PETITION FOR AN ADJUSTED NEED DETERMINATION
FOR SIX HOSPITAL-DESIGNATED OPERATING ROOMS IN WAKE COUNTY

PETITIONER

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STATEMENT OF REQUESTED ADJUSTMENT

Rex Hospital, Inc. (UNC REX) respectfully petitions the State Health Coordinating Council (SHCC) to create an adjusted need determination for six operating rooms (ORs) for Wake County in the *2022 State Medical Facilities Plan* (*2022 SMFP*) to be specifically designated for existing licensed acute care hospitals.

REASONS FOR REQUESTED ADJUSTMENT

UNC REX requests this adjustment given the continued and growing demand for hospital ORs in Wake County. UNC REX believes that there is a need for additional hospital OR capacity in the county for the reasons outlined in detail below. Of note, while the petition is not submitted under the abbreviated form due to the impact of COVID-19, UNC REX notes that the *Proposed 2022 SMFP* shows no need for additional ORs in Wake County, likely due to the depressed surgical volume arising from the pandemic. As such, it is appropriate to consider the need for additional ORs generated in multiple previous *SMFP*s as indicators of the need identified in this petition.

OR Need Methodology

Prior to 2001, the need methodology for ORs in the *SMFP* was limited to the ambulatory surgical facility (ASF) setting; specifically, development of ORs in licensed acute care hospitals was not subject to a need determination in the *SMFP*. As such, prior to 2001, hospitals had the flexibility to expand OR capacity as warranted by historical utilization and expected demand. Further, when the statute was amended to require regulation of all ORs regardless of setting, many hospitals added OR capacity before the need determinations were developed to ensure they were able to maintain sufficient OR capacity for the near term. Given these factors, the need for hospitals to develop additional ORs was minimal for several years, and the OR need methodology that began in the *2002 SMFP* generated few need determinations for several years. More recently, following extensive deliberation and input from providers and interested parties, the SHCC adopted a new OR methodology beginning in the *2018 SMFP* to address deficiencies of the prior methodology and to more appropriately determine the need for ORs, particularly in larger

metropolitan areas like the Triangle, of which Wake County is a part. In fact, Wake County is the second fastest growing county in North Carolina based on numerical growth.

Fastest Growing Counties in North Carolina (Numerical Growth)

County	*2021*	*2025*	*Population Change*
Mecklenburg	1,138,138	1,223,734	85,596
Wake	1,117,556	1,199,735	82,179
Johnston	216,670	239,055	22,385
Union	241,576	260,936	19,360
Durham	324,586	342,889	18,303

Source: North Carolina Office of State Budget and Management

The OR need methodology also changed to reflect input from larger hospitals, which found the previous methodology failed to adequately account for the level of services provided at tertiary and quaternary facilities. In particular, such facilities provide surgical care that is more specialized, often with specialties and cases that are not provided in smaller community hospital settings. In addition, due to the complexity of their cases, they often require more time and resources than other facilities to perform those cases.

While the current OR need methodology is rather complex, one of the primary changes from previous years is that a need determination is generated when any single system shows a deficit of at least two ORs, despite any surpluses at other systems in the service area. In this way, the OR need methodology in the *SMFP* is now similar to the methodology for acute care beds. Over the last several years, the OR need determinations have repeatedly been driven largely by hospital systems – and this is also true for Wake County. In fact, prior to the onset of the global COVID-19 pandemic, which negatively impacted healthcare utilization for providers across the country, the UNC Health system in Wake County generated a need for additional ORs in four consecutive *SMFPs*. To be clear, UNC REX supports the current methodology and believes it is generally effective at determining overall need for additional ORs; however, it believes the need specific to hospitals in Wake County is going unmet.

Growth in ASF Capacity in Wake County

The continuing need for additional OR capacity driven by hospital systems has remained, even though technological advances coupled with changes in healthcare reimbursement have resulted in a significant shift of healthcare from inpatient to outpatient settings in recent years. Understanding these trends and the need for additional ASF capacity, UNC REX continuously evaluates its outpatient cases and works with its surgeons to shift many of those that are ASF appropriate to freestanding settings. As a result of UNC REX's efforts as well as that of other providers, there has been huge growth in the number of ASFs in Wake County, both from the development of new ORs pursuant to *SMFP* need determinations and from the reorganization and/or relocation of hospital ORs to ASFs. The table below shows the dramatic growth in ASF capacity and utilization in Wake County in the last decade.

Year	*# of ASF ORs*	*# of ASF Cases*
2010	15	8,174
2020	30	26,320
Growth	**100%**	**222%**

Source: *2012 SMFP* and *Proposed 2022 SMFP*

As shown above, the number of ASF ORs in Wake County doubled in the last decade and the number of surgical cases performed in ASFs increased more than three-fold. The table below identifies OR need determinations from the *2018-2020 SMFPs* and whether the initial Agency decision was in favor of a hospital provider or an ASF provider.

SMFP	***Need Determination (# of ORs)***	***# and Type of Applicants***	***# of ASF ORs Approved in CON Review***	***# of Hospital-Based ORs Approved in CON Review***
2018	6	8 applicants* (7 ASF and 1 hospital)	2^	0
2019	2	5 applicants (3 ASF and 2 hospital)	2	0
2020	3	6 applicants (4 ASF and 2 hospital)	3	0
Total	**11**		**7**	**0**

*Note: There was a ninth application submitted; however, it was subsequently withdrawn.
^The remaining four were awarded in settlement: two ASF ORs and two hospital ORs at UNC REX.

As illustrated above, since 2018, a total of 11 ORs have been allocated to Wake County – all of which were driven by the OR utilization at hospital systems within the county. Of the 11 ORs allocated, seven were approved for ASFs – notably, none were initially approved for hospitals. While two of the six ORs allocated to Wake County in the 2018 *SMFP* were ultimately approved for a hospital setting via settlement, it is important to note that none of the ORs allocated to Wake County in recent years have been approved for hospitals by the Agency in its initial decision. Further, every year since 2018, UNC REX has generated a portion of the need for ORs in Wake County based on historical utilization, but every single UNC REX application for hospital ORs has been denied.

