

**STATE OF VERMONT
GREEN MOUNTAIN CARE BOARD**

**CERTIFICATE OF NEED APPLICATION
BY
THE UNIVERSITY OF VERMONT MEDICAL CENTER INC.
TO
REPLACE THE DA VINCI ROBOTIC SURGICAL SYSTEM**

Dated May 4, 2016

Spencer R. Knapp
Senior V.P. & General
Counsel

Steven J. Klein
Director of Legal Affairs &
Assistant General Counsel

Erika L. Smart
Assistant General Counsel

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SECTION I PROJECT OVERVIEW

A. Description of Project

The University of Vermont Medical Center Inc. (“UVM Medical Center”) hereby submits this Certificate of Need (“CON”) application in accordance with 18 V.S.A. Section 9440(c)(5), seeking expedited review and approval of a \$2.4 million project (the “Project”) to replace the existing da Vinci robotic surgical system, which was purchased in 2008, with a new da Vinci robotic surgical system. Specifically, this application seeks approval of the following:

- (1) Replacement of the da Vinci S Surgical System with a new generation da Vinci XI Dual Console System at a cost of \$2,360,000¹; and
- (2) An upgraded da Vinci xi Skills Simulator for training and credentialing at a cost of \$85,000;

The total cost of the Project, which is \$2,397,994², will be covered by budgeted capital funds, without the need for additional borrowing.

B. Project Rationale

The Project does not involve any new program or service, the expansion or modification of any existing service or program, or the construction of any new health care facilities. The Project involves only the replacement of an existing surgical robotic system, consistent with sound business practices. No facilities renovations will be required to replace the stand-alone surgical system which can simply be wheeled in and out of the operating room.

The da Vinci S surgical system currently in use at UVM Medical Center was purchased in 2008 and is now fully-depreciated. The system is exhibiting increasing amounts of down-time and unreliability, and lacks certain enhancements made available by current technology. In April 2015, Intuitive Surgical notified its customers that the da Vinci S Surgical System would reach end of life effective December 31, 2017. At that time, Intuitive Surgical will discontinue service and support, and end production of all replacement parts and accessories, making the robotic surgical system effectively obsolete.

¹ This amount includes a \$100,000 reduction in the purchase price as a result of the trade-in of UVM Medical Center’s existing da Vinci S Surgical System.

² The amount is inclusive of the CON application fee.

UVM Medical Center is the only healthcare facility in Vermont offering minimally invasive robotic surgery, which has become the standard of care for certain procedures, including treatment of gynecological cancers. Geographically, the health care facility closest to UVM Medical Center offering robotic surgery is Champlain Valley Physicians Hospital (“CVPH”) in Plattsburgh, NY. CVPH also utilizes an aging da Vinci S surgical system. At this time, UVM Medical Center is unaware of any plans for CVPH to replace its robot, which has a utilization rate of only 26%.

The Project is needed to enable UVM Medical Center to maintain the existing level of minimally invasive surgical services now provided, without disruption of care to patients and with quality enhancements made available by current technology. Furthermore, as Vermont’s only teaching hospital, replacing the surgical robot is critical to UVM Medical Center’s continued role in recruiting and training the next generation of Vermont surgeons.

C. Consistency with CON Criteria and Standards

The proposed Project meets the statutory criteria set forth in Section 9437 of the Vermont Certificate of Need law, and is consistent with the Health Resource Allocation Plan published on July 1, 2009 (“HRAP”) and the applicable HRAP CON standards, as explained in detail in Parts IV and V of this Application.

SECTION II DESCRIPTION OF UVM MEDICAL CENTER’S SURGICAL ROBOTICS PROGRAM

A. Overview of Robotic Assisted Surgery

Quickly becoming the standard of care for certain procedures, robotic-assisted surgery combines advanced robotic and computer technology to perform minimally invasive, minute, complex procedures that can reduce blood loss, speed recovery time, and shorten the length of hospital stay. Robotic surgery has become the standard of care for some procedures, such as prostatectomies. When compared to open surgery, evidence has shown that robotic assisted prostatectomies reduce patient complications (e.g. reduced rates of deep vein thrombosis and wound infection), reduce intra-operative blood loss, lower transfusion rates, reduce patient length of stay and improve potency rates.³

A robotic surgery system allows a surgeon seated at a console a few feet from the patient to control robotic surgical instruments while viewing a three-dimensional image of the surgical field. The high degree of precision provided by this technology allows smaller incisions, less invasive procedures and the ability to perform technically precise maneuvers not previously

