



March 31, 2021

Julie Faenza, Project Analyst  
Health Planning and Certificate of Need Section  
Division of Health Service Regulation  
North Carolina Department of Health and Human Services  
809 Ruggles Drive  
Raleigh, North Carolina 27603

RE: Comments regarding Novant Health Forsyth Medical Center Certificate of Need (CON) Application (Project ID # G-012031-21)

Dear Ms. Faenza:

Enclosed please find comments prepared by North Carolina Baptist Hospital (NCBH) regarding the CON application by Novant Health Forsyth Medical Center (NHFMC) to replace and relocate a cardiac catheterization laboratory to the Kernersville Medical Center. NCBH provides comprehensive medical care, including cardiac catheterization services, with exceptional patient service to residents of Forsyth County and surrounding communities. As a pre-eminent academic health system, we are currently fulfilling our mission to promote better health for all through collaboration, excellence, and innovation.

Because of our commitment to serving the best interests of citizens in this area, and in support of the State's Certificate of Need and health planning objectives, we are compelled to express our concerns regarding the costly and unnecessary plan described in the NHFMC application. Thank you for the opportunity to submit these comments. We recognize that your decision will be based upon the State's CON objectives and review criteria. Particular focus is on the need to maintain access to care without unnecessary costs. Any existing or new health service provider must accurately assess local needs and services, and should develop a plan that represents the least costly or most effective alternative. The NHFMC application fails on all accounts.

If you have any questions about the information presented here, please feel free to contact me at 336.716.1275.

Sincerely,

*Jena Folger*

Vice President, Network Growth, Strategy & Business Development

**COMMENTS ABOUT CERTIFICATE OF NEED PROJECT ID# G-012031-21  
NOVANT HEALTH FORSYTH MEDICAL CENTER**

**Submitted by North Carolina Baptist Hospital  
March 31, 2021**

On February 15, 2021, NHFMC submitted a Certificate of Need (CON) application to replace and relocate one cardiac catheterization laboratory (catheterization lab) from NHFMC to Novant Health Kernersville Medical Center (NHKMC). In accordance with North Carolina General Statute § 131E-185(a1)(1), North Carolina Baptist Hospital submits the following comments regarding the NHFMC application. These comments include *“discussion and argument regarding whether, in light of the material contained in the application and other relevant factual material, the application complies with relevant review criteria, plans, and standards”* (see N.C. General Statute § 131E-185(a1)(1)(c)). These comments demonstrate the various reasons why the application is not conforming to the CON Review Criteria and should therefore not be approved. Specifically, the Agency, in making the decision, should consider several key issues, including but not limited to, the following CON Review Criteria:

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

- (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. 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
- (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.

This document provides evidence of how the NHFMC application is not conforming to the CON Review Criteria, and how Novant's proposal is not the best alternative for the people of Forsyth County.

**CON Review Criteria**

- (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.**

The NHFMC application does not conform to Criterion (3) because the utilization projections are based on unrealistic patient origin projections plus overstated and unreasonable utilization assumptions, as discussed in the following paragraphs.

**Unrealistic Patient Origin Projection**

The NHFMC patient origin assumptions for cardiac catheterization patients at NHKMC are unreasonable. As shown in the tables below, the historical cardiac catheterization lab patient origin at NHFMC is vastly different than the projected NHKMC cardiac catheterization lab patient origin.

**NHFMC Cardiac Catheterization Lab Patient Origin**

Cardiac Cath Lab	Novant Health Forsyth Medical Center *	
	Last Full FY 01/01/2020 to 12/31/2020	
County or other geographic area such as ZIP code	Number of Patients	% of Total
Forsyth	1,659	38%
Surry	460	11%
Davidson	405	9%
Stokes	324	8%
Yadkin	234	5%
Davie	210	5%
Other^	1,027	24%
<b>Total</b>	<b>4,319</b>	<b>100%</b>

^ Other includes patients from the following counties and cities in North Carolina and other states, as well as patients without address information available: Wilkes, Guilford, Ashe, Galax (city), Carroll, Patrick, Alleghany, Grayson, Randolph, Iredell, Rockingham, Rowan, Henry, Catawba, Wake, Mecklenburg, Watauga, Burke, Tazewell, Brunswick, Cabarrus, Alamance, Volusia, Wythe, McDowell, Stanly, Pender, Alexander, Wayne, Martinsville (city), Vance, Santa Barbara, Columbiana, Lancaster, Greer, Currituck, Cleveland, Danville (city), Caldwell, Allegany, Carteret, Moore, Anderson, Nash, Harnett, Nevada, Horry, New Hanover, Johnston, Newport News (city), Bland, Newton, Gaston, Not Specified, Sullivan, Osage, Sussex, Avery, Union, Florence, Hancock, Person, Warren, Philadelphia, Hopewell (city), Radford (city), Wyoming, Floyd, Jackson, Richland, Kershaw, Roanoke

The previous table (from page 32 of the NHFMC application) shows the cardiac catheterization lab patient origin at NHFMC during CY2020. The following table (from page 34 of the application) shows Novant’s projected cardiac catheterization lab patient origin at NHKMC.

