

**STATE OF VERMONT
GREEN MOUNTAIN CARE BOARD**

In re: Application of the University of Vermont Medical)
Center for the Purchase of a da Vinci Xi)
Robotic Surgical System)
_____)

GMCB-011-22con

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 (CON) to purchase a da Vinci robotic surgical system. The cost of the project is \$2,460,000.

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 September 13, 2022, UVMMC filed a CON application and request for expedited review. On September 26, 2022, the Green Mountain Care Board (Board) informed UVMMC that expedited review was granted. The Board requested additional information regarding the project on September 23 and October 28, 2022, which UVMMC provided on October 4 and November 10, 2022. The application was closed on November 30, 2022.

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 is a tertiary/quaternary hospital serving more than one million people in Vermont and Northern New York and is the only teaching hospital in Vermont. UVMMC has had a robotic-assisted surgery program since 2008 and is the only hospital in the state that has such a program. In 2016, UVMMC purchased a new da Vinci Xi robot (da Vinci) to replace its robotic system that had become obsolete. This project involves the purchase of a second da Vinci Xi dual console robotic surgical system from Intuitive Surgical to be located on the Main Campus in Operating Room (OR) 19. Application (App.), 1, 11.

2. Minimally invasive surgery using robotics has become the optimal treatment modality for an increasing number of procedures, including gynecological; urologic; thoracic; bariatric; ear, nose and throat (ENT); colorectal; and bariatric surgeries. The most notable improvements in the

care of cancer patients using a robotics platform have been for the treatment of head and neck cancers where the robotic platform has led to the elimination of some high dose radiation protocols and disfiguring surgeries. For patients, robotic-assisted surgery can reduce blood loss and result in fewer post-operative complications, less scarring, shorter lengths of stay, reduced reliance on pain management, and better surgical outcomes. For providers, it offers superior visualization, precision, dexterity, and instrument range of motion. UVMMC represents that the availability of a surgical robot is central to recruiting and training the next generation of surgeons and that the da Vinci system is the technological leader in the surgical robotics market. App., 1-3, 5, 12-13, 15-19.

3. According to UVMMC, as not all patients and conditions are appropriate for robotic surgery, the surgeon assesses each patient for appropriateness. Elements such as the patient's disease state and co-morbidities are fundamental aspects of the evaluation. Surgeons are most likely to use the robotic-assisted surgery on patients who would benefit from the strengths of the robotic platform over other minimally invasive techniques. Response to Questions (Resp.) (October 4, 2022), 3.

4. In 2016, UVMMC performed approximately 375 urological and gynecological surgeries using the robotic platform. Volumes have since risen to approximately 480 robotic-assisted surgeries annually. UVMMC asserts that Gynecology and Urology alone could support the need for a second da Vinci. Demand has grown across a wide range of additional subspecialties where robotic-assisted surgery has become the standard treatment modality for certain procedures. The existing device is currently operating at approximately 137% of the single device utilization benchmark¹ and cannot absorb the growth in demand for the service. App., 1, 3.

5. UVMMC represents that a second da Vinci will promote access to high quality, timely robotic-assisted surgeries for patients in UVMMC's service area. Currently, UVMMC is losing patient volume to facilities in Boston, Albany, and Lebanon (NH), because patient need exceeds available time on the one existing device. Patients traveling out-of-state for robotic-assisted surgeries endure additional personal expense and inconvenience. A second da Vinci would allow patients in UVMMC's service area to receive their care closer to home. UVMMC asserts that it must be able to offer its patients advanced, appropriate quality healthcare services comparable to those offered outside of the region and that UVMMC's surgeons must have the most appropriate surgical options available for their patients. UVMMC also represents that increasing capacity will enhance provider recruitment and retention, including two recently recruited Cardiothoracic surgeons who will both require robotic capacity. App., 1-3, 9.

6. Providing surgical robot training is an essential component of surgical resident and fellow education. The UVMMC Urology Computer-Assisted Robotic Surgery Program offers complete Urology Resident and Advanced Urologic Attending training and includes both simulated and complete patient care. App., 6.

7. UVMMC states that its Medical Staff Credentials Committee ensures that every surgeon who intends to perform robotic-assisted surgery receives appropriate training and proctoring. To

¹ A benchmark of 350 procedures per device annually was based on vendor data for academic medical center usage rates. App., 3, n.1.

be eligible to request clinical privileges to perform robotic-assisted procedures, a practitioner must meet minimum threshold criteria, including completion of an accredited residency training program, hands-on training in the use of the da Vinci surgical platform, and privileges to perform open and laparoscopic procedures. Surgeons must perform 15 robotic-assisted procedures in an 18-month period to maintain clinical privileges for robotic surgery and all patient outcomes are reviewed. App., 6.

