

August 12, 2020

Christopher Ulrich, MD, Chair SHCC  
North Carolina State Health Coordinating Council  
c/o NC Division of Health Service Regulation  
Healthcare Planning and Certificate of Need Section  
2704 Mail Service Center  
Raleigh, NC 27699-2704

**Re: Wake Forest Baptist Health Comments regarding Mission Health Petition for a Need Determination for eight Burn ICU Beds**

Dear Dr. Ulrich:

Wake Forest Baptist Health (“WFBH”) appreciates the opportunity to comment on the Petition submitted by Mission Health for a need determination for 8 Burn ICU beds submitted to the State Health Coordinating Council (SHCC) in response to Summer Petitions for adjusted needs determinations for the 2021 State Medical Facilities Plan (“SMFP”).

WFBH operates 1 of 2 American Burn Association (“ABA”)-verified Burn Centers in North Carolina and 1 of 73 ABA-verified Burn Centers in the United States. As the petitioner mentions the term “comprehensive burn center” throughout its petition, it is assumed that the petitioner is referencing ABA-verified Burn Centers, as the term “comprehensive burn center” is not used in the burn community. The purpose of Burn Center verification is to maintain Burn Center quality and optimal outcomes by promoting patient safety, cost containment, regional education and outreach, injury prevention, innovation and research, and advocacy.

WFBH’s ABA-verified Burn Center is led by Dr. James H. Holmes IV. Dr. Holmes is a Professor of Surgery and Regenerative Medicine at Wake Forest University School of Medicine and the Director of the Burn Center at the Wake Forest Baptist Medical Center (WFBMC) in Winston-Salem, NC. Dr. Holmes is a national leader in Burn Surgery. He serves as a member of the American Burn Association Board of Trustees. Dr. Holmes is the Director of the American Burn Association Burn Research Network (ABuRN) and chairs its Burn Science Advisory Panel (BSAP). Dr. Holmes also maintains appointments to the American College of Surgeons National Committee on Trauma and the Board of Directors of the Coalition for National Trauma Research (CNTR). Please reference **Exhibit 1** for the bios of Dr. Holmes, Dr. Kevin Bailey, and Dr. Anju Saraswat, WFBH’s 3 dedicated burn surgeons. Please see **Exhibit 2** for letters of support.

Based on review of the petition, inclusive of a detailed review and input from WFBH’s leaders in Burn Surgery and Critical Care, WFBH strongly urges the SHCC to deny the petition for the reasons set forth below.

- 1. Burn ICU beds are highly specialized, complex care environments and, thus, appropriately considered a regional asset in the SMFP to ensure adequate volume and expertise to care for these patients. The patient numbers submitted by Mission Health to try and substantiate their “need” for Burn ICU beds is inadequate to obtain and maintain the expertise necessary to insure optimal burn outcomes for the citizens of Western NC.**
  - 2. North Carolina has sufficient Burn ICU access with 2 ABA-verified Burn Centers, 29 licensed burn ICU beds, and 8 additional Burn ICU beds under development.**
  - 3. The market analysis and methodology provided to calculate the "need" for 8 beds is inconsistent with SMFP methodologies and heavily relies on non-North Carolina residents.**
  - 4. The petition presents multiple statements regarding the care of burn injured patients as facts or standard of care, and this is not the case. While this may be the standard of care for HCA, these statements are not universally applicable to all Burn Centers or all burn patients.**
- I. Highly Specialized and Complex Care, Appropriately Provided by Regional Providers**

The provision of high-quality burn care requires a highly trained and specialized interdisciplinary team of experts to optimize the outcomes of the burn injured patient. These teams of experts are led by burn surgeons and involve professionals across multiple disciplines; their existence is enabled by regionalization of care, i.e. the hierarchical consolidation of patients with similar diagnoses in a geographic catchment area. Similar groupings have demonstrated benefits in many other complex surgical conditions (Mackenzie et al. 2006; Luft et al. 2007; Birkmeyer 2000; Birkmeyer et al. 2002). That the benefits of regionalization of care would extend to burn patients is unsurprising, and the long-standing ABA Verification process substantiates this. The vast majority of ABA-verified Burn Centers are regional centers and achieve better outcomes than non-verified Burn Centers, which tend to be smaller and serve more localized populations.

Successful and cost-effective burn management requires not only a surgeon experienced in burns and critical care, but a skilled nursing staff, physical and occupational therapists, social workers, nutritionists, pharmacists and chaplains. Pediatricians and child life specialists are standard when caring for younger patients (Kastenmeier et al. 2010). Bulleted below is further description of the level of specialization and experience required of surgeons, nurses and therapists at an ABA-verified Burn Center.

- Physicians: A surgeon with “experience” in treating burn patients is insufficient to provide the expertise and specialization that is necessary to ensure residents of Western North Carolina have access to quality burn care. By contrast, at an ABA-verified Burn Center, the surgeon Burn Center Director must be either Burn Fellowship trained or have direct burn care experience for at least two years in the previous 5 years.

Furthermore, the staff burn surgeons must have 2 or more years of mentored experience in caring for acute burn patients.

- Nurses: From a nursing perspective, just having an appropriate number of nurses is not sufficient. To ensure access to high quality burn care, the nurses must have experience in both burn care and critical care. The nursing staff at an ABA-verified Burn Center must have demonstrated expertise in burn care, perform annual burn-specific continuing education, and have a nurse leader/manager with direct burn and managerial experience. Burn nurses are a scarce commodity in medicine today, and burn nursing leaders/managers are even more scarce.
- Rehabilitation Therapy Providers: For rehabilitation therapy services, the same holds true; access to general physical and occupational therapy services is not sufficient. At an ABA-verified Burn Center, a minimum of a 1.0 FTE physical therapist and a 1.0 FTE occupational therapist are required to be solely dedicated to the care of burn patients. Additionally, the therapists must have burn-specific continuing education on an annual basis. Burn therapy expertise is quite finite and actually very limited in the US today.

It would be difficult to provide this level of expertise in a non-regionalized fashion, and the benefits are mutual to patients and providers. Providers stay busy enough to maintain their skills and competencies, while patients benefit from the derived expertise (Warden and Heimbach 2003). While multidisciplinary treatment has been shown to have a significant impact on a burn patient's quality of life after discharge (Sheridan et al. 2000), patients treated in high-volume centers have been shown in multiple studies to be more likely to discharge home, rather than to skilled nursing facilities, implying better functional outcomes at discharge (Pacella et al. 2006; Klein et al. 2008).

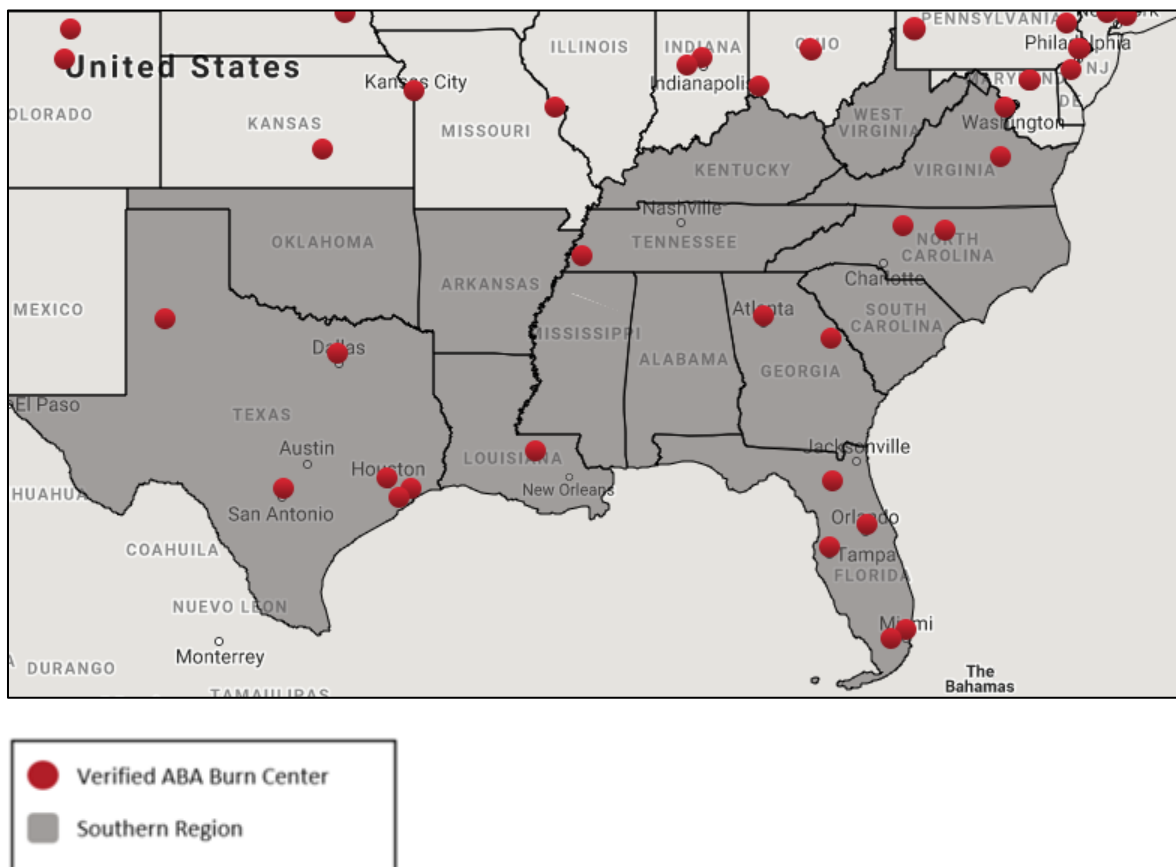
Optimal burn care requires a diverse team of professionals. Consolidation of resources in regional centers, including staff expertise and availability, has proven beneficial to patient outcomes and cost of care. Although the petitioner describes the availability of such resources at Mission Health in Section F and Exhibit 9 of the petition, the resources listed and described are no more than the expected services of any Joint Commission-approved acute care hospital. Additionally, the ~56 Western NC residents per year (Exhibit 3, top half) allegedly impacted by adding Burn ICU beds at Mission Health is insufficient for any provider or ancillary staff to establish and maintain expertise and proficiency in acute burn care; thus, outcomes would likely not be optimal, which is the opposite of the current situation for residents of Western NC. Finally, Dr. Michael Schurr, the sole surgeon at Mission Health who meets the qualifications cited earlier, did not provide a letter of support for the petition.