**Projected NHKMC Cardiac Catheterization Lab Patient Origin**

Fixed Cardiac Cath Lab	Novant Health Kernersville Medical Center *					
	1 <sup>st</sup> Full FY		2 <sup>nd</sup> Full FY		3 <sup>rd</sup> Full FY	
	01/01/2025 to 12/31/2025		01/01/2026 to 12/31/2026		01/01/2027 to 12/31/2027	
County or other geographic area such as ZIP code	Number of Patients **	% of Total	Number of Patients **	% of Total	Number of Patients **	% of Total
Forsyth County, NC	317	65.4%	382	65.4%	386	65.4%
Guilford County, NC	90	18.5%	108	18.5%	109	18.5%
Stokes County, NC	29	5.9%	34	5.9%	35	5.9%
Other^	49	10.2%	60	10.2%	60	10.2%
<b>Total</b>	<b>485</b>	<b>100.0%</b>	<b>584</b>	<b>100.0%</b>	<b>590</b>	<b>100.0%</b>

\* This should match the name provided in Section A, Question 4.

\*\* Home health agencies should report the number of unduplicated clients.

^ Other includes small numbers of patients from other counties in NC, and other states. Other is expected to be similar to historical medical/surgical patient origin. In CY 2020, Other acute care patients came from other counties in NC, FL, GA, NH, KY, MD, OH, PA, SC, UT, VA, VT, and WV

Note that Novant projects 18.5% of Kernersville cardiac catheterization lab patients to originate from Guilford County. This is unreasonable because, as shown by NHFMC’s historical data, Guilford County residents currently represent a small, undefined percent of Novant cardiac catheterization lab patients. Novant’s patient origin projection is based on the irrational assumption that Novant can steer significantly more patients away from Guilford County to the proposed new NHKMC cardiac catheterization lab, a hospital facility and service that offers a far more limited scope of service as compared to the nearby hospitals in Guilford County, and compared to NHFMC itself.

It is also unreasonable to assume that such a substantive number of Stokes County patients would shift to the proposed NHKMC cardiac catheterization lab, which again, is much more limited in scope than NHFMC, and is also located further from Stokes County than is NHFMC.

**Overstated and Unreasonable Utilization Assumptions**

The Novant methodology assumptions for both cardiac catheterization lab procedures and for angiography procedures are unreasonable for multiple reasons, including:

- Novant’s overall cardiac catheterization and angiography volume projections are overstated because the application excludes the actual decline in volumes due to COVID-19 during 2020 and incorrectly assumes that the impact of COVID-19 is temporary. The Novant projection makes no allowance or adjustment for the possibility that the impact of the pandemic may linger into the near or mid-term.
- Approximately two-thirds of recent Kernersville cardiac catheterization patient encounters are outpatient. As shown in the following table, NHFMC is losing market share among cardiac outpatients. Thus, Novant’s projected utilization, based upon 2019

data, is not realistic in projecting forward without any accounting for the ongoing NHFMC market share decline.

### Outpatient Market Share for Kernersville Cardiac Catheterization Patients

Facility Name	OP 2018	OP 2019	OP 2020	OP 2021 (Q1)
Forsyth Med Ctr	66.00%	67.65%	60.31%	54.24%
WF Baptist Med Ctr	13.00%	12.25%	18.04%	20.34%
Moses Cone - Greensboro	9.50%	9.80%	12.89%	15.25%
High Point Med Ctr	5.50%	2.45%	5.67%	0.00%
Duke University	4.00%	6.37%	3.09%	8.47%
University of NC	1.50%	0.49%	0.00%	0.00%
Carolinas Med Ctr	0.50%	0.49%	0.00%	1.69%
Presbyterian	0.00%	0.49%	0.00%	0.00%
Wesley Long Hospital	0.00%	0.00%	0.00%	0.00%
Cone High Point Med Ctr	0.00%	0.00%	0.00%	0.00%
Kernersville Med Ctr	0.00%	0.00%	0.00%	0.00%
<b>Grand Total</b>	<b>100.00%</b>	<b>100.00%</b>	<b>100.00%</b>	<b>100.00%</b>

