ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

Decision Date: May 18, 2017
Findings Date: May 18, 2017

Project Analyst: Mike McKillip
Assistant Chief: Martha Frisone

Project ID #: G-11299-17
Facility: Davie Medical Center
FID #: 080175
County: Davie
Applicants: Davie County Emergency Health Corporation
North Carolina Baptist Hospital
Project: Develop one additional shared operating room and one additional procedure room for a total of three operating rooms and three procedure rooms

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

(1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

CA

The applicants, Davie County Emergency Health Corporation d/b/a Davie Medical Center **[DMC]** and North Carolina Baptist Hospital **[NCBH]** propose to develop one additional shared operating room and one additional procedure room for a total of three operating rooms and three procedure rooms at the Davie Medical Center facility in Bermuda Run (Davie County) following completion of the project.

Need Determination

The 2017 State Medical Facilities Plan (SMFP) includes a need determination for one additional operating room for the Davie County operating room service area. Davie Medical Center proposes to develop one additional shared operating room and one additional procedure room for a total of three operating rooms and three procedure rooms at the hospital following completion of the project. Therefore, the applicants' proposal is consistent with the need determination in the 2017 SMFP.

Policies

There are two policies in the 2017 SMFP which are applicable to this review: Policy GEN-3: Basic Principles and Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.

Policy GEN-3

Policy GEN-3 states:

> *"A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area."*

Davie Medical Center (DMC) addresses Policy GEN-3 as follows:

Promote Safety and Quality – The applicants describe how they believe the proposed project would promote safety and quality in Section II.8, pages 20-23, and referenced exhibits. The information provided by the applicants is reasonable and adequately supports the determination that the applicants' proposal would promote safety and quality.

Promote Equitable Access – The applicants describe how they believe the proposed project would promote equitable access in Section VI, pages 70-79, and referenced exhibits. The information provided by the applicants is reasonable and adequately supports the determination that the applicants' proposal would promote equitable access.

Maximize Healthcare Value – The applicants describe how they believe the proposed project would maximize healthcare value in Section V.7, pages 66-67. The information provided by the applicants is reasonable and adequately supports the determination that the applicants' proposal would maximize healthcare value.

The applicants adequately demonstrates how their projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the need identified in the 2017 SMFP. The application is consistent with Policy GEN-3.

Policy GEN-4

Policy GEN-4 states:

> *"Any person proposing a capital expenditure greater than $2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.*
>
> *In approving a certificate of need proposing an expenditure greater than $5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.*
>
> *Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."*

The proposed capital expenditure for this project is greater than $5 million. In Section III.4, pages 37-39 109, the applicants state:

> *"DMC and WFBMC* [Wake Forest Baptist Medical Center] *are committed to constructing facilities that are energy efficient and promote water conservation. Specifically related to the proposed project, upon CON approval, DMC will, as part of the design phase, submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation."*

The applicants adequately demonstrate that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

Conclusion

In summary, the applicants adequately demonstrate that the proposal is consistent with the need determination in the 2017 SMFP, and is consistent with Policy GEN-3 and Policy GEN-4. Therefore, the application is conforming to this criterion.

(2) Repealed effective July 1, 1987.

(3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicants, DMC and NCBH, propose to develop one additional shared operating room and one additional procedure room for a total of three operating rooms and three procedure rooms at the Davie Medical Center facility in Bermuda Run (Davie County) following completion of the project. In Section I.13, page 10, the applicants state DMC is owned by NCBH, which is a member of the Wake Forest Baptist Medical Center (WFBMC) system. In Section II.1, page 13, the applicants describe the proposed project as follows:

> *"DMC and NCBH are proposing to obtain and operate the identified operating room as a shared inpatient/outpatient operating room in a new addition connected to the existing DMC. The proposed new addition will be approximately 10,500 square feet and cost approximately $13M. DMC also intends to develop an additional minor procedure room, expanded PACU* [post anesthesia care unit]*, and storage."*

Patient Origin

On page 57, the 2017 SMFP states, *"An operating room's service area is the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1."* In Figure 6.1, page 60 of the 2017 SMFP, Davie County is shown as a single-county operating room service area. Thus, in this application, the service area is Davie County. Providers may serve residents of counties not included in their service area.

In Section III.6, page 43, the applicants provide the projected patient origin for the first two operating years (FY2020-FY2021), as shown in the table below.

