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Petition to the State Health Coordinating Council
Requesting Special Need Determination for Dedicated Pediatric Operating Rooms
for Wake County in the 2013 State Medical Facilities Plan
August 1, 2012

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Statement of Requested Adjustment

WakeMed hereby petitions the State Health Coordinating Council (SHCC), requesting a special need determination for two (2) dedicated pediatric surgical operating rooms for the Wake County Service Area in Chapter 6 of the 2013 State Medical Facilities Plan (SMFP).

Reasons for Requested Adjustment

WakeMed requests an adjustment to the Operating Room Need Methodology in Chapter 6 of the 2013 SMFP, due to a growing demand for pediatric surgical services in Wake County. Currently, there is no provision in the SMFP for pediatric surgery, nor are any surgical operating rooms in Wake County or in North Carolina dedicated to pediatric surgery.

Current Standard Operating Room Need Methodology

The current standard need methodology for operating rooms, contained in Chapter 6 of the 2012 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 on page 8 of the annual Hospital License Renewal Applications (LRAs):

- Dedicated Open Heart Surgery;
- Dedicated C-Section (included in OR inventory, but excluded from need methodology);
- Other Dedicated Inpatient;
- Dedicated Ambulatory Surgery; and
- Shared Inpatient/Outpatient.

When a need is generated and an 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 in relation to the need in the service area. Surgical specialties to be provided in the new operating rooms 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 operating rooms.

Occasionally, the SHCC approves an allocation for specialty operating rooms, the most recent examples being the inclusion of three separate need determinations for a total of six single-specialty operating rooms in the 2010 SMFP.

Background

WakeMed 2010 Petition to the SHCC

In August 2010, WakeMed filed a petition to the SHCC requesting a special need determination for four dedicated pediatric operating rooms for Wake County, which would be included in the 2011 SMFP. The Agency Report of the petition noted that "...there is no comparable data included about pediatric population growth in other counties, or volume differences between pediatric and adult surgical cases in Wake or other counties." Further, the narrative states: "...the standard methodology resulting in two recent need determinations for Wake County, indicating that the methodology is responsive to increases in population and surgery case volumes with OR service areas." Based on this information, the petition was denied.

Pediatric Operating Room Work Group

In late 2010, the SHCC appointed a Work Group to study the provision of pediatric surgery in North Carolina, to examine the differences between pediatric and adult surgery, and to recommend potential changes in need methodology and/or reporting methods. The Work Group, which was staffed by SHCC members and pediatric physicians from throughout the state, had its first meeting on January 25, 2011, and met several times during 2011. The charge to the Work Group was as follows:

> *To investigate and develop recommendations about the need for the standard Operating Room Methodology to include a determination of need for dedicated pediatric operating rooms in the State Medical Facilities Plan.*

The Pediatric Operating Room Work Group set out to consider the implications of revising the operating room need methodology, data collection, the effect on overall need, flexibility and implications for ambulatory surgery centers. An overarching question addressed by the Work Group was: Do pediatric operating rooms fit into the standard Operating Room Need Methodology? Work Group members acknowledged that the standard Methodology does not address special populations.

The Chairman of the Work Group, Dr. Dennis Clements, presented a position paper at the Work Group's September 2, 2011 meeting which stated, in part:

1 - *We should allocate ORs for pediatric patients for safety reasons outside the usual CON for centers that do frequent and complex pediatric surgeries. The number of rooms required should be allocated on the number of total cases performed in a year. They should not be deducted from the hospital case load of the hospital.*
2 - *Better data collection should be initiated to document the number and type of pediatric OR cases that are being performed so that a revision of the OR need methodology can be made more precise in the future.*

The final report of the Pediatric Operating Room Work Group, dated September 9, 2011, stated that "Children should be operated on in operating rooms designed and equipped for children – including anesthesia and surgical equipment." Further, the report stated that "...children should have separate operating rooms, equipped for them and staff for them and rooms as contiguous as possible if multiple operations are being covered by one anesthesiologist." Please see Attachment 1.

The Work Group recommended that:

1) *There is a need to change the operating standard methodology to consider calculating need using a difference multiplier (1.125) for pediatric operating rooms;*

2) *This calculation means that all pediatric surgeries (except for circumcisions) be weighted 12.5% more than adult surgeries.*

3) *Pediatric patients for this chapter [Chapter 6 of the SMFP] will be defined as patients <18 years of age.*

The Work Group concluded that there may be special situations where providers could petition the SHCC for a special need determination for pediatric operating rooms. This Petition is responsive to that recommendation.

Trends in Pediatric Surgery

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. 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.[1]

The development of dedicated pediatric operating rooms is a growing trend across the nation. In May 2012, Johns Hopkins Hospital in Baltimore opened the Bloomberg Children's Center, a state-of-the-art facility that includes 10 dedicated pediatric operating rooms to accommodate a wide range of surgical specialties.