Source: NCBH, via NC Hospital Association Patient Data System

- The Novant application omits data for the numbers of patient encounters and types of procedures to be performed by the referenced five Novant Health cardiologists, and other vascular specialists who are to be recruited to Novant. Novant provides no data in the application to demonstrate that these physicians are going to be performing a high volume of procedures during the initial three project years. No projections are shown for any expected referrals of additional cardiologists to be recruited to NHKMC. Therefore, an assumption of volumes for NHKMC due to physician recruitment is unreliable.
- In Step 4 of its cardiac catheterization procedure methodology (Section Q, page 98 of the application), Novant applies a shift percent of 63.2% to the historical volume to arrive at the base year shift of patients from NHFMC to NHKMC. This percentage is unreasonably high because the proposed NHKMC catheterization lab represents a new facility: certainly in the early stages of operation, it is likely that a lower percentage of patients will choose to have cardiac catheterization procedures performed at the new facility. Novant should have assumed a ramp-up period to account for having a new service offering in a new location.
- In Step 6 of its cardiac catheterization procedure methodology (application page 99), Novant applies a percentage to the projected home zip code projection to arrive at a baseline projection of patients from other zip codes who would receive service at the NHKMC cardiac catheterization lab. This percentage is also unreasonably high because the proposed NHKMC catheterization lab is a new facility, and certainly in the early stages, it is likely that a lower percentage of patients from outside zip code 27284 will choose to have cardiac catheterization procedures performed at the new facility. Novant should have assumed gradual growth of patients willing to travel to Kernersville to obtain cardiac catheterization procedures at a new lab.
- In Step 7 of its cardiac catheterization procedure methodology, Novant projects procedure growth through the third project year based upon the projected adult

population growth rate. As previously described, the Novant patient origin projection is flawed, and thus, the population growth rate assumption is flawed. Further, given that Novant is proposing a new and limited cardiac catheterization service at NHKMC, Novant should have assumed a more conservative annual growth rate in order to account for the potential of slower than anticipated patient adoption of the new Kernersville service.

- In Step 3 of its angiography procedure methodology (page 102 of the application), Novant assumes that half of the 2019 historical volume will shift to NHKMC. Novant does not justify this 50% assumption in the application, and similar to the cardiac catheterization procedure methodology flaw, Novant should have assumed a ramp-up period to account for having a new service offering in a new location.
- In Step 4 of its angiography procedure methodology, Novant projects procedure growth through the third project year based upon the projected adult population growth rate. As previously described, the Novant patient origin projection is flawed, and thus, the population growth rate assumption is flawed. Further, given that Novant is proposing a new and limited cardiac catheterization service at NHKMC, it should have assumed a more conservative annual growth rate in order to account for the potential of slower than anticipated patient adoption of the new Kernersville service.
- The Novant proposal to offer interventional cardiology procedures beginning in the second project year is aggressive and overly optimistic. According to the Novant projections, NHKMC will have provided just 446 diagnostic cardiac catheterization procedures during the interim period and first full year of operation. Because interventional cardiology involves some extra degree of specialization and risk, development of protocols and logistics is essential. This requires time and experience among a facility setting and the clinical team. Three years is a more reasonable target to transition to intervention. As a local example, the cardiac catheterization lab at Kernersville Veteran's Administration (VA) clinic has been operational for five years, yet has not yet begun to provide interventional procedures.
- In its Form C.2b assumptions and methodology (Section Q), Novant attempts to describe the procedures that it projects would be performed at NHKMC's cardiac catheterization lab, and which procedures are not appropriate for Kernersville and would be excluded. However, the language of the Novant narrative is confusing, including the referenced CPT and ICD codes. For example, Novant's footnote on page 97 references several specific outpatient CPT codes: such as endovascular treatment of femoral/popliteal artery. In NCBH's experience, the vast majority of these procedures are typically performed on an outpatient basis. Novant seems to state in its footnote that it would either exclude these procedures at the NHKMC lab or perhaps perform as inpatient, which would add significant expense to payors and patients. Thus, what procedures would Novant include and project to perform at NHKMC, and is the proposed project economically harmful to patients? Also, in the same page 97 footnote, Novant lists a variety of inpatient ICD procedure codes, and again provides confusing language, which appears to indicate that, for example, Novant would perform right-sided procedures but not left-sided procedures. In short, it is difficult to assess the reasonableness of the Novant utilization projections given the confusing narrative included in the Form C.2b methodology description.

Novant fails to demonstrate that the population has a need for this project. The NHFMC application does not conform to Criterion (3) due to unrealistic patient origin projections, and overstated and unreasonable utilization projections.

**(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.**

As shown in the following table, Novant is proposing to relocate a cardiac catheterization lab from a facility (NHFMC) which provides significantly more Medicaid access than NHKMC. This proposal will result in less access for medically underserved persons in Forsyth County.

