

**Petition to the State Health Coordinating Council
Regarding a Special Need Determination for Dedicated Pediatric Surgical Operating Rooms
for Wake County in the 2011 State Medical Facilities Plan**

Petitioner: WakeMed Health & Hospitals
3000 New Bern Avenue
P.O. Box 14465
Raleigh, NC 27620-4465

Contact: W. Stan Taylor
Vice President, Corporate Planning
Phone: 919-350-8108
Email: staylor@wakemed.org

DFS Health Planning
RECEIVED

AUG 02 2010

Medical Facilities
PLANNING SECTION

Statement of Requested Adjustment

WakeMed hereby petitions the State Health Coordinating Council (SHCC), requesting a special need determination for four dedicated pediatric surgical operating rooms for Wake County in the 2011 State Medical Facilities Plan (SMFP).

Reasons for Requested Adjustment

WakeMed requests an adjustment to the operating room need methodology in Chapter 6 of the 2011 SMFP, due to growing demand for pediatric surgical services in Wake County. Currently, there is no provision in the SMFP for pediatric surgery, nor are any operating rooms in the state dedicated to pediatric surgery.

Current Operating Room Need Methodology

The current need methodology for operating rooms, found in Chapter 6 of the 2010 SMFP, does not distinguish between the various patient types served in surgical operating rooms. In the methodology, the following types of operating rooms (ORs) are recognized, but not differentiated from one another in the SMFP need methodology; these categories are also listed in the annual Hospital License Renewal applications:

- Dedicated open heart surgery;
- Dedicated C-section¹;
- Other dedicated inpatient;
- Dedicated ambulatory surgery; and
- Shared inpatient/outpatient.

¹ Note: Dedicated C-section ORs are included in the inventory, but excluded from the need methodology. Applicants may file for C-section ORs outside an SMFP allocation.

When a need is generated and allocation made for new operating rooms in the SMFP, applicants may file proposals for any type of surgical operating room, depending on their own identified need. Surgical specialties to be provided are at the discretion of the applicant, although applicants must delineate between multi-specialty and single-specialty ambulatory surgical operating rooms, and between freestanding and hospital-based ORs. Occasionally, the SHCC approves an allocation for specialty operating rooms, the most recent example being the inclusion of three separate need determinations for single-specialty operating rooms² in the 2010 SMFP.

Background

Historically, most health care providers have combined services for adult and pediatric patients within a single facility. In recent years, there has been a growing trend nationally, as well as within North Carolina, to provide distinct health care facilities for adults and children. Many larger hospitals, including WakeMed, have created specialized medical/surgical and intensive care units geared toward children, to better address their physical and emotional needs. Several hospitals across the state have developed or proposed dedicated children's emergency departments that provide a full range of services in a separate setting. North Carolina's first freestanding children's emergency department opened at WakeMed Raleigh Campus in 1997.

These separate facilities for pediatric patients are an outgrowth of the trend toward "patient-centered" and "family-centered" care, in which all care options are tailored to the individual patient, and caregiving activities revolve around providing comfort and emotional support to the patient, family and friends as active partners in the care process.³

The delineation of pediatric surgical services, with dedicated operating rooms and pre- and post-operative areas, represents another effort to distinguish between adult and pediatric health care services. Doing so improves patient safety and clinical outcomes, helps reduce medical errors, and boosts patient and family satisfaction.

With regard to appropriate venues for infant surgery, the American Pediatric Surgical Association recently stated:

"As a specialty, infant surgery is unique in its diagnostic range, health care skills required, complex medical environment, infrequency of conditions treated, and relative paucity of complete teams of qualified for safe practice. ...Because such neonatal and infant surgical conditions are relatively uncommon and teams of appropriately skilled professionals and health systems properly resourced for expert perioperative care of

² The 2010 SMFP contains need determinations for two single-specialty ambulatory surgical operating rooms each for the Triad Area (Guilford and Forsyth Counties – CON review date beginning April 1, 2010, Charlotte Area (Mecklenburg, Cabarrus and Union Counties – CON review date beginning August 1, 2010), and Triangle Area (Wake, Durham and Orange Counties – CON review date beginning December 1, 2010).