³ Robotic-assisted laparoscopic radical prostatectomy for localized prostate cancer [emerging technology evidence report]. Plymouth Meeting (PA): ECRI Institute; 2010 May.

possible. A robotic surgical suite is comprised of an ergonomic surgeon's console; a patient side cart with interactive robotic arms operated by the surgeon; and a high definition 3-D vision system that greatly enhances visualization of tissue planes and critical anatomy. Working from a console steps away from the patient side cart, the da Vinci system allows the surgeon's hand movements to be scaled, filtered and translated into precise movements of micro-instruments within the operative site. Unlike conventional laparoscopic surgery, the robotic arms move around a fixed pivot point which results in reduced port site trauma, less scarring and increased overall precision.

B. Case-Mix and Utilization

1. In General

UVM Medical Center acquired its first robotic surgical system in 2008. The da Vinci robot is currently used five days per week at UVM Medical Center, performing approximately 375 procedures annually. The majority of these are gynecological surgeries, most of these being hysterectomies, accounting for about 54% of the overall surgical volume for robotic-assisted surgery. Urology cases, most of these being prostatectomies, account for approximately 37% of the overall volume.

Urology

Over FY 2012 – 2015, the majority of robotic assisted surgery cases performed by UVM Medical Center's Urology Department have been prostatectomies and nephrectomies. During this time, procedure volumes have been relatively stable with approximately ninety (90) annual robotic prostatectomies and approximately thirty-five (35) annual robotic nephrectomies, totaling 375 robotic assisted surgeries over the three year period.

Each year, about 85-90% of all prostatectomies are performed robotically, and approximately 50% of nephrectomies are performed robotically. Surgeons are also performing most pyeloplasties robotically. The majority of urologic cases were performed by two surgeons who are primary users of the robot, and have demonstrated a growing practice each year.

With over 85% of all prostatectomies in the United States performed robotically, robotic prostatectomy has become the standard of care.⁴ Before robotic assisted surgery, the vast majority of prostatectomies were performed open because of the small surgical area that is dense with nerve bundles. Robotic surgery has enabled urologists to provide patients with the clinical benefits of minimally invasive prostatectomy. There are similar benefits seen in other urological procedures performed robotically. Studies have shown that robotic partial nephrectomies benefit

⁴ <http://www.cancer.gov/cancertopics/research/rise-of-robotic-surgery-for-prostate-cancer>

patients by improving post-operative kidney function when compared with open and laparoscopic procedures.⁵

Urological procedures currently offered with the robotic surgical system:

General Urology

- Pediatric Urology – UVM Medical Center offers the only comprehensive pediatric robotic surgery program outside of Boston Children’s Hospital in the New England region.
- Male Fertility – Reconstruction of congenital and acquired male fertility urologic disorders
- Female Urology – Reconstruction of acquired urologic disorders affecting the ureter and continence mechanisms
- Adult Reconstruction – Reconstruction of the kidney, ureter and bladder for congenital abnormalities that manifest themselves in adulthood

Urologic Oncology

- Renal Cancer – Partial/Nephron sparing nephrectomies
- Adrenal Cancer – Treatment of locally advanced and metastatic adrenal cancer
- Bladder Cancer – Treatment centering on partial/organ preserving and total cystectomy with urinary reconstruction
- Prostate Cancer – Surgical treatment of men with intermediate and high-risk prostate cancer
- Pelvic and Retroperitoneal Lymph Nodes – Diagnostic and therapeutic removal of lymph nodes to treat testicular, prostate, bladder and ureteral cancers

Gynecology

Over FY 2012 – 2015, the vast majority of the approximately 1,000 robotic assisted surgeries performed by UVM Medical Center’s Gynecology Department have been hysterectomies for malignant and pre-malignant conditions (881), followed by removal of adnexal structures and myomectomies. Each year, nearly 75% of all hysterectomies are performed robotically.

2. Utilization Rate

The annual utilization rate of the robotic surgery system is based on the following assumptions: (i) average robotic surgery procedure time of 4 hours, with two procedures performed daily; (ii) robotic surgery is performed 5 days per week for 50 weeks per year. In FY 2012, the utilization

⁵ Yu J, et al. The safety and effectiveness of Da Vinci surgical system compared with open surgery and laparoscopic surgery: a rapid assessment. *J Evid Based Med* 2014 May; 7(2):121-34.

rate was 84%, in FY 2013 it was 78%, and in FY 2014 it was 76%. When taking into account operational inefficiencies and scheduling challenges, the robotic surgery system is close to full utilization capacity.

