



Office of Health Care Access Certificate of Need Application

Final Decision

Hospital: Hospital of Saint Raphael

Docket Number: 04-30412

Project Title: Acquisition of a da Vinci™ Surgical System

Statutory Reference: Sections 19a-638 and 19a-639 of the Connecticut General Statutes

Filing Date: April 14, 2005

Decision Date: May 18, 2005

Default Date: July 13, 2005

Staff Assigned: Laurie Greci

Project Description: Hospital of Saint Raphael (“Hospital”) proposes to acquire a da Vinci™ Surgical System from Intuitive Surgical, Inc. at a total capital expenditure of \$1,612,620.

Nature of Proceedings: On April 14, 2005, the Office of Health Care Access (“OHCA”) received a Certificate of Need (“CON”) application from Hospital of Saint Raphael (“Hospital”) for the acquisition of da Vinci™ Surgical System from Intuitive Surgical, Inc. at a total capital expenditure of \$1,612,620. The Hospital is a health care facility or institution as defined by Section 19a-630 of the Connecticut General Statutes (“C.G.S.”).

A notice to the public concerning OHCA’s receipt of the Hospital’s Letter of Intent was published on December 24, 2004, in *The New Haven Register*. OHCA received no responses from the public concerning the Hospital’s proposal.

OHCA’s authority to review, approve, modify, or deny this proposal is established by Sections 19a-638 and 19a-639, C.G.S. The provisions of these sections, as well as the

principles and guidelines set forth in Section 19a-637, C.G.S., were fully considered by OHCA in its review.

Findings of Fact

Clear Public Need

Impact of the Proposal on the Hospital's Current Utilization Statistics Proposal's Contribution to the Quality of Health Care Delivery in the Region Proposal's Contribution to the Accessibility of Health Care Delivery in the Region

1. Hospital of Saint Raphael ("Hospital") is an acute care hospital located at 1423 Chapel Street, New Haven, Connecticut. *(April 14, 2005, CON Application, page 300)*
2. The Hospital proposes to acquire a da Vinci™ Surgical System ("da Vinci") from Intuitive Surgical, Inc., at a total capital expenditure of \$1,612,620. *(April 14, 2005, CON Application, page 2)*
3. The da Vinci is a state-of-the-art robotic surgical system that scales a surgeon's hand movements and translates them into precise movements of the proprietary instruments. *(April 14, 2005, CON Application, page 31)*
4. The Hospital has based the need for the da Vinci on the following:
 - Improved quality of care to patients;
 - Provision of State-of-the-Art technology for surgical patients;
 - Strengthening the Hospital's Centers of Excellence in Cancer, Heart, and Bariatric Surgery; and
 - Enhancement of the Hospital's Urology services.*(April 14, 2005, CON Application, pages 2 and 3)*
5. Some of the advantages of minimally invasive surgery are:
 - Shorter post-surgical recuperation time;
 - Less blood loss resulting in fewer transfusions;
 - Lowered risk of infections due to the smaller incisions; and
 - Improved morbidity.*(April 14, 2005, CON Application, pages 2 and 31)*
6. The Hospital will use the da Vinci to augment its Bariatric, Urology, and General Surgery services by allowing many surgical procedures to be performed as minimally invasive surgery for the first time. It will be used primarily for urologic and bariatric surgeries. *(April 14, 2005, CON Application, page 2)*
7. The Hospital is the largest bariatric center in the state and performs over 400 obesity surgeries annually. *(April 14, 2005, CON Application, page 4)*
8. The da Vinci includes a surgeon's console, a patient-side cart with interactive robotic arms, a vision system, proprietary instruments, and system software. *(April 14, 2005, CON Application, page 31)*

9. Some of the advantages of the da Vinci are:
 - Fine motor control;
 - Excellent three dimensional color vision;
 - Increased magnification;
 - Computer filters any hand tremors and transmit the surgeon's every movement to the robotic arms in real time;
 - Replicated, versus counter-intuitive, surgical instrument orientation; and
 - Enhanced surgeon ergonomics.