## II. North Carolina has Sufficient Access to Burn ICU Beds and Burn Centers

### *ABA-verified Burn Centers*

As illustrated below, WFBH operates 1 of 2 ABA-verified Burn Centers in North Carolina, 1 of 18 ABA-verified Burn Centers in the ABA Southern Region, and 1 of only 73 ABA-verified Burn Centers in the United States. As compared to other Burn Centers in the Southern Region, WFBMC is proximate to Western North Carolina and well positioned to serve these patients. The population per ABA-verified Burn Center in North Carolina is 4,767,742, as compared to other surrounding states like Tennessee at 6,346,105 and Virginia at 8,001,024. In the ABA Southern Region<sup>1</sup>, North Carolina is 1 of 7 states with an ABA-verified Burn Center and 1 of just 4 states with multiple ABA-verified Burn Centers. Nationally, South Carolina, along with 18 other states, does not have an ABA-verified Burn Center. The population per state and ABA-verified Burn Center is further illustrated below.

### ABA-verified Burn Centers in the Southern Region



Sources: <http://ameriburn.org/>

<sup>1</sup> The ABA identifies the Southern Region as Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, West Virginia, and Puerto Rico.

**Table 1: Southern Region Burn Centers  
(ABA-verified and Non-Verified Burn Centers)**

State	Population	# of ABA-verified Burn Centers	# of Non-Verified Burn Centers	Total # of Burn Center (ABA-verified and Non-Verified)	Pop. per ABA-verified Burn Center	Pop. per Total Burn Centers
Texas	25,145,561	6	1	7	4,190,927	3,592,223
Florida	18,801,310	5	1	6	3,760,262	3,133,552
North Carolina	9,535,483	2	0	2	4,767,742	4,767,742
Georgia	9,687,653	2	1	3	4,843,827	3,229,218
Louisiana	4,533,372	1	3	4	4,533,372	1,133,343
Tennessee	6,346,105	1	1	2	6,346,105	3,173,053
Virginia	8,001,024	1	2	3	8,001,024	2,667,008
Alabama	4,779,736	0	3	3	N/A	1,593,245
Arkansas	2,915,918	0	1	1	N/A	2,915,918
Kentucky	4,339,367	0	1	1	N/A	4,339,367
Mississippi	2,967,297	0	0	0	N/A	N/A
Oklahoma	3,751,351	0	2	2	N/A	1,875,676
South Carolina	4,625,364	0	1	1	N/A	4,625,364
West Virginia	1,852,994	0	1	1	N/A	1,852,994

WFBMC is the most proximate ABA-verified Burn Center to Mission Hospital. The petition states the drive time from WFBMC to Asheville, NC to be two hours and forty minutes based on an 8am departure; however, Google Maps actually estimates this drive time as a range from two hours and ten minutes up to two hours and forty minutes at the 8am departure time. From a mileage perspective, the distance from Mission Hospital to WFBMC is approximately 143 miles as compared to the distance from Mission Hospital to Doctors Hospital of Augusta (“DHA”), which is 185 miles.

*North Carolina Burn ICU Utilization and Capacity*

North Carolina's 2 ABA-verified Burn Centers are located at WFBMC in Winston-Salem and at UNC Hospital in Chapel Hill. WFBMC's Burn ICU includes 8 beds, while UNC's Burn ICU includes 21 beds. As indicated in Exhibit 6 of the petition, the occupancy rate of WFBMC's Burn ICU was 62.4% during FFY 2019. This occupancy rate converts to an average daily census of 4.99; conversely, this translates to an average of three open beds per day in the WFBMC Burn ICU. Per the North Carolina SMFP, the target occupancy rate of burn ICU beds is 80%. WFBMC's Burn ICU is approaching the 80% target occupancy but has not hit that threshold and, as such, has the capacity to care for additional patients prior to the development of its 4 CON approved beds.

In Exhibit 3, on page 6 of the petition, the petitioner provides a table identifying Western North Carolina "Comprehensive Burn Center" patients. According to this data, a total of 54

patients from Western North Carolina received care at a "Comprehensive Burn Center" in 2019. Of these 54 patients, 29 sought care outside of North Carolina - with 27 being cared for at DHA in Augusta and two at Grady Memorial Hospital in Atlanta. It is not clear to WFBH why these North Carolina patients are traveling outside North Carolina (and further away than WFBMC) for burn care. Assuming these patients had an ICU length of stay of 15.33 days, as presented in Exhibit 8 of the petition, these patients would have accounted for 444.57 days of care - or an average daily census of 1.22. With an occupancy rate of 62.4%, WFBMC has the capacity to care for these patients within their home state of North Carolina - closer to their home and family, and the care would be provided by nationally recognized burn surgeons who deliver the highest quality, most cutting edge burn care, including access to the latest treatments and clinical trials. Addition of 100% of these patients currently stated to be traveling out of state to a "Comprehensive Burn Center" would increase WFBMC's occupancy to 77.6%, leaving some capacity for additional growth while the additional 4 CON-approved beds are developed.

WFBMC and UNC each have a CON for the development of 4 incremental Burn ICU beds, for a total of 8 additional Burn ICU beds in North Carolina. Once operational, the addition of these incremental 8 Burn ICU beds will increase the North Carolina Burn ICU bed capacity by 28%. While these CONs were awarded in 2012, both projects have experienced delays in development. As described in WFBMC's progress reports, the originally proposed location from the CON application proved to be nonviable as a result of facility issues, including HVAC and air return issues that are required in critical care units. In its February 15, 2019 progress report, WFBMC described an extensive evaluation it undertook to explore all potential options for developing the 4 additional beds. A total of 5 different scenarios were evaluated, and it was determined that the best option is to develop the 4 incremental beds with the 8 existing beds in a new 12-bed unit. This new 12-bed unit will be located in space that is vacated upon WFBMC's completion of a new patient services building; the expected date of opening of the new 12-bed unit is July 1, 2024. Please reference **Exhibit 3** for the February 15, 2019 WFBMC Burn ICU bed progress report. This plan for expansion of the WFBMC Burn Center is "firm" & wholly committed to by WFBH.

The SMFP has not determined any need for additional burn ICU beds in North Carolina since 2012. The eight previously approved beds currently in development represent a significant inventory change over the 29 operational beds. WFBH believes the best approach for the SHCC at this time is to allow time for the approved beds come online, then reassess need for any additional burn ICU beds via the SMFP need methodology.

### **III. The Market Analysis and Methodology Provided to Calculate the "Need" for 8 Beds is Inconsistent with SMFP Methodologies**

Mission Health provides a methodology to determine that there is a "need" for 8 additional Burn ICU beds in North Carolina. This "need" is based on a market analysis and methodology that is inconsistent with all other SMFP methodologies utilized to determine service and facility needs. Concerns with the methodology are noted below.

- *The methodology includes outmigration of North Carolina residents to other states for treatment.*

The methodologies in the annual SMFP do not include outmigration of North Carolina residents to other states in any need determination methodologies for other services. The healthcare planning staff and members of the SHCC do not have insight into North Carolina residents that leave the state for treatment, as data for these patients is not available through the sources used to determine service needs, such as the annual license renewal applications. While outmigration to other states certainly occurs each year, this outmigration is not a consideration in SMFP need determination methodologies.

- *The methodology includes residents from outside of North Carolina that are presently seeking treatment at facilities outside of North Carolina.*

More disconcerting than the inclusion of the outmigration of North Carolina residents to other states for care, the petitioner includes in its methodology services provided to non-North Carolina residents at non-North Carolina facilities. In Exhibit 8, on page 16 of the petition, Mission Health claims there is a need for 8 additional Burn ICU beds in North Carolina, based on the utilization of patients from Western North Carolina and the Four State Region<sup>2</sup>. This projected need is heavily dependent on the utilization of non-North Carolina residents from Tennessee, Kentucky, Virginia, and South Carolina that are currently being cared for in a facility that is not based in North Carolina. In fact, a review of the NCHA data for burn inpatient acute care discharges<sup>3</sup> for patients originating from the Four State Region illustrates that only 21 patients from that region were discharged from a North Carolina hospital in 2019, reference Table 2 below. Exhibit 8 of the petition notes that a total 474 burn inpatients originated from the Four State Region in 2019. With only 21 of these discharges occurring at a North Carolina hospital, the remaining (and vast majority) are being cared for out of state. The provision of services outside of North Carolina to non-North Carolina residents is not within the scope of the North Carolina State Medical Facilities Plan and should not be included in a determination of need in North Carolina.

---

<sup>2</sup> Reference page six of the Mission Health petition for the petitioners definition of Western North Carolina and the Four State Region

<sup>3</sup> As defined in Attachment B of the petition

**Table 2**  
**Four State Region Burn Inpatients, Cared for Inside and Outside of NC**

	<b>2018</b>	<b>2019</b>
Four State Region Burn Inpatients, as Identified in Page 16, Exhibit 8 of the Petition	463	474
Four State Region Burn Inpatients Discharged from a North Carolina Hospital*	6	21
Four State Region Burn Inpatients Discharged from a non-North Carolina Hospital**	457	463
Percent of Four State Region Burn Inpatient Discharges treated at a non-North Carolina Hospital	99%	96%

\*Source: NCHA Patient Data System; years are federal fiscal years

\*\*Calculated by subtracting the number of patients discharged from a NC hospital from the total number of patients identified in Exhibit 8 of the petition

- *The assumption that 31% of burn discharges for NC providers and 50% for out of state transfers require an ICU bed is arbitrary and not supported by any creditable data or assumptions.*

A review of the same NCHA data noted above, for burn inpatient acute care discharges<sup>2</sup> who originated from anywhere and were discharged from a North Carolina hospital, illustrates that approximately 19% of burn inpatient acute care discharges require Burn ICU care, as defined by encounters with burn ICU revenue code 020. Please reference the table below.

