PETITION TO THE STATE HEALTH COORDINATING COUNCIL TO ADJUST THE 2009 STATE MEDICAL FACILITIES PLAN'S NEED DETERMINATION FOR THREE OPERATING ROOMS FOR RANDOLPH COUNTY

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Petition

Randolph Hospital, et al., hereby petitions the State Health Coordinating Council (SHCC) to adjust the 2009 State Medical Facilities Plan to allow for a special needs adjustment for three Operating Rooms in Randolph County.

Date August 1, 2008

Identification of Petitioners

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Background

Randolph Hospital and the co-petitioners filed a petition one year ago and also submitted a letter during the March 2008 SHCC meeting asking that the need for Operating Rooms in Randolph County be reviewed. The 2008 petition was denied by the SHCC, after a vote of 16 to 7, with many SHCC members indicating that they empathize with the unique rural community situation. Several spoke in favor of the Randolph petition.

Operating Room access and capacity in Randolph County remains a significant obstacle in the provision of surgical services as well as the retention and recruitment of physicians. This need is not reflected by the current OR need methodology and will not be answered by the proposed tiering system. This predicament has led to a repeat petition.

Reasons for the Proposed Adjustment

The State Medical Facilities Plan allows for special needs petitions to be presented for consideration if a particular geographic area or institution has special or unique circumstances that give rise to resource requirements that differ from those provided by the standard methodology presented in the SMFP. Randolph County has encountered a unique circumstance that would optimally be resolved with three additional Operating Rooms in order to provide continued access, quality, and reasonable costs of health care for the citizens of Randolph County. Specifically, Randolph County needs these additional Operating Rooms for the following reasons:

- To provide appropriate access to the medically underserved who require surgical services
- To insure quality
- To promote cost effectiveness
- To support recruitment and retention of surgeons
- To allow for more patient friendly access to surgical services at times that meet patients' needs
- To provide patient choice and efficiencies associated with ambulatory surgery
- To reflect the cumulative volume of surgical procedures regardless of whether they were performed in an Operating Room as requested in the 2008 hospital license renewal application

Residents of Randolph County are currently utilizing the equivalent of 6 additional operating rooms outside of Randolph County

This following table illustrates that more Randolph County citizens are currently having operating room procedures outside Randolph County than are seeking operating room services in Randolph County. In fact, the table below reveals that just in the contiguous counties, (which does not include OR procedures done at North Carolina Baptist, Duke, or UNC) Randolph County citizens support 6 additional Operating Rooms using the

current methodology. The great majority of these cases are outpatient surgeries, which could readily be performed locally if capacity existed. Utilizing Operating Rooms outside the county creates a unique situation because these surgeons are not accessible to the Randolph County citizens at night when an emergency may arise. Local on-call surgeons are treating these patients should complications arise in the Randolph Hospital emergency department. The petitioners recognize that not all services are available in Randolph County and that patients may have established relationships with physicians outside of the county. With the increased cost of fuel and the slowing U.S. economy, there will be increased pressure to consume services locally. Without additional operating room capacity, Randolph Hospital and the co-petitioners are constrained in their ability to improve local access to these patients. As a conservative estimate, applying Randolph Hospital's 2007 overall inpatient Market share of 44.5% to this volume would justify a need for 2.64 additional operating rooms in Randolph County. The SMFP recognizes the service area for operating rooms as each individual county, therefore capacity to provide surgical services to the population of each county should be available locally. This is a unique circumstance of Randolph County, and therefore creates a special need outside the OR methodology for 3 additional Operating Rooms.

Surgical Cases with Patient Origin of Randolph County
Source: 2006-2008 License Renewal Applications

		2005 cases on Randolph County Pts.	2006 cases on Randolph County Pts.	2007 cases on Randolph County Pts.
HealthSouth Surgical Center - GSO		220	157	0
Health South Southern Pines		574	507	518
High Point Surgical Center		789	752	812
Moses Cone Surgery Center		592	503	0
Surgical Eye Center - GSO		432	433	474
Wesley Long Surgical Center		179	199	0
Chatham Hospital	Inpt	9	15	2
	Outpt.	17	13	19
Alamance Regional	Inpt	6	8	6
	Outpt.	53	46	70
Thomasville Medical Center	Inpt	66	56	46
	Outpt.	249	246	209
Moses Cone Health System	Inpt	1354	1138	1094
	Outpt.	670	984	1523
High Point Regional	Inpt	483	481	421
	Outpt.	471	425	434
First Health Montgomery	Inpt	7	17	7
	Outpt.	64	56	48
First Health Moore Regional	Inpt	65	74	55
	Outpt.	93	55	44
		6393	6165	5782

Sum of OP cases	4403	4376	4151
Weight for OP cases	1.5	1.5	1.5
Hours devoted to OP cases	6605	6564	6226.5
Sum of Inpatient Cases	1990	1789	1631
Weight for Inpatient Cases	3	3	3
Hours devoted to IP cases	5970	5367	4893
OR hours needed to Accommodate Randolph County Patients treated outside of Randolph County	12575	11931	11119.5
Standard Hours of Operation per OR	1872	1872	1872
ORs being utilized in contiguous counties on Randolph County citizens	**6.7**	**6.4**	**5.9**
OR's needed in Randolph County by applying 44.5% Market Share	**3.0**	**2.8**	**2.6**

Randolph County has the fewest operating rooms in proportion to population of any county in North Carolina. This results in poor access to surgical services and difficulty in recruiting physicians.

Randolph Hospital is currently the sole provider of surgical services in Randolph County. The current operating room inventory of 5 rooms (excluding one c-section room) is used to provide inpatient and outpatient surgery to the estimated 144,000 people who live in Randolph County. The following chart speaks to the disparity in OR access in Randolph County compared to the State of North Carolina as a whole.

North Carolina Average OR to Population Ratio:	1 OR per 7,300 persons
North Carolina Median OR to Population Ratio:	1 OR per 10,900 persons
Randolph County Average OR to Population Ratio:	1 OR per 28,800 persons

The table below illustrates the ratio of operating rooms to population experienced in similar sized communities. This table reveals that Randolph County Citizens have the lowest degree of access to Operating Rooms of the comparative counties. This disparity causes a hardship as surgical services are not available in a timely fashion and patients frequently must travel away from their home to receive procedures that could be offered

locally if there was additional Operating Room Capacity. Further, Randolph County's rate of 1 OR per every 28,800 population is the highest in the state, which results in the unfavorable ranking of least accessible operating room to population rate in the entire state of North Carolina. The vast majority, 95% of the population, has a ratio of less than 1 operating room per 20,000 population. Thus, Randolph County citizens' access to operating rooms is far less than that of 95% of the counties in North Carolina. A listing of all North Carolina Counties is provided at the end of this petition. (Exhibit One) Also note that the three requested operating rooms will only bring the ratio of operating rooms to population to 1 OR per 18,000 population which is still far worse than the state median and average.

Population compared to Operating Rooms
Randolph County and Similar Sized Counties
Source: Thomson, Market Planner Plus and 2009 Draft SMFP

Geography: County	2007 Population	ORs minus exclusions	2007 Population per Operating Room
CATAWBA, NC	162,764	37	4,399
IREDELL, NC	143,740	25	5,750
CABARRUS, NC	165,979	24	6,916
WAYNE, NC	117,564	13	9,043
ROWAN, NC	122,659	11	11,151
DAVIDSON, NC	136,164	9	15,129
ONSLOW, NC	151,473	9	16,830
JOHNSTON, NC	129,022	7	18,432
UNION, NC	174,586	8	21,823
RANDOLPH, NC	143,945	5	28,789

Also, if you look across the state at other counties with 5 operating rooms, you will find that their populations range from 23,000 to 67,000. Randolph County's 144,000 citizens deserve the consideration of this statistic in a special need petition.