(December 16, 2004, Letter of Intent, page 40 and April 14, 2005, CON Application, pages 3 and 4)
10. The Hospital has recruited Geoffrey Nadzam, M.D., a robotically-trained fellow. Dr. Nadzam completed a surgical residence and a laparoscopic bariatrics and surgical robotics fellowship. While in fellowship, he performed over 30 general surgery cases with the da Vinci. *(April 14, 2005, CON Application, page 10)*
11. David Hesse, M.D., of the Hospital's Department of Urology, recently spent time observing robotic prostatectomy surgery in Alabama. Dr. Hesse, along with Dr. Thomas Martin, will participate in the Intuitive training program. It is intended that within the first year of acquisition both doctors will have completed their da Vinci training. *(April 14, 2005, CON Application, page 10)*
12. Surgeons intending to use the da Vinci at the Hospital of Saint Raphael:
 - Must be Board Certified or Board eligible within their surgical specialty;
 - Must be credentialed in laparoscopic or thoracic surgery for the procedure to be performed;
 - Show evidence of attendance at a hands-on da Vinci training program of at least 16 hours duration;
 - Must have at least 3 hours of personal time on the da Vinci utilizing animate or cadaver models;
 - Show evidence of observing at least 2 clinical cases utilizing the da Vinci;
 - Show evidence of 4 proctored patient uses of the da Vinci;
 - Provisional status will be changed to full privileges after four successful da Vinci cases and upon approval of the Director of Robotic Surgery;
 - Full privileges will be re-evaluated upon a formal review of the first 25 cases; and
 - Outcomes to be monitored include length of stay, blood loss, complications, operating room time, and conversion to laparoscopic or open procedure.

(April 14, 2005, CON Application, page 383)
13. Trained surgeons will be required to first assist in robotic procedures under the direct supervision of an experienced surgeon, such as Dr. Nadzam. Each surgeon will complete the required number of hours of training before using the robot independently in an actual surgical case. *(April 14, 2005, CON Application, pages 15 and 16)*
14. As part of the purchase agreement with Intuitive Surgical, Inc., Intuitive shall provide training for two surgeons and two support staff. The price of the training is \$6,000 per training session during the first year of the initial term of the purchase

agreement. The Hospital anticipated training 4 teams for a total training expense of \$24,000. (April 14, 2005, CON Application, page 16 and 316)

15. There are no Standard of Practice Guidelines for robotic surgery. The Hospital will adopt guidelines published by surgical societies as a Standard of Practice Guidelines once the publications become available. (April 14, 2005, CON Application, page 8)
16. The introduction of the da Vinci at the Hospital would be a first in the southern area of Connecticut. Yale-New Haven Hospital offers open prostatectomy and bariatric surgery, but does not offer minimally invasive robotic surgery. Hartford Hospital is the only other provider using the da Vinci in the state. (December 16, 2004, Letter of Intent, page 40 and April 14, 2005, CON Application, pages 3 and 6)
17. Due to the evolving nature of the technology, a quantitative methodology for projecting volumes has not been established. In order to project utilization of the da Vinci at the Hospital, key surgeons were interviewed to determine the appropriateness and likelihood of certain surgical procedures converting to the robotic approach. Based on the experience of these surgeons, the experiences of other robotic centers, and clinical publications, the volume projection was developed. It is anticipated that actual volumes will exceed those presented as surgeons become experienced with the da Vinci technology. (April 14, 2005, CON Application, pages 16 and 17 and April 26, 2005, Facsimile, page 2)
18. The projected volumes for procedures that may utilize the da Vinci during Fiscal Years 2006, 2007, and 2008, as well as the volume for the same procedures without the da Vinci are given in the following table:

Table 1: Projected Volumes by Procedure for Fiscal Years 2006, 2007, and 2008

| Procedure and ICD-9CM ¹ Code Number(s) | 2006 | | 2007 | | 2008 | |
|---|-------------|----------------|-------------|----------------|-------------|----------------|
| | <i>With</i> | <i>Without</i> | <i>With</i> | <i>Without</i> | <i>With</i> | <i>Without</i> |
| Urologic Surgery | | | | | | |
| Prostatectomy, 60.3 - 60.5 | 43 | 2 | 49 | 6 | 54 | 6 |
| Nephrectomy, 55.4 - 55.5 | 7 | 0 | 13 | 0 | 18 | 0 |
| Radical Excision, lymph node, 40.52 - 40.53 | 0 | 0 | 0 | 0 | 1 | 0 |
| Pyeloplasty, 55.87 | 1 | 0 | 1 | 0 | 2 | 0 |
| Cystectomy, 57.6 | 2 | 3 | 4 | 1 | 5 | 0 |
| Total Urologic Surgery | 53 | 5 | 67 | 7 | 80 | 6 |
| Bariatric Surgery | | | | | | |
| Gastric Bypass, 44.31 | 10 | 593 | 20 | 604 | 30 | 617 |
| Number of Procedures, Subtotal | 63 | 598 | 87 | 611 | 109 | 623 |
| Number of Procedures, Grand Total | 661 | | 698 | | 732 | |

(April 14, 2005, CON Application, page 28 and April 26, 2005, Facsimile, page 3)

¹ International Classification of Diseases (ICD), Ninth Revision, Clinical Modification (CM).

