Davie Medical Center
Petition for Adjustment to the Proposed 2019 SMFP
Davie County MRI Need Determination
July 25, 2018

1. Name, Address, Email Address, and Phone Number of Petitioner:

Davie Medical Center
Marisa A. Barone
Senior Health Planner, Strategic & Business Planning
Medical Center Boulevard
Winston-Salem, NC 27157
mbarone@wakehealth.edu
(336) 713-0697

2. Statement for the Proposed Adjustment

Davie Medical Center ("DMC") requests that an adjustment be made to the 2019 State Medical Facilities Plan ("SMFP") need determination for one (1) MRI in Davie County, by reducing the need to zero (0).

3. Reasons for the Proposed Adjustment

The Proposed 2019 SMFP identifies a need for one MRI scanner in Davie County. That need determination is based solely on the utilization of the mobile MRI scanner currently in operation at DMC under an MRI services agreement with Alliance Healthcare Services. As reported in Table 9P of the Proposed 2019 SMFP, that mobile MRI performed an adjusted total of 1,864 MRI scans in FY 2017. This was slightly above the SMFP threshold of 1,716 mobile MRI scans required to justify a need for a new fixed MRI scanner.

In addition to the need methodology in Chapter 9, the SMFP also has a policy which permits hospitals to apply for an MRI scanner if they do not currently have one. Specifically, Policy TE-3 provides as follows:

> ***Policy TE-3: Plan Exemption for Fixed Magnetic Resonance Imaging Scanners***
> *Qualified applicants may apply for a fixed magnetic resonance imaging scanner (MRI).*
>
> *To qualify, the health service facility proposing to acquire the fixed MRI scanner shall demonstrate in its certificate of need application that it is a licensed North Carolina acute care hospital with emergency care coverage 24 hours a day, seven days a week and that does not currently have an existing or approved fixed MRI scanner as reflected in the inventory in the applicable State Medical Facilities Plan.*
>
> *The applicant shall demonstrate that the proposed fixed MRI scanner will perform at least 850 weighted MRI procedures during the third full operating year.*
>
> *The performance standards in 10A NCAC 14C .2703 would not be applicable.*

The fixed MRI scanner must be located on the hospital's "main campus" as defined in G.S. 131E-176- (14n)a.

Policy TE-3 first appeared in the 2017 SMFP. DMC meets all of the requirements for applying for a fixed MRI pursuant to Policy TE-3. However, DMC did not immediately apply for a fixed MRI in 2017 because its services agreement with Alliance to provide mobile MRI services is not set to expire until September 16, 2019.

Based on the unnecessary expense that DMC would incur if it terminated the Alliance services agreement early, DMC waited until June 15, 2018 to file a CON application to acquire a fixed MRI scanner under Policy TE-3 to be located on the hospital campus. That application is non-competitive and is pending before the CON Section. The application development timetable projects that DMC will begin operating the fixed MRI beginning October 1, 2019. The application also projects that the fixed MRI scanner will perform 2,790 MRI procedures by the end of FY2023 (the third year of the project). Because the capital cost of the project is under $5,000,000, DMC has requested an expedited review, pursuant to N.C. Gen. Stat. § 131E-185(a1)(2). If an expedited review is granted, the CON Section must issue a decision within 90 days of July 1, 2017, the beginning date of the review, which would be September 29, 2018. DMC has been advised by the CON Section that if its CON application is approved prior to the SHCC's final meeting date, the need determination in the Proposed SMFP for one fixed MRI would be eliminated. The SHCC's final meeting on the 2019 SMFP is scheduled for October 3, 2018.

DMC believes that regardless of whether the CON Section conducts an expedited review of the pending CON application or issues a decision prior to October 3, 2018, the SHCC should remove the need determination in the 2019 SMFP for one additional MRI scanner in Davie County. DMC already meets all of the requirements of Policy TE-3. It is a licensed North Carolina acute care hospital with emergency care coverage 24 hours a day, seven days a week and does not currently have an existing or approved fixed MRI scanner. Further, as noted in the Proposed 2019 SMFP, the existing mobile MRI scanner already exceeds the minimum utilization threshold of 850 weighted scans required in Policy TE-3. Based on Agency reviews of prior Policy TE-3 applications, the CON Section is highly likely to approve the DMC application. Only two applications have previously been filed pursuant to this Policy, by FirstHealth Moore Regional Hospital – Hoke Campus (Project ID # N-11284-17) and Cape Fear Valley Hoke Hospital (Project ID # N-11445-18), and both were conditionally approved by the CON Section on April 28, 2017 and April 10, 2018, respectively. See Agency Decisions, *Attachments 1 and 2*.

Further, regardless of whether *this* CON application is approved, DMC will retain the right to file a CON application to obtain a fixed MRI scanner pursuant to Policy TE-3, which likely will eventually be approved. Under the current SMFP need methodology, where there is one existing or approved fixed MRI in a county, another is not needed until that MRI achieves 3,776 scans. That is more than twice the FY2017 utilization of the MRI scanner currently in operation at DMC. Further, according to the SMFP, the annual maximum capacity of a fixed MRI scanner is 6,864 procedures per year (66 hours per week x 52 weeks x 2 procedures per hour). Quite simply, while DMC does need a fixed MRI scanner, its current utilization does not warrant the development of *two* fixed MRI scanners in Davie County.

DMC believes that adoption of Policy TE-3 has created a situation which was not anticipated under the SMFP MRI need methodology. The current methodology is based, in part, on the number of fixed MRI scanners currently located in a service area, as shown in the table below.

Acute Care Bed Service Area Fixed Scanners	Inpatient and Contrast Adjusted Thresholds	Planning Threshold[1]
4 and over	4,805	70.0%
3	4,462	65.0%
2	4,118	60.0%
1	3,775	55.0%
0	1,716	25.0%

This tiered approach was developed as part of the 2005 SMFP, long before Policy TE-3 was adopted. See *Attachment 3* hereto. Thus, until adoption of Policy TE-3 in 2017, there was no likelihood that two fixed MRIs could be developed in the same service area and the same time frame despite the fact that existing weighted MRI utilization in the county was well below half of the capacity of one fixed MRI. Because DMC was delayed from applying for a fixed MRI scanner under Policy TE-3 until this summer due to the terms of the Alliance services agreement, this is exactly what may occur if this need determination is not removed.

Prior Petitions[2] seeking the reduction of need determinations in similar circumstances have been approved by the SHCC.

- The Proposed 2018 SMFP identified a need for one fixed MRI scanner in the Pasquotank/Camden/Currituck/Perquimans service area. That need determination was based on the utilization of the one fixed MRI in the county, owned and operated by Sentara Albemarle Medical Center ("SAMC"). SAMC filed a Petition seeking the removal of that MRI need determination from the SMFP, arguing that MRI volume trends in the service area did not support development of an additional MRI. Agency staff agreed, and supported elimination of the need. The Technology and Equipment Committee recommended approval of the Petition, which was adopted by the full SHCC. The 2018 SMFP signed by the Governor did not include a need determination for an MRI in Davie County.

  Like the SAMC Petition, volume trends do not support the need for an additional MRI in Davie County. DMC has only recently exceeded the SMFP threshold of 1,716 mobile MRI scans required to justify a need for a new fixed MRI scanner in Davie County. Assuming its pending CON application is approved, it only projects to be performing 2,790 procedures by FY2023. It is unlikely that DMC or any other applicant could demonstrate that the population of the County needs *a second* fixed MRI scanner in that same time period.

[1] These threshold percentages are based on the SMFP's assumed annual MRI maximum capacity of 6,864 MRI procedures per year.

[2] The three petitions referenced herein are attached as *Attachments 4-6*, respectively. Exhibits to those Petitions are not included.

- In 2016, the Proposed 2017 SMFP identified a need for one additional fixed cardiac catheterization equipment in Cumberland County. Cape Fear Valley Health System ("CFVHS") filed a Petition with the SHCC to remove that need determination, on the grounds that: (1) Harnett Health (an affiliate of CFVHS) had filed a CON application in 2016 to acquire fixed cardiac catheterization equipment for its hospital facility in Harnett Counties, pursuant to a special need determination in the 2016 SMFP; and (2) CFVHS expected to file a CON application for the September 1, 2017 review cycle for one additional piece of fixed cardiac catheterization equipment, based on a separate need determination in the 2016 SMFP for Cumberland County. Based on the relationship of the two hospitals, CFVHS anticipated that a number of Harnett County residents currently receiving cardiac catheterization services in Cumberland County would choose to remain in Harnett County once the Harnett Health need determination is filled, which would make the need for the additional cardiac catheterization equipment identified in the Proposed 2017 SMFP unnecessary. Agency staff, the Technology and Equipment Committee and the full SHCC agreed, and the 2017 SMFP did not include a need determination for an additional piece of fixed cardiac catheterization equipment in Cumberland County.