**Table 3:**  
**Burn Inpatient Acute Care Discharges from NC Hospitals**  
**Discharges with and without a Burn ICU Revenue Charge**

	<b>IP Acute Discharges</b>			<b>% of Yearly Total</b>		
	<b>2018</b>	<b>2019</b>	<b>Total</b>	<b>2018</b>	<b>2019</b>	<b>Total</b>
Does NOT have Burn ICU Rev Charge	1,127	1,162	2,289	79%	82%	81%
Has Burn ICU Rev Charge	298	256	554	21%	18%	19%
<b>Grand Total</b>	<b>1,425</b>	<b>1,418</b>	<b>2,843</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>

Source: NCHA Patient Data System; years are federal fiscal years  
Burn ICU Revenue Code: 0207

- *The petitioner's own data illustrates that residents of Western North Carolina cared for at a "Comprehensive Burn Center" outside of North Carolina occupy approximately 1.22 beds.*

In Exhibit 3, on page 6 of the petition, the petitioner provides a table identifying Western North Carolina "Comprehensive Burn Center" patients cared for both within and outside of North Carolina. According to this data, a total of 54 patients from Western North Carolina received care at a "Comprehensive Burn Center" in 2019. Of



these 54 patients, 29 sought care outside of North Carolina - with 27 being cared for at DHA in Augusta and 2 at Grady Memorial Hospital in Atlanta. Assuming these patients had an ICU length of stay of 15.33 days, as presented in Exhibit 8 of the petition, these patients would have accounted for 444.57 days of care - or an average daily census of 1.22. This average daily census is much lower than the 8-bed "need" projected in the petition and can be met by the existing North Carolina Burn Centers.

**IV. The petition presents multiple statements regarding the care of burn injured patients as facts or standard of care, and this is simply not the case. While this may be the standard of care for HCA, these statements are not applicable to all Burn Centers or all burn patients.**

Page 10 of the petition writes, *"In most cases, the standard of care for intubation is to use the Denver Criteria. Normally, only patients who satisfy these criteria-- including symptoms such as full-thickness facial burns, respiratory distress, and upper airway trauma - should be intubated. However, it is also the standard of care to intubate a burn patient during helicopter transport regardless of the Denver Criteria."* While this may be the standard of care for HCA, it is not the standard of care to intubate all burn patients prior to helicopter transport in North Carolina. There are no approved protocols in North Carolina that allow for the intubation of all burn patients prior to being flown in a helicopter. Current North Carolina Standardized EMS protocols are actually deemphasizing the need for prehospital intubation. Intubating all burn patients prior to air transport is dangerous and not necessary.

Dr. JE "Tripp" Winslow, MD MPH further explains, *"I know of no flight program where this is required. Prehospital EMS intubation, while an important procedure, also entails significant risk. Some of the risks of intubation include airway trauma, hypoxia, aspiration, esophageal intubation, and right main stem intubation. Badulak in the journal Burns found that burn patients should only be intubated if they meet the Denver criteria, which are a very specific. Baulak goes on to say that patients who do not meet the Denver criteria should not be intubated, because the risks outweigh any benefit. The statement that all burn patients should be intubated prior to transport is not true and sets a dangerous precedent."* Dr. Winslow is an Associate Professor of Emergency Medicine at Wake Forest School Medicine.

Page 8 of the petition discusses extensive travel associated with the Burn ICU stay and follow-up care. Specifically, the petitioner writes *"Such extensive travel is not just a one-time event. Many of these patients and their families must make the 5+ hour trek five or more times—for the initial emergency burn service through extended recovery, to subsequent admissions for skin grafts and other services, and to receive the follow-up, outpatient care they need during the extended recovery process. As such, the region is in dire need of a provider that can alleviate the existing travel burden and better meet the needs of burn patients and their families."* While it may be true that patients treated at DHA require 5 or more subsequent visits after the initial inpatient discharge, this statement is not universally applicable to all Burn Centers or all burn patients. By contrast, patients discharged from WFBMC's ABA-verified Burn Center generally require 1 or 2 subsequent visits, approximately 30% of which are provided via telemedicine. The use of telemedicine and the

lower overall volume of post-discharge visits results in significantly less travel requirements of patients and their families than what is presented in the petition.

Furthermore, the petitioner mentions the need to travel extensive distances for follow-up care throughout its petition. The petitioner also notes multiple times that it has all the resources in place, except the ICU beds, to be a "Comprehensive Burn Center". Burn ICU beds are not a requirement to provide follow-up outpatient care, or even inpatient acute care that does not require an ICU bed. If Mission Health has all the resources in place to be a "Comprehensive Burn Center", except the ICU beds, then surely it should have been providing all of the burn care necessary for smaller burns for years. That, however, is not the case. The addition of ICU beds is simply not necessary to enable the provision of subsequent care for the vast majority of burn patients in Western NC.

For the reasons stated above, WFBH respectfully requests the SHCC deny this petition. Thank you for the opportunity to comment on our concerns regarding the petition.

Sincerely,

*Jena Folger*

Jena R. Folger  
Vice President  
Wake Forest Baptist Health

## **Exhibit 1**

Biographies:  
Dr. James H. Holmes  
Dr. J. Kevin Bailey  
Dr. Anju Saraswat

## **James H. Holmes IV, MD FACS**

Dr. Holmes is a Professor of Surgery and Regenerative Medicine at Wake Forest University School of Medicine and the Director of the Burn Center at the Wake Forest Baptist Medical Center in Winston-Salem, NC, with appointments in the Department of General Surgery and the Wake Forest Institute for Regenerative Medicine. He received his medical degree from the University of Texas Southwestern Medical School in Dallas, TX and trained in General Surgery at the Virginia Mason Medical Center, including an Immunology Research Fellowship at the Virginia Mason Research Center/Benaroya Research Institute in Seattle, WA. Subsequently, he completed fellowships in Burn Surgery at the University of Washington Harborview Medical Center and Trauma/Surgical Critical Care at the University of Pennsylvania.

His clinical specialty is Burn Surgery, with research interests in the pathophysiology, treatment, & outcomes of burn injuries, as well as burn disaster/surge management. Dr. Holmes' current research focus is the development of skin substitutes and other alternatives to standard autografting of burn wounds. His investigative work has been supported by the National Institutes of Health, the US Department of Health & Human Services, and the Department of Defense. Dr. Holmes is also the Director of the American Burn Association Burn Research Network (ABuRN) and chairs its Burn Science Advisory Panel (BSAP), while maintaining appointments to the American College of Surgeons National Committee on Trauma and the Board of Directors of the Center for National Trauma Research.

## Biography J. Kevin Bailey, MD

Dr. Bailey completed undergraduate study at the Ohio State University before attending medical school at the University of Cincinnati. He stayed at the University of Cincinnati for his residency in General Surgery. After completion, he served for four years in the United States Air Force, during which time he trained in burn surgery at the Institute of Surgical Research. He then served as the Associate Director of the Burn Center at Miami Valley Hospital in Dayton, Ohio before returning to the University of Cincinnati. While in Cincinnati, he served as the Medical Director of the Burn Center and was a burn surgeon at Shriners Hospital for Children - Cincinnati. During his time there, he also completed a fellowship in Hand Surgery and began funded research in the use of lasers to modify burn scars.

In 2013, Dr. Bailey moved to the Ohio State University where he established a laser program for burn patients, treating both inpatient and outpatient victims of burn injury. In addition, he earned a Center for Clinical and Translational Science (CCTS) grant to conduct a pilot study using a porcine burn model that he developed. In collaboration with Heather Powell, PhD, the model has been used for multiple studies that have expanded our understanding of the modification of burn scars with lasers and compression garments (funded primarily by Shriners Hospitals for Children, totaling over \$2.6 million).

Dr. Bailey is Board Certified in General Surgery and Surgery of the Hand, and he joined the Wake Forest Department of Surgery in July, 2019. He continues a busy practice of acute burn care, hand surgery, and burn reconstruction, with a special interest in the study of the effects of laser therapy and compression therapy in modifying burn scars.

## Anju Saraswat MD

Dr. Saraswat is an Assistant Professor of Surgery at Wake Forest University School of Medicine and the Associate Director of the Burn Center at the Wake Forest Baptist Medical Center in Winston-Salem, NC. She received her medical degree from Northeast Ohio Medical University and trained in General Surgery at Riverside Methodist Hospital in Columbus, OH. She subsequently completed two fellowships in Acute and Reconstructive Burn Surgery at the University of California, Davis Medical Center and Shriners Hospitals for Children – Northern California and her Surgical Critical Care Fellowship at University of California, San Francisco Fresno.

Her clinical specialty is Acute and Reconstructive Burn Surgery with research interests in burn reconstruction and outcomes of burn injuries. Dr. Saraswat is a committee member of the Program Committee for the American Burn Association as well as an active Instructor of the American Burn Life Support Provider Course.

## **Exhibit 2**

### Letters of Support

8/11/2020

North Carolina State Health Coordinating Council  
Health Care Planning and Certificate of Need  
Division of Health Services Regulation  
809 Ruggles Drive  
Raleigh, NC 27603

RE: Petition for Special Need Adjustment for Burn Intensive Care Services in the Western North Carolina Region (HSA I) by Mission Hospital

Dear Members of the SHCC:

I write this letter in strong opposition to the Petition for Special Need Adjustment for Burn Intensive Care Services in the Western North Carolina Region (HSA I) by Mission Hospital.

I have practiced Burn Surgery in North Carolina my entire career, which began in January 2006 as the Director of the WFBMC Burn Center. I have a vested interest and successful track record in insuring that every North Carolinian has access to the highest quality burn care possible. North Carolina is fortunate to have 2 American Burn Association (ABA)-verified Combined Adult and Pediatric Burn Centers - the WFBMC Burn Center in Winston-Salem and the UNC Jaycee Burn Center in Chapel Hill. ABA Verification is the highest level of certification that a Burn Center can achieve and is currently awarded to only 73 Burn Centers in the US. It requires meeting stringent criteria on an on-going basis for this distinction.

