WakeMed

WakeMed Health & Hospitals

3000 New Bern Avenue
Raleigh, North Carolina 27610
919-350-8112

Office of the President & CEO

August 12, 2016

VIA ELECTRONIC MAIL

Christopher Ullrich, MD, Chairman
North Carolina State Health Coordinating Council
c/o Division of Health Service Regulation
Healthcare Planning and Certificate of Need Section
2704 Mail Service Center
Raleigh, NC 27699-2714

Re: Comments Opposing Petition Filed by UNC REX Healthcare for an Adjusted Need Determination for Two Units of Fixed Cardiac Catheterization Equipment in Wake County in the 2017 State Medical Facilities Plan

Dear Dr. Ullrich and Members of the State Health Coordinating Council:

WakeMed appreciates the opportunity to provide comments regarding the petition filed July 28, 2016 by UNC REX Healthcare ("Rex") requesting an adjusted need determination for two additional units of cardiac catheterization equipment for Wake County in the 2017 State Medical Facilities Plan (SMFP). For the reasons outlined below, WakeMed believes this petition should be denied.

Rex provides a number of arguments detailing why its petition should be approved; however, nearly all of these have been raised in previous requests. A significant portion of this latest Rex petition was spent airing its primary cardiology group's grievances with prior senior leadership at WakeMed. These old grievances have no bearing on present-day health planning decisions.

Over the past three years, WakeMed has provided a number of well-documented explanations outlining why Rex's petitions seeking additional cardiac catheterization capacity should not be approved, and the SHCC has heeded WakeMed's reasoning. WakeMed continues to stand by these justifications, as they remain valid. WakeMed supports the Certificate of Need Statute, the planning process that develops the annual State Medical Facilities Plan, and the fixed cardiac catheterization equipment need methodology contained in the SMFP. WakeMed believes that proliferation of health service facilities in areas where surpluses exist creates unnecessary duplication and fosters underuse of existing facilities. Moreover, it is in the public's best interest to promote efficiencies in the delivery of care in health care facilities in order to better contain expenditures.

Fixed Cardiac Catheterization Equipment Surplus in Wake County

Table 9W in the Proposed 2017 SMFP shows a surplus of 53 units of fixed cardiac catheterization equipment statewide. Of the 41 fixed cardiac catheterization equipment service areas in the state, surpluses exist in 28. Twelve service areas can be considered at equilibrium, with planning inventories that matches utilization. Only one service area, Cumberland, has a surplus, which resulted in a need determination in the 2016 SMFP. In the Wake County service area there is a surplus of *four* units, one of the largest surpluses in any single service area. Please see Attachment 1. Based on this data, it is difficult to assert that residents of North Carolina, and Wake County, do not have access to fixed cardiac catheterization equipment.

The annual State Medical Facilities Plan is developed under the governing principles of Safety and Quality, Access, and Value. The Rex petition offers no tangible improvements in these principles, particular Access. Wake County has five acute care hospitals, four of which currently offer cardiac catheterization services. Cardiac catheterization utilization has been declining at three of these facilities. Taking into account the excess capacity that exists for fixed cardiac catheterization equipment, one cannot justly claim that residents of Wake County need improved access for this service. Approval of the Rex petition would push the surplus of fixed cardiac catheterization equipment in Wake County to six units.

Reason for Growth in Cardiac Catheterization Volumes at Rex

On Petition page 4, Rex states that its "remarkable and unique growth" in cardiac catheterization drives the need for an adjusted need determination. This growth is due to *one factor and one factor only*: Wake Heart & Vascular's (now North Carolina Heart and Vascular's) shift of allegiance – and case volume – from WakeMed to Rex. WakeMed has stated in its comments regarding Rex's multiple petitions that increased utilization of Rex's cardiac catheterization equipment was brought on by WHV's migration to Rex. Much was written in the most recent petition regarding WakeMed's and Wake Heart & Vascular's failure to reach an affiliation agreement and the supposition that a "toxic environment" existed between the two parties. However, the details of the proposals, counterproposals and financial details cannot and should not be speculated upon.