³ Joseph, Anjali, Amy Keller and Katie Kronick, "Tranforming Care in Children's Hospitals Through Environmental Design", The Center for Health Design, 2008.

infants are limited in number, the association strongly advocates that the surgical care of high-intensity infants occur within facilities with the human and institutional resources outlined.”⁴

According to Dennis Lund, M.D., chief of pediatric surgery at American Family Children’s Hospital in Madison, Wisconsin:

“Children should be cared for by medical staff specially trained in the needs of pediatric patients and their diseases. Whenever possible, pediatric patients should be separated in their care from that of adults in a facility specially designed to meet their needs. And parents and families should be able to be with their children as much as possible.”⁵

Dr. Lund’s remarks are illustrative of the trend toward distinct children’s health care facilities and services. In North Carolina, no fewer than 12 acute care hospitals have developed either freestanding childrens’ hospitals or “hospitals-with-hospitals” focused on inpatient and outpatient services for pediatric patients. Please see the following table.

Hospital	City	Children’s Facility
Cape Fear Valley Medical Center	Fayetteville	Children’s Center
Carolinas Medical Center	Charlotte	Levine Children’s Hospital
Catawba Valley Medical Center	Hickory	Center for Women & Children
Duke University Hospital	Durham	Duke Children’s Hospital
Mission Hospitals	Asheville	Mission Children’s Hospital
New Hanover Regional Medical Center	Wilmington	Betty H. Cameron Women’s & Children’s Hospital
NorthEast Medical Center	Concord	Jeff Gordon Children’s Hospital
Pitt County Memorial Hospital	Greenville	Children’s Hospital at PCMH
Presbyterian Hospital	Charlotte	Hemby Children’s Hospital
UNC Hospitals	Chapel Hill	North Carolina Children’s Hospital
Wake Forest Univ. Baptist Medical Center	Winston-Salem	Brenner Children’s Hospital
WakeMed	Raleigh	WakeMed Children’s Hospital

Pediatrics Is Not a Distinct Surgical Specialty

Children are not small adults. They have a unique set of diseases and responses to diseases, as well as different social and emotional needs. Hospitalized children have been removed from their normal worlds of home, school and play. Supporting the involvement of family in the hospital partially mitigates this separation⁶. Thus, optimal design of health care facilities that

⁴ Stolar, Charles J.H., “Best practice for infant surgery – a position statement from the American Pediatric Surgical Association”, *Journal of Pediatric Surgery*, (2008) 43, 1585-1586.

⁵ “Children’s Hospital Opens New Operating Rooms”, accessed via Internet at <http://www.uwhealth.org/news/childrens-hospital-opens-new-operating-rooms/13828>

⁶ Coucil, Annie, and Sheila F. Cahnman, “Kids’ stuff: Features and factors driving children’s hospital design”, *Health Facilities Management*, June 2004, p.38.

serve children should incorporate features that address childrens' physiological and psychological differences.

Ideally, children should be cared for by medical staff specially trained in the needs of pediatric patients and their diseases. Whenever possible, children should be separated in their care from adults in a facility specially designed to meet their needs. Parents and family members should be able to remain with their children as much as possible throughout their hospital stay.

Pediatrics is not surgical specialty *per se*, but rather a patient population that is distinct from adults, one that runs the gamut from tiny neonates to adolescents. Most body-specific surgical specialties have their own board certification association, such as the American Board of Neurological Surgery, or American College of Chest Physicians. "Pediatric Surgery" is a catch-all term that encompasses the full gamut of pediatric surgical specialties, regardless of body location.

Differences Between Pediatric and Adult Surgery

The differences between pediatric and adult patients, and the unique needs of each patient population in surgery, are generally not delineated. Traditionally, pediatric surgical patients are treated in the same operating rooms as adults, with no distinction made for the obvious physiological differences in children. Unlike adult patients, who have mature, fully-grown bodies, children may range in size from newborns to adolescents. The variations in physical maturity in children create unique challenges for surgeons who perform surgical cases on these young patients.

Many large tertiary and academic medical centers perform their pediatric surgical cases in operating rooms dedicated to children, with equipment, instrumentation and staff geared specifically toward children. A key distinction for pediatric surgery is that often the surgeon cannot estimate the length of the case; pediatric surgical case time is dictated by the patient's condition prior to and during the procedure, the size of the patient, and response to treatment.