Financial Feasibility and Cost Effectiveness of the Proposal and its Impact on the Applicant's Rates and Financial Condition
Impact of the Proposal on the Interests of Consumers of Health Care Services and Payers for Such Services
Consideration of Other Section 19a-637, C.G.S.
Principles and Guidelines

19. The project's estimated total capital expenditure is \$1,612,600 and is itemized as follows:

Table 2: Proposed Capital Expenditure

| Item | Cost |
|--|--------------------|
| Da Vinci Robotic System with 4 th Arm | \$1,290,000 |
| Additional Instrument Sets | |
| 2 @ \$150,000 each | 300,000 |
| Recording Equipment | 15,000 |
| Insafflator | 5,400 |
| TV Monitor | 1,800 |
| Operator's Chair | 420 |
| Total | \$1,612,620 |

(April 14, 2005, CON Application, page 306)

20. The Hospital will utilize lease financing. The monthly lease payment will be \$31,176 at an interest rate of 6%. As the useful life of the equipment is 5 years, the term of the lease is also 5 years. *(April 14, 2005, CON Application, pages 13 and 14)*
21. The financial impact of the proposal will be the addition of \$322,500 in depreciation expense per year, \$129,000 in maintenance expense per year, and incremental interest expense. Training costs for the first year will be \$24,000. *(April 14, 2005, CON Application, page 15)*
22. The proposal requires the addition of one full-time equivalent, a urological physician's assistant at \$125,000 including benefits. *(April 14, 2005, page 327)*
23. The da Vinci is a mobile system that may be brought to operating rooms as needed. There will be no associated costs for construction or renovation. *(April 14, 2005, CON Application, page 16)*
24. The da Vinci will require disposable supplies for its operation. The cost per surgical case is \$1,500. *(April 14, 2005, CON Application, page 327)*

25. The Hospital's financial projection for revenue gains or losses from operations associated with the CON proposal are given in the following table:

Table 3: The Hospital's Incremental Financial Projections with the CON Proposal

| Description | FY 2006 | FY 2007 | FY 2008 |
|-------------------------------------|------------------|------------------|-------------------|
| Revenue from Operations | \$ 820,488 | \$1,122,403 | \$ 1,399,599 |
| Total Operating Expense | 793,760 | 1,083,826 | 903,371 |
| Gain from Operations | \$ 26,728 | \$ 38,577 | \$ 495,888 |
| Incremental Inpatient Urology Cases | 43 | 57 | 69 |
| Equivalent Full Time Employees | 1.0 | 1.0 | 1.0 |

(April 14, CON Application, page 327)

26. There is no State Health Plan in existence at this time. *(April 14, 2005, CON Application, page 2)*
27. The proposal is consistent with Hospital's long-range plan. *(April 14, 2005, CON Application, page 2)*
28. The Hospital's proposal will augment the Hospital's teaching and research responsibilities in the areas of minimally invasive surgery and the use of robotic technology. The Hospital intends to provide training to surgical fellows who express interest in robotic surgery. *(April 14, 2005, CON Application, pages 3 and 10)*
29. The acquisition of the da Vinci will position the Hospital to become an observation site for robotic surgery. In addition, under the direction of Dr. Nadzam, the Hospital intends to train surgical fellows interested in robotic surgery. *(April 14, 2005, CON Application, page 10)*
30. The Hospital has improved productivity and contained costs through energy conservation, group purchasing, reengineering, and the application of technology. *(April 14, 2005, CON Application, page 9)*
31. The Hospital has sufficient technical and managerial competence to provide efficient and adequate service to the public. *(April 14, 2005, CON Application, pages 225 to 260)*
32. The Hospital's rates are sufficient to cover the proposed capital expenditure and operating costs. *(April 14, 2005, CON Application, page 327)*

Rationale

The Office of Health Care Access (“OHCA”) approaches community and regional need for the proposed service on case by case basis. Certificate of Need (“CON”) applications do not lend themselves to general applicability due to a variety of complexity of factors, which may affect any given proposal; e.g. the characteristics of the population to be served, the nature of the existing services, the specific types of services proposed to be offered, the current utilization of services and the financial feasibility of the proposed services.