WakeMed has made a significant, long-term investment in invasive cardiology services, including the development of nine cardiac catheterization labs at Raleigh Campus and one lab at Cary Hospital, as well as construction of a heart center containing a full complement of diagnostic and interventional cardiac services, including a full-service hotel for patients and their families. The "one site of care" concept for cardiac services which Rex touts on Petition page 27, including cardiovascular testing, cardiac catheterization, and physician offices located under one roof, was pioneered in Wake County at WakeMed Raleigh Campus in the 1990s.

WakeMed built its array of cardiac services to accommodate the practices of Wake County's cardiologists, of which WHV (now NCHV) was and is the largest single group both in terms of membership and procedure volume. As recently as 2011, the 9 cardiac catheterization labs at WakeMed Raleigh Campus were utilized at 90 percent, while Rex's utilization was 70 percent. WHV's affiliation with Rex Hospital beginning in 2011, with its subsequent shift in case volume, is the *single event* that shifted the utilization balance of cardiac catheterization equipment in Wake County.

From the outset of WHV's affiliation with Rex, WakeMed questioned whether Rex could accommodate WHV physicians' volumes with its complement of 4 cardiac catheterization labs, and this prediction has

proven true. Beginning in 2014, Rex began petitioning the SHCC for adjusted need determinations for additional fixed cardiac catheterization equipment in Wake County because it did not have sufficient capacity to accommodate the additional volume of the WHV physicians, particularly as WHV migrated larger proportions of its cardiac catheterization lab volume to Rex.

Discussion of WakeMed's Higher Medicare Reimbursement

The Rex petition, on pages 5-6, points out that WakeMed receives higher Medicare reimbursement than Rex, and by extension, is a more expensive venue than Rex for cardiac catheterization. In reality, all hospitals in Wake County are reimbursed by Medicare at the same base rate. WakeMed Raleigh Campus, in particular, receives additional Medicare reimbursement to compensate for medical education and for Disproportionate Share Hospital (DSH) adjustments – payments to hospitals that provide higher proportions of care to Medicaid and uninsured patients. The inference that these additional payments somehow make WakeMed a more expensive facility is fallacious at best.

Status of Negotiations Regarding Collaboration

At its October 7, 2015 meeting, the SHCC encouraged leaders at WakeMed and Rex to enter into discussions regarding how to more effectively utilize the county's existing cardiac catheterization capacity. On Petition page 19, Rex states that "it is unclear how this collaborative solution can be developed", citing its perceived lack of progress in the negotiations. From WakeMed's perspective, these negotiations are still active. WakeMed has responded to issues raised and questions by Rex regarding emergency call coverages, credentialing, and availability of cardiac catheterization labs for Rex's cardiologists. WakeMed believes that a compromise can be reached, and is still committed to working with Rex to develop a mutually beneficial solution to this issue.

Approval of Rex Petition Would Be Precedent-Setting

WakeMed has stated, on multiple occasions, that approval of Rex's petitions for adjusted need determinations for fixed cardiac catheterization equipment would set a bad precedent for health planning, and continues to stand by this position.

If approved, the Rex petition could set a precedent in the form of inequity with "haves" and "have-nots" – essentially, providers with lower utilization would likely never generate sufficient volume to create a need determination of their own, nor would they be eligible to apply for the need determinations generated by other providers. The obvious by-product of this change would perpetuate underutilization of existing equipment and unnecessary duplication of resources within a service area. While Rex claims there is precedent for approval of its petition, these examples were not for fixed cardiac catheterization equipment. Historically, the SHCC has been unwilling to approve additional fixed cardiac capacity in a service area where a surplus already exists.

In 2011, the SHCC denied a petition filed by Iredell Health System for an adjusted need determination for fixed cardiac catheterization equipment in the Iredell service area in part because two other providers of cardiac catheterization located in Iredell County were in close proximity to Iredell Memorial Hospital, including one within 5 miles, and that local cardiologists could utilize these facilities to perform their cases. Please see Attachment 2 for the Agency Report on this petition. The circumstances in Wake County are similar to those in Iredell County, in that four of the five acute care hospitals in the county offer currently cardiac catheterization services. Given the distribution of cardiology practices and acute care hospitals within Wake County – Rex Hospital is located within 10 road miles and less than 15

minutes' driving time from Duke Raleigh Hospital, WakeMed Cary Hospital, and WakeMed Raleigh Campus -- the notion that patients in need of cardiac catheterization in Wake County cannot receive care in a timely manner is unsupported.

