

**STATE OF VERMONT
GREEN MOUNTAIN CARE BOARD**

In re: Application of the University of Vermont)
Medical Center, Replacement of PET/CT) GMCB-011-16con
System)
_____)

STATEMENT OF DECISION AND ORDER

Introduction

The University of Vermont Medical Center (UVMMC, or the Applicant) is Vermont's only tertiary care facility and academic medical center and the primary referral center for a region in Vermont and upstate New York that includes a population of more than one million people. In this Certificate of Need (CON) application, UVMMC seeks to replace its current fixed PET/CT system with a new Philips Vereos PET/CT system and to make the necessary renovations to house the new equipment. The total project cost is \$2,689,631.

For the reasons outlined below, we approve the application.

Procedural Background

On May 4, 2016, UVMMC filed a certificate of need application with the Green Mountain Care Board. The Board granted expedited review of the project on May 10, 2016 pursuant to 18 V.S.A. § 9440(c)(5) and received no competing application nor requests for Interested Party or Amicus Curiae status. The Board requested additional information of the applicant on June 17, 2016 and received responses June 28. The application was closed on July 14, 2016.

Findings of Fact

1. A PET/CT scanner is a dual imaging device that uses Positron Emission Tomography scans and Computed Tomography scans to make detailed images of a patient's internal organs and structures. Application (App.) at 4-5.
2. PET/CT scans are used for the diagnosis and treatment of cancer and neurological diseases and for the diagnosis of cardiovascular disease. Compared to other imaging methods, the higher accuracy and informational content of PET/CT scans help to reduce unnecessary patient surgeries, unnecessary diagnostic procedures, and the frequency of biopsies during cancer and neurology treatment. App. at 5. For cardiovascular disease, PET/CT scans enable more accurate diagnoses than traditional stress tests, produce fewer false positives, and decrease the need for costly angiograms and bypass surgery for many patients. *Id.* at 6.

3. UVMMC started offering PET/CT services in September 2004 through the use of a mobile PET/CT system stationed part-time on the grounds of the Fanny Allen Campus. App. at 6.
4. In February 2009, the State of Vermont Department of Banking, Insurance, Securities, and Health Care Administration (BISHCA, now the Department of Financial Regulation), approved the acquisition of a fixed PET/CT system. BISHCA found that the project would serve the public good by allowing UVMMC, which is Vermont's only tertiary care facility and has a robust cancer treatment program, to offer fixed PET/CT services to more patients, including certain high-risk inpatients and cardiac patients. App. at 7.
5. PET/CT systems have a useful life of 6-7 years and the equipment installed in 2009 is now fully-depreciated. App. at 3.
6. Congress recently passed legislation (2014)¹ to mandate the installation of radiation safety features in standalone CT equipment. CT scans produce many times the radiation of traditional x-ray machines to generate detailed, three-dimensional images. The federal law requires health care providers to use CT equipment that meets the standard of the National Electrical Manufacturers Association (NEMA). Failure to meet the NEMA CT standard results in a 5 percent reduction in Medicare payments for the CT exam, effective January 1, 2016, and 15 percent reduction in Medicare payments effective January 1, 2017 and beyond. UVMMC's existing PET/CT unit does not meet the NEMA CT Standard requirements. App. at 11-12. Medicare payment reductions have been minimal because UVMMC has been able to shift most standalone CT scans to its other CT scanners, all of which meet the NEMA CT Standard. Applicant Responses 6/28/16 (Responses) at 3.
7. UVMMC proposes to purchase and install a Philips Vereos PET/CT system to replace its existing Philips system. The new system will feature the digital PET system with digital photon counting technology, a 128-slice CT scanner, an ECG monitor, a dose reporting and notification system to comply with the NEMA CT Standard, and a sub-system power protection to provide temporary backup power in the event of a power failure. App. at 13.
8. The proposed Philips Vereos system has improved image quality, reduced radiation exposure for the patient, and improved speed and efficiency. The new system will expose patients to less radiation from the imaging equipment itself and also requires lower doses of radioactive pharmaceuticals administered to patients prior to their exams. App. at 11. Faster scanning times and increased clinical efficiency will allow clinicians to reduce the dosage of radioactive pharmaceuticals by an average of 40%. *Id.* at 12.
9. UVMMC's existing PET/CT unit is capable of performing approximately 2,340 scans per year. The new unit is projected to have a capacity of 2,600 scans per year. Responses at 1.

