

**STATE OF VERMONT  
GREEN MOUNTAIN CARE BOARD**

In re: Application of University of Vermont )  
Medical Center, Replacement of ) GMCB-023-18con  
Interventional Radiology Equipment )  
In Suite 22 )  
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**STATEMENT OF DECISION AND ORDER**

Introduction

In this Decision and Order, we review the application of the University of Vermont Medical Center (UVMMC, or the applicant) for a certificate of need to replace the equipment in Interventional Radiology (IR) Suite 22 and make related renovations to accommodate the new equipment for a total cost of \$2,144,622.

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 August 14, 2018, UVMMC filed a certificate of need (CON) application and request for expedited review, which the Board granted on August 23, 2018. The Board requested that the applicant provide additional information regarding the project on August 24 and October 30, 2018, which UVMMC provided on September 28 and November 8, 2018, respectively. The application was closed on November 13, 2018.

Jurisdiction

The Board has jurisdiction over this matter pursuant to 18 V.S.A. § 9375(b)(1) and 18 V.S.A. § 9434(b)(1).

Findings of Fact

1. UVMMC is Vermont’s largest hospital and only academic medical center and teaching hospital. Located in Burlington, the hospital is part of The University of Vermont Health Network, a six-hospital network serving patients throughout Vermont and Northern New York State.

2. UVMMC seeks to replace its Philips Allura FD10 (Allura) angiography system with a Philips Azurion 7 FD20 (Azurion) ceiling-mounted system in IR Suite 22, one of the four IR suites located on its main campus, Application (App.) at 3, and make renovations to accommodate the new equipment. The project does not involve any expansion or development of new programs or services. App. at 3.

3. UVMHC's IR program is the only one of its kind in the region, serving patients throughout Vermont and northern New York. Only Dartmouth-Hitchcock Medical Center and Albany Medical Center offer IR programs of similar complexity. App. at 4.

4. Angiography is a medical imaging technique used by interventional radiologists to visualize the inside of blood vessels in several parts of the body, including the heart and brain, allowing radiologists to determine whether the vessels are diseased, narrowed, enlarged or blocked. Catheter angiography, the focus of this project, works by inserting a thin tube into an artery through a small incision in the skin, threading the catheter through the arterial system to the desired location, and injecting contrast material or dye to make the blood vessels visible on the x-ray. The use of the catheter makes it possible to do real time imaging and to combine diagnosis and treatment into a single procedure. App. at 4.

5. Procedures using catheter angiography for the treatment of many vascular diseases are targeted, minimally invasive, and are generally less costly, less risky and less painful for patients than the use of open surgical procedures. They carry a lower risk of infection and patients experience quicker recovery times, and most IR procedures may be performed on an outpatient basis or require shorter hospital stays. App. at 4-5.

6. The applicant's current IR equipment was purchased in 2005 and is fully depreciated. Having exceeded a 10-year service life, typical for such equipment, it experiences increasing downtime and unreliability. Lacking newly available technological enhancements, the clarity of imaging is not optimal, and procurement of parts can be difficult and increase equipment downtime. App. at 6.

7. The Azurion is a more advanced and complex technology platform than the Allura system. The Azurion allows for teams of clinicians to complete different tasks simultaneously in the IR suite, and for personnel to pre-program routine task and user preferences. App. at 7.

8. The Azurion is a more efficient operating system than the Allura. The Azurion emits lower levels of radiation and requires less energy for cooling. App. at 6.

9. UVMHC's IR Department follows quality measures established by the National Society of Interventional Radiologists (SIR). The SIR-recommended benchmark for overall complication rates, a key quality measure, is between 1% and 4%, with a maximum threshold of 5%. UVMHC's IR procedure complication rate by identified grouping was 1.09% in 2016 and 0.85% in 2017. App. at 9.

10. UVMHC's quality assurance and improvement program is consistent with Joint Commission<sup>1</sup> standards. UVMHC collects, compiles, and analyzes data internally to monitor performance, and shares the data with other hospital divisions to assist in decreasing complications system-wide. The Interventional Radiology division meets monthly to review

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<sup>1</sup> The Joint Commission is an independent, not-for-profit organization that accredits and certifies nearly 21,000 health care organizations and programs in the United States.

practices and any complications related to patient procedures, and utilizes evidence-based protocols and practice standards established by SIR. App. at 10.