The SHCC has never made an adjusted need determination for fixed cardiac catheterization equipment in a multi-provider service area where a surplus existed, much less one where there is a *surplus of four* units.

Use of Mobile Cardiac Catheterization Lab at Rex

Rex indicated on pages 5-6 that it began contracting with a vendor in 2015 to provide mobile cardiac catheterization services to help alleviate capacity issues in its fixed labs. According to Table 9X in the Proposed 2017 SMFP, the mobile lab is available at Rex 7 days a week, but performed only 26 procedures in 2015 (please see Attachment 3). Rex provided no information in its petition regarding its mobile cardiac catheterization volume in 2016. On Petition page 10, Rex notes that this service costs $16,000 per month. Rex does not describe the criteria that must be met for the mobile cardiac cath lab to be utilized, but one can surmise that the equipment is significantly underutilized if it performs the equivalent of less than one procedure per day. Therefore, the monthly cost to Rex represents expenditures that could be avoided.

Ability to Utilize Other Hospitals for Cardiac Catheterization

On multiple occasions in its petitions, Rex has sidestepped the opinion that its affiliated cardiology physicians could utilize other Wake County hospitals for cardiac catheterization cases, citing duplication of resources, reduction in access, and a reduction in physician coverage at other hospitals.

According to the North Carolina Heart and Vascular web site, in addition to seeing patients at 15 office locations, NCHV physicians have admitting privileges at 7 acute care hospitals. Please see the table below.

Hospitals Where North Carolina Heart and Vascular Physicians Have Admitting Privileges
Source: http://ncheartvascular.com and Proposed 2017 SMFP

Facility	City	Owner/ Manager	Has Cardiac Cath Equipment?	Performs PCI Procedures?
Granville Medical Center	Oxford	Independent	No	N/A
Johnston Health	Clayton	UNC	No	N/A
Johnston Health	Smithfield	UNC	Yes	Yes
UNC REX Healthcare	Raleigh	UNC	Yes	Yes
Sampson Reg. Medical Center	Clinton	Independent	No	N/A
Wayne Memorial Hospital	Goldsboro	UNC	Yes	Yes
Wilson Medical Center	Wilson	Duke/LifePoint	Yes	Yes

Several of the hospitals listed above are affiliated with UNC Health Care System (parent of UNC REX), while others are unaffiliated or under the control of another entity. The alleged barriers that supposedly exist that preclude NCHV physicians from performing cases and/or admitting patients at other Wake County hospitals would seemingly also exist in at least *some* of these facilities.

On Petition page 20, Rex states:

> *"Increasing these physicians' access to cardiac catheterization capacity will in turn broaden the access for these patients across a broad region, including areas where no cardiac catheterization capacity exists or is provided on a diagnostic basis. For example, patients in Franklin, Harnett, and Sampson counties who see North Carolina Heart and Vascular physicians in local offices will have greater access to cardiac catheterization services, which are not available in their home county."*

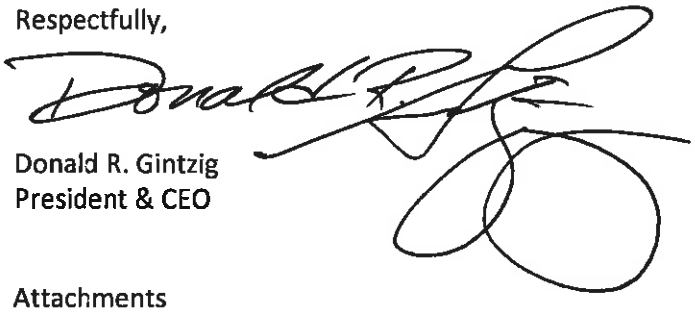
The passage above could easily describe the provision of cardiac catheterizations at Rex, WakeMed Cary Hospital, WakeMed Raleigh Campus, or Duke Raleigh Hospital. Ample capacity exists within the Wake service area that would allow this to occur.

Summary

Approval of the Rex petition would only serve to exacerbate the surplus of fixed cardiac catheterization equipment in Wake County. Developing additional fixed cardiac catheterization labs in Wake County would do nothing to contain costs, improve access, or enhance quality and safety. Further, WakeMed and Rex are currently engaged in discussions that may lead to better utilization of the county's cardiac catheterization equipment. For these reasons, the Rex petition should be denied.

