

VIRGINIA DEPARTMENT OF HEALTH

Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis

January 19, 2023

COPN Request No. VA-8671

Winchester Medical Center

Winchester, Virginia

Expand service by adding one Fixed PET scanner

Applicant

Winchester Medical Center (“WMC”) is a Virginia nonstock 501(c)(3) corporation organized in 1984. WMC is a wholly owned subsidiary of Valley Health System. There are two subsidiaries wholly or partially owned by WMC—The Winchester Medical Center Foundation and Northern WV Home Health, LLC. WMC is located in Winchester, Virginia, Planning District (“PD”) 7, Health Planning Region (“HPR”) I.

Background

WMC is a 495-bed acute care facility that provides a comprehensive array of inpatient and outpatient services, including but not limited to cardiology, behavioral medicine services, surgery, orthopedics, neurosciences, oncology, women’s services, and pediatrics. WMC is the region’s only Level II Trauma Center that serves a combined 13 counties in both Virginia and West Virginia as well as the City of Winchester, Virginia.

WMC aims to fulfill Valley Health’s (VH) mission by “serving our community by improving health.” The applicant reports increasing cancer incidence rates for their service area and propose converting WMC’s mobile positron emission tomography (PET) service to a fixed service with the aim of supporting the further development of cancer services of Valley Health at WMC.

A PET scan is an imaging test that can help reveal metabolic or biochemical functioning of tissues and organs. The PET uses radioactive drugs, also referred to as a “tracer”, to show normal and abnormal metabolic activity. Mayo Clinic reports that a PET scan can often show the abnormal metabolism of tracers before the abnormality/disease is able to be observed through computerized tomography (CT) and magnetic resonance imaging (MRI). Mayo Clinic advises the PET scan procedure takes approximately 30-45 minutes, but the entire process can take 2-4 hours. Afterwards, a radiologist interprets the scans.

PET scans can be useful in detecting cancer, revealing whether cancer has spread, checking on the effectiveness of a cancer treatment, and finding cancer recurrence. Additionally, PET scans are being utilized more frequently in heart disease patients, where the scan can reveal areas of decreased blood flow in the heart. PET scans can be used to evaluate certain brain disorders such as tumors, Alzheimer’s disease, and seizures.

PET scans have some disadvantages worth noting that can sometimes confuse treatment plans and outcomes.¹ The most important disadvantage is the relatively high levels of both false-negative and false-positive results; radiologists’ reports will use analogous expressions such as “indeterminate” or “suspicious.” The procedural and maintenance costs are also exceptional. Additionally, Aljubran, Badran, Alshaer et al.’s 2019 study indicated the frequent overuse of PET scans in non-indicated clinical scenarios.

The proposed fixed PET services will be used primarily for the diagnosis, staging, and restaging of oncology patients. WMC reports having diagnosed and treated 2,707 new cancer patients in 2019, 2,612 in 2000, and 3,162 in 2021; the survivors of cancers diagnosed in previous years also require ongoing evaluation and treatment. As the increase in cancer patients continues, the effect is compounding as the survivors who require continuous monitoring increases, too.

WMC anticipates its mobile PET services will perform 1,139 PET scans in 2022; this equates to 80% of the SMFP’s conversion threshold of 1,400 procedures. However, WMC has experienced consistent growth in PET volumes in recent years, as seen below in **Table 1**. From 2017 to 2022, the PET volume has grown an additional 98.9%, with an average rate of 16.4% yearly (or 20.5% if 2020 is excluded as an anomaly likely correlated with the Covid-19 pandemic). Assuming the average yearly rate continues, 2023 would yield an estimated 1,326 to 1,373 (depending on whether 2020 is excluded from the data set for the average rate calculation). 2024 would reasonably yield PET volumes exceeding the SMFP’s threshold of 1,400 procedures. February 2024 is the anticipated date of completion.

Table 1. WMC PET Scan Volumes

2017	2018	2019	2020	2021	2022*
574	653	756	718	967	1,139

Source: COPN Req. No. 8671

*Annualized

WMC proposes to convert their mobile PET service into a fixed site service by adding one fixed PET scanner within the existing Outpatient Diagnostic Center located at 300 Campus Boulevard, Winchester, Virginia, on the WMC campus. The location is currently outfitted with appropriate utilities and is zoned for healthcare facility use, all of which the applicant provided adequate evidence. The applicant proposes repurposing existing space within the diagnostic center to mitigate the need for constructing new space or encountering substantial renovation costs. The upfit of the current space will also utilize LED lighting and other energy efficient HVAC technologies already established in the Outpatient Diagnostic Center.

¹ Aljubran, A.H., Badran, A., Alshaer, O. *et al.* Pattern of use of positron emission tomography/computed tomography (PET/CT) scan in non-colorectal gastrointestinal cancers at KFSHRC, Riyadh, Saudi Arabia. *Egypt J Radiol Nucl Med* **50**, 60 (2019). <https://doi.org/10.1186/s43055-019-0067-y>

As seen in **Table 2**, the applicant is performing the highest rate of procedures per Mobile Vendor half-days. VHI reports three Mobile Vendor half-days for WMC; however, there is a discrepancy as the applicant reports Mobile Vendor PET services being available 5 days a week.

