

Comments on the Petition for Adjusted Need Determination for Shared/Fixed Cardiac Catheterization Equipment for Iredell County

VIA E-MAIL

DHSR.SMFP.Petitions-Comments@dhhs.nc.gov

Commenters:

Davis Regional Medical Center
and Lake Norman Medical Center

Contact:

Bryan Clyde Wood
Network CEO
Davis Regional Medical Center
and Lake Norman Medical Center
P.O. Box 3250
Mooresville, NC 28117
704 660-4010

Davis Regional Medical Center and Lake Norman Regional Medical Center appreciate the opportunity to submit comments regarding the petition filed by Iredell Health System (IHS) requesting an adjusted need for one unit of additional shared/fixed cardiac catheterization equipment for Iredell County in the 2022 State Medical Facilities Plan (SMFP). IHS's request for an adjusted need determination lacks adequate justification and should be denied. The petition fails to demonstrate the special circumstances that merit a need for additional cardiac catheterization capacity.

In 2011, the State Health Coordinating Council denied a petition by IHS in part because the two other providers of cardiac catheterization were in close proximity and that cardiologists could utilize these nearby facilities to perform their cases. As seen in Attachment A, the other reason the petition was denied was because the utilization fell short of the threshold in the methodology. Over the past ten years, the circumstances in Iredell County have not changed. IHS is still approximately 4 miles from Davis Regional Medical Center (Davis) and 20 miles from Lake Norman Regional Hospital (LNRMC). Cardiologists practicing at IHS still have the option to utilize these other nearby facilities. For all of these years, Iredell County has maintained a surplus of cardiac catheterization capacity with three units, one at each hospital. **Iredell Health System's requested need adjustment for a shared fixed cardiac catheterization laboratory remains contrary to the methodology and lacks supported by reasonable data.**

The Proposed 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, 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 which is 1,200 weighted procedures. This means that there is available capacity at all cardiac catheterization locations including IHS. Specifically, the standard methodology (Methodology 1) shows that Iredell County and IHS have no deficit for cardiac catheterization equipment.

Absence of Special Need Attributes

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

IHS reports that for the eight-month period from November 2020 through June 2021, it has performed a total of 542 weighted procedures. Based on the monthly average of 67.75, IHS will perform approximately 813 annual weighted procedures; this is far less than the 1,200 annual weighted procedures that is based on the threshold in the SMFP methodology.

The petitioner’s linear trend method to predict future utilization is not credible because it relies on eight-month data and ignores the current surge in COVID-19 cases. Based on the petitioner’s data, IHS currently averages less than 3 cardiac catheterization procedures per day and less than 1 STEMI patient per week. There is nothing special about the underutilized cardiac catheterization equipment in Iredell County.

Iredell residents have no barriers to travel to hospitals within the county or to hospitals in adjoining counties that have robust cardiac catheterization services. IHS is in close proximity to Davis and LNRMC as seen in the map Attachment B. Interstates I-40 and I-77 provide reasonable proximity to medical centers with both cardiac catheterization and open-heart programs in Mecklenburg, Forsyth and Catawba Counties.

Overall Surplus Capacity

Table 17A-3 of the Proposed 2022 SMFP correctly shows that Iredell County has an **overall surplus of cardiac catheterization capacity with three units, one at each hospital.** Historical utilization for all of the cardiac catheterization equipment in the service area is the proper focus of the SMFP planning methodology.

The following table shows the weighted procedures and the capacity calculations demonstrating that there is no need for additional cardiac catheterization capacity in Iredell County.

	2016	2017	2018	2019	2020
IHS Weighted Procedures	1,042	1,017	931	1,125	717
Number of Machines Needed Based on 80%	0.87	0.85	0.78	0.94	0.60
Davis Weighted Procedures	224	16	9	271	130
Number of Machines Needed Based on 80%	0.19	0.01	0.01	0.23	0.11
LNRMC Weighted Procedures	62	69	258	405	318
Number of Machines Needed Based on 80%	0.05	0.06	0.22	0.34	0.27
Totals	1,328	1,102	1,198	1,801	1,165
Number of Machines Needed Based on 80%	1.1	0.9	1.0	1.5	1.0
Iredell Facilities Cardiac Cath Inventory	3	3	3	3	3

Iredell County has adequate cardiac catheterization capacity because none of the facilities have individual deficits and the county has a large overall surplus. The petition explains that COVID-19 emergency exemption allows IHS to temporarily utilize its angiography/electrophysiology room to also perform cardiac catheterization procedures. Thus, it now has the capability to utilize two rooms to perform cardiac catheterization procedures. If this temporary procedure room were included in the IHS inventory, the facility would have a **surplus of 1.40 units** based on its 2020 utilization.