Thank you for your consideration of these comments. If you have questions or require additional information, please contact Stan Taylor at 919-350-8108.

Respectfully,



Donald R. Gintzig
President & CEO

Attachments

Fixed Cardiac Catheterization Equipment Planning Inventory and Need by Service Area				
Sorted in Descending Order by Equipment Surplus				
Source: Table 9W, Proposed 2017 SMFP				
Service Area	**Planning Inventory**	**Machines Needed at 80% Util.**	**Surplus/ (Deficit)**	
Forsyth	13	7	6	
Mecklenburg	17	11	6	
Guilford	12	7	5	
Durham/Caswell	9	5	4	
Pitt/Greene/Hyde/Tyrell	7	3	4	
Wake	17	13	4	
Catawba	5	3	2	
Gaston	4	2	2	
Iredell	3	1	2	
Burke	1	0	1	
Caldwell	1	0	1	
Carteret	1	0	1	
Cleveland	1	0	1	
Craven/Jones/ Pamlico	3	2	1	
Halifax/Northampton	1	0	1	
Haywood	1	0	1	
Henderson	1	0	1	
Lee	1	0	1	
Lenoir	1	0	1	
Nash	2	1	1	
Onslow	1	0	1	
Orange	4	3	1	
Randolph	1	0	1	
Robeson	2	1	1	
Rutherford	1	0	1	
Scotland	1	0	1	
Stanly	1	0	1	
Wilkes	1	0	1	
Alamance	1	1	0	
Buncombe/Graham/ Madison/Yancey	5	5	0	
Cabarrus	2	2	0	
Johnston	1	1	0	
Moore	5	5	0	
New Hanover	5	5	0	
Pasquotank/Camden/ Currituck/Perquimans	1	1	0	
Rowan	1	1	0	
Union	1	1	0	
Watauga	1	1	0	
Wayne	1	1	0	
Wilson	1	1	0	
Cumberland	4	5	(1)	
Total	142	89	53	

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 definition[1], 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.

Iredell County Fixed Cardiac Catheterization Utilization - FY 2010

Hospital	Number of Fixed Cardiac Catheterization Units	Diagnostic Cardiac Procedures	Therapeutic of Interventional (PCTA) Procedures	Diagnostic Equivalent Procedures	Fixed Cardiac Catheterization Equipment Needed at 80% Capacity
IMH	1	617	108	806	0.67
DRMC*	1	153	--	153	0.13
LNRMC**	1	77	--	77	0.06
Iredell County	3	847	108	1036	0.86

*DRMC operates one fixed unit of cardiac catheterization equipment (grandfathered)
**LNRMC operates one shared fixed cardiac catheterization unit

Iredell Health System states its current, July 2010 to June 2011 cardiac catheterization utilization of 1,440 diagnostic equivalents would trigger a county need determination for a second fixed unit, except for underutilization of DRMC's fixed unit and LNRMC's shared fixed unit. However, even at 1,440 diagnostic equivalents, a second fixed unit of cardiac catheterization equipment would not be generated at IMH under the standard SMFP methodology for fixed units (Methodology One), which divides the number of diagnostic equivalent procedures by an 80% capacity of one fixed unit (1,200 procedures). At 80% capacity, IHS would still show a need for only one fixed unit [1,440/1,200 = 1.21]. Furthermore, data provided by IHS to support its petition is from July 2010 to June 30, 2011, which does not correspond to the data used by the "Proposed 2012 SMFP." Rather, the petition data relies on IMH cardiac catheterization utilization performed 9 months after the 2012 SMFP's reporting period, which should be used to determine the need for additional fixed cardiac catheterization equipment in next year's 2013 SMFP.

Iredell Memorial Hospital credits its recent increase in cardiac catheterization procedures on the practice of nine cardiologists, including two interventionist cardiologists who recently joined the medical staff. However, the same physicians also have privileges and practice at DRMC which is located less than five miles from IMH in Statesville. According to comments submitted by DRMC, it began to perform interventional cardiac catheterizations in January 2011, and recently experienced a significant increase in cardiac catheterization procedures. Similar to the increased utilization discussed in IHS's petition, DRMC states its increased utilization occurred after the "Proposed 2012 SMFP" reporting period. Iredell Health System does not discuss the effect of DRMC's new interventional cardiac program on the number of interventional cardiac procedures projected to be performed at IMH, or the combined effect of increased cardiac catheterization utilization at both IMH and DRMC, which could trigger a county need determination for additional fixed cardiac catheterization equipment in the future.

