Comment on Petition for Cardiac Catheterization Equipment in Iredell County
2012 State Medical Facilities Plan

SUBMITTED BY:

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Davis Regional Medical Center (DRMC) is submitting this letter in opposition to a petition filed by Iredell Health System (IHS) on August 1, 2011. DRMC believes that there are several facts that were not presented in the petition filed by Iredell Health System (IHS) that are relevant to the issue at hand and which should be considered by the SHCC. These are summarized briefly in the following bullet points, then explained further in the body of this document.

- IHS' petition attempts to develop a need determination for which only it can be approved.
- The petition projects the continuation of a growth trend which is based on one-time events.
- The petitioner fails to consider other alternatives or address the need for angiography capacity in the service area.
- IHS completely ignores the capabilities of DRMC, which is located less than four miles away.
- IHS' petition effectively changes the methodology for shared fixed cardiac catheterization equipment.

Each of these issues is discussed below.

Limited Need Determination

The first major concern with the IHS petition is that it clearly attempts to have a need determination for which only it can be approved. While the SHCC has always been cautious not to endorse a single provider but to let the CON process determine which applicant, if any, should be approved, the language in the IHS petition, if adopted, would allow only it to be the only approvable applicant. Specifically, the language on page 1 of the petition states that the need should be allocated to a provider of both diagnostic and interventional cardiac catheterization cases. This limits the approved providers from the three existing to only two: IHS and DRMC. More directly, the language found under the table on page 1 states that the applicant must use existing equipment and show that it has performed therapeutic catheterization for the past 12 months. As IHS discusses in its petition, it has an existing unit of electrophysiology equipment which it intends to use for cardiac cath, if it can obtain CON approval. Further, although DRMC began providing interventional caths in January 2011 and thus will have been providing therapeutic catheterizations for the past 12 months before the *Proposed 2012 SMFP* is enacted, it is clear that IHS is attempting to prevent a provider with a newer interventional program from being approved. DRMC believes these efforts are indicative of the real motivation behind the IHS

petition: to have an limited allocation in the *2012 SMFP* for which only it can apply and be approved, effectively bypassing a competitive CON process. On this basis alone, DRMC believes the SHCC should deny the petition, knowing that it is not about providing better care or improving access, but about preventing competitors from being able to compete for a CON.

Unsupported Growth Trend

As members of the SHCC may recall from previous petitions for special need determinations, many request that the need be generated early, based on utilization that has occurred since the data for the pending *SMFP* was generated. While there certainly are special circumstances that merit additional consideration, the SHCC has often denied similar petitions, following the Agency's recommendation to wait for the data to drive a need determination in the future based on the standard methodology. For example, in 2002, Forsyth Medical Center filed a petition for a special need adjustment for an additional unit of cardiac catheterization equipment in the *2003 SMFP*, based on "recent, measurable, and sustainable change in practice patterns..." that had "given rise to extraordinary growth in diagnostic and interventional cardiac catheterizations." Data provided by the petitioner included annualized data for the first nine months of the Federal Fiscal Year and requested a need determination based on "more current" data than what was present in the *Draft 2003 SMFP*. The Agency report on the petition, provided for reference in Attachment 1, questioned the use of "current year data" that are not subject to the same review process as data provided in the Hospital License Renewal Applications. The Agency states in its report that "the Acute Care Committee [which was, at the time, responsible for cardiac catheterization in the *SMFP*] has recently witnessed examples of petitioners both 'achieving' and 'failing to achieve' projected utilization levels based on short-term trends. The Agency encourages caution in allocating permanent resources based on partial year data." Please see Attachment 1 for the Agency report from which these quotes originate.

It should be noted that the circumstances of the Forsyth petition closely mirror those of the IHS petition. On the first page of the Agency report, the analysis finds fault with Forsyth's approach, which looked at its own capacity, but "discounts capacity that has already been allocated in the methodology and capacity at Baptist Medical Center...application of the standard methodology "independently" to the figures reported by Forsyth Medical Center would generate a need projections for two additional units at that location, **but the additional capacity at Baptist ameliorates a portion of the need within Forsyth County**." [emphasis added] Through its analysis, the Agency was pointing out that the capacity at the other hospital in the county should be considered, and that the methodology is not a provider-based methodology. Unlike Statesville, where the cardiologists all have privileges at both hospitals (as discussed in more detail below), the medical staffs in Winston-Salem are much more separate; yet the Agency still believed that the capacity at Baptist was important to consider in its analysis. This analysis was accepted by the SHCC, which ultimately denied the petition and let the standard methodology be applied. It should also be noted that in the same year, petitions from Albemarle Hospital and Randolph Hospital for cardiac catheterization units were also considered. The only approved petition for cardiac catheterization that year was for shared fixed equipment from a single-hospital county with no existing fixed cardiac catheterization equipment: Randolph Hospital. These are just a few examples that document the rationale that has previously been used by the SHCC in cardiac catheterization allocations. DRMC believes that the same rationale, applied to the IHS petition, would result in its denial.

