

That ability has allowed the provision of higher doses of radiation each day, resulting in fewer, but longer treatments per patient. Application (App.), 1, 12, 13.

2. UVM Health Network (the “Network”) engaged ECRI¹, an expert healthcare consulting organization, to evaluate the technology, procedure volumes, utilization, and projected LINAC replacement needs across the Network. ECRI recommended the phased replacement of six Network LINACs over a five-year timeframe. CVMC’s is the first to be replaced, as it is the Network’s oldest, is in need of the most upgrades, and will no longer be supported by the vendor based on component obsolescence and technological advances. LINAC replacement projections were developed using industry-accepted benchmarks for age (15 years), beam hours (3,500), and factors influencing replacement needs such as intensity of use, technology obsolescence, and reliability. Following an in-depth review of technological offerings and economic impacts, a Network interdisciplinary team, with guidance from ECRI, selected Varian as the vendor for the six new LINACs and the TrueBeam model for CVMC, which is essentially an updated version of the existing model with better imaging and some additional capabilities. CVMC is the only site currently using the Varian platform for clinical reporting, making replacement and commissioning of a new LINAC quicker than at other sites, as the Network moves to fully align its Radiation Oncology Information Systems (ROIS) to Varian². App., 1- 3.

3. CVMC currently operates its LINAC near capacity with approximately 15 procedures performed daily (weekdays), for approximately 4,000 procedures annually. The project is not expected to increase procedure volumes. Instead, the project will enable CVMC to meet current and future demand and maintain patient access to services. This project does not create any new services or expand or modify existing services. CVMC does not anticipate additional volumes attributable to the project. Because this project is for the replacement of existing equipment at the same location, transportation services to the facility will be unchanged. App., 2, 3, 16.

4. The project also includes modifications to the LINAC bunker room and control room, as well as necessary upgrades to mechanical and electrical systems. These include cutting and coring existing concrete to facilitate replacement of the base frame and new under-slab utilities, new electrical feeds, replacement of the LINAC-dedicated chiller, ergonomically designed workspace, and new finishes. The project will consist of three phases and take approximately six months to complete. CVMC believes reuse of existing adequate support spaces yields the most cost-effective and reasonable construction. App., 1,2, 6, 11.

5. CVMC serves as a community hospital for most of its patients receiving radiation treatments. Most patients reside in towns within an approximate 35-mile radius of the facility, although some patients travel as much as 60 miles for treatments. Should the current LINAC fail or suffer significant downtime due to component or service unavailability, patient access to needed care would be impeded. Delays in care are both inconvenient and stressful for patients, and prolonged delays could impact the chance of a cure. If a delay was thought to be excessive, the patient would be transferred for care to UVM Medical Center. App., 4.

¹ ECRI is a non-profit independent expert on healthcare technology and safety. App., 1.

² ECRI’s recommendations include aligning Network hospitals to a single technology platform to foster integration of care and remote treatment planning. Using a common platform and software will provide cancer patients access to specialized treatment and treatment planning expertise from throughout the Network. App., 3.

6. The capital expense for this project is approximately \$3.66M, which includes \$2.6M for the equipment replacement, and \$1.06M for the facilities modifications and upgrades. CVMC plans to fund the project without debt financing. The project alone will not impact system costs. Implementing the full range of ECRI recommendations for integrating the treatment planning and oncology information system will over time improve efficiency by allowing distribution of work throughout the Network and incrementally decreasing the need for duplicative staffing. App., 7, 12.

7. CVMC Radiology Department follows a quality assurance/quality improvement program consistent with Joint Commission standards which require hospitals to collect data to monitor their performance and to use data and information to guide decisions and to understand variation in the performance of processes supporting safety and quality. The Department collects, analyzes, and reports data to investigate and evaluate risks, or potential risks, to patient safety and to develop action plans to reduce any risks that are identified. A patient receiving services who expresses a need for mental health services and is not in an acute crisis would be referred to their primary care physician. App., 10, 16.

8. CVMC's Radiation Oncology Department is accredited by a national agency; CVMC is accredited by the American College of Radiology. All patient treatments performed at CVMC are reviewed in weekly scheduled peer-reviewed meetings. A component of that review is to confirm that treatments meet standard published guidelines, most commonly the National Comprehensive Cancer Network (NCCN) guidelines. App., 10.