Table 2. HPRI PET Mobile Units and Vendor Half-Days: 2021

Facility	PD	Mobile Vendor (MV)	MV ½ Days	IP+OP Procedures	Procedures/ MV ½ Days
Winchester Medical Center	7	Valley Health System	3	973	325
			5*		194*
Augusta Health	6	Shared Imaging	3	739	247
Sentara RMH Medical Center	6	Sentara Healthcare	4	493	123
Novant Health UVA Culpeper Medical Center	9	Alliance Healthcare	2	123	62
Sentara Martha Jefferson Hospital	10	Sentara Healthcare	4	578	145

Source: Virginia Health Information & DCOPN Records

*VHI reports 3 MV half days while applicant reports 5 day-a-week access to PET services.

The applicant reports needing to convert their mobile PET into a fixed site PET machine in part because they do not have access to the machine for the timeframes needed to complete their procedure needs timely because of the mobile unit being at other locations. The applicant did not provide any information regarding the average wait time for a PET scan.

WMC currently operates mobile PET services via COPN Certificate VA-03663, issued April 12, 2002. COPN Certificate VA-03663 states:

- Ownership and Control: “Winchester Medical Center will own a mobile positron emission tomography (PET) scanner, coach and equipment and will be an approved vendor and site of PET services at WMC and other sites approved for the provision of PET services.”
- Scope of Project: “Establishment of mobile positron emission tomography (PET) at WMC, which hereby becomes an approved vendor and site for the provision of PET services, and other sites approved for the provision of PET services, subject to private contractual arrangements....”

Additionally, the cover letter associated with COPN Certificate No. VA-03663 states: “In the matter of WMC’s application, as amended, for the establishment of mobile PET services to be provided at WMC, and by contract, at RMH and AMC-...(b) The project will provide access to PET services for rural communities...” Both the applicant in the current proposed application and the COPN Certificate originally authorized for the mobile PET services indicated other locations are comingled with WMC regarding the mobile PET services.

The applicant did not address anywhere within the application who the other sites utilizing their mobile unit currently were, how they would be affected, or whether they agreed to refer all their normally mobile-conducted PET procedures to WMC's proposed fixed-site service. Additionally, the applicant reports the same staff operating the mobile unit would be able to operate the fixed unit, indicating the mobile unit would not continue to be in operation for those other unknown users. Furthermore, the applicant did not address the change in access to PET services for these rural communities.

DCOPN emailed Mary E. Welch-Flores at mzufall@valleyhealthlink.com on 12/21/2022 at 2:30PM and asked the following questions for clarification (in italics), with responses received being the underlined portions:

- *I wanted to clarify if Winchester Medical Center (WMC) is wanting to add one fixed PET scanner while the mobile unit continues to operate, or whether the proposal is to not have mobile services and only a fixed PET scanner?* Winchester Medical Center's plan is to convert the mobile service to a fixed service. Once a fixed unit is installed, it will no longer be necessary to bring the mobile unit to the hospital and will be decommissioned since it has come to its end of life. It is operationally important to have onsite daily availability of the fixed unit versus just periodic access to the mobile unit. Requesting a fixed PET scanner at WMC would increase availability of the unit (every day of the week). Under SMFP states that PET services should within 60 minutes driving time one way under normal conditions of 95% of the health planning district. Without WMC, there are no access entry points for PET services. WMC is the only site in planning district #7 that offer these services.
- *Besides WMC, what other locations are the current mobile PET scanner services servicing? (Page 11 of the application states that the mobile PET scanner's schedule only allows the unit to visit WMC 5 days a week due to serving other sites during the other days).* In 2002, the Virginia State Health Commissioner issued COPN No. VA-0336 to authorized Winchester Medical Center ("WMC") as a mobile PET service site. Historically, the mobile PET unit used at WMC was shared with a second site - Augusta Health. Currently, WMC is the only location utilizing the unit at this time. The mobile PET unit at WMC has been in operation since 2002. The current unit will be approximately 8 years old and reaching the end of its useful life by the time a fixed unit would be installed and operational. The mobile PET unit has had multiple service repairs within the last year. As a result, there have been 32 full or partial down time days during the period of January – June 2022 that has delayed patient appointments. WMC plans to replace the outdated and obsolete PET equipment. Because this is a large capital investment with long-term consequences, WMC has determined that the mobile PET equipment should be replaced with a fixed PET unit to meet the current and long-term needs of the patient population served by WMC. For this reason, WMC is requesting COPN authorization to convert its mobile PET service to a fixed PET service.