Need for Additional Hospital OR Capacity

Despite the growth in the number of ASFs that have been developed in Wake County through OR need determinations or reorganized/relocated hospital ORs, hospitals continue to drive much of the need for additional ORs given the inherently higher utilization of hospitals versus freestanding facilities. Hospitals are generally highly utilized due to the essential flexibility and capacity they provide. Specifically, while ASF ORs can treat many outpatient surgical cases, even with continuing improvements in technology and growing cost pressures, the need for some outpatient cases to be performed in a hospital setting is likely to persist for the foreseeable future. Of note, the Centers for Medicare and Medicaid Services (CMS) recently announced that it is reversing its 2021 plans to eliminate the inpatient only list, acknowledging that there are some procedures that are too clinically intense to perform in an outpatient setting.[1] In addition, while ASFs provide a convenient alternative for patients, unlike hospital ORs, they cannot be used for cases requiring an stay of more than 23 hours, nor are they available 24/7/365 for emergency cases. Moreover, hospital ORs typically have much greater capacity than those in ASFs, given longer hours of operation, as recognized in the *SMFP* need methodology. As discussed previously, a significant shift of ASF-appropriate outpatient cases has occurred from hospitals to ASFs in Wake County. This shift has resulted in an increase in the overall acuity of surgical cases performed in the hospital setting, both

[1] https://www.cms.gov/newsroom/press-releases/cms-proposes-rule-increase-price-transparency-access-care-safety-health-equity

inpatient and outpatient, increasing case times in some facilities, including UNC REX. As has clearly been illuminated during the COVID-19 pandemic, hospitals are essential; they provide care for outpatients (as well as inpatients) in ways that freestanding settings are not equipped to offer.

As shown below, based on FY 2019 data (preceding the pandemic), hospitals in Wake County experienced significantly higher utilization than ASFs:

FFY 2019 Wake County Operating Room Utilization by Site of Care

Site	*Total Surgical Hours**	*Standard OR Hours Total**	*Percent Capacity*
Freestanding ASF^	36,592	41,984	87%
Hospital	140,290	137,325	102%

Source: *2021 SMFP.*

*Standard Hours per OR per Year x OR inventory per Table 6A in *2021 SMFP* excluding any CON adjustments for future projects in order to accurately determine actual utilization.

^Raleigh Orthopaedic Surgery Center FFY 2019 cases are adjusted to reflect only those cases performed in its operating rooms as reported on its amended 2020 LRA (Exhibit C.4-1).

Please note that while data from FFY 2020 in the *Proposed 2022 SMFP* shows no need overall and less need for ORs in hospitals in Wake County, UNC REX believes FFY 2019 data in the *2021 SMFP* reflects OR need more accurately as it is not impacted by COVID-19. In particular, two of the three hospital systems show a combined need for six additional operating rooms. This need was reduced to three in the *2021 SMFP* because of placeholders from the *2020 SMFP* need determination; however, none of the ORs in the *2020 SMFP* need determination were approved for hospitals. Further, given the issues discussed below for hospitals in competitive CON reviews, it will likely continue to be difficult for hospitals in Wake County to obtain additional OR capacity in competitive reviews. As such, UNC REX believes these circumstances warrant an adjusted need determination for six additional ORs in Wake County designated for existing hospitals.

As noted in the table above, the capacity shown does not reflect any of the ASF capacity approved in recent years that has not been developed. This additional undeveloped capacity is shown below:

Site	*Undeveloped ORs*	*Standard OR Capacity**
Duke Health Green Level ASC	1	1,121
WakeMed Surgery Center-Cary^	1	1,121
Ortho NC ASC	1	1,121
RAC Surgery Center	1	1,121
Triangle Orthopaedics Surgery Center	1	1,121
Wake Spine and Specialty Surgery Center	1	1,121
2020 Need Determination#	3	3,363
Total	**9**	**10,089**

*Calculated as standard hours ÷ standard case time for Group 6 ASFs

^WakeMed was approved through settlement to develop two new ASFs; however, only one included a new (additional) OR and the other will be developed through a transfer of hospital-based ORs.

#While these are currently under appeal, if developed as approved by the CON Section, all will be located in ASFs.

Please note that the table above does not include ASF ORs that will be developed through the transfer of hospital ORs. In addition, two hospital ORs were approved through a settlement agreement. However, as explained below, no hospital ORs have been approved in a CON review in Wake County since 2018. The undeveloped capacity shown above will provide an increase in ASF capacity of nearly 25 percent. However, the *SMFP* methodology does not consider whether the additional ORs needed should be hospital- or ASF-based, and as discussed in the following section, it is nearly impossible for an applicant to be approved for additional hospital-based ORs in Wake County given the current CON process.

CON Review Process Challenges for Hospitals

Despite the need for additional ORs being generated by hospital systems, the CON process presents a challenge for these well-utilized hospitals. Please note that UNC REX does not intend to suggest that the development of ASF capacity is not important. In fact, UNC REX recognizes the significant benefits in providing outpatient surgery in an ASF setting, including lower cost. However, in competitive CON reviews for ORs, the comparative factors used during the CON review process naturally favor the development of ORs in the ASF setting despite the need for adequate hospital OR capacity for inpatient surgical cases and outpatient cases that can only be performed in hospital settings. In these reviews, the CON Section uses comparative factors such as geographic accessibility, competition from new providers, and access to lower cost services, all of which favor ASFs, which typically involve new locations, often by new providers and which offer a lower cost setting. In contrast, hospitals that apply for ORs are generally existing facilities, located in well-established areas of the county, and are more costly as compared to ASFs. All of these comparative factors automatically put hospital applicants at a disadvantage and do not consider the subset of patients who require the flexibility and capacity of hospitals and cannot be served by an ASF. Again, while these factors may be appropriate for the CON Section to use in its review, without additional hospital capacity, the well-utilized hospital systems are likely to continue generating need determinations for additional operating rooms for the foreseeable future.

