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March 31, 2010

Received by the
CON Section

31 MAR 2010 04:34

Michael J. Mckillip, Project Analyst
Certificate of Need Section
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, NC 27699-2704

Re: Comments

Dear Mr. McKillip:

This letter forwards the comments of Duke University Health System on the following certificate of need applications:

Project ID#

J-8463-10
J-8468-10
J-8469-10
J-8471-10

If you have questions about them or need further information, please let me know.

Sincerely,

Duncan Yaggy, Ph.D.
Chief Planning Officer
Duke University Health System

Comments on Application of WakeMed Cary Hospital

J-8463-10

Submitted by Duke University Health System d/b/a Duke Raleigh Hospital

WakeMed Cary has proposed to expand its facility with the addition of 3 shared operating rooms. In addition to concerns raised in the application itself, this project has been called into question by developments at WakeMed since the application's filing.

Acquisition of Surgical Care Affiliates

On March 24, WakeMed announced the acquisition of a majority interest in Surgical Care Affiliates, which owns and operates Blue Ridge Surgery Center in Raleigh.

In a March 24, 2010 press release that can be found on WakeMed's website at <http://www.wakemed.org/body.cfm?xyzpdqabc=0&id=247&action=detail&ref=198>, WakeMed states:

WakeMed Health & Hospitals and Surgical Care Affiliates (SCA) will enter into a formal agreement on March 31, 2010 to further enhance existing ambulatory surgery services throughout the WakeMed system.

WakeMed and SCA have been exploring a formal relationship for nearly 16 months as part of the long-term WakeMed Cary Hospital and overall WakeMed ambulatory strategy. The goal of this new partnership is to grow WakeMed's outpatient surgery business by providing WakeMed's surgical patients and physicians with outstanding service, including greater efficiencies, consistent practices across the system, and increased capacity for outpatient surgery throughout Wake County.

This acquisition is inconsistent with WakeMed's proposed project and many of its assertions in the application. First, WakeMed announced that it had contemplated this relationship for 16 months, yet did not disclose in its application that this was a possible alternative to meet any surgical capacity needs as required by Section III, p. 8 (see WakeMed application, p. 96).

Second, this development affects the accuracy of the information provided in the application. The data in Section II responding to the information required of applicant specified in 10A NCAC 14C.2102 are now incomplete. In addition to its existing facilities, WakeMed will now own a controlling interest in Blue Ridge Surgery Center, which has 6 outpatient operating rooms, and needs to account for that capacity in its projections.

Third, under this new contractual arrangement according to WakeMed's press release, moreover, "SCA will begin managing surgical services operations for WakeMed Cary Hospital and WakeMed North Healthplex Day Surgery program." This is not reflected in the information provided in response to 10A NCAC 14C.2105 regarding staffing and staff training. It is entirely possible that staffing changes will result from this new management, and the costs to this management relationship are not reflected in WakeMed's proformas.

Finally, and most importantly, the acquisition calls into question WakeMed's ability and desire to pursue the proposed project. In its application, WakeMed proposes to create outpatient blocked operating room schedules – in effect creating an ambulatory surgery block within the hospital – to create "operational efficiencies." However, Blue Ridge Surgery Center is only 10 miles from WakeMed Cary (12 minutes driving time, according to Google Maps), and is significantly underutilized. The 2010 State Medical Facilities Plan shows an outpatient volume at Blue Ridge Surgery Center of 5474 cases in 6 operating rooms, for a utilization rate of 58.5%. To the extent that WakeMed claims any pressure on its capacity at WakeMed Cary, additional outpatient procedures at WakeMed can be accommodated at Blue Ridge Surgery Center, freeing up operating room time for inpatient surgeries at WakeMed Cary. WakeMed will have every incentive to ensure full utilization at Blue Ridge Surgery Center before pursuing any construction at WakeMed Cary.

WakeMed's other operating room projects

In addition to WakeMed's new acquisition of SCA, WakeMed has several projects that are still incomplete and must be considered in evaluating whether WakeMed is ready, willing, and able to pursue the project proposed in its application. WakeMed's delay and/or outright failure to pursue operating room projects previously approved undercut any claim to need additional operating rooms in Cary now.