8. As noted earlier, the project involves the purchase of a second da Vinci dual console system from Intuitive Surgical to be located on the Main Campus in Operating Room (OR) 19. Once installed, most surgeries performed in OR 19 will use the da Vinci. OR 19 will remain available for non-robotic cases when necessary. The new da Vinci includes three components: a patient cart with robotic arms operated by the user, an ergonomic surgical console, and a vision cart. The da Vinci allows the user to replicate an open surgical environment while performing an operation through tiny incisions. A system's camera relays live, highly magnified and high definition 3-1 visualization of the operative area. The surgeon seated at a console a few feet from the patient, controls the surgical instruments that can be maneuvered in ways that are beyond the normal dexterity and range of motion of the human hand. App., 5.

9. OR 19 will be modified to accommodate the new system by relocating the scrub sink door and two EPIC monitors, modifying a workstation, and adding five dedicated 20-amp circuits in accordance with the manufacturer's installation requirements. Resp. (October 4, 2022), 1.

10. UVMMC states the project will not significantly increase surgical volumes. Many surgeries now performed open or laparoscopically will be converted to the robotic platform. The project will create an incremental increase in volume for robotic-assisted surgical procedures for which UVMMC patients must currently travel out-of-state. UVMMC projects the number of converted surgeries to be 449 in FY 2023, and 599 each year in FY 2024-FY2027. The increase in robotic surgeries is projected to be 149 in FY 2025, 297 in FY 2026, and 446 in FY 2027. App., 1, 4.

11. UVMMC represents that there are no planned increases in charges for procedures performed using robotic assisted technology. The cost for disposables used in robotic surgeries are comparable to those used for open and laparoscopic surgeries. The costs associated with these supplies in the pro forma represent the incremental costs for the robotic-assisted surgeries projected to be recaptured from patients currently going to out-of-state facilities once the device has been added. Resp. (October 4, 2022), 2.

12. UVMMC has reviewed published studies that demonstrate significantly shorter length of stays for robotic assisted surgeries compared to open surgical techniques. In its financial assessment, UVMMC estimates possible cost savings related to shorter lengths of stay to offset to the cost of purchasing the device. The Network Planning Team estimates an average savings of .75 days per procedure using evidenced-based recovery time savings estimates and then uses the average length of stay (ALOS) reduction of .75 days and a per-day estimate of \$1,200 in associated inpatient costs to calculate the potential cost avoidance due to the project. UVMMC projects a potential cost avoidance of \$396,917 for Year 1, and \$529,892 for Years 2-5. The total cost avoidance was estimated to be \$2,516,487 for the five years to offset the total expenses of

\$4,015,858, with revenues related to incremental cases totaling \$1,505,242. App., 7-8; Resp. (October 4, 2022), 2-3.

13. The total capital cost of the project is \$2,460,000 which includes equipment costs of \$2,350,000; \$70,000 in equipment contingency; and \$40,000 for facilities work to accommodate the new system. App., 2, 7; Resp. (October 4, 2022), 1. UVMMC included the project as an FY 2023 capital project in its FY 2022 and FY 2023 hospital budget submissions. App., 11. The project does not include any additional staff positions. App., 6, Staffing Report, Table 8B. The project will require approximately 50 hours of staff training, costing approximately \$10,000 in wages and backfill of staff. This unbudgeted expense is not included in the pro forma and will be incurred prior to the da Vinci becoming fully operational. App., 6.

14. UVMMC represents that there are no known or perceived conflicts of interest between the hospital and physicians and the vendor or manufacturer of the da Vinci device to be purchased. UVMMC explored vendor financing options and evaluated the financial impact of both leasing and purchasing the da Vinci system. The lease financing option was estimated to cost \$2,321,714 over 60 months with an estimated \$408,000 buy-out at the end of the lease term. This placed the five-year lease cost with buy-out at \$2.73 million versus \$2.45 million to purchase the device. Resp. (November 10, 2022), 1.

15. The project will be paid for with equity and its impact on UVMMC's margin will be minimal (\$49,370 in Year 1, -\$9,971 in Year 2, -\$10,560 in Year 3, -\$11,169 in Year 4, and -\$11,799 in Year 5). App., 22, Table 2, "Debt Financing Arrangement;" App., 24, Table 3B, "Income Statement."