  Similarly, even though the standard need methodology in the SMFP identifies a need for a fixed MRI scanner in Davie County, the unique circumstances related to DMC's pending SMFP Policy TE-3 application to acquire and begin operating a fixed MRI scanner in 2019 makes that need determination unnecessary.

- The Proposed 2018 SMFP initially identified a need for six operating rooms in Forsyth County, based upon the utilization of operating rooms at North Carolina Baptist Hospital ("NCBH"). However, it did not take into account the utilization of three ORs licensed to Wake Forest University Health Sciences and operated at Plastic Surgery Center of North Carolina ("PSCNC"), which the CON Section had approved to relocate to a new ASC in Clemmons called WFBH Outpatient Surgery Center – Clemmons ("OSCC"). The Proposed 2018 SMFP stated that the utilization of these ORs was not considered in the need determination calculations because PSCNC was an underutilized facility, and the need methodology normally does not include underutilized ORs in the need determination calculations.

  Wake Forest Baptist Health ("WFBH") petitioned the SHCC to include the PSCNC/OSCC ORs in the need methodology and reduce the Forsyth County OR need determination to four ORs, because (1) those three ORs were part of the same health system as NCBH, and (2) regardless of what had occurred in the past at PSCNC, OSCC would no longer be underutilized once the ORs are relocated to Clemmons. On the second point, WFBH's petition pointed out that the Agency's Performance Standard rules required OSCC to demonstrate that the ORs would exceed 1,872 hours per OR per year, or the application could not be approved. The SHCC agreed that in these circumstances, the OSCC ORs should be counted in the health system's OR capacity, and the final SMFP included a need for only four ORs in Forsyth County.

The WFBH petition perhaps is the most similar to the situation here. In both cases, the SMFP need methodology does not take into account circumstances which make the need determination unnecessary. In the prior situation, the Proposed 2018 SMFP uniformly removed underutilized ORs from the need methodology, but did not take into account the projected utilization of an approved application to relocate those ORs. In this case, the SMFP need methodology does not take into account a pending Policy TE-3 CON application which would eliminate the identified need for an additional fixed MRI.

A. Statement of the Adverse Effects on the Population

This proposal will have no adverse effects on the Davie County population. The proposed adjustment will reflect the true need for MRIs in Davie County, rather than an artificially high need determination which is not justified. If this proposal is not accepted, it is also possible that interested parties could undergo the expense to prepare and file CON applications, only to have their applications denied because the utilization projections were not deemed reasonable when compared to historical utilization in Davie County.

B. Statement of the Alternatives Considered

The only alternative considered by DMC was to do nothing, that is, accept the projected need determination in the Proposed 2019 SMFP. That alternative would not resolve the problem that the Proposed 2019 SMFP overstates the need for MRIs in Davie County.

4. The Project Will Not Result in an Unnecessary Duplication of Services

As explained above, WFBH's proposal will *prevent* an unnecessary duplication of services in Davie County.

5. The Project is Consistent with the Three Basic Principles Governing the Development of the SMFP: Safety and Quality, Access and Value

A. Safety and Quality

DMC agrees with the SMFP's recognition of "the importance of systematic and ongoing improvement in the quality of health services". The requested reduction of the need determination for one MRI in Davie County is consistent with this principle. Improvements in quality of services are furthered when healthcare providers are not expending funds for services which are not needed. Approval of this petition will promote safety and quality because it will enable existing and approved diagnostic imaging resources to be fully developed and utilized before additional unnecessary MRIs are developed.

B. Access

DMC also fully supports the principle of "equitable access to timely, clinically appropriate and high quality health care for all the people of North Carolina." DMC provides high quality inpatient and outpatient services that regularly and routinely serve indigent and medically underserved

patients. DMC subsidizes services to indigent and medically underserved patients by adhering to the WFBH Financial Assistance Policy and providing over $2 million annually in financial assistance to the medically underserved. During FFY 2017, 37% of DMC inpatient days of care and 41% of emergency department visits were attributed to self-pay/charity and Medicaid patients. Please reference ***Attachment 7*** for the relevant pages from the DMC 2018 License Renewal Application.

C. Value

DMC supports the SMFP's definition of "health care value" as "the maximum health care benefit per dollar expended." In this case, health care value will be achieved through the efficient use of the existing and approved services in Davie County. Davie Medical Center currently is the only provider of MRI services, and its mobile MRI scanner utilization barely meets the minimum threshold to trigger a need for an a fixed MRI. The likely approval of its Policy TE-3 CON application will readily fill that need. The addition of one ***more*** fixed MRI scanner, when DMC's projected utilization demonstrates that only one is needed, would result in underutilization of both fixed MRIs. Health care value will not be maximized by permitting the development of an unnecessary MRI which likely will have negative financial implications on existing services.

Conclusion

While DMC generally supports the MRI need methodology in the SMFP, in this instance, the availability of and DMC's application for a fixed MRI at its hospital facility in Davie County has rendered that need methodology moot. It appears that the relatively recently-adopted Policy TE-3 did not anticipate this "loophole" in the methodology, whereby the need generated by DMC is overstated under this unique fact situation.

For all of these reasons, DMC respectfully requests that the need determination for one additional MRI in Davie County be eliminated, resulting in a need determination of no additional MRIs in Davie County in the 2019 SMFP.

INDEX OF ATTACHMENTS:
DAVIE MEDICAL CENTER PETITION TO SHCC
JULY 25, 2018

ATTACHMENT	DESCRIPTION
1	April 28, 2017 Agency Decision approving FirstHealth Moore Regional Hospital – Hoke Campus Policy TE-3 CON application (Project ID # N-11284-17)
2	April 10, 2018 Agency Decision approving Cape Fear Valley Hoke Hospital Policy TE-3 CON application (Project ID # N-11445-18)
3	Pertinent Portions of 2005 SMFP
4	Sentara Albemarle Medical Center Petition to Remove the Fixed MRI Need Determination in the Pasquotank/ Camden/Currituck/Perquimans Service Area in the 2018 SMFP
5	Cape Fear Valley Health System Petition for an Adjusted Need Determination to Remove the Need for Fixed Cardiac Catheterization Equipment in Cumberland County in the Final 2017 SMFP
6	Wake Forest Baptist Health Petition for Adjustment to the Proposed 2018 SMFP Forsyth County Operating Room Need Determination
7	Pertinent pages from DMC 2018 License Renewal Application

ATTACHMENT
1

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

RESPONSE REQUIRED

April 28, 2017

Amy Graham
46 Memorial Drive
Pinehurst, NC 28374

Conditional Approval

Project ID #:	N-11284-17
Facility:	FirstHealth Moore Regional Hospital – Hoke Campus
Project Description:	Acquire one fixed MRI scanner pursuant to Policy TE-3
County:	Hoke
FID #:	100390

Dear Ms. Graham:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) has conditionally approved the above referenced certificate of need application. This decision was made after a review of the applications submitted for this cycle and after consideration of the Certificate of Need Law, N.C. Gen. Stat. §131E-175 et. seq. and regulations promulgated there under, the State Medical Facilities Plan, and other applicable information. Attached to this letter are the required findings made with respect to your application. The applicant shall not proceed with the construction, offering or development of this project until the certificate of need is issued. Further, the Agency shall not issue the certificate of need until all applicable conditions of approval have been met pursuant to N.C. Gen. Stat. §131E-187(a). The conditions are as follows:

1. FirstHealth of the Carolinas, Inc. shall materially comply with all representations made in the certificate of need application and supplemental information received April 16, 2017. In those instances where representations conflict, FirstHealth of the Carolinas, Inc. shall materially comply with the last made representation.

2. FirstHealth of the Carolinas, Inc. shall acquire no more than one fixed MRI scanner to be located at FirstHealth Moore Regional Hospital-Hoke Campus as part of this project.

3. FirstHealth of the Carolinas, Inc., as part of this project, shall not acquire any equipment that is not included in the project's proposed capital expenditures in Section F of the application and that would otherwise require a certificate of need.

4. FirstHealth of the Carolinas, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.

Response to the above conditions should be submitted to the Agency no later than 35 days from the date of the decision. Failure to respond within this time period may result in the Agency making a determination not to issue a certificate of need for the project referenced above.

The conditional approval is valid only for a capital expenditure of **$4,024,216**. If a cost overrun occurs that exceeds the approved capital expenditure amount, a new certificate of need may be required as determined by N.C. Gen. Stat. §131E-176(16)(e).