Population compared to Operating Rooms
Randolph County and Other Counties with 5 Operating Rooms
Source: Thomson, Market Planner Plus and 2009 Draft SMFP

Geography: County	2007 Population	Number of Operating Rooms (Minus exclusions)	2007 Population per Operating Room
RANDOLPH, NC	143,945	5	28,789
RUTHERFORD, NC	67,765	5	13,553
WILKES, NC	64,874	5	12,975
VANCE/WARREN, NC	63,492	5	12,698
STANLY, NC	60,788	5	12,158
COLUMBUS, NC	54,832	5	10,966
BEAUFORT/HYDE, NC	53,932	5	10,786
EDGECOMBE, NC	50,735	5	10,147
WATAUGA, NC	44,835	5	8,967
SCOTLAND, NC	37,326	5	7,465
HERTFORD, NC	23,686	5	4,737

Appropriate Access to surgical services is defined by Patients, Physicians, and Insurers

The quantitative data included in this document more than adequately supports a special need for three additional operating rooms in Randolph County. However, the most compelling case is made from narratives from our surgeons who encounter the problems associated with Operating Room access daily.

Dr. Charles West, an ENT surgeon who has practiced in Asheboro for 16 years and fellow petitioner, recently shared his experience with hospital staff. Dr. West explained that his patients often request to have procedures on Friday in order to recuperate over the weekend to avoid missing work. Because Dr. West only has surgical block time on Mondays, he is unable to accommodate this request. Therefore, the patient must decide whether to forego the procedure, miss extra days of work to accommodate Dr. West's schedule, or seek the service outside of Randolph County at a facility that may be able to offer more flexibility in scheduling the procedure. In addition, a large volume of Dr. West's surgical patients are children. His adult patients are automatically scheduled behind the pediatric cases, but patient (and parent) satisfaction decreases throughout the day as parents and hospital staff struggle to comfort a three year old who hasn't had food or drink since midnight the night before.

Dr. William Rabe, a dental surgeon who has practiced in Asheboro for 20 years explained that due to OR availability he has been forced to move procedures out of the hospital that he would be more comfortable conducting under general anesthesia. Recently, a patient was referred to his practice from a cardiothoracic surgeon because the patient required extensive dental work with anesthesia monitoring before a much needed heart surgery

could be performed. It was 3 ½ weeks before the procedure could be scheduled in local Operating Rooms which delayed the patient's impending heart surgery.

While a dedicated C-section room provides an available room ready for a procedure, smaller hospitals are not able to staff these rooms independent of the main operating room. While these cases are excluded from the Operating Room Need methodology, these cases occupy OR and anesthesia staff which requires one operating room to be taken out of service when a c-section case is being performed. Dr. Yates Lennon, an OB-Gyn echoed this sentiment in recent correspondence with hospital staff. Dr. Lennon writes,

"We, as a group of 4 only have two days a week in the OR. That limits us and inconveniences patients in several ways. From our Obstetrical practice standpoint it means that if we need to schedule more than two repeat c-sections in a week, one of those patients would not be the first case of the day. This is very inconvenient for the pregnant patient and also for the pediatricians who must leave their office hours to come to the hospital to attend on the infant.

An Ambulatory Surgery Center would open more start times for us to get these cases done first. Also, much of our Gynecology caseload is outpatient. What happens to our patients is that because we try to perform those outpatient cases first, many of our same day cases get delayed late into the afternoon. This creates problems for the OR in terms of call staffing, etc. Many times due to medical problems with some of our inpatient cases, the outpatient cases get delayed and then end up going home very late in the day. The OB/Gyn patient population would benefit greatly from the added rooms and the new scheduling opportunities it would provide."

Dr. Craig Gaccione, another Randolph County Ob-Gyn, expanded on this point saying, **"I completely agree that we have a problem with "access to care". Often times it is hard to get an "add on" scheduled the same day or next day. The patient often has to wait hours due to the busy schedule. At times the patient is in severe pain. Other situations include cases which are not emergent but could become emergent very quickly, so having the ability to work in what is usually a quick procedure or an outpatient procedure in a timely fashion could significantly improve the quality of care we provide."**

Not only do patients and physicians want input on when procedures are available, but insurance steerage has patients looking for Ambulatory Surgery Centers in order to avoid more costly co-pays. Dr. Richard Evans, a general surgeon practicing in Asheboro and joint petitioner, writes:

"Randolph County is in dire need of Outpatient operating rooms or an Ambulatory Surgical Center. The Hospital currently doesn't have adequate capacity for the cases generated by the surgeons such that block time has been taken away from various surgeons just this past year. The operating room committee has labored

extensively trying to maximize the number of cases done and improve utilization by employing evidence-based scheduling. This still has required the committee to deny surgeons operating room access. In addition, there is no capacity for new surgeons to put their cases, resulting in difficulty attracting surgeons to the community.

Much of the customer base in Randolph County bypasses the services of the hospital and goes outside of the county for their outpatient care since they can get more efficient care at Ambulatory Surgery Centers. Some of this is price driven as well as the fact that the hospital can't compete with these centers because of the efficiency. Thus Health plans and savvy consumers are directing the care elsewhere. Because of this disconnect the community suffers when the surgeons and specialists aren't able to generate adequate cases to support their practices resulting in specialists retiring, moving or failing to come and start practices.

By allocating additional operating rooms to the county, the care that citizens of Randolph County receive would be enhanced and the health care dollars can be efficiently utilized. Thus all aspects of the health care system can benefit."

The Rounding Rules used prior to the 2009 plan for the Operating Room Need Methodology have negatively impacted Randolph County

In the 2006 and 2007 SMFP, Randolph County showed a need for an Operating Room of .32 and .30, respectively, but based on the methodology, the need had to be greater than .50 to trigger an allocation. If this rounding consideration would have been part of the methodology since its inception, Randolph Hospital would have triggered a need in 2006 and 2007. Randolph Hospital believed that it was possible to trigger a need through the methodology. Of course, no one could foresee the effect that operating at that capacity would have on recruitment and retention of surgeons, staff turnover, physician satisfaction, patient satisfaction, etc. that ultimately lead to decreased volumes.

In order to accommodate this capacity in the existing OR's and to provide the best experience to surgical patients and the medical staff, Randolph Hospital filed a Letter of No Review with the Certificate of Need Section to outfit a procedure room with Flouroscopy equipment in order to move cystoscopy procedures out of an Operating Room. This freed up more space in the Operating Room Suite for those cases that required a sterile setting. However, this temporary solution had the unintended consequence of moving Randolph County further away from triggering the methodology for a much needed additional Operating Room in the county as recruitment and retention had already been negatively affected. Even though this volume still tied up OR staff, it could no longer be included on the licensure renewal form because it wasn't performed in a licensed operating room. This is evidenced by the table provided below. In the 2008 SMFP, Randolph County showed a surplus of .21 operating rooms. In the 2009 Draft SMFP, Randolph County is showing a surplus of .50 operating rooms. The following table depicts the need determinations over the past several years.

The variations in need determination are further evidence that the need methodology alone does not tell the whole story of the need for additional access in Randolph County. The table shown also illustrates that rounding has been an issue with the OR methodology since its inception.

Data Year	SMFP Year	Need in plan for Randolph County
2002	2004	1.28 Room Surplus in 2006
2003	2005	0.23 Room Surplus in 2007
2004	2006	(0.32) Room Deficit in 2008
2005	2007	(0.30) Room Deficit in 2009
2006	2008	0.21 Room Surplus in 2010
2007	2009	0.50 Room Surplus in 2011

The Spring 2008 petition filed by Franklin Regional Medical Center shed light on the important issue of incremental capacity as it relates to the methodology. The passages and chart below were extracted from Franklin Regional's petition to further illustrate the methodology's effect on rural hospitals.