The petitioner fails to demonstrate that there were any capacity constraints or delays in treating patients in 2019 due to the lack of adequate capacity prior to the COVID-19 pandemic. None of the facilities in Iredell County, including the petitioner, have raised concerns about long wait times, cancelled procedures, and unnecessary overnight stays in 2020 or in prior years. As seen in the table above, the utilization at LNRMC is increasing which helps meet the demand for cardiac procedures in southern Iredell County

Higher Utilization at Other Hospitals in North Carolina with One Cardiac Cath Lab

Multiple hospitals throughout North Carolina, each with one unit of cardiac catheterization equipment, have achieved and maintained higher cardiac catheterization utilization as compared to IHS. These include Alamance Regional Hospital, Caldwell Memorial Hospital, Haywood Regional Hospital, Johnston Health and Wayne UNC Health Care; each are the sole providers of cardiac catheterization in their respective counties. The Iredell petition neglects to explain why it has a special need for additional cardiac catheterization capacity at relatively low utilization while these other facilities, that are the sole providers in their service areas, should remain at their current one-room status.

Petition Omits Key Data

Instead of quantifiable data, the petition provided the unsupported statement, *“With permission to schedule cardiac catheterizations in the second laboratory, the hospital saw immediate positive results in patient service, operational efficiency, and physician satisfaction.”*

Standardized metrics have been proposed in the medical literature to evaluate efficiency, productivity and quality in cardiac catheterization labs.¹ However, the Iredell petition omits such operational measures that could be useful to evaluate the petitioner’s request including:

- Cases per room per month
- Percentage of days at full capacity
- Average case times
- On-time starts
- Room turnover times

The Agency should question the reasonableness of any petition that is seeking additional capacity but omits the most basic information such as hours of operation, average procedure times and percentages of staff overtime.

The absence of genuine performance data for 2019 and 2020 causes the petitioner’s claims regarding cost savings and scheduling efficiencies to be unreliable. IHS’s total weighted annual procedures decreased 36.3 percent from 1,125 procedures in 2019 to 717 procedures in 2020. With such a large decrease in total utilization, any hospital could easily reduce staff over-time and shorten the times between cases. Clearly, the overall volume reduction is what contributes to its reduced expenses and not some newfound efficiency. Having two procedure rooms temporarily available in 2020 due to the COVID-19 exemption, means that there were many days at IHS when one room is scheduled for two cases and the other room has only one case. The petitioner confuses the severe underuse of its procedure rooms with what it views as scheduling efficiency because the workload has been dramatically diminished.

Furthermore, the petition omits the utilization data for its electrophysiology and angiography procedures to demonstrate how the existing equipment is able to accommodate the competing scheduling requests for interventional radiologists and the cardiologists. Lacking this elementary information for both the cardiac catheterization lab and the electrophysiology/angiography room, the petitioner fails to demonstrate that it is maximizing its use of the existing equipment.

¹ [Journal of the American College of Cardiology](#)
[Volume 72, Issue 20](#), 13–20 November 2018, Pages 2507-2517

Iredell Health System is losing market share to the two other hospitals in Iredell County. In recent years, higher percentages of patients are choosing Davis Regional Medical Center and Lake Norman Regional Medical Center rather than IHS.

	2016	2017	2018	2019	2020
Iredell Health % of Total Weighted Procedures	78.46%	92.29%	77.71%	62.47%	61.55%
Davis and LNRMC % of Total Weighted Procedures	21.54%	7.71%	22.29%	37.53%	38.45%

Source: 2018 through Proposed 2022 SMFPs

The petitioner does not address this utilization trend because it reinforces the fact that patients and physicians can easily choose to access other cardiac catheterization providers in Iredell County.

Incorrect Interpretation of the Methodology and Speculative Projections

The petitioner’s request both misinterprets the cardiac catheterization methodology and improperly substitutes its own contrived projections instead of actual historical data. The petition makes false representations regarding cardiac catheterization methodology in the Proposed 2022 SMFP. Steps 4, 5 and 6 of Methodology 1 in the proposed 2022 SMFP document that the need for additional cardiac catheterization equipment is based on the combined utilization of all cardiac catheterization units in the service area. The petition wrongly attempts to demonstrate a need for additional capacity only at IHS. In reality there is no county-wide need nor a special need at IHS.