**Comparison of Medicaid Access**

<b>Payor Source</b>	<b>NHFMC</b>	<b>NHKMC</b>
Medicaid	14.6%	10.4%

Source: Novant CON application, pages 76-77.

Relocating a cardiac catheterization lab from NHFMC to NHKMC will have a negative impact on the medically underserved, low-income population of Forsyth County. Kernersville (and in particular, zip code 27284, which hosts NHKMC) has much higher median and average household incomes than does Winston-Salem (home of NHFMC), and also has a significantly lower percentage of families living below the federal poverty level, as shown on the following table.

**Income & Poverty Comparison of Winston-Salem & Kernersville**

<b>Income &amp; Poverty</b>	<b>Winston-Salem</b>	<b>Kernersville</b>	<b>27284</b>
Median Household Income	\$45,750	\$51,645	\$62,588
Average Household Income	\$71,423	\$72,938	\$79,553
Persons in Poverty	20.7%	12.2%	9.2%

Sources: U.S. Census Bureau QuickFacts for Winston-Salem & Kernersville, referenced March 16, 2021, [www.incomebyzipcode.com/northcarolina/27284](http://www.incomebyzipcode.com/northcarolina/27284) and [www.city-data.com/zips/27284](http://www.city-data.com/zips/27284)

The following table portrays the median household income by age of householder, showing that, across the board for each age cohort, Kernersville, and particularly zip code 27284, has much higher median household income than does Winston-Salem.



**Median Household Income Comparison**

<b>Median Household Income</b>	<b>Forsyth County</b>	<b>Winston-Salem</b>	<b>Kernersville</b>	<b>27284</b>
Householder < age 25	\$25,176	\$23,364	\$32,973	\$36,038
Householder age 25 -44	\$51,728	\$46,163	\$49,345	\$69,590
Householder age 45 -64	\$64,373	\$54,154	\$75,159	\$80,600
Householder age 65+	\$41,899	\$40,318	\$37,289	\$42,330

Source: [www.incomebyzipcode.com/northcarolina/27284](http://www.incomebyzipcode.com/northcarolina/27284)

NHFMC's proposal will relocate inner city Medicaid cardiac catheterization services to a more affluent suburban market. The household income data demonstrates that there would be detrimental consequences for low income persons if a cardiac catheterization lab were moved to NHKMC. Medicaid patients and many Forsyth County residents with fewer economic resources would reside further from these services. The end result would be a decrease in access to these healthcare services for Forsyth County residents with lower incomes.

The composition of racial distribution in Forsyth County further demonstrates that the proposed project is not the most effective alternative in terms of increasing access to healthcare services for Forsyth County's medically underserved residents. For example, Winston-Salem, which hosts NHFMC, has a comparatively much higher composition of African Americans (34.9%) than Kernersville (13.9%), and particularly zip code 27284, which includes NHKMC and has only 9.8% African Americans. Therefore, access to healthcare services for racial and ethnic minorities will be harmed by the reduction of capacity if NHFMC moves a catheterization lab to the less diverse far edge of Forsyth County.

**Race & Ethnic Origin Comparison**

<b>Race &amp; Origin %</b>	<b>Forsyth County</b>	<b>Winston-Salem</b>	<b>Kernersville</b>	<b>27284</b>
Black or African-American	27.5%	34.9%	13.9%	9.8%
Hispanic or Latino	13.3%	15.0%	12.3%	8.0%
Asian	2.6%	2.5%	1.8%	1.6%
White	66.6%	56.6%	77.6%	78.8%

Source: U.S. Census Bureau QuickFacts for Forsyth County, Winston-Salem & Kernersville, referenced March 16, 2021, & [city-data.com/zips/27284](http://city-data.com/zips/27284)

Further, the proposed relocation of cardiac catheterization capacity will negatively impact residents of neighboring counties that do not host cardiac catheterization services. In Section C.2 (page 32 of the application), Novant shows that during CY2020, residents of Surry, Stokes, Yadkin and Davie counties comprised 29% of cardiac catheterization lab patients at NHFMC. See the following table.