In comments by LNRMC, the hospital discusses the intent behind the SHCC's development of the standard need methodology for shared fixed cardiac catheterization equipment (Methodology Two), which LNRMC states was in response to a petition it submitted. LNRMC states Methodology Two was intended to provide a mechanism for mobile cardiac catheterization service area sites (without a fixed unit of cardiac catheterization equipment), to qualify for a shared fixed unit. In other words, the shared fixed methodology is meant to provide a way for mobile sites to develop or convert to fixed units, "without sacrificing the State standards for high utilization of expensive equipment" [Comments by LNRMC on IHS's petition]. Further, LNRMC states its shared fixed unit is not underutilized, as it performed 77 diagnostic cardiac catheterizations and a total of 2,775 angiography procedures in FY 2010, compared to zero (0) angiography procedures and zero (0) electrophysiology procedures

reported by Iredell Memorial Hospital for its dedicated EP/angiography equipment for the same time period [2011 Hospital Licensure Renewal Application].

The Petitioner states IMH's "under used" EP/angiography laboratory utilization is currently growing (306 procedures) with the addition of a new interventional radiologist and another physician who performs vascular angiography. However, the Petitioner did not discuss how the angiography equipment would provide sufficient capacity for performing both an additional number of diagnostic cardiac catheterization procedures, and an increasing number of angiography procedures.

With regard to access by the medically underserved population, G. Cecil Sheps Center data for Acute General Hospital Admissions by All Payers for FY 2009 showed IMH reported no uninsured patients, while DRMC reported 6.8% and LNRMC reported 3.6%. In regard to Medicaid, IMH ranked 3rd among the three hospitals in the percentage of Medicaid patients served. When outpatient surgery patients are considered, IMH showed no uninsured patients served, and for the number of uninsured emergency room patients, IMH also showed no uninsured patients, while the number of uninsured emergency room patients served at DRMC and LNRMC exceeded 20% at each facility.

The Petitioner does not request a revision of either Methodology One or Methodology Two, because IHS does not find the results of the methodologies' respective applications to be "inappropriate." Instead, IHS seeks to "conservatively" expand cardiac catheterization capacity at its own facility through means other than the standard need determination for fixed cardiac catheterization equipment. However, this request would benefit only one of three facilities in the Iredell County service area.

Further, approval of this request would not prevent the "adverse effect on providers and consumers" IHS claims would occur if its petition is denied. Specifically, the Petitioner states that before IMH started performing therapeutic cardiac catheterization procedures in 2008, "cardiac catheterization use in the county was low because referring physicians did not want to subject their patients to the risk of being transferred out mid-procedure for a therapeutic intervention. Nor did they want to subject patients to the extra costs associated with two hospital admissions for cardiac catheterization, one for diagnosis and another for interventional therapy. Consequently, most of Iredell Health System's primary service area residents traveled an hour or more to Winston-Salem, Charlotte, or Hickory, or they deferred care. High heart attack rates in the area testify to the amount of deferred care." However, even if IMH's existing EP/angiography cardiac catheterization laboratory was approved for use as a shared fixed cardiac catheterization laboratory, it would perform only diagnostic cardiac catheterization procedures, because CON Rule 10A NCAC 14C .1604(a) would prevent therapeutic procedures from being performed without open heart services at the hospital. Therefore, if a patient undergoing a diagnostic cardiac catheterization procedure on IMH's shared fixed equipment needed a therapeutic intervention "mid-procedure," the patient would still have to be transferred out or wait until IMH's fixed cardiac catheterization equipment was available.

