

**Department of Health and Human Services
Division of Licensing and Regulatory Services
State House, Augusta, Maine
Preliminary Analysis**

Date: 8/29/2007

Project: Proposal by Eastern Maine Medical Center to Purchase a Surgical Robot

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Directly Affected Party: NONE

Recommendation: APPROVE WITH CONDITIONS

Estimated Capital Expenditure per Applicant	\$1,330,308
Approved Capital Expenditure per CON	\$1,330,308
Maximum Contingency per CON	\$0
Total Approved Capital Expenditure with Contingency	\$1,330,308
Capital Investment Fund Impact per CON	\$ 319,544

I. Project Description

A. From Applicant

“Robotically-assisted minimally invasive surgery is the most recent evolution of advanced laparoscopic surgery. In September 2004, EMMC purchased the da Vinci Surgical System from Intuitive Surgical (currently the only commercially available system with the necessary capabilities) and performed the first procedure with this system in December 2004. The system consists of an ergonomically designed surgeon’s console, a patient-side cart with four interactive arms, the high performance InSite Vision System® and EndoWrist Instruments® which provide better control, dexterity and visualization than is available with conventional laparoscopic equipment. The use of these wrist instruments provides that the surgeon’s hand movements are scaled, filtered and seamlessly translated into precise movements of the endo wrist instruments (reposable instrumentation). The vision system provides for three dimensional visualization, enhanced dexterity, greater surgical precision and ergonomic comfort for the surgeon. **Attachment G** provides the typical layout for the technology. *(Not attached. On file at CONU.)* By purchasing this technology EMMC is ensuring that the benefits of minimally invasive surgery are accessible to a broader base of surgical patients throughout eastern and northern Maine.”

“EMMC’s investment in this technology will ensure that the surgical patients of eastern and northern Maine will have access to the most technological advanced minimally invasive surgical platform available today. Investing in robotics will ensure that EMMC will continue to provide superior surgical options and fulfill its mission as the region’s tertiary referral center. Standard of care surgical techniques utilize minimally invasive procedures whenever possible. Until recently, the least invasive surgical procedures have been endoscopic (camera assisted). Robotic surgery improves on conventional endoscopic surgery with smaller incisions and faster patient recovery times among other benefits.”

“Some programs have implemented this technology on systems with three arms (one camera and two surgical). The addition of the fourth arm (third surgical) in the system purchased by EMMC provides for better retraction and visualization of the operative site. It is necessary for certain types of urology and open heart procedures. The fourth arm will enable EMMC to provide minimally invasive surgery to respond to a wider range of patient needs in our region.”

“EMMC is the only hospital north of Portland to provide this technology. Maine Medical Center implemented similar technology in 2004.”

“Surgeons in several specialties are utilizing this system for a wide range of surgical procedures:

General Surgery (two surgeons)

- Laparoscopic Nissen fundoplication (reflux surgical correction)
- Adrenlectomy (excision of adrenal glands)

Urology Surgery (three surgeons)

- Prostatectomy, radical retro pubic

Retroperitoneal lymph node dissection
Cystectomy
Urethral reimplantation

Bariatric surgery (two surgeons)

Gastric bypass
Gastric banding

Cardiac surgery (two surgeons)

Coronary assisted bypass graft (CABG)

OB/GYN surgery (two surgeons)

Hysterectomy”

“To ensure patient safety, all surgeons performing robotic minimally invasive surgery have received training on the da Vinci system and are credentialed before performing any procedures. To maintain their credentials EMMC surgeons must participate in a minimum number of cases. The credentialing requirements are included as **Attachment H.**” *(Not attached. On file at CONU.)*

“No facilities renovations were necessary. The equipment is moveable and is used in two existing operating rooms.”

B. CONU Discussion

EMMC purchased the da Vinci equipment in 2004 at a cost of \$1,330,308 without first applying for or getting approval from the Commissioner of the Department of Human Services through the Certificate of Need Program as required by law. The CONU staff first learned of the purchase through an article published in the Bangor Daily news on December 13, 2005. EMMC was informed by the CONU that an application for CON was required to conform to statute. Because of EMMC’s willingness to comply, no enforcement action was taken at that time. EMMC has continued using the equipment and performing procedures until a final decision is made on its application.

II. Profile of the Applicant

A. From Applicant

Eastern Maine Medical Center (EMMC)

“EMMC is an acute care, non-profit community hospital, which began operations in 1892. EMMC serves as the referral hospital for the region, which includes Penobscot, Piscataquis, Aroostook, Washington, Hancock, Waldo, Knox, Kennebec, and Somerset counties. EMMC is licensed for 411 acute care nursing beds. EMMC offers a full range of specialty services including cardiac, oncology, hematology, nephrology, orthopedics, obstetrics, pediatrics, rehabilitation and palliative care, along with general medical and surgical services, with an active medical staff of over 300 physicians, including 67 surgeons. EMMC’s inpatient units operated at 86.3% occupancy in FY2006 (Oct.-July ytd). **Attachment A** includes a copy of EMMC's acute care license. *(Not attached. On file at*

CONU.) Eastern Maine Medical Center's primary address is: EMMC, 489 State St., Bangor ME 04401."

"In addition to acute care services, EMMC provides a wide range of ambulatory services. These include emergency, trauma and urgent care services, family practice services, outpatient surgery, physical and occupational therapy, cardiac wellness and rehabilitation, dialysis, surgical weight loss, diabetic and nutritional counseling, a wide range of imaging services and pediatric specialty services."

"EMMC has a transfer agreement for referral services with virtually all of the 12 critical access hospitals in the region. EMMC is one of three state designated trauma centers and provides hospital emergency preparedness services through the state Maine Regional Resource Center (MaRRC) grant program to 21 hospitals in this state. EMMC serves the largest geographic service area of any referral center in the state."

"EMMC has been selected two years in a row as one of the top 10 hospitals in the country for overall patient satisfaction for those hospitals submitting information to the Avatar market survey system. Recently, EMMC received the distinction of receiving Center of Excellence accreditation for the Bariatric Surgical weight loss program from the American Society of Bariatric Surgery. EMMC is the only hospital in Maine with this recognition."

"EMMC is a subsidiary of Eastern Maine Healthcare Systems (EMHS). The table in **Attachment B** shows the relationship between EMMC and other EMHS subsidiaries. The EMMC Board of Trustees is listed in **Attachment C**. CVs of key individuals for the project are contained in **Attachment D**." (Not attached. On file at CONU.)

"**Attachment E** contains **EMHS' FY 2003 and 2004 audited financial statements**, which include EMMC's financial activity." (Not attached. On file at CONU.)

Direct Service Affiliates

"Descriptions of our affiliated direct care provider organizations appear in **Attachment F**. (Not attached. On file at CONU.) They include: Acadia Hospital Corp. (AHC), Affiliated Laboratory, Inc (ALI), Blue Hill Memorial Hospital (BHMH), Charles A. Dean Memorial Hospital and Nursing Home, Inland Hospital, Rosscare, Sebasticook Valley Hospital (SVH), and The Aroostook Medical Center (TAMC)."

B. CONU Discussion

i. Criteria

That the applicant is fit, willing and able to provide the proposed services at the proper standard of care as demonstrated by, among other factors, whether the quality of any health care provided in the past by the applicant or a related party under the applicant's control meets industry standards.

ii. Analysis

The Division of Licensing and Regulatory Services, Medical Facilities Unit confirmed that Eastern Maine Medical Center is a fully licensed acute care hospital licensed in the State of Maine and is MaineCare and Medicare certified. The Division's most recent survey was completed on January 6, 2005. No major deficiencies were cited that would affect licensure. EMMC sent in a plan of correction on January 31, 2005 and it was accepted by the Department on February 14, 2005. The last Joint Commission report was completed on July 25, 2004. In that report, EMMC passed and no problems were identified in the surgical department.

The applicant has shown a long standing ability to provide hospital based services within licensing standards.

iii. Conclusion

Based on the discussion above the CONU recommends that the Commissioner determine that the applicant is fit, willing and able to provide the proposed services at the proper standard of care.

III. Capital Expenditures, Financing and Compliance

A. From Applicant

TABLE 1: CAPITAL EXPENDITURES BUDGET

DaVinci Robot	\$1,042,138
Additional (Third Surgical Arm)	200,000
Peripheral Equipment	83,170
CON Filing Fee	5,000
Total	\$1,330,308

Financing Plan

"This equipment was purchased with EMMC equity; no debt financing was used for this project."

Staffing

"No additional staff was required to implement this project. Staff training costs were included in the purchase price of the equipment."

Literature Review

"**Attachment I** includes representative literature describing the development and use of the technology. (*Not attached. On file at CONU.*) The original bibliography supplied by EMMC's Health Sciences Library contained synopses of 117 articles and is available upon request. Most studies have concluded that robotically-assisted laparoscopic surgery is safe with fewer complications, and a quicker recovery time. As with many other less-invasive procedures, operating room time can

be longer than with open surgical cases. Many authors conclude that more data is needed to fully analyze the cost/benefit of this system.”