Operating Room Temperature and Environment

Pediatric patients lose body heat more rapidly than adults, due to greater surface area as a percent of body weight. Therefore, pediatric surgical cases are typically performed in an environment that is unlike that for comparable adult cases. Because of their unique physiology and susceptibility to hypothermia, operating room temperatures for pediatric surgical cases are set higher, as high as 85 degrees⁷, as opposed to 68°-72°F degrees for adults. Infants and children must be kept warm during surgery to prevent hypothermia. To prevent heat loss due to conduction from a cold operating room table, a blanket warmer may be placed on the OR table. The body temperature of the pediatric patient must be monitored constantly to address any variations.

⁷ Phillips, Nancy Marie, *Berry and Kohn's Operating Room Technique, Tenth Edition*, 2004, Mosby, page 123.

While OR temperatures are controllable in individual rooms, the required temperature modification (e.g., going from 85°F to 68°F, or vice versa) between adult and pediatric surgical cases in a given room cannot be achieved quickly, a factor that adversely impacts OR turnaround time. In a busy surgery center, this can negatively affect patient throughput, and may delay response to an emergency case.

Instrumentation and Equipment

A child's small body and fragile tissues must be handled with gentleness and precision during surgery. Basic or standard instrumentation sets, sutures, needles, and other items used for surgical procedures on adults are duplicated in miniature for children.⁸ Size and weight are more critical factors than age in the selection of instrumentation and equipment. The pediatric surgeon can gauge what instrumentation may be needed in the pre-operative area, but often the patient's supply needs are not fully known until the case has begun.

Recent advances in minimally invasive surgical techniques allow surgeons to utilize miniaturized laparoscopic and thoracoscopic devices for a wide array of procedures. Progress has accelerated and the number of procedures that are being performed in children is rising rapidly. Increasingly younger patients now benefit from these techniques, with laparoscopy and thoracoscopy in neonates and infants the most recent applications.⁹

Infection Control

Infection control is paramount in health care settings, and in no area is infection control a more sensitive issue than in surgical cases. For pediatric patients, infection control is a concomitant concern to surgical instrumentation and equipment. The unique physiological needs of the smallest pediatric patients often require surgical procedures to be performed at the bedside, rather than in a sterile surgical operating room environment.

One of the most pressing issues in the health care industry today is the reducing the incidence of nosocomial, or health care-associated, infections, such as MRSA and VRE. Surgical site infections remain a significant problem for children and adults alike. Because children, particularly neonates and infants, have either underdeveloped or compromised immune systems, prevention of nosocomial infections is imperative. Dedicated pediatric operating rooms would help reduce the incidence of nosocomial infections by keeping children separated from adult patients.

⁸ *Ibid*, page 134.

⁹ Kalfa, Nicholas, Hossein Alla, Oliver Raux, *et al.*, "Tolerance of Laparoscopy and Thoracoscopy in Neonates", *Pediatrics*, 2005:116;e785-e791.

Anesthesia

Pediatric surgical cases create unique challenges for the anesthesiologist, as a child's age, weight, medical condition, and complicating diagnoses, when combined with the planned surgical procedure, may necessitate complex algorithms for the use and monitoring of anesthetic drugs. In the late 1990s, the Accreditation Council for Graduate Medical Education (ACGME) recognized pediatric anesthesia as a subspecialty within the discipline of anesthesiology. Children in high-risk groups, including neonates and young infants, as well as children who undergo complex surgical procedures are best cared for by anesthesiologists with special experience and/or training in pediatric anesthesia.¹⁰

Surgery is an inherently stressful event for any patient, and may be quite frightening to children. To alleviate pediatric patients' fear, anesthesia may be induced in a separate room just outside the operating room, with one or more family members present with staff, before the patient is moved to the operating room proper. In many hospitals and surgical facilities, this option may not be available.

A study published by Kain *et al*, indicated that the establishment of dedicated pediatric operating rooms resulted in significantly shorter anesthesia induction and emergence time. Furthermore, the decreased variability of anesthesia-controlled time may allow for better scheduling of surgical cases and for better surgeon and patient satisfaction.¹¹

Pre-Operative/Post-Operative Care

The unique needs of the pediatric patient do not end at the operating room: children benefit from separate pre-operative and recovery space, which keeps children and adults apart. Doing so is more calming to children, and allows for more parent-child interaction before and after the surgical case.