11. The management of IR patients at UVMMC is based on ACR Appropriateness Criteria from the American College of Radiology. All requests for exams are reviewed in advance and are preauthorized by insurance companies. App. at 11.

12. UVMMC is in compliance with Joint Commission requirements for infection prevention and surveillance. Its infection prevention team, led by the hospital epidemiologist, collects and analyzes data; evaluates products and procedures; develops and reviews evidence-based policies and procedures; consults on infection risk assessment, prevention and control strategies; conducts educational activities directed at interventions to reduce infection rates; interprets and implements changes mandated by regulatory, accrediting and licensing agencies; and participates in research projects. App. at 11.

13. The volume of IR cases at UVMMC grew by approximately 22% from 2012 to 2017, when more than 14,000 were performed. App. at 5. The number is projected to decline, however, because UVMMC, as of the end of Fiscal Year (FY) 2017, has begun to perform image-guided pain injections at the Pain Clinic rather than in IR suites. UVMMC projects 12,576 cases in FY 2018, and the same number annually for each of the first three years of the project's implementation. App. at Table 8 (Utilization Projections); Responses to Questions (Resp.) (Sept. 28, 2018) at 1- 2.

14. The project will be completed in two phases over a ten-week period. First-phase renovations include new architectural finishes (*e.g.* cabinets, desks, flooring, storage closets and upgrades to overhead structural steel supports) and upgrades to the electrical, HVAC, ventilation and sprinkler systems to Suite 22. The use of McClure 1, Room 1176 and a portion of Room 1174 will be changed from a staff bathroom to an equipment storage closet for the four main electrical cabinets. An uninterrupted power supply system will be installed in McClure 1, Room 1271 to support the new equipment. The renovations will be compliant with applicable FGI Guidelines and the applicant will consult with Burlington Electric Department regarding the use of energy efficient components. The square footage of the IR suite will remain unchanged at 572 square feet. App. at 8, 12.

15. Phase 2 includes the installation of the Philips Azurion ceiling-mounted equipment. The applicant expects the current shielding to be adequate, but if any modification is necessary, UVMMC will use funds from the contingency line item. The adequacy of the shielding system will be validated by a UVMMC radiation physicist as part of the acceptance testing of the new equipment. App. at 8.

16. The project was intentionally planned after the busier summer months when patient volumes typically decline. During the renovation and installation period, volumes will be accommodated by shifting clinically appropriate patients to other IR suites and fluoroscopy rooms, and by extending hours as needed. Resp. (Sept. 28, 2018) at 2.

17. The total project cost is \$2,144,622 which includes \$1,335,245 for the equipment and \$809,377 in renovations, design bidding/construction contingencies, construction manager fees, furniture, fixtures, architectural/engineering fees administrative and permitting fees. App. at 3.

18. UVMHC included \$2.4 million for the project in its FY 2018 capital budget submission to the Board. App. at 13. The project will be financed with working capital and will not require any borrowing of funds. App. at 3, 13.

### 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 to demonstrate 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 application 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 HRAP pursuant to section 18 V.S.A. §9405.

We conclude that the application meets this criterion, and aligns with statewide health care reform goals and principles. This project does not expand services, but will allow UVMHC, the only hospital in the region to offer this type of program, to continue offering treatments to patients in Vermont and upstate New York. With advances in technology, the treatments will be less costly, and most patients will recover faster and experience a reduced risk of infection. Findings of Fact (Findings) ¶¶ 3, 4. We further note that UVMHC participates in statewide health care reform efforts including OneCare Vermont, an Accountable Care Organization,<sup>2</sup> and the All Payer Model, which emphasize coordinated care and keeping patients well.