Pediatric Operating Rooms as a Component of Family-Centered Care

Family-centered care has moved into the mainstream in recent decades, in recognition of the importance of meeting the psychosocial and developmental needs of children and of the role of families in promoting the health and well-being of their children.[2] The American Academy of Pediatrics' Committee on Hospital Care released a policy statement in 2003 that outlines the benefits of family-centered care and provided specific recommendations for pediatricians to incorporate family-centered care into practice, including the following:

> *Parents and guardians should be offered the option to be present with their child during medical procedures and offered support before, during and after the procedure.*
>
> And,
>
> *Health care institutions should design their facilities to promote the philosophy of family-centered care. Pediatricians should advocate for opportunities for children and families to participate in design planning for renovation or construction of hospitals, clinics, and office-based practices.*[3]

Specially-designed pediatric operating rooms can be constructed to allow parents to come into the operating room, with their child, during the induction of anesthesia. Such actions are considered to epitomize family-centered care in surgery. At the American Family Children's Hospital in Madison, Wisconsin, the Pediatric Surgical Pavilion allows parents and siblings to be involved with the patient's care to reduce the stress associated with hospital care. Parents can accompany the child to the operating room where they can stay and comfort the child at the start of sedation. After surgery, children are brought to the Post Anesthesia Care Unit, where parents can join their children as they awaken.[4]

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

[2] American Academy of Pediatrics, Task Force on the Family. Family pediatrics, *Pediatrics*, 2003;111(suppl);1539-1587.

[3] American Academy of Pediatrics, Committee on Hospital Care, Institute for Family-Centered Care, Policy Statement: Family-Centered Care and the Pediatrician's Role, *Pediatrics*, 2003;112;691-696.

[4] "Children's Hospital Opens New Operating Rooms", accessed via internet at: http://www.uwhealth.org/news/childrens-hospital-opens-new-operating-rooms/13828.

Recently, UNC Hospitals filed a certificate of need application (Project No. J-8841-12) to expand the number of pre-op and post-op bays as well as the number and size of sedation rooms in its Children's Surgery and Sedation Center. Upon completion, UNC notes that "[t]he result will be a space that will allow staff to provide a better experience for the children and their families."

Pediatrics Refers to a Patient Population, Not a Distinct Surgical Specialty

As WakeMed noted in its previous petition, children have a unique set of diseases and conditions, as well as different social and emotional needs, than do adults. Hospitalized children have been removed from their normal worlds of home, school and play. Support and involvement of family members in the hospital partially mitigates this separation.[5] Thus, the optimal design of health facilities to serve children should incorporate features that address children's physiological and psychological differences.

Pediatrics is not a surgical specialty *per se*, but rather a unique patient population, 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 Collect of Chest Physicians. "Pediatric Surgery" is a catch-all term that encompasses the full range of pediatric surgical specialties, regardless of body type.

Pediatric Surgery is Different from 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.

<u>Operating Room Temperature and Environment</u>

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

[5] Coucil, Annie, and Sheila F. Cahnman, "Kids' stuff: Features and factors driving children's hospital design", *Health Facilities Management*, June 2004, p. 38.

set higher, as high as 85 degrees[6], as opposed to 65-68°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.

Temperatures in surgical suites can be modified, although the time required to warm an operating room by 20 degrees may be significant; likewise, cooling an OR for a following adult case may also be time-consuming and impact OR turnaround time and the OR schedule. In a busy surgery center, this negatively affects patient throughput and may delay response to an emergency case. In addition, the rapid temperature change, combined with associated changes in humidity, can create condensation on ceiling and fixtures that is highly undesirable[7].

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. Given that pediatric patients range from tiny neonates to full-grown adolescents, one size of equipment does not fit all, and the array of equipment sizes requires significant storage space.

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 reducing the incidence of nosocomial, or health care-associated, infections, such as MRSA and VRE. Surgical site

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[6] Phillips, Nancymarie, *Berry and Kohn's Operating Room Technique, Tenth Edition*, 2004, Mosby, page 123.

[7] Nunnally, R. Mark, "Rain out – Getting operating room humidity under control" *HFM Magazine*, September 2007.

[8] Phillips, Nancymarie, *Berry and Kohn's Operating Room Technique, Tenth Edition*, 2004, Mosby, page 134.

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

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.

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 anesthetic drugs, 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]

Clinical research indicates that pediatric operating rooms staffed exclusively by pediatric anesthesiologists can have a positive impact on induction time. A study conducted by Yale University demonstrated that the average length of induction decreased by 30 percent, and the length of emergence from anesthesia decreased by 42 percent. The Yale study also concluded that the establishment of dedicated pediatric ORs also decreased the variability of anesthesia-controlled time, which may allow for better scheduling of surgical cases.[11]

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.

