



COMMENT

Comment on Petition Regarding Cardiac Catheterization Equipment Adjusted Need Determination in Iredell County for the 2012 State Medical Facilities Plan

COMMENTER

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In response to a petition filed by Iredell Health System (IHS) on August 1, 2011, Lake Norman Regional Medical Center (LNRMC) is submitting this letter in opposition to the petition. The letter will provide relevant background information and analysis that should be an essential part of the State Health Coordinating Council's decision-making process. After reflecting on all the relevant information, it should be clear that the proposed petition should not be approved.

BACKGROUND AND HISTORY

As a request for an adjusted need determination for a shared fixed cardiac catheterization laboratory, LNRMC believes it is important to remember the development of the shared fixed cardiac catheterization methodology that is currently in the *SMFP*. Prior to 1993, cardiac catheterization equipment was not "per se" reviewable by the CON Statute. After the revisions to the law in 1993, cardiac catheterization equipment became reviewable regardless of capital cost, and the SHCC eventually developed a methodology for allocating additional units of equipment.

In 2000, the methodology for additional units of fixed equipment was similar to the methodology today, in which an 80 percent utilization standard was used to determine need for additional units in the county. What was not present in 2000 was the methodology for *shared* fixed cardiac catheterization equipment. Based on its belief in the need for such an addition to the cardiac catheterization methodology, Lake Norman Regional Medical Center presented a petition to the SHCC in the Spring of 2000 to develop such a methodology. The petition, included as Attachment 1 for reference, was approved by the SHCC and incorporated into the methodology beginning with the *2001 SMFP*. The language of the petition provides evidence of the intent of the petition that led to the development of a methodology for shared fixed equipment. Most notable among the various points raised by the petition are three key factors. First, the petition was presented as a method by which existing mobile sites could convert to fixed units, even though the volume of cardiac catheterizations alone would likely not support a

fixed unit. Second, the petition urged the SHCC to only allocate shared fixed equipment when no other fixed or mobile cardiac catheterization equipment is provided within the same hospital service system. Finally, and most importantly, the reason for developing the shared fixed methodology was the lack of any methodology by which mobile sites could ever develop or “convert” to fixed units; in other words, the methodology was written because mobile sites, at that time, had no way of converting to a fixed unit (as was contemplated in the MRI methodology at the time), even if the volume of the site was significant. All of these factors exist in the current methodology for cardiac catheterization equipment, as described by Methodology 2 in the cardiac catheterization section of Chapter 9 of the *Proposed 2012 SMFP*. As such, they are key components of the rationale behind the methodology that has existed for more than a decade and none of which exist at Iredell Health System.

ISSUES WITH IHS’ PETITION

In stark contrast to the thought process that created and that has maintained the shared fixed cardiac catheterization, or “Methodology 2” in the *SMFP*, IHS’ petition seeks to have a shared fixed unit allocated based on its facility need, even though it already has a fixed cardiac catheterization unit and when two other units of equipment exist in the service area, including a second unit in Statesville, only a few miles from IHS. In addition, unlike LNRMC when it filed its petition in 2000, there is a methodology that applies to IHS as an existing operator of fixed cardiac catheterization equipment that can allocate additional equipment in the future when the need is warranted by utilization.

As presented in LNRMC’s petition from 2000, there were, and still are, four legitimate reasons for the shared fixed methodology. They include the following key issues (as copied from page 3 of the LNRMC petition):

1. Provide a better alternative for sites that have no opportunity of ever acquiring full-time, fixed-based cardiac catheterization equipment within the service system, based on the current need methodology.
2. Provide another alternative for providers who have very limited choices among mobile cardiac catheterization vendors in North Carolina.
3. Provide another alternative for those providers who have little negotiating power to influence reasonable costs and quality service for patients, because of the limited number of choices for mobile vendors.
4. Promote more efficient utilization for providers with existing resources that could be used to improve patient care and patient convenience, without sacrificing the State’s standards for high utilization of expensive equipment.

Approval of the current IHS petition would meet none of these criteria that were established as part of the shared fixed methodology. In fact, the opposite is true:

1. IHS already has fixed cardiac catheterization equipment and the methodology provides an opportunity for development of additional equipment in the future.
2. IHS, as a fixed provider, does not have to rely solely on a limited number of mobile vendors, but can instead rely on its own staff and equipment.

3. IHS, as a fixed provider, is not limited by the mobile vendors and has control of its own costs and quality of care.
4. Rather than waiting for efficient utilization of existing resources, IHS is demanding that additional expensive equipment be allocated, regardless of the existing capacity on other units of equipment in the county.

Clearly, the IHS petition is not in keeping with the rationale behind the methodology for shared fixed cardiac catheterization equipment. The methodology for fixed cardiac catheterization equipment requires a certain utilization in the county before additional equipment is allocated. This prevents unnecessary duplication of existing health services and reduces unnecessary expenditures, a central part of the CON statute. Approval of this petition would essentially be the approval of a facility-specific methodology, which may exist for other services, such as acute care beds, but which has not existed for cardiac catheterization equipment since the inception of the methodology. Approval of the IHS petition would represent a significant departure from the methodology, allowing existing fixed providers to acquire additional units of fixed equipment that would, by definition, perform fewer cardiac catheterization procedures than would be required by other units owned by fixed providers.