Page 4 of the petition admits that “forecasting is an inexact science in the midst of a second COVID-19 surge.” Contrary to the SMFP methodology, the petitioner’s projections are mathematical deceptions that have no connection to the actual data in the Proposed 2022 Plan. The petitioner’s cardiac catheterization projections for IHS are based on partial-year data that has no validity for making future years’ projections.

The cardiac catheterization need methodology in the Proposed 2022 State Medical Facilities Plan is based on the 2020 data that was reported by all of the facilities in the service areas. While these numbers are self-reported they are actual volumes. In contrast, the petitioner’s contrive projections for its own facility are unreliable. No data is available for the same partial year period at the other cardiac catheterization facilities in Iredell County.

Physicians Recruitment is Not Unique to IHS

The petitioner believes that physician recruitment will boost its cardiac volumes to new heights. This prediction is entirely speculative because there is no data to support this premise. Physician recruitment is not a unique or special characteristic for a hospital. Both Davis Regional Medical Center and Lake Norman Regional Medical Center have commitments from additional

cardiologists recruited this year to support further growth in their utilization. The cardiologists that perform procedures at IHS have the option of obtaining privileges at both Davis Regional Medical Center and Lake Norman Regional Medical Center. Some cardiologists practicing in Iredell County already have active staff or courtesy staff privileges at more than one hospital.

Cardiologists Currently Performing Procedures at the Cardiac Catheterization Rooms in Iredell County	Iredell Health	Davis Regional Medical Center	Lake Norman Regional Medical Center
John Allan, MD	X	X	X
Ray Georgeson, MD	X	X	
Bradley Martin, MD	X	X	
Jips Zachariah, MD	X	X	
Naim Bouhoussein, MD	X		
James Bradford, MD	X		
Brian Hearon, MD		X	X
Stephen Iuliano, MD			X
Shomeet Patel, MD			X
Richard Scherczinger, MD			X
Daniel Koeler, MD			X

Sources: Hospital Records and Websites

Dr. Allan and the other cardiologists are not obligated to maintain privileges only at IHSs. Physicians and patients are free to choose what facilities they utilize in the future. There is no special need to add cardiac catheterization capacity at IHS based on these reasons.

Unnecessary Duplication

The petitioner seeks to add cardiac capacity when its historical data shows that it has no deficit and the service area has a large overall surplus of cardiac catheterization capacity. Approval of this petition would result in unnecessary duplication and underuse of the existing equipment. IHS is nowhere near the level that is needed to justify two cardiac catheterization procedure rooms as seen in the next table.

	# Cardiac Cath Units	2020 Total Weighted Procedures	Number of Machines Needed 2020
Iredell Health System	1 CON + 1 Temporary	717	0.60
Atrium Health Cabarrus	2	3,388	2.82
Carolina East Medical Center	2	2,132	1.78
Novant Health Presbyterian Medical Center	2	2,225	1.85
Nash General Hospital	2	1,706	1.42
Southeastern Regional Medical Center	2	1,569	1.31

Source: Proposed 2022 SMFP

The fact that the petitioner has existing equipment that was obtained specifically for electrophysiology and angiography procedures is not a unique factor because there have been multiple instances of other facilities acquiring similar equipment that is not subject to the limitations of need determinations. Previous CON applications for electrophysiology labs, angiography systems and peripheral vascular labs include:

CON Project ID # F-11691-19 Novant Health Presbyterian Medical Center
CON Project ID # O-11191-16 New Hanover Regional Medical Center
CON Project ID # F-11183-16 Novant Health Presbyterian Medical Center
CON Project ID # 10228-13 Wayne Memorial Hospital
CON Project ID # 10089-13 Watauga Medical Center

These CON projects include conditions that prohibit the equipment from being used to provide cardiac catheterization services as defined in N.C.G.S. 131E-176 (2g). If the IHS petition is granted, these other facilities may attempt the same misguided strategy to gain cardiac catheterization capacity that is unnecessary.

Adverse Effects

The petitioner's statements regarding the adverse effects on the providers and consumers are not accurate or compelling. Denial of the petitioner's request does not require IHS to give up equipment or capabilities because it already has abundant cardiac capacity that is operating at suboptimal utilization. Contrary to what the petition reports, the cardiac catheterization trends for Davis and particularly LNRMC show increasing utilization in 2018 and 2019. IHS fails to acknowledge that these competing hospitals are experiencing higher growth rates that could surpass its performance.