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.

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[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 Nov;11(7):540-4.

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, 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.

Need for Highly Specialized Support Services

While surgical cases are performed on pediatric patients at most North Carolina hospitals, only a handful of facilities have the depth and breadth of specialized support services required to perform complex surgical procedures, such as pectus deformity repair (chest wall reconstruction), esophagectomy (removal of all or part of the esophagus), and colectomy (remove all or part of the large intestine). Generally, procedures of this nature are performed in hospitals that offer trauma services, Level IV neonatal services, pediatric intensive care units, as well as pediatric surgeons, anesthesiologists and intensivists.

Number of Pediatric General Surgeons in North Carolina

The number of physicians in North Carolina who specialize in pediatric surgery is relatively small. According to the North Carolina Medical Board, a total of 28 pediatric surgeons currently practice in the state; most of these physicians are based in urban counties where large tertiary medical centers are located, such as Mecklenburg, Forsyth, Durham, Orange, and Wake Counties. Please see Attachment 2.

Disadvantage of Proposing Dedicated Pediatric Operating Rooms in Competitive CON Review Cycles

Certificate of need reviews for surgical operating rooms allocated to a service area through the annual SMFP tend to be highly competitive. In competitive review of surgical operating rooms, the specialized nature of pediatric surgery, coupled with the population they serve, as well as their higher charges and costs relative to other forms of surgical services, 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 surgery fits neither of these categories.

Pediatric patients, including neonates and young infants, are often subject to lengthy inpatient stays, which generate significantly higher total patient charges than general medical/surgical patients. In a competitive review cycle with proposals for shared or dedicated ambulatory surgical operating rooms, an applicant proposing dedicated pediatric operating rooms 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 most likely result in disapproval.

Data Supporting the Need for Dedicated Pediatric Operating Rooms in Wake County

Total Population Growth in Wake County

According to estimates from the North Carolina Office of State Budget and Management (OSBM), Wake County is home to 945,209 residents in 2012. By 2017, Wake County's total population is projected to be 1,041,571, an increase of 10.2 percent.[12]

Pediatric Population Growth in Wake County

OSBM estimates that in 2012, the population ages 0-17 in Wake County is 241,448, or approximately 25.5 percent of the total population. By 2017, this age group is projected to have a population of 259,542, an increase of 7.5 percent.[13] For perspective, the projected 2017 pediatric population in Wake County will be *greater* than the total projected population in 93 of North Carolina's 100 counties.[14]

Pediatric Surgical Cases Originating in Wake County

Information reported in the annual License Renewal Applications submitted by hospitals and ambulatory surgery centers to DHSR each year do not distinguish between adult and pediatric surgery. Currently, the best source of pediatric surgery data is Thomson Reuters' inpatient and outpatient databases. Because each patient record contains an Age field, analyses may be performed to differentiate adult and pediatric surgery.

According to data from Thomson Reuters, a total of 73,517 surgical cases were performed statewide on persons ages 0-17 in FY 2011. Of this, 7,970 cases, or approximately 11 percent of total, were performed on Wake County residents. Wake County comprised the highest proportions of pediatric surgery cases statewide in FYs 2009-2011. Please see Attachment 3.

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[12] Source: North Carolina Office of State Budget and Management, Annual County Population Totals, 2010-2019, May 8, 2012 release date, accessed at: http://www.osbm.state.nc.us/ncosbm/facts_and_figures/socioeconomic_data/population_estimates/demog/countytotals_2010_2019.html.

[13] Source: North Carolina Office of State Budget and Management, Projected County Totals – Standard Age Groups, May 8,2012 release date, accessed at: http://www.osbm.state.nc.us/demog/prsage.html.

[14] *Ibid.*

Table 1 Inpatient and Outpatient Surgery Cases Originating in Wake County Patients Age 0-17, 2009-2011 Source: Thomson Reuters						
Type of Surgery	**2009 Cases**	**2009 Percent of Total Cases**	**2010 Cases**	**2010 Percent of Total Cases**	**2011 Cases**	**2011 Percent of Total Cases**
Inpatient	1,120	13.5%	1,117	13.2%	1,096	13.8%
Outpatient	7,154	86.5%	7,331	86.8%	6,874	86.2%
Total	8,274	100.0%	8,448	100.0%	7,970	100.0%

While the proportion of pediatric surgery cases originating in Wake County is skewed heavily toward outpatients, the volume of inpatient surgical cases alone is sufficiently high that, when the standard Operating Room Need Methodology is applied, the result shows a need for 2 operating rooms. Please see the table below.