Since my arrival in 2006, I have diligently worked with the leadership at the UNC Jaycee Burn Center to develop a Burn System for NC whereby all North Carolinians have access to the highest quality burn care. The system we have developed is underpinned by the concept of “regionalization” of care, which has been shown to be associated with better outcomes in burns as well as multiple other surgical and medical conditions. We developed patient catchment areas for each Burn Center and have respected those for 15 years, while simultaneously collaborating during times of patient surges to insure neither Burn Center is overwhelmed. The driving impetus behind the actual creation of these catchment areas was the overall impact of travel on the patients and their families. We wanted any travel for burn care to be as minimal as possible. Mission Hospital was never interested in consistently providing burn care, beyond ED assessment and stabilization, for any burns at all during any of this time.

As such, Western NC is part of the WFBMC Burn Center patient catchment area. Recognizing that our patients and their families from Western NC many times have significant travel requirements and potentially limited financial resources, the WFBMC Burn Center has developed many protocols and processes to reduce the impacts. These span 24/7 prehospital EMS transport arrangements and telehealth capabilities, 24/7 real-time telehealth interfaces and direct collaboration with providers from consulting/referring facilities (e.g. - EDs, Urgent Care Centers, and physicians’ private offices), and reduced, in-person, follow-up visits via established telehealth interfaces for patients from Western NC.



These enhancements to care, tailored for our Western NC patients, have only been possible for us to achieve as part of our growth and development as an ABA-verified Adult and Pediatric Burn Center. The resources and personnel required to be an ABA-verified Burn Center, and hence deliver optimal outcomes for burn patients, are significant and not generally able to be provided by non-verified Burn Centers or other tertiary care facilities like HCA/Mission Hospital in Asheville. The resources cited in their petition do not even compare to what we have to offer burn patients from Western NC at the WFBMC Burn Center. The contention that HCA/Mission Hospital is capable of providing “comprehensive burn care”, which I equate to care at an ABA-verified Burn Center, is naïve at best, and it puts patient outcomes directly at risk.

The WFBMC Burn Center, which admits 350-400 adult and pediatric burn patients per year, is currently staffed and covered 24/7/365 by 3 Burn Fellowship trained Burn Surgeons, 2 of whom are also board-certified in Surgical Critical Care and the other is board-certified in Hand Surgery. The Nursing Staff for the Burn Center, and the Burn ICU in particular, is comprised of RNs and CNAs who are hired by the Burn Service Line and solely assigned to burn patients. The experience of the Nursing Staff ranges from over 35 years in burn care to new hires who complete an extensive burn-specific orientation that involves both burn critical and burn wound care. The Burn Center Nursing leadership/management is comprised of a Unit Manager and an Assistant Unit Manager, both of whom have over 10 years of direct burn care experience. The inpatient Rehabilitation Therapy cadre of the Burn Center has a dedicated, burn-specific PT, PTA, OT, and OTA, all with extensive burn therapy experience and credentials. Additionally, we have Substance Abuse Counselors, Social Workers, and Case Managers assigned just to the Burn Center who are uniquely experienced to assist our burn patients in dealing with the myriad of psychosocial ramifications of their burn injury. Finally, from a long-term burn reconstruction perspective, in addition to the 3 fellowship-trained Burn Surgeons who perform the full complement of long-term reconstruction procedures when needed by patients, the WFBMC Burn Center also has on staff a nationally recognized Plastic Surgeon with over 30 years of acute burn and burn reconstruction experience. The extensive and experienced complement of personnel and resources at the WFBMC Burn Center has taken years to develop, requires a certain level of patient volume and acuity to maintain expertise, and certainly represents a strong and enduring commitment to high-quality, optimal burn care by the WFBMC administration and WFBH system. This has ultimately translated into superior outcomes for all of the patients we treat, including those from Western NC, as manifested by on-going ABA Verification since 2009.

HCA/Mission contends that, if awarded 8 Burn ICU beds - which their cited patient numbers from Western NC do not at all support the need for, they will be able to provide “comprehensive burn care” utilizing the following:

1. A single Burn Surgeon who hasn't consistently cared for burn inpatients in over 5 years (Dr. Michael Schurr),
2. Trauma Surgeons with “experience” in caring for burn patients when no direct evidence of such “experience” or care was documented (e.g. - Dr. Shillinglaw “worked” at a facility with a Burn Center),
3. Hospital staff RNs without burn care experience,
4. Hospital staff rehab therapists without burn care experience,
5. General hospital ancillary services without burn care experience.

I am exceedingly concerned that this approach by HCA/Mission will lead to a dilution of the successfully regionalized burn care in NC currently associated with optimal patient outcomes and directly lead to a degradation in the quality of burn care provided to the people living in Western NC. Burn patients in Western NC, and Western North Carolinians in general, will likely suffer. Mission Hospital has never had an interest or sustained commitment to care of the burn-injured Western North Carolinian. The cited annual average of 56 patients impacted by not having a Burn Center in Asheville (Exhibit 3, top half) is completely insufficient to either establish or maintain expertise associated with optimal burn outcomes as can be provided to Western North Carolinians via our regionalized burn care at the WFBMC Burn Center.

Finally, the petition claims that burn patients from Western NC actually “choose” to seek burn care outside of NC. This is categorically false. Burn patients in Western NC, or anywhere for that matter, do not “choose” where to receive their burn care but are *referred* to a Burn Center by the provider(s) caring for them at the facility where they seek initial care, typically an Emergency Room. One will note in Exhibit 3 of the petition that the number of Western NC burn patients being treated at Doctors Hospital in Augusta, GA (an HCA facility & directly affiliated with the JMS Burn Centers, Inc/Burn & Reconstruction Centers of America, Inc) has steadily increased from 2017-2019 since HCA acquired Mission Hospital. This represents a direct corporate approach to care of the burn patients in Western NC, whereby they are sent out-of-state to an HCA facility for care that can be provided in NC. No concerns over travel requirements for, or financial ramifications of, such long-distance care seem to have been previously apparent.

For the sake of burn patients in Western NC, and Western North Carolinians in general, I respectfully urge the SHCC to deny the petition for 8 Burn ICU beds by HCA/Mission Hospital.

Best regards,



James H. Holmes IV, MD FACS  
Director, WFBMC Burn Center  
Professor of Surgery  
Wake Forest University School of Medicine  
Winston-Salem, NC 27157

10 August 2020

Members of the Committee,

Thank you for your service and dedication to North Carolina. It has come to my attention Doctors Hospital of Augusta is seeking to partner with Mission Hospital (Asheville, NC) in order to open a new Burn Center in North Carolina. *I believe that this collaboration will lead to a degradation of the care provided for this part of the State, and could ultimately lead to the decline of care for the remainder of the State as well.*

I see a number of challenges with the proposal. First, as a member of the American Burn Association verification review committee, I know firsthand the challenges of trying to create a list of resources, services, and personnel that can be used as a tool to reflect high quality and high value care of burn patients. I see a number of challenges with the proposal. I have attached a list of criterion deficiencies. *These criterion deficiencies are a list of what are considered the essential elements of burn care.* I hope that committee members will ask questions to delineate precisely what the business model will actually like. *Which of the criterion deficiencies are being deemed "optional" and what kind of "workarounds" are being proposed?* What critical pieces are being deliberately left out as part of the proposed business model?

Burn care is resource intensive and reliant on an entire team of people. To create the required system, a Burn Center needs (among many other team members) physical therapists, occupational therapists, pharmacists, anesthesiologists, and this does not include the cadre of other personnel in the unit and emergency department. These resources are needed for minor and major burns – both in an inpatient and outpatient capacity. In North Carolina, there are two verified Burn Centers that have those resources. Adding a third hospital to provide burn care is not needed and, paradoxically, the addition will degrade care if allowed to proceed.

It will be a disservice to the state in two ways. *First, it will immediately create two standards of care in the State. Patient's fortunate enough to come for care in Raleigh or Winston Salem will receive state of the art care in a Verified Burn Center. Those cared for in the new model would receive, at least a portion of, their care in a non-verified burn center and participate in a novel model consisting of a blend of a non-verified in-state care and out-of-state Verified Burn Center.* The second disservice is a consequence of the decline in total numbers of burn patients seen at each center (including the two currently verified centers). *With fewer patients, there is less need for dedicated personnel.* For example, our Burn Center is busy enough that we have a full-time physical therapist and a full-time occupational therapist. They are able to "cover" for one another when one is ill or on vacation. As a result, our patients always have a highly skilled specialist supervising their care. If we had lower volume, then it would not make sense to have

those specialists in full-time positions. This was my experience in Ohio. Ohio has eight Burn Centers for a state with a population roughly the same as North Carolina. We had a much lower patient load at the Ohio State University. As a result, we had a part-time pharmacist, a part-time physical therapist, and patients were housed in non-dedicated ICU rooms with nurses that were part-time Burn Nurses. It was a constant struggle to get patients the timely care that they needed. *The model of professionals who spend only a portion of their time with subspecialty care gives you a different system with inferior outcomes and inferior care conditions.*

When care is regionalized, it improves the care but patients (as consumers) note the dissatisfier associated with travel. This has been a challenge for regional care that has been examined by many authors, like Shalowitz et al (Gynecologic Oncology, 2018). In their study, patients clearly weighed travel distance against increased survival (most patients wanted at least a 6% increase in odds of survival to travel 50 more miles). Given that reality, I can imagine that DHA might suggest that they have a unilateral ability to offer more care closer to the homes of residents of Western North Carolina. In another time, that might have been a cogent point. *The reality is that one of the unintended consequences of current pandemic is that we have all evloved our ability to provide virtual care. This minimizes trips back to see us...from any distance.*

I am appreciative of the government of North Carolina and their ability to foresee the need to carefully examine, and appropriately limit at times, the addition of medical facilities. This State recognizes that the citizens do not, necessarily, benefit from simply building new hospitals when there is not a need. A process that needs to be duplicated by other States.

