STATE OF VERMONT **GREEN MOUNTAIN CARE BOARD**

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In re: Application of the University of Vermont Medical) Center to Replace a CT Scanner and Construct a Mobile Pad Addition to the Essex Primary Care Facility

GMCB-012-22con

STATEMENT OF DECISION AND ORDER

Introduction

In this Statement of Decision and Order we review the application of the University of Vermont Medical Center (UVMMC or "the Applicant") for a certificate of need (CON) to replace a CT scanner located in McClure Level 1, Room 1079 (CT Room 2) on its main campus and make associated renovations to the existing CT room and adjacent areas to accommodate the installation of the new replacement scanner. The project also includes the construction of an addition to the Essex Primary Care Facility to house a pad for a mobile imaging unit. UVMMC will rent a mobile CT trailer unit to be housed in the new addition for one year for \$69,000 during the installation of the new Spectral CT scanner ("the project") on its main campus. The mobile pad will also be available in the future to accommodate a mobile CT, MRI or PET/CT unit to provide temporary capacity during future equipment replacements. The total cost of the project is \$3,456,928.

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

Procedural Background

On September 28, 2022, UVMMC filed a CON application for the project and requested expedited review. On October 12, 2022, the Green Mountain Care Board (Board) granted UVMMC's request for expedited review. Between October 14, 2022, and March 17, 2023, the Board requested and UVMMC provided additional information regarding the project. The Board closed the application on April 13, 2023.

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. Computed tomography (CT) scanners use a rotating x-ray beam to produce cross-sectional images or "slices" of the inside of the body that can be combined to form a three-dimensional picture. The technology is widely used to diagnose muscle and bone disorders; pinpoint the location of tumors, infections, or blood clots; guide procedures such as surgery, biopsy, and radiation therapy; detect internal injuries or bleeding; detect and monitor conditions such as cancer, heart disease, lung nodules, and liver masses; and monitor the effectiveness of certain treatments. Application (App.), 14.

2. UVMMC's Radiology Department has six CT scanners. App., 2. Between fiscal years 2016 and 2021, CT scan volumes at UVMMC grew by nearly 30%, from 43,365 to 56,038 per year. App., 2. The number of CT scans provided to the inpatient population at UVMMC grew by almost 45% between fiscal years 2019 and 2021, driving a 7.4% increase in CT scan volumes overall. UVMMC expects CT scan volumes to continue to grow over the next decade. App., 3.

3. The oldest of UVMMC's CT scanners is a Philips Brilliance ("the Brilliance unit") unit located in McClure 1, Room 1079 (CT Room 2). This scanner is the hospital's last 64-slice unit; the other scanners are either 128- or 256-slice units, meaning they have more detectors and provide more data per revolution of the x-ray beam. *See* App., 1-2. The more slices a CT scanner has, the more quickly it can image the body and the more detailed those images are. Some procedures that are not possible on lower slice CT scanners are possible on CT scanners that have more slices. *See* Vermont Department of Banking, Insurance, Securities & Health Care Administration, Health Resource Allocation Plan (July 1, 2009), 76, n. 51.

4. The Brilliance unit is in its seventeenth year of service, having been installed in September 2005. The unit is fully depreciated and has reached the end of its service life. App. 1, 13. The unit's "downtime" increased from 15 hours in 2021 to 112 hours in 2022. Response to Questions (Resp.) (Nov. 17, 2022), 3. The unit's image quality has deteriorated, and its outdated technology raises concerns about ongoing service and maintenance. Additionally, the size of the Brilliance unit's bore - the opening that a patient moves through during a scan - does not accommodate bariatric patients. *See* App., 1, 4, 10, 15.