Table 2 Operating Room Need Based on Inpatient Pediatric Surgical Cases Originating in Wake County, 2009-2011				
Year	**Inpatient Cases**	**Inpatient Hours** (Cases x 3.0)	**ORs Needed** (Hours divided by 1872)	**ORs Needed – Rounded**[15]
2009	1,120	3,360	1.79	2
2010	1,117	3,351	1.79	2
2011	1,096	3,288	1.76	2

Table 3 uses the same pediatric case volumes at Table 2, but uses the recommendation of the Operating Room Work Group to "weight" the pediatric cases 12.5 percent higher than adult cases. The results further justify the need for 2 pediatric operating rooms.

[15] Per the standard Operating Room Need Methodology, fractions of 0.5 or greater are rounded to the next whole number.

Table 3 Operating Room Need Based on Inpatient Pediatric Surgical Cases Originating in Wake County, 2009-2011 Cases Weighted Based on Recommendations of Pediatric Operating Room Work Group					
Year	**Inpatient Cases**	**Weighted Cases** (Inpatient Cases x 12.5%)[16]	**Inpatient Hours** (Weighted Cases x 3.0)	**ORs Needed** (Hours divided by 1872)	**ORs Needed – Rounded**
2009	1,120	1,260	3,780	2.02	2
2010	1,117	1,257	3,771	2.01	2
2011	1,096	1,233	3,699	1.98	2

Based on the calculations in Tables 2 and 3, Wake County pediatric surgery cases alone show a need for 2 operating rooms.

Utilization of Surgical Operating Rooms in Wake County

Most of Wake County's existing surgical operating rooms are very well utilized, with little or no excess capacity as defined by the State. Data provided in the Proposed 2013 SMFP shows that Wake County surgical providers were utilized at 94.3 percent overall. Providers of shared operating rooms, which can be used to perform both inpatient and outpatient surgery, were utilized at 100.6 percent. Existing providers of shared operating rooms do not have sufficient OR capacity to devote to dedicated pediatric operating rooms. Please see the table below.

[16] Calculation: Cases x (1 + 0.125) = Weighted cases.

Table 4 Wake County Surgical Providers 2011 Surgical Operating Room Utilization Rates Source: Proposed 2013 State Medical Facilities Plan							
Provider	**Inpatient Cases**	**Outpatient Cases**	**Total Cases**	**Total Surgical Hours***	**Adjusted ORs****	**Threshold Utilization (hrs) - No. ORs x 1872**	**2011 Percent Utilization**
Hospital-Based Shared --							
Duke Raleigh Hospital	3,750	11,877	15,627	29,066	13	24,336	119.4%
Rex Hospital	6,564	22,410	28,974	53,307	27	50,544	105.5%
WakeMed Cary Hospital	1,961	6,145	8,106	15,101	9	16,848	89.6%
WakeMed Raleigh Campus	7,788	12,389	20,177	41,948	25	46,800	89.6%
Total Hospital-Based Shared	20,063	52,821	72,884	139,422	74	138,528	**100.6%**
Freestanding Ambulatory --							
Blue Ridge Surgery Center	0	6,935	6,935	10,403	6	11,232	92.6%
Raleigh Plastic Surgery Center	0	220	220	330	1	1,872	17.6%
Rex Surgery Center of Cary	0	1,821	1,821	2,732	4	7,488	36.5%
Southern Eye Assoc. Ophthalmic Surg. Ctr.	0	463	463	695	2	3,744	18.6%
Total Freestanding Ambulatory	0	9,439	9,439	14,159	13	24,336	**58.2%**
Total	**20,063**	**62,260**	**82,323**	**153,579**	**87**	**162,864**	**94.3%**
* - Based on SMFP standard of 3.0 hours per inpatient case and 1.5 hours per outpatient case. ** - Excludes dedicated C-section rooms and one room for each Level I or II trauma center.							

Definitions 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, references 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.

Adverse Effects of Denying or Delaying Petition

Should this Petition be denied, WakeMed believes that the long-term consequences could be significant for Wake County. With Wake County's total and pediatric populations projected 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 operating rooms at Wake County facilities

are already highly utilized, with utilization of shared operating rooms in service at 100.6 percent in 2011 (please see Table 4 above). 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, including academic medical centers with sufficient economies of scale to provide this service.

Alternatives to This Proposal

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

Status Quo

WakeMed has considered taking no action should this Petition be denied, in which 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 within their home county, located in one of the fastest-growing areas in the nation.

Develop Dedicated Pediatric Operating Rooms Through SMFP Standard Operating Room Methodology

WakeMed considered proposing dedicated pediatric surgical operating rooms in a certificate of need application for operating rooms allocated through the standard Operating Room Need Methodology in the annual SMFP. However, no allocation of operating rooms was made to Wake County in the 2012 SMFP, and the Proposed 2013 SMFP indicates that no operating rooms will be allocated next year.