{Begin excerpt from Spring 2008 Petition from Franklin Regional Medical Center}

The primary purpose of this Petition is to address the inequality inherent in the methodology for projecting OR need. According to the current methodology, every service area must achieve a projected OR deficit of 0.50 or greater in order to generate a need determination. A service area with fewer OR's must demonstrate higher projected OR utilization than a service area with more OR's in order to generate the required deficit of 0.50 or greater, when in fact, the opposite should be true. Service areas with fewer OR's should have lower thresholds for OR utilization because they are frequently served by small, rural providers that need additional OR's in order to attract and retain physicians and whose smaller physician base limits their ability to achieve high OR utilization. Any provider or service area without adequate OR capacity cannot provide the most cost-effective, most accessible, and highest quality of care to its patients.

Minimum Projected Utilization Rates for OR Need Determination

A	B	C	D	E
Existing # of OR's	*OR Deficit Threshold*	*OR's Required (A+B)*	*Projected Surgical Hours (C x 1,872 hours)*	*Minimum Projected Utilization Rate (D ÷[A x 1,872 hours])*
1	0.5	1.5	2,808	150.0%
2	0.5	2.5	4,680	125.0%
3	0.5	3.5	6,552	116.7%
4	0.5	4.5	8,424	112.5%
5	0.5	5.5	10,296	110.0%
6	0.5	6.5	12,168	108.3%
7	0.5	7.5	14,040	107.1%
8	0.5	8.5	15,912	106.3%
9	0.5	9.5	17,784	105.6%
10	0.5	10.5	19,656	105.0%

As another example of the increased burden on service areas with limited OR capacity, FRMC examined the impact in terms of additional hours per OR. In order for Franklin County to reach the 0.5 OR need to trigger an allocation, each of the three OR's in county must be projected to operate at the standard 1,872 hours per year, plus one-third of the additional hours needed to meet the 0.5 need threshold. Therefore, each OR must provide an additional 312 hours per year of service for an average of 1.2 additional hours per day per OR. In contrast, in order for the Pitt-Greene service area to reach the 0.5 OR need to trigger an allocation, each of the 32 existing OR's in the service must operate at the standard 1,872 hours per year, plus 6.75 minutes, which is each OR's share of the time needed to meet the 0.5 need threshold.

{End excerpt from Spring 2008 Petition from Franklin Regional Medical Center}

As evidenced in the passages above, an OR service area with 5 or fewer ORs experiences a vastly different and more taxing problem with incremental capacity than the service area with a larger inventory of operating rooms. This is evidence that the current methodology does not accurately reflect Operating Room need in more rural counties, and special needs petitions may be in order to address these needs. Specifically, the SHCC should take into consideration Service Areas that have historically qualified for an operating room based on the 2009 plan's change regarding rounding. (See 2009 Proposed SMFP page 53 for rounding specifications.) If this rounding change was applied retroactively, Randolph Hospital would trigger a need based on its 2004 and 2005 data in both the 2005 and 2006 SMFPs.

Based on the changes in data collection requested on the 2008 hospital licensure renewal application and the accompanying memo from Division of Health Services Regulation (DHSR) Planning Section, Randolph Hospital inadvertently understated surgical volumes

Historically, on page 8 of the hospital licensure renewal application, Randolph Hospital has followed the directions that implicitly state to only report the operating room cases that take place in a licensed operating room. In 2007, volumes totaled 1,321 inpatient cases and 3,234 ambulatory cases and were reported as such on the 2008 application. However, the 2008 hospital licensure renewal application now states to "Count all surgical cases, including cases performed in procedure rooms or in any other location." Randolph Hospital conferred with constituents at other Acute Care facilities, and due to the lack of a definition of "surgical procedures" and the risk of double counting volumes that are collected on subsequent pages of the licensure application, Randolph Hospital data was reported as it had been reported historically. Thus, 189 inpatient cases and 514 ambulatory procedures were not included on page 8 of the licensure application and therefore were not included in the operating room case totals that are ultimately used to develop need projections in the 2009 proposed SMFP. (This change would result in a need for 5.24 OR's in Randolph County, or a need for 1 OR in the 2009 Proposed SMFP.)

DHSR staff recently met with Randolph Hospital personnel and advised them to correct this misinterpretation with the Licensure Section so that the SHCC might consider this edited data for Randolph Hospital in the 2009 Proposed SMFP. A letter requesting to amend page 8 of Randolph Hospital's licensure application has been mailed to the licensure section and accompanies this petition as Exhibit Two.

The operating rooms at Randolph Hospital are staffed 8 hours per day, 253 days per year rather than the 9 hours per day, 260 days per year assumption in the state methodology.

In practice, the operating rooms at Randolph Hospital are staffed for 8 hours a day, 5 days a week, for 253 days per year. (This allows for seven recognized holidays when procedures are not scheduled.) This translates into "standard hours of Operating Room availability" for Randolph County surgeons and patients of 1,619 hours (253 days x 8 hours a day at 80% utilization) instead of the 1,872 hours (260 days x 9 hours a day at 80% utilization) used in the current operating room methodology. If the current Operating Room methodology were adjusted to reflect the actual availability of the Randolph County ORs, a need determination would have occurred in Randolph County in the 2007 SMFP. Even with decreasing surgery volumes experienced in 2007, this adjustment to the methodology would also trigger a need in the draft 2009 plan. This data is provided below and as Exhibit Three.

The following table depicts four scenarios:

1. The SMFP need determination methodology and outcome for the past 3 SMFPs which show a need for only 5 ORs in Randolph County.

2. The SMFP need determination if all surgical procedures regardless of location (per the 2008 Licensure Renewal Application directions and accompanying memo) are counted showing a need for 6 ORs in Randolph County.
3. The SMFP need determination if actual Randolph Hospital hours/days were used in the methodology showing a need for 6 ORs in Randolph County.
4. The SMFP need determination if both the Randolph Hospital hours/days were used in the methodology and all surgical procedures regardless of location are counted showing a need for 6 ORs in Randolph County.

Current OR Methodology
Standard Hours of Utilization vs. Actual OR Availability in Randolph County
Source: 2007 SMFP and Draft 2009 SMFP

Operating Room Service Areas	Projection of Surgical Operating Room Requirements										
	Estimated Total Surgery Hours							Application of Growth Factor			
	Surgical Cases reported as "Inpatient Cases" (w/ Exclusions)	Avg. Hours for Inpat. Cases	Esti-mated Hours for Inpat. Cases	Surgical Cases reported as "Ambulatory Cases"	Avg. Hours for Amb. Cases	Esti-mated Hours for Amb. Cases	Total Estimated Hours	Growth Factor (Population Change Rate)	Projected Surgical Hours Anticipated	Standard Hours per OR per Year (5/260/80%)	Projected Surgical Operating Rooms Required
Randolph County 2005 Volumes from 2007 SMFP	1,467	3.0	4,401	3,326	1.5	4,989	9,390	0.0563	9,918.66	1872	**5.30**
Randolph County 2006 Volumes from 2008 SMFP	1,249	3.0	3,747	3,208	1.5	4,812	8,559	0.0468	8,959.56	1872	**4.79**
Randolph County 2007 Volumes from 2009 Proposed	1,096	3.0	3,288	3,234	1.5	4,851	8,139	0.0354	8,427.12	1872	**4.50**
All Surgical Procedures per 2008 Licensure Form Def.	1,285	3.0	3,855	3,748	1.5	5,622	9,477	0.0354	9,812.49	1872	**5.24**
If Actual Capacity (8 hours for 253 days) was used w/ 2005 volumes	1,467	3.0	4,401	3,326	1.5	4,989	9,390	0.0563	9,918.66	1619	**6.13**
If Actual Capacity (8 hours for 253 days) was used w/ 2006 volumes	1,249	3.0	3,747	3,208	1.5	4,812	8,559	0.0468	8,959.56	1619	**5.53**
If Actual Capacity (8 hours for 253 days) was used w/ 2007 volumes	1,096	3.0	3,288	3,234	1.5	4,851	8,139	0.0354	8,427.12	1619	**5.21**
Using Actual Capacity (8 hours) and all Surgical Procedures	1,285	3.0	3,855	3,748	1.5	5,622	9,477	0.0354	9,812.49	1619	**6.06**