Projected Patient Origin for Surgical Services at DMC

County	Percent of Total Cases	PY 1 FY2020 Surgical Cases	PY 2 FY2021 Surgical Cases
Forsyth	37%	1,297	1,305
Davie	13%	469	472
Guilford	10%	363	366
Davidson	6%	225	226
Stokes	4%	128	128
Yadkin	3%	119	119
Surry	3%	118	118
Randolph	2%	79	80
Wilkes	2%	65	65
Catawba	1%	49	50
Rowan	1%	48	48
Rockingham	1%	48	48
Iredell	1%	41	42
Mercer	1%	30	30
Martinsville City	1%	25	25
Burke	1%	23	23
All Other*	11%	393	395
TOTAL	**100.0%**	**3,520**	**3,541**

Source: Table on page 43 of the application.
*The applicant states the counties included in the *"All Other"* category are *"counties with less than 1% patient origin."*

In Section III.5, page 40, the applicants provide the historical patient origin for outpatient surgical services at DMC. In Section III.6, page 43, the applicants state, *"It is assumed that patient origin in the first two fiscal years of operation will match the current patient origin by county as a percent of total surgical cases."* The applicants' projected patient origin for the proposed project is consistent with the historical patient origin for the outpatient surgical services provided at DMC as adjusted by including cases expected to shift from NCBH to DMC (See pages 41-42). The applicants adequately identified the population proposed to be served.

Analysis of Need

In Section III.1(a) and (b) of the application, the applicants describe the factors which they state supports the need for the proposed project, including:

- In the spring of 2017, DMC will relocate inpatient beds from the Mocksville campus to the Bermuda Run campus, which will enable DMC to provide inpatient surgical services at that facility (page 30).

- The historical growth in the utilization of surgical services at DMC from FY2013 to FY2016 (pages 30-33).
- The high percentage of patients who currently seek inpatient surgical services out of county and the projected growth in the demand for orthopedic inpatient surgical procedures (pages 32-34).

The information provided by the applicants in the pages referenced above is reasonable and adequately supported.

Projected Utilization

In Section IV.1, page 50, the applicants provide projected utilization for the existing and proposed operating rooms at the DMC Bermuda Run facility through the first three years of operation following completion of the project, which is summarized below.

Projected Davie Medical Center Surgery Utilization

	Prior Year FY2015	Prior Year FY2016	Interim Year FY2017	Interim Year FY2018	Interim Year FY2019	PY 1 FY2020	PY 2 FY2021	PY 3 FY2022
Outpatient Surgical Cases	2,510	3,006	2,878	2,895	2,913	2,930	2,948	2,966
Inpatient Surgical Cases	0	0	145	583	586	590	593	597
Total Surgical Cases	2,510	3,006	3,023	3,478	3,499	3,520	3,541	3,563
Shared Operating Rooms	2	2	2	2	2	3	3	3
Total Surgical Hours*	3,765	4,509	4,752	6,092	6,128	6,165	6,201	6,240
OR Need (@ 1,872 hours/OR)	2.0	2.4	2.5	3.3	3.3	3.3	3.3	3.3

Source: Table on page 50 of the application.
*Based on 1.5 surgical hours per outpatient surgical case and 3.0 surgical hours per inpatient surgical case.

As shown in the above table, the applicants project they will perform 2,966 outpatient surgical cases and 595 inpatient surgical cases in the three shared surgical operating rooms at the DMC Bermuda Run facility in the third operating year of the project. Based on the performance standards promulgated in 10A NCAC 14C .2103 (b)(1), the number of operating rooms required would be three [2,966 outpatient surgical cases X 1.5 hours + 597 inpatient surgical cases X 3.0 hours = 6,240 hours; 6,240 surgical hours/1,872 surgical hours per OR = 3.3 operating rooms].

In Section IV.1(b), pages 51-59, the applicants describe their assumptions and methodology for projecting utilization of the three shared operating rooms at DMC, as summarized below.

Step 1: Determine the Historical Surgical Volume for DMC

On page 51, the applicants state they reviewed the historical outpatient surgical utilization data for DMC and inpatient orthopedic surgical utilization performed at NCBH by DMC orthopedic surgeons for FY2015 and FY2016. The utilization is summarized in the table below:

Historical Utilization of Surgical Services at DMC and NCBH

	FY2015	FY2016
Outpatient surgical cases at DMC	2,510	3,006
Inpatient Orthopedic Surgical Cases at NCBH	476	576

Source: Table on page 52 of the application.

