

VIRGINIA DEPARTMENT OF HEALTH

Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis

January 21, 2020

COPN Request No. VA-8472

Winchester Medical Center

Winchester, Virginia

Expand CT services by adding one intraoperative CT 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, which is located in Planning District (“PD”) 7 within 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. In 2017, WMC operated four computed tomography (CT) scanners with a collective utilization rate of 133.7%.

Overall, the utilization rate for the 8 CT scanners in PD 7 was 106.6% in 2017, the most recent year for which data is available from Virginia Health Information (VHI). As noted in Table 1, presently, there are 9 COPN-approved CT scanners in PD 7. Utilization data that includes the additional one CT scanner is not yet available from VHI. As demonstrated below, there is a confirmed need for 9 CT scanners in PD 7, which means that at present, there is a no surplus or deficit within the planning district.

COPN authorized scanners = 9

Calculated Needed CT scanners = $63,107 / 7400 = 8.5$

Calculated Need = 9 CT scanners

Calculated Surplus = 0 CT scanners

Table 1. PD 7 CT Units: 2017

Facility	Number of Scanners	Number of Scans	Utilization Rate
Valley Health Page Memorial Hospital	1	3,358	45.4%
Valley Health Shenandoah Memorial Hospital	1	6,916	93.5%
Valley Health Warren Memorial Hospital	1	7,509	101.5%
Valley Health Winchester Medical Center ¹	4	39,580	133.7%
Winchester Imaging	1	5,744	77.6%
2017 Total and Average	8	63,107	106.6%
Current Total	9	n/a	n/a

Source: Virginia Health Information & DCOPN Records

Proposed Project

WMC proposes to add one intraoperative CT scanner. The applicant has provided assurances that the new CT scanner will not be used for diagnostic purposes. The intraoperative CT scanner will be housed in existing storage space within the surgical suite. When in use, it will be positioned in the operating room prior to the patient entering the operating room for surgery. The total capital and financing costs for the project are \$1,744,450.79 (Table 2). The project will be paid for by the use of WMC’s accumulated reserves.

Table 2. Capital and Financing Costs

Equipment Not Included in Construction Contract	\$1,727,179
Other Consultant Fees	\$17,271.79
TOTAL Capital and Financing Costs	\$1,744,450.79

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 of any medical equipment for the provision of...computed tomographic (CT) 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 taken into account when applicable.

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

¹ The Commissioner issued COPN No. VA-04594 to Winchester Medical Center on March 6, 2018, which authorized the addition of one CT scanner. The project is expected to become operational on January 31, 2020.

The applicant proposes to expand CT services at WMC through the addition of one intraoperative CT scanner. Currently, CT services exist at five locations in PD 7. As WMC currently offers CT scanning services, approval of the proposed project is unlikely to increase access to CT services in PD 7. Moreover, as the applicant has provided assurances that the intraoperative CT scanner will not be used for diagnostic imaging services, approval of the project will also not have a detrimental effect on existing diagnostic CT service providers.

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.

DCOPN is not aware of any 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 letters of support for the proposed project from Virginia Brain & Spine Center and Winchester Neurological Consultants. Collectively, these letters articulated several benefits of the proposed project. For example, these letters emphasized that the combination of these advanced technologies benefits patients by improving patient safety and making surgery more precise. Moreover, the letters articulated that having the intraoperative CT scanner in the operating room eliminates the need to transfer patients out of the sterile surgical environment for CT scanning, which lessens the risk of complications. DCOPN received no letters of opposition for the proposed project.

Public Hearing

DCOPN conducted the required public hearing on January 7, 2020. A total of five individuals were in attendance, all of whom indicated that they supported of the proposed project. The project was presented by one representative on behalf of Valley Health. No attendees voiced opposition to the proposed project.

(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. Given the unique nature of the proposed intraoperative CT scanner, as well as the lack of excess capacity with diagnostic CT scanners within the Valley Health Health System, the proposed project is more reasonable than the status quo. Moreover, it is arguable that the proposed

project is more advantageous than the status quo, as the addition of an intraoperative CT scanner at WMC would provide the benefits of real-time imaging within an operating room setting, providing improved tissue visualization and the ability to see the location of surgical instruments in relation to the patient. It is also notable that the high quality of the CT images would support minimally invasive surgeries, and meet a unique need for imaging in high-risk surgeries.

