



April 1, 2022

Gregory Yakaboski, Project Analyst
Healthcare 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 Iredell Memorial Hospital CON Application to operate second shared cardiac catheterization lab

Dear Mr. Yakaboski:

Enclosed please find comments prepared by Davis Regional Medical Center (DRMC) and Lake Norman Regional Medical Center (LNRMC) regarding the Iredell Memorial Hospital (IMH) CON application to develop a second shared cardiac catheterization lab. We appreciate your consideration of these comments during your review of the application.

If you have any questions about the information presented here, please contact me at 704.660.4010.

Sincerely,

Clyde Wood

Bryan Clyde Wood
Network CEO

OPPOSING COMMENTS REGARDING CERTIFICATE OF NEED APPLICATION
Iredell Memorial Hospital (F-012180-22)

Submitted by Davis Regional Medical Center and Lake Norman Regional Medical Center
March 31, 2022

Criterion (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.*

IMH does not demonstrate the need for the proposed project based on reasonable utilization projections, did not propose the least costly or most effective alternative, and did not show that its proposal is not unnecessarily duplicative of existing cardiac catheterization resources in the service area. Therefore, IMH fails to demonstrate how the proposed project will maximize healthcare value for resources expended in developing the proposed second cardiac catheterization lab. The discussions regarding analysis of need, including projected utilization, are found in Criterion (3), alternative methods in Criterion (4), and unnecessary duplication in Criterion (6). Therefore, the IMH application is not conforming to Criterion 1 because the applicant does not demonstrate that the proposal is consistent with Policy GEN-3.

Criterion (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 IMH application lacks justification and should be denied. The application fails to demonstrate the need that the service area population has for additional cardiac catheterization capacity.

The application fails to describe any unique or special attributes for the Iredell County service area and facilities that would justify the proposed change. Utilization trends for cardiac catheterization at IMH and Iredell County are not unusual. In 2020, COVID-19 caused utilization to decrease at all three hospitals within Iredell County. The county surplus of cardiac catheterization capacity simply grew larger.

In Section Q, Form C.2a, IMH projected its diagnostic-equivalent cardiac catheterization utilization for FFY2022. As replicated below, on this table IMH projects an astounding 49.1% volume increase from its historical FFY2021 utilization. To produce its desired volume projection in order

to attempt to justify this proposal, IMH relies on an unsupported and unjustified cardiac catheterization utilization projection methodology.

IMH CON application Form C.2a

| Form C.2a Historical and Interim Medical Equipment Utilization ^ Cardiac Catheterization and Angiography Iredell Memorial Hospital | Last Full FY | Interim Full FY |
|--|--------------------------------|--------------------------------|
| | F: 10/01/2020 T: 09/30/2021 | F: 10/01/2021 T: 09/30/2022 |
| Cardiac Cath Equipment (see Tab C) | | |
| # of Units | 1 | 1 |
| # of Diagnostic Procedures | 573 | 797 |
| # of Therapeutic Procedures | 162 | 275 |
| # of Diagnostic Equivalent Procedures | 857 | 1278 |
| Other Medical Equipment Shared Fixed Cardiac Catheterization Equipment (Angiography Only) | | |
| # of Units | 1 | 1 |
| # of Procedures | 521 | 719 |

F = From

T = To

^ Diagnostic Centers should add laboratory equipment to this form, not Form C.4.

Applicants may delete rows for types of medical equipment not included in the proposal.

Applicants may delete Interim Full FY columns if not needed.

This projection is completely unreasonable. The complex Section Q methodology IMH manufactured to forecast utilization is not credible. As an existing provider of cardiac catheterization services, IMH should most realistically project its future utilization based on its actual historical use. As documented in the three most recent SMFPs, during each of the past three years, IMH reported cardiac catheterization utilization of 809, 955, and 627. Under no circumstances is a 49.1% one-year increase reasonable. Instead, reasonably assuming population growth of 0.49% (as IMH calculates on page 117), a realistic expectation of projected IMH FFY2022 diagnostic-equivalent cardiac catheterization procedures is 861 (857 x (1.0049)). This is far less than the SMFP methodology threshold of 1,200 annual weighted procedures per cardiac catheterization lab.