The SHCC should also be aware that, like the Agency report referenced above, the IHS projections of utilization for its cardiac catheterization service should be considered just that—projections. What is not explained in the petition is that the trend that IHS projects to continue indefinitely is not based on

population growth, use rate increase or any other ongoing phenomenon. Rather, the increase is based primarily on the addition of two interventional cardiologists in Statesville within the past year. These cardiologists were needed in the community, and have resulted in increased cardiology volume, inpatient and outpatient, at both IHS and DRMC. DRMC believes that the residents of Statesville and Iredell County are fortunate to have two hospitals with both diagnostic and interventional cardiac catheterization capabilities. However, it does not believe that the growth in cardiac cath cases in the community due to a one-time event should be considered as the basis of a long-term trend, such as the recruitment of two cardiologists that has allowed interventional patients to remain in the community for care. Iredell County's population is growing, but not as fast as many other areas of the state, and not enough to be the sole driver of the growth projected by IHS. In addition, as the SHCC is well aware from a review of historical data in the *SMFP*, total diagnostic cardiac catheterization volume has not increased in the state since 2005, and total interventional cardiac catheterization volume has been flat for the same time period, even while tremendous population growth has been occurring. While certain areas of the state and some providers have experienced growth during this timeframe, DRMC does not believe that the trend projected by IHS should be reasonably expected to continue, given its basis in the recent recruitment of these two interventional cardiologists. It is simply incredible to believe that IHS has projected its cardiac catheterization volume to grow nearly eight-fold—from 108 cases in 2010 to 854 interventional cases in 2015—as it has done in Attachment 2 of its petition. Although the petition does not sum the total volume by type, the table below shows that IHS is petitioning for additional equipment based on its belief that it will achieve 854 interventional cases and a total of 3,548 diagnostic equivalents by 2015, as shown below.

IHS Projected Cardiac Catheterization Volume from Attachment 2

	Jul-14	Aug-14	Sep-14	Oct-14	Nov-14	Dec-14	Jan-15	Feb-15	Mar-15	Apr-15	May-15	Jun-15	Total
Diagnostic Cath	160	162	164	166	168	170	172	174	176	178	180	182	**2,052**
Interventional Cath	66	67	68	69	70	71	72	73	73	74	75	76	**854**
											Annual Dx Equivalents		**3,548**

As compared to its current interventional cardiac catheterization (PTCA) volume from Table 9Q in the *Proposed 2012 SMFP*, which places IHS near the bottom of providers in terms of volume, this growth to 854 interventional cases would make IHS one of the highest volume providers in the state, higher even than CarolinaEast, Gaston Memorial, NC Baptist, CMC-NorthEast and UNC Hospitals, all of which have long-standing open heart surgery and interventional cardiology programs. DRMC believes that this is clear evidence of the unreasonableness of IHS' petition.

Failure to Consider Alternatives

DRMC believes that the petition should also denied because IHS failed to address certain glaring alternatives. Most obvious is the ability to develop angiography equipment without the need for an additional regulated cardiac catheterization unit. The petitioner requests a shared unit of equipment that can do both cardiac catheterization as well as angiography cases; however, it fails to address why the SHCC should allocate equipment to be used for angiography cases. In fact, based on its 2011 Hospital License Renewal Application, IHS did not perform any angiography cases in 2010, as shown in Attachment 2. The basis for the SHCC to allocate equipment for this purpose is therefore unclear. Even though IHS discusses the physicians, including radiologists and a cardiologist, that are expanding their use of angiography, IHS can acquire additional units of angiography equipment or electrophysiology

equipment without any action or need determination from the SHCC. If IHS needs additional capacity for angiography or electrophysiology, it would be more prudent for it to add that unregulated equipment, than for the SHCC to allocate additional cardiac catheterization equipment to also be used for other types of cases.