Finally, as an existing provider of CT services, approval of the proposed project would not likely have a negative impact on any other existing CT providers, particularly in this instance, as the applicant has provided assurances that the proposed intraoperative CT will not be used for diagnostic imaging.

(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 \$1,744,450.79 (Table 2). The project will be paid for by the use of WMC's accumulated reserves. The costs for the project are reasonable and consistent with previously approved projects to add one intraoperative CT scanner. For example, COPN VA-04504 issued to Sentara Hospitals d/b/a Sentara Norfolk General Hospital to add one intraoperative CT scanner, which cost approximately \$2,000,000. The proposed project to add one intraoperative CT scanner will have several benefits. For example, placing an intraoperative CT scanner at WMC would support minimally invasive surgeries, and meet a unique need for imaging in high-risk surgeries. Moreover, the intraoperative CT scanner would provide the benefits of real-time imaging within an operating room setting, such as improved tissue visualization and the ability to see the location of surgical instruments in relation to the patient.

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

According to regional and statewide data regularly collected by VHI, for 2018, the average amount of charity care provided by the facilities in HPR I that reported such charity care for that year was 4.5% of all reported total gross patient revenues (Table 3). In that same year, WMC reported to have provided 1.75% in charity care for total gross patient revenues, which was the lowest 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.

Table 3: HPR I 2018 Charity Care Contributions

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%
UVA Transitional Care Hospital	\$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%
Winchester Medical Center	\$72,568,503	\$1,273,051	1.75%
Total \$ & Mean %	\$13,059,116,740	\$593,357,103	4.5%

Source: 2018 VHI 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 did not identify any other discretionary factors, not discussed elsewhere in this staff analysis report, to bring to the attention of the Commissioner as may be relevant to determining a public need for the proposed project.

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

The SMFP contains criteria/standards for computed tomography (CT) imaging services. They are as follows:

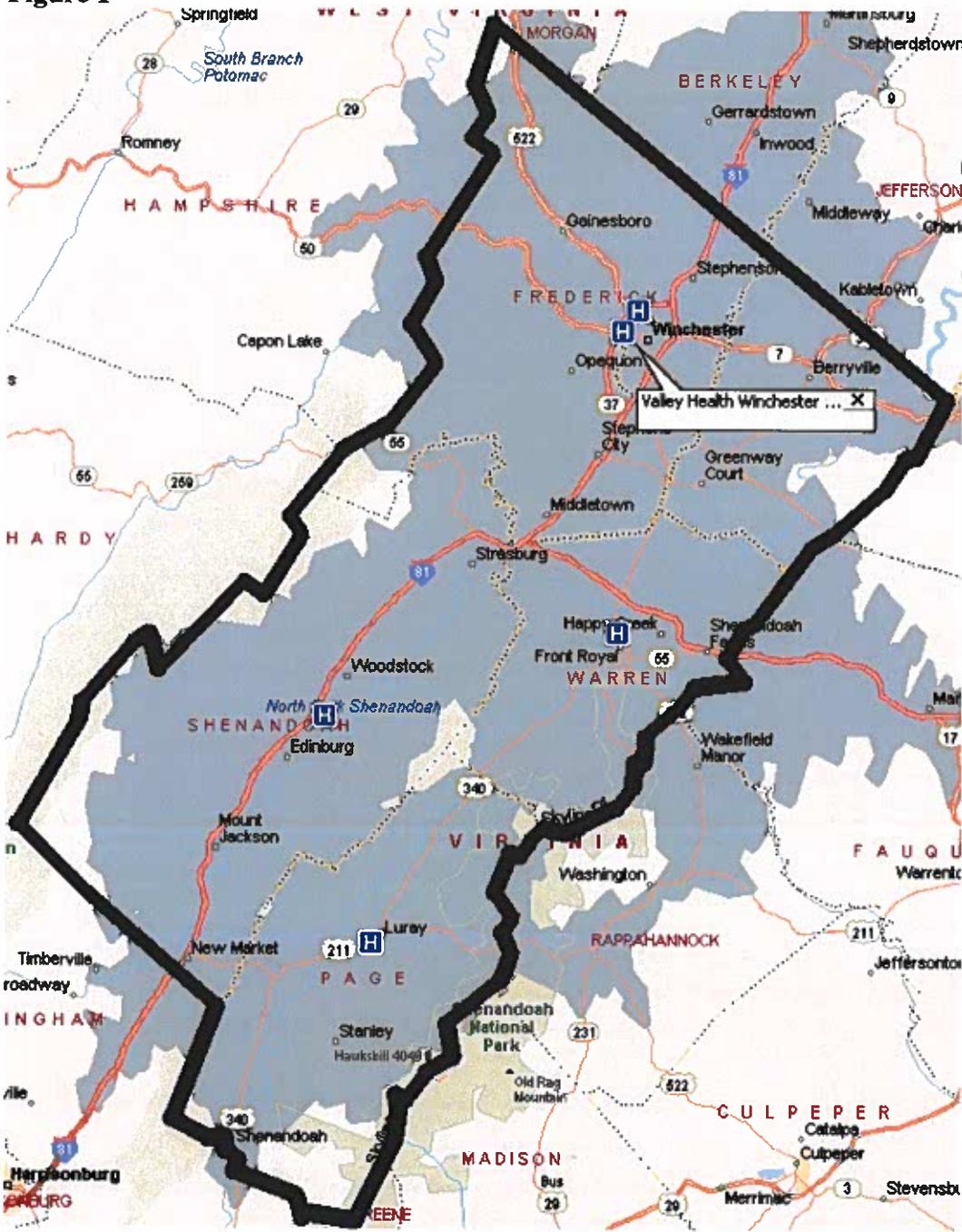
**Part II
 Diagnostic Imaging Services
 Article 1
 Criteria and Standards for Computed Tomography**