There is no need to for excess cardiac catheterization capacity at IHS in Statesville because the population growth is expected to be greater in southern region of Iredell County near Mooresville. (Please see Attachment C.) The IHS petition appears to be an attempt to gain cardiac capacity as a competitive advantage to lure cardiologists away from other facilities.

Within the past two years, Davis and LNRMC have invested hundreds of thousands of dollars in a new cardiac catheterization console and software upgrades. If the petition is approved it could cause underutilization of all providers' cardiac catheterization equipment in Iredell County making it more difficult to reinvest in equipment and services.

Conclusion

For all of these reasons, Davis Regional Medical Center and Lake Norman Regional Medical Center request the State Health Coordinating Council to deny the IHS petition. Thank you for your consideration.

ATTACHMENT A

Technology and Equipment Committee
Agency Report on
An Adjusted Need Determination Petition for
Shared Fixed Cardiac Catheterization Equipment at
Iredell Memorial Hospital
Proposed 2012 State Medical Facilities Plan

Petitioner:

Iredell Health System
557 Brookdale Drive
(P.O. Box 1828)
Statesville, NC 28677

Contact:

Ed Rush, President and CEO
704-873-5661

Request:

The Petitioner, Iredell Health System (IHS), requests an adjusted need determination for one shared fixed cardiac catheterization laboratory in Iredell County in a program that provides both diagnostic and therapeutic (interventional) cardiac catheterization. The Petition specifies that the certificate of need applicant for the shared fixed cardiac catheterization unit must use existing equipment and show evidence that therapeutic catheterization procedures have been provided for the past 12 months.

Background Information:

The "Proposed 2012 State Medical Facilities Plan (SMFP)" provides two need determination methodologies for cardiac catheterization equipment. Methodology One is the standard methodology for determining need for additional fixed cardiac catheterization equipment, and Methodology Two is the need determination methodology for shared fixed cardiac catheterization equipment. Application of these methodologies to utilization data in the "Proposed 2012 SMFP" does not generate a need determination for fixed cardiac catheterization equipment or for shared fixed cardiac catheterization equipment in Iredell County.

Shared fixed cardiac catheterization equipment is defined in the SMFP as "fixed equipment that is used to perform both cardiac catheterization procedures and angiography procedures." In practice, Methodology Two applies to cardiac catheterization service areas that do not offer fixed cardiac catheterization equipment, as stated:

"For cardiac catheterization equipment service areas in which a unit of fixed cardiac catheterization equipment is not located, need exists for one shared cardiac catheterization equipment (i.e. fixed equipment that is used to perform both cardiac catheterization procedures and angiography procedures) when:

- a. *The number of cardiac catheterization procedures as defined in 10A NCAC 14C .1601 (5) performed at any mobile site in the cardiac catheterization service area exceeds 240 (300 procedures X 80 percent) procedures per year for eight hours per week the mobile*

equipment is operated at the site during the 12 month period reflected in the 2010 Hospital License Renewal Application or the 2010 Registration and Inventory of Cardiac Catheterization Equipment on file with the North Carolina Division of Health Service Regulation; and

- b. No other fixed or mobile cardiac catheterization service is provided within the same cardiac catheterization equipment service area."*

Methodology Two, as it is written, does not apply to Iredell County which has three operational fixed cardiac catheterization labs: one each at Iredell Memorial Hospital (IMH), Davis Regional Medical Center (DRMC), and Lake Norman Regional Medical Center (LNRMC). An example of the applicability of Methodology Two is the adjusted need determination for a shared fixed cardiac catheterization lab in Lee County in the "2011 SMFP". Prior to the adjusted need determination approval, Lee County did not have a fixed unit, but county residents received mobile cardiac catheterization services at Central Carolina Hospital.

Iredell Memorial Hospital's Grandfathered, Fixed Cardiac Catheterization Equipment

Iredell Memorial Hospital acquired one fixed cardiac catheterization laboratory in 1989, prior to the equipment being regulated under the state's certificate of need (CON) law. The hospital performed only diagnostic cardiac catheterization services until 2008, when therapeutic (i.e., interventional) cardiac catheterizations were initiated. Because IMH's fixed unit is grandfathered under CON law, therapeutic procedures can be performed without the hospital having open heart surgery capability, as currently required in CON Rule 10A NCAC 14C .1604(a), as follows: *"If the applicant proposes to perform therapeutic cardiac catheterization procedures, the applicant shall demonstrate that open heart surgery services are provided within the same facility."*

The Petitioner supports its adjusted need determination request based on 1,440 diagnostic equivalent procedures performed on IMH's grandfathered fixed cardiac catheterization unit during the 12 month period of July 2010 to June 2011. At this utilization, IHS states that its fixed unit is averaging 96% of capacity, and would trigger the need for a second fixed cardiac catheterization unit in Iredell County if Davis Regional Medical Center's one fixed cardiac catheterization unit and Lake Norman Regional Medical Center's one shared fixed cardiac catheterization unit were not underutilized.