5. UVMMC plans to replace the Brilliance unit with a 256-slice Philips Spectral CT 7500 scanner ("the Spectral CT unit"), which will provide superior images. The new Spectral CT unit will improve tissue characterization and visualization and may reduce the need for follow-up scans. Unlike the existing Brilliance unit, the Spectral CT unit can produce images with and without contrast agents using a single scan instead of two separate scans. *See* App., 4; Resp., (Nov. 17, 2022), 2. The Spectral CT unit will be UVMMC's most advanced CT technology. App., 4. Finally, the Spectral CT unit can accommodate bariatric patients and the lower table provides better patient experience for individuals in wheelchairs. App., 1, 4, 10, 15.

6. UVMMC is accredited by the Joint Commission and is required to follow the FGI Guidelines for Design and Construction of Hospitals (FGI Guidelines) as a condition of accreditation. App., 12. All planned upgrades have been reviewed to ensure that applicable construction standards are met and that the upgrades comply with the FGI Guidelines. App., 5.

7. The project involves two components to be completed in phases, with 16 weeks spent in Essex and eight weeks on the main campus. App. 1. In advance of the CT equipment replacement, UVMMC will construct an addition to house a pad for a mobile imaging unit at its Essex Primary Care facility. UVMMC will rent a GE VCT 64-slice mobile CT scanner that will be placed at the

site for one year at a cost of \$69,000 while the Spectral CT unit is being installed and associated renovations are being made. *See* App., 1, 5-6, 9. The new Spectral CT unit will be placed in CT Room 2 on UVMMC's main campus. The installation includes the scanner and table assembly, along with the required support equipment. An uninterrupted power supply (UPS) that currently serves CT Rooms 1 and 2 will support the new Spectral CT unit and associated equipment, while a new, smaller UPS will be purchased and installed to serve the existing CT Room 1 equipment. Facility renovations will also be made in connection with the CT replacement and upgrades will be made to architectural, mechanical HVAC, electrical, and plumbing systems within various CT support rooms. Changes are also planned for neighboring rooms to accommodate the installation. App., 1, 4-5.

8. UVMMC determined that an addition to its Essex Primary Care facility, constructed in 2020, was the best location to house a mobile radiology unit as it was designed with ample parking and space to accommodate potential expansion. Essex Primary Care is centrally located in Chittenden County with good access by car and, like UVMMC's main campus, is served by public transportation (Green Mountain Transit). The addition will include general mobile trailer access space and a partial enclosure to house one mobile imaging unit as well as a storage/prep room and changing space. The addition has been designed to accommodate a variety of mobile imaging units, including MRI, CT, and PET/CT mobile trailers. App., 5-7.

9. UVMMC expects that the new Spectral CT unit will operate during the same hours as the existing Brilliance unit, from 8 a.m. to 8 p.m., Monday through Friday, while the temporary mobile unit at Essex Primary Care will be open during the same hours as the Essex facility, 8 a.m. to 5 p.m. App., 7; Resp. (Nov. 17, 2022), 2.

10. UVMMC consulted with Efficiency Vermont and the Burlington Electric Department regarding the project. The Burlington Electric Department, which provides efficiency assistance within Burlington, provided a letter stating that the replacement of the CT scanner and associated renovations at UVMMC's main campus embrace energy efficiency opportunities that can reasonably be expected with a project scope of this size. Resp. (Nov. 17, 2022), 3-4.

11. UVMMC anticipates using energy efficient LED lighting to meet general clinical imaging illumination requirements. HVAC equipment will be commissioned in accordance with FGI Guidelines, and UVMMC will use available technology to reduce energy consumption while ensuring a comfortable environment for patients and staff. App., 7.

12. The project includes no additional FTEs. FTEs assigned to work in CT Room 2 on the existing equipment will be trained to perform scans on the mobile CT unit at Essex Primary Care during installation of the new unit and associated renovations. The training will take approximately three days and will be performed during normal operating hours with minimal impact on patients. App., 7, Staffing Report, Table 8.

13. There are no technical obstacles with the Spectral CT unit's connectivity to the UVMMC network. The equipment will utilize the same Picture Archiving and Communication System as the current equipment, which has an established interface with Epic. UVMMC expects no impact on Epic or additional interfacing required by the project. App., 7.