- *What is the current wait time for patients to be scheduled for the current mobile PET services?* The current wait time schedule for PET services is two weeks out for both routine PET scans and specialty studies (with pharmaceuticals). With these extended wait times, providers are researching other scheduling options for their patients outside of WMC’s service area. Other delays in scheduling can be attributable to frequent downtime of the current unit for service repairs. There have been 32 full or partial down days during the period of January – June 2022.
- *The referenced cardiac population that would benefit from a fixed PET scanner- are they currently utilizing the mobile PET scanner or are they going to another fixed location?* The cardiac population is not currently utilizing the mobile unit at WMC, and it is understood that these patients are being sent out of the area for services. The current mobile unit cannot perform these types of studies. The establishment of a fixed PET unit will allow further capabilities for Winchester Medical Center to provide additional services for patients that are currently being referred out of the planning region for cardiac studies. As patient demand for PET services have increased, increase in utilization in the area of cardiology, PET services will increase.

Proposed Project

WMC proposes to convert its mobile PET scanning service to one fixed site PET scanner. The project will be paid for using WMC’s accumulated reserves. The Capital and Financing costs are outlined in **Table 3**. The costs are reasonable when compared to COPN Request No. VA-8558 (COPN Certificate No. VA-04756, issued August 16, 2021) project’s cost of \$6,261,000.

Table 3. Capital and Financing Costs

Direct Construction Costs	
Cost of Materials	\$ 543,910
Cost of Labor	\$ 815,865
Builder's Overhead	\$ 43,865
Builder's Profit	\$ 58,485
Subtotal	\$ 1,462,125
Equipment Not Included in Construction Contract	
Major Medical Equipment	\$ 2,500,000
Furniture	\$ 3,000
Signage	\$ 1,200
Communications (Information Systems)	\$ 18,000
Subtotal	\$ 2,522,200
Architectural and Engineering Fees	
Architect's Design Fee	\$ 98,500
Engineering Fees	\$ 41,500
Subtotal	\$ 140,000
Other Consultant Fees	
Insurance	\$ 2,500
Commissioning	\$ 6,000
Subtotal	\$ 8,500
Total Capital and Financing Cost	\$ 4,110,625

Source: COPN Request No. VA-8472

Project Definitions

Section 32.1 of the Code of Virginia defines a project, in part as, “The addition by an existing medical care facility described in subsection A of any new medical equipment for the provision of... positron emission tomographic (PET) scanning...A medical care facility includes “general hospitals...”

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 regarded 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.**

Geographically, WMC is located at the intersection of U.S 50 West and VA-37 and is easily accessible by I-66 and I-81. Additionally, public transport to WMC’s campus is available by a local bus service provided by the City of Winchester.

WMC serves a combined 13 counties in both Virginia and West Virginia as well as the City of Winchester, Virginia. The primary market of WMC comes from the following 7 zip codes:

- 22630, Front Royal, VA;
- 22602, Winchester, VA;
- 22655, Inwood, WV;
- 22601, Winchester, VA;
- 22603, Winchester, VA;
- 2657, Strasburg, VA; and
- 25411, Berkeley Springs, WV.

These 7 zip codes make up 48.7% of WMC’s patient population. During inclement weather, winter weather particularly, many of the rural areas within the 13 counties and 1 city served by WMC have two-lane roads that can become difficult to navigate.

There are only two other fixed PET sites in HPR I: UVA Medical Center and Medical Imaging of Fredericksburg. UVA Medical Center is 2 hours and 25 minutes for a 99.8-mile route, or 2 hours and 3 minutes for a 128-mile route from the proposed location at WMC. Medical Imaging of Fredericksburg is 1 hour and 54 minutes for an 81.9-mile route, or 1 hour and 50 minutes for a 93.1-mile route from the proposed location at WMC. The fixed-site information in combination with the information below in **Table 4** showcases that WMC is in an area without reasonable alternative access to PET services.

Table 4. Travel to HPR I PET Mobile Services from Proposed Project Location

Location	Distance from WMC	Time for Travel
Augusta Health	97.9 miles	1 hour and 43 minutes
Novant Health UVA Medical Center	47.5 miles	1 hour and 5 minutes
Sentara Martha Jefferson Hospital	101 miles	2 hours and 15 minutes
Sentara RMH Medical Center	72.4 miles	1 hour and 19 minutes

As previously discussed, WMC has mobile PET services that can currently meet the needs of the residents in the area it serves; by 2025, when the proposed project will be completed, the mobile PET services are estimated to inadequately address the PET scan needs of the residents in accordance with the SFMP’s 1,400 procedures threshold. This project is being proposed in a preventative manner to address the upcoming needs of the residents in the geographic area in which it serves. As the applicant answered above, the mobile unit is not currently servicing any other facilities. Therefore, it is reasonable to anticipate no change in access for patients with the transition of a mobile unit into a fixed unit at WMC.

Figure 1.