Even if operating rooms were allocated to Wake County, a certificate of need proposal for dedicated pediatric surgical operating rooms would be at a significant disadvantage in a competitive review. Pediatrics is not a distinct surgical specialty, such as orthopaedic surgery or urological surgery, and does not generate case volume equal to that of adult cases. Further, pediatric surgery requires a great deal of specialized support services to be offered in a safe, effective manner. Given the Agency's inclination for awarding operating rooms to the least costly alternative or to the applicant who proposes to serve the greatest number of patients, a CON application for dedicated pediatric surgical operating rooms would be at a distinct competitive *disadvantage*, particularly when pitted against providers of freestanding ambulatory surgery.

No Evidence of 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 Wake County have dedicated pediatric operating rooms.

Summary

Based on information provided in this Petition, WakeMed respectfully requests that the SHCC grant a special need determination of two (2) dedicated pediatric operating rooms to the Wake County Service Area for inclusion in the 2013 SMFP. Doing so will ensure that an adequate supply of 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.

Attachment 1

State of North Carolina
State Health Coordinating Council
Department of Health and Human Services • Division of Health Service Regulation
2714 Mail Service Center • Raleigh, North Carolina 27699-2714
Tel 919-855-3865 • Fax 919-715-4413

Beverly Eaves Perdue, Governor | William Wainwright, Chairman | Dennis Clements, Pediatric Operating Room Work Group

September 9, 2011

Colleagues,

Representative Wainwright has asked us to consider the NEED for the operating room standard methodology to be changed to determine pediatric operating rooms separately from adult ORs. And while doing that to consider:

1- changes in surgery cases data collection and tracking of OR use that would be needed,
2- a need to therefore reduce operating rooms of other types,
3- degree of flexibility to use the rooms if not otherwise being used, and
4- implications for ambulatory surgery centers.

Facts for consideration:

1) Children should be operated on in operating rooms designed and equipped for children – including anesthesia and surgical equipment. Children, particularly young children need different sized equipment for airway management, catheterization, IVs etc and it must be at hand at all times. OR temperatures also may need to be adjusted for maximum safety.

2) It is also apparent that pediatric surgical rooms need to be clustered as one pediatric anesthesiologist may be covering more than one room and not all anesthesiologists are comfortable or competent with children so rooms need to be as close together as possible to assure safety of airway management.

3) Children – particularly young children - need a longer time for induction of anesthesia – generally their parents are with the children during this time. And they need a space in which this can be performed. In addition, there is data that supports a small incremental time increase required to perform procedures on children – at least for some procedures.

4) Children – particularly less than 2 years of age – must go first in the morning to the OR – they are kept NPO overnight and because of their body mass to surface area ratios they become dehydrated quickly and can also become hypoglycemic.

All of these points suggest that from a clinician's safety perspective - children should have separate operating rooms, equipped for them and staffed for them and rooms as contiguous as possible if multiple operations are being covered by one anesthesiologist.

Constraints considered in changing the methodology:

1) The purpose of the SHCC driving the SMFP and the CON process is to match healthcare capital expenditures to community need, regardless of individual institutional need, and thereby eliminate excess capacity and runaway healthcare costs.

2) Exemptions to the plan, or exceptions to the needs methodology, should be few and far between, because it undermines the validity of the model, the intent of the process and it sets precedence. Where exemptions or exceptions are granted within the plan, great care must be taken to justify why such a change is needed.

3) Some Hospitals in the State have already segregated pediatric surgery without benefit of a change in O.R. needs methodology for pediatric patients.

4) Individual institutional need driven exceptions and desires can be addressed through petitions to the SHCC, through a process that is already in place.

Considering these points and counter-points, the Pediatric OR Work Group recommends the following for the 2013 N.C. SMFP:

1) There is a need to change the operating standard methodology to consider calculating need using a different multiplier (1.125) for pediatric operating rooms,

2) This calculation means that all pediatric surgeries (except for circumcisions) be weighted 12.5% more than adult surgeries.

3) Pediatric patients for this chapter will be defined as patients <18 years of age.

Rationale:

This is an imperfect resolution to a real problem. Pediatric Surgery rooms need to be designated, staffed and equipped specifically for children. Many centers now do a significant number of pediatric surgeries (see attached). There is no mechanism within the SMFP to require designating certain ORs as pediatric although many centers have already done so. Although the methodology is designed to project need for "generic" operating rooms, it is our recommendation that need determinations which result from the additional "weighting" of pediatric cases should be used to develop designated pediatric operating rooms.

It is also recommended that data (time and type of operation) begin to be collected separately for operations on children less than 18 so that in 3-5 years this methodology can be refined and made more precise for a future SMFP.