Further, the current CON competitive review process evaluates total outpatient cases as compared to the percent of dedicated outpatient ORs, determining that more ASF OR capacity is needed to achieve better parity between outpatient case volume and dedicated outpatient ORs to accommodate that volume[2]. As the SHCC may be aware, however, cases reported on license renewal applications (LRAs) as "outpatient," even for hospitals, may have involved an overnight stay or care provided outside of typical business hours. For example, patients at UNC REX that stay in the hospital post-operatively for fewer than two midnights are classified as outpatients, but they are not appropriate for an ASF setting given the need for overnight stays following surgery. While much of the surgical volume that was classified as inpatient five years ago has been removed from the inpatient only list, such as total joint cases, many of these cases are classified as outpatient, but still require an overnight stay and for a bed to be occupied until the patient can be discharged. As such, these cases are inappropriate for most ASFs.

Based on internal data for partial State Fiscal Year (SFY) 2021, 34 percent of surgical cases performed at UNC REX were classified as inpatient. However, 58 percent of surgical cases performed at UNC REX were either inpatient or were classified as outpatient or observation but involved an overnight stay, which

[2] In other words, in competitive OR reviews involving both proposed hospital and ASF ORs, the CON Section typically determines that if ASFs comprise a lower ratio of ORs in the county than the ratio of outpatient surgical cases, ASF ORs are preferred over hospital-based ORs. See https://info.ncdhhs.gov/dhsr/coneed/decisions/2021/feb/findings/2020-Wake-County-OR-Findings.pdf at page 134 for an example of this analysis which favors ASFs over hospitals in the review.

demonstrates that not all cases classified as outpatient are actually appropriate for an ASF setting. Most ASFs are not currently equipped or staffed to accommodate these patients, and with the severe staffing shortages faced in healthcare today, it would not be prudent to staff most ASFs through the night for the occasional patient who requires it, particularly when staff are already available in a hospital setting to provide 24/7 coverage. Also of note, UNC REX performs a number of outpatient surgical cases on patients who do not require an overnight stay, but who have advanced needs that require hospital resources commensurate with an inpatient case.

Similarly, the CON review process does not currently account for the outpatients that require higher levels of anesthesia care that may be inappropriate for an ASF. The American Society of Anesthesiologists (ASA) has developed a physical status classification system, including ASA classes 1 through 6, which is used by anesthesiologists to evaluate a patient's operative risks. Anesthesiologists currently consider many outpatients in ASA class 3 or 4 (and all patients in higher classes) inappropriate for an ASF setting. While ASA class is a useful tool to evaluate operative risk and appropriate setting, there are clearly anesthesia considerations that go beyond simply inpatient versus outpatient status, but those considerations are not accounted for the in the *SMFP* need methodology or the CON review process.

These challenges are not unique to the operating room methodology and CON process, and adjusted need determination petitions have been approved in the past to address these issues. Of note, WakeMed successfully petitioned the SHCC requesting a special need determination for 18 neonatal intensive care unit (NICU) beds for Wake County in the *2009 SMFP* (Attachment 1). Page one of the WakeMed Petition states:

> *"The current acute care bed need methodology, found in Chapter 5 of the 2008 SMFP, does not distinguish between the various types of inpatient services that can be provided in acute care beds. In the methodology, general acute care, intensive care, adult, and pediatric and neonatal services are all grouped as "acute care beds," despite the fact that each patient type's level of care and needs are disparate."*

WakeMed continued by pointing out that applicants proposing to develop NICU beds in a competitive acute care bed review were at a disadvantage, given the higher cost and lower volume represented by this service. Similarly, every outpatient case in the OR need methodology is grouped as an "outpatient" case despite the fact that each patient type's level of care and needs are disparate. At present, there is no distinction in the OR need methodology or the CON review process between cases that are ASF-appropriate outpatient cases and those that are not . The SHCC recognized this challenge relative to acute care beds and NICU beds in Wake County in 2009 in response to WakeMed's Petition, approving the need for additional NICU beds in sufficient number that enabled both Wake County providers of neonatal care, WakeMed and UNC REX, to be approved to develop NICU beds. UNC REX believes the similarities presented in this petition to the issues in the WakeMed petition warrant equal consideration and approval by the SHCC.

<u>Hospital OR Capacity Constraints</u>

Absent awards of additional hospital OR capacity, hospitals in Wake County and elsewhere must find alternative means to meet the continued and increasing demand for surgical services in the hospital setting. As the SHCC is well aware, procedure rooms can be built and utilized in licensed facilities and are not regulated as to what types of cases can be performed in those rooms. As a result, some facilities have chosen to utilize procedure rooms to perform surgical cases due to insufficient OR capacity. While such a

practice is often a necessity when facilities exceed their licensed OR capacity, prudent health planning would suggest that it would be more effective to allow the development of ORs to accommodate these surgical cases. Moreover, the OR need methodology in the *SMFP* considers only those surgical cases performed in licensed ORs. As such, the surgical cases performed in procedure rooms due to insufficient OR capacity are not reflected in the OR need methodology, thus artificially lowering the OR case volumes that might generate the need for additional ORs.

For all of the reasons outlined above, UNC REX is concerned that without an adjusted need determination for hospital-based ORs, the CON process will continue to restrict the development of hospital-based ORs in favor of more ASF capacity, as is the predisposition of the current CON review process, which will perpetuate an undesirable cycle. If capacity constraints at hospitals are not relieved and ASFs continue to operate less highly utilized ORs given the limitations of ASF capacity (shorter hours of operation, etc.), the OR utilization of hospital systems in Wake County will continue to generate more need, ASFs will continue to be approved, and so on with no relief for hospitals in sight, thus duplicating resources as new ASFs are developed in response to hospital-generated needs in the *SMFP* year after year.