14. The capital expense for the project is projected to be \$3,456,928, which includes approximately \$2.5 million for the equipment replacement, main campus renovation, and capitalized interest, and approximately \$945,000 for the mobile pad at the Essex Primary Care facility. *See* App.,1, 7-8, Financial Table 1, Project Costs.

15. The project will be financed with equity. The project will reduce UVMMC's Days' Cash on Hand by approximately 0.7 days. Resp. (Jan. 13, 2023), 2.

16. The financial tables submitted by UVMMC in connection with its application show an incremental negative operating margin for the project of between \$431,421 and \$471,402 per year, mostly due to depreciation of \$452,631 per year. *See* Resp. (Feb. 24, 2023), Income Statement, Table 3B. Generally, the average reimbursement for the five highest volume imaging services for Commercial payers is projected to be somewhat less for the Spectral CT unit than the existing 64-slice CT because of Spectral unit's ability to produce images with and without contrast agents using a single scan. *See* App., 4; Resp. (Nov. 17, 2022), 2; Resp. (Apr. 5, 2023), 2-3; Findings, ¶ 5, *supra*.

17. Capital for the CT equipment replacement and renovation was reserved by UVMMC in its fiscal year 2022 capital budget. Capital for the new mobile addition at the Essex Primary Care facility was included in UVMMC's fiscal year 2023 capital budget. App., 12.

18. UVMMC has negotiated a 57.5% pricing discount off the list price with Philips for CT scanner purchases. Resp. (Nov. 17, 2022), 3.

19. UVMMC complies with Joint Commission requirements on Infection Prevention and Surveillance. Its Infection Prevention Team was established in 1984 and strives to reduce and prevent healthcare-associated infections as part of the James M. Jeffords Institute for Quality and Operational Effectiveness. The team is led by the Hospital Epidemiologist and includes members certified in infection prevention. The team's infection prevention activities include collection and analysis of infection data; evaluation of products and procedures; development and review of evidence-based policies and procedures; consultation on infection risk assessment and prevention and control strategies; educational efforts directed at interventions to reduce infection risks; and application of epidemiological and quality improvement principles, including activities directed at improving patient outcomes. Resp. (Nov. 17, 2022), 1-2.

20. UVMMC's Radiology Department follows a quality assurance/improvement program consistent with Joint Commission standards, including Performance Improvement Standards PI.01.01.01 (requiring hospitals to collect data to monitor their performance) and LD.03.02.01 (requiring hospitals to use data and information to guide decisions and understand variation in the performance of processes supporting safety and quality). The Radiology Department collects, analyzes, and reports data in order to investigate and evaluate risks and potential risks to patient safety, and to develop action plans to reduce risks that are identified. UVMMC also has a Radiology Quality Committee that meets bi-monthly. This committee identifies and improves systems and processes that promote quality outcomes and patient safety; oversees monitoring activities intended to assess whether radiology services rendered were professionally indicated and

performed in compliance with applicable standards of care; and reviews and recommends actions based on quality metric reports. App., 10-11.

21. UVMMC providers make decisions regarding the appropriate and effective use of imaging with reference to the American College of Radiology's ACR Appropriateness Criteria, which are evidence-based guidelines that were developed to assist referring physicians and other providers in making the most appropriate imaging or treatment decision for a specific clinical condition and to avoid unnecessary or duplicative testing. App., 11, 13.

22. UVMMC has verified that it does not have financial incentives in place to encourage CT utilization. App., 13. UVMMC also states that there are no known or perceived conflicts of interest between hospitals and physicians and the vendor or manufacturer of the Spectral unit. App., 14.

23. If a patient seeking imaging at UVMMC or Essex Primary Care expresses a need for mental health services and is not in an acute crisis, providers would refer them back to their primary care physician. The primary care offices of the UVM Health Network have mental health professionals collaborating with their medical homes. For patients in acute crisis, providers would follow the UVM Health Network's suicide risk assessment protocol, which may include contacting 911 (from Essex Primary Care) or UVMMC's internal Medical Emergency Team (at the main campus) to facilitate an assessment of the patient and determine appropriate care. *See* App., 16-17.