Iredell Health System states it responded to its service area's cardiac mortality rate by developing a comprehensive cardiac care program. For clarification, however, the program is not a comprehensive cardiac care program by CON definition¹, because the hospital does not provide open heart surgery services, which is a separately regulated service under CON statute. IHS's program offers a coordinated continuum of care from primary care in the hospital's supported community health center, to certified preventive and rehabilitation programs and full time dedicated catheterization laboratory staff. The Petitioner states it has now reached limits on its response capability because the one fixed

¹ CON Rule 10A NCAC 14C .1601(8) states: "Comprehensive cardiac services program' means a cardiac services program which provides the full range of clinical services associated with the treatment of cardiovascular disease including community outreach, emergency treatment of cardiovascular illnesses, non-invasive diagnostic imaging modalities, diagnostic and therapeutic cardiac catheterization procedures, open heart surgery and cardiac rehabilitation services. Community outreach and cardiac rehabilitation services shall be provided by the applicant or through arrangements with other agencies and facilities located in the same city. All other components of a comprehensive cardiac services program shall be provided within a single facility."

cardiac catheterization laboratory is currently operating over capacity and into the evening/night. Further, the Petitioner states:

"If the special need is not approved, some patients will be forced out of the service area to get comparable quality care, unless Iredell Health System finds enough mobile unit capacity to fill the gap. Even so, extended use of mobile equipment is not a good solution. Other hospitals in the county do not have the staff to provide comparable service, or the policies to provide comparable charity care. Hence, referring physicians and patients will have only the out-of-county solution if Iredell Memorial cannot respond. Out-of-county care is not only stressful at the time of the procedure, it often results in breaks in care coordination; transition breaks in pharmaceutical regimens; and patient imposed breaks in follow up."

Iredell Memorial Hospital's Dedicated Electrophysiology (EP)/Angiography Equipment

In 2005, IMH received CON approval to acquire a second fixed unit of cardiac catheterization equipment to be used as a dedicated EP/angiography laboratory. The standard CON condition restricts IMH from performing cardiac catheterization procedures on the dedicated equipment, as follows:

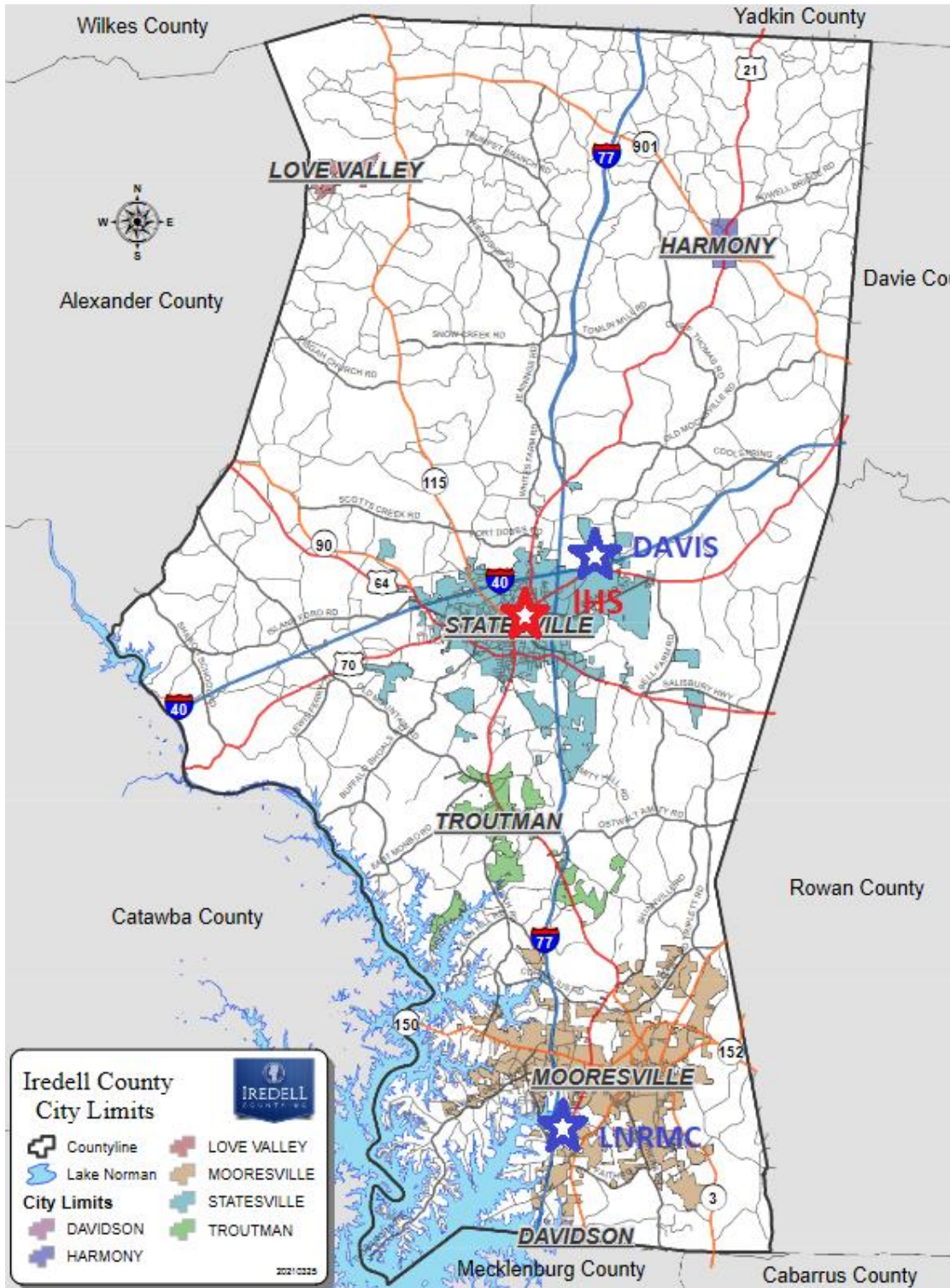
"Iredell Memorial Hospital, Inc. shall not perform any cardiac catheterization procedures, as defined in 10A NCAC 14C.1601(5), with the cardiac catheterization equipment in the angiography and electrophysiology laboratory, which shall be used for angiography and electrophysiology procedures."

In effect, the Petitioner seeks to remove the CON condition on Iredell Memorial Hospital's dedicated EP/angiography laboratory to gain additional capacity to perform diagnostic cardiac catheterization procedures. The Petitioner concludes that the shared use of its EP/angiography laboratory for performing additional diagnostic cardiac catheterizations is the best alternative for managing increased demand for cardiac catheterization services, and would be a "high value solution" because additional cardiac catheterization equipment would not have to be purchased.

Analysis:

Iredell Health System's request relies on current cardiac catheterization utilization performed after the "Proposed 2012 SMFP" FY 2010 reporting period (October 1, 2009 to September 30, 2010). For that period (FY 2010), IMH reported 806 diagnostic equivalent procedures, and the number of cardiac therapeutic procedures performed (108) actually declined from the previous year (139 procedures). At 806 diagnostic equivalent procedures, IHS's one fixed cardiac catheterization equipment operated at only 54% of capacity and generated a need for only 0.67 units of fixed equipment. As shown in the table below, the combined cardiac catheterization utilization performed on all three fixed cardiac catheterization units in Iredell County generated a need for only one fixed unit (0.86) in FY 2010.

ATTACHMENT B.



ATTACHMENT C.

Higher Growth Projected for South Iredell Zip Codes

<u>Zip Codes in North Iredell</u>	2021	2026	% Increase
28625 Statesville (North)	39,019	40,592	4.03%
28677 Statesville (South)	36,594	38,172	4.32%
28125 Mount Ulla	2,706	2,839	4.92%
28673 Sherille Ford	6,751	7,079	4.86%
28682 Terrell	1,281	1,355	5.78%
Combined	86,351	90,037	4.27%
<u>Zip Codes in South Iredell</u>	2021	2026	% Increase
28115 Mooresville (East)	48,699	54,967	8.78%
28117 Mooresville (West)	44,473	48,377	12.87%
28037 Denver (West of the Lake)	10,663	11,610	12.52%
28166 Troutman	25,773	29,000	8.88%
Combined	129,608	143,954	11.07%