**NHFMC Cardiac Catheterization Lab Patient Origin**

Cardiac Cath Lab	Novant Health Forsyth Medical Center *	
	Last Full FY 01/01/2020 to 12/31/2020	
County or other geographic area such as ZIP code	Number of Patients	% of Total
Forsyth	1,659	38%
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Other^	1,027	24%
<b>Total</b>	<b>4,319</b>	<b>100%</b>

^ Other includes patients from the following counties and cities in North Carolina and other states, as well as patients without address information available: Wilkes, Guilford, Ashe, Galax (city), Carroll, Patrick, Alleghany, Grayson, Randolph, Iredell, Rockingham, Rowan, Henry, Catawba, Wake, Mecklenburg, Watauga, Burke, Tazewell, Brunswick, Cabarrus, Alamance, Volusia, Wythe, McDowell, Stanly, Pender, Alexander, Wayne, Martinsville (city), Vance, Santa Barbara, Columbiana, Lancaster, Greer, Currituck, Cleveland, Danville (city), Caldwell, Alleghany, Carteret, Moore, Anderson, Nash, Harnett, Nevada, Horry, New Hanover, Johnston, Newport News (city), Bland, Newton, Gaston, Not Specified, Sullivan, Osage, Sussex, Avery, Union, Florence, Hancock, Person, Warren, Philadelphia, Hopewell (city), Radford (city), Wyoming, Floyd, Jackson, Richland, Kershaw, Roanoke

However, at the proposed NHKMC cardiac catheterization lab, the projected access for residents of these underserved counties is significantly lower, as shown in the following table (page 34 of the NHFMC application). Instead, Novant will replace these with a significant cohort of Guilford County residents, who already have abundant access to cardiac catheterization services at multiple facilities within their own county.

**Projected NHKMC Cardiac Catheterization Lab Patient Origin**

Fixed Cardiac Cath Lab	Novant Health Kernersville Medical Center *					
	1 <sup>st</sup> Full FY		2 <sup>nd</sup> Full FY		3 <sup>rd</sup> Full FY	
	01/01/2025 to 12/31/2025		01/01/2026 to 12/31/2026		01/01/2027 to 12/31/2027	
County or other geographic area such as ZIP code	Number of Patients **	% of Total	Number of Patients **	% of Total	Number of Patients **	% of Total
Forsyth County, NC	317	65.4%	382	65.4%	385	65.4%
Guilford County, NC	90	18.5%	108	18.5%	109	18.5%
Stokes County, NC	29	5.9%	34	5.9%	35	5.9%
Other^	49	10.2%	60	10.2%	60	10.2%
<b>Total</b>	<b>485</b>	<b>100.0%</b>	<b>584</b>	<b>100.0%</b>	<b>590</b>	<b>100.0%</b>

\* This should match the name provided in Section A, Question 4.

\*\* Home health agencies should report the number of unduplicated clients.

^ Other includes small numbers of patients from other counties in NC, and other states. Other is expected to be similar to historical medical/surgical patient origin. In CY 2020, Other acute care patients came from other counties in NC, FL, GA, NH, KY, MD, OH, PA, SC, UT, VA, VT, and WV

In summary, NHFMC did not adequately demonstrate that the needs of the population presently served at NHFMC will be met adequately by the proposed relocation because this population, particularly low income persons, racial and ethnic minorities and other underserved groups, will have less access to cardiac catheterization services upon completion of the proposed project. Therefore, the application is not conforming to Criterion (3a).

**(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.**

Novant failed to substantiate that it has proposed the least costly or most effective alternative. In Section E (page 54) of its application, NHFMC claims that there are no alternatives to the proposed project. However, it is unreasonable for Novant to not bother to consider and describe any potential alternatives. Further, the application is not conforming to all applicable statutory and regulatory review criteria. See Criteria (3), (3a), (5), (6), (12), (13a), (13c), and (18a). Therefore, NHFMC did not adequately demonstrate that its proposal is an effective alternative and the application is in non-conformance with this criterion.

- (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.**

Because NHFMC did not reasonably demonstrate the need for the proposed project (see Criterion 3), NHFMC did not demonstrate the financial feasibility of the proposal, and the NHFMC application is therefore non-conforming to Review Criterion (5).