In addition, multiple hospitals throughout North Carolina, each with one unit of cardiac catheterization equipment, have achieved and maintained higher cardiac catheterization utilization as compared to IMH. As shown in Table 17A-1 of the 2022 SMFP, Alamance Regional Medical

Center, Caldwell Memorial Hospital, Carteret General Hospital, Haywood Regional Hospital, Johnston Health and Sentara Albemarle Medical Center, and Wayne UNC Health Care each are the sole providers of cardiac catheterization in their respective counties, and each has higher historical cardiac catheterization utilization than IMH, and are managing the demand with existing capacity of one cardiac catheterization lab.

2022 SMFP Table 17A-1

Table 17A-1: Cardiac Catheterization Procedures by Facility and Type, 2020

| County | Hospital | Diagnostic | | | | Interventional | | | | Total |
|------------|--|------------|--------|-----------|--------|----------------|--------|-----------|--------|-------|
| | | Adult | | Pediatric | | Adult | | Pediatric | | |
| | | Fixed | Mobile | Fixed | Mobile | Fixed | Mobile | Fixed | Mobile | |
| Alamance | Alamance Regional Medical Center | 606 | - | - | - | 177 | - | - | - | 783 |
| Buncombe | Mission Hospital | 3,555 | - | - | - | 1,216 | - | - | - | 4,771 |
| Burke | Carolinas HealthCare System Blue Ridge | 386 | - | - | - | 136 | - | - | - | 522 |
| Cabarrus | Atrium Health Cabarrus | 1,711 | - | - | - | 958 | - | - | - | 2,669 |
| Caldwell | Caldwell Memorial Hospital | 310 | - | - | - | 277 | - | - | - | 587 |
| Carteret | Carteret General Hospital | 498 | - | - | - | 160 | - | - | - | 658 |
| Catawba | Catawba Valley Medical Center | 450 | - | - | - | 232 | - | - | - | 682 |
| Catawba | Frye Regional Medical Center | 1,955 | - | - | - | 1,047 | - | - | - | 3,002 |
| Cleveland | Atrium Health Cleveland | 13 | - | - | - | - | - | - | - | 13 |
| Craven | CarolinaEast Medical Center | 933 | - | - | - | 685 | - | - | - | 1,618 |
| Cumberland | Cape Fear Valley Medical Center | 984 | - | - | - | 1,615 | - | - | - | 2,599 |
| Durham | Duke Regional Hospital | 879 | - | - | - | 328 | - | - | - | 1,207 |
| Durham | Duke University Hospital | 4,081 | - | 216 | - | 1,445 | - | 164 | - | 5,906 |
| Forsyth | North Carolina Baptist Hospital | 2,156 | - | 18 | - | 1,202 | - | 34 | - | 3,410 |
| Forsyth | Novant Health Forsyth Medical Center | 2,299 | - | - | - | 1,256 | - | - | - | 3,555 |
| Gaston | Caromont Regional Medical Center | 1,741 | - | - | - | 566 | - | - | - | 2,307 |
| Guilford | Cone Health | 2,705 | - | - | - | 1,120 | - | - | - | 3,825 |
| Guilford | High Point Regional Medical Center | 2,897 | - | - | - | - | - | - | - | 2,897 |
| Halifax | Vidant North Hospital | 105 | - | - | - | 39 | - | - | - | 144 |
| Harnett | Betsy Johnson Hospital | 144 | - | - | - | 19 | - | - | - | 163 |
| Haywood | Haywood Regional Hospital | 595 | - | - | - | 201 | - | - | - | 796 |
| Henderson | Margaret R. Pardee Memorial Hospital | 241 | - | - | - | 30 | - | - | - | 271 |
| Iredell | Davis Regional Medical Center | 130 | - | - | - | - | - | - | - | 130 |
| Iredell | Iredell Memorial Hospital | 507 | - | - | - | 120 | - | - | - | 627 |
| Iredell | Lake Norman Regional Medical Center | 201 | - | - | - | 67 | - | - | - | 268 |
| Johnston | Johnston Health | 763 | - | - | - | 401 | - | - | - | 1,164 |
| Lee | Central Carolina Hospital | 269 | - | - | - | 35 | - | - | - | 304 |