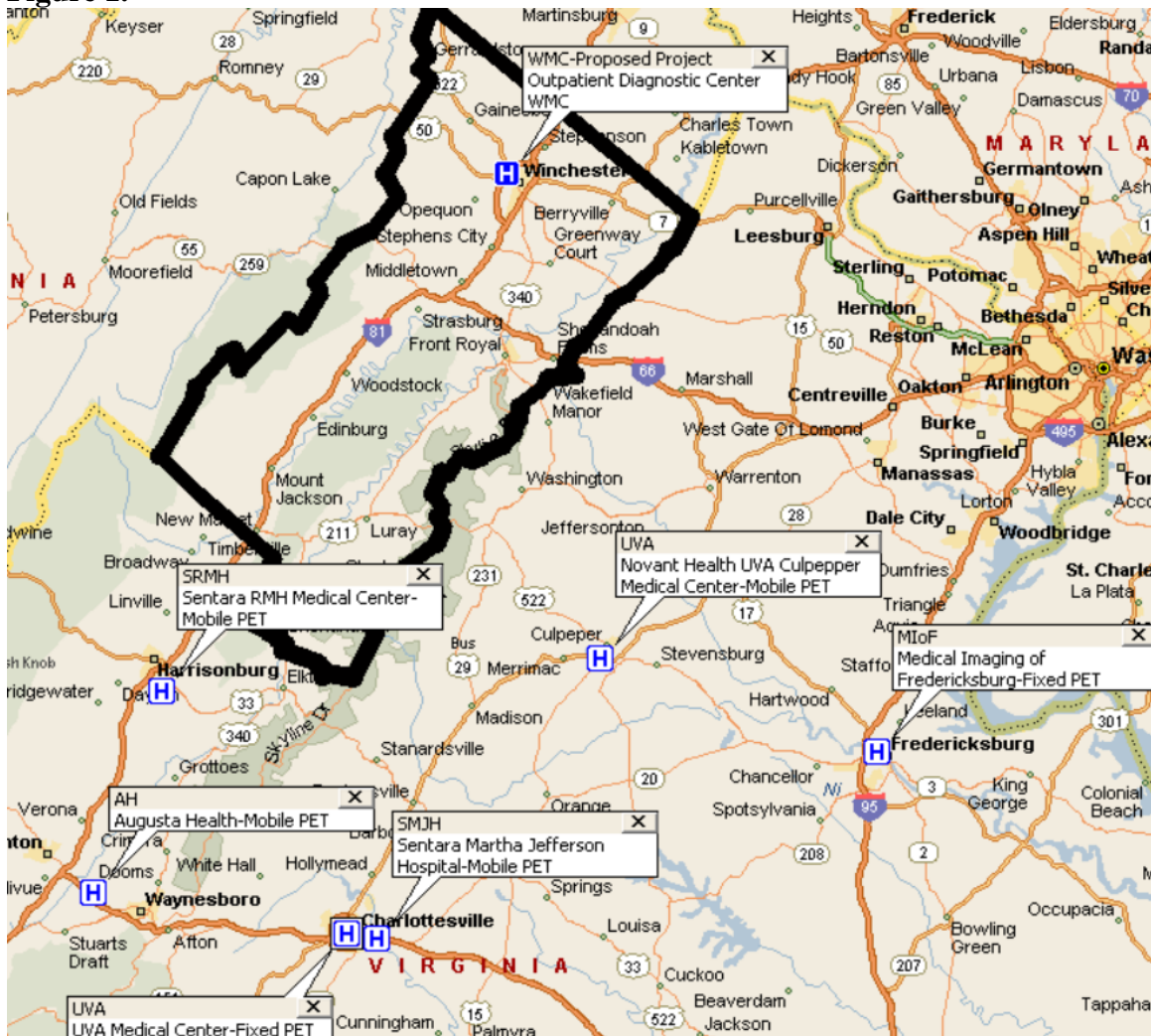


Figure 1 outlines the locations of all mobile and fixed PET scanning locations in HPR I. As shown, WMC is the only PET services provider in their district, with other PET providers being located a considerable distance away.

DCOPN is not aware of any additional geographic, socioeconomic, cultural, or transportation barriers to access to care.

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 26 letters of support for the proposed project. Collectively, these letters articulated several benefits of the proposed project to include the following:

- There is an increased demand for PET imaging services in the community in conjunction with an expansion of the professional medical community. As a result, patients have experienced extended wait times² and disruptions in care when seeking PET imaging services.
- Patients are being sent outside the area and state to obtain timely PET scanning services.
- WMC is a regional referral center, and the project will benefit the local community and surrounding communities that may not be able to afford more advanced technologies.
- PET scanning will give physicians an insight into treating tumors and treating patients in the community suffering from Cancer and Heart Disease.
- PET scans are crucial in the work up of malignancies and surveillance of malignancies. The presence of a permanent machine would improve timely access to scans, aiding in workups and expedites imagine integral to clinical decision making.

Public Hearing

DCOPN conducted the required public hearing on November 22, 2022. There was no voiced or written opposition to the project from either the public hearing notification or the applicant's provider notice letters.

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

The applicant has not identified any reasonable alternatives to the proposed project that would meet the needs of the population in a less costly, more efficient, or more effective manner. DCOPN does not find the status quo to be a reasonable alternative.

² As answered by the applicant above, wait times are approximately two weeks.

