that the total capital costs of the proposed project are reasonable and consistent with previously approved projects similar in scope. Furthermore, DCOPN finds that the project appears to be economically feasible both in the immediate and long-term. Finally, DCOPN concludes that approval of either portion of the proposed project is not likely to have a significant negative impact on the staffing or utilization of existing PD 7 providers of CT or MRI services.

DCOPN finds that the CT portion of the proposed project is generally consistent with the applicable criteria and standards of the SMFP and the Eight Required Considerations of the Code of Virginia. Approval of the proposed project will address the calculated deficit of CT scanners in PD 7 while simultaneously addressing the institutional need adequately demonstrated by the applicant. Moreover, DCOPN finds that no reasonable alternatives to the CT portion of the proposed project exist.

With regard to the applicant's proposal to convert its existing mobile MRI service to a fixed-site service, DCOPN finds the project to be generally inconsistent with the SMFP and the Eight

Required Considerations of the Code of Virginia. 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 in question—WMH's mobile service fell well short of this minimum threshold. Moreover, while utilization of the mobile MRI service at WMH has increased in recent years, the applicant's own projections for 2023 fall beneath this standard. Accordingly, DCON concludes that maintaining the status quo is a reasonable alternative to the MRI portion of the proposed project.

DCOPN Staff Recommendation

The Division of Certificate of Public Need recommends **denial** of Warren Memorial Hospital's request to convert one mobile MRI scanner to a fixed site MRI scanner 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 to convert its existing mobile MRI scanner to a fixed site scanner.

The Division of Certificate of Public Need recommends **conditional approval** of Warren Memorial Hospital's request to add one computerized tomography scanner (CT) to its existing inventory 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 cost of the proposed project is reasonable.

3. The proposed project appears economically viable in the immediate and the long-term.

4. There is no known opposition to the proposed project.

5. No reasonable alternatives to the proposed project exist.

6. The applicant has adequately demonstrated a unique institutional need for the proposed project.

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

Warren Memorial Hospital will provide computed tomography (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 7 in an aggregate amount equal to at least 3.8% of Warren Memorial Hospital's gross patient revenue derived from CT services. Compliance with this condition will be documented to the Division of Certificate of Public Need annually by providing audited or otherwise appropriately certified financial statements documenting compliance with the preceding requirement. Warren 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 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.

Warren Memorial Hospital, will provide 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 Warren 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.