In 2005, WakeMed filed an application to develop the Apex Day Surgery Center, to be located 5 miles from WakeMed Cary, in order "to better utilize four existing WakeMed operating rooms by converting them from hospital-based endoscopy operating rooms to free-standing ambulatory surgery operating rooms" and "offload some volume and help maintain efficient levels of utilization and effective operations at WakeMed Cary." (WakeMed Apex Day Surgery Center Application, J-7350-05, pp. 52, 62) The four endoscopy rooms, which themselves were part of an earlier application approved in 2004 but not developed, would relocate from Raleigh (2), Cary (1), and North (1). This center was approved and was scheduled to be open in October 2008. However, after approval, WakeMed has since attempted to move the project to Brier Creek, and then to a site next to WakeMed Raleigh, where the project is still pending. If they had built the operating rooms as originally planned, WakeMed Cary would have had the additional capacity it now claims it needs. WakeMed's shifting plans, coupled with

its new acquisition of SCA, raise serious doubt about the viability of the current proposed project.

Accommodation of Additional Volume

Even apart from the failure to include SCA's facilities in its projections, WakeMed's application is based on assumptions that call into question the projections that were provided. Specifically, the project calls for significant growth in volume, but will not include any expansion or renovation to existing pre-or post-operative rooms; it is difficult to understand how WakeMed could accommodate significant increases in surgery volumes at WakeMed Cary without expanding those areas also.

In addition, "WakeMed Cary does not expect that there will be a material change in the number of surgeons who perform surgery at the hospital", and staffing per operating room hour will actually decrease.

- Currently: 53.85 RNs => 0.43 RN per weekly OR hour
- Future: 67.25 RNs => 0.37 RN per weekly OR hour

Again, it is difficult to understand how WakeMed can accommodate expanded surgery volumes without additional surgeons and in cutting back its staff per operating room hour.

Methodology Concerns

Finally, the projections were developed using Thomson Reuters' ambulatory surgery database. This database does not provide reliable surgical volumes for this purpose; it includes some procedures which are not surgical procedures. In a March 17, 2010 email to the North Carolina Hospital Association, a Thomson Reuters' representative has specifically stated that it is a good thing that the state does not use its data for any need methodologies due to accuracy concerns. Additionally, recent changes in ambulatory surgery data submission from ICD-9 codes to CPTs need to be refined before use for such a purpose.

WakeMed claims that it is limiting the procedures from the Thomson Reuters database in its projections by ICD-9 Px codes to address this issue; however, even with that limitation, WakeMed would still be relying on volumes that exceed the actual number of surgical procedures it reports in its license renewal applications. For example, the database (as limited by ICD-9 Px codes) shows 525 procedures for WakeMed Apex in FY 2009, which has no operating rooms. Similarly, WakeMed Cary shows a volume of 9117 procedures under the Thomson Reuters database for FY 2009, compared to actual procedures reported of 8489 (including procedures in operating rooms and other). These discrepancies call into question WakeMed's projections.

The unreliability of using the Thomson Reuters data can also be seen in the numbers that it generates in different counties over the next several years under WakeMed's projections:

- Wake County use rate per 1,000 in FY 2009 is 91.95 and FY 2015 is 99.69
- Lee County use rate per 1,000 in FY 2009 is 126.09 and FY 2015 is 147.08
 - Population growth of 7,140 and surgery growth of 2,282
- Despite Halifax's nearly steady IP volume over the past 5 years, the use rate is projected to increase from 114.35 to 123.76

These increases are not credible and call into question the utility of the Thomson Reuters data for utilization projections, as Thomson Reuters itself acknowledges.

Conclusion

WakeMed's proposal does not meet the needs of Wake County for additional operating rooms.

Comments on Applications of Rex Hospital -- J-8469-10

and Rex Healthcare of Holly Springs -- J-8468-10

Submitted by Duke University Health System d/b/a Duke Raleigh Hospital

Rex Hospital has filed two coordinating applications, one for an additional operating room at Rex Hospital's main campus, and one for 2 operating rooms at a new ambulatory surgery center in Holly Springs. Because both rely on the same assumptions and are designed to work in tandem, Duke hereby submits comments on both together.

Rex's applications must be read in the context of the status of many of its recent projects. It identifies as the "two pressing concerns" driving the applications "the need to relieve capacity at Rex's main campus" and "to expand outpatient surgical capacity in the Holly Springs submarket." (Rex Holly Springs Application, p. 74). Rex states that the current operating rooms at its main campus are "over practical capacity," but the Rex system has 4 under-utilized rooms in Cary built in July 2003, 3 newly opened and not-yet-fully utilized rooms in Wakefield, 4 operating rooms still to be built in an orthopedic ambulatory surgery center with Raleigh Orthopedics, and 4 operating rooms to relocate to Macon Pond. Rex simply cannot credibly support the need for additional operating rooms while so many of its operating rooms, existing and approved, are not yet near capacity, or in some cases, even built.