IHS Ignores DRMC's Capacity

IHS failed to address other key facts in its petition regarding DRMC. Unlike other communities in which cardiologists may only practice at one provider, **all of the cardiologists in Statesville, including the two interventional cardiologists, have privileges and practice at both DRMC and IHS**. As such, the cardiac catheterization capacity at DRMC is available to all of the cardiologists. Moreover, none of the cardiologists is employed by either hospital; thus, physician employment and alignment issues do not present a constraint on the availability of capacity at both hospitals. The petition states that DRMC's utilization is lower than IHS', implying that local cardiologists utilize IHS to a greater degree. In reality, however, all of the cardiologists use both facilities, and DRMC's utilization, like IHS', is increasing. In the past, DRMC did not provide interventional cardiac catheterization; however, it recently began offering interventional services (as of January 2011) and its volume has increased as well. In fact, although IHS states that it is in the process of upgrading its equipment, DRMC has already replaced its equipment to provide state-of-the-art care. During the replacement of its fixed equipment, DRMC used a mobile provider, which did reduce its utilization during the time in which its fixed equipment was unavailable. Now that the new equipment is in place, DRMC's volume has been increasing substantially. Using the same timeframe as the IHS petition, July through June, for the year ending June 2011, DRMC's diagnostic-equivalent cardiac catheterization volume increased by over 42 percent, and one-half of that year was before any interventional cases were performed. Based on these facts, DRMC believes its volume will increase by more than 50 percent by the end of the year, compared to the previous year.

These details compel the consideration of two facts. First, contrary to IHS' assertions, DRMC is not a "chronically underutilized" facility. The use of a mobile service during equipment replacement, combined with the development of an interventional service indicate that DRMC's utilization can be expected to be higher in the future. Further, it is inherently improper for IHS to compare its 2011 data to DRMC's 2010 data, particularly when it is well-aware of the recent development of DRMC's interventional program. As DRMC's volume increases, along with that of other providers in the county, the existing need methodology can determine when additional units of equipment are rationally needed. A second fact that should be considered is that while DRMC's volume is increasing, there is still additional capacity that can be utilized by the same cardiologists who practice at IHS, all of whom have privileges and practice at DRMC as well. DRMC will admit and treat any patient of any of the cardiologists, just like IHS. Although the petition discusses the quality of the cardiac catheterization service at IHS, DRMC believes its program offers an equivalent level of quality. Specifically,

- DRMC's cardiac catheterization program meets or exceeds all the Practice Guidelines set by the American Heart Association Task force and the American College of Cardiology for the Management of Patients with ST–Elevation Myocardial Infarction (STEMI) throughout its hospital.
- DRMC has two board-certified cardiologists trained in the diagnosis and follow up treatment and rehabilitation plan for patients.
- DRMC provides standby emergency transport and open heart back up capacity at tertiary care institutions within 30 minutes travel time.

- DRMC has a nursing and cardiac catheterization technology staff who are dedicated to only the cardiac catheterization lab.
- DRMC conducts regular staff training and protocol development that incorporates new cardiac research findings.
- DRMC's program attains top scores on the CMS Medicare heart attack care quality index. DRMC has had three consecutive years in which it achieved a score of 100%.
- DRMC has obtained Chest Pain accreditation as of March 2011. DRMC was the first hospital to accomplish this in Iredell County.
- DRMC has begun the process of refining its program to sustain a door to revascularization time for STEMI.

Clearly, the cardiac catheterization service at DRMC is of as high or higher quality than that offered by IHS. The local cardiologists support the service at DRMC, as evidenced by its increasing utilization. DRMC is located less than four miles from IHS, and there are no geographic or other barriers that prevent patients or physicians from accessing either facility. In short, there are no compelling reasons for a "special need" to warrant an allocation of additional cardiac catheterization equipment in Iredell County at this time.

The Petition Addresses a Change in Methodology

Finally, the IHS petition, though presented as a special need adjustment, is in reality a methodology change petition and should therefore be considered in the Spring petition cycle, if at all. The type of equipment requested by the petition, shared fixed cardiac cath equipment, was designated only for providers without fixed equipment, not to augment the capacity of existing fixed providers. Methodology 2 of the cardiac catheterization section of Chapter 9 in the *Proposed 2012 SMFP* only contemplates the use of shared fixed equipment in service areas in which a mobile provider has reached a certain volume threshold, and in which no other fixed or mobile equipment is located. To allocate shared fixed equipment based on this petition would be to change the methodology for shared fixed equipment—to allow it to serve a different purpose. Not only would approval of the petition result in a special need in Iredell County, but it would effectively result in the use of shared fixed equipment as an adjunct to capacity for fixed providers that reach a certain threshold, as other providers would undoubtedly pursue similar petitions in the future.