Regards,



J. Kevin Bailey, MD  
Professor, Surgery  
[jkbailey@wakehealth.edu](mailto:jkbailey@wakehealth.edu)  
c 513.889.6807

Verification Criteria 10719

Criterion Number	Criterion	Criterion Level
1.1 (7)	The burn center hospital is currently accredited by the Joint Commission or equivalent.	1
1.2 (9)	The burn center has an identifiable medical and administrative commitment to the care of the patient with burns.	1
1.3 (9)	The burn center hospital maintains a specialized unit dedicated to acute burn care.	1
1.4 (4)	The burn center has designated ICU capable beds.	1
1.5 (9)	The burn center maintains an appropriate policy and procedure manual that is easily accessible by the burn team and reviewed regularly with appropriate documentation by the burn center director and the nurse leader.	1
1.6 (9)	Multi-disciplinary patient care conferences are held and documented at least weekly.	1
1.7 (7)	Renal dialysis, radiological services, including computed tomography scanning, and clinical laboratory services are available 24 hours per day.	2
1.8 (10)	The burn center hospital's policies and procedures regarding the use of allograft tissues are in compliance with all federal, state, and the Joint Commission (or equivalent) requirements, and, when feasible and appropriate, w	1
1.8 (11)	The burn center has a designated trauma center to coordinate care of patients with multi-trauma.	1
2.1 (12)	The burn center must have a sufficient volume of acute burn admissions on an ongoing basis.	1
2.2 (12)	Majority of admissions to the burn center are burn patients.	1
2.3 (15)	The burn center maintains an average daily census of 3 or more patients with acute burns.	1
2.4 (14)	No more than 3% of all patients with a primary diagnosis of a burn injury are admitted to another service per year (e.g. geriatrics, pediatrics, medicine).	1
2.5 (8)	No more than 3% of hospital admissions are transferred to another acute care facility.	1
2.6 (9)	The burn center director is a licensed surgeon (MD or DC) with board certification by American Board of Surgery or American Board of Plastic Surgery (or equivalent for international burn centers in which case a surgeon must	1
2.7 (7)	The burn center director has completed a one-year fellowship in burn treatment and/or has experience in the care of patients with acute burn injuries for two or more years during the previous five years.	1
2.8 (8)	The burn center director has ABLS (or equivalent) training.	1
2.9 (8)	The burn center director is responsible for the direction of burn center administrative functions.	1
2.9 (9)	The burn center director is responsible for the creation of policies and procedures within the burn center specifying all aspects of care for burned patients.	1
2.9 (11)	The burn center director is responsible for ensuring that all burn center team members conform to the burn center's locally established policies and procedures.	1
2.9 (12)	The burn center director is responsible for the approval of privileges for physicians participating in the burn service based on medical staff credentialing process.	1
2.9 (14)	The burn center director is responsible for the development and active participation in internal and external continuing medical education programs in the care and prevention of burn injuries.	1
2.9 (16)	The burn center director is responsible for the communications on a regular basis with referring physicians regarding patients who have been transferred.	1
2.10 (17)	In the event that the burn center director is not available, an accessible burn center staff surgeon is designated for administrative or clinical decisions.	1
2.11 (18)	The burn center director regularly participates in regional, national or international burn meetings.	1
2.12P	The burn center director demonstrates CME or evidence of education in pediatric burn care annually (e.g. Pediatric Advanced Life Support, pediatric topic review, local regional meetings, invited speakers, journal clubs etc.)	2
2.13 (20)	The burn center director has directed the total burn care of 50 or more acutely burned patients annually over a three-year period.	1
2.14P	The burn center director is involved in at least 25 pediatric cases annually.	2
2.15 (4)	The burn center director demonstrates ongoing involvement in burn-related research, community education, continuing medical education, prevention efforts and local regional or national burn advocacy.	1
4.1 (41)	Burn surgeons are licensed surgeons with board certification by American Board of Surgery, American Board of Plastic Surgery or equivalent based on review by Verification Committee.	1
4.2 (42)	Burn surgeons have demonstrated expertise in burn treatment, by two or more years of mentored experience in the management of patients with acute burn injuries.	1
4.3 (43)	Each burn surgeon has participated, including primary decision-making, in the care of sufficient acutely burned patients annually.	1
4.4 (43)	Each burn surgeon must participate in continuing medical education in burn treatment.	1
4.5 (44)	Burn surgeons have had ABLS (or equivalent) training.	2
4.6 (49)	Assigned burn center medical staff are promptly available on a 24-hour basis.	1
4.7 (48)	The burn center maintains an on-call schedule for residents, qualified healthcare professionals and burn surgeons for continuous responsibility of burn patients.	1
4.8 (100)	For centers that have residents involved in care of the burn patients an orientation program is provided for new residents.	2
4.9P	Burn center has physicians who are board certified or eligible for certification in one of the following: pediatric critical care medicine pediatric surgery or surgical critical care	2
4.10P	Burn surgeons have pediatric burn fellowship training or mentored clinical experience in pediatric burn surgery.	2
4.11P	All burn surgeons demonstrate CME in pediatric care or equivalent internal burn education in pediatric burn care annually.	2
5.1 (41)	All advanced practice providers who are routinely responsible for the care of burn patients conform to burn center criteria documenting appropriate training, patient care experience, continuing medical education, and current	1
5.2 (42)	All advanced practice providers participating in the burn service are credentialled by the hospital medical staff credentialing process and are approved by the burn center director.	1
5.3 (52)	The burn nurse leader or equivalent is a licensed Registered Nurse (RN) with a minimum of a baccalaureate degree in nursing.	2
5.4 (53)	There is at least one nurse leader or equivalent who is administratively responsible for the nursing care provided within the burn center.	1
5.5 (54)	A burn nurse leader or equivalent must have sufficient experience in burns and nursing leadership to lead the staff and manage the nursing program of the burn center.	1
5.6 (58)	A metric-based staffing system is in place to determine nurse-staffing needs for patients in the burn center.	2
5.7 (59)	There is a burn-specific competency-based training and continuing educational program for all nurses assigned to the burn center.	1
5.8 (57)	The burn nurse leader or equivalent routinely participates in multi-disciplinary patient care rounds and there is dissemination to the nursing staff.	1
5.9 (58)	The burn nurse leader or designee attends burn-specific continuing educational opportunities at least once every two years. These requirements can be addressed by attending regional, national or international burn meeting	1
5.10 (59)	There is nurse representation within burn center quality improvement processes.	1
5.9P	Nurses have pediatric certification or participate in pediatric specific continuing education or equivalent internal burn programming in pediatric burn care annually.	2
7.1 (60)	A comprehensive rehabilitation program is designed for burned patients within 24 hours of admission.	1
7.2 (61)	Physical and occupational therapists in the burn center are appropriately licensed in their respective disciplines and demonstrate ongoing continuing education in burn rehabilitation.	1
7.3 (62)	Therapy staffing is based upon burn center inpatient and therapy specific outpatient activity with at least one designated full-time equivalent burn physical therapist and one occupational therapist, but more depending on cas	1
7.4 (63)	Inpatients with an active rehabilitation plan must have care delivered as prescribed in the evaluation which should determine duration and frequency based on wound, include goals, outcome and plan for follow up.	1
7.5 (64)	Burn therapy services are provided 7 days per week for care of burn inpatients.	1
7.6 (65)	Burn therapists participate in multi-disciplinary rounds and quality improvement.	1
7.7 (66)	Therapists assigned to the burn center must show evidence of ongoing burn specific competency training.	1
7.8 (67)	Therapists must participate in burn-related CEU activity on a regular basis.	1
7.9P	Therapy staff participates in pediatric specific continuing education.	2
7.10P	Therapy department has pediatric age-appropriate therapeutic equipment.	2
8.1 (68)	Social service consultation is available to the burn service, as needed.	1
8.2 (68)	A dietitian with adequate critical care and burn experience is available on a daily basis for consultation.	1
8.3P	A pediatric dietitian with adequate critical care and burn experience is available on a daily basis for consultation.	2
8.4 (70)	A pharmacist with adequate critical care and burn experience is available on a 24-hour basis.	1
8.5P	A pediatric pharmacist with adequate critical care and burn experience is available on a 24-hour basis.	2
8.6 (71)	Respiratory therapists are available for the assessment and management of patients on the burn service on a continuous basis.	1
8.7 (72)	A psychological or psychiatric is available to the burn service on an as needed basis.	1
8.8P (72)	A child life/recreational therapist is available for children cared for in the program.	2
8.9 (100)	Burn team members are provided with a minimum of one regional, national or international burn-related continuing education opportunity annually OR demonstrate annual participation in internal educational process specific	1
8.10 (107)	A burn center orientation and ongoing continuing education program documents staff competencies specific to age appropriate care and treatment of burn patients, including critical care, wound care, and rehabilitation.	1
9.1 (103)	The burn center develops ongoing quality improvement projects to create a culture of safety and promote value-based programs.	1
9.2P	The pediatric burn center develops ongoing quality improvement projects to create a culture of safety and promote value-based programs.	2
9.3 (64)	Sufficient CI documentation is available to verify problems, identify opportunities for improvement, resolve the problem and provide loop-closure.	1
9.4 (53)	The burn center director is responsible for direction and active participation in the burn center Quality & Process Improvement Programs.	1
9.5 (62)	The burn center director is responsible for the risk-adjusted quality improvement program.	1
9.6 (63)	A multidisciplinary burn center committee participates in the quality improvement program, meets at least quarterly and is integrated into the hospital CI structure.	1
9.7 (67)	All life-threatening complications and deaths are discussed in a forum that includes specialist peers outside the core burn team, and are classified in a systemic fashion, so as to identify opportunities for improvement	1
9.8 (68)	The morbidity and mortality conferences are held at least monthly.	1
9.9 (64)	The morbidity and mortality conferences include specialist peer staff members other than those practicing in the burn center.	1