Many facilities performing a significant number of pediatric surgical cases utilize Child Life Specialists as part of their pre-operative and post-operative regimens. These specialists, who are typically graduate-level trained in social work and/or psychology, work with children and their families during pre-op time to help alleviate fears about their pending surgery, and in recovery to assist patients and their families in coping with pain, effects of anesthesia, etc.

Operating Room Size

To accommodate a higher number of staff needed to perform the surgical case, including the surgeon, nurses, surgical techs and anesthesiologist, as well as respiratory therapist,

¹⁰ Keenan, RL, Shapiro JH, Dawson K, "Frequency of anesthetic cardiac arrests in infants: effect of pediatric anesthesiologists", *Journal of Clinical Anesthesia*, (1991) 3:433-437.

¹¹ Kain ZN, Fasulo A, Rimar S, "Establishment of a Pediatric Surgery Center: Increasing Anesthetic Efficiency", *Journal of Clinical Anesthesia*, (1999) 11:540-544.

neonatologist, and pediatric intensivist, dedicated pediatric operating rooms are typically sized larger than standard operating rooms. Generally, a dedicated pediatric operating room is at least 600 square feet, and may be as large as 750 square feet.

Definition and References in State Regulatory Documents

The Certificate of Need Statute, contained in N.C.G.S. §§ 131E-175-190, does not contain any definitions or provisions for pediatric operating rooms.

The “Criteria and Standards for Surgical Services and Operating Rooms”, found in 10A NCAC 14C .2100 *et seq.*, do not define pediatric operating rooms or pediatric specialties.

The “Rules for Licensing of Hospitals”, contained in 10A NCAC 13B .3000 *et seq.*, are silent regarding adult and pediatric surgery, and do not provide any facility requirements for pediatric surgical services.

Need for Highly Specialized Support Services

High volume pediatric surgery programs require highly-specialized staffing and support services, and is typically found only in large, tertiary medical centers where there is sufficient demand, and where a critical mass of specialty services can be coordinated. To ensure that quality is maintained, pediatric services require support and/or consultation from a number of specialized ancillary and support services, including, but not limited to:

- Pediatric surgeons, such as:
 - pediatric general surgery;
 - pediatric otolaryngology;
 - pediatric ophthalmology;
 - pediatric urology;
 - pediatric orthopedic surgery;
 - pediatric neurological surgery;
 - pediatric plastic surgery;
- Pediatric intensivists;
- Pediatric anesthesiologists;
- General pediatricians;
- Pediatric staff nurses;
- Respiratory therapists;
- Cardiopulmonary services;
- Clinical pharmacists;
- Child life specialists; and
- Clinical dietitians.

In addition to routine general surgery, pediatric surgeons perform very complex cases, including cardiac, thoracic, urological, orthopaedic, gastrointestinal, and neurosurgical procedures. Moreover, these cases may be performed on neonates and infants, as well as children through adolescence. The pediatric age range, from birth through age 17, along with the associated range of clinical specialization, makes pediatric surgery a challenging and growing field that is not easily categorized. Innovations in medical science now allow premature and/or very low birthweight newborns (as young as 23 weeks gestation and/or under 600 grams), who only rarely survived a decade ago, to survive and thrive with the help of advanced neonatal care and newly developed surgical procedures. New laparoscopic instrumentation and techniques allow for procedures that were not possible until recently.

Disadvantage of Proposing Dedicated Pediatric Operating Rooms in Competitive Reviews

In certificate of need reviews, surgical operating room allocations tend to be highly competitive. In competitive reviews of surgical operating rooms, the specialized nature of pediatric operating rooms, coupled with the specific population they serve, as well as their higher charges and costs relative to other forms of surgical ORs, put prospective applicants for this service at a disadvantage. Generally, the CON Section is predisposed to award surgical operating rooms to applicants who propose the least costly alternative, and who propose to serve the greatest number of patients.

Pediatric patients, including neonates and young infants, are often subject to lengthy inpatient stays, which generate significantly higher total charges than general medical/surgical patients. In a competitive review with proposals for shared or dedicated ambulatory surgery ORs, dedicated pediatric operating room applications would likely appear considerably more expensive, and would appear to serve a very limited patient population. For these reasons, applying for dedicated pediatric operating rooms in a normal SMFP review cycle would likely result in disapproval.