As described above, not only is WMC the only facility in the district with PET services, but other sites offering PET services in the region are quite far for patients to travel (over an hour's drive one-way). By the time of the proposed project's implementation, the estimated procedures will exceed the SMFP's threshold. Letters of support from other providers in the community were in support of the proposed project as not all providers are capable of funding a fixed PET scanner. As a referral center, the applicant assures they already have working relationships within the community to aid in the transition of maximizing the use of the fixed PET scanner, to include being able to accept referrals for cardiology PET scans. Additionally, the project is being funded using WMC accumulated reserves and is proposed to be located within an outpatient diagnostic center on the WMC campus, mitigating the need for excessive construction and renovation costs.

(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 projects.

(iv) Any costs and benefits of the project.

The total capital and financing costs for the project are \$4,110,625, which are detailed above in **Table 3**. The project will be financed using WMC's accumulated reserves; there will be no outside financing or debt accrual with this project. The costs for the project are reasonable and consistent with previously approved projects to expand PET services through adding a fixed site scanner. For example, COPN VA-04765 issued to Chippenham & Johnston-Willis Hospital, Inc. approved the conversion of a mobile PET/CT site to a fixed PET/CT site with estimated capital costs of \$6,261,000.

The proposed project to add one fixed PET scanner will have several benefits. For example, placing a fixed PET scanner within the Outpatient Diagnostic Center on the WMC campus will allow for more timely scanning of WMC patients, but also more timely scanning of referral patients from other providers in the area. Moreover, the addition of the fixed site PET scanner will allow for patients with cardiac PET scanning needs to be addressed in their own community, rather than having to be referred to another area that can support taking these patients.

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

The WMC campus is located 80 miles west of Washington, D.C. and is situated on a major crossroads in the Northern Shenandoah Valley and greater Eastern Panhandle of West Virginia via the intersection of Route 50 West and Route 37. WMC is easily accessible by Interstates 66 and 81. WMC also has a helipad for receiving and dispatching emergency air

transports. A local bus service provided by the City of Winchester provides access to the WMC campus for residents.

According to regional and statewide data regularly collected by VHI for 2020, the average amount of charity care provided by the facilities in HPR I that reported such charity care for that year was 2.1% of all reported total gross patient revenues (**Table 5**). In that same year, WMC reported to have provided 1.00% in charity care for total gross patient revenues, which was less than the average charity care contribution in HPR I. Were the proposed project to be approved, WMC is expected to provide a level of charity care for total gross patient revenues that is no less than the equivalent average for charity care contributions in HPR I. In 2018, WMC was the lowest charity care contributor in HPRI, and in 2019, WMC contributed approximately half the charity care contribution percentage of the HPRI average.

Table 5: HPR I 2020 Charity Care Contributions

Health Planning Region I			
2020 Charity Care Contributions at or below 200% of Federal Poverty Level			
Hospital	Gross Patient Revenues	Adjusted Charity Care Contribution	Percent of Gross Patient Revenue:
Culpeper Regional Hospital	\$359,182,141	\$12,102,933	3.37%
University of Virginia Medical Center	\$5,962,089,202	\$186,745,010	3.13%
UVA Transitional Care Hospital	\$66,296,097	\$2,047,513	3.09%
Sentara RMH Medical Center	\$918,098,298	\$22,656,844	2.47%
Carilion Stonewall Jackson Hospital	\$137,363,522	\$2,944,339	2.14%
Martha Jefferson Hospital	\$731,733,007	\$11,500,103	1.57%
Page Memorial Hospital	\$63,530,998	\$792,862	1.25%
Augusta Medical Center	\$1,059,370,204	\$12,042,914	1.14%
Shenandoah Memorial Hospital	\$121,946,999	\$1,321,088	1.08%
Warren Memorial Hospital	\$150,609,573	\$1,621,917	1.08%
Stafford Hospital Center	\$287,238,184	\$3,044,975	1.06%
Winchester Medical Center	\$1,433,802,000	\$14,305,992	1.00%
Spotsylvania Regional Medical Center	\$589,741,098	\$5,843,457	0.99%
Mary Washington Hospital	\$1,429,424,065	\$13,513,637	0.95%
Bath Community Hospital	\$23,228,689	\$145,250	0.63%
Fauquier Hospital	\$412,365,921	\$1,528,892	0.37%
Total Facilities			16
Median			1.1%
Total \$ & Mean %	\$13,386,837,857	\$280,054,793	2.1%

Source: 2020 VHI Data

WMC does have a financial assistance program (FAP) to assist the lower income population. For patients not eligible for Medicaid, a 100% discount applies if the combined family income is 200% of the Federal Poverty Level. Additionally, the FAP includes a sliding scale system. All uninsured patients receive a 30% discount on their total charges. WMC has employees to assist patients with completing the FAP application.