The need for a new ambulatory surgery center in Holly Springs is especially tenuous. Rex claims that the new facility is required to alleviate pressure on the main campus from patients coming from the Holly Springs area. Specifically, it states that "If the Holly Springs surgery center is not allowed to be developed, the cases performed on patients of this service area would continue to come to Rex's main campus, but patients would not benefit from a local facility to meet their needs for surgical services." (Rex Holly Springs Application, p. 75) Rex cannot explain, however, why a new ambulatory surgery would alleviate that pressure when the Rex campus in Cary, open since 2003 and closer to any patient population from Holly Springs, has not. At page 119 of the Holly Springs application, Rex states that "all of the patients projected to shift to the Holly Springs facility are currently receiving care at Rex Hospital – Main Campus. Thus, they are already choosing Rex over other existing providers, even without local access to a surgery center. Moreover they are bypassing closer existing facilities such as WakeMed Cary to receive care." Rex does not state the obvious, which is that these patients must also be bypassing Rex's own closer existing facility in Cary.

In 2009, the Rex Surgery Center of Cary performed 1,104 hours per OR (47.2% of total capacity). Even by 2014, Cary's volume is only projected to hit 1,374 hours per hour (58.7% of total capacity). If a new Holly Springs facility could credibly claim to alleviate the volumes at

the main Rex campus, it would presumably alleviate volumes in Cary also, and Rex has not accounted for this in its projections. Alternatively, if these patients are choosing to receive services at the Rex main campus regardless of closer alternatives, Rex's assumptions about the need for a Holly Springs facility are fundamentally flawed. Rex and its patients would be better served by directing patients to its existing operating rooms in Cary which are closer and underutilized, without the expense and delay of new construction.

It should also be noted that Rex has been approved to construct a new diagnostic center in Holly Springs, but has not met its timetable to do so. Combined with the many operating room projects it has outstanding, this suggests that Rex may be unable to pursue yet another operating room project in a timely manner.

Methodology Concerns

Rex's projections were developed in part using Thomson Reuters' ambulatory surgery database. This database does not provide reliable surgical volumes for this purpose; it includes some procedures which are not surgical procedures. In a March 17, 2010 email to the North Carolina Hospital Association, a Thomson Reuters' representative has specifically stated that it is a good thing that the state does not use its data for any need methodologies due to accuracy concerns. Additionally, recent changes in ambulatory surgery data submission from ICD-9 codes to CPTs need to be refined before use for such a purpose.

Using Thomson Reuters data, Rex determined use rates per 1,000 population. Growth projections used the CAGR of these use rates for inpatient and outpatient surgery, growing the use rates along with the population. The problems with using this methodology can be seen in the wildly varying use rates that it generates in different counties over the next several years:

- Wake County use rate per 1,000 in CY 2009 is 82.8 and CY 2014 would be 86.8
- Johnston and Franklin have negative CAGRs, reducing their use rate below 70 per 1,000.

Basing its projections on Thomson Reuters data renders Rex's projections unreliable.

It should also be noted that although Rex at various places in its application refers to volumes shifting to the new OSCR facility, in Section IV of its applications it does not include projected volumes at the OSCR facility in which it has an ownership interest. The projections are therefore incomplete.

Geographic Need for Holly Springs Project

Rex intends to place the ambulatory surgery center in Holly Springs because of its projected high growth rate. However, in this case, the fastest growing sub-region in the county

does not create the largest number of new people who will need service. Due to the small starting population base, that growth results only in approximately 17,000 new people (12% of Wake County's total projected growth). Per data provided in the application, Wake County as a whole will grow by nearly 143,000 people over that period, and the Central region (as defined by Rex) will grow by 57,520 people. The county as a whole is not best served by Rex's proposed project.

Moreover, Duke understands that the community of Holly Springs most wants immediate access to urgent care services. Ambulatory surgery facilities are not designed, staffed or operated to provide urgent care services. Instead, they provide scheduled outpatient procedures during standard business hours. Immediate access is not paramount or necessary for scheduled outpatient surgery procedures. There is no time pressure to reach an ambulatory surgery center, nor any significant inconvenience resulting from a single trip of 10 to 20 miles.