Financial and Economic Feasibility

“EMMC is currently collecting clinical and financial data to measure quality, outcomes and cost. A challenge will be to capture and quantify all costs to Maine’s health care system, including non-hospital costs. EMMC’s direct cost data for the hospital admission involving the surgery will be relatively easy to collect; but to fully measure costs, analysis of the full episode of care will be necessary. Since there is general consensus that infections and other complications will be reduced, these avoided costs should be quantified and included in any economic analysis. Until recently this data was not easily available. The development of the “Claims Data Bank” by the Maine Health Information Center (MHIC) and Maine Health Data Organization (MHDO) may make such an analysis possible. The information technology and databases will exist to capture and analyze all related health care costs of a patient undergoing surgery – not just the hospital stay. Once data for 2005-2006 is available it will be possible to compare all health care costs for comparable patients undergoing surgery with and without robotically-assisted laparoscopy including pre- and post-surgical costs over a longer period of time.”

“EMMC has compiled financial data on the two highest volume procedures to date. It is premature to calculate non-hospital costs associated with these episodes of care. As shown in Table 6, EMMC will be able to support this project financially as there is a small operating margin on cases to date. There will be little impact to the State of Maine; as shown in Table 7, only 1.3% of the cases and 0.6% of net revenue of cases studied to date are Medicaid (MaineCare) patients.”

“Some researchers have reported longer operating time with use of the surgical robot, but forecast that these times could be reduced as surgeons and operating room staff gain experience on preparation and set-up of the equipment. EMMC believes that these small costs increases from longer operating room time (even if they are not reduced further with experience) will be off-set by lower post-surgical costs to the healthcare system and to the patient. In addition, robotic surgery will increase longevity of surgeons allowing these experts to serve Maine residents for longer than the use of non-robotics. See article published in EMMC’s “Eagle” report, 2005, **Attachment J.**” (*Not attached. On file at CONU.*)

TABLE 6 UPDATED: EMMC OPERATING COSTS
Highest Volume Robotically Assisted Procedures

FY2006 UPDATED					
<u>Gastric Bypass Surgery</u>					
Payor	Cases	ALOS	Est. Net Revenue	Total Expenses	Margin
Blue Cross	37	2.2	\$ 853,884	\$ 661,973	\$ 191,911
Commercial	13	1.9	\$ 306,205	\$ 236,670	\$ 69,535
Medicare	1	2.0	\$ 8,651	\$ 7,915	\$ 736
Other	1	2.0	\$ 15,657	\$ 18,437	\$ (2,780)
Total	52	2.1	\$1,184,397	\$ 924,995	\$ 259,402
-					
<u>Prostatectomy</u>					
Payor	Cases	ALOS	Est. Net Revenue	Total Expenses	Margin
Blue Cross	19	1.7	\$ 422,996	\$ 293,791	\$ 129,205
Commercial	16	1.2	\$ 329,375	\$ 223,486	\$ 105,889
Medicaid	1	1.0	\$ 8,804	\$ 16,974	\$ (8,170)
Medicare	26	1.9	\$ 246,277	\$ 410,392	\$ (164,115)
Total	62	1.6	\$1,007,452	\$ 944,643	\$ 62,809
<u>Total Both Procedures</u>					
Payor	Cases	ALOS	Est. Net Revenue	Total Expenses	Margin
Blue Cross	56	2.0	\$1,276,880	\$ 955,764	\$ 321,116
Commercial	29	1.5	\$ 635,580	\$ 460,156	\$ 175,424
Medicaid	1	1.0	\$ 8,804	\$ 16,974	\$ (8,170)
Medicare	27	1.9	\$ 254,928	\$ 418,307	\$ (163,379)
Other	1	2.0	\$ 15,657	\$ 18,437	\$ (2,780)
Total	114	1.8	\$2,191,849	\$1,869,638	\$ 322,211

FY2007 YTD (October-June)					
<u>Gastric Bypass Surgery</u>					
Payor	Cases	ALOS	Est. Net Revenue	Total Expenses	Margin
Blue Cross	26	2.1	\$ 625,211	\$ 448,953	\$ 176,258
Commercial	23	2.1	\$ 577,261	\$ 410,688	\$ 166,573
Other	2	2.0	\$ 32,448	\$ 36,319	\$ (3,871)
Total	51	2.1	\$1,234,920	\$ 895,960	\$ 338,960
<u>Prostatectomy</u>					
Payor	Cases	ALOS	Est. Net Revenue	Total Expenses	Margin
Blue Cross	22	1.2	\$ 314,246	\$ 301,673	\$ 12,573
Commercial	15	1.1	\$ 288,070	\$ 199,579	\$ 88,491
Self-Pay	1	1.0	\$ -	\$ 16,264	\$ (16,264)
Medicare	22	1.4	\$ 184,923	\$ 320,485	\$ (135,562)
Total	60	1.2	\$ 787,239	\$ 838,001	\$ (50,762)
<u>Total Both Procedures</u>					
Payor	Cases	ALOS	Est. Net Revenue	Total Expenses	Margin
Blue Cross	48	1.7	\$ 939,457	\$ 750,626	\$ 188,831
Commercial	38	1.7	\$ 865,331	\$ 610,267	\$ 255,064
Medicare	22	1.4	\$ 184,923	\$ 320,485	\$ (135,562)
Self-Pay	1	1.0	\$ -	\$ 16,264	\$ (16,264)
Other	2	2.0	\$ 32,448	\$ 36,319	\$ (3,871)
Total	111	1.6	\$2,022,159	\$1,733,961	\$ 288,198

TABLE 7: PAYOR MIX

Payor	Percent Distribution of:		
	Cases	Revenue	Expenses
Blue Cross	50.7%	60.2%	51.2%
Commercial	22.7%	26.1%	21.7%
Medicaid	1.3%	0.6%	1.4%
Medicare	24.0%	12.0%	24.2%
Other	1.3%	1.1%	1.5%
Total	100%	100%	100%

Source: EMMC Financial System

EMMC SURGICAL ROBOT INCREMENTAL OPERATING COSTS

	Year 1	Year 2	Year3
	FY 2005	FY 2006	FY 2007
*Depreciation	\$190,044	\$190,044	\$190,044
Maintenance	\$ 0	\$129,500	\$129,500
Total	\$190,044	\$319,544	\$319,544

* 7 year useful life

“All cases using this equipment are cases that would have been either with laparoscopic or open surgical procedures. The surgical departments have added no additional staff due to the acquisition of surgical robot. Training costs for surgeons and nurses was covered by the equipment vendor at no additional charge to EMMC. Supply costs per procedure are unchanged since the surgical robot was put into service.”

B. CONU Discussion**i. Criteria**

The economic feasibility of the proposed services is demonstrated in terms of:

- Capacity of the applicant to support the project financially over its useful life, in light of the rates the applicant expects to be able to charge for the services to be provided by the project;
- Applicant’s ability to establish and operate the project in accordance with existing and reasonably anticipated future changes in federal, State and local licensure and other applicable or potentially applicable rules;

ii. Analysis

The CONU financial analysis considers information contained in the 2006 Almanac of Hospital Financial and Operating Indicators and generally accepted accounting standards in determining the financial capability of the hospital to support this proposed project.

The review of financial indicators is important because they present a fair and equitable representation of the financial health of an organization and can present appropriate comparisons. This provides a sound basis for a determination of whether the hospital has the ability to commit the financial resources to develop and sustain the project. While there are a number of indicators that are used in the industry, the ones applied to this review have been selected due to their direct relevance to the financial health of the applicant. The following analysis is based upon information contained in the record. One item of terminology needs to be defined. Throughout the analysis, a comparison of high-performance and low-performance hospitals is referenced. These groups are based on the uppermost and lowermost quartiles of hospitals based on their return on investments. CONU chose not to

specifically discuss return on investment, but instead to use that ratio to group all hospitals in regards to making a comparison to the particular project and applicant.

The third full year of operation of this project is EMMC's FY 2007 which is the current fiscal year. The last audited financial statements available from EMMC are FY 2006. Complete pro-forma financial statements were not submitted by the applicant but are not needed because the equipment was purchased in late FY 2004. For purposes of this application, EMMC's audited financial statements on file through FY 2006 are sufficient to evaluate this project.

Profitability

Non-profit hospitals need to perform at financially sustainable levels in order to carry out their public missions. An adequate operating margin is a key indicator of the financial health of a hospital.

According to the 2006 Almanac of Hospital Financial and Operating Indicators, operating margins in the high performing hospital group have seen greater improvements in margins while hospitals in the low performing group are sliding. High performing hospitals are doing better now than five years ago. Over the same time, lower performing hospitals are generally doing worse than five years ago. There is a widening gap between high and low performing hospitals. Improvement in operating profits for high-performing hospitals drives this widening performance gap. As a comparison, operating margins in the Northeast Region are considerably lower than in other regions.