3. Case Selection

Not all patients are good candidates for robotic assisted surgical procedures. Patients are carefully vetted to make sure there is a clinical benefit to robotic assisted surgery versus traditional laparoscopic or open surgery. For example, Gynecology only performs robotic assisted surgery on patients with oncologic conditions, such as uterine, ovarian or cervical cancer, patients with complicated surgical history, and patients with a complicated medical history, such as severe endometriosis or large uterine fibroids. Elective surgical procedures are performed only on patients who fit the criteria for clinical appropriateness.

B. Training, Credentialing & Education

UVM Medical Center, through its Medical Staff, has a Credentialing Committee whose purpose is to ensure that every surgeon who intends to perform robotic assisted surgery receives appropriate training and proctoring. In order to be eligible to request clinical privileges to perform robotic assisted procedures, a practitioner must meet the following minimum threshold criteria:

- Completion of a residency training program at an Accreditation Council for Graduate Medical Education (ACGME) or American Osteopathic Association (AOA) accredited institution;
- All training must have taken place in an accredited ACGME or AOA training program;
- All experience must be current and from an institution with formal performance monitoring requirements;
- Successful completion of a hands-on training program in the use of the da Vinci surgical platform, including personal experience on the system during the course, using an animate model or cadaver;
- Observation of two live cases using the da Vinci surgical system in the operating room;
- Privilege to perform open procedures;
- Privilege to perform laparoscopic procedures; and
- Documentation of at least two proctored cases at UVM Medical Center

In addition to the Credentialing Committee, the UVM Medical Center Robotics Committee has been instrumental in the development of surgical robotic operations. This committee acts as a working group to research and provide credentialing recommendations and to address operational issues. The committee is chaired by a urologist who was an early adopter of robotic surgery at UVM Medical Center, as well as the Director of Perioperative Services and representatives from anesthesia, nursing, and scheduling.

At UVM Medical Center, urologists and gynecologists each 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 robotic 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.

The efficiency of surgical robotic procedures is greatly impacted by the effectiveness of the complete surgical team. UVM Medical Center has established specialty-specific robotic support teams and has a surgical robotics coordinator. Staffing support for robotics is also available on the evening shift, if needed.

Providing surgical robot training is an essential component of surgical resident and fellow education. The UVM Medical Center Urology Computer-Assisted Robotic Surgery Program offers complete Urology Resident and Advanced Urologic Attending training, and includes both simulated and complete patient care. On average, five urology residents and three gynecology residents complete robotic surgery training each year.

C. Need for Replacement of the da Vinci S Surgical System

Currently, UVM Medical Center has a successful robotic surgery program that is dependent on an aging and increasingly unreliable da Vinci S system, acquired in 2008. The system needs to be replaced, consistent with sound business practices, in order for UVM Medical Center to maintain its robotics program without disruption of patient care. The current equipment is fully depreciated, is at the end of its expected useful life, and has experienced significant and increasing downtime. The system was repaired 18 times in 2012, 23 times in 2013, 21 times in 2014 and 22 times in 2015. More importantly, the da Vinci S system is no longer in production, so when repairs are necessary, a limited number of refurbished parts are available. Effective December 31, 2017, Intuitive Surgical will discontinue all service and support of the da Vinci S model, making the robotic surgical system effectively obsolete.⁶

The new generation of the da Vinci offers advanced features, functionality and technology compared to the da Vinci S, all of which will enhance patient care. At this time, Intuitive Surgical's da Vinci remains the only system cleared in the United States for robotic assisted surgery. The new generation system, the da Vinci Xi, has more capabilities than the first generation model and is optimized for more complex procedures. Updated technologies include new overhead instrument arms designed to facilitate anatomical access from virtually any position; a new digital endoscope that creates a simpler, more compact design with improved visual definition and clarity; an ability to attach the endoscope to any arm, providing flexibility for visualizing the surgical site; smaller, thinner arms with newly designed joints that offer a greater range of motion; longer instrument shafts designed to give surgeons greater operative

⁶ See Exhibit 1, End of Life and Discontinuation of *da Vinci S* Surgical System, Service, Support and select accessories.

reach; and the addition of a fluorescent imaging system, which enables real-time visualization and assessment of vessels, bile ducts and tissue perfusion.