8.10 (96.)	The morbidity and mortality conferences include documentation of loop closure.	1
8.11 (98.)	Clinical team members involved in the direct care of the burn patients participate in at least 50% of the morbidity and mortality conferences.	1
8.12 (100)	Sentinel events are discussed in a timely manner at multi-disciplinary intensive reviews during which time a non-involved peer leads a discussion with all involved parties and areas for improvement and loop closure are identified.	1
8.13 (101)	The burn program conducts audits of their benchmarked outcomes data using available resources such as NBRP, LHC, NHRN, or CMS) at least quarterly.	1
8.14 (103)	The burn center has policies for infection control with regular monitoring for hospital-acquired infections, multi-drug resistant organisms and compliance.	1
8.15 (104)	The burn center participates in the ABA's National Burn Repository or other equivalent data collection/entry as tool and submits data every year.	1
8.16 (105)	The burn center database includes all patients who are admitted to the burn center hospital for burn care.	1
8.17F	Evidence of at least one on-going QI metric in pediatric specific rehabilitation issues (i.e. garment compliance, splint compliance, rates of contracture, success with releases, etc.)	2
10.1 (11.)	The burn center has written guidelines for the triage, treatment, and transfer of burned patients from other facilities.	1
10.2 (22.)	The burn center director is responsible for the coordination with regional EMS authorities regarding triage and transport of burn patients.	1
10.3 (18.)	The burn center maintains access to an EMS system for the transport of patients with burns from referral sources within the service area.	1
10.4 (19.)	The burn center offers input into the quality improvement of pre-hospital care of burn patients.	1
11.1 (28.)	Written protocols developed with input from the burn center guide the care of burn patients in the emergency department.	1
11.2	Emergency department is available 24/7	2
11.3P	Emergency physicians are board certified or eligible for certification by an appropriate emergency medicine board according to current requirements in pediatric emergency medicine.	2
11.4P	Evidence of collaborative clinical practice and educational activities between the burn program and the emergency services.	2
11.5P	Emergency service representative serves as a liaison to the burn quality care program.	2
12.1 (14.)	Burn centers caring for critically ill patients must demonstrate facilities, protocols and personnel specific to the care of critically ill patients.	1
12.2P	The burn program works collaboratively with the pediatric critical care providers, although all significant therapeutic decisions involving burn patients are approved by the burn program, and the burn program is made aware of all decisions.	2
12.3P	A PICU representative serves as a liaison to the burn quality improvement program.	2
12.4P	There are protocols for burn specific care in collaboration with the PICU.	2
12.5P	PICU works in concert with the Burn Center Director to develop protocols for intensive care.	2
13.1 (6.)	The burn center has timely access to operating rooms.	1
13.2 (8.)	A dedicated OR team with burn experience is available for the burn operating theatre.	2
13.3 (9.1)	A dedicated anesthesia team with burn experience is available for the burn operating theatre.	2
13.4P	For centers admitting patients under 2 years of age and requiring surgery, an anesthesiologist with certification in pediatric anesthesiology is available 24/7	2
13.5P	A pediatric anesthesiology representative serves as a liaison to burn quality improvement program.	2
14.1 (66.)	Physical examination is available	2
14.2 (68.)	The burn center coordinates with local and/or regional rehabilitation centers for inpatient rehabilitation.	1
14.3 (71.)	The burn center coordinates with local and/or regional outpatient facilities for ongoing outpatient therapy needs of patients needing rehabilitation after discharge.	1
15.1 (74.)	The burn center has appropriate outpatient facilities, including adequate facilities for wound care.	1
15.2 (75.)	The outpatient facility must be able to provide for appropriate pain management during wound care.	2
15.3 (69.)	The burn center provides appropriate multi-disciplinary follow-up.	1
15.4 (76.)	For continuity of care, staffing of the outpatient area should be by multi-disciplinary experienced burn team members, approved by the burn center director and nurse leader.	2
15.5 (65.)	The burn center provides access to outpatient social service, pharmacist and dietary consultations, as needed.	2
15.6 (77.)	A representative of the outpatient staff participates in weekly multi-disciplinary burn conferences and the burn center QI program.	1
15.7 (78.)	The burn center provides coordinated transition of care to the outpatient setting.	1
15.8 (79.)	The burn center follows >75% of all patients who transition to the outpatient setting.	1
15.9 (82.)	A burn therapist is available in the outpatient clinic to provide services, including follow up, as needed.	1
16.4 (81.)	The burn center provides brief psychological screening/intervention.	1
16.5P (83.)	The burn center provides evaluation of patient developmental status (for children).	2
16.6 (84.)	The burn center provides timely access to reconstructive surgery.	2
16.7 (86.)	The burn center facilitates access to peer-to-peer and burn survivor resources for patient and family support. Provide access to peer support (such as but not exclusively a Phoenix Society SQAR program).	1
16.8 (87.)	The burn center provides access to vocational counseling.	2
16.9 P	Burn center has established relationship with one of the many camps and demonstrated active attempts of recruitment for children to attend.	2
17.1 (111)	Burn program is involved in local, regional, national, or international prevention outreach efforts.	1
17.2 (108)	The burn program regularly participates in regional education related to burn care.	1
17.3 (110)	The burn center participates regularly in community burn outreach programs.	2
18.1 (112)	Burn Center multi-disciplinary staff, under the leadership of the burn center director, work locally, regionally, or nationally to advocate for burn related health care issues.	2
18.2 (113)	The burn center multi-disciplinary staff is involved in research (including basic science, clinical, industry-sponsored, QI, multi-center) and presents posters or oral presentations at hospital based, regional national or international meetings.	2
19.1 (21.)	The burn center interfaces with regional trauma centers to coordinate care of patients with multiple injuries and to develop regional educational programs, disaster planning and advocacy efforts.	2
19.2 (22.)	The burn center has a written Mass Casualty Disaster Plan for the triage and treatment of those patients burned in a mass casualty incident occurring within its service area.	1
19.3 (23.)	The Mass Casualty Disaster Plan is reviewed and updated as needed and on an annual basis by EMS representatives and the burn center director.	2
19.4 (24.)	There are current (within the past 3 years) written memoranda of understanding with other burn centers regarding secondary triage.	1
19.5 (25.)	The burn center must maintain accurate and up to date contact information for burn surgeons and managers on the ABA website.	2

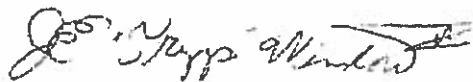
August 12, 2020

In North Carolina it is not the standard of care to intubate all burn patients prior to helicopter transport. There are no approved protocols in North Carolina that allow for the intubation of all burn patients prior to being flown in a helicopter.

Current NC Standardized EMS protocols are actually de-emphasizing the need for prehospital intubation. Intubating all burn patients prior to air transport is dangerous and not necessary. I know of no flight program where this is required. Prehospital EMS intubation while an important procedure also entails significant risk. Some of the risks of intubation include airway trauma, hypoxia, aspiration, esophageal intubation and right main stem intubation.

Badulak in the journal Burns found that patients should only be intubated if they meet the Denver criteria which are very specific. Baulak goes on to say that patients who do not meet the Denver criteria should not be intubated because the risks outweigh any benefit. The statement that all burn patients should be intubated prior to transport is not true and sets a dangerous precedent.

James E. Winslow, MD MPH



Associate Professor  
Department of Emergency Medicine  
Wake Forest Baptist Health

## **Exhibit 3**

February 15, 2019  
WFBMC Burn ICU Bed Progress Report



**Certificate of Need  
Progress Report Form**

County: Forsyth Date of Progress Report: February 15, 2019  
Facility: North Carolina Baptist Hospital Facility ID #: 943495  
Project ID #: G-8842-12 Effective Date of Certificate: October 26, 2012

Project Description: To add no more than 4 burn ICU beds for a total of 12 burn ICU beds in Forsyth County.

**A. Status of the Project**

1. Describe in **detail** the **steps taken** to complete the project since the CON was issued or since the last progress report was submitted. **Inadequate responses to this question will result in the certificate holder being asked to redo the progress report.**

Since the last progress report, NCBH has done an extensive evaluation to explore all potential options for developing the additional four approved Burn ICU beds, for a total of 12 beds. NCBH evaluated the following scenarios:

- 1) Validated that the beds had to be developed to ICU standard (vs general acute care standard):

NCBH sought guidance from the Healthcare Planning and Certificate of Need, Acute and Home Care Licensure, and Construction Sections of DHR to determine if the beds could be developed to an acute care versus an ICU standard based on the definition of "burn intensive care services" in NC G.S. § 131E-176 and the conditions of its CON. If possible, development of the beds to the lower standard of care would have provided more potential options for development. However, after a conference discussion, all three sections determined that the beds had to be developed as ICU beds.

- 2) Assessed if the additional four burn ICU beds could be located within the existing footprint of the Burn ICU and Burn Step-Down units:

NCBH assessed whether or not the additional four beds could fit into the footprint of the existing Burn ICU and Burn Step-Down units. However, there is not adequate space in these units to accommodate the beds.

- 3) Assessed possible locations within the existing hospital to fully relocate the Burn ICU to accommodate a total of 12 beds (eight existing plus four approved):

NCBH assessed all locations throughout the main hospital campus to determine potential locations to move the entire unit, but was unable to identify an appropriate space. Functionally, the Burn Step-Down unit must be co-located with the Burn ICU. These two "sister" units operate under one management structure, share staff and other resources, and require proximity to each other. Because of the required proximity of these two units, NCBH was unable to identify a new location within the existing main hospital campus that could accommodate the service.

- 4) Evaluated whether or not the additional four beds were still needed:

NCBH evaluated past, current, and forecasted performance to assess whether or not the additional beds were needed. Based on this assessment, NCBH determined that the beds are still needed. A second burn surgeon has recently been recruited (this is a replacement provider) and a third is being recruited.

- 5) Assessed possible locations upon completion of the planned construction of a new patient service building (**Attachment 1**) on the NCBH campus:

NCBH assessed possible locations for the twelve bed (eight existing plus four new) Burn ICU and accompanying Burn Step-Down unit that would become available upon the completion of the new patient services building described in **Attachment 1**. **NCBH determined that the best option for development of the four additional Burn ICU beds (for a total of twelve beds) is to place the new 12-bed unit in space that is vacated upon completion of the new patient services building.**

2. **Identify all changes to this project approved after the issuance of the certificate, including:**

- a. **Cost Overruns and/or Changes of Scope (Include the Project ID #s);**
- b. **Material Compliance determinations; and**
- c. **Declaratory Rulings**

Not applicable. The project will likely exceed 115% of the approved amount in the CON and therefore will require a cost overrun CON which will be appropriately filed as the project is more fully scoped-out.