Elimination of Procedure Rooms in Main Campus Project

Rex claims that it will be moving procedures from four existing procedure rooms to the new operating room. In its hospital application, it states that "these minor procedure rooms have historically been an important part of Rex's surgery services." (Rex Main Campus Application, p. 77) Rex does not adequately address how it can close those rooms and accommodate that "important part" of its services in a single operating room. (Rex also does not make clear whether it will be closing these rooms regardless of approval of this project.) In its Main Campus application at pages 34-35, it appears that the number of procedures performed in procedure rooms, reflected in the difference between total cases "regardless of location" and those performed in operating rooms, is 8174 for FY2009, totaling 27.5% of its non-C-Section volume. It is difficult to understand how Rex intends to accommodate these procedures in a single additional operating room.

It is unclear whether Rex intends to continue to do any significant surgical volume in other, unidentified procedure rooms. Rex's total cases in the operating rooms at Rex's main campus and Macon Park (to which 4 rooms will be relocated from the main campus) in FY 2014 is projected to be 26,277, well less than the 31,125 it claims to have performed "regardless of location" at Rex's main campus in FY 2009. If the excess procedures can and will be done in procedure rooms, it is unclear why Rex would eliminate those rooms in favor of a single operating room. If, instead, its total volumes are decreasing, it is unclear why it needs an additional operating room at its main campus or additional capacity in Holly Springs.

Conclusion

Rex's proposals do not meet the needs of Wake County for additional operating rooms.

Comments on Application of Holly Springs Surgery Center

J-8471-10

Submitted by Duke University Health System d/b/a Duke Raleigh Hospital

Holly Springs Surgery Center, LLC and Novant Health, Inc. (collectively, "HSSC") propose a 3 operating room ambulatory surgery center in Holly Springs. This project does not meet the needs of Wake County.

Need for the Project

First, HSSC's proposal purports to address the specific needs of the Holly Springs community. Duke does not dispute the growth of Holly Springs; however, the fastest growing region does not equate to the largest number of new people who will need service. The projected population growth between 2009 and 2014 may be one of the highest rates in the area, but due to the small starting population base, that growth results only in approximately 20,000 new people (12% of Wake County's total projected growth). Wake County as a whole will grow by nearly 250,000 people over that period, and that growing population is not best served by HSSC's project.

Moreover, as the HSSC application acknowledges, the community of Holly Springs most wants immediate access to urgent care services (See HSSC Application, p. 48). Ambulatory surgery facilities are not designed, staffed or operated to provide urgent care services. Instead, they provide scheduled outpatient procedures during standard business hours. Immediate access is not paramount or necessary for scheduled outpatient surgery procedures. There is no time pressure to reach an ambulatory surgery center, nor any significant inconvenience resulting from a single trip of 10 to 20 miles.

In addition, this center, as contemplated, is in the nature of a specialty facility primarily providing orthopedic services (comprising 75% of surgeons by projected specialty), which does not best meet the needs for surgical services in the service area. The most recent operating rooms to be awarded in Wake County were for the purpose of an orthopedic ambulatory surgery facility which is still under development, and an additional single specialty ambulatory surgery demonstration project will also be available in a review later this year. Another such facility is not currently needed. While HSSC claims that it will offer specialties other than orthopedic surgery, and its projections assume such specialties, there are no ENT or urological surgery practices that have committed to performing surgeries there. Moreover, the general surgeons and neurosurgeons who submitted letters of support for the project practice primarily in Durham and Orange Counties, and have treated a minimal numbers of patients from the Holly Springs area in

the past. It is unclear how they will be able to significantly broaden the scope of services to be offered in a Holly Springs surgery center.

Lack of Support

In addition to creating question as to the breadth of service to be offered at the proposed facility, the letters of support also undercut HSSC's projections. For example, while their letters state support for the project, the neurosurgeons from Durham County do not commit to or even anticipate any particular volume of procedures to be done in HSSC's proposed operating rooms. Other surgeons supporting the project express an interest in performing procedures in the proposed procedure room, but do not anticipate any volumes in the operating rooms themselves.

Perhaps for these reasons, even the town of Holly Springs does not support this project.

Concerns with Financial Assumptions

HSSC's assumed payor mix for this project is not reasonable for the population to be served. HSSC assumes a mix of 48% private, 31% Medicare, 9% Medicaid, and 7% self-pay, "based on data from other Novant Ambulatory Surgery Centers, ASC CON applications, and Wake County License Renewal Applications." This assumption does not take into account the demographics of this specific area, which skews younger and higher income than the county in general.

Conclusion

HSSC's proposal does not meet the needs of Wake County for additional operating rooms.