Elective replacement of major medical equipment follows an industry-standard replacement schedule of seven years. This is consistent with UVM Medical Center's strategic plan, which calls for the timely replacement of major capital equipment before it becomes obsolete and can no longer function adequately for patient care. Failure to replace the aging equipment would inevitably lead to the demise of UVM Medical Center's surgical robotics program. As the only academic institution in the state of Vermont, loss of the surgical robotics program would have significant negative impacts on the mission of UVM Medical Center to provide high-quality academic healthcare for a rural region, and the ability to recruit and retain the best and brightest students and faculty.

UVM Medical Center currently offers state of the art cancer care to patients in Vermont, northern New York, and New Hampshire. After the robotics program was introduced in 2008, the surgical oncologic treatment options offered at UVM Medical Center became comparable to those offered in major urban cancer centers. Prior to the introduction of the surgical robotics program, patients diagnosed with cancer or other complex surgical conditions who had financial means, would travel to Boston or New York City to have robotic surgery to avoid more invasive alternatives. However, since the inception of the surgical robotics program, all appropriate patients, regardless of insurance or personal finances, have had the opportunity to receive the benefits of this treatment technology. If the current da Vinci system fails and is not replaced, oncological surgical treatment options for urologic and gynecologic patients will regress to only those options offered a decade earlier. Patients would be forced to go elsewhere for treatment, and UVM Medical Center would no longer be able to offer comprehensive cancer care for the rural population of Vermont.

All major academic medical centers are utilizing robotic assisted surgery. All major surgical training programs are also teaching their residents and fellows to perform surgery using the robotic system. If UVM Medical Center does not have a functional robotic surgery system, it will be difficult to recruit and retain young and/or established faculty to the institution. Recruiting the best and brightest physicians is critical to treating patients, but also to teaching the next generation of physicians.

SECTION III DESCRIPTION OF PROJECT COMPONENTS

As indicated above, the Project includes the purchase of a replacement surgical robotic system, as well as a skills simulator to support training and credentialing. This is described directly below.

A. Equipment

UVM Medical Center plans to purchase a da Vinci Xi Dual Console System from Intuitive Surgical for \$2,360,000, which includes freight charges. The surgical system is stand-alone and

will not require any additional construction or facilities work. The unit can simply be wheeled into the operating room where the current surgical system resides.

In addition, the purchase package includes a skills simulator to assist with training and credentialing. The skills simulator is software that contains a variety of exercises and scenarios specifically designed to give users the opportunity to improve their proficiency with the da Vinci surgeon's console controls. The software turns the existing surgeon console into a practice platform that can be used in or outside the operating room. No additional system components are required. This set-up allows users to practice unassisted or with supervision, according to preference. Built-in metrics enable users to assess skills, receive real-time feedback and track progress. The open architecture of the system software allows for the future development and incorporation of additional practice modules. Simulation in all forms is an important part of the learning experience for surgical technology, but is especially critical in an academic teaching environment. The skills simulation software provides additional learning opportunities for residents, maximizing their practice time and ensuring they get as much technical exposure as possible. The cost of the skills simulator software is \$85,000.

The quote from Intuitive Surgical for the equipment is included as Exhibit 3 to this application.

SECTION IV CONSISTENCY WITH THE HRAP CON STANDARDS

The applicable CON Standards are **bolded** below followed by an explanation as to how the Project is consistent with each standard.

CON STANDARD 1.1: Applicants shall include published GMCB quality measures for services related to a specific application, for the applicant and other hospitals that report on that quality measure. The applicant shall demonstrate how the project will improve or assist in the improvement of the relevant quality measures, if the applicant's score is not above the national or the Vermont average.

UVM Medical Center is unaware of any GMCB publications on quality measures for surgical robotic assisted procedures. However, quality outcomes are currently collected and reviewed by individual departments and are reported out through the OR Steering Committee and the UVM Medical Center Robotics Committee. This data is compared to other programs of like size and is reported internally. All cases are reviewed in the department's respective Quality Assurance Programs. For cases performed between October 2012 and December 2015, UVM Medical Center had a mortality rate of 0% compared with all academic medical centers, which had a mortality rate of .14%.⁷

⁷ *Patient Outcomes by Hospital/Hospital System*, Oct 2012 – Dec 2012. Burlington: The University of Vermont Medical Center [producer]. Clinical Data Base/Resource Manager, v. 1.5.1.10, Vizient, Inc. [distributor].

