

**STATE OF VERMONT
GREEN MOUNTAIN CARE BOARD**

In re: Application of the University of Vermont)
Medical Center, Replacement) GMCB-012-19con
Of Magnetic Resonance Imaging)
(MRI) System)
_____)

STATEMENT OF DECISION AND ORDER

Introduction

In this Decision and Order, we review the application of the University of Vermont Medical Center (UVMMC or “applicant”) for a certificate of need to replace its GE Excite 1.5T Magnetic Resonance Imaging (MRI) System with a Philips Ingenia Ambition 1.5T X (Philips) MRI imaging system and to renovate its MRI spaces, for a total cost of \$2,858,512.

For the reasons set forth below, we approve the application and issue the applicant a certificate of need, subject to the conditions set forth therein.

Procedural Background

On May 1, 2019, UVMMC filed a certificate of need (CON) application and request for expedited review. The Board granted expedited review on May 9, 2019. The Board requested that the applicant provide additional information regarding the project on May 17 and June 13, 2019, which UVMMC provided on May 23 and June 26, 2019, respectively. The application was closed on July 1, 2019.

Jurisdiction

The Board has jurisdiction over this matter pursuant to 18 V.S.A. § 9375(b)(8) and 18 V.S.A. § 9434(b)(2).

Findings of Fact

1. UVMMC currently has four fixed MRI systems and one mobile MRI system. Application (App.) at 6. UVMMC seeks to replace one of its fixed MRI systems, a 21-year-old General Electric Excite 1.5T MRI system installed in 1998 in the McClure Building, Lobby Level, Room L-131, with a Philips Ingenia Ambition 1.5T X (Philips 1.5T MRI) MRI system at the same location. UVMMC also seeks to make certain facilities renovations to house the new MRI system and to improve patient accessibility. Specifically, it seeks to renovate non-ADA-compliant MRI patient bathroom and changing areas; add another MRI patient holding area to accommodate current patient volumes; and renovate an existing MRI support equipment space and staff break/locker room. App. at 3, 6-7, 10.

2. The project is vital and necessary to enable UVMMC, the only tertiary and regional referral center in Vermont, with a service area of approximately one million people, to maintain its existing level of MRI services and implement quality enhancements made possible by the new MRI without a disruption in patient care. App. at 4, 18; Response to Questions (Resp.), Revised Statutory Criteria Submission (May 23, 2019) at 19.

3. The project involves routine replacement of 21-year-old MRI equipment that has reached the end of its useful life. This MRI has experienced increased downtime recently, requiring approximately 40 service calls during the past year, as well as image quality issues. App. at 8. Furthermore, it does not have the bore aperture needed to accommodate bariatric and claustrophobic patients and lacks certain functionality and enhancements available with the new equipment. The replacement MRI has improved image quality and a wide bore aperture that will accommodate bariatric and claustrophobic patients. App. at 6, 9. Currently, UVMMC must rely on its other MRIs to serve these patients, which can cause wait times that exceed industry standards for MRI access. App. at 8-9. As noted above, the project also involves renovations to changing and bathroom areas to be compliant with the Americans with Disabilities Act (ADA) and renovations to the waiting room and staff break and locker rooms. The project does not involve any new programs or services. App. at 3-4.

4. The benefits of MRIs are well documented and have become a standard of care for the diagnosis of many types of conditions. MRI is a diagnostic imaging technique that uses magnetic fields and radio waves to produce two or three-dimensional images of organs, soft tissues, bones and virtually all other structures inside the body. MRI images often provide physicians with a better assessment of various body parts than other imaging modalities, (e.g. X-ray, ultrasound and CT imaging) resulting in better detection of disease and improved diagnosis. Furthermore, because MRI uses magnetic fields and radio waves to generate images, it does not expose patients to radiation. App. at 4.

5. The Philips 1.5T MRI will provide improved image quality for the diagnosis of diseases and provide advanced technological functionality for neurology, oncology and cardiac software applications used by physicians making diagnoses in these areas. App. at 9. The Philips 1.5T MRI also has improved micro-cooling technology that requires significantly less helium for cooling, allowing for hours of high-performance imaging with no negative impact on image quality. This is desirable in a busy hospital radiology department. App. at 9. Lastly, the Philips 1.5T MRI allows shorter breath holds, which provides greater comfort for the patients, especially pediatric patients, and voice guidance during the imaging is provided through noise reducing headphones and entertainment screens. App. at 10.

