

Minutes of Meeting
Health Services Council
Project Review Committee-II

DATE: 5 August 2004 TIME: 3:00 PM

LOCATION: Health Policy Forum

ATTENDANCE:

Committee II: Present: Raymond C. Coia, Maria R. Gil, Daniel F. McKinnon (Chair), Robert J. Quigley (Vice Chair), DC, Reverend David Shire

Not Present: Victoria Almeida, James Daley, Rosemary Booth Gallogly, Wallace Gernt, Catherine E. Graziano, Denise Panichas, Larry Ross

Staff: Valentina D. Adamova, Michael K. Dexter, Joseph G. Miller, Donald C. Williams

Public: (see attached)

1. Call to Order and Approval of Minutes

The meeting was called to order at 3:05 PM. Staff noted that conflict of interest forms are available to any member who may have a conflict.

2. General Order of Business

The first item on the agenda was the application of Bayside Endoscopy Center, LLC d/b/a Bayside Endoscopy Center at Kent County, LLC for a certificate of need for development of a Freestanding Ambulatory Surgery Center at 1351 South County Trail in East Greenwich.

Maria Gil stated for the record that she is recusing herself with respect to the application of Bayside Endoscopy Center, LLC.

Mr. Miller, legal counsel to the Department, stated that when the public hearing portion ended there was a document that Mr. Zimmerman submitted as an amendment to his report. He stated that a stipulation to allow this document into the record was signed by all the Parties involved. He stated that another document, an amendment to an attachment to the application that was left out, is going to be added to the record and that there were no objections from any of the Parties. He noted that additionally the applicant submitted a second amendment to the 'Real Estate Option Agreement' on 5 August 2004 and there were no objections to add it to the record. Dr. Quigley

stated that both Parties would be given an opportunity to address the Committee today.

Mr. Tauber, legal counsel to Kent County Memorial Hospital (“Kent Hospital”), made a presentation to the Committee as follows:

- The question before the Committee this afternoon is whether Bayside has proven that there is public need for an additional Freestanding Ambulatory Surgery Center (“FASC”) in Rhode Island.**

- Bayside Endoscopy Center, LLC (“Bayside”) has not proven that there is need and therefore Kent urges the Committee to vote no on Bayside’s application.**

- What’s not before the Committee is the question whether there needs to be more cancer screenings in Rhode Island, or whether colonoscopies are a good method in assisting in cancer screening.**

- Kent Hospital is in favor of cancer screening, and it believes that colonoscopies play an important role in providing those screenings. It is eager to make sure that cancer screening is clinically appropriate, cost effective, and consistent with patient preferences.**

- Mr. Zimmerman’s report shows that there is no current need for dedicated endoscopy rooms in Rhode Island. This is consistent with the hospital records that Kent Hospital produced in the course of the public meeting, which demonstrate that there is current unused capacity at Kent Hospital.**

- Bayside may try to focus your attention on the notion that sometime in the future there may be a need and Mr. Zimmerman’s report talks about there being a need in a couple of years for additional rooms.**

The Health Services Council and the Department of Health have not historically worked on conjecture about what's going to happen in the future, the focus has been on what is going on now.

- In addition, Mr. Zimmerman acknowledges that his prediction of future need is based on the assumption that the prior growth rate will continue into the future, which he described as explosive and also testified that it was unlikely to continue for the long-term.

- In the interim, many new technologies may come on the scene. There is already some development of procedures like virtual colonoscopies and a variety of other screening methods that can be helpful in addressing the issue of colorectal cancer screening. So we just don't know what the future will bring.

- The Council should be considering what's going on right now and the point is that Bayside has not demonstrated that right now there is need for additional rooms.

- Bayside has talked about waiting time for appointments. There is no waiting time at Kent Hospital for any procedure that the doctor identified as being needed, and the patient gets scheduled the same or next day.

- Screening procedures are scheduled at the convenience of the doctor and the patient, and, if they desire, an appointment can be made within a week or two. The critical point is that there is no wait time except that which the patients and the doctors establish for themselves.