The applicant should be aware that according to the Certificate of Need law any affected person shall have thirty (30) days after the date of decision to file a petition for a contested case on this approval. Further, if you are aggrieved by the conditions of the decision you may file a petition for a contested case hearing in accordance with N.C. Gen. Stat. §150B, Article 3, as amended. This petition must be filed with the Office of Administrative Hearings, 6714 Mail Service Center, Raleigh, North Carolina 27699-6714 within thirty (30) days of the date of this decision. [Note: Effective October 1, 2009, OAH requires a filing fee with submittal of petitions for contested cases. Please direct all questions regarding this fee to OAH Clerk's Office (919-431-3000).]

N.C. Gen. Stat. §150B-23 provides that a party filing a petition must also serve a copy of the petition on all parties to the petition. Therefore, if you file a petition for a contested case hearing, you must serve a copy of the petition on the Department of Health and Human Services by mailing a copy of your petition to:

Lisa G. Corbett
Department of Health and Human Services,
Office of Legal Affairs,
Adams Building – Room 154
2001 Mail Service Center
Raleigh, North Carolina, 27699-2001

It is requested that a copy of the petition also be served on the Agency.

The certificate of need will not be issued before the completion of this 30 day period ending **May 30, 2017.** If a contested case request is received within the thirty (30) day period, the certificate will not be issued until the appeal is resolved (10A NCAC 14C .0208).

The timetable for completion of the project is the timetable outlined in the certificate of need application, unless an adjustment has been made by the Agency because the review period was extended. The timetable for this project is as follows:

Ordering of Medical Equipment	August 15, 2017
Final Drawings and Specifications to Construction Section, DHSR	September 15, 2017
Construction Contract Executed/Contract Award	December 1, 2017
25% Completion of Construction	February 1, 2018
50% Completion of Construction	April 1, 2018
75% Completion of Construction	June 1, 2018
Completion of Construction	August 15, 2018
Operation of Medical Equipment	September 1, 2018
Occupancy/Offering of Services	October 1, 2018
Licensure	October 1, 2018

If the decision is appealed, the timetable set forth in this letter will be adjusted accordingly before the Certificate of Need is issued. Please contact this office if any clarification of this decision is required.

Please refer to the Project ID # and Facility ID # (FID) in all correspondence.

Sincerely,

Julie Halatek
Project Analyst

Lisa Pittman
Team Leader, Certificate of Need

Attachment

cc: Construction Section, DHSR
Acute & Home Care Licensure & Certification Section, DHSR
Paige Bennett, Assistant Chief, Healthcare Planning, DHSR

CERTIFICATE OF SERVICE

I hereby certify that I have served the foregoing notice of **conditional approval** on the following person by placing a copy in an official depository of the United States Postal Service in a postage-paid, first class envelope addressed as follows:

Amy Graham
46 Memorial Drive
Pinehurst, NC 28374
Project ID #: N-11284-17
FID #: 100390

This the 28th day of April, 2017.

_____
Julie Halatek
Project Analyst, Certificate of Need

ATTACHMENT
2

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

RESPONSE REQUIRED

April 10, 2018

Sandy Godwin
1638 Owen Drive
Fayetteville, NC 28302

Conditional Approval

Project ID #:	N-11445-18
Facility:	Cape Fear Valley Hoke Hospital
Project Description:	Develop a fixed MRI scanner in the existing acute care hospital in Hoke County pursuant to Policy TE-3
County:	Hoke
FID #:	100392

Dear Ms. Godwin:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) has conditionally approved the above referenced certificate of need application. This decision was made after a review of the applications submitted for this cycle and after consideration of the Certificate of Need Law, N.C. Gen. Stat. §131E-175 et. seq. and regulations promulgated there under, the State Medical Facilities Plan, and other applicable information. Attached to this letter are the required findings made with respect to your application. The applicant shall not proceed with the construction, offering or development of this project until the certificate of need is issued. Further, the Agency shall not issue the certificate of need until all applicable conditions of approval have been met pursuant to N.C. Gen. Stat. §131E-187(a). The conditions are as follows:

1. Hoke Healthcare, LLC shall materially comply with all representations made in the certificate of need application and any supplemental responses. In the event that representations conflict, Hoke Healthcare, LLC shall materially comply with the last made representation.

2. Hoke Healthcare, LLC shall acquire no more than one fixed MRI scanner to be located at CFV Hoke Hospital as part of this project.

3. Hoke Healthcare, LLC shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.

4. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Hoke Healthcare, LLC shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:

   a. Payor mix for the services authorized in this certificate of need.
   b. Utilization of the services authorized in this certificate of need.
   c. Revenues and operating costs for the services authorized in this certificate of need.
   d. Average gross revenue per unit of service.
   e. Average net revenue per unit of service.
   f. Average operating cost per unit of service.

5. Hoke Healthcare, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.

Response to the above conditions should be submitted to the Agency no later than 35 days from the date of the decision. Failure to respond within this time period may result in the Agency making a determination not to issue a certificate of need for the project referenced above.

The conditional approval is valid only for a capital expenditure of **$3,966,000.** If a cost overrun occurs that exceeds the approved capital expenditure amount, a new certificate of need may be required as determined by N.C. Gen. Stat. §131E-176(16)(e).

The applicant should be aware that according to the Certificate of Need law any affected person shall have thirty (30) days after the date of decision to file a petition for a contested case on this approval. Further, if you are aggrieved by the conditions of the decision you may file a petition for a contested case hearing in accordance with N.C. Gen. Stat. §150B, Article 3, as amended. This petition must be filed with the Office of Administrative Hearings, 6714 Mail Service Center, Raleigh, North Carolina 27699-6714 within thirty (30) days of the date of this decision. [Note: Effective October 1, 2009, OAH requires a filing fee with submittal of petitions for contested cases. Please direct all questions regarding this fee to OAH Clerk's Office (919-431-3000).]

N.C. Gen. Stat. §150B-23 provides that a party filing a petition must also serve a copy of the petition on all parties to the petition. Therefore, if you file a petition for a contested case hearing, you must serve a copy of the petition on the Department of Health and Human Services by mailing a copy of your petition to:

Lisa G. Corbett
Department of Health and Human Services,
Office of Legal Affairs,

Adams Building – Room 154
2001 Mail Service Center
Raleigh, North Carolina, 27699-2001

It is requested that a copy of the petition also be served on the Agency.

The certificate of need will not be issued before the completion of this 30 day period ending **May 10, 2018.** If a contested case request is received within the thirty (30) day period, the certificate will not be issued until the appeal is resolved (10A NCAC 14C .0208).

The timetable for completion of the project is the timetable outlined in the certificate of need application, unless an adjustment has been made by the Agency because the review period was extended. The timetable for this project is as follows:

1. Financing Obtained _____ October 1, 2018
2. Drawings Completed _____ January 15, 2019
3. Construction/Renovation Contract(s) Executed _____ March 15, 2019
4. 25% of Construction/Renovation Completed
   (25% of the cost is in place)_____ May 15, 2019
5. 50% of Construction/Renovation Completed _____ August 1, 2019
6. 75% of Construction/Renovation Completed _____ October 15, 2019
7. Construction/Renovation Completed_____ January 2, 2020
8. Equipment Operational _____ March 15, 2020
9. Building/Space Occupied_____ March 25, 2020
10. Licensure Obtained _____ March 15, 2020
11. Services Offered_____ April 1, 2020
12. Facility or Service Accredited _____ October 1, 2020
13. Final Annual Report Due_____ December 31, 2023

If the decision is appealed, the timetable set forth in this letter will be adjusted accordingly before the Certificate of Need is issued. Please contact this office if any clarification of this decision is required.

Please refer to the Project ID # and Facility ID # (FID) in all correspondence.

Sincerely,

Celia C. Inman
Project Analyst

Lisa Pittman
Team Leader, Certificate of Need

Attachment

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

CERTIFICATE OF SERVICE

I hereby certify that I have served the foregoing notice of **conditional approval** on the following person by placing a copy in an official depository of the United States Postal Service in a postage-paid, first class envelope addressed as follows:

Sandy Godwin
1638 Owen Drive
Fayetteville, NC 28302

This the 10th day of April, 2018.

_____
Celia C. Inman
Project Analyst, Certificate of Need

ATTACHMENT 3

Table of Contents

The 2005 State Medical Facilities Plan

North Carolina
State Health Coordinating Council
Medical Facilities Planning Section
Division of Facility Services
Department of Health and Human Services

Methodology for Determining Need

The methodology includes need thresholds arranged in tiers based on the number of scanners, weighting of procedures based on complexity, and a component addressing MRI service areas that have no fixed MRIs, but have mobile MRIs serving the area. The methodology for determining need is based on fixed and mobile procedures performed at hospitals and freestanding facilities with fixed MRI scanners and procedures performed on mobile MRI scanners at mobile sites in the MRI service areas.