CON STANDARD 1.3: To the extent neighboring health care facilities provide the services proposed by a new health care project, an applicant shall demonstrate that a collaborative approach to delivering the service has been taken or is not feasible or appropriate.

UVM Medical Center is the only healthcare facility in Vermont that offers robotic assisted surgery. The next closest healthcare facility offering surgical robotics is Champlain Valley Physician's Hospital (CVPH) in New York. As noted above, CVPH is also using the da Vinci S model which will reach end of life in 2017. With a low utilization rate of 26%, plans to replace the CVPH for its surgical robotic system are uncertain.

CON STANDARD 1.4: If an application proposes services for which a higher volume of such service is positively correlated to better quality, the applicant shall show that it will be able to maintain appropriate volume for the service and that the addition of the service at the facility will not erode volume at any other Vermont facility in such a way that quality at that facility could be compromised.

By replacing equipment that has reached the end of its useful life, this application, if approved, will allow UVM Medical Center to *maintain* its current volume levels for robotic assisted surgical procedures. As the only surgical robotics program in Vermont, acquisition of a replacement robot will not change the distribution of these services in Vermont, nor will it affect or erode volumes at other hospitals.

The UVM Medical Center Credentialing Committee assures that every surgeon who intends to perform robotic assisted surgery receives appropriate training and proctoring. The UVM Medical Center Robotics Committee has been instrumental in the development of surgical robotic operations. This committee acts as a working group to research and provide credentialing recommendations and to address operational issues. While there are no recognized standards for robotic surgery training programs, at UVM Medical Center, urologists and gynecologists each must perform 15 procedures in an 18-month period to maintain clinical privileges for robotic surgery. Only a small number of surgeons utilize robotic surgery at UVM Medical Center, and all are easily exceeding the minimum threshold of cases needed to maintain privileges.

CON STANDARD 1.7: Applicants seeking to develop a new health care project shall explain how such project is consistent with evidence-based practice. Such explanation may include a description of how practitioners will be made aware of evidence based practice guidelines and how such guidelines will be incorporated into ongoing decision making.

Currently, there are no recognized standards for robotic surgery training programs, but some professional organizations such as the American Urological Association (AUA) and the American Association of Gynecologic Laparoscopists (AAGL) are developing guidance for healthcare facilities.

UVM Medical Center surgeons follow evidence-based guidelines in decision making around the use of robotics during surgical procedures. Clinical appropriateness criteria are used diligently and are based on evidence-based practice.

CON STANDARD 1.8: Applicants seeking to develop a new health care project shall demonstrate, as appropriate, that the applicant has a comprehensive evidence-based system for controlling infectious disease.

The University of Vermont Medical Center is in compliance with Joint Commission requirements on Infection Prevention and Surveillance.

The University of Vermont Medical Center Infection Prevention Team was established in 1984 and as part of the James M. Jeffords Institute for Quality and Operational Effectiveness continues to strive to reduce and prevent healthcare-associated infections. A knowledgeable and effective infection prevention team is an important component of a successful infection prevention and control program. UVMCMC has an experienced team with proven success in reducing healthcare-associated infections. The team is led by the Hospital Epidemiologist and includes members certified in infection prevention. The teams' infection prevention activities incorporate the following:

- 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, prevention and control strategies including activities related to occupational health, construction and disaster planning
- Educational efforts directed at interventions to reduce infection risks
- Interpretation and implementation of changes mandated by regulatory, accrediting and licensing agencies
- Application of epidemiological and quality improvement principles including activities directed at improving patient outcomes
- Participation in research projects.

CON STANDARD 3.4: Applicants subject to budget review shall demonstrate that a proposed project has been included in hospital budget submissions or explain why inclusion was not feasible.

The cost for this Project was included in UVM Medical Center's approved capital budget, which was submitted to GMCB.

CON STANDARD 3.7: Applicants proposing to replace diagnostic or therapeutic equipment shall demonstrate that existing equipment is fully depreciated, or the cost of the early replacement, including the cost of the remaining depreciation on existing equipment, is less costly than keeping the existing equipment.