	2004 Northeast Median	2004 Maine State Median	2004 EMMC's	2006 EMMC's
Operating Margin	1.60%	3.10%	3.22%	2.68%

The Maine State average for 2004 was 3.1%. EMMC's in 2004 was 3.22, slightly above the average which puts them in the 50th percentile. The trend for the State of Maine has been inconsistent with a low of -1.2 to a high of 3.1 over the 2000 to the 2004 period. EMMC had a spike in their operating margin in 2005 to 8.39% but went back to 2.68% in 2006. The reason for the spike in the operating margin for 2005 may be contributed to a one time settlement EMMC received from the State of Maine to settle MaineCare claims for the period 1996-2003.

The effect of this project on operating margins for the first three years of operation (2005-2007) is minimal given the number of procedures being done and the estimated new third year incremental operating costs (\$319,544) associated with this project. EMMC's operating margin decreased from 3.05% in FYE 2004 to 2.56% in FYE 2006 but not as a result of this project.

Liquidity

Liquidity measures a hospital's ability to manage change and provide for short-term needs for cash. Liquidity alleviates the need for decision making to be focused on short term goals and allows for more efficient planning and operation of a hospital.

Days Cash On Hand is a ratio that is industry accepted, easily calculated, and used to determine a hospital's ability to meet cash demands.

According to the 2006 Almanac of Hospital Financial and Operating Indicators, high performing hospitals have approximately 80 days cash on hand while low performing hospitals have 45 days cash on hand. Urban hospitals with revenues greater than \$150 million had approximately 81.9 days cash on hand in 2004.

	2004 Northeast Median	2004 Maine State Median	2004 EMMC's Average	2006 EMMC's
Days Cash on Hand	81.20 Days	73.40 Days	68.10 Days	52.53 Days

In 2004 the average days cash on hand from all sources for hospitals in the State of Maine was 73.4 days. The CONU calculated days cash on hand for EMMC in 2004 as approximately 68 days indicating that EMMC was between the 25th to 50th percentile. EMMC's days cash on hand has declined to 65.04 in 2005 and to 52.53 in 2006.

According to the same source, the average days cash on hand between 2000 and 2004 remained about 68 days. Maine had 15% less days cash on hand than the Northeast Region at 80 days, 12 days more than the Maine average.

The impact of this proposed project has little effect with days cash hand on per audited financial statements as the project has only added minimal new third year incremental operating costs (\$319,544). The decrease in the number of days cash on hand of 68.10 in FYE 2004 to 52.53 in FYE 2006 is as a result of total operations and not this small project.

Capital Structure Ratios

Many long term creditors and bond rating agencies evaluate capital structure ratios to determine the hospitals ability to increase its amount of financing. During the past 20 years, the hospital industry has radically increased it's percentage of debt financing. This trend makes capital structure ratios important to hospital management because these ratios are widely used by outside creditors. Values for these ratios ultimately determine the amount of financing available to a hospital. Debt service coverage is the most widely used capital structure ratio. Debt service coverage minimums are often seen as loan requirements when obtaining financing. Debt service coverage is the ratio of earnings plus depreciation and interest expense to debt service requirements. In 2004 the median Maine hospital's debt service coverage (DSC) was 3.45x.

	2004 Northeast Median	2004 Maine State Median	2004 EMMC's Average	2006 EMMC's Average
Debt Service Coverage	3.12	3.45	9.59	10.01

EMMC had a DSC in 2004 of 9.59x which places the hospital in the range of 90th - 100th percentile. The statewide trend for 2000-2004 is inconsistent with a low of 2.39 in 2002 and a high of 3.71 in 2000. The DSC for EMMC in 2005 increased significantly to 17.11 and then declined to 10.01 in 2006. The reason for the spike in DSC for 2005 may be contributed to a one time settlement EMMC received from the State of Maine to settle MaineCare claims for the period 1996-2003.

EMMC did not borrow any funds for this project. EMMC has the capacity and the ability to have adequate debt service coverage.

According to the 2006 Almanac of Hospital Financial and Operating Indicators, Fixed Asset Financing: “Low performance hospitals have historically used more debt to finance net fixed assets than high performance hospitals. With the removal of capital cost pass throughs, long term debt will become most costly relative to equity. High performance hospitals are restructuring their capital positions to reflect this shift in the relative costs of debt and equity capital. However, we expect fixed asset financing ratios to continue to remain stable during the next 5 (five) years as hospitals curtail their growth in new capital expenditures and reduce their reliance on long term debt.”

	2004 Northeast Median	2004 Maine State Median	2004 EMMC's Average	2006 EMMC's Average
Fixed Asset Financing	62.9	54.3	55.0%	51.0%

The Northeast has considerably higher rates in financing fixed assets than other regions. The 2004 average for hospitals in the State of Maine was 54.3 percent in regards to fixed asset financing. In 2004, EMMC's capital structure ratio was at 55 percent, which is at the 50th percentile for the State of Maine. For the years 2000-2004, hospitals with revenues similar to EMMC averaged 68 percent.

The fixed asset financing ratio over the past 5 years has remained relatively consistent in the State of Maine.

The applicant is not using any outside sources to fund this project. EMMC's fixed asset financing ratio has remained constant throughout FY 2004-2006 and this project is not expected to influence this ratio in FY 2007.

Efficiency Ratios

According to the 2006 Almanac of Hospital Financial and Operating Indicators, total asset turnover (TAT) provides an index of the number of operating revenue dollars generated per dollar of asset investment. Higher values for this ratio imply greater generation of revenue from the existing investments of assets. Larger hospitals usually have lower values for turnover than smaller hospitals. This can be attributed to two factors. First, larger hospitals are most likely to have newer physical plants. Second, capital intensity is often greater in larger hospitals due to more special services and higher levels of technology.

	2004 Northeast Median	2004 Maine State Median	2004 EMMC's Average	2006 EMMC's Average
Total Asset Turnover	1.06	1.18	1.39	1.42

In 2004, according to the source cited above, Maine hospitals had a TAT ratio of 1.18. For 2004 EMMC had a TAT of 1.39 times increasing to 1.42 times in 2005 and 2006.

In the period of 2000 – 2004 there has been a steady increase in the TAT for Maine hospitals.

This project has not had a significant impact on the TAT of EMMC.

iii. Conclusion

The CONU concludes that the applicant can financially support this project. Demands on liquidity and capital structure have been adequate to support the project. This project has shown little impact on the financing and turnover ratios for EMMC. The hospital has shown significant earnings which have not been significantly impacted by this project. The applicant did not borrow any funds to undertake this project. This project did not involve a construction component requiring a Marshall and Swift comparison.

CONU recommends the Commissioner determine that the economic feasibility of the project has been demonstrated.

IV. Needs to be Met

A. From Applicant

Service Area

“EMMC defines its Primary Service Area as the Bangor Hospital Service Area (HSA). EMMC's Referral Service Area for tertiary care services includes all HSAs, excluding the Bangor HSA, from the Rockland HSA to the Ft. Kent HSA.”

“The 2006 estimated and 2016 projected population in EMMC's Total Service Area is shown in Table 2.”

TABLE 2
ESTIMATED and PROJECTION POPULATION
EMMC TOTAL SERVICE AREA

PRIMARY SERVICE AREA (1) Projected			
<u>Age Group</u>	<u>2006</u>	<u>2016</u>	<u>% Change</u>
0-17	27,093	26,300	-2.9%
18-44	52,796	50,988	-3.4%
45-64	37,806	40,790	7.9%
65+	16,693	22,661	35.8%
Total	134,388	140,739	4.7%
REFERRAL SERVICE AREA (2)			
<u>Age Group</u>	<u>2006</u>	<u>2016</u>	<u>% Change</u>
0-17	76,943	71,409	-7.2%
18-44	124,227	114,623	-7.7%
45-64	115,315	119,021	3.2%
65+	61,145	75,218	23.0%
Total	377,630	380,271	0.7%
TOTAL SERVICE AREA (3)			
<u>Age Group</u>	<u>2006</u>	<u>2016</u>	<u>% Change</u>
0-17	104,036	97,709	-6.1%
18-44	177,023	165,611	-6.4%
45-64	153,121	159,811	4.4%
65+	77,838	97,879	25.7%
Total	512,018	521,010	1.8%

Source:2006 estimate per Maine State Planning Office, excludes unorganized territories.

(1) Bangor Hospital Service Area

(2) All Hospital Service Areas from Waterville to Ft. Kent (excluding Bangor HSA).

(3) Primary plus Referral Service Areas

“EMMC’s minimally invasive surgical patients come from all parts of northern, eastern and central Maine. For example, EMMC’s first 24 patients undergoing robotically-assisted gastric bypass surgery in 2005 came from 10 of Maine’s 16 counties, from Cumberland to Aroostook Counties. Table 3 includes current and project volume for robotically assisted surgery.”