Approval of the petition would also change the cardiac cath methodology from a county-based need determination to a provider-based need. While a provider-driven need methodology is used for planning for some services in the *SMFP*, most of the technology and equipment methodologies require the entire county to reach a certain threshold before a need is generated, including cardiac catheterization. DRMC is also affected by these types of methodologies. For example, DRMC is the only hospital in Iredell County without a linear accelerator. As a result, it is unable to provide radiation oncology services to its patients. IHS, however, has two linear accelerators which are, together, performing fewer procedures than the threshold for one linear accelerator in the need methodology. Using the IHS standard, these could be considered "chronically underutilized," and their low utilization prevents the generation of a need for an additional linac, for which DRMC could apply to better serve its patients. Similar circumstances in other service areas undoubtedly prevent providers from offering additional services to their patients; a central part of the planning process is limiting the allocation of additional equipment when existing equipment is not at capacity and when existing providers are fully capable of meeting the needs of the patients, as DRMC and its cardiologists clearly are regarding cardiac catheterization.

If the SHCC wishes to consider amending the cardiac cath methodology, whether to lower the threshold to generated need for cardiac cath, to change to a provider-driven need methodology or to change the function of shared fixed cath equipment as IHS proposes, it certainly may do so; however, DRMC believes that such a change should be considered in the Spring to allow more careful consideration of the implications and unintended consequences before taking action.

Summary

In conclusion, DRMC understands the growth of cardiac cath utilization in Statesville. Like IHS, DRMC has also benefited from the additional interventional cardiologists that have recently begun to practice at the two hospitals. In the long term, there may be a need for additional cardiac cath equipment in the county, if volume at the facilities continues to increase. DRMC does not believe that the utilization at IHS will grow to the degree it projects in its petition, and it supports the rationale that has been used by the SHCC in denying other similar petitions in the past. When the demand truly exists for additional capacity, DRMC believes that the need determination should be available to any hospital in the county and should not be artificially limited to ensure only one provider can be approved.

Attachment 1

Agency Report
regarding the
Petition from Forsyth Medical Center
requesting
One Additional Unit of Fixed Cardiac Catheterization Equipment

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Petitioner

Forsyth Medical Center
Jeff Lindsay, Executive Director, Cardiac Services
Barbara Freedy, Business Planning
3333 Silas Creek Parkway
Winston-Salem, NC 27103

Request

The petitioner requests "...one additional fixed cardiac catheterization machine, for a total of two needed in Forsyth County in the 2003 SMFP."

Background Information

Need for additional Fixed Cardiac Catheterization Equipment is addressed in Chapter 8 of the Draft 2003 State Medical Facilities Plan. The Plan defines "...capacity of an item of cardiac catheterization or cardiac angioplasty equipment as 1,500 diagnostic-equivalent procedures per year, with the trigger of need at 80% of capacity" or 1,200 procedures. *(Note: "Weighting" for the "diagnostic-equivalent procedures" is identified on page 63 of the Draft 2003 Plan.)*

The standard methodology used to project need for additional units of fixed cardiac catheterization equipment compares a current inventory of operational and pending fixed cardiac catheterization units to the projected number of units needed based on a "weighted total" number of procedures reported on the previous year's license renewal applications. Utilization in excess of 1,200 procedures counts toward the need for additional equipment in a county. Because "rounding" is only allowed when the projected need reaches 0.5 additional units, in effect a county must show 600 procedures above the basic 1,200 procedures *(i.e., 50% above the "trigger")* before additional units of fixed cardiac catheterization equipment are allocated.

Analysis/Implications

The petition requests one additional unit of fixed cardiac catheterization equipment based on "...recent, measurable, and sustainable change in practice patterns..." that have "...given rise to extraordinary growth in diagnostic and interventional cardiac catheterizations." The petition presents data for the first nine months of the Federal Fiscal Year and annualizes projected totals for the remaining period. It prorates the number of cardiac catheterization machines "in operation" during past reporting periods, rather than basing projected need on the licensed plus pending units. This may be a more precise approach for stating utilization of the equipment at Forsyth Medical Center, but it

discounts capacity that has already been allocated in the methodology and capacity at Baptist Medical Center. As shown in Table 8I of the Draft 2003 Plan, application of the standard methodology "independently" to the figures reported by Forsyth Medical Center would generate a need projection for two additional units at that location, but the additional capacity at Baptist ameliorates a portion of the need within Forsyth County. *(NOTE: In prorating the number of units of equipment in operation, the footnote on page 3 of the petition indicates that "FMC's fourth cath lab became operational in 7/2001. In a progress report to the Certificate of Need Section dated February 11, 2002, FMC indicated March/2001 as the date for "Operation of equipment-service available.")*

The petition does not challenge application of the methodology in the Draft 2003 Plan, which already indicates a need for one additional unit of fixed cardiac catheterization equipment in Forsyth County. It seeks an additional opportunity based on "more current" data from Forsyth Medical Center, which would normally be the basis for next year's Draft 2004 Plan.