Yet another complicating factor for hospitals is the current situation with diversion status. In the past, when a hospital was experiencing an acute strain on capacity, Wake County Emergency Medical Services (EMS) would divert patients to other hospitals in the county to relieve some of the strain. At present, every Wake County hospital is regularly reporting capacity constraints, and Wake County EMS is unable to accommodate diversions. Certainly contributing to this phenomenon is insufficient OR capacity in existing Wake County hospitals. For example, when a patient presents to a hospital emergency department via Wake County EMS and requires surgery, the hospital is unable to move that patient from the emergency department to the OR until an OR becomes available. This excessive demand on hospital providers in Wake County results in inpatient backlogs, long turnaround times, and more time in the hospital – all of which are detrimental to patient care.

Of note, mechanisms are in place to provide hospitals experiencing a strain on acute care bed capacity temporary relief when needed in the form of temporary bed overflow approval. This past year, UNC REX had additional inpatient bed capacity through the COVID-19 waiver which allowed it to adjust its bed capacity when necessary. In prior years, UNC REX has been approved for temporary bed overflow status; however, there is no similar mechanism that allows a hospital to temporarily increase its OR capacity. While additional bed capacity afforded by the COVID-19 waiver and temporary bed overflow status is critical, it also further strains UNC REX's OR capacity absent any corresponding flexibility to expand its OR capacity as demand dictates.

UNC REX believes that the special circumstances in Wake County warrant the need for the requested adjustment of six ORs specifically designated for existing licensed acute care hospitals located in Wake County. If this Petition is approved, any existing hospital in Wake County could apply for additional ORs, and given the need in Wake County UNC REX expects that many would likely be interested in expanding their hospital OR capacity.

ADVERSE EFFECTS ON THE POPULATION THAT ARE LIKELY TO ENSUE IF THE ADJUSTMENT IS NOT MADE

The most obvious adverse effect of failure to approve this Petition is that the need for additional hospital OR capacity in the county will continue to go unmet. Without the approval of this Petition, patients in Wake County will continue to suffer from delays in treatment and lack of access to appropriate, convenient care. Moreover, Wake County EMS will continue to face emergency department backlogs and

may eventually have to consider diverting patients outside of Wake County. Inadequate hospital OR capacity will also limit surgeon recruitment efforts; while patients of Wake County need increasing access to healthcare, additional surgeons may be difficult to recruit if there is uncertainty that hospital OR block time will be available to them. The requested adjustment of six ORs specifically designated for existing licensed acute care hospitals located in Wake County would allow existing hospitals to seek CON approval for additional operating rooms to alleviate ongoing capacity constraints and ensure adequate access to essential hospital services for patients in a timely manner. Further, the allocation specifically for hospitals would allow the CON process to continue awarding additional OR capacity to ASFs, ensuring access to care in these settings as well.

ALTERNATIVES CONSIDERED

While one alternative might seem to be relocating ORs from ASFs back to a hospital setting, this is not feasible for UNC REX, given the shared ownership of UNC REX's ASFs with physicians and the fact that they are well utilized and are an important component in delivering value-based care to Wake County residents. As such, UNC REX considered two remaining alternatives, including maintaining the status quo and petitioning for fewer than six ORs. While it is possible that UNC REX could maintain the status quo and not petition for additional ORs specifically designated for existing licensed acute care hospitals located in Wake County, there is a long-standing projected need for additional hospital OR capacity in Wake County. Hospitals in Wake County will continue to generate additional *SMFP* needs until their need for additional capacity is met. Thus, the status quo was not determined to be an effective alternative. UNC REX also considered requesting a different number of ORs. However, as noted above, UNC REX believes that requesting six ORs is the most reasonable alternative. Further, as previously discussed, seven of 11 ORs allocated to Wake County in the *2018-2020 SMFPs* were initially approved for ASF providers despite the fact that the OR need in each of those *SMFPs* was driven by hospital systems. UNC REX believes it is reasonable and appropriate to request that six ORs be allocated to existing hospital systems in the *2022 SMFP*.

EVIDENCE THAT THE PROPOSED CHANGE WOULD NOT RESULT IN UNNECESSARY DUPLICATION

UNC REX does not believe that the proposed change will result in unnecessary duplication of health resources. As mentioned previously, while there are ASFs in Wake County with additional capacity, the hospital systems in Wake County have projected deficits for many years. Further, as noted previously, if capacity constraints at hospitals are not relieved and ASFs continue to operate less highly utilized ORs given the limitations of ASF capacity (shorter hours of operation, etc.), the OR utilization of hospital systems in Wake County will continue to generate more need, ASFs will continue to be approved, and so on with no relief for hospitals in sight, thus duplicating resources as new ASFs are developed in response to hospital-generated needs in the *SMFP* year after year. As such, UNC REX believes approval of this Petition will actually serve to prevent unnecessary duplication of existing resources.

EVIDENCE OF CONSISTENCY WITH THE THREE BASIC PRINCIPLES

As detailed below, UNC REX believes that this Petition is consistent with the three basic principles: 1) safety and quality, 2) access, and 3)value.

Safety and Quality

Quality and safety can clearly be enhanced through the addition of six hospital ORs in Wake County. As noted above, the lack of sufficient local access to hospital-based ORs may result in inpatient backlogs, long turnaround times, and more time in the hospital – all of which are detrimental to patient care. Further, as hospitals continue to face capacity constraints, the likelihood increases that more and more surgical cases will be performed in procedure rooms, which are not regulated like licensed ORs. Given the volume of patients appropriate for hospital surgical services, the requested adjustment of six ORs specifically designated for existing licensed acute care hospitals located in Wake County is essential to ensuring quality and safety in the service area.

