

**STATE OF VERMONT
GREEN MOUNTAIN CARE BOARD**

In Re: Application of the University of Vermont)
Medical Center, Replacement of da Vinci) GMCB-010-16con
Robotic Surgical System)
_____)

STATEMENT OF DECISION AND ORDER

Introduction

The University of Vermont Medical Center (UVMMC, or the applicant) is Vermont’s only tertiary care facility and academic medical center. In this Certificate of Need (CON) application, UVMMC seeks to replace its existing da Vinci Surgical System with a new generation da Vinci XI Dual Console System. The total project cost is \$2,347,931 which includes \$2,931 for administrative expenses and permits. Application (App.) at 3 (Page revised Sept. 16, 2016).

For the reasons outlined below, we approve the application.

Procedural Background

On May 4, 2016, UVMMC filed a CON application with the Green Mountain Care Board. The Board granted expedited review of the project on May 10, 2016 pursuant to 18 V.S.A. § 9440(c)(5) and received no competing application nor requests for Interested Party or Amicus Curiae status. The Board requested additional information of the applicant on July 1, 2016 and received responses August 8, 2016. The Board Chair and staff conducted a site visit on September 6, 2016. On September 16, 2016, the applicant submitted revised financial tables and pages 3 and 9 of the application to correct errors in the original submission.* The application was closed on September 21, 2016.

Findings of Fact

1. UVMMC proposes to purchase and install a da Vinci XI Dual Console System (da Vinci) to replace the existing da Vinci Surgical System purchased in 2008, App. at 3, as part of UVMMC’s ongoing robotic-assisted surgery program. A robotic-assisted surgery system allows a surgeon to perform using robotic surgical arms, which the surgeon controls with a hand-operated console while viewing a high-definition, three-dimensional camera image of the surgical field. App. at 4-5.

2. At UVMMC, the da Vinci is only used for specific urological and gynecological procedures for which robotic-assisted surgery has become the standard of care, and is used to perform approximately 375 procedures per year. App. at 5; Responses to Questions (August 8, 2016) (Responses) at 2, 7. UVMMC will continue to use the new da Vinci for urological surgeries (primarily prostatectomies and nephrectomies) and gynecological surgeries. App. at 5-

* All citations to the financial tables refer to the revised tables received September 16, 2016.

6. For gynecological surgeries, the da Vinci is only used on patients with oncologic conditions such as uterine, ovarian or cervical cancer, and for surgery on patients with complications such as severe endometriosis or large uterine fibroids. App. at 7.

3. Nationally, compared to open surgeries, patients undergoing prostatectomies performed with the da Vinci usually experience reduced complications (*e.g.* reduced rates of deep vein thrombosis and wound infection), reduced blood loss, lower transfusion rates, and reduced length of stay. App. at 4; Responses at 5. Annually, 85-90 percent of prostatectomies and 50 percent of nephrectomies are performed robotically. App. at 5. For hysterectomies, robotic surgery reduces blood loss, post-operative complications, operative time, and the average length of stay is slightly reduced compared to traditional laparoscopic surgery. Responses at 6. Approximately 75 percent of all hysterectomies are performed with the robot. App. at 6.

4. UVMMC tracked outcome measures for prostatectomies performed with the da Vinci for October 2012 through June 2016 and found lower mean length of stay, lower mortality index, lower intensive care unit cases and lower complication rates compared to procedures performed without the da Vinci. The tracked data for the same period for hysterectomies shows decreases in each of these measures except for complication rates, which are higher due to the complicated medical histories of many of the patients undergoing robotic surgery. Responses at 9-10.

5. The closest facility to UVMMC offering robotic surgery is Champlain Valley Physicians Hospital in Plattsburgh, New York, with no other Vermont hospital offering this surgical option. App. at 4. All major academic centers are utilizing robotic assisted surgery and training residents and fellows to perform surgery using this system in addition to the standard laparoscopic and open surgical techniques. App. at 9.

6. The existing da Vinci system is eight years old, is fully depreciated, and has reached the end of its useful life, causing increased down time and unreliability. Due to equipment failure repairs and scheduled maintenance, it experienced downtime of approximately 98 hours in 2012, 161 hours in 2013, 99 hours in 2014, 53 hours in 2015 and 42 hours through July 15, 2016. Responses at 14. In April 2015, Intuitive Surgical notified customers that the existing system would reach the end of its useful life effective December 31, 2017, and that at that time, it will discontinue service and support and end production of parts and accessories, making the existing system obsolete. App. at 8.