DATA SUPPORTING NEED FOR DEDICATED PEDIATRIC OPERATING ROOMS IN WAKE COUNTY

Population Growth in Wake County

Based on current estimates, Wake County became North Carolina's most populous county in 2010¹². The N.C. State Demographer's Office estimates that 920,307 people reside in Wake County in 2010. This total population is projected to increase to 1,058,779 residents by 2015¹³, an increase of 15.1 percent. By comparison, the State's total population is projected to grow by 7.2 percent during the same time period.

¹² Ehlers, Matt and Jim Morrill, "It's Wake's turn as state population king", Raleigh (N.C.) *News & Observer*, July 18, 2010, accessed at <http://www.newsobserver.com/2010/07/18/586491/its-wakes-turn-as-population-king.html#storylink=misearch>

¹³ Source: North Carolina Office of State Budget and Management, State Demographer's Office, Projected Annual County Population Totals, 2010-2019, May 4, 2010 release.

Wake County's 0-17 population, estimated at 224,540 in 2010, is projected to grow to 254,561 by 2015¹⁴, an increase of 13.4 percent. According to the State Demographer's Office, Wake County will surpass Mecklenburg as most populous for population ages 0-17 as early as 2014.

Pediatric Surgical Case Volumes in Wake County

Data from Thomson Reuters indicates that the volume of pediatric surgical cases is growing in Wake County, as evidenced in the following table:

Table 2 Surgical Cases, Wake County Residents, Ages 0-17, Regardless of Facility FYs 2005-2009 Source: North Carolina Patient Data System/Thomson Reuters Note: Counts DRGs in 2005-2007, and MS-DRGs in 2008-2009							
Type of Surgery	2005	2006	2007	2008	2009	Percent Change 2005-09	CAGR, 2005-09
Inpatient Cases	840	952	1,076	1,096	1,047	24.6%	5.66%
Outpatient Cases	5,827	6,281	6,969	7,774	7,743	32.9%	7.37%
Total	6,667	7,233	8,045	8,870	8,790	31.8%	7.16%

During the period 2005-2009, total pediatric surgical volume for Wake County residents increased by nearly one-third, with an annual growth rate of over 7 percent. Inpatient case volume alone increased by approximately 25 percent from 2005-2009. This clearly demonstrates that demand for pediatric surgery in Wake County is strong, and should continue to grow.

Adverse Effects of Denying or Delaying Petition

Should this Petition be denied, WakeMed believes that the consequences could be significant for Wake County. With Wake County's population expected to continue to grow at a high rate, and overall utilization of pediatric surgery on the rise, demand for pediatric surgery is expected to grow. Surgical services at Wake County facilities are already highly utilized, with utilization of ORs in operation at 96 percent in 2009 (please see Table 3 below); applications for operating room need determinations are very competitive. As demand for pediatric services continues to grow, larger proportions of patients will be forced to seek care in out-of-county facilities, particularly at academic medical centers with sufficient economies of scale to provide this service.

¹⁴ Source: North Carolina Office of State Budget and Management, State Demographer's Office, Projected County Totals by Age, May 3, 2010 release.