Table 17A-1: Cardiac Catheterization Procedures by Facility and Type, 2020

| County | Hospital | Diagnostic | | | | Interventional | | | | Total |
|-------------|---|------------|--------|-----------|--------|----------------|--------|-----------|--------|-------|
| | | Adult | | Pediatric | | Adult | | Pediatric | | |
| | | Fixed | Mobile | Fixed | Mobile | Fixed | Mobile | Fixed | Mobile | |
| Lenoir | UNC Lenoir Health Care | 360 | - | - | - | - | - | - | - | 360 |
| Mecklenburg | Atrium Health Pineville | 930 | - | - | - | 734 | - | - | - | 1,664 |
| Mecklenburg | Carolinas Medical Center | 2,137 | - | 118 | - | 902 | - | 191 | - | 3,348 |
| Mecklenburg | Novant Health Huntersville Medical Center | 486 | - | - | - | 187 | - | - | - | 673 |
| Mecklenburg | Novant Health Matthews Medical Center | 925 | - | - | - | 519 | - | - | - | 1,444 |
| Mecklenburg | Novant Health Presbyterian Medical Center | 933 | - | - | - | 738 | - | - | - | 1,671 |
| Moore | First Health Moore Regional Hospital | 2,628 | - | - | - | 1,076 | - | - | - | 3,704 |
| Nash | Nash General Hospital | 770 | - | - | - | 535 | - | - | - | 1,305 |
| New Hanover | New Hanover Regional Medical Center* | 2,201 | 522 | - | - | 2,004 | - | - | - | 4,727 |
| Onslow | Onslow Memorial Hospital | 10 | - | - | - | 2 | - | - | - | 12 |
| Orange | UNC Hospitals | 1,831 | - | 92 | - | 1,012 | - | 45 | - | 2,980 |
| Pasquotank | Sentrara Albermarle Medical Center | 877 | - | - | - | 5 | - | - | - | 882 |
| Pitt | Vidant Medical Center | 2,846 | - | 7 | - | 947 | - | 14 | - | 3,814 |
| Randolph | Randolph Hospital | - | - | - | - | - | - | - | - | - |
| Robeson | Southeastern Regional Medical Center | 713 | - | - | - | 489 | - | - | - | 1,202 |
| Rowan | Novant Health Rowan Medical Center | 396 | - | - | - | 230 | - | - | - | 626 |
| Rutherford | Rutherford Regional Medical Center | 94 | - | - | - | - | - | - | - | 94 |
| Scotland | Scotland Memorial Hospital | 291 | - | - | - | 92 | - | - | - | 383 |
| Stanly | Atrium Health Stanly | - | - | - | - | - | - | - | - | - |
| Union | Atrium Health Union | 332 | - | - | - | 123 | - | - | - | 455 |
| Vance | Maria Parham Medical Center | 101 | - | - | - | 29 | - | - | - | 130 |
| Wake | Duke Raleigh Hospital | 514 | - | - | - | 160 | - | - | - | 674 |
| Wake | Rex Hospital | 3,600 | - | - | - | 2,732 | - | - | - | 6,332 |
| Wake | WakeMed | 2,258 | - | - | - | 1,385 | - | - | - | 3,643 |
| Wake | WakeMed Cary Hospital | 404 | - | - | - | 98 | - | - | - | 502 |
| Watauga | Watauga Medical Center | 369 | - | - | - | 112 | - | - | - | 481 |
| Wayne | Wayne UNC Health Care | 1,064 | - | - | - | 303 | - | - | - | 1,367 |