Best Regards,

Dennis Clements, III, MD

Attachment

cc: Drexdal Pratt, Director, DHSR

Pediatric Inpatient Surgical Cases (without Circumcision)

Sorted by Volume of Pediatric Cases

County	Hospital	Total Inpt	Ped Inpt	Ped Inpt %
Orange	UNC Hospitals	11,258	1,927	17.1%
Mecklenburg	Carolina Medical Center	16,750	1,811	10.8%
Durham	Duke University Hospital	16,069	1,718	10.7%
Forsyth	North Carolina Baptist Hospitals	12,862	1,403	10.9%
Wake	WakeMed Raleigh	10,966	664	6.1%
Mecklenburg	Presbyterian Hospital	7,579	387	5.1%
Buncombe	Mission Hospitals	14,352	374	2.6%
Pitt	Pitt County Memorial Hospital	11,631	370	3.2%
Cabarrus	Carolinas Medical Center - NorthEast	5,567	241	4.3%
Cumberland	Cape Fear Valley Medical Center	6,962	230	3.3%
New Hanover	New Hanover Regional Medical Center	11,200	187	1.7%
Guilford	Moses Cone Health System	13,624	154	1.1%
Robeson	Southeastern Regional Medical Center	1,951	84	4.3%
Wayne	Wayne Memorial Hospital	2,630	79	3.0%
Wake	Rex Hospital	8,171	78	1.0%
Forsyth	Forsyth Medical Center	9,766	78	0.8%
Moore	FirstHealth Moore Regional Hospital	7,212	72	1.0%
Sampson	Sampson Regional Medical Center	624	72	11.5%
Randolph	Randolph Hospital	1,104	64	5.8%
Guilford	High Point Regional Health System	4,523	57	1.3%
Gaston	Gaston Memorial Hospital	4,353	57	1.3%
Wake	Duke Health Raleigh Hospital	3,222	53	1.6%
Catawba	Catawba Valley Medical Center	2,355	51	2.2%
Union	Carolinas Medical Center - Union	1,596	50	3.1%
Onslow	Onslow Memorial Hospital	928	50	5.4%
Wilson	Wilson Medical Center	2,000	46	2.3%
Scotland	Scotland Memorial Hospital	928	42	4.5%
Lenoir	Lenoir Memorial Hospital	1,503	42	2.8%
Burke	Grace Hospital	1,044	40	3.8%
Alamance	Alamance Regional Medical Center	2,246	40	1.8%
Nash	Nash General Hospital	2,261	39	1.7%
Harnett	Betsy Johnson Regional Hospital	753	36	4.8%
Craven	CarolinaEast Medical Center	3,841	36	0.9%
Johnston	Johnston Memorial Hospital	1,358	35	2.6%
Wilkes	Wilkes Regional Medical Center	632	31	4.9%
Columbus	Columbus Regional Healthcare System	1,177	31	2.6%
Iredell	Lake Norman Regional Medical Center	1,444	31	2.1%
Surry	Northern Hospital of Surry County	864	30	3.5%

Note: 2009 Thomson data (10/08 - 09/09) provided by The Cecil G. Sheps Center. Total surgical cases are listed for facilities that reported both adult and pediatric surgical cases.

9/1/2011

PEDIATRIC GENERAL SURGEONS IN NORTH CAROLINA - ACTIVE LICENSES ONLY

Source: North Carolina Medical Board, web site: http://www.ncmedboard.org/, accessed 7/30/2012