Access

The requested adjusted need determination is needed to provide sufficient access to hospital ORs in Wake County to meet the continued and increasing demand for hospital surgical cases, including those outpatient cases that require an overnight stay or are otherwise not appropriate for an ASF setting. As mentioned previously, adequate access to hospital services, including ORs, in Wake County is essential. Hospitals continue to be the safety net providers for the community, and their importance has been highlighted with the pandemic. Thus, the proposed six ORs will ensure that existing hospital providers in Wake County have the opportunity to seek CON approval to expand hospital OR capacity and provide adequate access to hospital-based surgical services for all, including the medically underserved.

Value

This Petition also promotes value. While ASFs may be more cost effective from a reimbursement standpoint, it is important to note that ASFs do not have the flexibility or the capacity to perform every outpatient case in Wake County. Given the continued push to lower the total cost of care and focus on population health by all payors, including Medicare and BCBS, Wake County hospitals need the additional OR capacity that this Petition will allow to serve a growing patient population. This Petition will provide Wake County with additional hospital OR capacity to meet the needs of area patients and ensure adequate access.

SUMMARY

UNC REX supports the standard OR need methodology in the *SMFP*. However, as detailed above, UNC REX believes that the special circumstances in Wake County warrant the need for the requested adjustment of six ORs specifically designated for existing licensed acute care hospitals.

UNC REX appreciates your careful consideration of this Petition. Please let us know if we can assist the Council, its committees, and the staff during the process.

ATTACHMENT 1

Petition to the State Health Coordinating Council Regarding a Special Need Determination for Neonatal Beds For the 2009 State Medical Facilities Plan

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Contact: W. Stan Taylor
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Statement of Requested Adjustment

WakeMed hereby petitions the State Health Coordinating Council (SHCC) requesting a special need determination for 18 neonatal beds for Wake County in the 2009 State Medical Facilities Plan (SMFP).

Reasons for Requested Adjustment

WakeMed requests an adjustment to the acute care bed need methodology in Chapter 5 of the 2009 SMFP, due to growing demand for neonatal beds in Wake County.

Current Acute Care Bed Need Methodology

The current acute care bed need methodology, found in Chapter 5 of the 2008 SMFP, does not distinguish between the various types of inpatient services that can be provided in acute care beds. In the methodology, general acute care, intensive care, adult, and pediatric and neonatal services are all grouped as "acute care beds", despite the fact that each patient type's levels of care and needs are disparate.

Page 4 of the annual Hospital License Renewal Application lists no fewer than 15 specific acute care bed "units", and hospitals may provide additional categories (please see Attachment 1). Yet, all licensed acute care beds are grouped as if one bed type. Level II and III beds are grouped with medical/surgical, obstetric, gynecology, pediatric, orthopedic, and oncology beds. Level IV neonatal beds, the highest designation in North Carolina, are categorized as "intensive care" beds.

Neonatal Beds Differ From Other Types of Acute Care Beds

DRG Definitions

Neonatal patients generally fall into DRG 385-390[1], which are distinguished from normal newborns (DRG 391). The following table contains descriptions for neonatal DRG's:

Table 1: Neonatal DRG Descriptions

DRG No.	Description
385	NEONATES, DIED OR TRANSFERRED TO ANOTHER ACUTE CARE FACILITY
386	EXTREME IMMATURITY OR RESPIRATORY DISTRESS SYNDROME, NEONATE
387	PREMATURITY W MAJOR PROBLEMS
388	PREMATURITY W/O MAJOR PROBLEMS
389	FULL TERM NEONATE W MAJOR PROBLEMS
390	NEONATE W OTHER SIGNIFICANT PROBLEMS

State Definitions

Although they are categorized as "acute care beds", neonatal beds are unique in nature and therefore do not readily conform with other categories of acute care beds. Neonatal beds are highly specialized resources that serve a limited, yet highly fragile, population.

The Certificate of Need Law, contained in N.C.G.S.§ 131E-176(15b) defines "neonatal intensive care services" as follows:

> *"...those services provided by a health service facility to high-risk newborn infants who require constant nursing care, including but not limited to continuous cardiopulmonary and other supportive care."*

The Criteria and Standards for Neonatal Services, found in 10A NCAC 14C .1400 *et seq.*, define Levels I thru IV neonatal services as follows:

> *"Level I neonatal services" means services provided by an acute care hospital to full term and pre-term neonates that are stable, without complications, and may include neonates that are small for gestational age or large for gestational age.*
>
> *"Level II neonatal service" means services provided by an acute care hospital in a licensed acute care bed to neonates and infants that are stable without complications but require special care and frequent feedings; infants of any weight who no longer require Level III or Level IV neonatal services, but still require more nursing hours than normal infants; and infants who require close observation in a licensed acute care bed.*

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[1] Beginning in FY 2008, Medicare implemented MS-DRGs, which are not included in the FY 2007 Thomson inpatient database.

"Level III neonatal service" means services provided by an acute care hospital in a licensed acute care bed to neonates or infants that are high-risk, small (approximately 32 and less than 36 completed weeks of gestational age) but otherwise healthy, or sick with a moderate degree of illness that are admitted from within the hospital or transferred from another facility requiring intermediate care services for sick infants, but not intensive care. Level III neonates or infants require less constant nursing care than Level IV services, but care does not exclude respiratory support.

"Level IV neonatal service" means neonatal intensive care services provided by an acute care hospital in a licensed acute care bed to high-risk medically unstable or critically ill neonates (approximately under 32 weeks of gestational age) or infants requiring constant nursing care or supervision not limited to continuous cardiopulmonary or respiratory support, complicated surgical procedures, or other intensive supportive interventions.

Level I neonatal care is generally provided in unlicensed newborn bassinets. In 10A NCAC 14C .1401(8), a "neonatal bed" is defined as follows:

"...a licensed acute care bed used to provide Level II, III or IV services."

Therefore, this Petition is centered around the provision of Levels II, III and IV care.