The application is also consistent with the HRAP, which identifies needs in Vermont's health care system, resources to address those needs, and priorities for addressing them on a statewide basis. 18 V.S.A. § 9437(1). Although not updated since 2009—the HRAP is currently being revised—the applicant has demonstrated that this project is consistent with the relevant HRAP standards.<sup>3</sup> See, HRAP Standard (Standard) 1.6 (applicant will collect and monitor data relating to quality and outcomes related to the proposed new project); Standard 1.7 (applicant has

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<sup>2</sup> See, e.g., <https://www.uvmhealth.org/medcenter/pages/about-uvm-medical-center/partnerships/accountable-care.aspx>; <https://onecarevt.org/ModelsOfCare>.

<sup>3</sup> 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 Health Resource Allocation Plan (HRAP), which is in the process of being updated. In the interim, we consider the current applicable HRAP standards will apply.

explained how the project is consistent with evidence-based practice); Standard 1.8 (applicant shall demonstrate that it has a comprehensive evidence-based system for controlling infectious disease; Standards 1.9, 1.10, 1.12 (project is cost-effective, energy efficient and conforms with applicable FGI Guidelines); Standard 3.4 (project has been included in hospital budget submissions); Standard 3.7 (existing equipment is fully depreciated).

## II.

Under the second criterion, an applicant must demonstrate that the project cost is reasonable because the applicant's financial condition will sustain any financial burden likely to result from completion of the project and that 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 "including 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." The applicant must show 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 \$2,144,622 for the replacement of critical IR equipment and related renovations to accommodate the new equipment is reasonable. Findings ¶ 17. The project will not create a financial burden to the applicant, which will finance the project without taking on additional debt. Findings ¶ 18.

We further find that the project will not unduly increase the costs of care or unduly impact the affordability of care for consumers. The project is a straight replacement of existing IR equipment that has reached its useful life. Finding ¶ 6. The new equipment will be more technically advanced, will not experience the significant downtime that occurs with the current equipment, and will be less costly to operate. Finding ¶¶ 6, 7. The project will also improve the quality of patient care, produce speedier recoveries and reduced risk of infection. Finding ¶ 5. We are also persuaded that there are no viable, cost-effective alternatives to the project; the equipment in IR Suite 22 has reached the end of its useful life and must be replaced. Findings ¶ 6.

We conclude that the applicant has demonstrated that the cost is reasonable and has satisfied the second criterion.<sup>4</sup>

## 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).

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<sup>4</sup> We find that subsection D of 18 V.S.A. § 9437(2) concerning energy efficiency, is not applicable to this project, which involves only minor renovation necessary to accommodate the new equipment.

Again, this project entails the replacement of existing equipment and does not add new services or expand the applicant's service offerings. Finding ¶ 2. The equipment being replaced has outlived its useful life, experiences frequent downtime, and the quality of imaging has declined. Finding ¶ 6. UVMMC is the only entity in Vermont offering IR services, and replacement of the aging equipment is needed to assure access to needed services for residents of UVMMC's service area in Vermont and northern New York. Finding ¶ 3. Based on these facts, we conclude that there is an identifiable and existing need for the project, satisfying 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).

We find that the applicant has demonstrated both an improvement in the quality of, and greater access to, health care. As we discussed above, the existing equipment is experiencing typical symptoms of equipment past its useful life including increasing downtime and degradation of image quality. Finding ¶ 6. The new equipment will be more technically advanced, produce higher quality imaging and reduce patient recovery time and the risk of infection. Finding ¶¶ 5, 7. In addition to improving the quality of care, the reduced downtime, resulting in greater availability of the equipment, will ensure greater access to needed services for patients in UVMMC's service area.

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 a straight replacement of essential IR equipment. Finding ¶ 2. The project does not expand services, nor offer additional ones. Finding ¶ 2. Rather, the project upgrades needed equipment that has passed its useful life, and will ensure that critical services will continue to be available to patients in the UVMMC service area. Finding ¶ 6. We therefore conclude that there will be no negative impact on any other services UVMMC offers, and 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, *see* Finding ¶ 2, we find that this criterion has been satisfied.

VIII.

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

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). Because this project does not involve mental health care services, this criterion is 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: December 19, 2018 at Montpelier, Vermont.

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

GREEN MOUNTAIN  
CARE BOARD  
OF VERMONT

Filed: December 19, 2018

Attest: Jean Stetter, Administrative Services Director