6. Common uses of the MRI for detection of diseases include: imaging major organ systems including the heart, liver, biliary tract, kidneys, spleen, bowel, pancreas, prostate and adrenal glands; blood vessels for diagnosis of aneurysms and arterial blockages; detection of breast tumors; detection of lesions in abdominal region; musculoskeletal system for diagnosis of joint or cartilage tears; and the neurological system for detection of tumors and diagnosis of multiple sclerosis, Alzheimer's disease and dementia. App. at 5.

7. Driven by an aging population and a gradual shift to this safer imaging modality, UVMMC's MRI volumes have been steadily increasing over the past decade, growing roughly 15% between 2014 and 2018. MRI volumes across all of UVMMC's units were 18,070 in FY 2014; 18,785 in FY 2015; 18,971 in FY 2016; 19,209 in FY2017; and 20,818 in FY 2018; with a projected volume of 20,527 for FY 2019 (with or without the project). App. at 7-8; Resp. (June 26, 2019) at 1-2; Revised Table 7. Data provided by UVMMC from the Centers for Medicare and Medicaid Services (CMS) shows that UVMMC's utilization for medical imaging is below national averages. Resp. (June 21, 2019) at 3-4. Because the MRI is a replacement, no additional volumes due to the replacement MRI are anticipated. Resp. (June 26, 2019) at 1-2.

8. UVMMC is compliant with The Joint Commission's requirements on Infection Prevention and Surveillance. UVMMC's Infection Prevention Team has been in place since 1984, is led by the hospital's epidemiologist, and includes members certified in infection prevention. The team's activities include collection and analysis of infection data; evaluation of products and procedures; development and review of evidence-based policies and procedures; educational efforts directed at interventions to reduce infection risks; interpretation and implementation of changes mandated by regulatory accrediting and licensing agencies; and application of epidemiological and quality improvement principles, including activities that improve patient outcomes. App. at 15.

9. As discussed above, renovations will be made to the existing MRI room to accommodate the new MRI system. Patient bathrooms and changing rooms will also be renovated to be ADA-compliant; another MRI patient holding area will be added to accommodate current patient volumes; and an existing MRI support equipment room (which also currently serves as a staff break and locker room) will be renovated to create adequate MRI support space. App. at 10-11. Architectural renovations and upgrades to the mechanical, heating ventilation and air conditioning (HVAC) and plumbing systems will be made as part of the project to be compliant with FGI Guidelines for Hospitals and Health Care Facilities. Entities accredited by The Joint Commission are required to be compliant with current FGI Guidelines. App. at 10-11, 16.

10. The total cost of the project is \$2,858,512, which will be financed with working capital, with no issuance of debt. App at 19, Exhibit 2, Tables 1-2. The project will take a total of 26 weeks to be implemented in six phases. App. at 12-13. The current MRI is fully depreciated. App. at 3, 8, 17. All permanent and temporary displacements associated with the project are included in the project total cost. Resp. (June 26, 2019) at 1. The only alternative to replacing the MRI equipment, which is past its useful life, would be to delay replacement for a later date. Resp. to Questions, Revised Statutory Criteria Submission (May 23, 2019) at 20. The project was included in UVMMC's capital budget. In its 2019 hospital budget submission, \$5.1 million in MRI capital investments are reflected for fiscal year 2019-2020. App. at 16.

11. UVMMC will work with Burlington Electric Department to ensure that the design and products used for the project are energy efficient. Energy efficient LED lighting will be used to meet general and clinical illumination requirements and HVAC equipment will utilize the best possible technology to reduce energy consumption while ensuring a comfortable environment for patients. App. at 16, 20.

12. The project, which involves routine equipment replacement, will not result in any increase in the cost of medical care, will not raise charges for MRI imaging and will require no changes in staffing. App. at Exhibit 2, Table 8; Resp. to Questions, Revised Statutory Criteria Submission (May 23, 2019) at 20.

13. UVMMC has safeguards in place to prevent unnecessary and duplicative testing, which it will continue to follow. These safeguards include duplicative order checks by review of electronic medical records, utilization of decision support tools within the medical record that assist ordering providers to choose the right imaging modality; radiologist review to confirm MRI is the best imaging modality for the patient; and obtaining insurance pre-authorization to ensure payor agreement that MRI is a necessary service for a patient. App. at 17.