Table 4: Poverty Rates in PD 7 Compared to Virginia and West Virginia 2020

<u>Location</u>	<u>Population</u>	<u>Poverty Rate</u>
Virginia	8,631,393	10.20%
West Virginia	1,793,716	16.80%
Clarke County	14,783	7.20%
Frederick County	91,419	7.50%
Page County	23,709	13.40%
Shenandoah County	44,186	9.80%
Warren County	40,727	9.20%
City of Winchester	28,120	13.30%
PD 7	242,944	10.07%

Source: U.S. Census Bureau 2020 data

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

DCOPN is unaware of any other factors that may be relevant to the determination of public need that have not already been addressed in this report.

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

The SMFP contains criteria/standards for positron emission tomography (PET) imaging services. They are as follows:

12VAC5-230-200. Travel time. PET services should be within 60 minutes driving time one way under normal conditions of 95% of the health planning district using a mapping software as determined by the commissioner.

PET services are available within 30 minutes driving time one way under normal conditions of 95% of the population in PD 7. WMC’s project does not propose to redistribute or establish new PET services within PD 7, but to enhance access to PET services to patients that WMC services within the area, as exemplified in **Figure 2**. The outlined pink area shows the approximate 30-minute drive time range of the proposed location. As a significant portion of their referrals come from West Virginia, it is imperative to address the census in that portion of the map, too. Below in **Figure 3**, captured from the US Census Bureau, shows the increase in population for Berkely County, which included population center, Inwood, WV.

Figure 2.

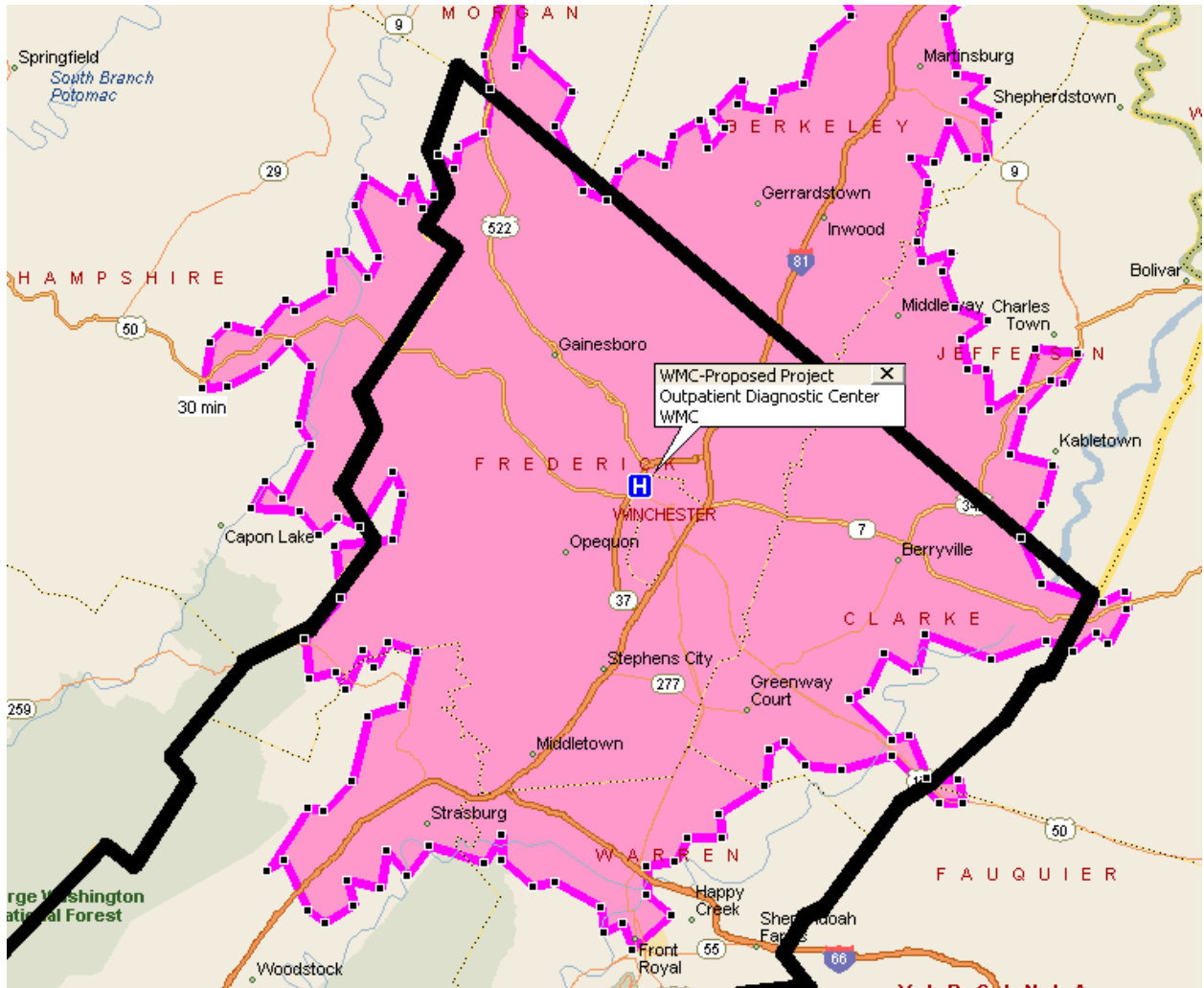


Figure 3.