16. The collection and monitoring of data relating to healthcare quality and robotic assisted surgical outcomes will remain unchanged. UVMMC follows quality assurance/quality improvement programs consistent with Joint Commission standards. Each respective department utilizing the da Vinci collects, analyzes, and reports data in order to investigate and evaluate the potential risks to patient safety. Expanding the robotic surgical program will not impact established protocols and adherence to evidence-based practices. UVMMC surgeons seeking to use the da Vinci must be credentialed and proficient in its use and will make decisions regarding the appropriate and effective use of the device with consideration of relevant guidance and recommendations of professional organizations such as the American Urological Association, the American College of Obstetricians and Gynecologists, and the American Association of Gynecologic Laparoscopists. UVMMC will remain in compliance with the applicable standards and requirements relating to infectious disease control, including the Joint Commission requirements on infection prevention and surveillance. App., 10.

17. UVMMC states the project will not affect existing services provided by the hospital. No services will be displaced and OR 19 will be made available for traditional surgeries as needed. App., 5, 13.

18. UVMMC expects the new da Vinci robotic surgical system will be operational in three to six months following the approval of the CON. App., 2.

19. If patients express a need for mental health services while being seen for robotic surgery and are not experiencing an acute crisis, UVMMC would refer them to their primary care physician to assess need and determine next steps. For patients experiencing an acute crisis, UVMMC would follow its suicide risk assessment protocol, which may include contacting 911 or its internal Medical Emergency Team to facilitate an assessment to determine appropriate care. Resp. (October 4, 2022), 2.

20. UVMMC's Main Campus can be accessed by private and public transportation. 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). 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 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; 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 Health Resources Allocation Plan (HRAP) identifies needs in Vermont's health care system, resources to address those needs, and priorities for addressing them on a statewide basis.² The factual findings reflect that the proposed project meets the relevant HRAP standards, namely:

- Standard 1.2 (applicants shall show that services have been shown to improve health), Findings, ¶¶ 2, 3, 5;
- Standard 1.3 (collaborative approach to delivering service has been taken or is not feasible or appropriate), Findings, ¶¶ 1, 5;
- Standard 1.6 (collect and monitor data relating to health care quality and outcomes), Findings, ¶ 16;
- Standard 1.7 (project is consistent with evidence-based practices), Findings, ¶ 16;

² 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://gmcbboard.vermont.gov/sites/gmcb/files/documents/Vermont%20Health%20Resource%20Allocation%20Plan%202009%207.1.09.pdf>.

- Standard 1.8 (comprehensive evidence-based system for infectious disease), Findings, ¶ 16;
- Standard 3.4 (project was included in hospital budget submissions), Findings, ¶ 13;
- 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, ¶ 12;
- Standard 3.22 (clinical efficacy of the diagnoses or procedures to be performed), Findings, ¶¶ 2, 3, 4, 12;
- Standard 3.23 (show that the equipment reduces costs and/or improves quality), Findings, ¶¶ 2, 12; and
- Standard 3.24 (an applicant shall disclose any potential financial conflicts of interest between hospitals and physicians and an equipment purchase). Findings, ¶14.

II.

The second criterion requires an applicant to demonstrate that the cost of the project is reasonable. The applicant must show that it can sustain any financial burden likely to result from the project; that 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; that less expensive alternatives do not exist, would be unsatisfactory, or are not feasible or appropriate; and that appropriate energy efficiency measures have been incorporated into the project. 18 V.S.A. § 9437(2).

Based on our review of the record, we are sufficiently comfortable that the Applicant can sustain the financial burden likely to result from the project. The project will cost approximately \$2,460,000 and will be financed with equity. Its impact on UVMMC's margin will be minimal. UVMMC projected shorter lengths of patient stay due to use of the da Vinci of 4.9 days compared to 6.1 days with open surgeries. This reduction of patient stays will result in cost savings or avoidance of costs to partially offset the cost of the project. Findings, ¶¶ 12, 13, 14.

We also conclude that less expensive alternatives are not available, would be unsatisfactory, or are not feasible or appropriate.³ Robotic-assisted surgeries are less invasive, result in shorter length of patient stays and carry a lower risk of complications than open surgeries. There is sufficient demand from the Urology and Gynecology departments alone to support the addition of the second machine. The da Vinci system is an appropriate choice for a surgical robotics system. Findings, ¶¶ 2, 4, 5, 12.