9. CVMC complies with Joint Commission requirements on Infection Prevention and Surveillance. Its Infection Prevention Team strives to reduce and prevent healthcare-associated infections as part of the Department of Quality & Performance Improvement. The team is supported by an Infectious Disease Physician and includes members certified in infection prevention. App., 10, 11.

10. CVMC is working with Efficiency Vermont in its planning and implementation of the project. CVMC will use replacement energy-efficient LED lighting to meet general and clinical procedure illumination requirements. The reworked mechanical HVAC ventilation equipment will be improved with the controls to reduce energy consumption as much as possible while ensuring a comfortable environment for patients and will be commissioned in accordance with the requirements from the FGI Guidelines and the standards set forth by the American Association of Healthcare Engineers. App., 11.

11. The project was included in the capital budget submitted to the GMCB in July 2023, for replacement of the unit in FY2025. App., 12.

12. There are no known perceived conflicts of interest between the hospitals and physicians, and the vendor or manufacturer of this equipment. App., 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). The 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 show that the proposed project aligns with statewide healthcare reform goals and principles because the project takes into consideration healthcare 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). CVMC has satisfied this criterion.

The project takes into consideration delivery system reform by fostering efficiencies at CVMC and across the UVM Health Network. Replacing the CVMC LINAC represents an initial step in providing integrated care for the hospital's cancer patients who will benefit from remote treatment planning and expertise from practitioners at other Network facilities. Replacement of the CVMC LINAC also addresses community needs. Most patients are traveling from within a 35-mile radius for treatment. If the current device were to fail or experience prolonged downtime, CVMC cancer patients would be forced to travel to other facilities for treatment, causing unnecessary inconvenience and stress during their illness. Replacing the aged-out equipment will allow CVMC cancer patients to continue to reliably receive their treatments closer to home. Findings of Fact (Findings), ¶¶ 2,3, 5.

The Health Resources Allocation Plan (HRAP) identifies needs in Vermont's healthcare system, resources to address those needs, and priorities for addressing them on a statewide basis.³ The factual findings reflect that the proposed project meets the relevant HRAP standards, namely:

- Standard 1.6 (collect and monitor data relating to health care quality and outcomes), Findings, ¶ 7;
- Standard 1.7 (project is consistent with evidence-based practices), Findings, ¶ 8;
- Standard 1.8 (comprehensive evidence-based system for infectious disease), Findings, ¶ 9;
- Standard 1.9 (project is cost-effective and reasonable energy conservation measures have been taken), Findings, ¶ 4;
- Standard 1.10 (project is energy efficient), Findings, ¶ 10;
- Standard 1.12 (project complies with the Guidelines for Design and Construction of Health Care Facilities as issued by the Facilities Guidelines Institute), Findings, ¶ 10;

³ 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%20Plan%202009%207.1.09.pdf>.

- Standard 3.4 (project was included in hospital budget submissions), Findings, ¶ 11;
- Standard 3.7 (project replace existing equipment that is fully depreciated), Findings, ¶¶ 1, 2;
- Standard 3.19 (an applicant seeking to purchase a piece of diagnostic or therapeutic equipment shall include an analysis of whether other health care system costs may be reduced through more effective interventions through the use of the equipment), Findings, ¶ 6;
- Standard 3.20 (project addresses the appropriateness of distribution as compared to population), Findings, ¶ 4 ;
- Standard 3.22 (clinical efficacy of the diagnoses or procedures to be performed), Findings, ¶¶ 2- 4;
- Standard 3.24 (an applicant shall disclose any potential financial conflicts of interest between hospitals and physicians and an equipment purchase). Findings, ¶ 12;
- Standard 3.25 (linear accelerator will perform an adequate number of treatments yearly), Findings ¶ 1.

II.

Under the second criterion, an applicant must show 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 costs of medical care or an undue impact on the affordability of medical care for consumers, and less expensive alternatives are not feasible or appropriate. *See* 18 V.S.A. § 9437(2). CVMC has satisfied this criterion.