Operating Room Service Areas	Inventory of Existing Operating Rooms			Adjustment	Adjustment	Adjustment for CONs Issued, Settlement Agreements and Previous Need	Adjusted Planning Inventory (Surgical Operating Rooms)	Projected Surgical Operating Room Deficit or Surplus (Surplus shown as a "-")	Projected Need for New Surgical Operating Rooms
	Number of Inpatient Operating Rooms	Number of Ambulatory Operating Rooms	Number of Shared Operating Rooms	Exclusion of Dedicated C-Section Rooms	Exclusion of One OR for each Level I, II, & III Trauma Center & Burn Unit				
Randolph County 2005 Volumes from 2007 SMFP	1	0	5	-1	0	0	5.00	0.30	0
Randolph County 2006 Volumes from 2008 SMFP	1	0	5	-1	0	0	5.00	-0.21	0
Randolph County 2007 Volumes from 2009 Proposed	1	0	5	-1	0	0	5.00	-0.50	0
All Surgical Procedures per 2008 Licensure Form Def.	1	0	5	-1	0	0	5.00	0.24	1
If Actual Capacity (8 hours for 253 days) was used w/2005 volumes	1	0	5	-1	0	0	5.00	1.13	1
If Actual Capacity (8 hours for 253 days) was used w/ 2006 volumes	1	0	5	-1	0	0	5.00	0.53	1
If Actual Capacity (8 hours for 253 days) was used w/ 2007 volumes	1	0	5	-1	0	0	5.00	0.21	1
Using Actual Capacity (8 hours) and all Surgical Procedures	1	0	5	-1	0	0	5.00	1.06	1

While we are not petitioning to change the SMFP methodology to reflect an 8 hour day, we are presenting this data to underscore the need for a special need determination.

As evidenced in Randolph County, a small surplus according to the Operating Room methodology still translates into significant concerns in terms of scheduling, the ability to recruit surgical specialists, preferred start times, delayed cases, patient convenience, room

availability for emergency cases, as well as delays in start time that then require overnight observations (increased cost).

The proposed Tiering methodology in the 2009 SMFP does not answer the special need discussed in this petition.

Randolph Hospital has been monitoring the development of the tiered methodology. Randolph Hospital agrees with the general intent to make adjustment for similar size hospitals and differences in capacity. However, as the tiering is currently applied, the tiering methodology is not shown to answer the special need articulated in this petition. A comprehensive review of the tiering methodology is beyond the scope of this petition. Randolph Hospital finds it interesting to note that Tier 3 where Randolph Hospital is classified includes the largest collection of hospitals including: 76 facilities, many community hospitals, several critical access hospitals and even a few long-term acute care facilities. For Randolph Hospital, the projections in the tiered methodology show a numerical room utilization rate of 66% that simply does not reflect the access issues that are present in a smaller community. Randolph Hospital does not support the tiering methodology proposed in the 2009 SMFP as it fails to consider practical aspects of staffing constraints, patient choice and convenience needed to accommodate surgeons and their patients in small community hospitals.

The need methodology is not reflecting the additional need in Randolph County to provide quality surgical services.

Quality is also of the utmost importance when providing surgical services, or in any aspect of health care. While Randolph Hospital and the surgeons who perform cases there do an excellent job, the opportunity to offer surgery in an ambulatory setting would eliminate otherwise healthy outpatients requiring surgery being exposed to the inpatient environment and vice versa. Being able to separate these services would allow for the streamlining of processes that would improve turn around time and operating efficiencies that would therefore improve the quality of the service provided to the citizens of Randolph County.

The additional need determination will allow proposals to develop an ambulatory surgical center which will free up block time at the hospital operating rooms.

By moving some of the outpatient surgery to an ASC, this would free up block time in the O.R. schedule at the hospital. The result of this would be increased room availability for emergency cases and fewer delayed cases. As patient access is increased, both in-patient and outpatient volumes will increase.

Adverse Effects on the Population If the Adjustment is Not Made

There are several adverse effects on the population if the adjustment is not made. These include:

1. Compromised ability to recruit and retain physicians
2. Continued comparatively low access to surgical service capacity compared to that of all other North Carolina counties
3. Potential for lack of patient comfort and quality outcome risk with continued constraints on capacity
4. Lost opportunity to improve patient return to work times
5. Existing practices will not be able to grow, thereby reducing the ability to increase access to care and to provide much needed emergency coverage to the Randolph Hospital Emergency Department

The current constraints on capacity are impeding the ability to recruit and retain physicians.

Historically, Randolph Hospital has shown a positive correlation between physician recruitment and retention and surgical volume. This suggests that given access, patients want to stay home for their care. In order for Randolph Hospital and the surgeons who practice there to meet patient demand, patients need to be provided with the option of receiving care in an ambulatory surgery setting. Operating Rooms need to be readily available for urgent and emergent cases in the inpatient setting without compromising a patient's ability to receive non-emergent and elective procedures in an Ambulatory environment.

The ability to recruit and retain physicians is paramount to the health and wellness of the people of Randolph County. Currently, there are vacancies in 3 surgical specialties, which translate into a need for 4 surgeons. The physician recruitment office at Randolph Hospital fields questions from many prospective surgeons, and has encountered instances where several potential surgical candidates would not consider an otherwise competitive opportunity after hearing that there was not an Ambulatory Surgery Center in Randolph County. Also, one orthopedic surgery candidate who did interview declined the offer due to the unavailability of block time in the operating rooms. Dr. Lance Sisco, an Orthopedic Surgeon who practices in Asheboro and fellow petitioner, shared his thoughts about the effect of the lack of Operating Room capacity on recruitment and retention in a letter to the hospital recently. Dr. Sisco wrote:

"I am an orthopedic surgeon who has been in practice for 16 years. I have been on active staff at Randolph Hospital for the last 5 years. This community is in dire need of an Ambulatory Surgery Center for many reasons. Briefly, an ASC would improve patient access to care, reduce costs and improve quality of care. Three additional rooms in Randolph County would allow this to happen as a joint-venture between the physicians and the hospital.

Having an ASC here would greatly enhance our ability to recruit more orthopedic surgeons and other specialists to our community. Over the last 4 years, the hospital has been unsuccessful in recruiting an additional orthopedic surgeon. There are 4 orthopedic surgeons here, including myself. Two are in their 60's and very near retirement. My partner is 58, and wants to retire in 2 years. Soon, I may be the only orthopedic surgeon in Asheboro. This would very negatively impact patient access to orthopedic care. Emergency room orthopedic coverage would not be 24/7. We need at least 4 orthopedic surgeons here. We have interviewed several orthopedic surgeons over the last 4 years. All were very concerned over the lack of an ASC, and this played a major role in their decision not to come here.