Performance Standards for Neonatal Beds

Neonatal beds have standards for utilization that are different from those in the general acute care bed methodology. According to 10A NCAC 14C .1403, a facility that wishes to add Level II beds must demonstrate that its existing neonatal beds are utilized at least 50% during the first year of operation, and at least 65% during the third year following project completion. A facility seeking additional Level III or Level IV beds must demonstrate that the projected occupancy of its total Level III and Level IV beds will be at least 75% during the third year following project completion.

These thresholds differ from the performance standards for acute care beds, contained in 10A NCAC 14C .3803(a), which mandate the following utilization levels by facility size in the third year following project completion:

Avg. Daily Census	Target Util. by Third Year
Less than 100	66.7%
100-200	71.4%
Greater than 200	75.2%

Another important distinction is that, unlike general acute care beds, there is no tiered capacity threshold for neonatal beds based on unit size. Thus, neonatal units of 2 beds or 20 beds are held to the same utilization standard.

Limitations Regarding Patients That May Be Served in Neonatal Beds

Newborns may suffer from a host of conditions that require neonatal inpatient care, including one of more of the following:

- Low birth weight (under 2500 grams) or Very low birth weight (under 1500 grams);
- Less than 36 weeks' gestation (for Level II care) or Less than 32 weeks' gestation (for Levels III or IV care);
- Hypoglycemia;
- Neonatal sepsis;
- Transient tachypnea;
- Low APGAR scores;
- High bilirubin;
- Congenital anomalies;
- Infant aspiration syndrome.

Level II, III and IV neonatal beds are reserved exclusively for newborn infants with major health problems or special care needs such as those listed above. *Adults and pediatric patients may not be admitted to neonatal beds*. Therefore, neonatal beds have less flexibility in terms what types of patients may fill these beds.

Need for Highly Specialized Support Services

Neonatal services require highly-specialized staffing and support services, and are 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, neonatal programs require support and/or consultation from a number of ancillary and support services, including but not limited to:

- Neonatologists;
- Pediatric intensivists;
- General pediatricians;
- Pediatric surgeons;
- Neonatal nurse practitioners;
- Neonatal staff nurses;
- Respiratory therapists;
- Cardiopulmonary services;
- Clinical dietitians; and
- Social services staff.

Longer Lengths of Stay

While some neonatal patients spend only a few days in a Level II, III or IV bed, the most critically ill infants may spend weeks or months in a neonatal unit. Data from Thomson indicates that, statewide, patients with DRGs 385-390 had a average length of stay of 7.9 days in FY 2007, ranging from 2.6 days for DRG 390 to 41.0 days for DRG 386. Length of stay is influenced by the patient's initial condition(s), and response to therapeutic measures while in the neonatal unit. Because length of stay cannot be predicted from patient to patient, utilization is widely variable.

Review Disadvantages in Comparison to other Acute Care Bed Types

In competitive reviews of acute care beds, the highly specialized nature of neonatal beds, coupled with the specific population they serve as well as their higher charges and costs relative to other forms of acute care beds, put prospective applicants for this service at a disadvantage. Generally, the CON Section is predisposed to award bed allocations to applicants who propose the least costly alternative, and that propose to serve the greatest number of patients. Neonatal patients are subject to lengthy inpatient stays, which generate significantly higher total charges than general medical/surgical patients. In a competitive review with proposals for medical-surgical beds, neonatal bed applications would appear considerably more expensive, and would appear to serve a very limited patient population.