7. Compared to UVMMC's existing equipment, the new da Vinci offers advanced features, functionality and technology. The newly designed overhead instrument arms facilitate anatomical access from any position, and are smaller and thinner with joints that provide an expanded range of motion and instrument shafts that allow the surgeon greater reach. A fluorescent imaging system enables real-time visualization and assessment of vessels, bile ducts and tissue perfusion. App. at 8-9. The purchase also includes a skills simulator to improve the surgeon's proficiency with the da Vinci console controls and which is critical for assisting with training and credentialing. The open architecture of the system allows for the addition of practice models that may be developed in the future. App. at 10.

8. UVMMC does not have plans to expand robotic assisted surgery to new service lines or procedures. Responses at 10. If robotic assisted surgery were to become the standard of care for other procedures, UVMMC would assess appropriateness of expanded usage. *Id.*

9. UVMMC has protocols in place to evaluate each case and determine whether there is a clinical benefit to robotic assisted surgery compared to traditional laparoscopic or open surgery for gynecological cases, and to open surgery for urological cases. App. at 7.

10. The option to perform a procedure robotically is discussed between the surgeon and patient. Nursing care coordinators review all proposed robotic cases in advance for appropriateness prior to scheduling; if they have any concerns, the case is brought to the Quality Assurance and Improvement Committee (QA Committee) and respective Division Director, who discuss any concerns with the surgeon. Responses at 7.

11. Surgeons must be credentialed by the Credentialing Committee to perform robotic assisted surgery at UVMMC. The surgeon must meet educational, training and proctoring requirements that include completion of a residency training program at an accredited institution. The training must be current and from an institution with formal performance monitoring requirements and the surgeon must successfully complete hands-on training that includes the use of a model or cadaver, and must observe two live da Vinci surgeries in the operating room. Additionally, the surgeons must be authorized to perform open and laparoscopic procedures at UVMMC, and have at performed at least two documented, proctored robotic surgeries. App. at 7; Responses at 3-4.

12. Currently 11 surgeons are credentialed to perform robotic assisted surgeries at UVMMC. Responses at 3. Urologists and gynecologists must perform 15 procedures in an 18-month period to maintain clinical privileges for robotic surgery and all patient outcomes are reviewed. The Urology Department peer-reviews every surgical case during its monthly quality assurance meeting. The Gynecology department peer reviews all robotic surgery procedures for which complication forms have been completed at its monthly quality assurance meeting. App. at 8.

13. In the decision making process for the use of the da Vinci, surgeons follow evidence based guidelines and clinical appropriateness criteria based on evidence based practice. Quality outcomes are collected and reviewed by individual departments and are reported out through the Operating Room Steering Committee and the UVMMC Robotics Committee. This data is compared to similarly sized programs and are reported internally. Cases performed between 2012 and 2015 had 0% mortality rate compared with all academic centers' rate of .14%. App. at 10.

14. UVMMC does not project any change in overall surgical procedures and does not project increases in the number of robotic assisted surgeries performed. Responses at 1-2. The new da Vinci will continue to be available for use five days a week performing approximately 375 procedures annually. App. at 5.

15. The total project cost is \$2,347,931 which includes \$100,000 in trade-in value for the existing da Vinci. The vendor has agreed to replace any unused inventory with inventory compatible with the new system at no extra cost. Responses at 13. UVMMC plans to fund the purchase with working capital and to incur no additional debt; it does not project any increase in the cost of medical care and will not raise its charges. App. at 15; Table 2. UVMMC projects that the perioperative Department will continue to generate over \$53 million in excess revenue over expenses annually. *Id.*

16. The cost of the project was included in UVMMC's capital budgets for FY15 (actual) FY16 (budgeted) as approved by the Board. App. at 12. The project does not involve any new program, service or increase in utilization and no construction activity is required for the project. App. at 3; Tables 1, 7; Responses at 2.

Standard of Review

Vermont's certificate of need 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 to demonstrate that each of the criteria set forth in 18 V.S.A. § 9437 is met. Rule 4.000, § 4.302(3). We review each of these criterion below.