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, an applicant must demonstrate 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; 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). The HRAP identifies needs in Vermont's health care system, resources to address those needs, and priorities for addressing them on a statewide basis.¹

The project reasonably aligns with health care payment and delivery system reform initiatives. The project involves the replacement of a seventeen-year-old CT scanner that is at the

¹ The Vermont legislature in Act 167 (2018) made several changes to the State's CON law. 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. The Health Resource Allocation Plan is posted to the Board's website at https://gmcboard.vermont.gov/sites/gmcb/files/documents/Vermont%20Health%20Resource%20Allocation%20Pla n%202009%207.1.09.pdf.

end of its useful life and is experiencing image deterioration and increased downtime. Findings of Fact (Findings), ¶ 4. The new scanner will provide more accurate images with improved tissue characterization and visualization and will generate images with and without contrast agents using a single scan instead of two separate scans. Findings, ¶ 5. This has the potential to lead to earlier and more accurate diagnoses that, in turn, may lead to better treatment outcomes at less cost. While performing CT scans that are duplicative or not clinically indicated can lead to higher overall health care costs, UVMMC providers use evidence-based guidelines that were developed to assist them in making the most appropriate imaging or treatment decision for a specific clinical condition and to avoid unnecessary or duplicative testing. Additionally, UVMMC's Radiology Quality Committee oversees monitoring activities to assess whether radiology services were professionally indicated and performed in compliance with applicable standards of care. Findings, ¶¶ 20-21.

The project also addresses current and future needs in a manner that balances statewide needs. UVMMC serves patients across Vermont and northern New York. CT scanners are powerful diagnostic tools that are important in the practice of modern medicine. *See* Findings, ¶ 1. CT scan volumes at UVMMC grew by nearly 30% between fiscal years 2016 and 2021 and UVMMC expects continued growth in these volumes over the next decade. Findings, ¶ 2. UVMMC needs to replace its Brilliance scanner, which, again, is at the end of its useful life, if it is to meet current and future needs for this type of imaging. *See* Findings, ¶ 4.

Finally, the project is consistent with appropriate utilization of services, as identified by HRAP:

- Standard 1.6 (collect and monitor data relating to health care quality and outcomes), *see* Findings, ¶ 21.
- Standard 1.7 (project is consistent with evidence-based practices), *see* Findings, ¶ 21.
- Standard 1.8 (comprehensive, evidence-based system for controlling infectious disease), Findings, ¶ 19.
- Standards 1.9 1.10 (costs and methods of construction are necessary and reasonable; reasonable energy conservation measures have been taken; and Efficiency Vermont or similar organization has been consulted), *see* Findings, ¶¶ 6-7, 10-11, 14, 18.
- Standard 1.12 (construction projects shall comply with FGI Guidelines), Findings, ¶¶ 6, 11.
- Standard 3.4 (applicants subject to budget review must demonstrate that a proposed project has been included in hospital budget submissions), Findings, ¶ 17.
- Standard 3.6 (applicants proposing a project involving CT must provide information on current use, document the effectiveness of internal program to prevent overuse, and verify applicant does not have financial incentives in place to encourage CT utilization), *see* Findings, ¶¶ 2, 21-22.
- Standard 3.7 (applicants proposing to replace diagnostic or therapeutic equipment must demonstrate that existing equipment is fully depreciated, or the cost of the early replacement is less costly than keeping the existing equipment), Findings, ¶ 4.

- Standard 3.20 (appropriateness of distribution of equipment, availability of trained personnel, patient need vs. convenience, and protocols to reduce risk for repetitive testing), *see* Findings, ¶¶ 2, 20-21.
- Standard 3.24 (disclosure of potential financial conflicts of interest between hospitals and physicians and an equipment purchase), Findings, ¶ 22.

For the reasons stated above, we conclude that UVMMC has satisfied the first criterion.

II.