Step 2: Project Growth Rate of Inpatient and Outpatient Surgical Cases at DMC

On pages 52-55, the applicants state they reviewed the historical growth in surgical services utilization at DMC and NCBH from 2014 to 2016, as well as growth projections provided by the Advisory Board Company, studies from the Journal of Bone and Joint Surgery, and Davie County population growth projections provided by the North Carolina Office of State Budget and Management. The applicants state, *"To be conservative and to account for operating room capacity constraints that will result from the introduction of inpatient surgical services at DMC, the most conservative growth rate of 0.6% per year was chosen for the projections (Table 17)."*

Step 3: Project Outpatient Surgical Cases at DMC

On page 56, the applicants provide the following table showing their outpatient surgical service utilization projections:

Outpatient Surgery Volume Projection

	Baseline	*Interim Years*			*Project Years*		
	FY 2016	***FY 2017***	***FY 2018***	***FY 2019***	***FY 2020***	***FY 2021***	***FY 2022***
Outpatient Surgical Volume Projection	*2,861*	*2,878*	*2,895*	*2,913*	*2,930*	*2,948*	*2,966*

Step 4: Project Inpatient Surgical Cases at DMC

On page 56, the applicants describe their assumptions regarding inpatient surgical projections as follows:

> *"FY 2016 is the last full fiscal year of available data and is used as the baseline year in the volume projections. As DMC will begin offering inpatient surgical services in the last quarter of FY 2017, FY 2016 inpatient surgical volume for the providers/DRGs that will be transferring to DMC was grown by 0.6% as noted above. (Table 20) ... The baseline volume of 576 cases represents 68% of the FY 2016 surgical volume of Drs. Lang, Langfitt, and Shields and 74% of the total DRG 470 surgical volume at NCBH. DMC assumes the remaining 32% of Drs. Lang, Langfitt, and Shields FY 2016 volume will remain at NCBH.*

DMC chose to only model surgical cases for Drs. Lang, Langfitt, and Shields with DRG 470 to shift from NCBH to provide a conservative projection. As mentioned, DRG 470 represents 68% of their surgical volume and is representative of uncomplicated primary joint replacement surgeries. Complicated primary joint replacements, revision joint replacements, and all other surgical procedures performed by these surgeons are anticipated to remain at NCBH. In addition, primary joint replacements performed by any other Orthopedic Surgeon (26% of NCBH primary joint replacement volume), is expected to remain at NCBH."

On page 58, the applicants provide the following table showing their inpatient surgical service utilization projections:

Inpatient Surgery Volume Projection

	Baseline	***Interim Years***			***Project Years***		
	FY 2016	***FY 2017***	***FY 2018***	***FY 2019***	***FY 2020***	***FY 2021***	***FY 2022***
Inpatient Surgical Volume, DRG 470 Select Physicians at NCBH	*576*	*435*	*0*	*0*	*0*	*0*	*0*
Inpatient Surgical Volume, DRG 470 Select Physicians at DMC	*0*	*145*	*583*	*586*	*590*	*593*	*597*
Total	*576*	*579*	*583*	*586*	*590*	*593*	*597*

Step 5: Project Total Outpatient and Inpatient Surgical Cases at DMC

On page 58, the applicants provide the following table showing their combined outpatient and inpatient surgical service utilization projections:

Inpatient, Outpatient and Total Surgical Volume Projection

	Baseline	***Interim Years***			***Project Years***		
	FY 2016	***FY 2017***	***FY 2018***	***FY 2019***	***FY 2020***	***FY 2021***	***FY 2022***
Outpatient Surgical Cases	*2,861*	*2,878*	*2,895*	*2,913*	*2,930*	*2,948*	*2,966*
Inpatient Surgical Cases	*0*	*145*	*583*	*586*	*590*	*593*	*597*
Total Cases	*2,861*	*3,203*	*3,478*	*3,499*	*3,520*	*3,541*	*3,563*

As discussed above, the applicants project surgical volumes at the proposed operating rooms at the DMC Bermuda Run facility based on the baseline (FY2016) historical utilization of the surgical services at DMC and NCBH, and increased those baseline volumes by 0.6 percent per year, which is equal to the projected annual rate of population growth for Davie County. The applicants assume a rate of growth in surgical volumes at DMC that is lower than the average annual rate of growth in surgical cases at DMC from 2014 to 2016 of 17 percent, and also lower than the Advisory Board Company and the Journal of Bone and Joint Surgery projected surgical utilization growth rates which were cited by the applicants. Exhibit 12 contains letters from surgeons expressing support for the proposed project and their intention

to perform surgeries at the DMC facility. Projected utilization of the three shared surgical operating rooms at DMC is based on reasonable and adequately supported assumptions. Therefore, the applicants adequately demonstrated the need to develop one additional shared surgical operating room at the DMC Bermuda Run facility.