IMH fails to demonstrate that there were any capacity constraints or delays in treating patients in 2019 due to lack of adequate capacity prior to the COVID-19 pandemic. None of the facilities in Iredell County, including IMH, have raised concerns about long wait times, cancelled procedures, and unnecessary overnight stays in 2020 or in prior years. On page 69 of the application, IMH states that “by April 2022, IMH will have two cardiovascular procedure rooms with the same equipment. Staff are trained to use both pieces of equipment for either cardiac catheterization or angiography. Side by side use of the equipment reduces turnover time and adds to efficiency.” The IMH application relies on convenience, not need, to support its claim to need to permanently utilize the interventional angiography equipment to perform cardiac catheterization procedures. The IMH application appears to be designed more to preserve existing IMH market share of cardiac catheterization procedures, and to prevent market entry of future cardiac catheterization equipment. Thus, the application fails to demonstrate the need of the population to be served.

In summary, IMH failed to demonstrate that the projected procedure volume for its existing and proposed cardiac catheterization equipment is based on reasonable and supported assumptions. Therefore, the IMH application is nonconforming to Criterion 3 because it does not demonstrate the need that the population has for the proposed additional capacity.

Criterion (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.”*

IMH does not demonstrate that the alternative proposed in its application is the most effective to meet the need because the application is not conforming to all statutory and regulatory review criteria and administrative rules. An application that does not demonstrate need cannot be approved, and thus also cannot be the most effective alternative. Therefore, the IMH application is not conforming to Criterion (4).

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.”*

IMH’s financial projections are not based on reasonable utilization projections, as discussed in the Criterion 3 comments. Consequently the financial projections are unreliable, and therefore the application is not conforming to Criterion (5).

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.”*

IMH’s utilization projections are not based on reasonable utilization projections. The discussion regarding projected utilization is found in Criteria (3) above. Consequently an application that does not demonstrate need for the project also does not demonstrate that the project will not result in unnecessary duplication of existing health service capabilities or facilities. Therefore the IMH application is not conforming to Criterion (6).

In addition, IMH fails to demonstrate that its proposal would not result in unnecessary duplication of cardiac catheterization service, because two other providers of cardiac catheterization (DRMC and LNRMC) are located in close proximity to IMH. As IMH acknowledges on page 80 of its application, physicians who are using IMH cardiac catheterization services also have privileges at DMRC. These cardiologists could utilize the nearby DRMC and LNRMC facilities to perform their cases. Therefore, IMH is proposing to unnecessarily duplicate existing and available health service capabilities. Approval of the IMH application would result in unnecessary duplication and underuse of the existing cardiac catheterization equipment in Iredell County. Tables 17A-1 of the 2022 SMFP (shown below) portrays the historical utilization for all of the cardiac catheterization equipment in the Iredell County service area.