12VAC5-230-90. Travel time.

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

Currently there are nine COPN authorized CT scanners in PD 7. The heavy black line in Figure 1 is the boundary of PD 7. The grey shaded area includes all locations that are within 30 minutes driving time one way under normal conditions of CT services in PD 7. Figure 1 clearly illustrates that open-heart surgical services are already well within a 30 minute drive under normal conditions of 95% of the residents of the planning district. As WMC already offers CT services, the proposed project will not improve access to CT services in PD 7.

Figure 1



12VAC5-230-100. Need for new fixed site or mobile service.

- A. No new fixed site or mobile CT service should be approved unless fixed site CT services in the health planning district performed an average of 7,400 procedures per existing and approved CT scanner during the relevant reporting period and the proposed new service would not significantly reduce the utilization of existing providers in the health planning district. The utilization of existing scanners operated by a hospital and serving an area distinct from the proposed new service site may be disregarded in computing the average utilization of CT scanners in such health planning district.**

Not applicable. WMC is requesting to add CT capacity at an existing medical care facility, not to establish a new fixed or mobile CT imaging site.

- 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.**

DCOPN has excluded existing CT scanners used solely for simulation prior to the initiation of radiation therapy from its inventory and average utilization of CT scanners in PD 7 with respect to the proposed project.

12VAC5-230-110. Expansion of fixed site service.

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

As previously discussed, WMC currently utilizes four CT scanners with one additional CT scanner set to commence operations on January 31, 2020. With respect to WMC's current CT utilization, its CT scanners performed 39,580 scans in 2017. Even including the CT scanner that is set to become operational on January 31, 2020, this equates to a utilization rate of 107%, which exceeds the SMFP standard for demonstrating a need for additional capacity. With that said, it is arguable that this standard is not applicable regarding the proposed project, as the applicant has provided assurances that the intraoperative CT scanner would be used exclusively in an operating room setting, and not for diagnostic purposes.

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 CT scanner and that the proposed conversion will not significantly reduce the utilization of existing CT providers in the health planning district.

Not applicable. WMC is not proposing to add or expand mobile CT services or to convert authorized mobile CT scanners to fixed site scanners.

12VAC5-230-130. Staffing.

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

The applicant states that the proposed intraoperative CT scanner would be under the direction or supervision of the board certified radiologists that currently direct or supervise WMC's CT services.

12VAC5-230-80. When Institutional expansion needed

A. Notwithstanding any other provisions of this chapter, the commissioner may grant approval of 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.

As previously discussed, WMC currently utilizes four CT scanners with one additional CT scanner set to commence operations on January 31, 2020. With respect to WMC's current CT utilization, its CT scanners performed 39,580 scans in 2017. Even including the CT scanner that is set to become operational on January 30, 2020, this equates to a utilization rate of 107%, which exceeds the SMFP standard for demonstrating a need for additional capacity. With that said, it is arguable that this standard is not applicable regarding the proposed project, as the applicant has provided assurances that the intraoperative CT scanner would be used exclusively in an operating room setting, and not for diagnostic purposes.

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.