MRI Tiered Planning Thresholds

Acute Care Service Area Fixed Scanners	Inpatient and Contrast Adjusted Thresholds	Planning Threshold
4 and over	4,805[1]	70.0%
3	4,462[2]	65.0%
2	4,118[3]	60.0%
1	3,775[4]	55.0%
0	1716[5]	25.0%

The above tiering is based on the assumption that the time necessary to complete 1.0 MRI procedure (a basic outpatient procedure without contrast) is 30 minutes, or an average throughput of two procedures per hour on an MRI scanner. Capacity of a single MRI scanner is defined as that of a MRI scanner being available and staffed for use at least 66 hours per week, and 52 weeks per year. The resulting capacity of a fixed MRI scanner is defined below:

Annual Maximum Capacity of a Single Fixed MRI Scanner =
66 hours per week x 52 weeks x 2 procedures per hour = 6,864 procedures annually

This definition of capacity represents 100% of the procedure volume the equipment is capable of completing, given perfect scheduling, no machine or room downtime, no cancellations, no patient transportation problems, no staffing or physician delays and no MRI procedures outside the norm.

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[1] 6,864 X 70% = 4,805
[2] 6,864 X 65% = 4,462
[3] 6,864 X 60% = 4,118
[4] 6,864 X 55% = 3,775
[5] 6,864 X 25% = 1716

Received-Healthcare Planning
7/25/2017

ATTACHMENT
4

PETITION FOR AN ADJUSTMENT TO A NEED DETERMINATION

Petition to Remove the Fixed MRI Need Determination in the Pasquotank/Camden/Currituck/Perquimans Service Area in the *2018 State Medical Facilities Plan*

PETITIONER

Sentara Albemarle Medical Center
1144 N. Road Street
Elizabeth City, NC 27909

Coleen Santa Ana
President
252-384-4604
CFSANTA1@sentara.com

STATEMENT OF THE PROPOSED CHANGE

Sentara Albemarle Medical Center (SAMC) respectfully petitions the State Health Coordinating Council (SHCC) to remove the need determination for one fixed MRI scanner in the Pasquotank/Camden/Currituck/Perquimans service area in the *2018 State Medical Facilities Plan* (*SMFP*). Table 9R in the *Proposed 2018 SMFP* shows a need for an additional fixed MRI scanner for that service area; SAMC requests that the need determination be removed and that there would be no need for a fixed MRI scanner in that service area in the *2018 SMFP*.

REASON FOR THE REQUESTED ADJUSTMENT

For the past decade, SAMC has been the sole provider of MRI services in the four-county service area. While the hospital's mobile MRI scanner served two sites in Currituck County in the mid-2000s, the volume at these sites was low and SAMC is currently the only site of MRI service in the service area. As the only MRI provider in the four-county area, SAMC believes that despite the proposed need determination, there is no need for an additional fixed MRI scanner in the service area, for the following reasons.

1. **Negative volume trends**

Over the past five years, MRI volume in the service area has changed only slightly. As shown in the table below, the utilization has fluctuated slightly, but the overall trend has been a slight decline in volume.

SMFP *Year*	*Service Area MRI Volume (weighted procedures)*
2014	3,790
2015	3,720
2016	3,603
2017	3,304

Proposed 2018	3,776
CAGR*	**-0.1%**

*Compound Annual Growth Rate

The range of volume during this time has been small, with a difference of only 486 procedures between the highest and lowest volume years. In contrast, MRI volume across the state has grown at a much higher rate over the same time frame.

SMFP *Year*	***Statewide MRI Volume (unweighted scans^)***
2014	791,443
2015	777,633
2016	800,182
2017	848,142
Proposed 2018	852,633
CAGR*	**1.9%**

*Compound Annual Growth Rate
^Weighted procedures are not shown for the state in the *SMFP*.

SAMC does not believe any compelling reasons exist at present that would change the historical growth rates in the service area, at least not significantly enough to fully utilize the existing fixed scanner (see discussion under #3 below). As such, SAMC does not believe that another fixed MRI scanner is needed in the service area at this time.

2. Low population with minimal growth

The four counties in the service area are small, rural and experience relatively low population growth. As shown below, the projected compound annual growth rate over the next five years for the combined service area population is less than one percent.

County	***2017 Population***	***2022 Population***	***Compound Annual Growth Rate***
Pasquotank	40,112	40,381	0.1%
Camden	10,223	10,224	0.0%
Currituck	26,764	29,611	2.0%
Perquimans	13,779	14,373	0.8%
Total	**90,878**	**94,589**	**0.8%**

Source: NC Office of State Budget and Management; September 2016 projections, accessed July 2017.

Although Currituck County has a higher growth rate than the other counties in the service area, its population is still relatively low, and could likely not support a fixed MRI scanner. To that point, Table 9P in the *Proposed 2018 SMFP* shows that no county with a population lower than Currituck's has a fixed MRI scanner, except those with a hospital, which Currituck

County does not have. Further, none of the MRI sites in counties of a similar or smaller size, whether fixed or mobile, have the volume required to demonstrate need for a second fixed MRI scanner in a Certificate of Need review, which is 3,775 weighted procedures. Thus, SAMC does not believe that the current and projected population growth in the service area warrants a second fixed MRI scanner.

3. Sufficient MRI capacity

According to the *SMFP*, the annual maximum capacity of a fixed MRI scanner is 6,864 procedures per year. With only 3,776 procedures performed in FY 2016, the existing scanner at SAMC is capable of performing an additional 3,088 procedures before reaching capacity. Given the historical volume and population trends, SAMC believes that the existing fixed scanner has sufficient capacity to meet any normal growth for the foreseeable future.

Moreover, SAMC owns an existing mobile MRI scanner, which is able to provide additional capacity at SAMC if needed. In 2015, SAMC replaced its mobile MRI scanner following confirmation from the CON Section that the transaction was exempt from review. As part of that exemption notification, SAMC was approved to provide mobile MRI services at three sites: Sentara Kitty Hawk Advanced Imaging Center and Spring Arbor Assisted Living, both in Dare County, and SAMC in Pasquotank County. In FY 2016, the mobile MRI scanner performed 647 weighted procedures at two of those sites: Sentara Kitty Hawk and SAMC. Clearly, the mobile scanner has sufficient capacity to provide additional service to the Pasquotank/Camden/Currituck/Perquimans service area, if needed. Further, an existing mobile MRI scanner, particularly one with available capacity, is a more prudent option for a rural multi-county area than a second fixed MRI scanner, which would not likely be well utilized.

4. Difficulty meeting CON rules

Another reason for removing the need determination is the likelihood that a CON applicant, including SAMC, would have difficulty meeting the prospective performance standards in the CON rules for fixed MRI scanners. The CON rules, which were written to mirror the *SMFP* methodology, require an applicant in a service area with one existing fixed MRI scanner to project that the proposed MRI scanner will achieve a minimum of 3,775 weighted procedures by the third project year. If the applicant has an existing fixed MRI scanner, it has to reasonably project that each scanner will achieve 3,775 procedures. Since SAMC performed 3,776 weighted procedures in FY 2016, generating the proposed need determination by a single weighted procedure, it would essentially need to project its volume to double by the third project year in order to meet this standard.

If the need remains in the *2018 SMFP*, and if SAMC applies for the additional fixed MRI scanner, assuming the additional scanner is made operational by October 2019 (the start of FY 2020), the third project year would be FY 2022. Thus, SAMC would need to project 7,550 (3,775 x 2 = 7,550) weighted procedures by FY 2022. To grow from 3,776 procedures in 2016 to 7,550 in 2022 requires a 15.5 percent compound annual growth rate. As shown

above, not only has the service area not experienced that level of historical growth, the state as a whole has not grown at that rate. While a few urban and suburban areas with high growth and inmigration may be able to rationalize a 15 percent annual growth rate, SAMC is doubtful that the Healthcare Planning and Certificate of Need Section would find such a rate reasonable in a CON review in its service area.

5. SAMC was previously approved for a second fixed scanner that was never developed.

As many members of the SHCC may be aware, the current methodology for fixed MRI scanners was developed for the *2005 SMFP*. During the early to mid-2000s, MRI volume was rapidly increasing, as clinical applications for the technology increased and costs for the equipment decreased. During this time of growth and subsequent to the *2006 SMFP*, SAMC was approved to develop a second fixed MRI scanner. As shown below, MRI volume was increasing during this time, and if the trend had continued, a second scanner would have been needed.