2022 SMFP Table 17A-1

Table 17A-1: Cardiac Catheterization Procedures by Facility and Type, 2020

| County | Hospital | Diagnostic | | | | Interventional | | | | Total |
|------------|--|------------|--------|-----------|--------|----------------|--------|-----------|--------|-------|
| | | Adult | | Pediatric | | Adult | | Pediatric | | |
| | | Fixed | Mobile | Fixed | Mobile | Fixed | Mobile | Fixed | Mobile | |
| Alamance | Alamance Regional Medical Center | 606 | - | - | - | 177 | - | - | - | 783 |
| Buncombe | Mission Hospital | 3,555 | - | - | - | 1,216 | - | - | - | 4,771 |
| Burke | Carolinas HealthCare System Blue Ridge | 386 | - | - | - | 136 | - | - | - | 522 |
| Cabarrus | Atrium Health Cabarrus | 1,711 | - | - | - | 958 | - | - | - | 2,669 |
| Caldwell | Caldwell Memorial Hospital | 310 | - | - | - | 277 | - | - | - | 587 |
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| Cleveland | Atrium Health Cleveland | 13 | - | - | - | - | - | - | - | 13 |
| Craven | CarolinaEast Medical Center | 933 | - | - | - | 685 | - | - | - | 1,618 |
| Cumberland | Cape Fear Valley Medical Center | 984 | - | - | - | 1,615 | - | - | - | 2,599 |
| Durham | Duke Regional Hospital | 879 | - | - | - | 328 | - | - | - | 1,207 |
| Durham | Duke University Hospital | 4,081 | - | 216 | - | 1,445 | - | 164 | - | 5,906 |
| Forsyth | North Carolina Baptist Hospital | 2,156 | - | 18 | - | 1,202 | - | 34 | - | 3,410 |
| Forsyth | Novant Health Forsyth Medical Center | 2,299 | - | - | - | 1,256 | - | - | - | 3,555 |
| Gaston | Caromont Regional Medical Center | 1,741 | - | - | - | 566 | - | - | - | 2,307 |
| Guilford | Cone Health | 2,705 | - | - | - | 1,120 | - | - | - | 3,825 |
| Guilford | High Point Regional Medical Center | 2,897 | - | - | - | - | - | - | - | 2,897 |
| Halifax | Vidant North Hospital | 105 | - | - | - | 39 | - | - | - | 144 |
| Harnett | Betsy Johnson Hospital | 144 | - | - | - | 19 | - | - | - | 163 |
| Haywood | Haywood Regional Hospital | 595 | - | - | - | 201 | - | - | - | 796 |
| Henderson | Margaret R. Pardee Memorial Hospital | 241 | - | - | - | 30 | - | - | - | 271 |
| Iredell | Davis Regional Medical Center | 130 | - | - | - | - | - | - | - | 130 |
| Iredell | Iredell Memorial Hospital | 507 | - | - | - | 120 | - | - | - | 627 |
| Iredell | Lake Norman Regional Medical Center | 201 | - | - | - | 67 | - | - | - | 268 |
| Johnston | Johnston Health | 763 | - | - | - | 401 | - | - | - | 1,164 |
| Lee | Central Carolina Hospital | 269 | - | - | - | 35 | - | - | - | 304 |

Page 310 of the 2022 State Medical Facilities Plan states, “The capacity of a unit of cardiac catheterization equipment is defined as 1,500 diagnostic-equivalent procedures per year, with the trigger of need at 80% of capacity.” As seen in Table 17A-3 of the 2022 SMFP (also shown below), Iredell County has no need for additional cardiac catheterization capacity because the existing equipment at all three hospitals in Iredell County combined was utilized substantially below the 80% trigger (1,200 weighted procedures). This means that there is available capacity at all three cardiac catheterization locations including IHS. Table 17A-3 shows that Iredell County has a surplus of cardiac catheterization capacity with three total units, one at each hospital. The cardiac catheterization need methodology in the 2022 SMFP is based on the actual historical 2020 utilization volume reported by all of the facilities in the service areas. Iredell County has more than adequate cardiac catheterization capacity because none of the three facilities have individual deficits, and Iredell County has a large overall surplus. Table 17A-3 shows the existing county inventory (capacity) of three (3) labs, which is much higher than the calculated machines required of 0.98 labs.

Davis Regional Medical Center & Lake Norman Regional Medical Center
Opposing Comments regarding application F-012180-22