	Winchester city, Virginia	Berkeley County, West Virginia
Population Estimates, July 1 2022, (V2022)	NA	NA
PEOPLE		
Population		
Population Estimates, July 1 2022, (V2022)	NA	NA
Population Estimates, July 1 2021, (V2021)	28,136	126,069
Population estimates base, April 1, 2020, (V2022)	NA	NA
Population estimates base, April 1, 2020, (V2021)	28,120	122,076
Population, percent change - April 1, 2020 (estimates base) to July 1, 2022, (V2022)	NA	NA
Population, percent change - April 1, 2020 (estimates base) to July 1, 2021, (V2021)	0.1%	3.3%
Population, Census, April 1, 2020	28,120	122,076

12VAC5-230-230. Adding or expanding mobile PET or PET/CT services.

A. Proposals for mobile PET or PET/CT scanners should demonstrate that, for the relevant reporting period, at least 230 PET or PET/CT appropriate patients were seen, and that the proposed mobile unit will not significantly reduce the utilization of existing providers in the health planning district.

Not applicable to proposal as proposal is not for expansion of mobile PET scanner.

B. Proposals to convert authorized mobile PET or PET/CT scanners to fixed site scanners should demonstrate that, for the relevant reporting period, at least 1,400 procedures were performed by the mobile scanner and that the proposed conversion will not significantly reduce the utilization of existing providers in the health planning district.

WMC anticipates its mobile PET service will perform 1,139 PET scans in 2022. This equates to 80% for the SMFP's conversion threshold. As **Table 1** demonstrates, WMC has experienced consistent growth in PET volumes in recent years, with 2020 being the exception. 2020 was during the pandemic which likely affected WMC's growth of PET volumes. Currently, the mobile PET scanner's schedule only allows the unit to visit WMC 5 days per week. The mobile PET is servicing other sites during the rest of the week. The applicant states the limited availability of the PET unit has made it impossible for WMC to reach the 1,400-conversion threshold. Once the PET unit is installed, WMC anticipates that PET volumes will exceed the 1,400 conversion threshold during the first year of operation. As discussed previously, by 2025, the year the fixed site is anticipated to be operational, the mobile PET volume conversion rate will likely be exceeded.

12VAC5-230-240. Staffing PET services should be under the direction or supervision of one or more qualified physicians. Such physicians shall be designated or authorized by the Nuclear Regulatory Commission or licensed by the Division of Radiologic Health of the Virginia Department of Health, as applicable.

The applicant has provided assurances that PET services at CRMH will be under the direct supervision of one or more qualified physicians/radiologists. The applicant provided the curriculum vitae Dr. Paul Armstrong Hill MD, MPH, MS showing his qualifications to supervise PET services. Dr. Hill, MD, MPH, MS is a Board-certified Radiologist with extensive experience in both the applied and academic settings.

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

As the sole PET services provider in PD 7, approval of the proposed project would inescapably improve access to essential health care services for PD 7 residents due to the general benefits derived from the implementation of this technology in a more efficiently operational manner. Moreover, WMC is a referral source for many other providers in the area who would benefit from increased timely access to PET services.

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.

There are no other PET services sites, mobile or fixed, within the district of the proposed project. Within HPR I, there are only two other fixed PET sites: UVA Medical Center and Medical Imaging of Fredericksburg. UVA Medical Center is 2 hours and 25 minutes for a 99.8-mile route, or 2 hours and 3 minutes for a 128-mile route from the proposed location at WMC. Medical Imaging of Fredericksburg is 1 hour and 54 minutes for an 81.9-mile route, or 1 hour and 50 minutes for a 93.1-mile route from the proposed location at WMC. Please see **Table 4** regarding the distance from the proposed location from the other locations offering PET mobile services in HPR I. As discussed previously, WMC is a referral center for other providers in the area and would increase timely PET scanning services to those areas, too.

As **Table 1** demonstrates, WMC has experienced consistent growth in PET volumes in recent years, with 2020 being the exception. During 2020, the Covid-19 pandemic can be reasonably assumed to have affected WMC’s growth of PET volumes. The applicant states the limited availability of the PET unit has made it impossible for WMC to reach the 1,400 conversion threshold. Once the PET unit is installed, WMC anticipates that PET volumes will exceed the 1,400 conversion threshold during the first year of operation. As discussed previously, by 2025, the year the fixed site is anticipated to be operational, the mobile PET volume conversion rate will likely be exceeded.

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 total capital and financing costs for the project are \$4,110,625. The project will be financed using WMC’s accumulated reserves; there will be no debt financed with this project. DCOPN concludes the costs for the project are reasonable and consistent with previously approved projects to expand PET services through adding a fixed site scanner. For example, COPN VA-04765 issued to Chippenham & Johnston-Willis Hospital, Inc. approved the conversion of a mobile PET/CT site to a fixed PET/CT site with estimated capital costs of \$6,261,000. **Table 3** above details the costs, while **Table 5** gives an abbreviated view of the costs.