Standard of Review

Vermont's CON process is governed by 18 V.S.A. §§ 9431-9446 and Green Mountain Care Board Rule 4.000 (Certificate of Need). An applicant bears the burden of demonstrating that each of the criteria set forth in 18 V.S.A. § 9437 is met. Rule 4.000, § 4.302(3).

Conclusions of Law

I.

Under the first statutory criterion, the applicant must show that the proposed project aligns with statewide health care reform goals and principles because the project takes into consideration health care payment and delivery system reform initiatives; addresses current and future community needs in a manner that balances statewide needs (if applicable); and is consistent with appropriate allocation of health care resources, including appropriate utilization of services, as identified in the Health Resource Allocation Plan (HRAP). 18 V.S.A. § 9437(1).

We conclude that the project aligns with statewide health care reform goals and principles. This project does not expand services or increase projected volumes or charges but will improve the MRI imaging services UVMMC offers to patients. Findings of Fact (Findings) ¶¶ 2-3, 7. We further note that UVMMC has implemented safeguards to prevent overutilization of these services. Findings ¶ 13.

As required by 18 V.S.A. § 9437(1), the project is also consistent with the HRAP,¹ which identifies needs in Vermont's health care system, resources to address those needs, and priorities for addressing them on a statewide basis. *See* HRAP Standards 1.6 (applicant will collect and monitor data relating to health care quality and outcomes); 1.8 (applicant has a comprehensive evidence-based system for controlling infectious disease); 1.9, 1.10, and 1.12 (project is cost-effective, energy efficient and conforms with applicable FGI Guidelines); 3.4 (project has been included in hospital budget submissions); 3.5 (MRI capacity shall not be increased until capacity is in excess of valid state, regional and/or national benchmarks for medically necessary exams);

¹ The Vermont legislature in Act 167 (2018) made several changes to the State's CON law. *See* <https://legislature.vermont.gov/assets/Documents/2018/Docs/ACTS/ACT167/ACT167%20As%20Enacted.pdf>. As amended by Act 167, 18 V.S.A. § 9437(1)(C) continues to reference the HRAP, which is in the process of being updated. In the interim, we consider the current HRAP standards.

3.7 (existing equipment is fully depreciated); 3.19 (whether health care system costs may be reduced through more effective interventions through the use of the equipment); and 3.20 (address appropriateness of such distribution as compared to population, the availability of appropriately trained personnel, urgent versus non-urgent use and appropriate protocol to reduce the risk of repetitive testing).

Based on the above, we conclude that the applicant has met the first criterion.

II.

Under the second criterion, an applicant must demonstrate that the cost of the project is reasonable because the applicant's financial condition will sustain any financial burden likely to result from completion of the project and because the project will not result in an undue increase in the costs of medical care or an undue impact on the affordability of medical care for consumers. The Board must consider and weigh relevant factors, such as "the financial implications of the project on hospitals and other clinical settings, including the impact on their services, expenditures and charges [and whether such impact] is outweighed by the benefit of the project to the public." Under the second statutory criterion, the applicant must also demonstrate that less expensive alternatives do not exist, would be unsatisfactory, or are not feasible or appropriate; and if applicable, that the project has incorporated appropriate energy efficiency measures." 18 V.S.A. § 9437(2)(A-D).

After reviewing the record, we believe that the project's total cost of \$2,858,512 for the replacement of standard and necessary MRI equipment and the specified renovations is reasonable. The project will not create a financial burden to the applicant, which will finance the project with existing capital and will not take on additional debt to support the project. Finding ¶ 10.

We further find that the project will not unduly increase the costs of care, will not unduly impact the affordability of care for consumers, and any fiscal impact is outweighed by the benefit of the project to the public. The project includes a straight replacement of existing MRI equipment that is 21 years old and has begun to fail, is not available for use at all the times it is needed and does not accommodate bariatric or claustrophobic patients. The project also includes renovations necessary to comply with the ADA and to better accommodate MRI services. Findings ¶¶ 3, 9. The applicant will not increase its rates as a result of the project and does not expect changes in staffing. Finding ¶ 12.