An ASC delivers care much more efficiently, and this reduces costs. Health Insurance companies know this and steer their patients to ASC's in their preferred provider network, which are in Guilford County, some 25 miles away. This is an inconvenience to the patients in Randolph County. This out-migration of outpatient surgery patients greatly reduces our volume of surgery. This is the main reason our current O.R. volumes are artificially low. The longer this referral pattern continues the more market share we will lose. It could come to the point where it is not economically feasible for surgeons, such as myself, to practice in Asheboro. Ninety percent of the surgery I do is out-patient…"

Randolph County is in critical need of Orthopedic Surgeons, Ophthalmologists, and an ENT surgeon. All of these searches are impeded by the lack of an ASC as these specialties are outpatient driven. For the past 15 years, Randolph Hospital has been very successful with recruitment overall and continues to recruit to medical specialties, but recruitment in surgical specialties is suffering because of the lack of OR capacity in the county.

Without the additional need determination, Randolph County will continue to have the lowest access to operating rooms in the entire state of North Carolina.

The following table illustrates the ratio of population (per 1,000) to Operating Rooms for the counties contiguous to Randolph. This table illustrates that the citizens of Randolph County are at a disadvantage in the availability of operating rooms and that this requires them to seek care outside of the Operating Room Service Area. In fact, Chatham County's Critical Access Hospital has more OR capacity per population than Randolph County.

Population (per 1,000) compared to Operating Rooms
Randolph County and Contiguous Counties
Source: Thomson Market Planner Plus and 2009 Draft SMFP

Geography: County	2007 Population	ORs minus exclusions	2007 Population per Operating Room
Moore/ Hoke	115,628	27	4,283
Guilford	451,316	92	4,906
Stanly	60,788	5	12,158
Montgomery	24,889	2	12,445
Alamance/Caswell	166,347	12	13,862
Davidson	136,164	9	15,129
Chatham	46,955	2	23,478
Randolph	143,945	5	28,789

While it might be argued that these counties have surpluses in Operating Room capacity, it cannot be argued that these surpluses translate into readily available operating room space. Rather, some degree of alternative facility site is necessary for the community to provide patients with adequate choice in where care is delivered as well as providing surgeons with appropriate facilities and available times that are conducive to the busy lives of their patients. In an ambulatory surgery center, it is necessary to adjust the scheduling so that there is ample time for patient recovery prior to the close of business. The current methodology does not take into account that in order to recognize the cost savings associated with outpatient surgery (reduced overnight stays), surgeries must be performed in the morning hours or preceding a weekend to allow for appropriate recovery for patients before being discharged home.

In absence of the needs adjustment, we will be continually challenged in delivering quality, patient comfort, and good outcomes.

Our current OR capacity is not always conducive to ideal patient care. Due to our current capacity constraints, we often have patients who have to be scheduled for procedures in the late afternoon. This can be a particular strain when patients have to go without water and food nearly all day prior to the procedure. This can be especially challenging for pediatric patients and their families. There is emerging evidence that good outcomes are more difficult to achieve with afternoon surgery times. A recent study by Duke University Medical Center found that patients who undergo surgery late in the afternoon are more likely to experience unexpected adverse events related to their anesthesia than are patients whose operations begin in the morning.[1] (See Exhibit 4)

[1] Wright et al., Journal Quality & Safety in Health Care, August 2006

Without the additional operating room, Randolph County will continue to have limited access and will be unable to consider patient convenience and productivity concerns.

We need additional OR capacity so we can reduce time away from work for employees in our community. In the present economy and tight job market, patients continue to report that they simply cannot take multiple days during the week to recover for fear for losing their job.

Without the additional capacity, Randolph Hospital and the surgeons in Randolph County will not have the opportunity to grow the surgical services available to residents of their service area.

Finally, in absence of additional capacity, Randolph Hospital and the surgeons that operate in the operating rooms in Randolph County do not have the opportunity to grow their practices due to the constraints of only having access to the existing 5 operating rooms in Randolph County. In addition, the difficulty in recruiting and retaining physicians stands to have detrimental effects to the health care of citizens of Randolph County because adequate surgeons are needed to provide emergency backup to the emergency department at Randolph Hospital.

No Feasible Alternatives

Because the service area for operating rooms is defined by county, and the only operating rooms in the county are highly utilized and located within one provider, petitioning the state is the only alternative to add Operating Rooms to the 2009 SMFP for Randolph County. The addition of an OR allocation to Randolph County will enable applicants to further develop and expand access to surgical services that will benefit the service area.

Justification for Three Operating Rooms

Last year, Randolph Hospital, et. al, petitioned for one room in a conservative effort to gain OR access based almost solely on the assumptions set forth in the OR methodology. That is not the intended purpose of a special need petition. The State Medical Facilities Plan allows for special needs petitions to be presented for consideration if a particular geographic area or institution has special or unique circumstances that give rise to resource requirements that differ from those provided by the standard methodology presented in the SMFP. In an effort to meet the basic principles of Cost, Quality, and Access as stated in the SMFP, we are presenting a case for the optimal solution for our OR needs. The citizens of Randolph County deserve the same access that is afforded to other counties. They deserve the cost savings, efficiencies, and flexibilities that an Ambulatory Surgery Model provides without compromising their access to inpatient surgical care. Our physicians want to be able to meet the needs of their customers and provide them with options in when they receive their care. Randolph Hospital needs to be able to retain its medical staff and add desperately needed surgeons in order to assure ongoing emergency medical coverage to its patients. Today's healthcare consumer demands that.

The data provided in this petition easily makes a quantitative case based on the methodology to at minimum justify one additional Operating Room. Three operating rooms would allow Randolph County Surgeons to begin to reduce outmigration and provide the citizens of Randolph County with OR access comparable to other communities throughout the state. One OR alone does not provide the economies of scale or the access to more than 6 surgical specialties that need an ASC to offer appropriate care to their patients. Two operating rooms address the issue of economies of scale to a degree, but wouldn't provide any room for growth and recruitment given the multiple specialty use. In fact, last year this petition listed only 10 co-petitioning physicians because many didn't believe that one additional OR would address the problem. Now, 22 co-petitioners are included because they believe that 3 ORs can address the access issues and aid in recruiting additional surgeons. Two of these surgeons currently acknowledge taking all of their OP cases out of town because an ASC offers greater convenience. They stated that they would prefer to perform their cases locally.

A consultant that specializes in ASC development has advised the Hospital and Randolph County surgeons. They offer the following narrative in support of a multiple room ASC.

"From an operations perspective, we consider an OR at maximum capacity when we reach approximately 1200 cases per year. When we look at the case volume committed to the proposed surgery center in Asheboro, having a facility with 3 operating rooms, we believe, makes the most sense to accommodate multiple specialties.

Having 3 operating rooms allows us much greater flexibility in the following circumstances:

- **When a physician is delayed with their current surgery, and ends up needing more time, this impacts the schedule for the remainder of the day. Again, with the case volume anticipated with at least 6 specialties, this could be a very common occurrence. Having less than three operating rooms will result in decreased efficiencies and unnecessary delays.**
- **It is our experience that some cases will need to be added on a short amount of notice (orthopedics, gyn). With 2 fully scheduled operating rooms, there is no allowance for this.**
- **If we have 2 operating rooms that are fully scheduled to begin with, it does not allow for expansion of any type in the future or growth from surgeons that will be recruited into the area. One of our purposes is to play a role in decreasing healthcare costs by allowing these cases to be done in a less expensive environment. We are only able to do this if we have the ability to add on cases and expand. This has a positive effect by creating more opportunities for the physicians and increasing access locally to the entire community.**

- **Having 3 operating rooms will allow Randolph Hospital to recruit new physicians more effectively. Typically, hospitals in markets such as Randolph's have more challenges recruiting new physicians than those in larger markets. With anything less than 3 operating rooms, the surgery center will be at capacity soon after opening and will not allow for new cases and newly recruited physicians to be part of an ASC.**
- **Patients will be attracted to the many efficiencies of an ambulatory surgery center and will stay in the community for their outpatient, and other healthcare needs.**

Randolph Hospital and the co-petitioners realize that a need determination in the 2009 SMFP is paramount and that the long CON, planning, and development time to build operating room facilities leads us to ask for this appropriate allocation of operating rooms.