TABLE 3: EMMC ROBOTICALLY ASSISTED MINIMALLY INVASIVE SURGICAL PROCEDURES	
Estimated and Projected: 2005-2008	
Fiscal Year (*)	Cases
2005 (9 months)	84
2006	134
2007 (43 weeks)	150
2007 estimated	184
2008 projected	200
(*) FY2005 9 months January-September	
(*) FY2007 10 months October-July	
Source: EMMC Surgical Department	

Minimally Invasive Surgery (MIS)

“The term minimally invasive surgery can be used interchangeably with laparoscopy or endoscopic surgery. Minimally invasive surgery is performed through dime-sized (1-2 cm) incisions (operating ports). This is in contrast to the much larger incisions used in conventional open surgery which are often as large as 6-12 inches (15-30 cm) long.”

“The advantages of conventional laparoscopic and robotically–assisted laparoscopic surgery are that they enable shorter recovery times for patients and result in less pain, reduced blood loss with fewer transfusions, fewer infections, reduced hospitalization costs and a faster return to normal activities for the patient.”

“While conventional, non-robotically assisted, MIS has become standard-of-care for particular surgical procedures, it has not always appropriate for more complex or delicate procedures, such as prostatectomy and mitral valve repair. Complex surgical procedures that require fine-tissue manipulation, such as dissecting and suturing, can be more difficult and less precise using conventional MIS (laparoscopy or endoscopic surgery) than with open surgery. Complex procedures such as cardiac surgery also require an excellent view of the operative field and the ability to maneuver instruments within the chest cavity, abdomen or pelvis with precision and control. For example, in cardiac surgery, a conventional open approach involves a medial sternotomy (cutting through the sternum and spreading open the rib cage). With MIS cardiac surgery, this is not necessary.”

“Robotically-assisted” Minimally Invasive Surgery

“Robotically-assisted Minimally Invasive Surgery builds on the advances of conventional MIS by providing the surgeon with the benefits of greater surgical precision, increased range of motion, improved dexterity, enhanced visualization and improved access. Robotically-assisted laparoscopic surgery enables the use of MIS techniques for more complex procedures and benefits a broader range of patients.”

“The two major drawbacks of conventional laparoscopic surgery are that it relies on the use of rigid, hand-held instruments and visualization provided by a standard two-dimensional video monitor. While this technology enables smaller incisions than with an open procedure, it limits the surgeon’s sense of depth of field, dexterity and precision. Standing at the patient’s side, the surgeon must

operate in a counter-intuitive fashion, moving the long-shafted instrument handle in precisely the opposite direction (counter-intuitive) as the intended movement of the instrument tip. The surgeon maneuvers the instruments while looking up at a two-dimensional image of the operating field projected on a tableside video monitor and while instructing an assistant on how to position the surgical camera.”

“In contrast, robotically-assisted laparoscopic surgery incorporates state-of-the-art robotic technologies that provide natural depth of field and allow a surgeon’s hand movements to be scaled, filtered and translated into precise micro-movements of tiny instruments at the operative site. The superior visualization, enhanced dexterity, precision and control enable the surgeon to perform a complex procedure such as radical prostatectomy, through dime-sized operating ports. The robotics allows “intuitive” hand motion to control instrumentation.”

“As reported in the literature (including in several articles included in Attachment I) earlier versions of this system did not provide the surgeon with tactile feedback sensations from the operative field back to the surgeon procedure. This is also a short-coming of conventional laparoscopic surgery. The robot-assisted system used by EMMC includes enhancements that correct this. This force feedback provides a substitute for tactile sensation that is provided through an open surgical approach. This feedback is augmented by the enhanced vision provided by the high-resolution three-dimensional images that are not available in conventional laparoscopic procedures.”

“A benefit to hospitals implementing this type of minimally invasive surgery may also be a reduction of the “learning curve”. In *Nature Clinical Practice* (December 2004) Wiklund reports that after 100 robot-assisted radical prostatectomies, surgeons reduce operating room time to less than two hours compared to over three hours for conventional laparoscopic surgery. The full article is included in Attachment I.” (*Not attached. On file at CONU.*)

Ahlering et al in the *Journal of Urology* (2003) report:

“It has been suggested that the outcome of robot-assisted laparoscopy after 10 operations is comparable to the experience of skilled laparoscopic surgeons after more than 100 conventional laparoscopic cases.”

“Benefits experienced by most patients receiving robotically-assisted MIS compared to open or conventional laparoscopic procedures include shorter hospital stays, substantially less pain, lower risk of infection, reduced blood loss, fewer transfusions, less scarring, faster recovery and a quicker return to normal daily activities. None of these benefits can be guaranteed for an individual case, as surgery can be both patient- and procedure-specific.”

“Before 2004, patients from Maine had to leave the state to receive the benefits of this type of surgery. EMMC’s robotically-assisted minimally invasive surgery program has benefited a wide variety of patients to date, summarized in Table 4:”

**TABLE 4: EMMC ROBOTICALLY ASSISTED MINIMALLY INVASIVE
SURGICAL PROCEDURES
January 2005-June 2006**

Operation	<u>FY2005</u>	<u>FY2006</u>	<u>FY2007</u>
Adrenalectomy	2		
CABG - Coronary Artery Bypass Graft	5		
Cholecystectomy	8	2	
Colectomy	4		
Colpopexy			3
Gastric Banding	10	1	
Gastric Bypass	24	52	57
Gastrectomy			1
Hemigastrectomy	1		
Hernia repair	1		
Hysterectomy		6	18
Left Lateral Liver Resection w/RF	1		
Nephrectomy		2	
Nissen Fundoplication	6	4	3
Prostatectomy, Radical Retropubic	21	62	67
Pyleoplasty		2	
Radical Prostatectomy, Bilat Hernia Rep	1		
Retroperitoneal Lymph Node Dissection		2	
Ureteral Reimplant		1	
Vesicle Fistula Repair			1
Grand Total	84	134	150

Notes:

FY2005 9 months January-September

FY2007 10 months data

Clinical areas where the highest number of EMMC patients will benefit are Prostatectomies, Coronary Artery Bypass Grafts (CABG) and Bariatric Surgery

Radical Prostatectomy

“Radical prostatectomy, the surgical removal of the prostate and surrounding cancerous tissues, is considered the “gold standard” in the treatment of prostate cancer. Radical prostatectomy is a complex and delicate procedure due to many factors, including the location of the prostate gland deep inside the pelvis. In radical prostatectomy, the surgeon removes the entire prostate gland along with both seminal vesicles, both ampullae’s (the enlarged lower sections of the vas deferens), as well as additional surrounding tissues. The section of urethra that runs through the prostate is cut away; and possibly with it some of the sphincter muscle that controls the flow of urine.”

Three Approaches to Radical Prostatectomy: Open, Laparoscopic and Robotically-Assisted Laparoscopic Surgery

“The emergence of radical prostatectomy as a preferred prostate cancer treatment has corresponded with wider availability of minimally invasive surgery. Studies show that for many patients, a minimally invasive approach can reduce complications and promote faster recovery times. In the United States today, surgeons use one of three approaches to radical prostatectomy: open surgery, laparoscopic surgery and robotically-assisted laparoscopic surgery; the latter two being considered minimally invasive.”

“Open prostatectomy requires an 8-10 inch incision of the abdomen for direct access to the operative site. In comparison, conventional laparoscopic and robotically-assisted laparoscopic approaches require several dime-sized incisions, or operating ports, to introduce the narrow-shafted instruments. During an MIS prostatectomy the surgeon and assistants maneuver the instruments from outside the body, under vision provided by a surgical camera.”

“The advantages to the patient of laparoscopic and robot-assisted laparoscopic prostatectomy over conventional open surgery include smaller incisions that often result in less post-operative pain, less scarring, reduced blood loss and need for transfusions, and an improved quality of life including a faster return to normal activities.”

“In addition to the advantages of robotically-assisted laparoscopic surgery over conventional open surgery described earlier in this section, recent studies suggest that robotically-assisted laparoscopic prostatectomy may offer improved long-term cancer control and a lower incidence of impotence and urinary incontinence.”

“Due to these advantages, robotically-assisted laparoscopic prostatectomy has become the fastest growing treatment for prostate cancer in the United States. This year, it is expected that 20% of all prostatectomies will be performed using this technique. This percentage is projected to grow rapidly.”

CABG Surgery

“EMMC is one of 3 heart surgery centers in Maine and the largest provider in northern, central, and eastern Maine. EMMC is a member of the Northern New England Cardiovascular Study Group, nationally recognized for their research on improving clinical outcomes for heart care. EMMC offers a full range of medical and cardiac services, with the exception of transplants. EMMC has 3 cardiac cath labs, 2 cardiac OR's and offers primary angioplasty for emergency patients, which has been found to be a best practice for patients suffering acute myocardial infarctions.”

“Surgeons historically have used the open sternotomy approach to heart surgery to provide the necessary visibility and space required for the surgeon's hands and instruments to be in proximity to the operative site. This approach typically requires a one foot-long incision. The procedure as conventionally performed requires the patient be connected to a heart-lung machine while heart is stopped during the bypass surgery.”