Minor Procedure Room

As part of the project, the applicants propose to develop one additional minor procedure room, for a total of three procedure rooms at DMC. On page 60, the applicants provide a table showing the historical annual rate of growth in minor procedures at DMC from FY2014 to FY2016 ranged from 10% to 113%, with an average annual rate of growth of 38%. On pages 61-62, the applicants state:

> *"Annualized FY 2017 volume is used as the baseline year in projections for the minor procedure rooms at DMC. Pain management procedures done in an operating room during FY 2017 were removed from the total outpatient surgical case volume at DMC and added to the minor procedure room volume. It is assumed that these cases will transfer to a minor procedure room in FY 2017 and beyond to provide capacity for the new inpatient cases effective in 2017. ... The baseline volume of 754 cases was grown at 10% annually to project minor procedure volume during interim and project years."*

On page 61, the applicants provide the following table showing their minor procedure room utilization projections:

Minor Procedure Volume Projection

	Historic	***Interim Years***			***Project Years***		
	FY 2016	***FY 2017***	***FY 2018***	***FY 2019***	***FY 2020***	***FY 2021***	***FY 2022***
Minor Procedure Projection – Growth of Existing Volume	*519*	*566*	*621*	*682*	*748*	*821*	*901*
Pain Management Shift from OR	*145*	*188*	*206*	*226*	*249*	*273*	*299*
Total	*664*	*754*	*828*	*908*	*997*	*1,094*	*1,201*

Projected utilization of the minor procedure rooms at DMC is based on reasonable and adequately supported assumptions. Therefore, the applicants adequately demonstrated the need to develop one additional minor procedure room at the DMC Bermuda Run facility.

Access

In Section VI.2, pages 70-71, the applicants state their commitment to provide services to all patients who need the services regardless of their ability to pay, racial/ethnic origin, age, gender, physical or mental conditions or other conditions that would classify them as underserved. In Section VI.13, page 76, the applicants reports that 57.3 percent of surgical

cases at DMC were provided to Medicare or Medicaid recipients in FY2016. In Section VI.14, page 76, the applicants project that 57.3 percent of surgical cases will be provided to Medicare or Medicaid recipients at the DMC Bermuda Run facility in the second year of operation following completion of the project. The applicants adequately demonstrate the extent to which all residents, including underserved groups, will have access to the proposed services.

Conclusion

In summary, the applicants adequately identified the population to be served, demonstrated the need the population has for the project and adequately demonstrated the extent to which all residents, including underserved groups, will have access to the proposed services. Therefore, the application is conforming to this criterion.

(3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

(4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

In Section III.8, pages 46-47, the applicants describe the following alternatives:

- Maintain the Status Quo – The applicants state this was not an effective alternative due to the historical and projected growth in utilization of the surgical services at DMC.
- Convert an Existing Minor Procedure Room into an Operating Room – The applicants state this was not an effective alternative due to the growing demand for minor procedures at DMC, and because that alternative would not address the need to expand the PACU or add needed space for storage of surgical supplies.

After considering that alternative, the applicants state the alternative represented in the application is the most effective alternative to meet the identified need.

Furthermore, the application is conforming to all applicable statutory review criteria, and thus, the application is approvable. An application that cannot be approved is not an effective alternative.

In summary, the applicants adequately demonstrate that this proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions.

1. **Davie County Emergency Health Corporation d/b/a Davie Medical Center and North Carolina Baptist Hospital shall materially comply with all representations made in the certificate of need application.**

2. **Davie County Emergency Health Corporation d/b/a Davie Medical Center and North Carolina Baptist Hospital shall develop one additional operating room for a total of no more than three operating rooms.**

3. **Davie County Emergency Health Corporation d/b/a Davie Medical Center and North Carolina Baptist Hospital shall develop and implement an energy efficiency and sustainability plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.**

4. **Davie County Emergency Health Corporation d/b/a Davie Medical Center and North Carolina Baptist Hospital 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.**

(5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicants, DMC and NCBH, propose to develop one additional shared operating room and one additional procedure room for a total of three operating rooms and three procedure rooms at Davie Medical Center by constructing an addition to the existing facility.

<u>**Capital and Working Capital Costs**</u>

In Section VIII.1, pages 90-91, the applicants state the total capital cost for the proposed addition is projected to be as follows:

DMC Operating Room Project Capital Cost

Cost Category	**Projected Capital Cost**
Construction Costs	$7,000,000
Miscellaneous Project Costs	$6,668,000
TOTAL CAPITAL COST	**$13,668,000**

Source: Table on pages 90-91 of the application.