Physician Name	Primary Specialty	County	Practice Name	Board-Certified in Pediatric Surgery?
Adamson, William Talbot	Pediatric Surgery	Orange	UNC School of Medicine – Pediatric Surgery	yes
Adibe, Obinna Ogochukwu	Pediatric Surgery	Durham	Duke University Dept. of Surgery – Pediatric Surgery	no
Albert, Deborah Louise	Pediatric Surgery	New Hanover	NHRMC Physician Group	yes
Attorri, Robert Joseph	Pediatric Surgery	Mecklenburg	Pediatric Surgical Associates	yes
Bambini, Daniel Andrew	Pediatric Surgery	Mecklenburg	Pediatric Surgical Associates	yes
Cosper, Graham Harvey	Pediatric Surgery	Mecklenburg	Pediatric Surgical Associates	yes
Erickson, Kimberly McCrudden	Pediatric Surgery	Orange	UNC School of Medicine – Pediatric Surgery	yes
Farooqui, M. Schuaib	Pediatric Surgery	Guilford	M. Schuaib Farooqui, M.D.	no
Graham, Dwight David	Pediatric Surgery	Buncombe	Mission Children's Hospital	yes
Hoehner, Jeff Carl	Pediatric Surgery	Durham	Duke University Dept. of Surgery – Pediatric Surgery	yes
Hoover, John David	Pediatric Surgery	Wake	Wake Specialty Physicians	yes
Lee, Sang Il	Pediatric Surgery	Orange	UNC School of Medicine – Pediatric Surgery	no
Martin, Abigail Ellen	Pediatric Surgery	Durham	Duke University Dept. of Surgery – Pediatric Surgery	yes
McLean, Sean Edward	Pediatric Surgery	Orange	UNC School of Medicine – Pediatric Surgery	yes
Morton Jr., Duncan	Pediatric Surgery	Mecklenburg	Pediatric Surgical Associates	yes
Pendse, Prabhakar Damodar	Pediatric Surgery	New Hanover	University Physicians – SEAHEC	no
Petty, John Kenneth	Pediatric Surgery	Forsyth	WFUBMC Dept. of General Surgery	yes
Phillips, J. Duncan	Pediatric Surgery	Wake	Wake Specialty Physicians	yes
Pillai, Srikumar Biswanath	Pediatric Surgery	Cabarrus	Carolina Pediatric Surgery	yes
Pranikoff, Thomas	Pediatric Surgery	Forsyth	Wake Forest School of Medicine	yes
Rice, Henry Elliott	Pediatric Surgery	Durham	Duke University Medical Center	yes
Rodeberg, David Anthony	Pediatric Surgery	Pitt	ECU School of Medicine	yes
Schmelzer, Thomas Michael	Pediatric Surgery	Mecklenburg	Pediatric Surgical Associates	yes
Schulman, Andrew Mark	Pediatric Surgery	Mecklenburg	Pediatric Surgical Associates	yes
Turner, Charles Siewers	Pediatric Surgery	Forsyth	Wake Forest University Medical Center	yes
Wadie, George Michel	Pediatric Surgery	Wake	Wake Specialty Physicians	no
Wiener, Timothy Mowll	Pediatric Surgery	Orange	UNC School of Medicine – Pediatric Surgery	yes
Zeller, Kristin Anne	Pediatric Surgery	Forsyth	WFUBMC Dept. of General Surgery	yes

Attachment 2

Attachment 3

Surgical Cases by County of Origin, 2009-2011									
Patients Age 0-17									
Sorted by 2011 Total Cases									
Source: Thomson Reuters									
	2009			2010			2011		
County	Inpt. Cases	Outpt. Cases	Total Cases	Inpt. Cases	Outpt. Cases	Total Cases	Inpt. Cases	Outpt. Cases	Total Cases
Wake	1,120	7,154	8,274	1,117	7,331	8,448	1,096	6,874	7,970
Mecklenburg	955	6,303	7,258	956	6,605	7,561	983	6,407	7,390
Guilford	499	3,523	4,022	530	3,505	4,035	516	3,499	4,015
Forsyth	417	2,626	3,043	389	2,387	2,776	384	2,340	2,724
Cumberland	419	2,314	2,733	429	2,202	2,631	386	1,977	2,363
Union	250	1,985	2,235	223	1,984	2,207	226	1,968	2,194
Gaston	238	1,854	2,092	212	1,825	2,037	239	1,915	2,154
Cabarrus	245	1,824	2,069	193	1,814	2,007	214	1,799	2,013
Durham	322	1,515	1,837	292	1,485	1,777	324	1,328	1,652
Buncombe	213	1,327	1,540	250	1,348	1,598	234	1,355	1,589
Johnston	215	1,465	1,680	204	1,469	1,673	211	1,320	1,531
Iredell	168	1,329	1,497	172	1,400	1,572	158	1,369	1,527
Catawba	166	1,450	1,616	150	1,412	1,562	129	1,335	1,464
Pitt	176	1,254	1,430	174	1,206	1,380	180	1,242	1,422
Onslow	209	1,085	1,294	194	1,224	1,418	211	1,128	1,339
Robeson	241	1,225	1,466	243	1,068	1,311	236	1,079	1,315
Davidson	148	1,173	1,321	194	1,219	1,413	159	1,145	1,304
Alamance	197	925	1,122	175	1,266	1,441	144	1,018	1,162
Rowan	140	1,003	1,143	149	998	1,147	118	974	1,092
New Hanover	182	1,018	1,200	156	1,022	1,178	158	918	1,076
Randolph	177	900	1,077	199	999	1,198	160	910	1,070
Cleveland	142	854	996	129	880	1,009	128	838	966
Harnett	150	902	1,052	111	802	913	135	758	893
Lincoln	79	634	713	64	709	773	74	681	755
Craven	112	565	677	118	603	721	115	632	747
Wayne	165	713	878	157	586	743	142	579	721
Orange	121	672	793	124	676	800	99	611	710
Nash	114	729	843	110	659	769	97	583	680
Burke	130	680	810	90	653	743	82	594	676
Wilkes	87	652	739	72	552	624	82	580	662
Lee	94	561	655	109	606	715	106	554	660
Brunswick	124	649	773	94	626	720	96	559	655
Moore	99	612	711	87	638	725	85	567	652
Wilson	85	528	613	98	533	631	87	539	626
Caldwell	81	629	710	84	628	712	83	540	623
Stanly	81	602	683	50	583	633	50	570	620
Surry	84	621	705	103	523	626	104	504	608
Rockingham	97	594	691	111	580	691	87	514	601
Henderson	85	512	597	100	539	639	83	445	528
Lenoir	96	244	340	87	179	266	79	411	490
Franklin	63	412	475	65	418	483	55	414	469
Rutherford	47	452	499	72	371	443	72	381	453
Sampson	146	427	573	128	393	521	99	348	447
Beaufort	64	345	409	65	334	399	70	353	423