“Newer techniques are being explored to improve the results and to minimize pain felt by the patient during recovery from CABG. One technique aimed at improving outcomes for the patient is performing the bypass operation without use of a heart lung machine. During the procedure the heart

continues to pump blood while surgeons perform the bypass operations on the beating heart. Other techniques in development involve the use of smaller incisions to perform CABG. All of these techniques are considered minimally invasive heart surgery. The goal of these techniques is provide the patient with reduced pain, faster recovery and less neurocognitive morbidity.”

“However, many cardiac surgeons feel this reduced access limits visualization and impedes access to the operative field. In contrast, the miniaturized instruments of the system purchased by EMMC allow the surgeon to access the heart and its vessels through tiny incisions in the chest, rather than through a medial sternotomy. The ‘wristed’ instruments mimic the movements of the surgeon’s hands and wrists, giving excellent flexibility and control when operating on delicate tissue. The system used at EMMC also provides surgeons with a three-dimensional view of the operating field that includes a 10-power magnification, providing an enhanced view of tissue and organs compared to conventional laparoscopic procedures. Similar to other surgical procedures that use robotically-assisted MIS, the advantages of robot-assisted CABG surgery result in less blood loss and pain and usually a shorter hospital stay for the patient.”

“Dr. Felix Hernandez, EMMC’s Chief of Surgery and a cardiac surgeon, reports that there are two primary reasons for EMMC’s incomplete adoption of robotic assisted surgery for cardiac surgical procedures: the planned utility upgrade to the inpatient operating rooms (the surgical robot equipment is used primarily in two of the ten operating suites), and the further development of other minimally invasive cardiac surgery techniques.”

“First, EMMC use of the surgical robot for cardiac surgery cases had to be delayed until a planned upgrade providing 100 amp electrical service to several operating suites was completed. EMMC felt that safety would be further enhanced if use of the surgical robot for cardiac surgery cases was delayed until this upgrade was completed. The operating suites needed additional electrical service to optimally power all of the equipment needed for cardiac surgery equipment (perfusion machine, slush machine, warming equipment). Non-cardiac robot-assisted surgical cases, which do not require this additional support equipment, were able to proceed. To complete the upgrade without interrupting surgical service availability took almost one year. This planned utility upgrade would have been performed even if the surgical robot had not been purchased and does not affect the capital cost of the surgical robot equipment.”

“The second reason for the low number of cardiac cases performed with the surgical robot is the development of other surgical techniques at EMMC. These techniques, such as minimally invasive valve surgery, allow EMMC cardiac surgeons to offer procedures that were less surgically traumatic to our patients than the standard approaches. EMMC has been successful with the adoption of these minimally invasive cardiac surgery techniques and at the current time, there is not a well defined benefit to the robotically assisted cardiac surgery procedures over the new minimally invasive procedures with respect to patient outcomes. EMMC surgeons are awaiting further information from regional, national and international studies of the efficacy of robotically assisted valve procedures.”

“Robotically assisted coronary artery bypass procedure volumes have remained low nationally. This technology has been used mainly for Left Internal Mammary Artery bypasses to the Left Anterior Descending (LIMA>LAD) coronary artery. This is used in some centers as part of a “hybrid procedure” where a patient has stents placed in some coronary vessels and a LIMA>LAD done with

robotically assisted technology. However, these procedures have not gained general acceptance because the primary advantage to a surgical revascularization lies in the completeness of the revascularization, in a patient with multi-vessel disease, leading to superior long-term outcomes. Combining a single vessel bypass (surgical) with multiple stents would negate a good portion of this advantage while still subjecting the patient to the same level of risk.”

“As shown in Table 3 above, even without the cardiac procedures, the 184 estimated cases for 2007 will exceed the 160 cases originally projected.”

Bariatric Surgery and EMMC’s Surgical Weight Loss Program

“Obesity is a serious medical condition affecting more than a quarter of the population of the United States and is the second leading cause of premature death. EMMC’s Surgical Weight Loss (SWL) Program has been recognized as a national center of excellence by the American Society for Bariatric Surgery and Surgical Review Corporation as well as by some insurance companies. EMMC’s program uses a comprehensive approach to ensure that potential patients receive appropriate care and have the greatest opportunity for successful outcomes. The SWL is coordinated through EMMC’s Diabetes and Nutrition Center. Prior to surgery potential surgery patients are required to attend educational sessions and support groups (which are open to the public). Patients also receive the support of dietitians, physical therapists, psychologists and, if needed, the EMMC Sleep Lab.”

“One of the tools used in EMMC’s comprehensive program is bariatric surgery. An effective and increasingly common surgical approach to weight loss is Roux-en-Y gastric bypass surgery. Gastric bypass surgery reduces the size of the stomach using surgical stapling. This step restricts the volume of food that can be consumed at one time. The procedure also bypasses a section of the small intestine, reducing the body’s ability to absorb calories. EMMC is now able to perform gastric bypass, as well as gastric banding, using robotically-assisted MIS. Use of this state-of-the-art surgical system allows the surgeon enhanced visualization of the anatomical structures with the additional precision needed to access the surgical field, which is often a challenge with extremely large patients.”

“The ergonomic benefits of the new system are explained by EMMC’s Dr. Michelle Toder who would often suffer hand and shoulder surgery strain while operating on extremely large patients (as do other surgeons). To quote Dr. Toder:”

“My feet, shoulders, and thumbs would go numb after standing and working on large patients for long periods of time. I don’t get that with robotics, so this technology allows me to continue to do what I love to do.”

“The full article describing EMMC’s experience is included in **Attachment J**. (*Not attached. On file at CONU.*)

“EMMC’s robotically-assisted bariatric surgery program has the highest volumes in the Northeast. The EMMC program has an affiliation with Stanford University in California, recognized as the Center of Excellence for this procedure in the west. Recently, operating room staff from Johns Hopkins visited EMMC to receive training in robotically-assisted bariatric surgery.”

Quality improvement. Evidence-based measures to document outcomes

“Since robotically-assisted surgery at EMMC is relatively new, EMMC has only been able to collect quality and outcomes data for a short period. EMMC is currently accumulating this data so that sufficient information will be available for quality, safety, and outcomes analysis. The Chief of Surgery, Felix Hernandez, MD, a cardiothoracic surgeon, has formed a MIS (Minimally Invasive Surgery) group consisting of all EMMC surgeons who perform laparoscopies and robotically assisted surgeries. This group meets regularly to review cases, Morbidity & Mortality reports, and discuss approaches and techniques and which new cases are appropriate for this program. This group also oversees proctoring of surgeons learning the new system and advises on credentialing and privileging criteria (see Attachment H). At this time, credentialing requirements have been developed for general, urology and cardiovascular minimally invasive surgery procedures.”

Patient satisfaction and clinical benefits to patients

“Robotically-assisted surgery is less invasive than other surgical approaches resulting in higher patient satisfaction because of the many benefits to the patient that include:”

- Reduced hospital length of stay
- Reduced blood loss
- Less post-operative pain and discomfort
- Lower risk of infection
- Faster recovery and return to normal function
- Reduced acuity of post-operative care

Patient safety

“Because this technique provides the surgeon with enhanced visualization, improved movement and control of the surgery with finer movements, complications are reduced. There is reduced blood loss and fewer transfusions are required.”

Shorter hospital average length of stay (ALOS)

“Nationally, hospitals are reporting shorter average length of stay with the implementation of robotically-assisted MIS. Table 5 shows results from EMMC’s two most frequent robotically-assisted surgical procedures performed to date. There is a much shorter ALOS for radical prostatectomy patients (1.63 compared to 3.56 hospital days) and a slightly shorter ALOS for gastric bypass patients (2.10 days compared to 2.30 days) for procedures performed in FY2006. The number of other procedures performed to date at EMMC is lower than for gastric bypass and radical prostatectomies, making specific average length of stay comparisons at this time less meaningful. Once more clinical data is accumulated, EMMC will be able to perform a more detailed clinical assessment and compare the “with robot” and “without robot” cases while accounting for variables such as age and acuity. For these two highest volume procedures combined, the 128 patients stayed in the hospital an average of 0.83 days less than those that did not receive their surgery with use of the robot. There is potential for significant savings with use of the robot. EMMC anticipates performing 200 surgeries in 2008. Even if the ALOS reduction is only 0.5 days for these cases, the reduction of 100 patient days could result in significant cost savings to the health care system.”