Availability of Funds

In Section VIII.3, page 92, the applicants state that the $13,668,000 in project capital costs for the proposed addition will be funded by the accumulated reserves of Wake Forest Baptist Medical Center (WFBMC). In Exhibit 24, the applicants provide a letter dated February 13, 2017, from the Vice President, Treasury for WFBMC documenting its intention to provide accumulated reserves in the amount of $13,668,000 to finance the proposed construction project. Exhibit 25 contains a copy of the audited financial statements for WFBMC for the years ended June 30, 2015 and 2016 which indicate that WFBMC had $649 million in *"Funds designated for capital improvements"* and $236 million in cash and cash equivalents as of June 30, 2016. The applicants adequately demonstrate that sufficient funds will be available for the capital needs of the project.

Financial Feasibility

In the pro forma financial statements (Form C), the applicants project that operating revenue will exceed expenses in the first three full years of operation of the project, as shown in the table below.

Projected Revenue and Expenses for Surgical Services at DMC

	PY1 FY2020	PY2 FY2021	PY3 FY2022
Total Surgical Cases	3,520	3,541	3,563
Total Net Revenue	$33,970,600	$37,318,645	$41,067,555
Average Net Revenue/Case	$9,651	$10,539	$11,526
Total Operating Expenses	$18,934,555	$19,744,892	$20,686,289
Net Income (Loss)	**$15,036,044**	**$17,573,892**	**$20,381,266**

The assumptions used by the applicants in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the financial section of the application for the assumptions used regarding costs and charges. The discussion regarding utilization projections found in Criterion (3) is incorporated herein by reference. The applicants adequately demonstrate the availability of sufficient funds for the operating needs of the project and that the financial feasibility of the proposal is based upon reasonable and adequately supported assumptions regarding projected utilization, costs and charges.

Conclusion

In summary, the applicants adequately demonstrate the financial feasibility of the proposal is based upon reasonable and adequately supported assumptions regarding projected utilization, costs and charges. Therefore, the application is conforming to this criterion.

(6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicants, DMC and NCBH, propose to develop one additional shared operating room and one additional procedure room for a total of three operating rooms and three procedure rooms at Davie Medical Center.

On page 57, the 2017 SMFP states, *"An operating room's service area is the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1."* In Figure 6.1, page 60 of the 2017 SMFP, Davie County is shown as a single-county operating room service area. Thus, in this application, the service area is Davie County. Providers may serve residents of counties not included in their service area.

The 2017 SMFP identifies a need determination for one additional operating room for the Davie County service area. DMC is the only provider of surgical services located in Davie County. DMC proposes to add one shared operating room for a total three operating rooms. The applicants do not propose to develop more operating rooms than are determined to be needed in the service area. The applicants adequately demonstrate the need the population proposed to be served has for the additional operating room at DMC, and adequately demonstrated that the projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

The applicants adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved operating rooms in Davie County. Therefore, the application is conforming to this criterion.

(7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

In Section VII.2, page 81, the applicants provide the current and proposed (FY2021) full-time equivalent (FTE) staffing for the surgical services at DMC, as summarized in the table below.

Position	Current Staffing FTE Positions	Proposed Staffing FTE Positions
Manager Perioperative Services	1.0	1.0
Clinical Coordinator	1.2	1.2
Nurse Assistant I	1.0	2.0
Surgical Specialist II	2.1	3.1
OR Instrument Technician I	1.1	1.1
OR Instrument Technician II	1.1	1.1
Certified Medical Assistant	0.3	0.3
Staff Nurse II	18.3	23.1
OR Technician	6.5	9.4
Materials Coordinator	1.0	1.0
Surgical Case Coordinator	1.0	1.0
TOTAL	**34.6**	**44.3**

Source: Tables on page 81 of the application.

In Section VII.3, page 82, and Section VII.7, pages 85-86, the applicants describe their experience and process for recruiting and retaining staff. In Section VII.9, the applicants identify Wayne Meredith, M.D., as the Medical Director for surgical services at DMC. The applicants adequately demonstrate the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

(8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section II.2, pages 16-17, the applicants identify and describe the manner in which they will provide the necessary ancillary and support services. Exhibit 12 of the application contain copies of letters from area physicians and surgeons expressing support for the proposed project. The applicants adequately demonstrate that necessary ancillary and support services are available and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

(9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

(10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
(i) would be available under a contract of at least 5 years duration;
(ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
(iii) would cost no more than if the services were provided by the HMO; and
(iv) would be available in a manner which is administratively feasible to the HMO.

NA

(11) Repealed effective July 1, 1987.