Fiscal Year	***Service Area MRI Volume (weighted procedures)***
2005	4,490
2006	4,793
2007	4,877
CAGR	4.2%

Source: 2007-2009 *SMFP*s

Before the project was developed, however, the economic downturn occurred, with the greatest impact in rural areas like northeastern North Carolina. As unemployment grew, healthcare volume declined, including for technology like MRI. Although the economy improved from the height of the recession, other factors, such as the push by insurers for pre-authorization and the implementation of health reform, continued to suppress growth in volume for services like MRI, as shown below.

Fiscal Year	***Service Area MRI Volume (weighted procedures)***
2008	4,277
2009	4,253
2010	3,834
CAGR	-5.3%

Source: 2010-2012 *SMFP*s

As a result, SAMC (at the time not part of Sentara Healthcare) decided not to develop the second fixed MRI scanner and relinquished its Certificate of Need. With 3,776 procedures performed in FY 2016 (as shown in the *Proposed 2018 SMFP*), SAMC's MRI volume is 22 percent lower than the highest volume year, 2007, when the sole fixed MRI scanner at

SAMC performed 4,877 procedures[1]. SAMC does not expect MRI volume in the service area to exceed this historical level in the near future; thus, the existing fixed MRI at SAMC is sufficient to meet the current and expected future need in the service area.

ADVERSE EFFECTS IF PETITION IS NOT APPROVED

If the petition is not approved, the need determination will remain in the final *2018 SMFP*. It is possible that another entity will apply for the MRI scanner and project sufficient volume to be approved. However, the CON process does not require such an applicant to demonstrate volume for all the MRI scanners in the service area; thus, the second scanner could project volume on its scanner that would effectively leave the scanner at SAMC with little to no volume and still be approved. Given the trends documented above, SAMC believes that it is not reasonable to assume that a total of 7,550 MRI procedures will be performed in the service area in the near future. As such, the SHCC should consider that two fixed MRI scanners in the service area would not both be well-utilized, and the second MRI scanner would be unnecessary duplication.

ALTERNATIVES CONSIDERED

SAMC considered not filing a petition and potentially applying for the need determination in the *2018 SMFP*. However, given the cost of submitting an application, the cost of developing a second fixed MRI scanner, and the available capacity of SAMC's fixed and mobile MRI scanners to serve the area, SAMC determined that the best alternative was to ask the SHCC to remove the need determination.

UNNECESSARY DUPLICATION

As discussed above, SAMC believes that the need determination could lead to unnecessary duplication, given the available capacity of fixed and mobile MRI scanners to serve the area. Thus, the approval of the petition will obviate the potential for unnecessary duplication.

BASIC PRINCIPLES

Safety and Quality

The existing MRI service at SAMC provides care in a safe and high quality manner, and can continue to do so while meeting the expected future volume demand of the patients it serves. As part of Sentara Healthcare, SAMC has a mission to improve health every day. This mandate is pursued through a disciplined strategy to achieve Top 10% performance in key measures through shared best practices, transformation of primary care through clinical integration and strategic growth that adds value to the communities it serves. This mission will ensure that patients have access to MRI services in the service area, without needing a second fixed MRI scanner at this time.

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[1] Although the *2009 SMFP* shows an inventory of two fixed MRI scanners at Albemarle Hospital, the second MRI scanner shown was a placeholder for the approved but inchoate fixed MRI scanner, which was never developed.

Access

Sufficient MRI capacity exists in the service area to meet the need of the population for some time. SAMC, a not-for-profit hospital with a mission to serve the community, provides care to all in medical need of services, including the medically underserved, without regard to age, race, gender, disability, payor status, or ability to pay. Compared to a second fixed MRI scanner, SAMC's mobile MRI scanner can more effectively provide access at multiple sites across the multi-county service area and beyond. Given these factors, SAMC does not believe that approval of the petition will prevent anyone in the service area from accessing MRI services as needed.

Value

The removal of the need determination for the service area will enhance value by preventing the potential development of an unneeded second MRI scanner. The existing fixed and mobile MRI scanners in the service area can accommodate any reasonable and anticipated growth in volume, which will increase their utilization, helping to maximize the value of the existing capacity in the service area.

CONCLUSION

SAMC supports the standard MRI methodology in the *SMFP*, which takes a tiered approach to determining need in order to ensure access to the service in areas with different levels of existing capacity. However, given the unique factors in the Pasquotank/Camden/ Currituck/Perquimans service area, such as negative volume trends, low population growth, sufficient fixed and mobile MRI capacity, and the triggering of the need determination by a single procedure, SAMC believes that the citizens of North Carolina, particularly those in northeastern North Carolina, would best be served by removing the need determination from the *2018 SMFP*.

ATTACHMENT
5

North Carolina State Health Coordinating Council
c/o Medical Facilities Planning Section
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Re: Cape Fear Valley Health System Petition for an Adjusted Need Determination to Remove the Need for Fixed Cardiac Catheterization Equipment in Cumberland County in the *Final 2017 SMFP*

I. Petitioner

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II. Requested Adjustment

Cape Fear Valley Health System (CFVHS) requests an adjusted need determination to remove the need allocation for one additional fixed cardiac catheterization equipment in Cumberland County in the *Final 2017 State Medical Facilities Plan* (*Final 2017 SMFP*).

Chapter 9, Cardiac Catheterization, should be changed as follows:

Table 9Y: Fixed Cardiac Catheterization Equipment Need Determination
(Proposed for Certificate of Need Review Commencing in 2017)

Cardiac Catheterization Service Area	Shared Fixed Cardiac Catheterization Equipment Need Determination*	Certificate of Need Application Due Date**	Certificate of Need Beginning of Review Date
Cumberland	0	NA	NA

*Need determinations shown in this document may be increased or decreased during the year pursuant to Policy GEN-2 (see Chapter 4).
**Application due dates are absolute deadlines. The filing deadline is 5:30 p.m. on the application due date. The filing deadline is absolute (see Chapter 3).

III. Reasons for Proposed Adjustment

Cardiac catheterization volume at CFVMC continues to increase, as shown in the following table. As a result, the methodology in the Annual SMFP generated a need determination for another cardiac catheterization unit in Cumberland County in the *Proposed 2017 SMFP*.

Cape Fear Valley Medical Center
Cardiac Catheterization Total Cases*

	FFY 2013	FFY 2014	FFY 2015	FFY 2016 Oct-May Annualized
Total Cardiac Cath	2,993	3,768	4,144	4,430

Source: SMFPs; 2016 CFVHS DSS
*Unweighted

However, the SMFP cardiac catheterization methodology is based upon a single county service area and does not take into account the impact of the developing cardiac catheterization services in Harnett County, at Harnett Health which is managed by CFVMC.

The *2016 State Medical Facilities Plan* identified a need for a new shared fixed cardiac catheterization unit in Harnett County and an additional fixed cardiac catheterization unit in Cumberland County. Harnett Health submitted a CON for the unit in Harnett County for the May 1, 2016 CON application review cycle. Harnett Health's application was the only application received, and no comments in opposition to the application were submitted. Harnett Health and CFVHS expect an approval on this CON Application by the end of July, as the Application was granted an expedited review.

The Harnett Health need was based upon a special need petition submitted by Harnett Health and it will be the first unit located in Harnett County. Residents of Harnett County historically have sought cardiac catheterization services in Fayetteville, Raleigh and Pinehurst as illustrated in the following market share table.

Harnett County Cardiac Catheterization Equipment Market Share

Facility	FY 2013	FY 2014	FY 2015 Q1 -Q3
Cape Fear Valley Medical Center	16.4%	15.6%	24.2%
Central Carolina Hospital	3.0%	2.1%	2.0%
Duke Raleigh	0.6%	0.2%	0.6%
Duke Regional Hospital	0.0%	0.0%	0.4%
Duke University Medical Center	4.0%	3.6%	3.3%
First Health Moore Regional Hospital	14.8%	13.6%	14.3%
Johnston Medical Center-Smithfield	1.6%	0.5%	3.3%
Rex Healthcare	12.0%	16.2%	17.1%
University of North Carolina Hospitals	5.9%	4.9%	4.1%
WakeMed	40.0%	41.3%	28.6%
WakeMed Cary	1.1%	1.0%	0.9%
All Other	0.5%	0.9%	1.1%
Total Diagnostic and Interventional	100.0%	100.0%	100.0%

Source: Truven Data

As shown in the previous table, there is not one dominant provider for cardiac catheterization for residents of Harnett County; however, Cape Fear Valley Medical Center (CFVMC) meets the need for a significant portion of the population. Once the new cardiac catheterization unit at Harnett Health becomes operational in 2017, Harnett Health and CFVHS expect a significant number of Harnett County residents currently seeking care at CFVMC will choose to remain in Harnett County. This will impact the utilization of cardiac catheterization services at CFVMC.