Table 5. Capital and Financing Costs

Direct Construction Costs	\$ 1,462,125
Equipment Not Included in Construction Contract	\$ 2,522,200
Architectural and Engineering Fees	\$ 140,000
Other Consultant Fees	\$ 8,500
Total Capital and Financing Cost	\$ 4,110,625

The proposed project would be staffed by the same personnel currently operating the mobile PET services. They currently have 2 FTEs (two Technologists or one Technologist and one Tech Assistant) to staff the scanner 5 days per week. WMC currently employs two full-time

Radiologic Technologists (1 Nuclear Medicine Tech and 1 Imaging Tech Assistant). WMC has an opening for 1 additional full-time position; however, the current employees will be able to staff the proposed project.

As outlined below in **Table 6**, the applicant expects the following returns for the next 7 years:

Table 6: Financial Projections-Incremental

	2022 Projected Total Business	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Total Incremental
Outpatient (OP) Encounters	1,139	114	228	342	342	342	342	342	2,051
Gross Charge/Volume OP	\$8,300	\$8,632	\$8,977	\$9,336	\$9,709	\$10,098	\$10,052	\$10,922	
OP Revenue (\$)	9,449,106	984,001	2,044,029	3,188,683	3,320,601	3,453,424	3,591,561	3,735,225	20,317,524
Cash Flow for WMC (\$)	(4,110,625)	311,970	648,694	1,013,944	1,057,936	1,102,358	1,148,621	1,196,800	2,369,697

Source: COPN Req. No. VA-8671 Application

- 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.**

While the fixed PET scanner will not provide a specific innovation in the delivery of health services, it will decrease time needed to make clinical decisions by providers as they will be able to have their patients undergo a PET scan more quickly than can be done with the current mobile PET scanning services. The fixed PET scanner is proposed to occupy space within WMC's Outpatient Diagnostic Center and will facilitate faster access to PET scan referrals from outside outpatient providers. WMC has 9 transfer agreements with other hospitals working in conjunction to meet the needs of healthcare needs.

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

Not applicable. The applicant is not a teaching hospital or affiliated with a public institution of higher education or medical school in the area to be served. Approval of the proposed project would not contribute to the unique research, training or clinical mission of a teaching hospital or medical school.

DCOPN Findings and Conclusions

DCOPN finds that the proposed project to expand PET services through converting mobile PET services to a fixed-site PET scan service at the Outpatient Diagnostic Center on WMC's campus is generally consistent with the applicable criteria and standards of the SMFP and the eight Required Considerations of the Code of Virginia. As previously, discussed, the current mobile PET scans are less than the 1,400-threshold detailed in the SMFP; however, by the time the project is operational, the threshold will reasonably be surpassed. This project is being proposed in a preventative manner to address the upcoming needs of the residents in the geographic area in which it serves as well as to increase availability for cardiac patients to have access to PET closer to their communities.

Additionally, WMC's mobile PET service is the only access to PET scanning in the district, with limited options throughout the region. Furthermore, as WMC is an existing provider of PET services, approval of the proposed project would not likely have a negative impact on any other existing PET providers, particularly in this instance, as there are no competing PET scan services in the district. The closest PET services fixed or mobile, in Virginia are located over one hour's one-way drive-time from the proposed fixed-site location.

DCOPN finds that the proposed project is more advantageous than the status quo, as the conversion of mobile PET scan services to fixed-site PET scan services will reduce patient wait times, will expedite clinical decision making for life-threatening diagnoses including cancers and heart disease, and will widen the availability of .

Furthermore, given that the project has no opposition from other providers, health care professionals or community representatives, in conjunction with the 26 letters of support (including letters from outside providers), it can be inferred that the project is generally supported by the community in PD 7. Finally, DCOPN finds that the total capital and financing costs for the project are reasonable. The total capital and financing costs for the project are \$4,110,625 (**Table 3**). The project will be paid for using WMC's accumulated reserves. The costs for the project are reasonable and consistent with previously approved projects for similar services. For example, COPN VA-04765 issued to Chippenham & Johnston-Willis Hospital, Inc. approved the conversion of a mobile PET/CT site to a fixed PET/CT site with estimated capital costs of \$6,261,000.

DCOPN Staff Recommendation

The Division of Certificate of Public Need recommends **conditional approval** of the proposed project to expand PET services through the addition of a fixed site PET unit at Winchester Medical Center for the following reasons:

1. The 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 project is more favorable than the alternative of the status quo.

3. The project proposes to reduce patient wait and travel times with the potential to improve patient outcomes.
4. There is no known opposition to the project.
5. The capital and financing costs are reasonable.

Recommended Condition

Winchester Medical Center will provide PET 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 0.7% of Winchester Medical Center's total patient services revenue derived from PET services provided at Winchester Medical Center 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. Winchester Medical Center 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.