(12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

The applicants, DMC and NCBH, propose to develop one additional shared inpatient/outpatient operating room in a new addition connected to the existing DMC. The proposed new addition will be approximately 10,500 square feet, and will also include an additional minor procedure room, expanded PACU and storage. Exhibit 28 contains a certified cost estimate from an architect that estimates construction costs that are consistent with the project capital cost projections provided by the applicants in Section VIII.1, page 90 of the application. In Section IX.8, pages 106-107, the applicants describe the methods that will be used by the facility to maintain efficient energy operations and contain the costs of utilities. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicants adequately demonstrate that the cost, design and means of construction represent the most reasonable alternative for the proposed addition and renovations, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced

difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section VI.13, page 76, the applicants report the following payer mix for DMC's surgical cases and non-surgical procedures for FY2016:

Payer Category	Surgical Cases as Percent of Total	Non-Surgical Procedures as Percent of Total
Self Pay/Indigent	1.7%	3.7%
Commercial Insurance	0.4%	0.4%
Medicare/Medicare Managed Care	52.6%	32.6%
Medicaid	4.7%	6.7%
Managed Care	35.2%	46.3%
Other*	5.5%	10.4%
Total	**100.00%**	**100.00%**

*The applicants state the *"Other"* category includes liability, other government programs, Tricare, and Workers Compensation.

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the service area, Davie County, and statewide.

Percent of Population						
County	**% 65+**	**% Female**	**% Racial & Ethnic Minority***	**% Persons in Poverty****	**% < Age 65 with a Disability**	**% < Age 65 without Health Insurance****
Davie	19%	51%	15%	14%	9%	18%
Statewide	15%	51%	36%	17%	10%	15%

Source: http://www.census.gov/quickfacts/table, 2014 Estimate as of December 22, 2015.
*Excludes *"White alone"* who are *"not Hispanic or Latino"*
***"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable…The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."*

However, a direct comparison to the applicants' current payer mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

The applicants adequately demonstrate that they currently provide access to medically underserved populations. Therefore, the application is conforming to this criterion.

(b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.11, page 75, the applicants state,

"Internal Revenue Code (RC) Section 501(r), enacted by the Patient Protection and Affordable Care Act, requires tax exempt hospitals exempt under IRC Section 501(c) to have a written financial assistance policy and emergency medical care policy that provided to eligible financial assistance patients. ... Furthermore, the EMTALA policy ensures that emergency medical care is provided without discrimination and regardless of ability to pay."

In Section VI.10, page 74, the applicants states that no civil rights access complaints have been filed against any WFBMC facility in last five years. The application is conforming to this criterion.

(c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

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In Section VI.14, pages 76-78, the applicants projects the following payer mix for DMC surgical cases and non-surgical procedures during the second operating year (FY2021):

Payer Category	Surgical Cases as Percent of Total	Non-Surgical Procedures as Percent of Total
Self Pay/Indigent	1.5%	3.7%
Commercial Insurance	0.4%	0.4%
Medicare/Medicare Managed Care	52.9%	32.6%
Medicaid	4.4%	6.7%
Managed Care	35.2%	46.3%
Other*	5.6%	10.4%
Total	**100.00%**	**100.00%**

*The applicants state the *"Other"* category includes liability, other government programs, Tricare, and Workers Compensation.

On page 78, the applicants state projected payer mix is based on the historical payer mix for surgical services at DMC and NCBH. The minor differences in the percentages for surgical cases are due to including inpatient cases in the projections. The applicants adequately demonstrate that medically underserved populations will have access to the proposed services. Therefore, the application is conforming to this criterion.

(d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section VI.9, pages 73-74, the applicants describe the range of means by which a person will have access to DMC's surgical services. The applicants adequately demonstrate that the facility will offer a range of means by which patients will have access to the proposed services. Therefore, the application is conforming to this criterion.

(14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

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In Section V.1, page 63, the applicants state that DMC is part of the WFBMC system, which has extensive relationships with area health professional training programs. Exhibit 10 contains a copy of DMC's policy regarding the provision of clinical experience to health professional students. The applicants state DMC currently has training arrangements with

Forsyth Technical Community College, Guilford Technical Community College, Winston-Salem State University, and Wake Forest University. The information provided is reasonable and adequately supports a determination that the application is conforming to this criterion.

(15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.

(18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicants, DMC and NCBH, propose to develop one additional shared operating room and one additional procedure room for a total of three operating rooms and three procedure rooms at Davie Medical Center.