The second criterion requires an applicant to demonstrate that the cost of the project is "reasonable" because the applicant can sustain any financial burden likely to result from the project; the project will not result in an undue increase in the cost of care or an undue impact on the affordability of medical care for consumers; less expensive alternatives do not exist, would be unsatisfactory, or are not feasible or appropriate; and appropriate energy efficiency measures have been incorporated into the project. 18 V.S.A. § 9437(2).

UVMMC can sustain any financial burden likely to result from the project. The capital expense, just under \$3.5 million, will be financed with equity, reducing UVMMC's Days' Cash on Hand by approximately 0.7 days. Findings, ¶¶ 14-15. The impact on UVMMC's operating margin will be minimal. *See* Findings, ¶ 16.

The project will not result in an undue increase in the cost of care or an undue impact on the affordability of care for consumers. The project will not have a negative material impact on other clinical settings. Generally, the projected average reimbursement for the five highest volume imaging services for Commercial payers is projected to be somewhat less for the Spectral CT unit than the existing Brilliance unit, given the Spectral unit's capacity to produce images with and without contrast agents using a single scan. Findings, ¶¶ 5, 16.

Less expensive alternatives to the project do not exist, would be unsatisfactory, or are not feasible or appropriate. Continuing to utilize the existing Brilliance unit is an unsatisfactory alternative. The unit has been in operation for seventeen years and is at the end of its useful life, raising concerns about ongoing maintenance and servicing, deteriorating image quality and increased downtime. Findings, ¶ 4. UVMMC has reasonably determined that the unit needs to be replaced and that the Spectral CT unit is the most appropriate replacement due to its advanced technology and larger bore. *See* Findings, ¶ 5. Construction of the new addition for a mobile unit pad at the Essex Primary Care facility will temporarily allow outpatient CT scans to continue for one year while the new Spectral equipment is being installed and renovations are being completed and, once the CT replacement is complete, the pad can be used on a short-term basis for CT, MRI, and/or PET/CT mobile units during future equipment replacement projects to meet patient demand for imaging services if needed. *See* Findings, ¶ 7-8.

Finally, appropriate energy efficiency measures have been incorporated into the project. See Findings, $\P\P$ 10-11.

For the reasons stated above, we conclude that UVMMC has satisfied the second criterion.

The third criterion requires that the applicant demonstrate that there is an "identifiable, existing, or reasonably anticipated need for the proposed project which is appropriate for the applicant to provide." 18 V.S.A. § 9437(3).

There is a need for the project. The project involves the replacement of a CT scanner that has reached the end of its useful life. Replacing this scanner now will avoid potential downtime and servicing issues and will improve the speed and the quality of the images, to the benefit of patients and providers. *See* Findings, ¶¶ 3-5. Finally, the construction of the mobile pad at the Essex Primary Care facility will meet a need to continue performing outpatient CT scans while the new scanner is being installed and the associated renovations are being made to the main campus. *See* Findings, ¶¶ 7-8.

Based on the above, we conclude that the UVMMC has satisfied the third criterion.

IV.

To satisfy the fourth criterion, the applicant must demonstrate that the project improves the quality of health care or provides greater access for Vermonters, or both. 18 V.S.A. § 9437(4).

This project is likely to improve quality by offering better, higher resolution images and reducing the need for multiple or follow-up scans in some cases. The project will provide greater access in that the CT scanner will be available to a wider pool of patients. Furthermore, the existing Brilliance unit is at the end of its useful life and has experienced increasing downtime and it needs to be replaced to maintain current levels of access. *See* Findings, ¶¶ 4-5. Finally, the addition of the mobile pad and short-term rental of the mobile CT unit at Essex Primary Care will maintain access to needed CT imaging services during the installation of the new Spectral CT unit and completion of the associated renovations. In addition, the mobile pad will accommodate CT, MRI and PET/CT mobile units on a short-term basis during replacements of such equipment in the future so that imaging needs are not disrupted during the period when such equipment is being replaced. *See* Findings, ¶¶ 7-8.