DATA SUPPORTING NEED FOR ADDITIONAL NEONATAL BEDS IN WAKE COUNTY

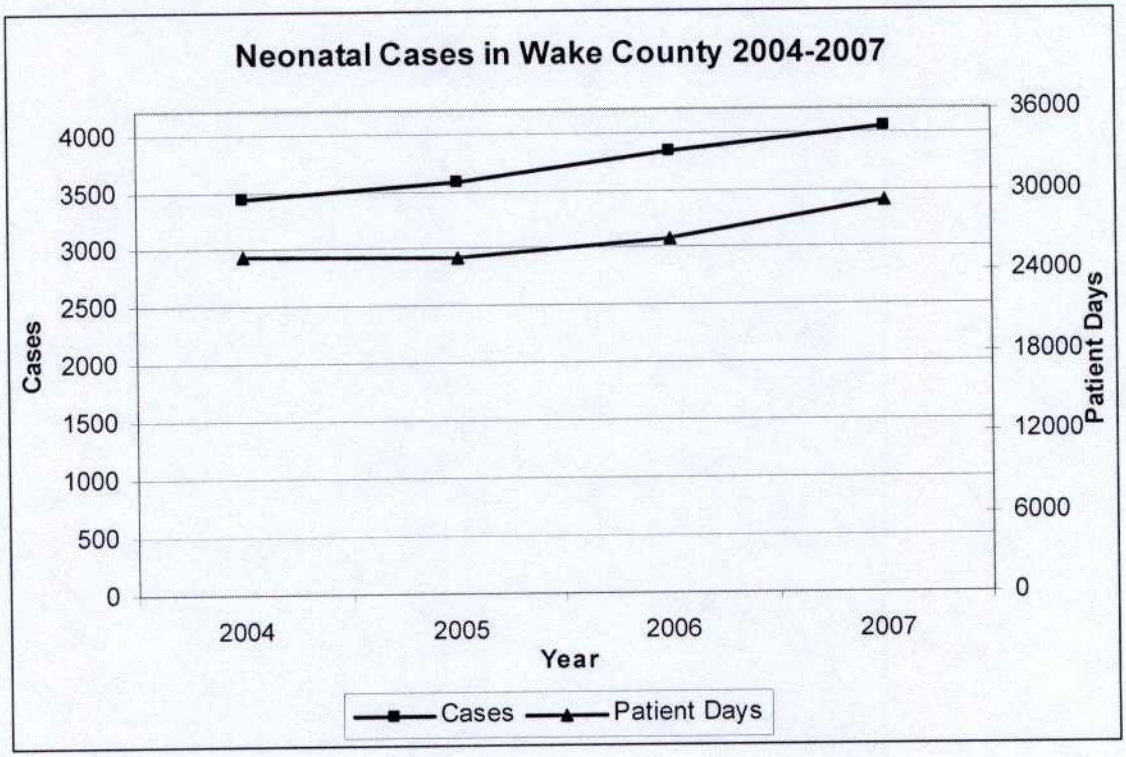
Total Population Growth in Wake County

The N.C. State Office of Management and Budget estimates that 867,228 people reside in Wake County in 2008. This total population is projected to increase to 1,019,246 residents by 2013, an increase of 17.5%. By comparison, the State's total population is projected to grow by 7.9% during the same time period. Based on current projections, Wake County is slated to become North Carolina's most populous county by 2016. Population growth in Wake County will strain existing providers of neonatal intensive care services, as existing resources will be insufficient to meet demand. Neonatal providers in neighboring counties, located in academic medical centers, treat patients from a wide geographic area and will be unable to meet the need in Wake County.

Trends in Neonatal Patients in Wake County

The volume of neonatal patients in Wake County is increasing. Data obtained from the Thomson N.C. Statewide Inpatient Database show that, in 2004, there were 3,445 neonatal cases (DRG 385-390) originating in Wake County, with 25,162 corresponding patient days. By 2007, this had increased to 4,051 cases and 29,133 days – this represents a 17.6% increase in cases, and 15.8%% increase in patient days.. Please see the following table and corresponding graph.

Table 2: Total Neonatal Cases and Days from Wake County, 2004-2007 Source: Thomson						
	FY 2004	**FY 2005**	**FY 2006**	**FY 2007**	**Percent Change, 2005-07**	**Annual Rate of Growth**
Neonatal Cases	3,445	3,573	3,831	4,051	17.6%	4.13%
Neonatal Patient Days	25,162	25,079	26,351	29,133	15.8%	3.73%



Clearly, there is an increasing trend in neonatal volume in Wake County. In 2007, neonatal patients from Wake County filled, on average, approximately 80 beds per day [calculation: 29,133 patient days ÷ 365 = 79.82 average daily census]. This is approximately 42% higher than the number of neonatal beds currently located in the county.

Utilization of Existing Providers Wake County of Neonatal Services

Three Wake County acute care hospitals offer neonatal beds, as follows:

Table 3: Current Inventory of Neonatal Beds in Wake County				
Facility	**No. of Level II Beds**	**No. of Level III Beds**	**No. of Level IV Beds**	**Total Neonatal Beds**
WakeMed Raleigh Campus	0	24	12	36
Rex Hospital	0	12	0	12
WakeMed Cary Hospital	0	8	0	8
Total	0	44	12	56

Data submitted to the Division of Health Service Regulation in annual License Renewal Applications indicate that, in total, the existing neonatal beds were utilized at 84.9% in FY 2006 and 84.4% in FY 2007. The Level III beds were utilized at 82.7% in FY 2006 and 82.8% in FY 2007. Utilization of the Level IV beds was 93.0% and 90.0% in FYs 2006 and 2007, respectively. These occupancy levels are well above the performance standards set forth in 10A NCAC 14C .1403(2) and (3), and indicate that additional neonatal beds are needed in Wake County. Neonatal beds in Wake County are so highly-utilized that patients are being referred to facilities outside Wake County because of the lack of available beds.

Increasing neonatal case volume, coupled with rising utilization among providers of neonatal beds in Wake County, means that an increasing proportion of patients must rely on out-of-county facilities for available neonatal beds.

Ratio of Neonatal Beds to Population

Compared with other major urban centers in North Carolina, Wake County has a lower ratio of neonatal beds to population, despite having a birth rate that is similar with that of other urban counties. While information regarding live births for 2007 has not yet been published by the State Center for Health Statistics, data obtained from Thomson indicate that Wake County had an estimated 2007 birth rate of 16.57 births per 1000 population, with 13,799 live births (in DRG 385-391). Of these, 4,051 births, or 29.4% of total, were considered neonatal cases (DRG 385-390), the highest number of neonatal cases statewide.

With only 56 neonatal beds, Wake County has a ratio of 6.72 beds per 100,000 population, far lower than any of the other ten most populous counties in North Carolina. Yet, Wake County's neonatal cases per 100,000 population ranks higher than most other urban counties, with the exception of Durham and Mecklenburg Counties.

Table 4: 2007 Neonatal Beds and Neonatal Cases Per 100,000 Population For Ten Most Populous Counties in North Carolina Sources: Thomson and N.C. State Demographer's Office					
County	**2007 Total Population**	**Total Neonatal Beds**	**Neonatal Beds per 100,000 Pop.**	**Total Neonatal Cases (DRGs 385-390)**	**Neonatal Cases per 100,000 Pop.**
Mecklenburg	862,835	147	17.04	3,915	486.4
Wake	**832,875**	**56**	**6.72**	**4,051**	**453.7**
Guilford	460,784	42	9.11	1,980	429.7
Forsyth	338,480	79	23.34	1,395	412.1
Cumberland	313,600	44	14.03	1,012	322.7
Durham	254,588	71	27.89	1,430	461.7
Buncombe	225,870	51	22.58	641	283.8
Gaston	201,094	16	7.96	727	361.5
New Hanover	189,856	33	17.38	625	329.2
Onslow	169,466	18	10.62	731	431.4

Need for Additional Level IV Neonatal Beds in Wake County

The State considers Level III and Level IV units to be fully utilized at 75% occupancy. Existing providers of neonatal services in Wake County are being utilized well above this level. Given that Wake County neonatal patients filled 80 beds per day during 2007, but only 56 neonatal beds are located within the county, there is clearly a need for additional neonatal bed capacity in Wake County.