On page 57, the 2017 SMFP states, *"An operating room's service area is the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1."* In Figure 6.1, page 60 of the 2017 SMFP, Davie County is shown as a single-county operating room service area. Thus, in this application, the service area is Davie County. Providers may serve residents of counties not included in their service area.

The 2017 SMFP identifies a need determination for one additional operating room for the Davie County service area. DMC is the only provider of surgical services located in Davie County. DMC proposes to add one shared operating room for a total three operating rooms. The applicants do not propose to develop more operating rooms than are determined to be needed in the service area.

In Section VI.7, pages 66-67, the applicants discuss how the project will promote the cost-effectiveness, quality and access to the proposed services. See also Sections II, III, V, VI and VII where the applicants discuss the impact of the project on cost-effectiveness, quality and access to the proposed services

The information in the application is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicants adequately demonstrate the need for the proposed project and that it is a cost-effective alternative. The discussions regarding analysis of need, including projected utilization, and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicants adequately demonstrate that they will provide quality services. The discussion regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicants demonstrate that they will provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (1), (3) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, no WFBMC facilities are currently out of compliance with a CMS Condition of Participation, nor have any other incidents occurred within the eighteen months immediately preceding submission of the application through the date of this decision, for which any sanctions or penalties related to quality of care were imposed by the State on any other facility owned and operated by WFBMC in North Carolina. After reviewing and considering information provided by the applicants and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at WFBMC facilities, the applicants provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

(b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The application is conforming with all applicable Criteria and Standards for Surgical Services and Operating Rooms promulgated in 10A NCAC 14C .2100. The specific criteria are discussed below:

SECTION .2100 – CRITERIA AND STANDARDS FOR SURGICAL SERVICES AND OPERATING ROOMS

10A NCAC 14C .2103 PERFORMANCE STANDARDS

(a) In projecting utilization, the operating rooms shall be considered to be available for use five days per week and 52 weeks a year.

-C- In Section II.10, page 24, the applicants state that surgical services at DMC are projected to operate five days per week and 52 weeks a year.

(b) A proposal to establish a new ambulatory surgical facility, to establish a new campus of an existing facility, to establish a new hospital, to increase the number of operating rooms in an existing facility (excluding dedicated C-section operating rooms), to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall:

(1) demonstrate the need for the number of proposed operating rooms in the facility which is proposed to be developed or expanded in the third operating year of the project based on the following formula: {[(Number of facility's projected inpatient cases, excluding trauma cases reported by Level I or II trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and C-section rooms, times 3.0 hours) plus (Number of facility's projected outpatient cases times 1.5 hours)] divided by 1872 hours} minus the facility's total number of existing and approved operating rooms and operating rooms proposed in another pending application, excluding one operating room for Level I or II trauma centers, one operating room for facilities with designated burn intensive care units, and all dedicated open heart and C-section operating rooms or demonstrate conformance of the proposed project to Policy AC-3 in the State Medical Facilities Plan titled "Exemption From Plan Provisions for Certain Academic Medical Center Teaching Hospital Projects;" and

(2) The number of rooms needed is determined as follows:

(A) in a service area which has more than 10 operating rooms, if the difference is a positive number greater than or equal to 0.5, then the need is the next highest whole number for fractions of 0.5 or greater and the next lowest whole number for fractions less than 0.5; and if the difference is a negative number or a positive number less than 0.5, then the need is zero;

(B) in a service area which has 6 to 10 operating rooms, if the difference is a positive number greater than or equal to 0.3, then the need is the next highest whole number for fractions of 0.3 or greater and the next lowest whole number for fractions less than 0.3, and if the difference is a negative number or a positive number less than 0.3, then the need is zero; and

(C) in a service area which has five or fewer operating rooms, if the difference is a positive number greater than or equal to 0.2, then the need is the next

highest whole number for fractions of 0.2 or greater and the next lowest whole number for fractions less than 0.2; and if the difference is a negative number or a positive number less than 0.2, then the need is zero.

-C- The Davie County operating room service area has two operating rooms. In Section IV.1, pages 58-59, the applicants provide projections of surgical case volumes, surgical hours, and operating room need, which is summarized below:

Davis Medical Center Projected Surgery Volume and Operating Room Need			
	PY 1 FY2020	**PY 2 FY2021**	**PY 3 FY2022**
Projected DMC Outpatient Surgery Cases	2,930	2,948	2,966
Projected DMC Inpatient Surgery Cases	590	593	597
Total Surgical Hours Required*	6,165	6,202	6,239
Operating Rooms Needed (1,872 hours per OR)	3.3	3.3	3.3

Source: Tables on page 59 of the application.
*Surgical hours required based on 1.5 hours per outpatient surgical case and 3.0 hours per inpatient surgical case.