**TABLE 5 UPDATED: EMMC AVERAGE LENGTH of STAY
GASTRIC BYPASS AND PROSTATECTOMY PATIENTS
FY2006 and FY2007YTD (Oct-June)**

<u>Gastric Bypass Surgery</u>				
-	FY2006		FY2007 (9 months)	
	Cases	ALOS (*)	Cases	ALOS (*)
Technique				
Robotically-Assisted	52	2.10	51	2.12
without Robot	63	2.30	42	2.00
Total	115	2.21	93	2.06
<u>Radical Prostatectomy Surgery Patients</u>				
-	FY2006		FY2007 (9 months)	
	Cases	ALOS (*)	Cases	ALOS (*)
Technique				
Robotically-Assisted	62	1.63	60	1.23
without Robot	16	3.56	26	2.38
Total	78	2.03	86	1.58
<u>Total For Both Procedures</u>				
-	FY2006		FY2007 (9 months)	
	Cases	ALOS (*)	Cases	ALOS (*)
Technique				
Robotically-Assisted	114	1.84	111	1.64
without Robot	79	2.56	68	2.15
Total Both Procedures	193	2.13	179	1.83
(*) Hospital Average Length of Stay				
Sources: EMMC Financial Databases				

“Because use of the surgical robot is still relatively new, there is still insufficient volume to report meaningful, quantifiable data for specific procedures. Peer review of complications for these procedures is handled by EMMC’s regular Morbidity & Mortality reviews. EMMC is also studying the usefulness and feasibility of peer review meetings for chart review of the robot assisted surgical cases. The specific protocols and filters needed for this chart review are being developed and need to be finalized before the particular peer review program is implemented.”

“EMMC also plans to work with the National Surgical Quality Improvement Program (NSQIP). The NSQIP is a nationally validated, risk-adjusted, outcomes-based program to measure and improve the quality of surgical care. The program employs a prospective, peer controlled, validated database to quantify 30-day risk-adjusted surgical outcomes among all hospitals in the program. Participating hospitals and their surgical staff are provided with the tools, reports, analysis, and support necessary to make informed decisions about improving quality of care. EMMC will receive benchmarking reports which allow the monitoring of quality improvements in comparison to peer hospitals nationally. EMMC began reporting data (up to 136 variables) on robotically-assisted bariatric surgery and radical prostatectomy data as of July 1, 2007. These two procedures account for nearly 90% of the robot assisted surgery cases at EMMC. It will be a while before there is enough data to report.”

“While it is still too soon to quantify the information, EMMC urologist Dr. Rao reports that use of the surgical robot at EMMC is resulting in minimal blood loss, nerve sparing is meticulous, incontinence rates are low, margin positive rates are diminished, patients recover in a shorter time with no complications and are able to return to their normal activities quickly. These successful results are because the surgical robot allows the surgeon in effect to become four-handed with greatly enhanced control and precision.”

B. CONU Discussion

i. Criteria

That there is a public need for the proposed services as demonstrated by certain factors, including, but not limited to:

- Whether, and the extent to which, the project will substantially address specific health problems as measured by health needs in the area to be served by the project;
- Whether the project will have a positive impact on the health status indicators of the population to be served;
- Whether the services affected by the project will be accessible to all residents of the area proposed to be served; and
- Whether the project will provide demonstrable improvements in quality and outcome measures applicable to the services proposed in the project;

ii. Analysis

This project, if approved, would be the second surgical robot being used in Maine, the other being at Maine Medical Center in Portland. To date the applicant has used the surgical robot to perform a large percentage of the operations in the radical prostatectomy and bariatric surgery areas. Research provided by the applicant, via printed articles and data provided from actual experiences, have shown that patients are experiencing better outcomes with the surgical robot. The procedures are less invasive to the patient, blood loss is less, pain is diminished, nerve sparing is meticulous, incontinence rates are low, margin positive rates are diminished, recovery times are shorter with fewer complications, patients are able to return to their normal activities quickly and average length of stay in the hospital is shorter. The only drawback at this time is that the time spent in the OR appears to be longer with the robot. It is expected over time as a physician becomes more adapted and skilled at using the robot time spent in the OR will be reduced.

iii. Conclusion

CONU recommends that the Commissioner determine that the public need for this project has been established.

V. Alternatives Considered

A. From Applicant

- **“No purchase.** Since the only similar system in Maine is in Portland, not implementing this project would mean that the residents of northern and eastern Maine would have only limited access to the benefits of this type of minimally invasive surgery. EMMC is likely the only medical center north of Portland with the range of specialty surgeons and support services to implement this advancement in minimally invasive surgery.”
- **“Do not purchase fourth arm.** The addition of the fourth arm (third actuator arm) allows the use of three working surgical ports. This system has been successfully used elsewhere for a wide variety of procedures. While not purchasing the optional fourth arm would have reduced the capital cost (and obviated the need for a CON application), it would have also reduced the types of cases that could have been treated with robotically-assisted MIS as well as reduced the benefits in other cases; reducing the number of patients from our region that would have benefited advanced minimally invasive surgery.”

“According to Newlin et al in the *Journal of Laparoendoscopic & Advanced Surgical Techniques* (2004): (See Attachment I)” (Not attached. On file at CONU.)

“The four-arm modified da Vinci device brings advantages. With the additional working port, the surgeon can now use an instrument to provide retraction or exposure. Intra-abdominal surgery often involves a wider operative field involving organs with more variability in their position than surgery performed in other body compartments. In gastrointestinal surgery, where the operative field commonly requires significant dissection or complex exposure, an added instrument under the direct control of the operating surgeon may be appreciated more than in other operative fields that are less dynamic or smaller. More complex procedures may be able to be performed with less reliance on an assistant to perform these tasks.”

“Newlin also discuss the drawbacks of this equipment (the full article is included in Attachment I) including high capital cost and longer set-up time in the operating room but concludes:”

“Despite these drawbacks, the da Vinci computer-assisted surgery device modified with a fourth arm allows the surgeon greater control and more capabilities with less reliance upon an assistant surgeon. With the fourth arm, the da Vinci device can be utilized with maneuvers such as passing and cutting sutures, retraction, and instrument changes being performed by a non-physician OR assistant.”

“Our initial experience with the modified four-arm da Vinci computer-assisted telesurgery device shows that the device can be used to perform complicated surgical procedures safely and effectively

with less involvement of the assistant surgeon. More experience and study is needed to determine the cost-effectiveness of this device”

B. CONU Discussion

i. Criteria

The proposed services are consistent with the orderly and economic development of health facilities and health resources for the State as demonstrated by:

- The impact of the project on total health care expenditures after taking into account, to the extent practical, both costs and benefits of the project and the competing demands in the local service area and statewide for available resources for health care;
- The availability of State funds to cover any increase in State costs associated with utilization of the project’s services; and
- The likelihood that more effective and accessible, or less costly. Alternative technologies or methods of service delivery may become available.

ii. Analysis

As reported from the Bureau of Insurance contained in Section VI the impact on third party payors is minimal.

Total 3rd year incremental operating costs are projected to be \$319,544 (Depreciation and Maintenance Costs) and of that amount MaineCare’s 3rd year cost is \$4,154 ($\$319,544 \times 1.30\%$ (MaineCare payor mix)), which is both the Federal and State portions combined. Currently the impact to the State portion of the budget per year would be approximately \$945 ($\$4,154 \times 35\%$) if MaineCare reimbursed 100% of costs. The CONU recognizes that MaineCare does not reimburse 100% of its’ share of the costs to EMMC therefore, the actual impact on the budget would be somewhere less than \$945.

iii. Conclusion

The CONU recommends that the Commissioner determine that the proposed project is consistent with the orderly and economic development of health facilities.

VI. State Health Plan

A. From Applicant

“This project involved a capital expenditure in 2004 and was fully implemented in December 2004 when the first robotically-assisted laparoscopic procedure was performed. A CON is required because once all project costs were capitalized it was determined that the capital expenditure exceeded the limit for Major Moveable Equipment at that time (as of September, 2004). If the same expenditure were made in 2005 or 2006 no CON would have been required.”

“The preliminary Maine State Health Plan had been issued in July 2004. This project meets many of the criteria in the 2004 Plan as well as the draft plan of 2005 and the recently released 2006-2007 plan.”

“The three priorities listed in the 2004 Maine State Health Plan focus on (A.) public health and safety, (B.) lower cost of care and (C.) access to care.”

Projects that protect public health and safety

- ***Projects with the primary objective of eliminating threats to patients' safety.***

“Because this technique provides the surgeon with enhanced visualization, improved movement and control of the surgery with finer movements, complications are reduced. There is reduced blood loss with fewer transfusions, a lower risk of infection and a shorter hospital stay. EMMC is currently collecting data on patients to track outcomes including complication rates, average hospital stay and other data necessary to verify the safety and efficacy of this program.”

- ***Projects that incorporate comprehensive disease detection, treatment and rehabilitation, that show evidence of leading to decreases in appropriate utilization, and other evidence-based strategies to reduce the impact of such chronic illness as cardiovascular disease, cancer, asthma, chronic lung disease, diabetes and mental illness, furthering the goal of moving our health care system toward the chronic care model.***

“In addition to the advantages of robotically-assisted laparoscopic surgery over conventional open surgery described, recent studies suggest that robotically-assisted laparoscopic prostatectomy may offer improved long-term cancer control and a lower incidence of impotence and urinary incontinence.”