- Bayside talked about patient preferences. Dr. Pignone, an expert on colorectal cancer screening from the University of North Carolina

Medical School and the US Preventive Task Force, which is a national organization established by the federal government as an independent commission to look at issues of preventive health, testified at the public meeting that research shows that some 40% patients simply won't agree to have colonoscopies.

- Bayside also relies on a well-known Rhode Island myth that Rhode Islanders don't like to travel to support the notion that there needs to be another facility in the Warwick area. People travel to Providence from the far distances of Warwick all the time. Indeed, Dr. Trupiano, his colleagues and their patients go up to Bayside's facility in Providence right now.**

- Bayside claims that some patients prefer earlier but no doubt some patients prefer later appointments, for instance third shift workers.**

- As Kent demonstrated during the course of the public meeting, Kent offered as a way of accommodating patients who prefer not to miss a day of work to have additional operating hours on Saturday. But Dr. Trupiano's group and other GI docs at Kent decided that they didn't want Saturday.**

- What this comes down to is a question of doctors' preference and not the patients' preference.**

- Bayside has also spent a lot of time trying to demonstrate that colonoscopies are the gold standard, the gold standard for screening. Rhode Island Cancer Council, the American Cancer Society, the US Preventative Task Force, all agree that several different methods are effective and safe and satisfactory for screening. The peer review literature on the matter does not show that colonoscopies are**

anymore effective than the other methods available.

· In conclusion, we are not here to debate whether there should be more cancer screenings, whether colonoscopies can be helpful. The question before the Committee is whether Bayside has demonstrated current public need for another FASC in Rhode Island, it has not done so. Mr. Zimmerman's report makes that clear, that there is no current need for additional endoscopy rooms in Rhode Island, therefore Kent Hospital urges the Committee to vote no on this application.

Mr. Zubiago, legal counsel to the applicant, made a presentation to the Committee as follows:

· He introduced people that are associated with Bayside Endoscopy Group, Inc.: Dr. Quirk, Dr. Trupiano, Linn Freedman, co-counsel, and Dr. Sepe. All these doctors are doctors with University Gastroenterology and they are also owners of an entity that owns Bayside. From Symbion there is Mr. Curtis and Mr. Donadio both Vice Presidents with Symbion and Mr. Stanley, President of the single specialty unit at Symbion.

· Page #1 of the handout identifies the Parties: Bayside is owned by Bayside Endoscopy Group, owned by 10 local physicians and SARC/Providence, Inc., subsidiary of Symbion.

· Bayside thinks it has clearly demonstrated that there is need for this endoscopy unit in Kent County.

· Page #4 describes the reasons for this application, number one being that it satisfies the present community need.

· Counsel for Kent Hospital stated that the Zimmerman report says

that there is need starting in 2006, and there are certain points where we disagree with the analysis of Mr. Zimmerman. Mr. Zimmerman makes it clear that there is a need in 2006, and it will take time to construct this facility and it wouldn't be open until April or May in 2005.

- The facility will also bring additional quality professionals to the Kent County area. Those professionals already own an existing facility in Providence, which underwent a change in effective control about a year ago.
- Another facility would help the Department of Health fulfill the goal of its Cancer Committee, that 75% of all adults over the age of 50 obtain screening.
- Mr. Tauber argues that this is not about the need for screenings but it is because you can't have screenings unless you have a facility.
- Kent Hospital's expert, Dr. Pignone, testified that colonoscopy was the gold standard, and that the more colonoscopies you have the more it will reduce the cancer rate because it allows the whole colon to be visualized.
- If there are pre-cancerous polyps they can be taken care of during a colonoscopy.
- Other procedures such as a sigmoidoscopy, if there is a polyp, the patient has to have a colonoscopy or some other procedure, which is expensive and doesn't make sense.
- Page #6 shows the applicant's public need analysis, which differs from Mr. Zimmerman's since it looks at the population and what percentage of the population would need a colonoscopy.