The Requested Adjustment Will Not Unnecessarily Duplicate Health Services

Since no other entity provides surgical services in Randolph County, there is not a risk for duplicating health services. A Three Operating Room allocation for the county will allow for operating efficiencies, which will improve quality, improve access, and improve cost savings to the community.

The allocation of these operating rooms will also allow for the collaboration of the hospital and numerous physicians in order to best address the changing health care needs of the population of Randolph County by creating an environment where multi-specialty Ambulatory Surgery can be offered to the citizens of Randolph County.

Conclusion

Based on the aforementioned reasons, we strongly encourage the SHCC to carefully consider the petition presented by Randolph Hospital, et al. and determine there is a need for three additional operating rooms in Randolph County.

Respectfully submitted this 1st day of August 2008.

By: Randolph Hospital, et al.
Robert E. Morrison
President
364 White Oak Street
Asheboro, NC 27203
336-629-8882
rem@randolphhospital.org

RANDOLPH HOSPITAL

Exhibits

Exhibit One: North Carolina Population and OR inventory

Exhibit Two: Licensure Section Correspondence

Exhibit Three: OR Utilization Models

Exhibit Four: Duke Health Article

Randolph Hospital, et. al. Petition
August 1, 2008

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Exhibit One
North Carolina Population and OR Inventory (2007)

Geography: County	2007 Population	Number of Operating Rooms (Minus exclusions)	Population divided by number of ORs
RANDOLPH, NC	143,945	5	28,789
CHATHAM, NC	46,955	2	23,478
PENDER, NC	45,600	2	22,800
UNION, NC	174,586	8	21,823
DAVIE, NC	40,235	2	20,118
YADKIN, NC	38,966	2	19,483
JOHNSTON, NC	129,022	7	18,432
LINCOLN, NC	72,521	4	18,130
FRANKLIN, NC	53,303	3	17,768
ALEXANDER, NC	35,271	2	17,636
ONSLOW, NC	151,473	9	16,830
GRANVILLE, NC	48,842	3	16,281
BLADEN, NC	32,125	2	16,063
DUPLIN, NC	47,818	3	15,939
BRUNSWICK, NC	94,227	6	15,705
DAVIDSON, NC	136,164	9	15,129
MCDOWELL, NC	44,036	3	14,679
Alamance /Caswell Total	166,347	12	13,862
ROBESON, NC	138,460	10	13,846
RUTHERFORD, NC	67,765	5	13,553
Halifax/Northampton Total	78,283	6	13,047
WILKES, NC	64,874	5	12,975
ANSON, NC	25,728	2	12,864
ASHE, NC	25,551	2	12,776
Vance/Warren Total	63,492	5	12,698
MONTGOMERY, NC	24,889	2	12,445
Pasquotank/Camden/Currituck/Gates/Perquimans Total	98,219	8	12,277
MARTIN, NC	24,461	2	12,231
STANLY, NC	60,788	5	12,158
STOKES, NC	47,508	4	11,877
ROWAN, NC	122,659	11	11,151
CALDWELL, NC	77,442	7	11,063
COLUMBUS, NC	54,832	5	10,966
CLEVELAND, NC	98,038	9	10,893
ROCKINGHAM, NC	97,970	9	10,886
Beaufort/Hyde Total	53,932	5	10,786
PERSON, NC	42,942	4	10,736
DGECOMBE, NC	50,735	5	10,147
UMBERLAND, NC	312,860	31	10,092
CARTERET, NC	67,511	7	9,644
BERTIE, NC	19,098	2	9,549
Jackson/Graham/Swain Total	56,875	6	9,479
LEE, NC	65,846	7	9,407
HARNETT, NC	92,809	10	9,281
Cherokee/Clay Total	36,264	4	9,066
WAYNE, NC	117,564	13	9,043
WATAUGA, NC	44,835	5	8,967
WAKE, NC	824,755	94	8,774
DARE, NC	34,745	4	8,686
SURRY, NC	74,664	9	8,296
GASTON, NC	198,586	24	8,274
MACON, NC	32,993	4	8,248
HAYWOOD, NC	57,135	7	8,162
SAMPSON, NC	62,855	8	7,857
WILSON, NC	77,549	10	7,755
RICHMOND, NC	46,330	6	7,722
TRANSYLVANIA, NC	30,262	4	7,566
SCOTLAND, NC	37,326	5	7,465
NASH, NC	96,158	13	7,397
BURKE, NC	81,017	11	7,365
AVERY, NC	14,095	2	7,048
CABARRUS, NC	165,979	24	6,916
WASHINGTON, NC	13,329	2	6,665
Craven/Jones/Pamlico Total	111,206	17	6,542
POLK, NC	19,461	3	6,487
HENDERSON, NC	101,627	16	6,352
LENOIR, NC	55,491	9	6,166
Chowan/Tyrell Total	18,292	3	6,097
ALLEGHANY, NC	11,722	2	5,861
MECKLENBURG, NC	831,600	143	5,815
IREDELL, NC	143,740	25	5,750
MITCHELL, NC	16,450	3	5,483
Buncombe/Madison/Yancey Total	259,551	50	5,191
GUILFORD, NC	451,316	92	4,906
HERTFORD, NC	23,686	5	4,737
EW HANOVER, NC	188,502	41	4,598
ATAWBA, NC	162,764	37	4,399
Pitt/Green Total	165,320	38	4,351
Moore/Hoke Total	115,628	27	4,283
FORSYTH, NC	351,368	83	4,233
DURHAM, NC	241,059	73	3,302
ORANGE, NC	125,198	38	3,295
	8,875,425	1,212	7,323

Exhibit Two

RANDOLPH HOSPITAL

July 30, 2008

Ms. Azzie Conley
Chief
Acute and Home Care Licensure and Certification Section
2711 Mail Service Center
Raleigh, NC 27699-2711

Re: Randolph Hospital's 2008 Licensure Renewal Application ~ Request to amend data

Dear Ms. Conley,

After a July 11, 2008, meeting with the State Medical Facilities Planning section of the Division of Health Services Regulation, we find it necessary to ask the Licensure Section to amend page eight of our 2008 Licensure Renewal application form.

Historically, on page eight of the hospital licensure renewal application, Randolph Hospital has followed the directions that implicitly state to only report the operating room cases that take place in a licensed operating room. In 2007, volumes totaled 1,321 inpatient cases and 3,234 ambulatory cases and were reported as such on the 2008 application. However, the 2008 hospital licensure renewal application now states to "Count all surgical cases, including cases performed in procedure rooms or in any other location." Randolph Hospital conferred with constituents at other Acute Care facilities, and due to the lack of a definition of "surgical procedures" and the risk of double counting volumes that are collected on subsequent pages of the licensure application, data was reported as it had been reported historically. Thus, 189 inpatient cases and 514 ambulatory procedures were not included on page eight of the licensure application and therefore were not included in the operating room case totals that are ultimately used to develop need projections in the 2009 proposed State Medical Facilities Plan.

The Planning Section staff recently met with Randolph Hospital personnel and advised them to correct this oversight with the Licensure Section so that the State Health Coordinating Council might consider this edited data for Randolph Hospital in the 2009 Proposed SMFP.

I have also attached a copy of a memo dated October 31, 2007, from Victoria McClanahan, Planning Section, which outlines that "DHSR is relying upon the facilities where surgery is performed to determine which procedures are surgical procedures."

