

**Minutes of Meeting  
Health Services Council  
Project Review Committee-I**

**DATE: 23 October 2007    TIME: 2:30 PM**

**LOCATION: Conference Room C  
Department of Administration**

**ATTENDANCE:**

**Committee-I: Present: Victoria Almeida, Esq., (Vice Chair), John W. Flynn, Amy Lapierre, Thomas M. Madden, Esq., Robert J. Quigley, DC, (Chair), Larry Ross**

**Not Present: Joseph V. Centofanti, M.D., Robert Ricci, Robert Whiteside**

**Excused Absence: Edward F. Almon, Robert S.L. Kinder, M.D.**

**Staff: Valentina Adamova, Michael K. Dexter, Chrystele Lauture (Intern), Joseph G. Miller, Esq., Christine Tice (Intern)**

**1. Call to Order, Approval of Minutes, Conflict of Interest Forms and Time Extension for the Minutes Availability**

**The meeting was called to order at 2:30 PM. The Chairman noted that conflict of interest forms are available to any member who may have a conflict. Minutes of 13 March 2007 Project Review Committee-meeting were approved as submitted. The Chairman requested a motion for the extension of time for the availability of minutes pursuant to the Open Meetings Act. A motion was made, seconded and passed by a vote of five in favor and none opposed (5-0) that the availability of the minutes for this meeting be extended beyond the time frame provided for under the Open Meetings Act. Those members voting in favor were: Flynn, Lapierre, Madden, Quigley, Ross.**

## **2. General Order of Business**

**The first item on the agenda was Miriam Hospital's [Lifespan Corporation] Change Order Request to the 2 November 2006 approval of the Certificate of Need to acquire and operate a da Vinci S Surgical System to perform minimally invasive robotic surgery. Staff noted that the applicant is requesting to expand the use of the da Vinci unit and removal of condition of approval number seven. Staff noted that waiving the condition of approval number seven would not relieve the applicant from complying with rules and regulations regarding Certificate of Need including those pertaining to tertiary or specialty care services.**

**Ms. Colletta, Chief Operating Office and Dr. Sax, Surgeion-in-Chief, from the Miriam Hospital represented the applicant. A PowerPoint presentation was made. The applicant noted that the November of 2006 approval limited allowable robotic procedures to prostate, foregut, and mitral valve. The prostate surgeries were limited to two surgeons in a non-competitive environment to perfect the procedure. The first fifteen cases are proctored in that there are meetings before and after the surgery to ensure the correct technique and protocol are used. In the first year there were 34 prostate procedures performed. The applicant had a patient die due to a pulmonary embolism. A root cause analysis was performed and Department of Health reviewed the training and credentialing of the attending physicians. The death was not due to the use of the robot but due to complications that are common with the procedure and can happen with open surgery as well.**

**The applicant explained that they chose to concentrate on just doing the prostate procedures over the foregut and mitral procedure because the prostate are the simplest procedure of the three. This was a good opportunity to get very good at basic minimally invasive techniques. To the Chairman's question regarding the percent of prostate surgeries performed on the robot, the applicant answered that the open surgeries are now less than 10% of all prostate surgeries compared to 100% a year ago. The robot has decreased the length of stay to 2.5 days, blood transfusions to only 6% of the time,**

**and reduced recovery time.**

**The applicant discussed the reasons for the proposed expansion of services to urology, cardiac surgery, colorectal and GYN procedures. The applicant believes that there is a need for these procedures in Rhode Island and the minimally invasive technology benefits the patients to the extent that the procedures need to be expanded. The applicant noted that GYN would be the next area that the surgeons would become proficient in if the request is granted.**

**To Mr. Flynn's question about access to the unit by other Lifespan hospitals, the applicant responded that other hospitals in the Lifespan system had agreed that Miriam was an ideal location for the robot and all robotic procedures are transferred to Miriam. Surgeons from other Lifespan hospitals can use the robot once credentialed by Miriam.**

**To questions regarding minimum number of surgeries to ensure quality care, the applicant answered that there is a minimum of 25 robotic surgeries a month necessary to keep up the skills of the surgeon. The applicant noted that as more robotic procedures are allowed the more protocols that will have to be created either based on national standards or Miriam's individual standards.**

**Staff asked about collaboration with other facilities. The applicant stated that some surgeons have a majority of their practice at other**

**hospitals but wanted to expand their practice to robotic surgery at Miriam. These surgeons go through the credentialing process. The applicant noted the financial impact of additional procedures which would not increase the operating cost. A total of 365 cases are projected to be performed on the unit.**

**The applicant addressed the Committee concern regarding the use of the unit for charity care. The applicant stated that there was no charity care provided on the unit last year because there were no applications. The applicant noted Miriam's involvement in men's health. To Ms. Lapierre's question regarding about the possibility of sourcing charity care patients from local health centers, the applicant responded that they have focus efforts so far on the Rhode Island Free Clinic. The applicant did note that the health centers are a reasonable suggestion. To the Chairman's question if the applicant has seen any results from their efforts with the Rhode Island Free Clinic, the applicant stated that while there has been an increase in screenings, there has been no charity care robotic procedure.**

**The Chairman requested that the applicant provide in writing a description of Miriam's effort with regards to charity care and on the collaboration efforts with other hospitals. Ms. Lapierre requested that the applicant include information about outreaching to community health centers. To questions from staff, the applicant noted that a doctor from Miriam would be located at the Rhode Island Free Clinic.**

**With regards to the waiver of the applicant from condition number seven which require prior review and approval for the use of the unit for additional procedures, the applicant noted that all such procedures must receive FDA approval already. The applicant responded that it is hard to predict where technology is going to go and it is possible for the minimally invasive techniques be used for any laparoscopic surgery. The wavier would allow surgeons to use the unit for new procedures right away. Staff wanted to know what the standard would then be for monitoring new procedures. The applicant responded that a nationally defined standard would be best.**

**To Ms. Lapierre's question regarding the ability of the unit to handle the projected volume, the applicant responded that the projected procedure mix would get the unit very close to capacity.**

**The Chairman noted that condition number seven was a precautionary condition.**

**Mr. Madden noted that the applicant has a two part request, for both specifically identified and other procedures. He asked the applicant to discuss their plans for adhering to proper standard and maintaining proctoring conditions in a similar manner to those used for the currently approved procedures. Staff noted condition of approval number six which requires the applicant to adhere to Connecticut standards for training and asked whether the applicant is requesting**

change to that condition as well. The applicant noted that they would be requesting slight changes. The Chairman requested that the applicant put their request in writing.

Staff's memo regarding the zero charity care performance of the unit was noted. Ms. Colletta noted that Miriam is trying to get each surgeon to provide at least one robotic case free to the Rhode Island Free Clinic. She noted that a letter has been sent to the surgeons and one surgeon has already signed on. Dr. Sax noted that physicians will take patients that don't have insurance. He noted that any future surgeon who become credentialed with Miriam for robotic surgery will receive a letter and be asked to do the same.

Mr. Quigley asked the representative from Women & Infants hospital if he was comfortable with the collaboration with Miriam. The representative agreed.

To a question from Mr. Ross, the applicant confirmed that the number of complication experienced by Miriam with regards to the unit has been normal.

Staff noted that the next meeting on this request would be held on 6 November 2007.

There being no further business the meeting was adjourned at 4:10PM.

**Respectfully Submitted,**

**Valentina D. Adamova, MBA**