Projected utilization, which is based on reasonable and adequately supported assumptions, supports the need for three operating rooms. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

(c) A proposal to increase the number of operating rooms (excluding dedicated C-section operating rooms) in a service area shall:

(1) demonstrate the need for the number of proposed operating rooms in addition to the rooms in all of the licensed facilities identified in response to 10A NCAC 14C .2102(b)(2) in the third operating year of the proposed project based on the following formula: {[(Number of projected inpatient cases for all the applicant's or related entities' facilities, excluding trauma cases reported by Level I or II trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and C-section rooms, times 3.0 hours) plus (Number of projected outpatient cases for all the applicant's or related entities' facilities times 1.5 hours)] divided by 1872 hours} minus the total number of existing and approved operating rooms and operating rooms proposed in another pending application, excluding one operating room for Level I or II trauma centers, one operating room for facilities with designated burn intensive care units, and all dedicated open heart and C-Section operating rooms in all of the applicant's or related entities' licensed facilities in the service area; and

(2) The number of rooms needed is determined as follows:

(A) in a service area which has more than 10 operating rooms, if the difference is a positive number greater than or equal to 0.5, then the need is the next highest whole number for fractions of 0.5 or greater and the next lowest whole number for fractions less than 0.5; and if the difference is a negative number or a positive number less than 0.5, then the need is zero;

(B) in a service area which has 6 to 10 operating rooms, if the difference is a positive number greater than or equal to 0.3, then the need is the next

highest whole number for fractions of 0.3 or greater and the next lowest whole number for fractions less than 0.3, and if the difference is a negative number or a positive number less than 0.3, then the need is zero; and

(C) in a service area which has five or fewer operating rooms, if the difference is a positive number greater than or equal to 0.2, then the need is the next highest whole number for fractions of 0.2 or greater and the next lowest whole number for fractions less than 0.2; and if the difference is a negative number or a positive number less than 0.2, then the need is zero.

-C- Davie Medical Center is the only licensed facility with operating rooms in the service area. In Section IV.1, pages 58-59, the applicants provide projections of surgical case volumes, surgical hours, and operating room need, which is summarized below:

Davis Medical Center Projected Surgery Volume and Operating Room Need			
	PY 1 FY2020	**PY 2 FY2021**	**PY 3 FY2022**
Projected DMC Outpatient Surgery Cases	2,930	2,948	2,966
Projected DMC Inpatient Surgery Cases	590	593	597
Total Surgical Hours Required*	6,165	6,202	6,239
Operating Rooms Needed (1,872 hours per OR)	3.3	3.3	3.3

Source: Tables on page 59 of the application.
*Surgical hours required based on 1.5 hours per outpatient surgical case and 3.0 hours per inpatient surgical case.

Projected utilization, which is based on reasonable and adequately supported assumptions, supports the need for three operating rooms. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

(d) An applicant that has one or more existing or approved dedicated C-section operating rooms and is proposing to develop an additional dedicated C-section operating room in the same facility shall demonstrate that an average of at least 365 C-sections per room were performed in the facility's existing dedicated C-section operating rooms in the previous 12 months and are projected to be performed in the facility's existing, approved and proposed dedicated C-section rooms during the third year of operation following completion of the project.

-NA- The applicants do not propose to develop an additional dedicated C-section operating room.

(e) An applicant proposing to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall:

(1) provide documentation to show that each existing ambulatory surgery program in the service area that performs ambulatory surgery in the same specialty area as proposed in the application is currently utilized an average of at least 1,872 hours per operating room per year, excluding dedicated open heart and C-Section operating rooms. The hours utilized per operating room shall be calculated as follows: [(Number of projected inpatient cases, excluding open heart and C-sections performed in dedicated rooms, times 3.0 hours) plus (Number of projected

outpatient cases times 1.5 hours)] divided by the number of operating rooms, excluding dedicated open heart and C-Section operating rooms; and

(2) demonstrate the need in the third operating year of the project based on the following formula: [(Total number of projected outpatient cases for all ambulatory surgery programs in the service area times 1.5 hours) divided by 1872 hours] minus the total number of existing, approved and proposed outpatient or ambulatory surgical operating rooms and shared operating rooms in the service area. The need is demonstrated if the difference is a positive number greater than or equal to one, after the number is rounded to the next highest number for fractions of 0.50 or greater.

-NA- The applicants do not propose to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program.

(f) The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this Rule.

-C- The applicants provide documentation of their assumptions and provide data supporting their methodology in Section IV.1(d), pages 51-59 of the application.