Agency Recommendation:

In seeking an adjusted need determination, the rule of thumb is for a petitioner to provide compelling evidence that "unique or special attributes" of a service area or facility exist that differ from those determined by the annual SMFP's standard need methodology. The standard methodology for "fixed cardiac catheterization equipment" (Methodology One) shows no need for additional equipment in Iredell County. Methodology Two, for "shared fixed cardiac catheterization equipment," is based on circumstances that do not exist in Iredell County, and also shows no need for additional

equipment. The Petitioner bases its need on IMH's recent cardiac catheterization utilization, which covers a time span for which comparable data from other providers is not yet available, thereby limiting an analysis of the true impact on the total population of Iredell County. While a petitioner may request an adjustment to either of the two standard need determination methodologies, Iredell Health System's requested need adjustment for a shared fixed cardiac catheterization laboratory is contrary to Methodology Two and is unsupported by reasonable data. The basic question for the SMFP each year is whether there is sufficient capacity in a given service area to meet the needs of service area residents. Based on utilization data from the standard reporting period for existing fixed cardiac catheterization equipment in Iredell County, the current equipment capacity is sufficient. As IMH's more recent cardiac catheterization utilization may fluctuate over time, it should be compared to data from all providers for the same time period in future SMFPs. Therefore, based on the above analysis, and in support of the standard methodologies for cardiac catheterization equipment, the Agency recommends denial of the petition.

Table 9X: Mobile Cardiac Catheterization Capacity and Volume

Facility	Days/Week On Site	Procedure Capacity	Procedures Reported in 2015
Novant Health Brunswick Medical Center	0.50	150	--
Central Carolina Hospital	1.00	300	--
Columbus Regional Medical Center	0.50	150	37
Community Memorial Health Center	1.00	300	--
FirstHealth Richmond Memorial Hospital	1.00	300	21
Maria Parham Medical Center	1.00	300	17
Northern Hospital of Surry County	1.00	300	--
Novant Health Huntersville Medical Center	1.00	300	--
Novant Health Thomasville Medical Center	1.00	300	156
Rex Hospital	7.00	2,100	26
N.C. Total: 10	15.00	4,500	257

7. **Specialized Cardiac Services** (for questions, call 855-3865 [Healthcare Planning])

(a) Cardiac Catheterization	Diagnostic Cardiac Catheterization ICD-9 37.21, 37.22, 37.23, 37.25 -	Interventional Cardiac Catheterization ICD-9 00.66, 99.10, 36.06, 36.07, 36.09; 35.52, 35.71, 35.96
1. Number of Units of Fixed Equipment	4	
2. Number of Procedures* Performed in Fixed Units on Patients Age 14 and younger	0	0
3. Number of Procedures* Performed in Fixed Units on Patients Age 15 and older	3,332	2,058
4. Number of Procedures* Performed in Mobile Units	18	8
	Electro-physiology ICD-9 37.26, 37.27, 37.34, 37.70, 37.71, 37.72, 37.73, 37.74, 37.75, 37.76, 37.77, 37.79, 37.80, 37.81, 37.82, 37.83, 37.85, 37.86, 37.87, 37.89, 37.94, 37.95, 37.96, 37.97, 37.98, 37.99, 00.50, 00.51, 00.52, 00.53, 00.54	
5. Number of Units of Fixed Equipment	2	
6. Number of Procedures on Dedicated EP Equipment	1,290	

*A **procedure** is defined to be one visit or trip by a patient to a catheterization laboratory for a single or multiple catheterizations. Count each visit once, regardless of the number of diagnostic, interventional, and/or EP catheterizations performed within that visit.

Name of Mobile Vendor: First Health Cardiology Services

Number of 8-hour days per week the mobile unit is onsite: 7 8-hour days per week.
(Examples: Monday through Friday for 8 hours per day is 5 8-hour days per week. Monday, Wednesday, & Friday for 4 hours per day is 1.5 8-hour days per week)

(b) Open Heart Surgery	Number of Machines/Procedures
1. Number of Heart-Lung Bypass Machines	3
2. Total Annual Number of Open Heart Surgery Procedures Utilizing Heart-Lung Bypass Machine	460
3. Total Annual Number of Open Heart Surgery Procedures done without utilizing a Heart-Lung Bypass Machine	10
4. Total Open Heart Surgery Procedures (2. + 3.)	470
Procedures on Patients Age 14 and younger	
5. **Of total in #2,** Number of Procedures on Patients Age 14 & younger	0
6. **Of total in #3,** Number of Procedures on Patients Age 14 & younger	0