The new wide bore replacement equipment will benefit both patients and providers; it is more technically advanced, will not experience the significant downtime that occurs with the current equipment that has exceeded its useful life, and will improve the quality of patient care through enhancements that provide advanced technological functionality for neurology, oncology and cardiac software applications used by physicians making diagnoses in these areas. Additionally, the new replacement equipment has a wide bore aperture that will accommodate bariatric and claustrophobic patients, noise reducing headphones for patients and voice guidance during imaging, and shorter required breath holds, each of which improves patient comfort, experience and ultimately quality of the image. Findings ¶¶ 3-6. We are also persuaded that there

are no viable, cost-effective alternatives to the project; the 21-year old MRI equipment has reached the end of its useful life and must be replaced. Findings ¶ 10.

We further find that the project has incorporated appropriate energy efficiency measures. Findings ¶ 11.

We conclude that the applicant has demonstrated that the cost is reasonable and has satisfied the second criterion.

III.

Under the third criterion, the applicant must show that “there is an identifiable, existing, or reasonably anticipated need for the proposed project that is appropriate for the applicant to provide.” 18 V.S.A. § 9437(3).

This project entails the replacement of existing, critically needed medical equipment in Vermont’s only tertiary care facility and does not add new services or expand the applicant’s service offerings. MRI imaging is a standard diagnostic tool used for imaging organs, soft tissues, bones and virtually all other structures inside the body. MRI images often provide physicians with a better assessment of various body parts than other imaging modalities, (e.g. X-ray, ultrasound and CT imaging) resulting in better detection of disease and improved diagnosis, without exposing patients to radiation. Findings ¶¶ 2-6. The equipment being replaced has outlived its useful life, experiences frequent downtime and delays in patient care, and the older technology does not accommodate bariatric or claustrophobic patients. Findings ¶¶ 2, 3.

Based on these facts, we conclude that applicant has satisfied the third criterion.

IV.

The fourth criterion requires that the applicant demonstrate that the proposed project will improve the quality of health care in Vermont, provide greater access to health care for Vermonters, or both. 18 V.S.A. § 9437(4).

As already discussed, the existing equipment is experiencing symptoms typical of equipment that is past its useful life, including increasing downtime and unavailability for needed patient care. The new equipment will increase access to care because it will be available for use on a regular and predictable basis. Findings ¶¶ 2-6. The new equipment will also provide improved image quality for the diagnosis of diseases; will provide advanced technological functionality for neurology, oncology and cardiac software applications used by physicians making diagnoses; and will accommodate bariatric and claustrophobic patients, thus improving quality of care and increasing access. Furthermore, the renovations for ADA compliance improve the quality of and access to health care. Finding ¶¶ 3, 9.

We therefore find that the applicant has met this criterion.

V.

The fifth criterion requires that the applicant demonstrate that the project will not have an undue adverse impact on any other services it offers. 8 V.S.A. § 9737(5). The project is primarily a straight replacement of essential MRI equipment, plus related renovations. Finding ¶ 3. The project does not expand or offer new services; rather, the project upgrades needed 21-year-old equipment to ensure that critical diagnostic services will continue to be available to patients in UVMMC's service area. Findings ¶¶ 2-3, 12. As the project simply improves an existing service and does not adversely impact any other services offered by UVMMC, we find that the criterion has been satisfied.

VI.

The sixth criterion was repealed during the 2018 legislative session. *See* 18 V.S.A. § 9437(6) (repealed).

VII.

The seventh criterion requires that the applicant adequately consider the availability of affordable, accessible transportation services to the facility, if applicable. As the project does not relocate, add or expand any patient services, we find that this criterion is not applicable.

VIII.

Next, if the application is for the purchase or lease of new Health Care Information Technology, it must conform to the Health Information Technology Plan established under section 18 V.S.A. 9351 (8). The criterion is not applicable to this project.

IX.

Last, the applicant must show the project will support equal access to appropriate mental health care that meets the Institute of Medicine's triple aims. 18 V.S.A. § 9437(9). The project neither involves mental health care services nor does it pose any barriers to mental health treatment, and the criterion is therefore not applicable.

Conclusion

Based on the above, we conclude that the applicant has demonstrated that it has met each of the required statutory criterion under 18 V.S.A. § 9437. We therefore approve the application and issue a certificate of need, subject to the conditions outlined therein.

SO ORDERED.

Dated: July 30, 2019 at Montpelier, Vermont.

s/ Kevin Mullin, Chair)
)
s/ Jessica Holmes)
)
s/ Robin Lunge)
)
s/ Tom Pelham)
)
s/ Maureen Usifer)

GREEN MOUNTAIN
CARE BOARD
OF VERMONT

Filed: July 30, 2019

Attest: Jean Stetter, Administrative Services Director