- Mr. Zimmerman in his analysis just looked at the number of facilities and then using linear regression projected how that would increase. This is a logical method of doing it, but we think ours is better because it looks at the actual population. Our numbers look at the actual number of people that are going to need screening.**
- We took evidence from Bayside's facility in Providence, which has 6 rooms and treats over 12,000 patients a year. During the public hearings we identified how many of those patients would need an upper endoscopy and diagnostic endoscopy.**
- From the data from the Providence facility we've learned that is that there is clear need.**
- Page #9 shows a chart that looks at the population in the proposed facility's service area (Kent County, North Kingstown and Exeter). This facility would not provide services to the entire state.**
- Work through the analysis, it shows a total need of 15,590 cases in Kent County. We originally assumed that Kent can provide 7,000, but they later testified its 6,400.**
- We are not trying to take any cases from Kent County; to the contrary we are trying to meet that additional need for all of these screening endoscopies and colonoscopies.**
- We feel that our analysis, which looks at the population, gives this Committee a clear and present picture of what that need is. The analysis projects the need at over 8,500 cases and that's why we submitted an application seeking two rooms with a capacity for 4,000 cases a year.**
- We believe that is the present need and we put in ample evidence in**

the record to shows that.

· Page #10 talks about the Zimmerman report's assumptions. He assumes that each endoscopy unit in the state would do 2,000 cases, but the record shows that there are only 3 facilities that meet that goal Bayside's Providence facility and the others are in Westerly and Newport.

· The report states that the need starts in 2006, as opposed to Bayside's analysis that the need is now and in 2005.

· Mr. Zimmerman's report confirms the rapid growth and the explosive rate for colonoscopies. The report does say that additional need is most apparent for endoscopy rooms statewide and this application only focuses on Kent County area. The report identifies need in 2006 for 3 or 4 rooms, and those are rooms that somebody is going to have start building in 2005 and Bayside proposes only to build 2 rooms.

· Mr. Zimmerman admits that he doesn't take patient preference into consideration, and that he didn't review our analysis.

· Kent Hospital is the only provider of endoscopies in Kent County area of 6,400 cases a year. If you use that number, the need at Kent County is over 9,000 cases, which creates a need for at least 2 rooms.

· In summary, even if you accept Mr. Zimmerman's report that the need is in 2006, it takes time to build an additional facility. In addition the report says that there will be a need for 3 or 4 at that time, and the application is only for 2 rooms.

· We think the record is replete with evidence where by you can look at the Zimmerman report in a different light and looking at the actual population, the literature tells on proper percentages for screening

colonoscopies, and when you look at that number on that exhibit, you will see that there is ample need for those rooms.

- The other argument before this Committee is affordability.**
- Bayside Endoscopy Group and Symbion's affiliate (SARC/Providence, Inc.) have shown that they can run a well their Providence facility.**
- The financial information submitted makes it clear that they can afford to do this, and there is clearly a need.**
- Medicare pays for colonoscopy and it is acknowledged that this is a good screening tool that saves people from getting cancer and makes the system less expensive.**
- For all of those reasons we submit that this certificate of need application should be approved.**

Dr. Quigley inquired as to the discrepancy between the waiting times for colonoscopies presented by the applicant and counsel for Kent Hospital. Mr. Zubiago stated that the application contains an affidavit stating that there was a wait at Kent Hospital for screening colonoscopies and counsel for the hospital stated that there is no wait for any patient who had an immediate need for colonoscopy. Mr. Zubiago stated that this is not for screening colonoscopies but for a patient with an immediate need. He noted that the issue of the 2-month waiting time relates to screening colonoscopies and scheduling. He stated that the affidavit shows that the way Kent does its scheduling makes it difficult to book screening colonoscopies. He stated that the sooner the colonoscopy is scheduled the more there

is compliance from the patient to go through with it. He stated that there is evidence in the record to show that there is a problem with booking screening colonoscopies at Kent Hospital.

Dr. Quigley inquired if Bayside's Providence facility or Kent Hospital perform screening colonoscopies on Saturdays. Mr. Zubiago answered no. Dr. Quigley inquired as to why the already existing facility in Providence is not being expanded instead to make it more cost effective. Ms. Freedman stated that an affidavit from the scheduling person at Bayside indicates that patients would rather wait to be able to schedule at Kent Hospital than get a colonoscopy or an endoscopy in a shorter amount of time up in Providence because of transportation and parking.