The *2016 State Medical Facilities Plan* also identified a need for a new fixed cardiac catheterization unit in Cumberland County, as previously noted. CFVHS will be submitting a CON Application for a fourth cardiac catheterization unit to meet the need identified for Cumberland County for the September 1, 2016 CON application review cycle.

As stated in the *2016 State Medical Facilities Plan*, "It is further determined that fixed and mobile cardiac catheterization equipment and services shall only be approved for development on hospital sites." CFVHS' two hospitals, CFVMC and Highsmith Rainey Specialty Hospital, are the only licensed acute care hospitals located in Cumberland County. Therefore, CFVHS will be the only applicant for this additional unit of cardiac catheterization equipment.

In projecting utilization for the CON to be submitted by CFVHS in August, both the increasing population in the service area and the shift of cardiac catheterization volume from CFVMC to Harnett Health are being taken into consideration. The resulting CFVMC volume reflects a need for only four cardiac catheterization units in Cumberland County as shown in the following table.

CFVMC Projected Cardiac Catheterization Equipment Need

	FFY 2016 Annualized	Weighted Population Growth Rate Ages 55+	FFY 2017	FFY 2018	PY 1 FFY 2019	PY 2 FFY 2020	PY 3 FFY 2021
Projected Cardiac Catheterization Volume	4,430	2.0%	4,520	4,612	4,707	4,803	4,901
Potential Volume Shifted to Harnett		90%		-370	-644	-824	-840
Projected Adjusted CFVMC Cardiac Catheterization Volume				4,242	4,062	3,979	4,061
Therapeutic Cardiac Catheterization					1,764	1,728	1,764
Diagnostic Cardiac Catheterization					2,298	2,251	2,297
Weighted Cardiac Catheterization Procedures					5,386	5,276	5,384
Cardiac Cath Equipment Needed @ 1,200 Procedures Per Room					4.5	4.4	4.4
CFVMC Cardiac Catheterization Room Inventory					4.0	4.0	4.0
Additional Need Rounded to SMFP Standards					0.5	0.4	0.4

While not guaranteed, CFVHS does expect its application for a fourth cardiac catheterization unit to be approved. The approval of these two CON applications, one in Harnett County, and one in Cumberland County in the CFVMC Service Area, will result in a net increase in cardiac catheterization equipment of two new cardiac catheterization units. Once approved these two cardiac catheterization units are expected to be operational in 2017 (Harnett Health) and 2018 (CFVMC). CFVHS believes that cardiac catheterization capacity in the CFVHS Service Area, which includes Harnett County, will be sufficient to meet the demand at that time as illustrated in the above table.

CFVHS respectfully requests that the need for an additional cardiac catheterization unit in Cumberland County be removed from the *Proposed 2017 SMFP* until the impact of the new unit in Harnett County is determined.

IV. Statement of Adverse Effects on the Population if the Adjustment is Not Made

CFVHS believes the addition of the fifth cardiac catheterization unit in Cumberland County, currently identified as a need determination in the *Proposed 2017 SMFP*, will have an adverse effect on both providers and consumers if it is not adjusted.

First, CFVHS will be applying for the additional cardiac catheterization unit identified as needed in Cumberland County in the *2016 SMFP*. With the additional capacity resulting from the addition of a fourth unit, and the new unit in Harnett County, CFVHS does not see the need for an

additional unit so soon as discussed above. CFVHS does not desire to increase unnecessary capacity through the acquisition of a fifth cardiac catheterization unit. It should also be noted that the *Proposed 2017 State Medical Facilities Plan* states, "It is further determined that fixed and mobile cardiac catheterization equipment and services shall only be approved for development on hospital sites."

CFVHS' two hospitals, CFVMC and Highsmith Rainey Specialty Hospital, are the only licensed acute care hospitals located in Cumberland County, and therefore, they are the only potential applicants for this additional unit of cardiac catheterization equipment. It would not make sense to include a need determination for additional cardiac catheterization equipment when the only potential applicant for that equipment does not foresee at the present time a need for the additional equipment.

Second, the acquisition of unnecessary cardiac catheterization equipment may impact the costs associated with providing cardiac catheterization services in Cumberland County.

V. Alternatives considered

Because of available capacity on the existing cardiac catheterization units plus the new unit in Harnett County, the only logical alternative is to avoid creating an unnecessary need determination for one (I) unit of fixed cardiac catheterization equipment in Cumberland County in the *2017 State Medical Facilities Plan.*

This alternative resulted in the submission of this petition for an adjusted need determination in Cumberland County.

VI. Duplication of Health Resources

Adjusting the need determination for one (I) unit of fixed cardiac catheterization equipment in Cumberland County will most assuredly not result in duplication of health services in the area, but rather would avoid the duplication of health services from being proposed.

VII. Consistency with SMFP Basic Principles

The proposed adjustment is consistent with these basic principles in that safety and quality, access and value, all of which are associated with the existing provision of cardiac catheterization services in Cumberland County, will not be impacted. Based on the expected expansion of cardiac catheterization capacity in Harnett and Cumberland County, adjusting the need determination will eliminate the possible duplication of services, which would help maintain cardiac catheterization volumes at the existing provider location and would eliminate the expenses associated with acquiring and operating an additional cardiac catheterization unit in the service area.

1. Safety and Quality Basic Principle

The State of North Carolina recognizes the importance of systematic and ongoing improvement in the quality of health services. Providing care in a timely manner is a key component of assuring safety and quality care to the citizens of Cumberland Service Area and southeastern North Carolina. Emerging measures of quality address both favorable clinical outcomes and patient satisfaction, while safety measures focus on the elimination of practices that contribute to avoidable injury or death and the adoption of practices that promote and ensure safety.

2. Access Basic Principle

Although a need in the *2016 SMFP* does not guarantee Harnett Health a Certificate of Need, the hospital has an excellent track record of serving all persons and the application was not contested by any other provider. It is anticipated that the application will be approved the end of July. CFVHS manages Harnett Health and believes that the opening of this facility provides improved access to the residents of Harnett County currently seeking care at CFVMC. As a result, CFVHS does not believe a fifth cardiac catheterization unit is not needed at CFVMC at time. Both CFVHS and Harnett Health have a long history of providing care for the uninsured and the underinsured as evidenced in their annual licensure renewal applications.

The impact of economic barriers is twofold. First, individuals without insurance, with insufficient insurance, or without sufficient funds to purchase healthcare will often require public funding to support access to regulated services. CFVHS and Harnett Health are the safety net providers for patients in Harnett and Cumberland Counties regardless of income or insurance. Neither provider has any barriers to care for the uninsured and the underinsured.

3. Value Basic Principle

The SHCC defines health care value as maximum health care benefit per dollar expended. Disparity between demand growth and funding constraints for health care services increases the need for affordability and value in health services. Measurement of the cost component of the value equation is often easier than measurement of benefit. Cost per unit of service is an appropriate metric when comparing providers of like services for like populations. The cost basis for some providers such as CFVHS and Harnett Health may be inflated by disproportionate care to indigent and underfunded patients.

Measurement of benefit is more challenging. Standardized safety and quality measures, when available, can be important factors in achieving improved value in the provision of health services. CFVHS participates in a variety of benchmark programs to compare the use of inpatient and outpatient resources to other hospitals and uses this information to improve processes and decrease costs wherever possible.

VIII. Conclusion

CFVHS believes that the addition of a shared fixed cardiac catheterization unit in Harnett County and the addition of a fourth cardiac catheterization unit at CFVMC, resulting in a total of five cardiac catheterization units in the two counties, will meet the need identified in the *Proposed 2017 SMFP* for a fifth cardiac catheterization unit in Cumberland County. Therefore, CFVHS requests that the need for a fifth cardiac catheterization unit in Cumberland County be removed from the *Proposed 2017 SMFP.*

ATTACHMENT 6

Wake Forest Baptist Health
Petition for Adjustment to the Proposed 2018 SMFP
Forsyth County Operating Room Need Determination
July 25, 2017

1. **Name, Address, Email Address, and Phone Number of Petitioner:**

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2. **Statement for the Proposed Adjustment**

Wake Forest Baptist Health ("WFBH") requests that an adjustment be made to the 2018 State Medical Facilities Plan ("SMFP") need determination for operating rooms ("ORs") in Forsyth County, by reducing the need for ORs from six (6) to four (4).

3. **Reasons for the Proposed Adjustment**

The Proposed 2018 SMFP need methodology for ORs differs from previous years and is based upon recommendations from the SHCC's Operating Room Methodology Workgroup (the "Workgroup"). The new methodology is summarized below:

- Facilities are grouped by the total number of surgical hours derived from data reported on the License Renewal Application.
- Operating room deficits and surpluses are calculated separately for each health system.
- Availability and utilization assumptions are based on the group to which the facility is assigned.
- Need determination calculations use case times reported by the facility, adjusted for outliers.
- When a need is calculated, the minimum need determination is two operating rooms. The maximum operating room need determination in a single service area is six.