Hospital of Saint Raphael (“Hospital”) proposes to acquire a da Vinci™ (“da Vinci”) Surgical System. The da Vinci is a state-of-the-art robotic surgical system that combines electronics and software to integrate robotic and minimally invasive surgical procedures. The da Vinci is a state-of-the-art robotic surgical system that scales a surgeon’s hand movements and translates them into precise movements of the proprietary instruments. Additional advantages of the da Vinci include three dimensional color vision and increased magnification of tissues. The technological advantages are beneficial to patients by reducing blood loss, risk for infection and post-operative pain. The recovery time and inpatient hospital stays are, in turn, shortened, a benefit to the Hospital as well as to patients.

The da Vinci will augment the Hospital’s surgical services by allowing surgeons to perform many procedures as minimally invasive surgeries for the first time at the Hospital. It will be used primarily for urologic and bariatric surgeries. The Hospital has recruited an experienced da Vinci surgeon, Dr. Geoffrey Nadzam. Dr. Nadzam completed a laparoscopic bariatrics and surgical robotics fellowship. Dr. Nadzam will train and supervise additional surgeons to use the da Vinci. The Hospital is the largest bariatric center in the state. Overall, the Hospital estimates that it will perform 600 or more bypass surgeries each year for the next three years. In FY 2006, 2007, and 2008, the Hospital proposes that ten, 20, and 30 gastric bypass surgeries, respectively, will be performing using the da Vinci. This proposal will not affect other area providers. The da Vinci will be provided to the Hospital’s existing patient base. In addition, the Hospital will be the first provider in southern Connecticut to have the da Vinci surgical system.

The proposal’s total capital expenditure of \$1,612,620 will be lease financed. As the da Vinci is a mobile system, there are no associated construction or renovation costs. The Hospital expects that the proposal will yield revenue gains of \$26,728, \$38,577, and \$495,888 during the first three years of operations, respectively. The Hospital expects that number of surgeries using the da Vinci will increase as additional surgical procedures implement the technology. The Hospital’s volume and financial projections appear to be reasonable and achievable. Therefore, OHCA concludes that the CON proposal is financially feasible and cost effective.

In summary, the acquisition of the da Vinci surgical system by the Hospital will improve patient care and enhance the quality of the surgical services that are provided by the Hospital.

Based upon the foregoing Findings and Rationale, the Certificate of Need application of Hospital of Saint Raphael to acquire a da Vinci™ Surgical System, at a total proposed capital expenditure of \$1,612,620, is hereby GRANTED.

Order

Hospital of Saint Raphael is hereby authorized to acquire a da Vinci™ Surgical System at a total capital expenditure of \$1,612,620, subject to the following conditions:

1. This authorization shall expire on May 18, 2007. Should the Hospital's da Vinci surgical system not be operational by that date, the Hospital must seek further approval from OHCA to completed the project beyond that date.
2. The Hospital shall not exceed the approved capital expenditure of \$1,612,620. In the event that the Hospital learns of potential cost increases or expects that final project costs will exceed those approved, the Hospital shall file with OHCA a request for approval of the revised project budget.
3. The Hospital shall perform procedures that have been approved for the da Vinci™ Surgical System by the Food and Drug Administration. The numbers and types of procedures performed using the da Vinci™ Surgical System shall be reported to OHCA on a semi-annual basis calendar year basis, e.g. January through June and July through December. The reporting period begins with the first procedure performed and extends for a period not to exceed two full calendar years. Each semi-annual filing shall be submitted to OHCA by no later than one month following the end of the reporting period. The semi-annual reports shall include the following:
 - The number of procedures performed by type of procedure and by the surgeon performing the procedure;
 - The number of procedures by type of procedure and by the patient's town of origin by zip code; and
 - The average length of time to perform the procedures by type of procedure.
4. The Hospital shall report to OHCA the names of surgeons granted authorization by the Hospital to perform surgeries using the da Vinci™ Surgical System. The Hospital shall provide to OHCA a summary of the surgeon's training and a copy of the Curriculum Vitae. The duration and timing of the surgeon reports shall correspond with the reporting period of Condition #3.

All of the foregoing constitutes the final order of the Office of Health Care Access in this matter.

By Order of the
Office of Health Care Access

May 18, 2005

Signed by Cristine A. Vogel
Commissioner

CAV:lkj