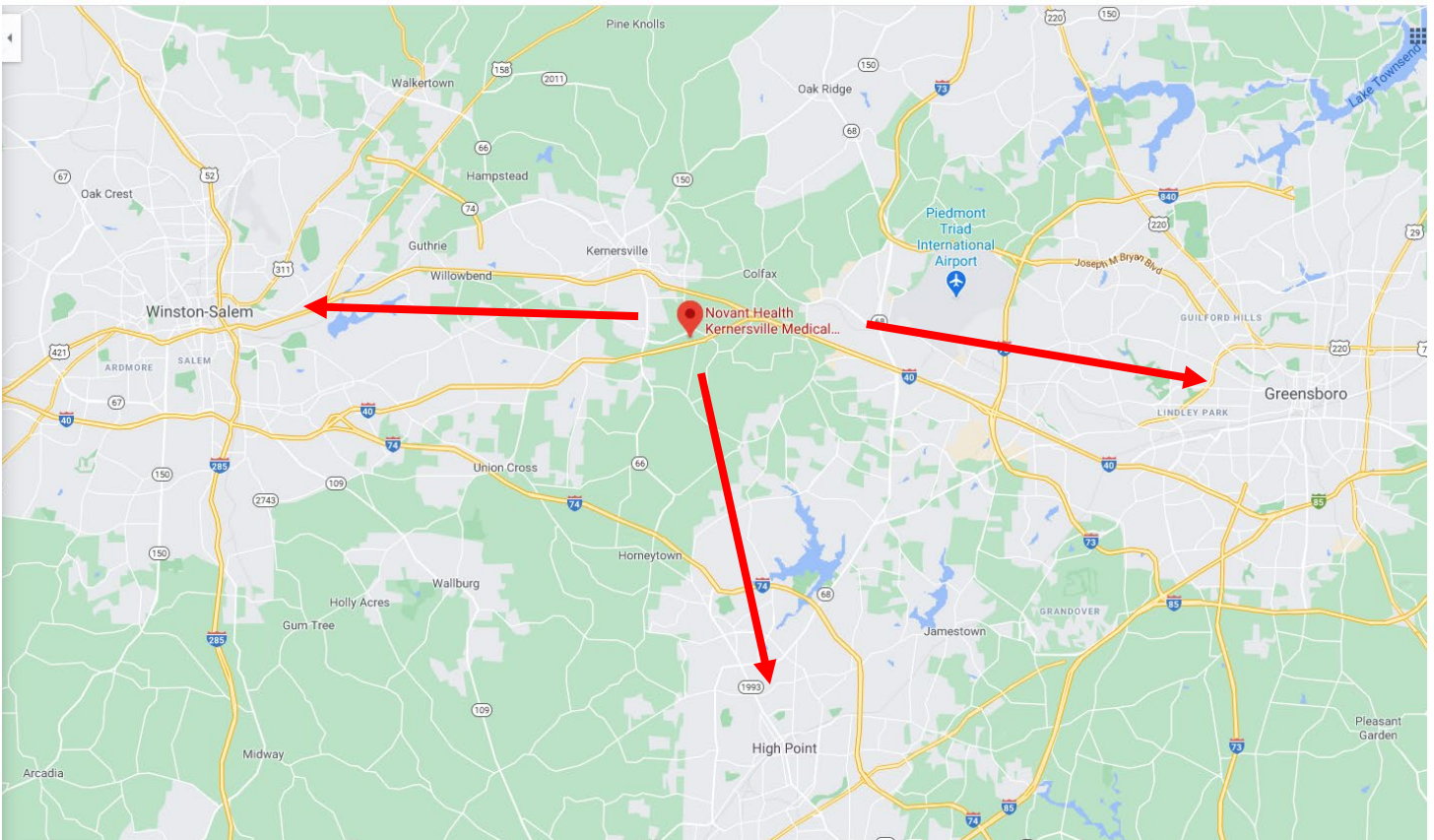
Also, in its application, NHFMC did not provide Forms F.2 and F.3 for the cardiac catheterization service at NHFMC, but only for NHKMC. One could argue that this is contrary to the application form instructions in Section F.4b, which directs hospital applicants to complete the revenue and operating cost forms not solely for each hospital service included in the proposal, but also for “*the entire hospital facility if the proposal involves developing a new campus of an existing facility*” (page 61 of NHFMC application). NHFMC is proposing to develop a new campus for its cardiac catheterization lab: its CON application does not include Forms F.2a/b and F.3a/b for the NHFMC cardiac catheterization service, and thus provides no information regarding the financial impact of the proposal on the cardiac catheterization services remaining at the NHFMC Winston-Salem campus. Therefore, NHFMC did not demonstrate the long-term financial feasibility of the proposal, based upon projections of the costs and charges, and is not conforming to Criterion (5).

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

NHFMC failed to demonstrate the need it has to replace and relocate a cardiac catheterization lab. As described in the comments related to Criterion (3), NHFMC did not adequately evidence in its application that the project is needed. Therefore, the NHFMC application does not demonstrate that the proposal is not unnecessarily duplicative, and is non-conforming to Review Criterion (6).

In addition, NHFMC is proposing to relocate cardiac catheterization services to Kernersville (less than 1/8<sup>th</sup> mile from the Guilford County border), whose residents already have abundant access to cardiac catheterization services from a variety of nearby local providers. As shown on the following map, Kernersville is located proximate to Winston-Salem, Greensboro and High Point. Specifically, established cardiac catheterization programs exist at High Point Medical Center in High Point, Cone Health Moses Cone Hospital in Greensboro, and of course, in Winston-Salem at NHFMC and NCBH. Novant Health did not demonstrate that sufficient cardiac catheterization lab capacity does not currently exist to serve patients in Kernersville, and that patients do not currently have adequate access to the proposed services. Indeed, development of cardiac catheterization services in Kernersville will merely duplicate the many cardiac catheterization programs which are already conveniently available to Kernersville residents.