¹ H.R. 4302 (113th): Protecting Access to Medicare Act of 2014, Pub. L. 113-93, Sec. 218.

10. Approximately 1,200 PET/CT exams have been performed at UVMMC each year since the acquisition of the fixed unit in 2009. Inpatient exams account for about 15 percent and outpatient exams account for about 85 percent. 64 percent of exams are for the diagnosis and treatment of cancer. 34 percent are for cardiac scans, and 2 percent are for neurologic diseases. App. at 7-8.
11. UVMMC does not project any change in volume of scans with the new equipment, nor will UVMMC increase charges for PET/CT procedures as a result of the project. Responses at 2, 4; App. at 22. In order to prevent over-utilization of services, UVMMC protocols require PET/CT services to be reviewed by a radiologist specializing in both nuclear medicine and cross-sectional imaging before the exam can take place, and to discuss alternative imaging where appropriate. According to data provided in the application, Vermont has the sixth lowest utilization rate for PET/CT services in the United States. App. at 19.
12. UVMMC is the only hospital in Vermont to use PET/CT technology for cardiac testing. App. at 8. The proposed new PET/CT system will additionally enable UVMMC to offer quantitative myocardial blood flow testing (QMBF), a cardiac test not currently available at UVMMC. App. at 12.
13. Quality of PET/CT services at UVMMC is monitored by the Nuclear Medicine Department through Radiologist peer review, which includes review of both examinations and patient satisfaction. The applicant states that collection, reporting, and monitoring of quality data will continue with the new equipment. App. at 14-15.
14. UVMMC's PET/CT program is accredited by the American College of Radiology (ACR) and follows the evidence-based practice guidelines adopted by the ACR. UVMMC's continuing medical education and certification of technologists, physicists, and radiologists was found to meet or exceed ACR requirements. App. at 14-16.
15. The infection rate at UVMMC for patients treated with diagnostic and interventional procedures is less than one percent and is monitored by the UVMMC Infection Prevention Team. App. at 17.
16. The PET/CT service operates full-time, Monday through Friday, 7:00 AM to 5:00 PM, and is staffed at all times by two licensed technologists: a nuclear medicine PET technologist and a CT technologist. App. at 7.
17. The cost of the new Philips Vereos Digital PET/CT system is \$2,750,000, less the trade-in amount of \$380,000 for the existing equipment, for a total purchase price of \$2,370,000. The quote is fully inclusive of all needed accessories and add-ons. ECRI, the Board's medical technology consultant, has advised the Board that the price quoted is among the lowest it has seen for Vereos.
18. Minor renovations are required to house the new PET/CT equipment. The construction cost estimate is reasonable and meets the industry standard and complies with all

requirements of the 2014 edition of the Facility Guidelines Institute's *Guidelines for Hospitals and Outpatient Facilities* (FGI Guidelines). The applicant confirmed that the shielding will be tested prior to and after completion of the construction. Responses at 1-2.

19. Renovations will take four weeks to complete. Installation, testing, physician validation, and training take another three weeks. A mobile unit will be located at the Fanny Allen Campus during this period at a cost of \$86,500. App. at 14; Responses at 3-4, Table 3B. The cost of renovations and contingencies are \$319,631. App. at Table 1.
20. The total project cost is \$2,689,631, which UVMMC plans to fund with working capital, unless the equipment vendor were to present favorable financing options that would not increase the overall cost of the project. App. at Table 2. The cost of the project was included in UVMMC's capital budget for Actual FY15 and Budget 2016 as approved by the Board.

Standard of Review

Vermont's certificate of need process is governed by 18 V.S.A. §§ 9431-9446 and Green Mountain Care Board Rule 4.000 (Certificate of Need). The applicant bears the burden to demonstrate that each of the criteria set forth in 18 V.S.A. § 9437 is met. Rule 4.000, § 4.302(3). We review each of these criterion below.