At least two important factors must be considered: the accuracy of the data and the use of "current year data." Data from the annual license renewal applications are self-reported and not verified by the Medical Facilities Planning Section. The data reported for October 1, 2002 through September 30, 2001 have been compared to data compiled by the Cecil B. Sheps Center for Health Services Research at UNC-Chapel Hill (Sheps Center). The Sheps Center reports are generated from North Carolina Hospital Discharge and Ambulatory Surgery Databases as reported through *Solucient*. That comparison follows:

Comparison of Data: 2002 Hospital License Renewals to Sheps Report

Forsyth Medical Center

October 1, 2000 through September 30, 2001

	'02 Lic Ren.	Sheps Rpt.	Difference
Inpatient Card. Cath.		2679	
Outpatient Card. Cath.		1232	
Total:	**4046**	**3911**	**-135**
Inpatient Angioplasty		1308	
Outpatient Angioplasty		127	
Total:	**1787**	**1435**	**-352**
"Weighted Totals":	**7173.25**	**6422.25**	**-751**

The decreased totals for FFY2001 from the Sheps Center report appears to indicate less projected need by Forsyth Medical Center than that shown in the Draft 2003 Plan.

Another key issue in consideration of this request is the use of current year data, annualized for the remainder of FFY 2002 and projected forward for FFY 2003. While that approach has been used previously, the Acute Care Committee has recently

witnessed examples of petitioners both "achieving" and "failing to achieve" projected utilization levels based on short-term trends. The Agency encourages caution in allocating permanent resources based on partial year data.

In addition, the petition makes several references to "...obtaining a 5th cath lab pursuant to the Replacement Equipment Exemption Request filed in May, 2002." At present, the State Medical Facilities Plan acknowledges only four authorized units of cardiac catheterization equipment at Forsyth Medical Center. If it is pursuing a 5th piece of cardiac catheterization equipment outside of the Plan, and has the opportunity to apply for an additional unit pursuant to the 2003 Plan, it should have sufficient capacity to bridge the period between the 2003 and 2004 State Medical Facilities Plans.

Agency Recommendation

The Agency recommends that the request for an additional unit of cardiac catheterization equipment in Forsyth County, beyond the single unit already identified in the Draft 2003 Plan, be denied.

Attachment 2

Scans Performed on Mobile CT Scanners *(Multiply # scans by Conversion Factor to get HECT Units)*

	Type of CT Scan	# of Scans		Conversion Factor		HECT Units
1	Head without contrast		X	1.00	=	
2	Head with contrast		X	1.25	=	
3	Head without and with contrast		X	1.75	=	
4	Body without contrast		X	1.50	=	
5	Body with contrast		X	1.75	=	
6	Body without contrast and with contrast		X	2.75	=	
7	Biopsy in addition to body scan with or without contrast		X	2.75	=	
8	Abscess drainage in addition to body scan with or without contrast		X	4.00	=	

10d. Other Imaging Equipment

	Number of Units	Number of Procedures		
		Inpatient	Outpatient	Total
Dedicated Fixed PET Scanner	1	59	377	436
Mobile PET Scanner	0			
PET pursuant to Policy AC-3	0			
Other Human Research PET Scanner	0			
Ultrasound equipment	2	1,925	5,155	7,080
Mammography equipment	2	99	8,347	8,446
Bone Density Equipment	1		942	942
Fixed X-ray Equipment (excluding fluoroscopic)	3	8,162	26,413	34,575
Fixed Fluoroscopic X-ray Equipment	4	533	1,780	2,313
Special Procedures/ Angiography Equipment (neuro & vascular, but not including cardiac cath.)	1	0	0	0
Coincidence Camera	0			
Mobile Coincidence Camera Vendor:	0			
SPECT	2	795	1,425	2,220
Mobile SPECT Vendor:	0			
Gamma Camera	0			
Mobile Gamma Camera Vendor:	0			

* PET **procedure** means a single discrete study of one patient involving one or more PET scans. PET **scan** means an image-scanning sequence derived from a single administration of a PET radiopharmaceutical, equated with a single injection of the tracer. One or more PET scans comprise a PET procedure. **The number of PET procedures in this table should match the number of patients reported on the PET Patient Origin Table on page 27.**

10e. Lithotripsy

	Number of Units	Number of Procedures		
		Inpatient	Outpatient	Total
Fixed				
Mobile	1		111	111

Lithotripsy Vendor/Owner:
PIEDMONT STONE