The Proposed 2018 SMFP goes on to define "health system" to include all licensed health service facilities with operating rooms located in the same service area that are owned by:

- the same legal entity (i.e., the same individual, trust or estate, partnership, corporation, hospital authority, or the State or political subdivision, agency or instrumentality of the State); or
- the same parent corporation or holding company; or
- a subsidiary of the same parent corporation or holding company; or
- a joint venture in which one or more of the participants in the joint venture owns a licensed health service facility with operating rooms located in the same service area.

Based upon this methodology, North Carolina Baptist Hospital ("NCBH"), which is part of the WFBH health system, has been assigned to Group 1, under Step 4 of the Proposed 2018 SMFP OR need methodology since it is an Academic Medical Center Teaching Hospital. In its initial recommendations to the SHCC, the Workgroup found that there were a total of 48 ORs in the WFBH health system, based upon 45 existing and approved ORs[1] at NCBH and three ORs approved to be developed in Clemmons known as WFBH Outpatient Surgery Center – Clemmons ("OSCC").[2] See Attachment 1, SMFP Operating Room Tables 6A-6B presented at the May 2, 2017 Acute Care Services Committee meeting. Although not specifically discussed, Table 6A also implicitly recognized that the three ORs approved for OSCC would be relocated from the Plastic Surgery Center of North Carolina ("PSCNC") ambulatory surgical center.

The Workgroup and Agency staff properly found that NCBH and OSCC are part of the same health system, as defined in the Proposed 2018 SMFP. NCBH is a subsidiary of Wake Forest University Baptist Medical Center ("WFUBMC"). OSCC is owned by Wake Forest Ambulatory Ventures, LLC ("WFAV"), in which Wake Forest University Health Sciences ("WFUHS") holds a controlling interest. WFUHS, like NCBH, is a subsidiary of WFUBMC. In addition, although never mentioned in the Proposed 2018 SMFP, WFUHS owns the PSCNC ambulatory surgical center. See Attachment 2, 2017 License issued to WFUHS to operate PSCNC. Thus, both the existing and proposed ambulatory surgical centers are part of the same health system as NCBH.

However, at the June 7, 2017 SHCC meeting, the Acute Care Services Committee recommended increasing the need determination for Forsyth County from four to six ORs. See Attachment 3, Acute Care Services Committee Recommendations to the North Carolina State Coordinating Council June 7, 2017. Attachment 3 states that this update and others were based on "corrections and updates to the tables" made following the Committee's May 2, 2017 meeting. This recommendation was accepted by the SHCC. See Attachment 4, pertinent portions of the Proposed 2018 SMFP.

A review of Tables 6A and 6B of the Proposed 2018 SMFP shows that OSCC is no longer grouped with NCBH as part of one health system. Rather, the OSCC ORs are grouped with the PSCNC ORs. For need determination purposes, Table 6B reports an adjusted planning inventory for the two facilities of zero. Further, the end of Table 6B appears to explain the reasons why these ORs are not counted in the SMFP inventory.

> *Plastic Surgery Center of North Carolina is an underutilized facility that is relocating all ORs to Clemmons Medical Park Ambulatory Surgical Center, which is under development. As such, no ORs or placeholders are included in the need determination calculations for these facilities.*

[1] The seven approved ORs included in the need determination were awarded to NCBH for a Policy AC-3 project. The Proposed 2018 SMFP need determination now counts Policy AC-3 ORs in determining service area need. In addition, NCBH has two trauma/burn ORs which are excluded from the SMFP need determination.

[2] This is the name WFBH intends to use for the new ambulatory surgical center. It is referenced in the CON issued to WFAV and in the Proposed 2018 SMFP as Clemmons Medical Park Ambulatory Surgical Center. See Attachments 4 and 6.

NCBH believes that the failure to include these three ORs results in an overstatement of the Forsyth County OR need. As shown in Attachment 2, whether the PSCNC ORs are underutilized or not, they are part of the WFBH health system, and should be counted in determining WFBH's future need for additional ORs.

Further, while those ORs are currently underutilized at PSCNC, those ORs will not be underutilized once they are relocated to OSCC. In order for the CON Section to approve the WFAV CON application and issue a CON for the OSCC ambulatory surgical center, WFAV was required to demonstrate to the CON Section that ***all three ORs*** to be relocated to the facility would be needed pursuant to the requirements of N.C. Gen. Stat. §131E-183(a)(3) and the Performance Standards in 10A NCAC 14C.2103. In particular, the Performance Standards require the applicant to demonstrate that by the third year of operation, the number of case hours in its proposed ORs will exceed 1,872 hours per OR per year. WFAV made that demonstration, projecting that OSCC would have 4,716 case hours by the third year of operation. See Attachment 5, pertinent portions of WFAV Supplemental Settlement Information.[3] The CON Section concluded that this projection was reasonable, and a CON was issued to WFAV effective January 19, 2012. See Attachment 6, CON issued to WFAV for Project I.D. #G-1608-10. According to its most recent Progress Report filed with the CON Section, WVAV projects that the facility will be licensed and operational on January 1, 2018. See Attachment 7, July 18, 2017 Progress Report (without attachments).[4] On this date PSCNC will cease operating as a licensed facility. Therefore, on the date the 2018 SMFP becomes effective, there will be no chronically underutilized licensed ambulatory surgical center in Forsyth County.

Table 6B of the Proposed 2018 SMFP projects a need for 6.65 additional ORs in Forsyth County by 2020. Since OSCC is expected to be licensed at the beginning of 2018, that facility's third year of operation will be 2020. Because the CON Section has already found that OSCC's projected utilization of 4,716 case hours for year three justified a need for three ORs, it is reasonable to assume that OSCC's ORs will fulfill the SMFP's identified need in 2020 for those three ORs.

The need identified in the Proposed 2018 SMFP for six ORs is based solely upon the existing and projected utilization of ORs in the WFBH health system, particularly only at NCBH. The information contained in the Proposed 2018 SMFP regarding NCBH's existing and approved ORs, combined with WFAV's projected third year utilization for the OSCC ambulatory surgical center, demonstrate that there is not a need for six ORs in Forsyth County. Because the SMFP need methodology caps the number of new ORs in any one service area to six ORs, the need determination is rounded down to six ORs in Table 6C. If the three ORs currently licensed to PSCNC which will be relocated to OSCC are included as part of WFBH's health system, the need would be reduced from 6.65 to 3.65 = four ORs. WFBH believes that this is a more accurate reflection of the true need for ORs in Forsyth County in the 2018 SMFP.

[3] The WFAV application was initially disapproved by the CON Section, but was approved following a settlement.

[4] WFAV's previous Progress Report (which is also included in Attachment 7), also projected that the facility would be open by January 1, 2018. WFAV inadvertently failed to include the licensure date. By law, the license would have to be issued by the State before the facility could begin operation. See N.C. Gen. Stat. §131E-147(a).

A. Statement of the Adverse Effects on the Population

This proposal will have no adverse effects on the Forsyth County population. The proposed adjustment will reflect the true need for ORs in Forsyth County, rather than an artificially high need determination which is not justified. If this proposal is not accepted, it is also possible that interested parties could undergo the expense to prepare and file CON applications, only to have their applications denied because the utilization projections were not deemed reasonable when compared to historical utilization in Forsyth County.

B. Statement of the Alternatives Considered

The only alternative considered by WFBH was to do nothing, that is, accept the projected need determination in the Proposed 2018 SMFP. That alternative would not resolve the problem that the Proposed 2018 SMFP overstates the need for ORs in Forsyth County.

4. The Project Will Not Result in an Unnecessary Duplication of Services

As explained above, WFBH's proposal will *prevent* an unnecessary duplication of services in Forsyth County. This is especially true where, as here, the data for Novant Health, the only other health system in Forsyth County whose ORs and cases are included in the SMFP need determination currently shows a *surplus* of almost seven ORs.

5. The Project is Consistent with the Three Basic Principles Governing the Development of the SMFP: Safety and Quality, Access and Value

A. Safety and Quality

WFBH agrees with the SMFP's recognition of "the importance of systematic and ongoing improvement in the quality of health services". The requested reduction of the need determination for ORs in Forsyth County is consistent with this principle. Improvements in quality of services are furthered when healthcare providers are not expending funds for services which are not needed. Approval of this petition will promote safety and quality because it will enable existing and approved surgical resources to be fully developed and utilized before additional unnecessary ORs are developed.