Conclusions of Law

Pursuant to 18 V.S.A. § 9437(1), we conclude that the application is consistent with Vermont's Health Resource Allocation Plan (HRAP). The HRAP, last published in 2009, identifies needs in Vermont's health care system, resources to address those needs, and priorities for addressing them on a statewide basis. While the HRAP contains no specific requirements for robotic surgery systems, it does require that applicants proposing to purchase diagnostic and therapeutic equipment demonstrate that the equipment is clinically effective, that the proposed equipment serves an appropriately-sized population in relation to its cost, and if the proposed purchase replaces older equipment, that the old equipment is fully depreciated. CON Standards 3.7, 3.20, 3.22. Here, the applicant provided compelling documentation of the clinical effectiveness of robotic assisted surgery for urological and gynecological patients. Findings of Fact (Findings) ¶¶ 3-4. The applicant is Vermont's only tertiary hospital, serves Vermont's largest metropolitan area, and has performed robotic surgery, with positive outcomes, since 2008 in the same geographical region. Finding ¶ 5. Finally, the existing system will not increase the cost of patient care, is fully depreciated and will reach the end of its useful life in 2017. Findings ¶¶ 6, 15.

We further conclude that the applicant satisfies the more general requirements of the HRAP for quality measures and outcomes, and has therefore satisfied the first criterion.

Pursuant to the second criterion, 18 V.S.A. § 9437(2), we conclude that the applicant has shown that the cost of the project is reasonable, the applicant can sustain any financial burden resulting from the project, the project will not result in an undue increase the cost of medical care, and that less expensive alternatives are not feasible or appropriate. UVMMC obtained a favorable price for the replacement da Vinci and skills simulator, including \$100,000 trade in for

the existing da Vinci and will fully fund the project with working capital without incurring additional debt. Finding ¶ 15. UVMMC has confirmed that charges for the da Vinci will not increase as a result of the purchase of the new equipment. *Id.* Finally, less expensive alternatives are neither feasible nor appropriate; the existing equipment will soon be obsolete, and as Vermont's only tertiary care facility and teaching hospital, UVMMC is the appropriate venue for both surgeon training in da Vinci use and for performing oncologic urological and gynecological surgeries that may experience better outcomes when robotic, rather than open or laparoscopic surgery, is used. Findings ¶¶ 3, 4, 5, 6.

Pursuant to the third criterion, 18 V.S.A. § 9437(3), the applicant has demonstrated an identifiable, existing and reasonably anticipated need for the project. UVMMC is Vermont's only tertiary care facility and teaching hospital, and has been training residents and fellows and performing surgeries with the existing da Vinci since 2008. Finding ¶ 1. UVMMC performs approximately 375 surgeries annually using the da Vinci, robot-assisted surgery is the standard of care for certain conditions, and UVMMC's data shows positive indicators associated with the da Vinci's use. Findings ¶¶ 2, 3, 4, 5. Further, if UVMMC did not replace the da Vinci, patients would need to travel out-of-state to obtain robotic surgeries. We therefore conclude that the replacement of the da Vinci is needed and its use will continue into the future.

The applicant has also satisfied the fourth criterion, 18 V.S.A. § 9437(4), by demonstrating that the project will improve the quality of care and provide greater access to health care for Vermonters. The quality of care will increase because the new da Vinci has more advanced features, functionality and technology than the existing one, allowing for better performance as well as a more user-friendly piece of equipment for surgeons and staff. Finding ¶ 7. Access to care will also increase because the new unit will not experience the escalating maintenance needs and increasing downtime that occurs now with the existing da Vinci. Findings ¶ 6, 7.

We further conclude that UVMMC's proposed purchase of the replacement da Vinci is consistent with the remaining statutory criteria to the extent they are applicable. The project will not have an undue adverse impact on other services provided by the applicant because the proposed project maintains a service essential to appropriate standards of care. *See* 18 V.S.A. § 9737(5). The ways in which the project will serve the public good have been adequately addressed in our discussion of other criteria. *See* 18 V.S.A. § 9737(6). The project will remain located in Vermont's largest population center and is accessible by public transportation *See* 18 V.S.A. § 9737(7). Finally, the project is not an information technology purchase as contemplated in 18 V.S.A. § 9351. *See* 18 V.S.A. § 9737(8).

Based on the above, we conclude that the applicant has met each applicable statutory criterion, and issue a certificate of need on this date.

Order

Pursuant to 18 V.S.A. § 9440(d), the Green Mountain Care Board approves the application of the University of Vermont Medical Center and a Certificate of Need shall issue.

SO ORDERED.

Dated: September 29, 2016 at Montpelier, Vermont

s/ Alfred Gobeille)

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s/ Cornelius Hogan)

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s/ Jessica Holmes)

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s/ Betty Rambur)

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s/ Allan Ramsay)

GREEN MOUNTAIN
CARE BOARD
OF VERMONT

Filed: September 29, 2016

Attest: s/ Janet Richard
Green Mountain Care Board
Administrative Services Coordinator