3. **If the project is not going to be developed exactly as approved (including the previously approved changes identified in #2 above), describe all differences between the project as approved and the project as currently proposed. Such changes include, but are not limited to, changes in the:**

- a. **Site;**
- b. **Design of the facility;**
- c. **Number or type of beds to be developed;**
- d. **Medical equipment to be acquired;**
- e. **Proposed charges; and**
- f. **Capital cost of the project.**

Not applicable. As the project is more fully scoped-out, it is estimated that that capital cost will exceed 115% of the amount in the CON. A cost overrun CON application will be appropriately filed. The location of the 12-bed unit will remain on the NCBH main campus as defined in NC G.S. § 131E-176.

4. **Pursuant to N.C. Gen. Stat. § 131E-181(d), the Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) cannot determine that a project is complete until “the health service or the health service facility for which the certificate of need was issued is licensed and certified and is in material compliance with the representations made in the certificate of need application.” To document that new or replacement facilities, new or additional beds or dialysis stations, new or replacement**

equipment or new services have been licensed and certified, provide copies of correspondence from the appropriate sections within the Agency and the Centers for Medicare and Medicaid Services (CMS).

Not applicable.

**B. Timetable**

1. Complete the following table. The first column must include the timetable dates found on the certificate of need. If the Agency has previously authorized an extension of the timetable in writing, you may substitute the dates from that letter in the first column.
2. Are you requesting a timetable extension? X Yes No If the answer is yes, enter your proposed completion dates in the third column of the table below. Proposed completion dates are contingent upon Agency approval.
3. Explain the reason(s) for the delay in development:

This recent development delay was the result of 1) the master facility plan not addressing these beds as originally planned and 2) for the reasons explained in response to question A.1, the only space that will adequately accommodate the beds and service will not be available until after the completion of the new patient services building.

PROJECT MILESTONES	Projected completion date from certificate	Actual completion date	Proposed completion date*
	Month/day/year	Month/day/year	Month/day/year
Obtained funds for the project			
Final drawings and specifications sent to Construction, DHSR	July 1, 2013		
Final drawings approved by Construction, DHSR			
Acquisition of land/facility			
Construction contract executed	Sept. 1, 2013		June 1, 2022
25% completion of construction	Nov. 1, 2013		December 1, 2022
50% completion of construction	Jan. 1, 2014		June 1, 2023
75% completion of construction	Mar 1, 2014		December 1, 2023
Completion of construction	May 1, 2014		June 1, 2024
Ordering of medical equipment	Jan. 1, 2014		December 1, 2023
Operation of medical equipment	Jan. 1, 2014		July 1, 2024
Occupancy/offering of services	June 1, 2014		July 1, 2024
Licensure			
Certification			

\*Proposed completion dates are contingent upon Agency approval.

- C. **Medical Equipment Projects** – If the project involves the acquisition of any of the following equipment: 1) major medical equipment as defined in N.C. Gen. Stat. § 131E-176(14o); 2) the specific equipment listed in G.S. 131-176(16); or 3) equipment that creates a diagnostic center as defined in N.C. Gen. Stat. § 131E-176(7a), provide the following information for each piece or unit of equipment: 1) manufacturer; 2) model; and 3) date acquired.

Not applicable.

**D. Capital Expenditure**

1. What is the total approved capital cost of the project indicated on the certificate of need?  
\$1,365,770
2. Complete the table below and provide supporting documentation, which may include:
  - a. Copies of executed contracts and purchase orders. If you previously provided them, you do not need to provide another copy.
  - b. If applicable, copies of the Contractors Application for Payment [AIA G702] with Schedule of Values [AIA G703].

	Capital Expense Since Last Report	Total Cumulative Capital Expenditure
Purchase Price of Land	_____	_____
Closing Costs	_____	_____
Site Preparation	_____	_____
Construction/Renovation Contract(s)	_____	_____
Landscaping	_____	_____
Architect / Engineering Fees	_____	_____
Medical Equipment	_____	_____
Non-Medical Equipment	_____	_____
Furniture	_____	_____
Consultant Fees (specify)	_____	\$1,410
Financing Costs	_____	_____
Interest during Construction	_____	_____
Other (specify)	_____	\$6,097
<b>Total Capital Cost</b>	<b>\$0</b>	<b>\$7,507</b>

3. What is the projected remaining capital expenditure required to complete the project?  
\$1,358,263
4. Will the total actual capital cost of the project exceed 115% of the approved capital expenditure on the certificate of need? If yes, explain the reasons for the difference.

Most likely yes. A cost overrun CON application will be appropriately submitted upon development of a new project budget.

E. **Certification** – The undersigned hereby certifies that the responses to the questions in this progress report and the attached documents are correct to the best of his or her knowledge and belief. In addition, I acknowledge that incomplete progress report forms will not be accepted and must be resubmitted upon notification from the Agency Project Analyst.

Signature:



Name and Title

Marisa Barone, Director, Strategic Planning and Regulatory / CON

Telephone Number

336.713.0697

Email address

mbarone@wakehealth.edu



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER  
GOVERNOR

MANDY COHEN, MD, MPH  
SECRETARY

MARK PAYNE  
DIRECTOR

VIA EMAIL ONLY

March 26, 2018

Lynn S. Pitman  
North Carolina Baptist Hospital  
lpitman@wakehealth.edu

**Exemption from Review - Pursuant to G.S. 131E-184(g)**

**Record #:** 2550  
**Facility Name:** North Carolina Baptist Hospital  
**FID #:** 943495  
**Business Name:** North Carolina Baptist Hospitals  
**Business #:** 1819  
**Project Description:** Construction of new patient services building on the NCBH Main Campus to accommodate ED, surgical services, 38 ORs and recovery space, 28-bed ICU, and mechanical space  
**County:** Forsyth

Dear Ms. Pitman:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of March 15, 2018 the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(G). Therefore, you may proceed to offer, develop or establish the above referenced project without a certificate of need.

However, you need to contact the Agency's Construction and Acute and Home Care Licensure and Certification Sections to determine if they have any requirements for development of the proposed project.

It should be noted that this determination is binding only for the facts represented by you. Consequently, if changes are made in the project or in the facts provided in your correspondence

**HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION**

WWW.NCDHHS.GOV

TELEPHONE 919-855-3873

LOCATION: EDGERTON BUILDING • 809 RUGGLES DRIVE • RALEIGH, NC 27603

MAILING ADDRESS: 2704 MAIL SERVICE CENTER • RALEIGH, NC 27699-2704

AN EQUAL OPPORTUNITY/ AFFIRMATIVE ACTION EMPLOYER

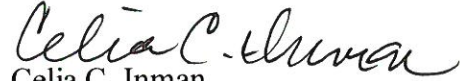



Ms. Pitman  
Page 2  
March 26, 2018

referenced above, a new determination as to whether a certificate of need is required would need to be made by the Agency. Changes in a project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.

If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

  
Celia C. Inman  
Project Analyst

  
Martha J. Frisone  
Chief, Healthcare Planning and  
Certificate of Need Section

cc: Construction Section, DHSR  
Amy Craddock, Assistant Chief, Healthcare Planning, DHSR  
Acute and Home Care Licensure and Certification Section, DHSR

March 15, 2018

Ms. Martha Frisone, Chief  
Ms. Celia Inman, Project Analyst  
Healthcare Planning and Certificate of Need Section  
Division of Health Service Regulation  
2704 Mail Service Center  
Raleigh, NC 27699-2704



**Re: Request for Confirmation of Exemption for North Carolina Baptist Hospital (FID # 943495) for Construction of New Patient Services Building on the NCBH Campus**

Dear Ms. Frisone and Ms. Inman,

Pursuant to N.C.G.S. § 131E-184(g), Exemptions from Certificate of Need Review, I am writing to request confirmation that the project described below for North Carolina Baptist Hospital ("NCBH") is exempt from review.

NCBH intends to demolish Parking Deck B due to age and weakening of the structure. This post tension deck has deteriorated over the years to the point at which that top level can no longer be used for parking. Parking Deck B is centrally located on the NCBH campus; therefore, in its place a new patient services building is planned for construction. Please see Exhibit 1 for a NCBH campus map. The new patient services building will total approximately 260,000 square feet and encompass seven levels.<sup>1</sup> The planned services for each level are as follows:

- Level 1: Expansion of the Emergency Department
- Level 2: Surgical Services Waiting, Prep & Post
- Level 3: 20 Operating Rooms ("OR")
- Level 4: Mechanical Floor
- Level 5: 18 ORs and Recovery Space
- Level 6: 28-Bed ICU
- Level 7: Mechanical Floor

The 38 operating rooms planned for levels three and five of the new patient services building will be relocated from their existing location on the 1<sup>st</sup> floor of Ardmore Tower. The 28 ICU beds planned for the 6<sup>th</sup> floor of the patient services tower will be relocated from 5<sup>th</sup> Floor North Tower. The vacated spaces on the 1<sup>st</sup> floor of Ardmore Tower and the 5<sup>th</sup> floor of North Tower will be decommissioned, with future use of the locations to be determined.

NCBH believes this project is exempt from review, as described below. Pursuant to N.C.G.S. § 131E-184(g),

*"The Department shall exempt from certificate of need review any capital expenditure that exceeds the two million dollar (\$2,000,000) threshold set forth in G.S. 131E-176 (16) b. if all of the following conditions are met:*

---

<sup>1</sup> NCBH intends to replace Parking Deck B with a new deck on another part of the hospital campus. NCBH is still in the process of determining where on the campus to locate that parking deck. Once that determination is made, NCBH will submit additional correspondence to the CON Section seeking exemption for that parking deck from CON review under N.C.G.S. § 131E-184.