B. Access

WFBH also fully supports the principle of "equitable access to timely, clinically appropriate and high quality health care for all the people of North Carolina." WFBH provides high quality inpatient and outpatient services that regularly and routinely serve indigent and medically underserved patients. WFBH subsidizes services to indigent and medically underserved patients by providing $5.3 million a year to support the Downtown Health Plaza operating in eastern Winston Salem. Downtown Health Plaza provides more than 62,000 visits per year to more than 20,000 patients of which more than 30% are uninsured.

In addition, a primary reason why PSCNC's current ORs are underutilized is because it is a single-specialty ambulatory surgical center, whose physician operators limit their practice to elective, private pay cosmetic surgery. As set forth in its CON, WFAV was approved to develop a multi-specialty, accredited ambulatory surgical center facility, which will serve a much broader group of patients, including the medically underserved. That facility will be open in only a few months. OSCC's ORs, together with the other existing and approved ORs in Forsyth County and the four additional ORs which WFBH proposes to be included in the 2018 SMFP, will provide ample access to surgical services in the service area.

C. Value

WFBH supports the SMFP's definition of "health care value" as "the maximum health care benefit per dollar expended." In this case, health care value will be achieved through the efficient use of the existing and approved ORs in Forsyth County. With the exception of NCBH's ORs, surgical services in Forsyth County are already underutilized. The addition of six more ORs, when NCBH's and OSCC's projected utilization demonstrate that only four are needed, would result in further underutilization. Health care value will not be maximized by permitting the development of unnecessary ORs which likely will have negative financial implications on existing facilities.

Conclusion

While WFBH generally supports the need methodology developed by the Workgroup and adopted by the SHCC, it appears that the chronic underutilization of PSCNC has created a "loophole" in the methodology, whereby the need generated by WFBH is overstated, because neither PSCNC's ORs nor its cases are counted in the need determination, despite the fact that PSCNC is part of WFBH's health system under the Proposed 2018 SMFP definitions. Further, OSCC is not yet open and has no historical utilization. As a result, three ORs that are approved to be developed by WFAV and will be licensed and operational at the same time the 2018 SFMP becomes effective, are not considered in determining the future need for ORs in Forsyth County.

By way of contrast, five ORs approved to be relocated from Rex Hospital to Rex Surgery Center of Wakefield (three ORs) and Rex Hospital Holly Springs (two ORs) *are* included as part of the UNC Health Care health system Wake County inventory, for determining the need for additional ORs in Wake County. See Attachment 4, Tables 6A and 6B. It makes no sense to *exclude* the underutilized ORs at PSCNC and the approved OSCC facility from WFBH's inventory when determining Forsyth County need, while *including* more fully utilized ORs at Rex Hospital and two approved facilities in UNC Health Care's inventory when determining Wake County need.

For all of these reasons, WFBH respectfully requests that the need determination for six additional operating rooms in Forsyth County be reduced, resulting in a need determination of a total of four additional operating rooms for Forsyth County in the 2018 SMFP.

INDEX:
WAKE FOREST BAPTIST HEALTH PETITION TO SHCC
JULY 25, 2017

ATTACHMENT:	DESCRIPTION
1	Pertinent portions of SMFP Operating Room Tables 6A-6C presented at May 2, 2017 Acute Care Services Committee meeting
2	2017 License issued to WFUHS for PSCNC ambulatory surgical center
3	Acute Care Services Committee Recommendations to the North Carolina State Coordinating Council June 7, 2017
4	Pertinent portions of Proposed 2018 SMFP
5	Pertinent portions of WFAV Supplemental Settlement Information for Project I.D. #G-1608-10
6	CON issued to WFAV effective January 19, 2012 for Project I.D. #G-1608-10
7	March 21 and July 18, 2017 Progress Reports for Project I.D. #G-1608-10

ATTACHMENT
7

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

MEMORANDUM

DATE: November 13, 2017

TO: **Davie Medical Center -- Bermuda Run**

FROM: Azzie Y. Conley, RN, Section Chief

SUBJECT: **2018 Hospital License Renewal Application**

PLEASE READ CAREFULLY

Enclosed is your 2018 License Renewal Application. Please complete this application and return the original no later than January 16, 2018 to the address below.

Mailing Address
Acute and Home Care
Licensure and Certification Section
1205 Umstead Drive
2712 Mail Service Center
Raleigh, NC 27699-2712

Overnight Address (UPS and FedEx Only)
Acute and Home Care
Licensure and Certification Section
1205 Umstead Drive
Raleigh, NC 27603

Data on file with the Division indicates that your facility/entity is a **Hospital** totaling **50** beds. Your annual licensure fee, as authorized by G.S. 131E-77, is **$1,225.00**. This amount is comprised of a base fee of **$350.00** plus an additional per bed fee of **$17.50**.

Payment should be in the form of check, money order or certified check and must be payable to "**NC - DHSR.**" Payment should include the facility's license number and be submitted with your license renewal application. A separate check is required for each licensed entity.

Your completed license renewal application **and** the **annual licensure fee** must be received by January 16, 2018 to ensure your license remains valid. Failure to possess a valid license may compromise your facility's ability to operate and/or adversely impact its funding sources.

For questions regarding this page, please contact Azzie Conley at (919) 855-4646.

In accordance with Session Law 2013-382 and 10A NCAC 13B .3502(e) on an annual basis, on the license renewal application provided by the Division, the facility shall provide to the Division the direct website address to the facility's financial assistance policy. This Rule applies only to facilities required to file a Schedule H, federal form 990. Please use Form 990 Schedule B and/or Schedule H as a reference.

1) Please provide the main website address for the facility:

www.wakehealth.edu/Davie-Medical-Center/

2) In accordance with 131E-214.4(a) DHSR can no longer post a link to internet Websites to demonstrate compliance with this statute.

   A) Please provide the website address and/or link to access the facility's charity care policy and financial assistance policy:

www.wakehealth.edu/Insurance-and-Billing/Uninsured-Financial-Assistance.htm

   B) **Also, please attach a copy of the facility's charity care policy and financial assistance policy:** Feel free to email the copy of the facility's charity care policy to: DHHS.DHSR.Hospital.CharityCare.Policy@dhhs.nc.gov.

3) Please provide the following financial assistance data. All responses can be located on Form 990 and/or Form 990 Schedule H.

Contribution, Gifts, Grants and other similar Amounts *(Form 990; Part VIII 1(h))*	**Annual Financial Assistance at Cost** *(Form 990; Schedule H Part I, 7(a)(c))*	**Bad Debt Expense** *(Form 990; Schedule H Part III, Section A(2))*	**Bad Debt Expense Attributable to Patients eligible under the organization's financial assistance policy** *(Form 990; Schedule H Part III, Section A(3))*
—	1,429,454	866,608	—

AUTHENTICATING SIGNATURE: this attestation statement is to validate compliance with GS 131E-91 as evidenced through 10A NCAC 13B .3502 and all requirements set forth to assure compliance with fair billing and collection practices.

Signature:_____ **Date:**_____

Print Name of Approving Official:_____

E. Reimbursement Source. (For "Inpatient Days," show Acute Inpatient Days only, excluding normal newborns.)

Campus – *if multiple sites*: _____

Primary Payer Source	* Inpatient Days of Care (total should be the same as D.1.a – q total on p. 6)	Emergency Visits (total should be the same as G.3.b. on p. 8)	Outpatient Visits (excluding Emergency Visits and Surgical Cases)	Inpatient Surgical Cases (total should be same as 9.d. Total Surgical Cases-Inpatient Cases on p. 12)	Ambulatory Surgical Cases (total should be same as 9.d. Total Surgical Cases-Ambulatory Cases on p. 12)
Self Pay/Indigent/Charity	342	2,948	1,572	1	42
Medicare & Medicare Managed Care	757	3,567	22,391	123	1,521
Medicaid	382	3,403	2,542	8	78
Commercial Insurance	9	134	382	5	10
Managed Care	321	4,855	17,895	93	855
Other (Specify)	139	466	2,408	22	151
TOTAL	1,950	15,373	47,190	252	2,657

* Represents acute care from D1 & swing from D11.

F. Services and Facilities

1. Obstetrics

	Enter Number of Infants
a. Live births (Vaginal Deliveries)	–
b. Live births (Cesarean Section)	–
c. Stillbirths	–

d. Delivery Rooms - Delivery Only (not Cesarean Section)	–
e. Delivery Rooms - Labor and Delivery, Recovery	–
f. Delivery Rooms – LDRP (include in Item "**D.1.m**" on Page 6)	–
g. Normal newborn bassinets (Level I Neonatal Services) Do not include in section "D. Beds by Service" on Page 6	–

2. Abortion Services Number of procedures per Year –

(Feel free to footnote the type of abortion procedures reported)