The project will be paid for without debt financing and will not create an unsustainable financial burden or adversely impact CVMC's financial health. The project does not add equipment or services but replaces existing equipment that is fully depreciated with new, comparable equipment with service coverage and extended warranty. There will be no loss of revenue or new revenue due to the project, nor any material impact to CVMC's operating margin. Findings, ¶¶ 3, 4, 6.

The project will not unduly increase the costs of care or unduly impact affordability for consumers. CVMC's existing LINAC is at the end of its service life, and its continued use increases the risk of mechanical failure and prolonged downtime at the expense of cancer patients. This project was planned in consultation with ECRI and based on ECRI's recommendations. The Network anticipates that system-wide efficiencies can be achieved as six Network LINACs are replaced over five years and moved to a common integrated platform; over time the project will increasingly benefit CVMC patients by allowing for remote treatment planning and expertise from across the Network. *See* Findings, ¶¶ 2, 3, 5.

Finally, there are no less expensive alternatives to the project. The existing unit has reached the end of its service life and needs replacement. The project, as structured, is the most feasible, cost-effective alternative. *See* Findings, ¶¶ 2-4.

III.

Under the third criterion, an 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). CVMC has satisfied this criterion.

First, there is an identifiable, reasonably anticipated need for the project. External beam radiation using a LINAC is the most common type of treatment and the standard of care for treating most localized solid tumors. The LINAC now in use at CVMC is 15 years old, fully depreciated, and at the end of its service life. The existing unit's continued use puts the device at increasing risk of mechanical failure and prolonged downtime. The unavailability of radiation services at CVMC will cause unnecessary stress and inconvenience for cancer patients. *See Findings, ¶¶ 1, 2, 5.*

IV.

Under the fourth criterion, an applicant must demonstrate that the project will improve the quality of healthcare in the State or provide greater access to healthcare for Vermont's residents, or both. 18 V.S.A. § 9437(4). CVMC has satisfied this criterion.

If the current LINAC were to fail or experience significant downtime, Vermonters would need to travel or delay treatments, risking negative health impacts. The project is an important step in the Network's planned investment in radiation therapy resulting in an integrated radiation treatment delivery system in which services will be supported by a networked IT and equipment structure. *See Findings, ¶¶ 2, 3, 5.*

V.

To satisfy the fifth criterion, the applicant must 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). CVMC has satisfied this criterion.

This project does not create any new services or expand or modify existing services. CVMC does not anticipate additional volumes attributable to the project. *See Findings, ¶¶ 2, 7-8.*

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).* As discussed in the other Conclusions, CVMC has demonstrated that the project will serve the public good.

VII.

The seventh criterion requires an applicant to show that they have adequately considered the availability of affordable, accessible transportation services to the facility. 18 V.S.A. § 9437(7). CVMC has satisfied this criterion.

This project is for the replacement of existing equipment at the same location, transportation services to the facility will be unchanged. Findings, ¶ 3.

VIII.

The ninth criterion pertains to applications for the purchase or lease of new Health Care Information Technology and does not apply to this project. *See* 18 V.S.A. § 9437(8).

IX.

The final criterion requires an applicant to show that the project will support equal access to appropriate mental health care that standards of quality, access, and affordability equivalent to other components of health care as part of an integrated, holistic system of care, as appropriate. *See* 18 V.S.A. 9437(9). CVMC has satisfied this criterion.

If a patient receiving services at CVMC 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 provider, working with their mental health care colleagues, would be in the best position to assess the short and long-term needs and next steps for an individual seeking mental health services. Findings, ¶ 7.

Conclusion

The Board issues a Certificate of Need to the Applicant based on our conclusion that it has met its burden of proof.

Order

Pursuant to 18 V.S.A. § 9440(d), the Green Mountain Care Board approves the application of University of Vermont Medical Center and orders that a certificate of need shall issue, subject to the conditions set forth in that document.

SO ORDERED.

Dated: October 21, 2024, at Montpelier, Vermont.

_____)
s/ Owen Foster, Chair)

s/ Jessica Holmes)

s/ Robin Lunge)

s/ Thom Walsh)

GREEN MOUNTAIN
CARE BOARD OF
VERMONT

*Member Murman did not
participate in the vote on this
matter

Filed: October 21, 2024, at Montpelier, Vermont

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).