Dr. Sepe stated that the Providence facility is at near capacity and there is no room to physically further expand the facility. He stated that the facility performed over 13,000 cases this year. He stated that to schedule a screening colonoscopy with him right now would require close to a 3-month waiting time. He noted that there is capacity for emergency needs but that's separate. He noted that there is an active relationship with Rhode Island Hospital where he performs 400-500 procedures. Mr. Zubiago stated that based on the applicant's analysis there is ample need for both facilities in Kent County and Kent Hospital's rooms would remain busy and this application would not hurt Kent Hospital.

Mr. Tauber stated that Kent Hospital put into the record its own records to demonstrate that one can get a screening colonoscopy scheduled for the next week, which is contrary to what the applicant suggested. Mr. Zubiago stated that the problem with that analysis is that the time that Kent Hospital is saying is available is at 4 or 5 PM when patients will not schedule screening colonoscopies. He stated that there is a lot of prep-work requiring drinking fluid and fasting and patients do not want to wait until 4 PM. Mr. Tauber stated that the records he was referring to are for scheduling before 2 PM and Dr. Trupiano and his group scheduled less than 20% of their block time into the future for that time frame. Mr. Zubiago stated that he is disputing that information and the applicant submitted an affidavit to that affect.

Mr. Shire inquired if the proposed facility would need to establish a relationship with a hospital for emergency procedures. Mr. Zubiago stated that the proposed facility would enter into discussions with Kent Hospital. Dr. Baute, President of Kent Hospital, stated that the applicant advised the hospital regarding filing of its application but there was no further communication for transport privileges.

Mr. Shire stated that Medicare began paying for colonoscopies in 2001 and the Zimmerman report incorporates rapid growth into its analysis. He inquired whether that might level off in the future. Mr. Zimmerman stated that his was also his concern but he cannot answer that question. Dr. Quirk stated that Mr. Zimmerman uses a

linear regression analysis basis for his projections. He noted that he has a MPH in clinical outcomes and noted that the problem with this analysis is that the future utilization is going to be different from the past because there is a whole new group of people that are able to get colonoscopy because of that Medicare change in 2001. He stated that the projected future numbers are actually underestimated because of several factors that drive procedures. He noted that one of the factors is patients' qualification for a procedure and if they are broadened more patients will receive the procedure. He noted that the second factor is the supply of physicians, and there are more gastroenterologists now in Rhode Island than before. He stated that these factors are not reflected in Mr. Zimmerman's analysis. He stated that more doctors capable of performing a procedure allows for greater demand, and facilities are necessary to match that demand. He stated that the national polyps study shows that 37.5% of patients that undergo colonoscopy that are greater than age 50 are going to have polyps. He stated that it is recommended for those patients to receive colonoscopies sooner, such as in 3 years, because it is no longer screening but surveillance. He stated that the greater the population that undergoes colonoscopy procedure now, the more demand there is in the future. He noted that Rhode Island has an aging population and that would indicate there is going to be an ongoing need.

Dr. Quirk stated that Associated Press recently published an article by Dr. Brugge, Director of Endoscopy at Massachusetts General

Hospital (“MGH”). He stated that MGH projected 25,000 endoscopic procedures for one year when their new facility was built and those projections were outstripped in one year. He stated that the demand is much greater than anticipated. He stated that a second publication by the Federal Trade Commission and Department of Justice brought up a crucial point about the certificate of need process. He noted that the publication stated that the process was often used by encumbered healthcare institutions to keep out competition. He stated that there is tremendous need, and people do get angry about waiting. He stated that doctors also have to contend with malpractice suits because of failure to diagnose. He noted that patients everywhere, not just Rhode Island, don’t like to travel. He provided an example, that in Europe there is industrialize screening where the service goes to the factories as an incentive for workers to get colorectal cancer screenings. He stated that if the goal of the Department of Health is believed than people need to get their screenings done and it needs to be made easier. He stated that he doesn’t believe the demand is going to level off but rather keep increasing in the foreseeable future.