### Kernersville Proximity to Local Cardiac Catheterization Services



For these reasons, the NHFMC application does not demonstrate that it is not unnecessarily duplicative, and is non-conforming to Review Criterion (6).

- (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.**

NHFMC proposes to spend over \$3.2 million to construct spaces at NHKMC to accommodate a new cardiac catheterization lab. As described earlier with regard to review Criterion (4), NHFMC’s application claimed that there are no alternatives to consider. However, NHFMC could certainly replace its aging cardiac catheterization lab on site at NHFMC without the additional expense of millions of dollars to relocate a cardiac catheterization lab to a more affluent part of Forsyth County. Therefore, NHFMC has not demonstrated that the construction cost will not unduly increase the costs of providing health services, and therefore, the application is not conforming to Criterion (12).

- (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;**

Novant did not demonstrate that its proposed relocated cardiac catheterization services will serve the medically underserved populations to the same level as the percentage of the Forsyth County population which is medically underserved. Specifically, NHKMC's historical Medicaid payor mix of 10.4% (p. 76) is lower than the 15.2% of Forsyth County residents who are living below the Federal poverty level (per US Census Bureau), and lower than the historical Forsyth County Medicaid eligible mix of 24.15% (per North Carolina Medicaid)<sup>1</sup>.

- 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**

As shown in the following table, Novant is proposing to relocate a cardiac catheterization lab from a facility (NHFMC) which provides significantly more Medicaid access than does NHKMC. This will result in significantly less access for medically underserved residents of Forsyth County, as shown on this table comparing the CY2020 Medicaid payor mix at NHFMC and NHKMC, as documented by Novant in Section L.1 (pages 76-77) of its application.

#### Comparison of Medicaid Access

Payor Source	NHFMC	NHKMC
Medicaid	14.6%	10.4%

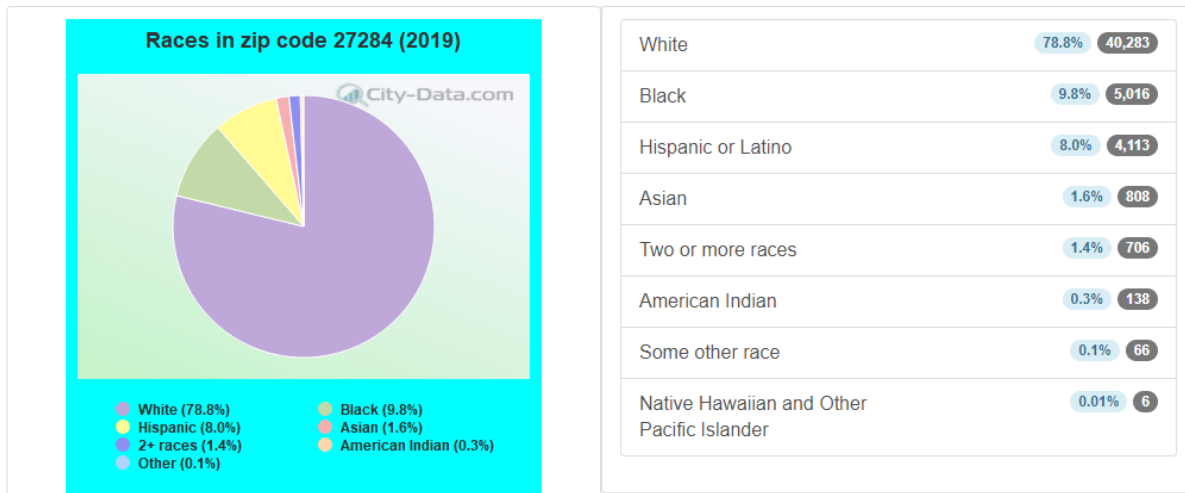
Novant's proposal will relocate inner city Medicaid cardiac catheterization capacity out to a more affluent suburban market. The large Winston-Salem NHFMC facility also provides efficiencies of scale for lower income and racial minorities in one location. The medical specialists and equipment needed to serve this population are typically based around the large medical center. Moving cardiac catheterization resources out to the more affluent, less diverse suburbs goes against protecting the medically indigent as identified in the State Health Plan. As one example, transportation can be challenging for low income persons and for racial minorities, who may not

<sup>1</sup> <https://medicaid.ncdhhs.gov/documents/reports/enrollment-reports/medicaid-and-health-choice-enrollment-reports>

have access to a car. Winston-Salem Transit Authority has several bus lines that travel within Winston-Salem to NHFMC. However, access via public transit in or to Kernersville is much more limited.