WMC is a part of the Valley Health Health System. However, Valley Health Health System does not have any facilities with multiple CT scanners in PD 7 that would warrant a reallocation of resources.

C. This section is not applicable to nursing facilities pursuant to § 32.1-102.3:2 of the Code of Virginia.

Not applicable. The proposed project is not germane to nursing facilities.

D. Applicants shall not use this section to justify a need to establish new services.

Not applicable. The applicant is not proposing to establish a new service.

Required Considerations Continued

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

As the sole intraoperative CT scanner in PD 7, approval of the proposed project would necessarily improve access to essential health care services for PD 7 residents due to the general benefits derived from the implementation of this technology in an operating room setting.

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

WMC is one of several acute care service providers in PD 7. As has been discussed, in 2017, WMC operated four CT scanners with a collective utilization rate of 133.7%. Even including the CT scanner that is set to become operational on January 30, 2020, this equates to a utilization rate of 107%. The applicant has made assurances that, if approved, the proposed CT scanner will be utilized exclusively in an operating room setting, and will not be used for diagnostic imaging purposes. Should the proposed project receive approval, the intraoperative CT scanner at WMC would provide a useful alternative and greater access to this emergent technology. Were the proposed project to be approved, due to the scanner's limited use in an operating room setting, accessibility to CT scanning services within the 30-minute timeframe would not change at all.

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.

DCOPN concludes that the projected capital costs are reasonable. The total capital and financing costs for the project are \$1,744,450.79 (Table 2). The project will be paid for by the use of WMC's accumulated reserves. Consequently, there will be no financing costs associated with the project. The costs for the project are reasonable and consistent with previously approved projects to add one intraoperative CT scanner. For example, COPN VA-04504 issued to Sentara Hospitals d/b/a Sentara Norfolk General Hospital to add one intraoperative CT scanner, which cost approximately \$2,000,000.

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.**

As the sole COPN approved intraoperative CT scanner in PD 7, approval of the proposed project would provide an improvement in the delivery of health services, with particular emphasis on surgical services. Moreover, the introduction of CT technology within an operating room setting would introduce new technology that promotes quality, as the addition of an intraoperative CT scanner at WMC would provide the benefits of real-time imaging within an operating room setting, such as improved tissue visualization and the ability to see the location of surgical instruments in relation to the patient. It is also notable that the high quality of the CT images would support minimally invasive surgeries, and meet a unique need for imaging in high-risk surgeries. No cooperative efforts to meet regional health care needs were addressed by the applicant. DCOPN did not identify any other relevant factors to bring to the Commissioner's attention.

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 CT services through the addition of a dedicated intraoperative CT unit WMC 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, in 2017, WMC operated four CT scanners with a collective utilization rate of 133.7%. Even including the CT scanner that is set to become operational on January 31, 2020, this equates to a utilization rate of 107%., which exceeds the SMFP standard for demonstrating a need for additional capacity. Furthermore, as an existing provider of CT services, approval of the proposed project would not likely have a negative impact on any other existing CT providers, particularly in this instance, as the applicant has provided assurances that the proposed intraoperative CT will not be used for diagnostic imaging.

Moreover, DCOPN finds that the proposed project is more advantageous than the status quo,

as the addition of an intraoperative CT scanner at WMC would provide the benefits of real-time imaging within an operating room setting, such as improved tissue visualization and the ability to see the location of surgical instruments in relation to the patient. It is also notable that the high quality of the CT images would support minimally invasive surgeries, and meet a unique need for imaging in high-risk surgeries.

Furthermore, given that the project has no opposition from other providers, health care professionals or community representatives, 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 \$1,744,450.79 (Table 2). The project will be paid for by the use of WMC's accumulated reserves. The costs for the project are reasonable and consistent with previously approved projects to add CT scanner services. For example, COPN VA-04550 submitted by University of Virginia Medical Center to add one CT scanner, which cost approximately \$2,015,000; and COPN VA-04562 submitted by Stafford Hospital, LLC, to add one CT scanner, which cost approximately \$1,043,400.

DCOPN Staff Recommendation

The Division of Certificate of Public Need recommends **conditional approval** of the proposed project to expand CT services through the addition of a dedicated intraoperative CT 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 introduce a new application of the CT imaging technology into the operating room, with the potential to improve patient outcomes.
4. There is no known opposition to the project.
5. The capital and financing costs are reasonable.

Winchester Medical Center will provide intraoperative CT 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 4.5% of Winchester Medical Center's total patient services revenue derived from intraoperative CT 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.