Dr. Quigley inquired as to Mr. Zimmerman’s opinion on this matter. Mr. Zimmerman stated that 20 years ago Lithotrip suddenly discovered new ways to treat kidney stones and this created an explosive demand for Lithotrip services. He stated that when Medicare reduced its reimbursement the demand for Lithotrip services went down. He noted that the case with colonoscopies is

similar, where there is a new service that's catching the attention of everyone. He stated that when people have gotten used to it and if Medicare decided change the reimbursement rates then people might not want to pay the additional amount and physicians may decide that can't afford to do quite so many.

Dr. Quirk stated that there is a difference between treating a kidney stone and reducing the risk of colon cancer particularly in the state where there is the highest rate of colon cancer in the country. He noted that this is not a new technique and it will be around for a long time, even if virtual colonoscopy does come about, because the polyps would still need to be removed. He stated virtual colonoscopies would be doing more procedures on people who did not want to get a colonoscopy before and a large number of those patients are going to have polyps. He stated that the demand is still going to be there and the only treatment for polyps is either endoscopy or surgery.

Dr. Quigley stated that while the CON might be accused of protecting the existing facilities, this Committee is mainly interested in quality and the affordability.

Mr. Coia inquired if there is an optimal time that would be most beneficial to do these screenings, is there a block of time when facilities are seeing most of the testing being done and is that one of the reasons there is need for more available space during those

hours. Dr. Quirk stated that most patients want to get their elective test done early in the day because they've fasted the day before. He stated that from 7 AM to 4 PM is the time when people want to get their exams done. He noted that for emergency procedures, people don't mind getting it later in the afternoon. He noted that with screening colonoscopies, the idea is to make it easier for the patient so that they comply and go through with the test.

Mr. Coia inquired if there is evidence in the booking history that people would rather wait and get it done in the early hours than do it at 4 PM. Dr. Quirk answered yes and stated that there are also medical reasons as to why people want to get it done earlier, such as diabetes. He noted that people are willing to postpone an appointment in order to get it done early in the morning.

Mr. Zubiago noted that this isn't physician convenience but patient convenience. He stated that the reason the facility is not open on Saturday because the patients won't come.

Mr. Hynes, President of Care New England Health System, stated that it's very difficult to run hospitals. He noted that Kent Hospital made a considerable investment when it expanded its endoscopy capacity 2 years ago. He stated that the concern is that when the facility was expanded it was done so on the strength of demand. He noted that since that demand is going to walk away the hospital is concerned. He proposed a suggestion that the hospital and the physicians work

together and see what, if any, additional capacity could be created at the hospital and there by accommodating both the physicians and the patients who don't want to travel and certainly the unit cost, which are not insignificant at that institution.

Mr. Zubiago stated that it was made clear that the applicant's analysis shows that both Kent Hospital's and the proposed facility's rooms would be full. He stated that Kent Hospital is not going to be hurt by this.

Mr. Hynes stated that this is similar to what happens with other sub-specialties. He noted that several years ago there was an approval an outpatient facility across the street from the hospital to perform cataract surgery, which caused the volume in the hospital in that particular sub-specialty to plummet. He stated that if this application as it is presently put together is approved, there will be more units that will be requested, and within 2 years there will be virtually no endoscopies done at the Kent Hospital, unless they happen to be for acutely ill patients. He stated that the hospital has to provide a broad range of services to a variety of people but if the only people who are going to seek services are the most severely ill then the system is not going to be able to afford that.

Mr. Tauber stated that in term of scheduling at Kent Hospital, it solicited its entire GI Department about opening on Saturday and, except for one, all the doctors said no. He also noted that the

Associated Press article referred to Boston Medical Center, which expanded its hours until 7 PM and it would not have done that if patients were not willing to come. Mr. Zubiago stated that this is a patient issue and not a doctor issue.

Dr. Quigley stated that because of the voluminous record the Committee would need to spend more time reviewing it. The next meeting with Bayside was tentatively scheduled for 12 August 2004.

There being no further business the meeting was adjourned at 4:05 PM.

Respectfully submitted,

Valentina D. Adamova