Table 3 2009 Utilization of Wake County Surgical Facilities Source: 2010 License Renewal Applications/Proposed 2011 State Medical Facilities Plan									
column:	A	B	C	D	E	F	G	H	I
Facility	Inpt. Cases (excl. C-sections)	Est. Inpt. Hours (Col.A x 3)	Outpt. Cases	Est. Outpt. Hours (Col.C x 1.5)	Total Cases (Col.A + Col.B)	Est. Total Hours (Col.B + Col.D)	Total ORs Needed (Col.F ÷ 1872)	Current OR Inventory (excl. C-section rooms and excl. for Trauma/ Burn)	Percent Util. (Col.G ÷ Col.H)
Existing ORs in Operation:									
Blue Ridge Surgery Center	0	0	5,904	8,856	5,904	8,856	4.73	6	79%
Duke Raleigh Hospital	3,004	9,012	10,817	16,226	13,821	25,238	13.48	13	104%
Raleigh Plastic Surgery Center	0	0	276	414	276	414	0.22	1	22%
Raleigh Women's Health Org.	0	0	2,170	3,255	2,170	3,255	1.74	2	87%
Rex Hospital (incl. Rex-Wakefield & Rex-Cary) ^a	8,799	26,397	24,567	36,851	33,366	63,248	33.79	31	109%
Rex Surgery Center of Cary	0	0	0	0	0	0	0.00	0	
Southern Eye Associates	0	0	515	773	515	773	0.41	2	21%
WakeMed Cary Hospital	1,947	5,841	7,273	10,910	9,220	16,751	8.95	9	99%
WakeMed Raleigh Campus (incl. WakeMed North) ^b	7,839	23,517	13,177	19,766	21,016	43,283	23.12	26	89%
Total Utilization for ORs in Operation	21,589	64,767	64,699	97,049	86,288	161,816	86.44	90	96%
Approved/Under Development:									
Orthopaedic Surgery Center of Raleigh ^c	0	0	0	0	0	0	0.00	4	NA
Rex Macon Pond Surgery Center	0	0	0	0	0	0	0.00	4	NA
WakeMed Raleigh Surgery Center ^{c,d}	0	0	0	0	0	0	0.00	4	NA
NOTES:									
^a Includes 4 ORs slated for relocation to Rex-Macon Pond (under development)									
^b Includes 4 shared ORs that will be relocated to WakeMed Raleigh Surgery Center (under development).									
^c Facility approved but not yet operational.									
^d Will open with 8 ORs, including 4 ORs relocated from WakeMed Raleigh Campus.									

Alternatives to This Proposal

In its consideration of this Petition, WakeMed contemplated several alternatives, which are discussed below.

Status Quo

WakeMed has considered no action should this Petition be denied, in which case no dedicated pediatric surgical operating rooms would be made available to the residents of Wake County. Should this be the case, pediatric patients would have no access to specialized facilities for surgical services.

Develop Dedicated Pediatric Operating Rooms Through SMFP General Operating Room Methodology

WakeMed considered proposing dedicated pediatric surgical operating rooms in a certificate of need application for operating rooms allocated in the annual SMFP. However, such a proposal would be at a significant disadvantage in a competitive review. Pediatrics is not a distinct surgical specialty, does not generate volume equal to that of adult cases, and requires a great deal of specialized support services. Given the Agency's penchant for awarding operating rooms to the least costly alternative or the applicant who proposes to serve the greatest number of patients, a CON application for dedicated pediatric operating rooms would be at a competitive disadvantage, particularly against freestanding ambulatory surgical facilities.

Convert Existing or Approved Operating Rooms to Dedicated Pediatric Use

The WakeMed system is approved to operate 46 surgical operating rooms, not counting dedicated C-section rooms. However, due to pressing capacity constraints at its Raleigh and Cary inpatient facilities, and rising demand for ambulatory surgery, none of these ORs are allocated to pediatric surgery. Information provided in its annual Hospital License Renewal applications indicates that WakeMed's existing ORs are highly utilized, particularly at WakeMed Cary and WakeMed Raleigh Campus, home of the system's centralized pediatric services, including pediatric med/surg beds, pediatric ICU, and pediatric emergency department. WakeMed is currently developing a dedicated ambulatory surgery center adjacent to its Raleigh Campus. Projections indicate that these ORs will exceed their utilization projections within three years of opening. Converting existing or approved operating rooms to dedicated pediatric use would prevent their full utilization. Moreover, to gain maximum utility, pediatric surgical procedures should be performed in shared inpatient/outpatient rooms.

No Evidence of Unnecessary Duplication of Services

Providers of surgical services in Wake County are well-utilized, and additional ORs dedicated to pediatric surgery would not duplicate existing services. No facilities in the area have dedicated pediatric operating rooms.

Summary

Based on the information provided in this Petition, WakeMed respectfully requests that the State Health Coordinating Council grant a special need determination of four dedicated pediatric operating rooms in Wake County for inclusion in the 2011 State Medical Facilities Plan. Doing so will ensure that an adequate supply of dedicated pediatric surgical services will be in place to meet growing demand within Wake County, and that these services are provided in the most appropriate setting for children.

Because of the limited patient population and unique circumstances of these operating rooms, WakeMed further requests that these operating rooms be excluded from the general Operating Room Inventory in Chapter 6 of the SMFP.