“Robotically-assisted laparoscopic surgery is a tool used in EMMC’s comprehensive Surgical Weight Loss Program that serves patients with obesity. These patients are at high risk for chronic disease such as diabetes, hypertension and heart problems, spinal and knee problems, depression, and increased risk of cancer. By providing the option of surgical weight loss to residents of the region, the impact of these chronic conditions will be reduced.”

“Obesity is viewed by some organizations as a chronic illness. EMMC has the only Surgical Weight Loss Center of Excellence in Maine. EMMC’s comprehensive and successful SWL progress includes the full range of services, including robotically assisted MIS surgery.”

- ***Projects that reflect a redirection of resources and focus on population-based health and prevention.***

“This project was financed with EMMC equity. The resources for EMMC’s population-based health prevention programs come from operating funds. Such programs would rarely involve a capital investment that would require CON approval.”

- *Projects that demonstrate best practices in building construction, renovation and operation to minimize environmental impact both internally and externally (e.g. “green” energy)*

“This project involved no new construction, so the criteria relating to building construction is not applicable.”

Projects that contribute to lower costs of care and greater efficiencies

- **Projects that will reduce future demand for health care services.**

“If SWL intervention is successful, patients will have reduced their risk factors for other chronic diseases that prove costly.”

- **Projects that result in reduced operating costs for existing facilities.**

“As explained in more detail elsewhere in this application, these surgical patients will have fewer complications, shorter hospital length of stay and fewer re-admissions, reduced transfusions and other benefits. It is anticipated that the total cost to the healthcare system per episode of care will be reduced.”

- **Projects that physically consolidate hospitals or services that serve all or part of the same area that demonstrate an appropriate, cost effective use for the “abandoned” infrastructure.**

“Not applicable.”

- **Telemedicine projects that facilitate improvements and cost-efficiencies in the quality of diagnosis and treatment in smaller, rural communities.**

“There has been preliminary work at academic medical centers investigating the feasibility of surgeons at remote locations operating on patients using telemedicine and robotic surgery. Those techniques are experimental and EMMC has no plans to pursue that area in the near future.”

Projects that advance access to services and reflect a collaborative, evidence-based strategy for introducing new services and technologies

“EMMC’s approach to altering this advancement has been to closely collaborate with surgeons and clinicians familiar with the benefits of this evolution in care and with the training required to optimize quality and outcomes.”

- *Projects that make the best use of existing capacity/infrastructure in initiatives focused on expanding access to ambulatory or primary care services.*

“The majority of patients that will benefit from this type of surgery will be inpatients. Because the surgery is less invasive than open or conventional laparoscopic surgery, patients will be out of the hospital and back to their normal routine sooner - in effect, become ambulatory quicker than if this project had not been implemented.”

- ***Projects introducing new technology or services will only be considered if evidence is provided showing detailed analysis of peer reviewed research and data supporting the technology and need and clearly detailing the impact of the project on health care spending in Maine over the short, medium and long term time horizons. Projects must be recommended by the Maine Quality Forum and documented evidence of collaboration exists to assure shared use of new resources across the state, rather than proliferation and/or duplication of new technology.***

“The surgical system purchased by EMMC is an enhancement of existing minimally invasive laparoscopic surgery. Medical and other staff at EMMC reviewed this system extensively before proceeding with the project. This included literature review and site visits to hospitals already using this equipment. As mentioned earlier in this application, EMMC’s program has an affiliation with Stanford University and has provided training for operating room staff from Johns Hopkins. These collegial relationships will provide an exchange of information to ensure that EMMC will maintain high standards of care.”

“Since the only other Maine hospital using this technology is Maine Medical Center in Portland, EMMC’s surgical robot cannot be considered a duplication of services. Patients undergoing procedures with this system are acutely ill patients who would require open or conventional laparoscopic surgery at EMMC or another hospital.”

In addition, high priority will be assigned to applicants able to demonstrate the following:

- ***Applicants demonstrating adequate evidence of good faith efforts in meeting the voluntary price and cost targets established by the Dirigo Health Reform Act, PL 469.***

“At the time this equipment was purchased EMMC had demonstrated a willingness to comply with Dirigo’s voluntary financial targets. EMMC experienced the following changes in expense per case mix adjusted Discharge (CMAD) since fiscal year 2002:”

Change from fiscal year 2002 to 2003 – (1.2%)

Change from fiscal year 2003 to 2004 - 1.9%

“EMMC was well under the Dirigo target of limiting the increase in cost per case mix adjusted discharge to 3.5%.”

- ***Applicants demonstrating investment in and/or use of an electronic medical records system with an HL7 interface, allowing for exchange of information.***

“Eastern Maine Healthcare Systems has invested nearly \$30 million into an electronic medical records infrastructure that is fully HL7 compliant. As an organization EMHS has gone beyond this recommendation by committing to becoming a fully integrated clinical system facility using a fully integrated single-vendor solution (Cerner’s Millennium system). The successful implementation of an HL7 compliant infrastructure is evidenced by the fact that EMMC currently is able to integrate other vendor software with its primary care area electronic medical records and patient financial systems.”

Projects that involve any of the following characteristics cannot be considered priority projects

- **Projects that duplicate existing services or facilities in a region or community that has existing capacity for such services.**

“There is no duplication of services as EMMC is the only hospital north of Portland offering this service. There was no expansion of services, just a shift to less invasive surgery for EMMC patients requiring these types of procedures.”

- **Projects that result in an increase in the number of inpatient beds in the State.**
- **Projects that involve the construction of a new hospital (other than replacement facilities).**
- **Projects that involve major expansions of existing services and/or facilities.**

“No beds or new construction were added for this project.”

B. CONU Discussion

i. Criterion

Is Consistent with the State Health Plan. For this determination, the Commissioner will be guided by the priority criteria set forth in the State Health Plan. Those projects meeting the greatest number of criteria in any of the relevant priority groupings will be given the highest priority and consideration for approval by the Commissioner.

State Health Plan goals targeted by

State Health Plan Priority

Applicant include:

Improve Patient and Staff Safety

Highest Priority

Contribute to lower cost of care and increased efficiencies

High Priority

Advance access to services

High Priority

Less than a 0.5% increase on regional insurance premiums

Priority Consideration

ii. Analysis

The CONU received the required assessment by Dora Mills, M.D. Director, Maine Center For Disease Control and Prevention to Catherine Cobb, Director, Division of Licensing and Regulatory Services, and was sent via e-mail dated June 1, 2007, and makes the following comments:

“The applicant proposes their prior purchase of a four-arm robotically-assisted minimally invasive surgery (MIS) system be approved. The applicant states that this system provides smaller incisions and faster patient recovery times than other MIS. It is stated that this system also provides enhanced abilities to provide such common surgeries as gastric banding and bypass, prostatectomy, coronary bypass graft, and urological surgery.”

“The proposal is aligned or somewhat aligned with several of the State Health Plan’s priorities. For instance, the applicant shows that the use of this equipment is shown to reduce complications and

quicken recovery. The equipment's use in prostatectomies and gastric surgeries can be part of a more comprehensive approach to effectively address prostate cancer and obesity, though it does not appear the applicant has invested significantly in a service area-wide comprehensive prevention-to-treatment initiative that this equipment fits into. The applicant says it has invested in an electronic medical records system." "The proposal addresses several specific and common health problems faced by the population, including prostate cancer and obesity. There is some evidence that the proposal will have an impact on some health status indicators, such as those related to obesity and prostate cancer. The service is available to some degree to all living in the service area, though it is unclear if it is available for say, uninsured low-income obese patients desiring gastric surgery. EMMC says it will gather and track its own data to measure improvements in quality and outcomes such as shorter hospital stay, fewer complications, reduced pain and blood loss, and quicker recovery time."

William A. Bremer, Bureau of Insurance assessment memorandum to Phyllis Powell, Manager CONU dated June 25, 2007 states the following:

"The Bureau of Insurance applied the assessment model that was previously developed internally with support from its consultant, Milliman, Inc., of Minneapolis, MN, in order to develop an estimate of the impact that this CON project is likely to have on private health insurance premiums in Eastern Maine Medical Center's service area and in the entire state of Maine. I have worked with you and your staff at the CON Unit, using data and support from the U.S Census Bureau, the State Planning Office, the State Office of Integrated Access and Support, and the Bureau of Insurance, as well as Elmer Doucette, VP and CFO, and Jean Mellett, Director of Planning, EMMC, and her staff, to perform this assessment."

"The methodology compares the CON project's Year 3 operating costs (adjusted to the year ending June 30, 2007) to the estimated private health insurance average premium per person for the same period—which is the period of time for which the 2006-2007 capital investment fund has been established. Based on the model, I estimate that the maximum impact of this CON project on private health insurance premiums in Eastern Maine Medical Center's service area for the project's third year of operation will be approximately \$0.047 per \$100 (0.047%) of premium. I further estimate that this project, in its third year of operation, will have an impact on statewide private health insurance premiums of approximately \$0.012 per \$100 (0.012%) of premium."

iii. Conclusion

The CONU considered the assessment from the Maine Center For Disease Control and Prevention and the assessment from the Bureau of Insurance (BOI) as noted above.