- (1) *The sole purpose of the capital expenditure is to renovate, replace on the same site, or expand the entirety or a portion of an existing health service facility that is located on the main campus.*
- (2) *The capital expenditure does not result in (i) a change in bed capacity as defined in G.S. 131E-176(5) or (ii) the addition of a health service facility or any other new institutional health service other than that allowed in G.S. 131E-176(16)b.*
- (3) *The licensed health service facility proposing to incur the capital expenditure shall provide prior written notice to the Department, along with supporting documentation to demonstrate that it meets the exemption criteria of this subsection.*

The development of the new patient services building has the sole purpose of renovating, replacing on the same site, and expanding a portion of an existing health service facility that is located on the main campus of NCBH. No new institutional health services will be developed. NCBH is licensed for 40 ORs and 802 general acute care beds. This project includes the relocation of 38 ORs from the 1<sup>st</sup> floor of Ardmore Tower and 28 acute care beds from 5<sup>th</sup> floor of North Tower to the new patient services building. The vacated spaces will be decommissioned, with future use of those locations to be determined at a later date. The new patient services tower will contain 38 relocated ORs and 28 relocated ICU beds. Two ORs will remain on the 1<sup>st</sup> floor of Ardmore Tower.

Further, all of the proposed relocated services will remain on the main campus. Pursuant to N.C.G.S. § 131E-176(14n),

*"Main campus" means all of the following for the purposes of G.S. 131E-184 (f) and (g) only:*

- a. *The site of the main building from which a licensed health service facility provides clinical patient services and exercises financial and administrative control over the entire facility, including the buildings and grounds adjacent to that main building.*
- b. *Other areas and structures that are not strictly contiguous to the main building but are located within 250 yards of the main building.*

NCBH is a licensed health service facility that provides clinical and patient services. The NCBH campus is located at Medical Center Blvd, Winston-Salem, NC 27127. Financial and administrative control over NCBH is administered by the Chief Executive Officer ("CEO") and the Chief Financial Officer ("CFO"), whose offices are located within the NCBH campus on Medical Center Blvd. The new patient services building will be located in space currently occupied by Parking Deck B. The ORs that will be relocated to the new patient services building will be relocated from the 1<sup>st</sup> floor of Ardmore Tower. The ICU beds that will be relocated to the new building will be relocated from the 5<sup>th</sup> floor of North Tower. The offices of the CEO and the CFO are located on the 10<sup>th</sup> floor of Janeway Tower. Please see Exhibit 1 which includes an NCBH campus map and denotes the location of the office of the CEO and CFO as well as the location of Parking Deck B, Ardmore Tower, and North Tower.

The proposed project also does not result in a change in bed capacity as defined in G.S. 131E-176(5) nor in the addition of a health service facility or any other new institutional health service other than that allowed in G.S. 131E-176(16)b.

N.C.G.S. 131E-176(5) defines change in bed capacity as

*(i) any relocation of health service facility beds, or dialysis stations from one licensed facility or campus to another, or (ii) any redistribution of health service facility bed capacity among the categories of health service facility bed as defined in G.S. 131E-176(9c), or (iii) any increase in the number of health service facility beds, or dialysis stations in kidney disease treatment centers, including freestanding dialysis units.*

N.C.G.S. § 131E-176(16)u. describes the services related to ORs and gastrointestinal endoscopy rooms which constitute new institutional health services:

*The construction, development, establishment, increase in the number, or relocation of an operating room or gastrointestinal endoscopy room in a licensed health service facility, other than the relocation of an operating room or gastrointestinal endoscopy room within the same building or on the same grounds or to grounds not*



*separated by more than a public right-of-way adjacent to the grounds where the operating room or gastrointestinal endoscopy room is currently located.*

The project includes relocation of ORs and general acute beds from the 1<sup>st</sup> floor of Ardmore Tower and the 5<sup>th</sup> floor of North Tower to a new patient services building to be constructed in the location of the existing Parking Deck B. The general acute care beds will not be relocated from one facility or campus to another, will not be redistributed among the categories defined in N.C.G.S. 131E-176(9c), and will not be increased. The ORs will be not be increased in number or relocated to a new facility. Both the ORs and general acute care beds will be relocated to a new tower to be constructed on the same grounds as their existing locations.

NCBH is licensed for a total of 40 ORs and 802 general acute care beds and is not proposing additional ORs or general acute care beds as part of this project. Please Exhibit 2 for NCBH's license.

The only other possible new institutional health service which could be applicable to this project is major medical equipment (see N.C.G.S. § 131E-176(16)p.), which is defined in N.C.G.S. § 131E-176 (14o) as

*a single unit or single system of components with related functions which is used to provide medical and other health services and which costs more than seven hundred fifty thousand dollars (\$750,000). In determining whether the major medical equipment costs more than seven hundred fifty thousand dollars (\$750,000), the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the major medical equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater. Major medical equipment does not include replacement equipment as defined in this section.*

NCBH does not intend to purchase any single piece of equipment which costs more than \$750,000, including surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the medical equipment for this project.

NCBH respectfully requests that the CON Section confirm that, based on the facts stated above as well as the information included in the Exhibits, the above-described project meets all of the exemption criteria in N.C.G.S. § 131E-184(g).

Please let me know if you have any questions or if additional information is needed.

Sincerely,



Lynn S. Pitman, MHA  
Associate Vice President  
Clinical Operations and Space Optimization

## INDEX OF EXHIBITS

1. NCBH Campus Map
2. NCBH License

# State of North Carolina

Department of Health and Human Services  
Division of Health Service Regulation

*Effective January 01, 2018, this license is issued to  
North Carolina Baptist Hospital  
to operate a hospital known as  
North Carolina Baptist Hospital  
located in Winston Salem, North Carolina, Forsyth County.*

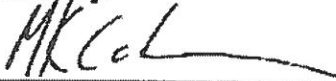
*This license is issued subject to the statutes of the  
State of North Carolina, is not transferable and shall remain  
in effect until amended by the issuing agency.*

*Facility ID: 943495  
License Number: H0011*

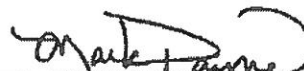
*Bed Capacity: 885  
General Acute 802, Rehabilitation 39, Psych 44.*

*Dedicated Inpatient Surgical Operating Rooms: 4  
Dedicated Ambulatory Surgical Operating Rooms: 0  
Shared Surgical Operating Rooms: 36  
Dedicated Endoscopy Rooms: 10*

Authorized by:

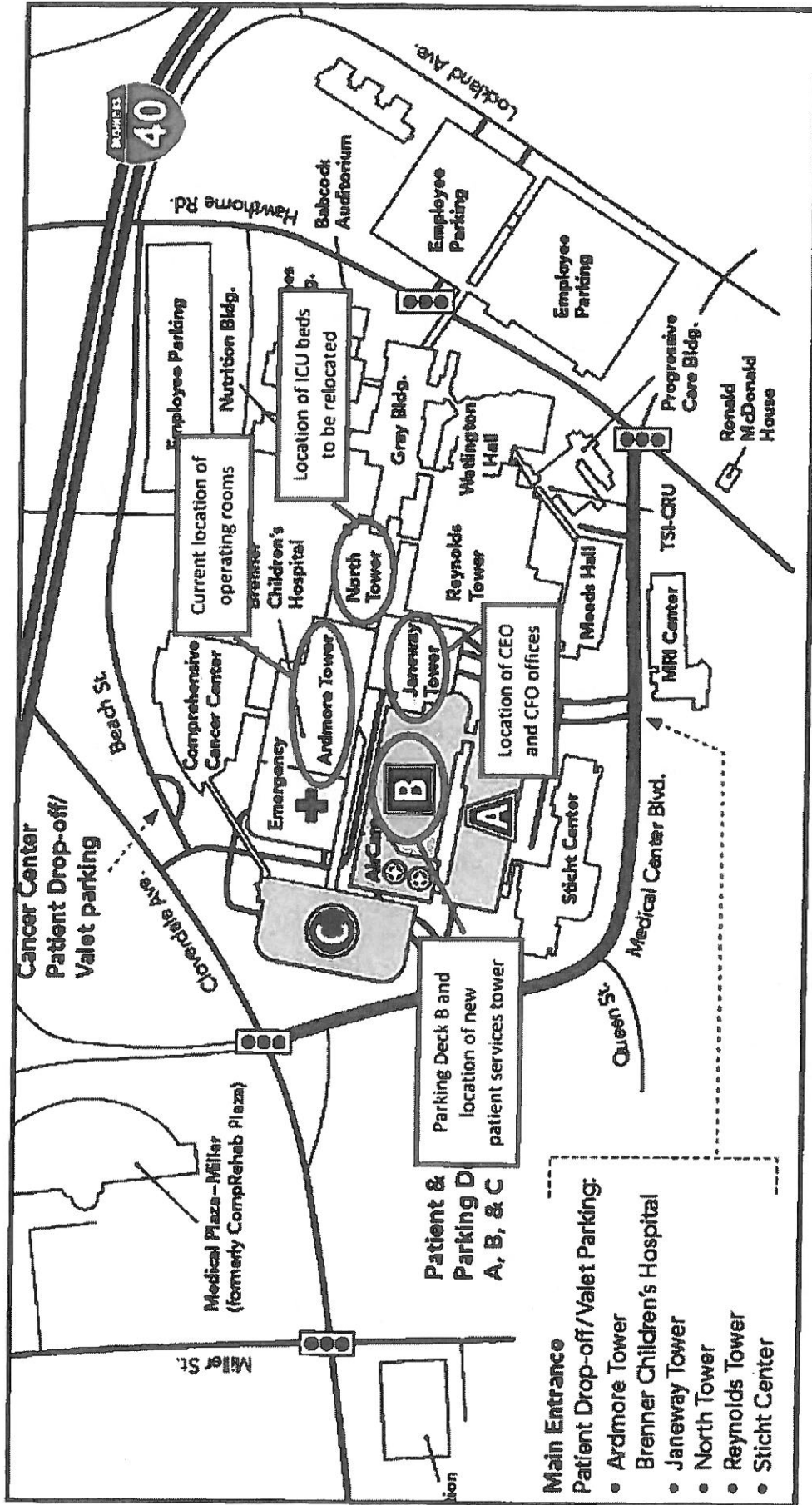


Secretary, N.C. Department of Health and  
Human Services



Director, Division of Health Service Regulation

Exhibit 1: NCBH Campus Map



- Main Entrance**
- Patient Drop-off/Valet Parking:**
- Ardmore Tower
  - Brenner Children's Hospital
  - Janeway Tower
  - North Tower
  - Reynolds Tower
  - Sticht Center