Conclusions of Law

Pursuant to 18 V.S.A. § 9437(1), we conclude that the application is consistent with Vermont's Health Resource Allocation Plan (HRAP). The HRAP, last published in 2009, identifies needs in Vermont's health care system, resources to address those needs, and priorities for addressing them on a statewide basis. *See* 18 V.S.A. § 9437(1). The HRAP has specific requirements for PET/CT systems and related projects. First, the HRAP requires that an applicant not increase its CT scanning capacity unless it demonstrates that such capacity is necessary in reference to state, regional and/or national benchmarks for medically necessary exams per year. HRAP Standard 3.6. Second, the applicant must provide data regarding current use, document the effectiveness of its internal program to prevent overuse, and verify that it has no financial incentives in place encouraging overuse. *Id.* As a threshold matter, the proposed purchase is for the replacement of an existing PET/CT scanner used in an ongoing program at UVMMC. The existing scanner is nearing the end of its useful life and fully depreciated, Finding of Fact (Finding) ¶ 5, and replacing it would not significantly alter treatment patterns and frequency at UVMMC or in Vermont as a whole. Additionally, while the new unit would be capable of a moderately larger number of scans per year, UVMMC has since 2009 confined annual utilization to an average of 1,200 scans, which is well below both the existing unit's capacity and nationwide averages. Findings ¶¶ 10-11. Accordingly, we conclude that the applicant has satisfied CON Standard 3.6.

The Board additionally concludes that the applicant satisfies the applicable CON standards of the HRAP for the purchase of diagnostic and therapeutic equipment, Findings ¶¶ 7-12, for quality measures and outcomes, Findings ¶¶ 13-16, and for construction and renovation, Findings ¶¶ 18-20.

Pursuant to the second criterion, 18 V.S.A. § 9437(2), we conclude that the applicant has shown that the cost of the project is reasonable. UVMMC obtained a favorable price for the replacement unit, Finding ¶ 17, and demonstrated that the project would be funded entirely with working capital or would be debt-financed only on favorable terms. Finding ¶ 20. The Board's hospital finance staff reviewed the application and had no concerns that the applicant would be unable to meet the project's cost. *Id.* UVMMC has confirmed that charges for PET/CT would not increase as a result of the purchase of the new unit. Finding ¶ 11. Less expensive alternatives are neither feasible nor appropriate, as disapproving the application would soon deprive Vermont's only tertiary hospital of an imaging technology necessary to maintain acceptable standards of care.

Pursuant to the third criterion, 18 V.S.A. § 9437(3), the applicant has demonstrated both an existing and reasonably anticipated need for the project. UVMMC, Vermont's only tertiary hospital, has been performing PET/CT scans since 2004. Finding ¶ 3. After utilization review, UVMMC has performed roughly 1,200 scans per year since 2009, providing an essential imaging service for many of Vermont's cancer, cardiac, and neurological patients. Finding ¶ 10. We conclude that it is reasonable to expect this need will continue. Additionally, recent federal legislation requires facilities offering PET/CT scans to upgrade to new, lower-radiation units or face reduced compensation for Medicare patients. Finding ¶ 6.

The applicant has also satisfied the fourth criterion, 18 V.S.A. § 9437(4), by demonstrating that the project will increase the quality of and access to healthcare for Vermonters. Quality will improve because Vermonters will be exposed to less radiation and experience faster scanning times than possible with the existing unit. Finding ¶ 8. The new unit has more advanced imaging capability than the existing unit, and will also allow UVMMC to perform QMBF testing for cardiac patients. Findings ¶¶ 8, 12. Replacing the existing unit and continuing UVMMC's PET/CT program will promote access to healthcare by allowing service to continue within the state's largest metropolitan area.

We further conclude that UVMMC's proposed purchase is consistent with the remaining statutory criteria to the extent they are applicable. The project will not have an undue adverse impact on other services provided by the applicant because the proposed project maintains a service essential to appropriate standards of care; the ways in which the project will serve the public good have been adequately addressed in our discussion of other criteria; the project is located in Vermont's largest population center and accessible by public transportation; and the project is not an information technology purchase as contemplated in 18 V.S.A. § 9351. *See* 18 V.S.A. § 9737(5), (6), (7), (8).

Based on the above, we conclude that the applicant has met each applicable statutory criterion, and issue a certificate of need on this date.

Order

Pursuant to 18 V.S.A. § 9440(d), the Green Mountain Care Board approves the application of the University of Vermont Medical Center and a Certificate of Need shall issue.

SO ORDERED.

Dated: September 7, 2016 at Montpelier, Vermont

s/ Alfred Gobeille)
)
s/ Cornelius Hogan)
)
s/ Jessica Holmes)
)
s/ Betty Rambur)
)
s/ Allan Ramsay)

GREEN MOUNTAIN
CARE BOARD
OF VERMONT

Filed: September 7, 2016

Attest: s/ Janet Richard
Green Mountain Care Board
Administrative Services Coordinator