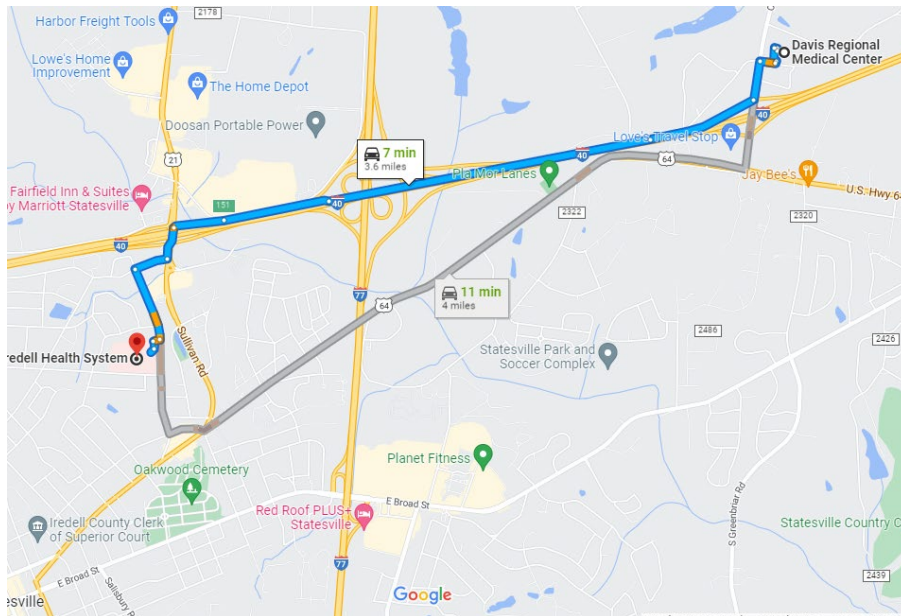
2022 SMFP Table 17A-3

Table 17A-3: Fixed Cardiac Catheterization Equipment, Capacity and Volume

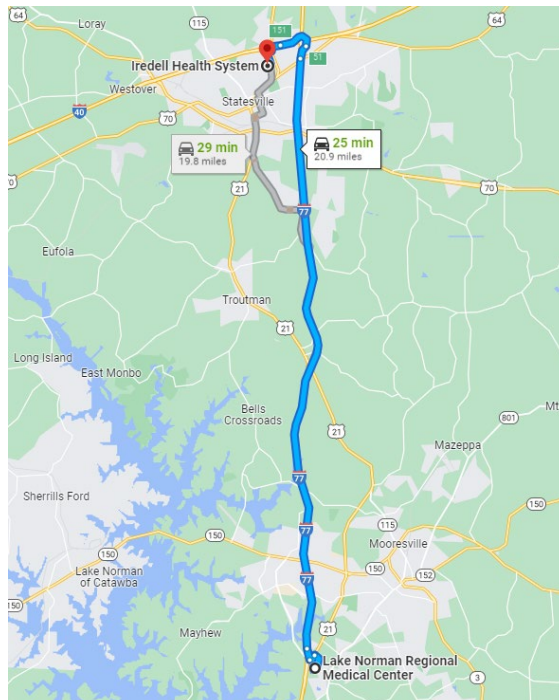
| A | B | C | D | E | F | G | H | I | J | K |
|--|---|-------------------|---------------------------------|--------------------------|--------------------------|------------|-----------------------------------|--|--|--|
| Cardiac Catheterization Equipment Service Areas | Facility | Current Inventory | CON Issued/ Pending Development | Pending Review or Appeal | Total Planning Inventory | # of Units | 2020 Procedures (Weighted Totals) | Machines Required Based on 80% Utilization | Number of Additional Machines Required by Facility | Number of Additional Machines Needed by Service Area |
| Iredell | Davis Regional Medical Center | 1 | | | 1 | c | 130 | 0.11 | 0 | |
| | Iredell Memorial Hospital | 1 | | | 1 | c | 717 | 0.60 | 0 | |
| | Lake Norman Regional Medical Center | 1 | | | 1 | e | 318 | 0.27 | 0 | |
| | TOTAL | 3 | | | 3 | | | 1 | | 0 |
| Johnston | Johnston Health | 1 | | | 1 | c | 1,465 | 1.22 | 0 | |
| | TOTAL | 1 | | | 1 | | | 1 | | 0 |
| Lee | Central Carolina Hospital | 1 | | | 1 | c | 330 | 0.28 | 0 | |
| | TOTAL | 1 | | | 1 | | | 0 | | 0 |
| Lenoir | UNC Lenoir Health Care | 1 | | | 1 | c | 360 | 0.30 | 0 | |
| | TOTAL | 1 | | | 1 | | | 0 | | 0 |
| Mecklenburg | Atrium Health Pineville | 3 | | | 3 | a | 2,215 | 1.85 | 0 | |
| | Carolinas Medical Center | 9 | | | 9 | a | 4,334 | 3.61 | 0 | |
| | Novant Health Huntersville Medical Center | 1 | | | 1 | b | 813 | 0.68 | 0 | |
| | Novant Health Matthews Medical Center | 1 | | | 1 | e | 1,833 | 1.53 | 1 | |
| | Novant Health Presbyterian Medical Center | 2 | | | 2 | b | 2,225 | 1.85 | 0 | |
| | TOTAL | 16 | | | 16 | | | 10 | | 0 |
| Moore | FirstHealth Moore Regional Hospital | 6 | | | 6 | b | 4,511 | 3.76 | 0 | |
| | TOTAL | 6 | | | 6 | | | 4 | | 0 |
| Nash | Nash General Hospital | 2 | | | 2 | c | 1,706 | 1.42 | 0 | |
| | TOTAL | 2 | | | 2 | | | 1 | | 0 |
| New Hanover | New Hanover Regional Medical Center | 5 | | | 5 | b | 5,708 | 4.76 | 0 | |
| | 2021 Need Determination | 1 | | | 1 | | | | | |
| | TOTAL | 6 | | | 6 | | | 5 | | 0 |