As previously described in response to Criterion (3a), access to healthcare services for racial and ethnic minorities will be harmed by Novant's proposed reduction of capacity if NHFMC moves a catheterization lab to the less diverse far edge of Forsyth County. Kernersville, and particularly zip code 27284, is much less racially and ethnically diverse than both Winston-Salem and Forsyth County.

### Races in Zip Code 27284



For all these reasons, the Novant application is not conforming to Criterion (13) with regard to underserved access.

**(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.**

Novant Health is nonconforming with Criterion (18a) because competition already exists to provide cardiac catheterization services Novant proposes to provide. The Novant Health proposal does not positively enhance competition in the service area because Novant is only proposing to serve cardiology patients who already go to Novant Health.

As the NHFMC application is non-conforming with Criteria (3), (3a), (4), (5), (6), (12), (13a) and (13c), it should thus also be found non-conforming with Criterion (18a). NHFMC did not

reasonably demonstrate the need the population projected to be served has for the proposed project, did not demonstrate that the reduction and relocation of the service will not negatively impact the ability of low income persons, racial and ethnic minorities, and other underserved groups to obtain needed health care, did not demonstrate its proposal is the least costly or most effective alternative, did not demonstrate the financial feasibility of the project, and did not adequately demonstrate that its proposal would not result in the unnecessary duplication of services in Forsyth County. Thus, the proposed NHFMC project will not have a positive impact on cost effectiveness and on access to services.

Further, NHFMC did not demonstrate that the proposed project will have a favorable impact on quality of services. Hospitals and other healthcare facilities perform a wide variety of procedures on patients every year. According to the State Center for Health Statistics, cardiovascular disease is the second leading cause of death in North Carolina<sup>2</sup>. Cardiovascular care is thus one of the largest consumers of healthcare dollars; coronary heart disease alone costs the United States \$219 billion each year<sup>3</sup>. Because of the high cost of health care and its impact on government budgets, cardiovascular care will continue to be scrutinized in terms of cost, quality and access. To deliver cost effective, optimal cardiovascular care for every patient, it is imperative to secure the best outcomes for every procedure. Quality cardiovascular patient care should ensure that the right patient has the right procedure with the right execution, resulting in the right outcome.

There have been hundreds of studies about the impacts of volume on quality in the delivery of health care. Generally, scientific studies conclude that volume is linked to quality of care. There is merit to the adage “practice makes perfect”. This is the case with regard to cardiology care; the association between institutional volume and outcomes has been demonstrated for cardiac catheterization among adults. A 2016 study finds an association between daily catheterization volume and complication rates<sup>4</sup>. Thus, it is concerning that NHFMC is proposing to relocate a cardiac catheterization lab to establish a much smaller NHKMC lab, where cardiac catheterization procedure volume will be significantly lower than at NHFMC. From a quality of care perspective, the Novant proposal does not demonstrate a favorable impact on quality of care, and therefore is not conforming to Criterion (18a).

A further quality-related question regarding the Novant proposal is its plan to offer interventional cardiology procedures beginning in the second project year. This aggressive timetable seems overly aggressive from a safety/quality perspective. According to the Novant projections, NHKMC will have provided just 446 diagnostic cardiac catheterization procedures during the interim period and first full year of operation. Because interventional cardiology involves some extra degree of specialization and risk, development of protocols and logistics is essential. This requires time and experience among a facility setting and the clinical team. Three years is a more reasonable target to transition to intervention. As a local example, the cardiac

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<sup>2</sup> [https://schs.dph.ncdhhs.gov/data/vital/lcd/2018/pdf/TblsA-F\\_rev4.pdf](https://schs.dph.ncdhhs.gov/data/vital/lcd/2018/pdf/TblsA-F_rev4.pdf)

<sup>3</sup> Centers for Disease Control, Heart Disease Facts.

<sup>4</sup> Kipp Slicker, Wesley G. Lane, Ola O. Oyetayo, Laurel A. Copeland, Eileen M. Stock, Jeffrey B. Michel, John P. Erwin, Daily cardiac catheterization procedural volume and complications at an academic medical center, *Cardiovascular Diagnosis & Therapy*, Vol 6, No 5, October 2016



catheterization lab at Kernersville Veteran's Administration (VA) clinic has been operational for five years, yet has not yet begun to provide interventional procedures.

### **Summary**

To summarize reasons the Agency should deny the Novant Health Forsyth Medical Center application: the NHFMC application is nonconforming with Criteria (3), (3a), (4), (5), (6) (12), (13a), (13c) and (18a). Because it is nonconforming with the review criteria, the application cannot be approved.