The applicant has demonstrated it will protect public health and safety and contributes to lower cost of care and great efficiencies as surgery is less invasive for the patient, recovery times are reduced, less blood loss and inpatient stays are shorter.

The applicant has stated that this service is available to all patients including the uninsured low-income.

The CONU agrees with the assessment by the BOI. The State Health Plan recognizes a project cannot be considered a priority if the regional cost to third party payors exceed an increase greater than .5%. The BOI concluded this project will have an impact of less than .5% to regional insurance costs.

CONU recommends that the Commissioner determine that this project meets the requirements of the State Health Plan.

VII. Outcome and Community Impact

A. From Applicant

“By improving outcomes for patients with such chronic conditions as cancer and obesity, this project will reduce the post-surgical complications and improve the quality of life for these patients and reduce the impact of these chronic conditions on Maine’s healthcare system. For example, robotically –assisted laparoscopic surgery is a tool used in EMMC’s comprehensive Surgical Weight Loss Program which serves patients with obesity. These patients are at high risk for chronic diseases such as diabetes, hypertension and heart problems, spinal and knee problems, depression, and increased risk of cancer. The robotically-assisted laparoscopic equipment at EMMC facilitates the offering of surgical weight loss to residents of the region as an option to treat their chronic disease.”

B. CONU Discussion

i. Criteria

Ensures high-quality outcomes and does not negatively affect the quality of care delivered by existing service providers;

ii. Analysis

The applicant has stated that use of the surgical robot at EMMC is resulting in minimal blood loss, nerve sparing is meticulous, incontinence rates are low, margin positive rates are diminished, patients recover in a shorter time with no complications and are able to return to their normal activities quickly. EMMC no longer performs radical prostatectomies without the robot. No other robotic surgery equipment exists in EMMC’s service area that would affect existing service providers.

The Maine Quality Forum provided the following analysis:

“The robotic surgery program at Eastern Maine Medical Center as described in the application reflects attention to several domains of quality evaluation. Overall, the center has approached robotic surgery in a programmatic way.”

“From the standpoint of safety and effectiveness, the minimally invasive surgery group and subgroups convened at EMMC have put credentialing criteria in place which help to ensure adequate training and experience and which probably help concentrate the surgical volumes in the hands of a small group of surgeons. In the future, it may be possible to discern whether there is evidence to support minimal

volume performance criteria; at the present time, the accepted observation that procedures are often safer when done by high-volume surgeons in high-volume hospitals applies.”

“As noted, there are few if any true randomized controlled clinical trials on which to base a claim that robotic surgery is safer, faster, or associated with quicker ambulation times or shorter lengths of stay than conventional surgery. These conclusions are intuitive and are based on considerable observational, mostly single-site studies. The weight of the evidence, nevertheless, would suggest that robotic surgery is safe in the appropriate circumstances.”

“As such, robotic surgery can most strictly be described as an emerging technology. This raises the question of whether EMMC, as a tertiary center serving a large portion of Maine’s population, is an appropriate venue for this service. Given the demonstrated promise of these techniques, the EMMC program’s commitment to quality, and the demonstrated and projected case volume, we believe that it is.”

“The applicant has made clear its intention to report on outcomes. It is presumed but not documented that specific outcome quality metrics (mortality, infection, blood loss, transfusion requirement, conversion to open procedure) will be maintained as well as cost data, operating times, and length of stay. Moreover, the applicant cites “association with academic medical centers to share knowledge with experts.” It would be helpful for the application to specify these associations more fully, and note whether the association for general and urologic surgery includes data sharing and peer review, as it presumably would in the Northern New England Cardiovascular Disease Study Group for cardiac procedures.”

“Finally, the applicant suggests that Maine’s paid-claims database could be used to help quantify savings in the system associated with the use of this technology. This is an innovative use of this database, and the Maine Quality Forum would be happy to assist in the development of this project. It would also be interesting to evaluate the usefulness of the paid claims data to support clinical quality evaluation as well.”

iii. Conclusion

CONU recommends that the Commissioner determine that this project ensures high-quality outcomes and has demonstrated that it will not affect the quality of care by existing service providers.

VIII. Service Utilization Impact

A. From Applicant

The applicant did not provide any information for this section.

B. CONU Discussion

i. Criterion

Does not result in inappropriate increases in service utilization, according to the principles of evidence-based medicine adopted by the Maine Quality Forum, as established in Title 24-A, section 6951.

ii. Analysis

The CONU has determined that patients needing these operations would not increase just because of the surgical robot. The surgical robot is used for better outcomes for patients not to increase surgeries being performed.

iii. Conclusion

The CONU recommends that the Commissioner determine that this project will not result in inappropriate increases in service utilization.

IX. Other**i. Criterion**

Can be funded within the Capital Investment Fund. 22 M.R.S.A. Sec. 335 (7).

ii. Analysis

The small hospital project cycle ended up having one project to review therefore, it is not a competitive cycle. The CIF has been introduced to limit the development of hospital projects to a level sustainable in regards to its impact on the growth of healthcare costs. The CONU has determined that, if approved, this project can be funded within the CIF.

The statutes and policy manual is clear what the implications of noncompliance are regarding failure of a healthcare facility not to be granted a certificate of need by the commissioner prior to implementing a project that requires a certificate of need. These include withholding of license, withholding of funds, injunction and civil penalty of not more than \$5,000. The applicant should volunteer to pay the Department a sum \$5,000 in lieu of the Department taking civil action against the applicant to recover the withholding of all funds received by the applicant prior to CON approval and for any civil penalty for violation of CON statutes.

X. Timely Notice**A. CONU Discussion**

Letter of Intent filed:

May 3, 2006

Subject to CON review letter issued:

May 8, 2006

Technical assistance meeting held:

June 15, 2006

CON application filed	October 13, 2006
CON certified as complete:	November 6, 2006
Public informational meeting held:	November 17, 2007

As listed above, all the necessary paperwork was filed on a timely manner to be placed into the 2007 Small Hospital Review Cycle

i. Conclusion

The CONU has determined a timely notice was given.

XI. Findings and Recommendations

Based on the preceding analysis, the CONU makes the following findings and recommendations:

- A.** That the applicant is fit, willing and able to provide the proposed services at the proper standard of care as demonstrated by, among other factors, whether the quality of any health care provided in the past by the applicant or a related party under the applicant's control meets industry standards;
- B.** The economic feasibility of the proposed services has been demonstrated in terms of the:
 - 1) Capacity of the applicant to support the project financially over its useful life, in light of the rates the applicant expects to be able to charge for the services to be provided by the project; and
 - 2) The applicant's ability to establish and operate the project in accordance with existing and reasonably anticipated future changes in federal, state and local licensure and other applicable or potentially applicable rules;
- C.** That there is a public need for the proposed services has been demonstrated by certain factors, including, but not limited to:
 - 1) the project will substantially address specific health problems as measured by health needs in the area to be served by the project;
 - 2) the project will have a positive impact on the health status indicators of the population to be served;
 - 3) the services affected by the project will be accessible to all residents of the area proposed to be served; and
 - 4) the project will provide demonstrable improvements in quality and outcome measures applicable to the services proposed in the project;
- D.** That the proposed services are consistent with the orderly and economic development of health facilities and health resources for the State as demonstrated by:
 - 1) The impact of the project on total health care expenditures after taking into account, to the extent practical, both costs and benefits of the project and the competing demands in the local service area and statewide for available resources for health care;
 - 2) The availability of State funds to cover any increase in State costs associated with utilization of the project's services; and

- 3) The likelihood that more effective, more accessible or less costly alternative technologies or methods of service delivery may become available;

In making a determination under this subsection, the commissioner shall use data available in the state health plan under Title 2, section 103, data from the Maine Health Data Organization established in Title 22 Chapter 1683 and other information available to the commissioner. Particular weight must be given to information that indicates that the proposed health services are innovations in high quality health care delivery, that the proposed health services are not reasonably available in the proposed area and that the facility proposing the new health services is designed to provide excellent quality health care.

- E.** That the project is consistent with the State Health Plan;
- F.** That the project ensures high-quality outcomes and has demonstrated that it will not negatively affect the quality of care delivered by existing service providers;
- G.** That the project has demonstrate that it will not result in inappropriate increases in service utilization, according to the principles of evidence-based medicine adopted by the Maine Quality Forum; and
- H.** That the project can be funded within the Capital Investment Fund.

i. Conclusion

CONU recommends that the Commissioner **APPROVE** this project with the following conditions:

1. The applicant should volunteer to pay the Department a sum \$5,000 in lieu of the Department taking civil action against the applicant to recover the withholding of all funds received by the applicant prior to CON approval and for any civil penalty for violation of CON statues.
2. The applicant should work with the Maine Quality Forum to develop a database to help quantify savings in the system associated with the use of this new technology; and report outcomes of procedures using this technology.