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Mail To: P.O. Box 1048, Asheboro, NC 27204-1048
Web Site: www.randolphhospital.org

Exhibit Two

These additional 189 inpatient cases and 514 ambulatory cases are the result of adding in procedures that are regarded as surgical cases at Randolph Hospital, but are performed safely in other procedure rooms. After consultation with 15 surgeons in a variety of specialities, Randolph Hospital is refreshing our licensure data to include procedures deemed to be surgical in nature by these surgical professionals. These are procedures that are performed by surgeons and are performed in operating rooms in small hospitals, i.e. cystoscopy and OP minor surgery.

Please accept this letter and the amended page eight that is attached for your records so that data from Randolph Hospital may be refreshed in the 2009 SMFP.

Please do not hesitate to contact me if you need additional information or if you would like to discuss this further.

Sincerely,

Robert E. Morrison
President

Attachments: Revised page 8 – Randolph Hospital 2008 Licensure Renewal Application
October 31, 2007 memo from Victoria McClanahan

C: Victoria McClanahan, Planning Section

8. Surgical Operating Rooms and Cases

a) Surgical Operating Rooms

[1] Report *Surgical Operating Rooms* built to meet the specifications and standards for operating rooms required by the Construction Section of the Division of Health Services Regulation, and which are fully equipped to perform surgical procedures. These surgical operating rooms include rooms located in Obstetrics and surgical suites.

NOTE: If this License includes more than one campus, please submit the Cumulative Totals **and** COPY this sheet and Submit a duplicate of this page for each campus.

(Campus – *If multiple sites*: _____ **)**

Type of Room	Number of Rooms
Dedicated Open Heart Surgery [from 7.(b) 1.]	
Dedicated C-Section	1
Other Dedicated Inpatient Surgery	
Dedicated Ambulatory Surgery	
Shared - Inpatient / Ambulatory Surgery	5
Total of Surgical Operating Rooms	6

[2] Does this facility have approval for additional surgical operating rooms (i.e., **not** listed above) **that are being developed** pursuant to a Certificate of Need? _____ Yes __X_ No #Rooms

[3] Does this facility have approval for additional surgical operating rooms (i.e., **not** listed above) **that are being developed** pursuant to the exemption provided in Senate Bill 714? _____ Yes __X_ No #Rooms

b) **Surgical Cases by Specialty Area** - Enter the number of surgical cases by surgical specialty area in the chart below. Count each patient undergoing surgery as one case regardless of the number of surgical procedures performed while the patient was having surgery. Categorize each case into one specialty area – Total Surgical Cases is an unduplicated count of surgical cases. Count all surgical cases, including cases performed in procedure rooms or in any other location.

Surgical Specialty Area	Inpatient Cases	Ambulatory Cases
Cardiothoracic (excluding Open Heart Surgery)		
Open Heart Surgery (from 7.(b) 5.)		
General Surgery	706	1368
Neurosurgery		
Obstetrics and GYN (excluding C-Sections)	154	461
Ophthalmology	2	118
Oral Surgery	3	41
Orthopedics	297	826
Otolaryngology	14	452
Plastic Surgery		
Urology	101	458
Vascular		
Other Surgeries (which do not fit into the above categories)	8	24
Number of C-Section's Performed in Dedicated C-Section OR's	226	
Number of C-Section's Performed in Other OR's		
Total Surgical Cases	1511	3748

Exhibit Two

North Carolina Department of Health and Human Services
Division of Health Service Regulation
State Medical Facilities Planning Section
2714 Mail Service Center ▪ Raleigh, North Carolina 27699-2714

Michael F. Easley, Governor

Dempsey Benton, Secretary

Robert J. Fitzgerald, Director
Phone: 919-855-3865
Fax: 919-715-4413

Memorandum

To: Mike Vicario, North Carolina Hospital Association
From: Victoria McClanahan, Planning Section
Subject: 2008 License Renewal Applications
Date: 10.31.07

In an effort to improve data collection, DHSR made some changes to the Hospital and Ambulatory Surgical Facility License Renewal Applications for 2008. The changes were made after careful consideration of feedback from hospital planners, from the Operating Room Work Group, from DHSR staff and others. Please review the instructions on the 2008 License Renewal Applications carefully to ensure accurate completion of the forms.

To assist those completing the Applications, DHSR offers the following additional information related to changes to "Reporting Period" and "Surgical Operating Rooms and Cases".

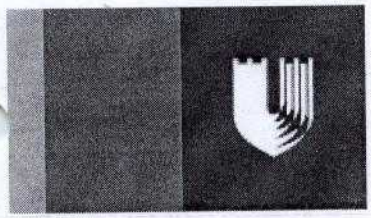
- "Reporting Period": DHSR expects all hospitals to report data for the same time period: October 1, 2006 through September 30, 2007. This change was made to increase consistency between the License Renewal Application (LRA) acute care days data and the Thomson acute care days data. As all hospitals are aware, each year when preparing the Proposed Plan, the License Renewal Application acute care days data are reconciled with the Thomson acute care days data. Requiring all hospitals to report data for the same time period eliminates a source of discrepancy between the LRA data and the Thomson data.
- "Surgical Operating Rooms and Cases": It has become apparent to DHSR that counting only cases performed in Operating Rooms does not provide an accurate count of all surgical cases performed in a facility because surgery is sometimes performed outside of an Operating Room and Operating Rooms are sometimes used for non-surgical cases. DHSR recognizes that facilities work hard to report accurate data and we attribute inaccuracies in surgical case reporting to the LRA data reporting format. Consequently, DHSR has changed the format for surgical case reporting such that we are now asking for a count of all surgeries regardless of where in the facility the surgery was performed. The goal is to obtain a more accurate count of surgical cases, which will improve the Operating Room need projections. In order to accomplish this goal, DHSR is relying upon the facilities where surgery is performed to determine which procedures are surgical procedures. DHSR recognizes that there may be disagreement among facilities as to whether or not some procedures should be counted as surgical procedures. However, we believe that overall there will be consistency among facilities as to which procedures are surgical procedures.

Thank you for your attention. Feel free to contact Victoria McClanahan at (919) 855-3868 or at victoria.mcclanahan@ncmail.net if you have other questions about reporting Acute Care or Surgical data.

Exhibit Three

Operating Room Service Areas	Projection of Surgical Operating Room Requirements										
	Estimated Total Surgery Hours							Application of Growth Factor			
	Surgical Cases reported as "Inpatient Cases" (w/ Exclusions)	Avg. Hours for Inpat. Cases	Esti-mated Hours for Inpat. Cases	Surgical Cases reported as "Ambulatory Cases"	Avg. Hours for Amb. Cases	Esti-mated Hours for Amb. Cases	Total Estimated Hours	Growth Factor (Population Change Rate)	Projected Surgical Hours Anticipated	Standard Hours per OR per Year (9/260/80%)	Projected Surgical Operating Rooms Required
Randolph County 2005 Volumes from 2007 SMFP	1,467	3.0	4,401	3,326	1.5	4,989	9,390	0.0563	9,918.66	1872	**5.30**
Randolph County 2006 Volumes from 2008 SMFP	1,249	3.0	3,747	3,208	1.5	4,812	8,559	0.0468	8,959.56	1872	**4.79**
Randolph County 2007 Volumes from 2009 Proposed	1,096	3.0	3,288	3,234	1.5	4,851	8,139	0.0354	8,427.12	1872	**4.50**
All Surgical Procedures per 2008 Licensure Form Def.	1,285	3.0	3,855	3,748	1.5	5,622	9,477	0.0354	9,812.49	1872	**5.24**
If Actual Capacity (8 hours for 253 days) was used w/ 2005 volumes	1,467	3.0	4,401	3,326	1.5	4,989	9,390	0.0563	9,918.66	1619	**6.13**
If Actual Capacity (8 hours for 253 days) was used w/ 2006 volumes	1,249	3.0	3,747	3,208	1.5	4,812	8,559	0.0468	8,959.56	1619	**5.53**
If Actual Capacity (8 hours for 253 days) was used w/ 2007 volumes	1,096	3.0	3,288	3,234	1.5	4,851	8,139	0.0354	8,427.12	1619	**5.21**
Using Actual Capacity (8 hours) and all Surgical Procedures	1,285	3.0	3,855	3,748	1.5	5,622	9,477	0.0354	9,812.49	1619	**6.06**