| Onslow | Onslow Memorial Hospital | 1 | | | 1 | c | 14 | 0.01 | 0 | |
| | TOTAL | 1 | | | 1 | | | 0 | | 0 |
| Orange | UNC Hospitals | 4 | | | 4 | a | 3,876 | 3.23 | 0 | |
| | TOTAL | 4 | | | 4 | | | 3 | | 0 |
| Pasquotank/ Camden/ Currituck/ Perquimans | Sentara Albemarle Medical Center | 1 | | | 1 | c | 886 | 0.74 | 0 | |
| | TOTAL | 1 | | | 1 | | | 1 | | 0 |
| Pitt/Greene/ Hyde/Tyrell | Vidant Medical Center | 7 | | | 7 | a | 4,545 | 3.79 | 0 | |
| | TOTAL | 7 | | | 7 | | | 4 | | 0 |
| Randolph | Randolph Hospital | 1 | | | 1 | e | 0 | 0.00 | 0 | |
| | TOTAL | 1 | | | 1 | | | 0 | | 0 |
| Robeson | Southeastern Regional Medical Center | 2 | | | 2 | b | 1,569 | 1.31 | 0 | |
| | TOTAL | 2 | | | 2 | | | 1 | | 0 |
| Rowan | Novant Health Rowan Medical Center | 1 | | | 1 | e | 799 | 0.67 | 0 | |
| | TOTAL | 1 | | | 1 | | | 1 | | 0 |

Further, Iredell County residents have no barriers to travel to any hospitals within the county, or to hospitals in adjoining counties that have robust cardiac catheterization services. As seen in the following Google maps, IMH is in close proximity to DRMC and LNRMC. DRMC is located just 3.6 miles away from IMH, and LNRMC is located 20.9 miles away from IMH. Both facilities are easily accessed by interstate highways.

Travel Distance between IMH and DRMC



Travel Distance between IMH and LNRMC



Interstate 40 and Interstate 77 also provide reasonable proximity to medical centers with both cardiac catheterization and open-heart programs, located in Mecklenburg, Forsyth and Catawba counties.

In summary, the IMH application clearly represents unnecessary duplication of existing health service capabilities and facilities, and is not conforming to Criterion (6).

Criteria (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.”*

IMH’s application fails to conform to Criterion (18a) because the proposal does not demonstrate that it will promote cost effective services. The applicant’s projected utilization is not based on reasonable and adequately supported utilization projections. The discussions regarding projected utilization, alternatives, and unnecessary duplication are found in Criteria (3), (4), (5), and (6), are incorporated herein by reference.