Surgical Cases by County of Origin, 2009-2011									
Patients Age 0-17									
Sorted by 2011 Total Cases									
Source: Thomson Reuters									
	2009			2010			2011		
County	Inpt. Cases	Outpt. Cases	Total Cases	Inpt. Cases	Outpt. Cases	Total Cases	Inpt. Cases	Outpt. Cases	Total Cases
Haywood	65	426	491	47	374	421	57	359	416
Columbus	78	389	467	74	393	467	68	339	407
Duplin	93	252	345	75	281	356	89	314	403
Richmond	93	317	410	71	315	386	77	323	400
Edgecombe	74	388	462	69	374	443	50	344	394
Carteret	53	326	379	55	287	342	51	329	380
Davie	42	395	437	35	354	389	30	337	367
Granville	58	359	417	48	324	372	44	319	363
Scotland	64	304	368	60	299	359	56	307	363
Stokes	38	389	427	50	335	385	43	319	362
Pender	51	312	363	62	272	334	53	285	338
Vance	70	321	391	59	300	359	70	261	331
Halifax	89	336	425	72	321	393	62	268	330
Alexander	50	319	369	25	294	319	30	287	317
McDowell	67	292	359	61	259	320	53	261	314
Hoke	58	249	307	62	287	349	53	251	304
Chatham	58	246	304	55	293	348	56	244	300
Yadkin	40	277	317	40	233	273	46	245	291
Person	59	236	295	52	216	268	44	207	251
Watauga	32	178	210	31	195	226	25	214	239
Ashe	26	251	277	29	193	222	35	200	235
Macon	39	149	188	32	210	242	32	196	228
Montgomery	48	184	232	33	190	223	29	181	210
Anson	28	174	202	31	124	155	34	147	181
Bladen	30	185	215	49	157	206	47	132	179
Madison	28	102	130	28	131	159	26	124	150
Greene	16	135	151	28	111	139	33	113	146
Martin	35	167	202	32	222	254	27	117	144
Bertie	18	148	166	25	102	127	13	112	125
Yancey	16	118	134	14	100	114	26	95	121
Avery	10	104	114	16	120	136	12	105	117
Mitchell	13	75	88	14	79	93	23	92	115
Jackson	23	118	141	24	111	135	32	81	113
Hertford	18	154	172	13	111	124	12	99	111
Transylvania	19	108	127	20	80	100	18	90	108
Swain	24	77	101	27	81	108	23	78	101
Warren	17	97	114	10	65	75	12	88	100
Caswell	17	66	83	12	68	80	18	82	100
Polk	12	82	94	11	56	67	21	73	94
Pasquotank	7	122	129	0	101	101	2	92	94
Washington	15	68	83	13	62	75	10	79	89
Jones	11	60	71	11	69	80	24	64	88
Cherokee	24	108	132	20	86	106	17	71	88
Northampton	27	79	106	11	69	80	14	74	88

Surgical Cases by County of Origin, 2009-2011									
Patients Age 0-17									
Sorted by 2011 Total Cases									
Source: Thomson Reuters									
	2009			2010			2011		
County	Inpt. Cases	Outpt. Cases	Total Cases	Inpt. Cases	Outpt. Cases	Total Cases	Inpt. Cases	Outpt. Cases	Total Cases
Chowan	4	76	80	5	67	72	10	69	79
Pamlico	4	55	59	12	54	66	12	55	67
Alleghany	12	51	63	11	42	53	10	49	59
Perquimans	1	62	63	8	49	57	5	45	50
Dare	10	48	58	12	34	46	7	41	48
Clay	10	44	54	13	21	34	5	34	39
Currituck	3	27	30	1	24	25	3	30	33
Graham	13	27	40	7	43	50	7	25	32
Camden	0	30	30	3	30	33	2	23	25
Hyde	4	24	28	8	22	30	3	21	24
Tyrrell	6	22	28	0	23	23	2	21	23
Gates	2	33	35	1	25	26	0	12	12
Total	10,865	66,582	77,447	10,516	65,978	76,494	10,239	63,278	73,517