Operating Room Service Areas	Inventory of Existing Operating Rooms			Adjustment	Adjustment	Adjustment for		Projected Surgical	
	Number of Inpatient Operating Rooms	Number of Ambulatory Operating Rooms	Number of Shared Operating Rooms	Exclusion of Dedicated C-Section Rooms	Exclusion of One OR for each Level I, II, & III Trauma Center & Burn Unit	CONs Issued, Settlement Agreements and Previous Need	Adjusted Planning Inventory (Surgical Operating Rooms)	Operating Room Deficit or Surplus (Surplus shows as a "-")	Projected Need for New Surgical Operating Rooms
Randolph County 2005 Volumes from 2007 SMFP	1	0	5	-1	0	0	**5.00**	**0.30**	**0**
Randolph County 2006 Volumes from 2008 SMFP	1	0	5	-1	0	0	**5.00**	**-0.21**	**0**
Randolph County 2007 Volumes from 2009 Proposed	1	0	5	-1	0	0	**5.00**	**-0.50**	**0**
All Surgical Procedures per 2008 Licensure Form Def.	1	0	5	-1	0	0	**5.00**	**0.24**	**1**
If Actual Capacity (8 hours for 253 days) was used w/2005 volumes	1	0	5	-1	0	0	**5.00**	**1.13**	**1**
If Actual Capacity (8 hours for 253 days) was used w/ 2006 volumes	1	0	5	-1	0	0	**5.00**	**0.53**	**1**
If Actual Capacity (8 hours for 253 days) was used w/ 2007 volumes	1	0	5	-1	0	0	**5.00**	**0.21**	**1**
Using Actual Capacity (8 hours) and all Surgical Procedures	1	0	5	-1	0	0	**5.00**	**1.06**	**1**



DukeHealth.org

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Exhibit Four

News

Time of Surgery Influences Rate of Adverse Health Events Due to Anesthesia

DURHAM, N.C. – Patients who undergo surgery late in the afternoon are more likely to experience unexpected adverse events related to their anesthesia than are patients whose operations begin in the morning, a new analysis by Duke University Medical Center researchers suggests.

In the more than 90,000 surgeries analyzed, only a small percentage of the adverse events reported actually caused harm to the patients, the researchers said. The vast majority of events involved such serious though lesser problems as those related to pain management requiring additional attention to patients' pain and postoperative nausea and vomiting.

"This is one of the first studies to show that there is a difference in patient outcomes depending on the start time of surgery," said Melanie Wright, Ph.D., a human factors specialist in the Duke University Human Simulation and Patient Safety Center. Human factors specialists study how people behave physically and psychologically in different environments. Previous studies, she said, have examined the effects on patient outcomes of such factors as fatigue, sleep deprivation and circadian rhythms among health care workers.

In addition to spotting problems related to anesthesia, Wright and her colleagues also found that surgery patients experienced a significant increase in "administrative delays" during late afternoon, which might contribute to the increase in adverse events that occur during this time. The delays included waiting for laboratory test results, doctors running late, transporters not being available to move patients and rooms not being ready on time.

The team published its findings in the August 2006 issue of the journal Quality & Safety in Health Care. The research was supported by the Anesthesia Patient Safety Foundation.

Based on their findings, Wright and her colleagues suggest a number of factors that might contribute to variations in health outcomes. These factors include fatigue among health care providers, swings in the circadian rhythms that influence a person's natural ups and downs over the course of a day, and institutional work schedules.

"Health care is a 24-hour-a-day business, and it is not unexpected that factors such as fatigue, circadian rhythms, personnel shift changes and scheduling may affect patient care over the course of a day," Wright said. "We believe that

identifying the specific periods when problems are most likely to occur is an important step in the overall process of making surgery safer and ensuring that patients have a good experience."

For their analysis, the researchers drew on a database of all of the 90,159 surgeries performed at Duke Hospital over a four-year period beginning in 2000. Maintained by the Department of Anesthesiology, the database contains a record of each surgical patient's course of treatment, including any adverse events experienced, from hospital admission to discharge.

Wright's team divided all reported problems into one of three categories: "error," "harm" and "other adverse events."

The researchers identified 31 instances of error. These involved problems related to inserting tubes into patients' throats to maintain respiration and by improper dosing of patients with anesthetic agents.

They found 667 instances of harm, which included such events as prolonged sedation, wound infection and postoperative nausea and vomiting. Postoperative nausea and vomiting accounted for 35 percent of the harm events.

They assigned 1,995 events to the "other" category. These events included potentially dangerous changes in blood pressure and operating room equipment problems. About half these events were problems related to adequate management of patients' pain through anesthetic techniques and pain medication during surgery and immediately afterward.

The team then matched each adverse event with the time the patient's surgery began and conducted statistical analyses to identify differences in the rates of events over various times of day.

"We found that adverse events were most common for operations starting between 3 p.m. and 4 p.m.," Wright said. "Furthermore, the predicted probability of an adverse event in the "other" category increased from a low of 1 percent at 9 a.m. to a high of 4.2 percent at 4 p.m."

Wright said that many factors, involving both patients and hospitals, may contribute to increased rates of adverse events late in the afternoon. For example, patients may be more susceptible to either pain or post operative nausea and vomiting in the late afternoon. We don't know if issues such as not having eaten all day or spending a stressful day waiting in the hospital may have an influence on this, Wright said.

Late afternoon also is a time when changes in the teams that administer anesthesia during surgery coincide with natural circadian rhythm lows, Wright said. The circadian rhythm serves as the body's internal clock that regulates

sleep, brain wave activity and other bodily functions. Circadian lows occurring around 3 p.m. to 5 p.m. and again at 3 a.m. to 5 a.m may affect human performance of complex tasks such as those required in anesthesia care. Changes in anesthesia care teams usually occur around 7 am and again between 4 pm and 6 pm. End of day fatigue, a circadian low point, and changes in care team are all occurring around 3 pm to 6 pm and may be interacting in a way that affects patient care, she said.

The team's analysis also found 9,497 administrative delays that were not categorized as adverse events but may have an influence on them. "We found a significant increase in administrative delays in the late afternoon. It is possible that there is a relationship between these delays and the increase in adverse events," Wright said.

Wright cautioned that the study was a retrospective analysis of past operative cases based on self-reports by doctors and nurses of events that occur. A prospective study with unbiased observer documentation of events as they occur is needed to determine exactly what steps in the delivery of health care are responsible for the adverse events and how such events can best be avoided.

Wright and her team are now planning such a study to compare each step in the delivery of care for patients enrolled for surgery during two time periods: 9 a.m. to noon and 3 p.m. to 6 p.m. These times were identified in the current analysis as when the incidence of adverse events is lowest (first thing in the morning) and highest (late afternoon).

Also, Wright recently has received a grant from the National Institutes of Health to develop new processes of collecting and displaying information on patients undergoing surgery in order to improve patient safety.

Other Duke researchers involved in the study were Barbara Phillips-Bute, J. B. Mark, Mark Stafford-Smith, Katherine Grichnik, B. C. Andregg and Jeffrey Taekman.

About This Page

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