The da Vinci S Surgical System currently in use is fully depreciated. Despite routine preventative maintenance, the current system is experiencing increasingly frequent downtime as

it nears end of life. The system was repaired 18 times in 2012, 23 times in 2013, 21 times in 2014 and 22 times in 2015. Effective December 31, 2017, Intuitive Surgical will discontinue all service and support of the da Vinci S model, making UVM Medical Center's existing robotic surgical system effectively obsolete.⁸

CON 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. As appropriate, hospitals shall provide scientific evidence supporting the migration of such equipment and technology outside of tertiary care facilities.

UVM Medical Center is Vermont's only tertiary care facility and the only facility in the state that offers robotic assisted procedures. It is appropriate for UVM Medical Center to continue to provide these needed services. The minimally-invasive approach that is used for certain robotic assisted procedures has demonstrated that compared to open surgery, there is a reduction in intraoperative blood loss, lower blood transfusion rates, reduced patient length of stay, and faster recovery time.⁹

All patients are carefully vetted to make sure there is a clinical benefit to robotic assisted surgery versus traditional laparoscopic or open surgery. For example, Gynecology only performs robotic assisted surgery on patients with oncologic conditions, such as uterine, ovarian or cervical cancer, patients with complicated surgical history, and patients with a complicated medical history, such as severe endometriosis or large uterine fibroids.

The decision to perform an open, laparoscopic, or robotic assisted procedure is based on each individual patient, but it is important to ensure that both options remain available.

CON STANDARD 3.20: Applications to purchase diagnostic or therapeutic equipment, or to expand facilities to accommodate major medical equipment purchases, shall address the appropriateness of such distribution as compared to population, the availability of appropriately trained personnel, an evaluation of patient need versus convenience, urgent versus non-urgent use, and appropriate protocol to reduce the risk of repetitive testing (both within the facility purchasing the equipment and within the health care system).

UVM Medical Center is not proposing to expand facilities to accommodate major medical equipment. Instead, the proposal set forth in this application simply seeks the replacement of an outdated and depreciated surgical robotic system. No changes will occur related to the distribution of surgical robotic equipment in Vermont or the availability of trained personnel.

⁸ See Exhibit 1, End of Life and Discontinuation of *da Vinci S* Surgical System, Service, Support and select accessories.

⁹ Robotic-assisted laparoscopic radical prostatectomy for localized prostate cancer [emerging technology evidence report]. Plymouth Meeting (PA): ECRI Institute; 2010 May.

UVM Medical Center already employs fully-trained physicians, nurses and technicians who can safely and efficiently perform robotic assisted surgical procedures. Since the efficiency of surgical robotic procedures is greatly impacted by the effectiveness of the complete surgical team, UVM Medical Center has established specialty-specific robotic support teams and has a surgical robotics coordinator. Staffing support for robotics is also available on the evening shift, if needed. This application, if approved, will not require any changes in UVM Medical Center's staffing of the surgical robotics program.

UVM Medical Center has developed a process by which appropriate candidates for robotic surgery versus traditional open surgery are identified. Patients must meet certain pre-determined criteria to be identified as an appropriate candidate for robotic surgery. In Gynecology, only patients with gynecologic malignancies or complex gynecologic conditions are offered robotic surgery.

CON STANDARD 3.22: For applications involving the purchase of diagnostic or therapeutic equipment, applicants shall establish, through the submission of evidence in the form of peer-reviewed or similar articles, the clinical efficacy of the diagnoses or procedures to be performed.

The surgical robot is a nationally accepted therapeutic tool for certain surgical procedures. In many cases, it is a proven, highly effective surgical option based on clinical need and appropriateness of the patient. Robotically performed prostatectomies and hysterectomies have become the new standard of care around the country. According to a 2011 study, four out of five prostatectomies are performed robotically, an increase from about 67% in 2009.¹⁰ A 2013 article noted that "recent data suggests a decline in the rate of abdominal hysterectomy following the introduction of robotic surgical system technology at specific institutions." Furthermore, in the same article, Matthews, et al reported "an overall decline in the rate of abdominal hysterectomy following the introduction of the robotic approach at their academic institution".¹¹ The same trend holds true at UVM Medical Center.

CON STANDARD 3.24: An applicant shall disclose potential financial conflicts of interest between hospitals and physicians and an equipment purchase.

There are no potential financial conflicts of interests between UVM Medical Center and its physicians related to or created by the Project. As such, CON Standard 3.24 is not applicable to the proposal.