Using historical utilization data for neonatal services at WakeMed Raleigh Campus, WakeMed Cary Hospital and Rex Hospital, existing providers of neonatal services in Wake County could justify a total of 63 neonatal beds at their *FY 2007 utilization levels* [calculation: 17,242 patient days ÷ 365 = 47.2 ÷ 0.75 = 62.98, rounded 63]. Increasing neonatal case volume, coupled with rising utilization among providers of neonatal beds in Wake County, means that more patients must rely on out-of-county facilities for available neonatal beds.

If Wake County's neonatal cases continue to grow at a rate of 4.13% per year and patient days continue to grow at a rate of 3.73% per year (see Table 2 above), it is estimated that Wake County residents will need approximately 99 neonatal beds per day by 2013. Assuming 75% of these patients remain in Wake County facilities, this translates to a need for 18 additional neonatal beds by 2013. Please see Table 5 below.

Table 5:
Wake County Neonatal Bed Utilization Trend and Beds Needed Through 2013

Year	Wake Co. Neonatal Cases *(increased 4.13% per year after 2007)*	Wake Co. Neonatal Pt. Days *(increased 3.73% per year after 2007)*	Avg. Daily Census (Pt. Days ÷ 365)	Avg. Daily Census Assuming 75% of Pts. Remain at Wake Co. Facilities	Surplus/ (Deficit) Based on 56 Beds
2004-actual	3445	25162	68.9	51.7	**4.3**
2005-actual	3573	25079	68.7	51.5	**4.5**
2006-actual	3831	26351	72.2	54.1	**1.9**
2007-actual	4051	29133	79.8	59.9	**(3.9)**
2008	4218	30220	82.8	62.1	**(6.1)**
2009	4392	31348	85.9	64.4	**(8.4)**
2010	4574	32518	89.1	66.8	**(10.8)**
2011	4763	33731	92.4	69.3	**(13.3)**
2012	4960	34990	95.9	71.9	**(15.9)**
2013	5165	36296	99.4	74.6	**(18.6)**

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 neonatal beds on the rise, demand for neonatal beds is expected to grow. As demand for neonatal services continues to grow, larger proportions of patients will be forced to seek care in out-of-county facilities. The closest neonatal programs outside Wake County, at Duke University Hospital and UNC Hospitals, were utilized at 93.8% and 75.7%, respectively, during 2007.

Alternatives to This Proposal

WakeMed has considered several alternatives to this proposal.

Status Quo

WakeMed has considered no action should this Petition be denied, in which case no additional neonatal beds would be made available to the residents of Wake County.

Develop Additonal Neonatal Beds Through SMFP General Acute Bed Methodology

WakeMed Raleigh Campus and WakeMed Cary Hospital have been awarded acute care beds via SMFP need determinations in recent years. However, these beds were earmarked for adult intensive care and medical-surgical patients, given that these were

judged to be the most critically needed new beds. Also, neonatal beds were deemed too expensive to warrant approval during competitive CON reviews. For these reasons, WakeMed has not pursued additional neonatal beds allocated to Wake County through the annual SMFP.

Convert Approved General Medical-Surgical Beds to Neonatal

WakeMed has received State approval for a total of 102 acute care beds since 2005. However, due to pressing capacity constraints at its Raleigh and Cary inpatient facilities, none of these beds were allocated to neonatal services. WakeMed is increasing the number of adult medical-surgical and intensive care beds at both campuses. Projections indicate that these beds will exceed their utilization projections within three years of opening.

No Evidence of Unnecessary Duplication of Services

Providers of neonatal services in Wake County are well-utilized, and additional beds would not duplicate existing services.

Summary

Based on the information provided in this Petition, WakeMed respectfully requests that the State Health Coordinating Council grant a special need determination of 18 neonatal beds in Wake County for inclusion in the 2009 State Medical Facilities Plan. Doing so will ensure that an adequate supply of neonatal beds will be in place to meet growing demand within Wake County.

Attachment 1

All responses should pertain to **October 1, 2006 through September 30, 2007.**

D. Beds by Service (Inpatient – Do Not Include Observation Beds or Days of Care) [Please provide a Beds by Service (p. 4) for each hospital campus (see G.S. 131E-176(2c))]

Please indicate below the number of beds usually assigned (set up and staffed for use) to each of the following services and the number of census inpatient days of care rendered in each unit. NOTE: If your facility has a designated unit(s) for chemical dependency treatment and/or detoxification, please complete the patient origin sheet pertaining to Psychiatric and Substance Abuse Services. If your facility has a Nursing Facility unit and/or Adult Care Bed unit please complete the supplemental packet for Skilled Nursing Facility beds.

Licensed Acute Care (provide details below) *Campus* _____	**Licensed Beds as of September 30, 2007**	**Staffed Beds as of September 30, 2007**	**Annual Census Inpt. Days of Care**
Intensive Care Units			
a. Burn *			*
b. Cardiac			
c. Cardiovascular Surgery			
d. Medical/Surgical			
e. Neonatal Beds Level IV ** (Not Normal Newborn)			**
f. Pediatric			
g. Respiratory Pulmonary			
h. Other (List)			
Other Units			
i. Gynecology			
j. Medical/Surgical ***			***
k. Neonatal Level III ** (Not Normal Newborn)			**
l. Neonatal Level II ** (Not Normal Newborn)			**
m. Obstetric (including LDRP)			
n. Oncology			
o. Orthopedics			
p. Pediatric			
q. Other (List) _____			
1. Total General Acute Care Beds/Days (a through q)			
2. Comprehensive In-Patient Rehabilitation			
3. Inpatient Hospice			
4. Detoxification			
5. Substance Abuse / Chemical Dependency Treatment			
6. Psychiatry			
7. Nursing Facility			
8. Adult Care (Home for the Aged)			
9. Other			
10. Totals (1 through 9)			

* Please report only Census Days of Care of DRG's 504, 505, 506, 507, 508, 509, 510 and 511.

** Per C.O.N. rule definition. Refer to Section .1400 entitled Neonatal Services. (10A NCAC 14C)

*** Exclude Skilled Nursing swing-bed days. (See swing-bed information next page)