Based on the above, we conclude that the fourth criterion is satisfied.

V.

The fifth criterion requires an applicant to show that the project "will not have an undue adverse impact on any other existing services provided by the applicant." 18 V.S.A. § 9437(5).

Replacing the existing Brilliance unit with the Spectral unit will not affect other existing services provided by UVMMC. The Spectral unit has enhanced functionality and the construction of a mobile pad and short-term rental of a mobile CT unit at Essex Primary Care will ensure that imaging needs continue to be met during the project's renovation and installation period, mitigating potential negative impacts that might otherwise occur from the installation of a new CT

scanner and completion of associated renovations at UVMMC's main campus. *See* Findings, ¶¶ 4-5, 7-8.

We conclude that the fifth criterion is satisfied.

VI.

What was previously the sixth criterion is now an overarching consideration, namely that the project serves the public good. *See* Act 167 (2018), § 6 (repealing 18 V.S.A. § 9437(6) and moving the "public good" language to the lead-in sentence). Our administrative rule identifies factors that we may consider in determining whether a project will serve the public good, including whether the applicant has demonstrated that it has analyzed the project's impact on the healthcare system and the project furthers effective integration and coordination of health care services, and whether the project will have an adverse impact on existing facilities' ability to provide medically necessary services to all in need, regardless of ability to pay or location of residence (Rule 4.000, § 4.402(3)(c), (f)).

For reasons explained in the criteria above, the project will serve the public good.

VII.

The seventh criterion requires that the applicant adequately consider the availability of affordable, accessible patient transportation services to the facility. 18 V.S.A. § 9437(7). We find this condition has been satisfied. The project is primarily located on UVMMC's main campus in Burlington, which is served by Green Mountain Transit. The Essex Primary Care facility where the mobile pad will be constructed and the mobile CT scanner will be temporarily located, is also served by Green Mountain Transit. Findings, ¶ 8. We previously concluded that UVMMC adequately considered the availability of affordable, accessible transportation to the Essex Primary Care facility. *In re Application of University of Vermont Medical Center, Replacement of Building for Essex Adult Primary Care*, GMCB-001-19con, Statement of Decision and Order (May 31, 2019), 8.

VIII.

The eighth statutory criterion states that if the application is for the purchase or lease of new Health Care Information Technology, it must conform to the Health Information Technology Plan. 18 V.S.A. § 9437(8). As the project does not involve the lease or purchase of new Health Care Information Technology, this criterion is not applicable. *See* Findings, ¶ 13.

IX.

The ninth and final criterion requires the applicant to demonstrate that the project supports equal access to appropriate mental health care that meets standards of quality, access, and affordability equivalent to other components of health care as part of an integrated, holistic system of care, as appropriate. 18 V.S.A. § 9437(9). This project involves the replacement of an existing CT scanner. At these practices, UVMMC's referral process for patients who express a need for mental health services and are not experiencing an acute crisis includes referring them back to

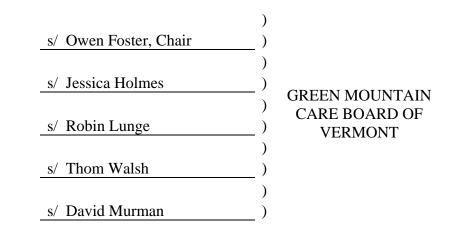
their primary care physicians who will work with their mental health care provider colleagues to best assess the patient's needs. For patients in acute crisis, the practices follow UVMMC's suicide risk assessment protocol. Findings, \P 23. To the extent this criterion is applicable to the project, we find that it is satisfied.

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: May 1, 2023 at Montpelier, Vermont.



Filed: May 1, 2023

Attest: s/ Jean Stetter, Administrative Services Director Green Mountain Care Board

NOTICE TO READERS: This decision is subject to revision of technical errors. Readers are requested to notify the Board (by email, telephone, or in writing) of any apparent errors, so that any necessary corrections may be made. (email address: donna.jerry@vermont.gov).