¹⁰ Lowrance, et. al. "Contemporary Open and Robotic Radical Prostatectomy Practice Patterns Among Urologists in the United States". The Journal of Urology, June 2012. Web 03 February 2015. <http://prostatecancerinfonk.net/2012/04/19/annual-volume-of-radical-prostatectomies-in-us-doubled-between-2003-and-2009/>

¹¹"AAGL Position Statement: Robotic-Assisted Laparoscopic Surgery in in Benign Gynecology". The Journal of Minimally Invasive Gynecology. 12 December 20 2. Web 03 February 2015.

SECTION V
CONSISTENCY WITH 18 V.S.A. § 9437

This Application demonstrates, and the Commissioner should find, that the Project complies and is fully consistent with the statutory criteria set forth in 18 V.S.A. Section 9437

The statutory language contained in Section 9437 is **bolded** below followed by Fletcher Allen's explanation of how the Project is consistent with each requirement.

1. The Application is consistent with the HRAP.

As indicated in Section IV, the Project is consistent with each of the HRAP CON standards and all other applicable provisions of the HRAP.

2. The cost of the project is reasonable, because:

A. the applicant's financial condition will sustain any financial burden likely to result from completion of the project;

The Project will not create a "financial burden" for UVM Medical Center. The costs of the Project will be paid from available working capital without incurring additional debt. The only incremental cost of the Project is depreciation.

The enclosed CON Financial Tables show the financial performance of UVM Medical Center's Perioperative Department, which includes the da Vinci Robot and all surgical services offered by UVM Medical Center. Table 3C shows that even with the addition of depreciation and the maintenance contract for the new da Vinci robot, the Perioperative Department will continue to generate over \$53M in excess revenue over expenses on an annual basis. Thus, the applicant will not be financially burdened by the project.

B. the project will not result in an undue increase in the costs of medical care. In making findings under this subdivision, the commissioner shall consider and weigh relevant factors, including:

- i. the financial implications of the project on hospitals and other clinical settings, including the impact on their services, expenditures, and charges;**
- ii. whether the impact on services, expenditures, and charges is outweighed by the benefit of the project to the public; and**

The Project involves routine equipment replacement and will not result in *any* increase in the costs of medical care. UVM Medical Center will also not *raise* its charges as a result of the Project.

Moreover, robotic assisted surgery is not a revenue generator for UVM Medical Center. While robotic assisted surgery may cost more to perform, the reimbursement rates are the same as for

laparoscopic surgery. In spite of the lower margins, the technology is offered for patients who are clinically appropriate. Increased costs are not passed on to patients.

C. less expensive alternatives do not exist, would be unsatisfactory, or are not feasible or appropriate;

Reasonable alternatives to replacing the robotic surgical system are not appropriate or feasible. The only alternative to replacing the robotic surgical system at this time would be to delay its replacement. That would not be appropriate or satisfactory, nor would it be consistent with sound business practices for replacing major capital equipment that is nearing the end of its useful life. Delayed replacement would lead to continued down time and disruptions of patient care, and eventually to the demise of the Robotics program at UVM Medical Center.

There is an identifiable, existing, or reasonably anticipated need for the proposed project which is appropriate for the applicant to provide;

The need for this Project is demonstrated throughout this Application, and is specifically addressed in Sections I(B), II(B) and II(C), which are incorporated herein by reference.

3. The project will improve the quality of health care in the state or provide greater access to health care for Vermont's residents, or both;

The Project will enable UVM Medical Center to continue offering minimally invasive robotic-assisted surgical procedures to patients throughout Vermont. As the only surgical robotics program in the State, Vermont residents would not otherwise have access to this technology, which for certain procedures, is the new standard of care.

4. The project will not have an undue adverse impact on any other existing services provided by the applicant;

The Project will not have a material impact on any other existing services offered by UVM Medical Center. All existing services will continue to be provided by UVM Medical Center.

5. The project will serve the public good;


The Project will serve the public good in numerous ways, as stated throughout the application.


CONCLUSION


Based upon the information contained in this Application, UVM Medical Center respectfully asks that the Application be APPROVED expeditiously and that a CON for the project be issued.

Dated at Burlington, Vermont this 4th day of May, 2016

THE UNIVERSITY OF VERMONT MEDICAL CENTER INC.

By: 
Spencer R. Knapp
Sr. V.P and General Counsel

And: 
Steven Klein, Director of Legal Affairs &
Assistant General Counsel

And: 
Erika Smart
Assistant General Counsel

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