Next, we analyze whether the applicant has demonstrated that 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. In our analysis, we 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 these impacts, if any, are outweighed by the benefit of the project to the public. 18 V.S.A. § 9437(2)(B).

³ Incorporation of energy efficiency measures does not apply to this project. *See* 18 V.S.A. § 9437(2)(D).

UVMMC states there is no anticipated or planned increases in charges for procedures performed using the robotic-assisted technology and no addition in staffing resulting from installing an additional device which increases capacity and availability of the device for its surgeons. The one existing da Vinci robotic-assisted surgical device does not have the capacity to accommodate more time-sensitive cases, which results in patients from UVMMC's service area having to travel out-of-state for such care at additional personal cost and inconvenience. Findings, ¶ 4, 5, 10, 11, 12.

We conclude that the Applicant has satisfied the second criterion.

III.

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). UVMMC currently has one da Vinci device, operating at approximately 137% of the single device utilization benchmark and the one device lacks sufficient capacity to absorb the growth in demand for the service. In addition to Gynecology and Urology, demand has grown across a wide range of subspecialties where robotic-assisted surgery has become the standard treatment modality for certain procedures. Due to the lack of capacity, many patients needing time-sensitive surgical procedures must either travel out-of-state for robot-assisted surgery, at increased cost and inconvenience, or have their procedures performed with open surgery or laparoscopically. Additionally, robotic-assisted surgery is an essential training component of the surgical residency programs at UVMMC, which is the only tertiary care and teaching hospital in Vermont. The availability of a surgical robot is central to recruiting and training the next generation of surgeons. Findings, ¶¶ 1, 2, 4, 5, 7.

Based on the above, we conclude that the project meets 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).

Minimally invasive surgery using robotics has become the optimal treatment modality for an increasing number of procedures in a variety of subspecialties, including gynecology, urology, thoracic, bariatric, and ENT. For patients, robotic-assisted surgery can reduce blood loss and result in fewer post-operative complications, less scarring, shorter lengths of stay, and better surgical outcomes. Findings, ¶¶ 2, 5.

Based on the above, we conclude that the project meets the fourth criterion.

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). UVMMC states the project will not affect existing services provided by the hospital. No services will be displaced and OR 19 will be made available for traditional surgeries as needed. Findings, ¶ 8. We conclude that it 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. GMCB Rule 4.000, § 4.402(3). The following factors are relevant to this project, and we therefore address them here: Rule 4.000, § 4.402(3)(c) (impact on healthcare system and effective integration and coordination of health care services) and § 4.402(3)(f) (impact on existing facilities to provide medically necessary services to all in need, regardless of ability to pay or location of residence).

The project will serve the public good by increasing capacity for robotic-assisted surgery so that patients in UVMMC’s service area do not have to travel out-of-state at additional cost and inconvenience to the patient and their families for a service that should be available close to home. In addition, robotic-assisted surgery is an essential training component of the surgical residency programs at UVMMC, which is the only teaching hospital in Vermont. The availability of a surgical robot is central to recruiting and training the next generation of surgeons. As such, the addition of a da Vinci robotic surgical system will have a positive impact on the healthcare system. Findings, ¶¶ 2, 4, 5.

The project will not have a negative effect on existing facilities. No other facility in Vermont has a da Vinci robotic assisted surgical device. Findings, ¶ 1.

As such, the project will serve the public good. Findings, ¶¶ 2, 4-5.

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. UVMMC’s Main Campus can be accessed by private and public transportation. Findings, ¶ 20.

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 a new Health Care Information Technology, this criterion is not applicable.

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). For patients seen at UVMMC for procedures eligible for robotic-assisted surgery experiencing an acute mental health crisis, UVMMC would follow its suicide risk assessment protocol, which may include contacting 911 or its internal Medical Emergency Team. For patients not experiencing an acute crisis, UVMMC would refer them back to their primary care physician to assess patients’ needs and determine next steps. Findings, ¶ 19. We find this criterion 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: March 15, 2023 at Montpelier, Vermont.

_____)	
s/ Owen Foster, Chair)	
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s/ Jessica Holmes)	
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s/ Robin Lunge)	
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s/ David Murman)	
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s/ Thom Walsh)	
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GREEN MOUNTAIN
CARE BOARD OF
VERMONT

Filed: March 15, 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).