OTHER CONCERNS

Utilization

As the only cardiac catheterization provider in Iredell County utilizing a shared fixed unit of equipment, LNRMC also wishes to address other issues underlying the IHS petition. In particular, LNRMC takes exception with the language in the petition which references its cardiac catheterization equipment as “chronically underutilized.” While that language is used in certain *SMFP* methodologies, specifically the operating room methodology, it is not contained within the cardiac catheterization methodology and should therefore not be used as the basis of determining need for additional units of equipment, either shared or dedicated cardiac catheterization units. Moreover, the need determination under which LNRMC applied for and was granted a certificate of need for its shared fixed unit specifically contemplated the fact that it would not be as well utilized as other pieces of equipment based on the number of cardiac catheterization cases it performs, because it would be shared between cardiac catheterization and angiography cases. The case volume presented in the *Proposed 2012 SMFP* is based on the volume reported on the 2011 Hospital License Renewal Applications (HLRA). The HLRA does not request angiography volume, but specifically only asks for cases performed with ICD-9 codes associated with cardiac catheterization, as shown in Attachment 2. In fact, the page that does request the volume for the other imaging equipment, including neuro and vascular angiography (also provided in Attachment 2), shows that LNRMC provided over 2,775 angiography procedures in 2010—hardly the “chronic underutilization” as characterized by IHS. Clearly, LNRMC is utilizing its equipment as intended and as approved by its certificate of need, for both cardiac catheterization cases and angiography procedures. In contrast, Iredell Memorial Hospital interestingly lists zero neuro and vascular angiography cases on its HLRA, shown in Attachment 3, even though its petition clearly states that it performs angiography procedures as well. In fact, as also shown in Attachment 3, Iredell Memorial Hospital lists zero electrophysiology procedures, even though its petition references its electrophysiology cases on page 5 of its petition.

Interventional Cases

LNRMC's other concern is that IHS states that much of its growth has occurred recently, since the data reported on its 2011 HLRA, and that a significant portion of that growth has occurred in interventional cases. Because IHS acquired its existing cardiac catheterization equipment prior to the CON statute change in 1993, it is able to provide interventional cases, which not only are counted as 1.75 diagnostic-equivalent cases in the methodology, but also draw a higher number of patient than diagnostic-only facilities. If LNRMC were also able to provide interventional cases at its facility, it is confident that its cardiac catheterization numbers would be higher as well. LNRMC does not believe that it should be penalized or considered "chronically underutilized" on the basis of the timing of its acquisition of cardiac catheterization equipment, which prevents it from being able to use its equipment for interventional cases.

SUMMARY

As the provider who successfully petition for the development of the shared fixed cardiac catheterization methodology in 2000, LNRMC is very familiar with its purpose and usefulness. The IHS petition is clearly not in keeping with the purpose of shared fixed equipment, but seeks to allow the allocation of cardiac catheterization equipment which will not be used for as many cardiac catheterization cases as the current equipment in Iredell County must perform. Approval of the petition will open the door to other providers across the state petitioning for similar need determinations, which will effectively permanently lower the required threshold for generating additional need determinations for cardiac catheterization equipment. LNRMC urges the SHCC to uphold the current methodology for shared fixed cardiac catheterization equipment by denying the petition.

Attachment 1

PETITION

North Carolina State Health Coordinating Council

Submitted to

Michael C. Tarwater, Chair
Acute Care Committee
c/o Medical Facilities Planning Section
Division of Facility Services
2714 Mail Service Center
Raleigh, NC 27699-2714

Submitted by

P. Paul Smith, Jr.
Executive Director
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Requested Change

Lake Norman Regional Medical Center requests the following addition to the cardiac catheterization need methodology.

- a. Conversion from mobile cardiac catheterization to shared fixed cardiac catheterization equipment

A need exists for shared fixed cardiac catheterization equipment in a hospital service system served by a mobile cardiac catheterization unit when:

- 1) The number of procedures performed at any mobile site exceeds 200 procedures per year during the twelve month period reflected in the 2000 licensure application or the 1999 inventory of cardiac catheterization equipment on file with the Division of Facility Services; and,
- 2) No other fixed or mobile cardiac catheterization service is provided within the same hospital service system.

Shared equipment means fixed equipment that is used to perform both cardiac catheterization procedures and angiography procedures.

b. Addition of fixed cardiac catheterization equipment

A need exists for additional cardiac catheterization equipment when a provider's equipment utilization is at or above 80% of capacity ... [continue with current need determination language as found on page 68 of the 2000 SMFP].

Reason for Request

The introduction of mobile cardiac catheterization capabilities into North Carolina was, and still is, an efficient method for allowing hospitals such as Lake Norman Regional Medical Center to provide a much needed service. This method has promoted greater utilization of cardiac catheterization equipment by allowing hospitals that do not have sufficient volumes to support one fixed piece of equipment to share that equipment. That concept is still valid and appropriate, and LNRMC is not seeking to undermine or eliminate that concept.

Rather, LNRMC is seeking to extend the application of that concept from not only sharing mobile cardiac catheterization equipment among multiple sites, but also allowing providers that meet certain criteria to share the same piece of equipment for multiple uses within one facility. The result is the same -- equipment that is better utilized.

In the past, such an option has not been ideal from a clinical perspective because cardiac catheterization and angiography procedures are best performed using different sized image intensifiers. However, recent technological changes, including the introduction of digital technology to this equipment, allow both the cardiologist performing the cardiac catheterization procedure and the radiologist performing the angiography procedure to use the same image intensifier while achieving the clarity and range of field each requires. With these technological advantages, dual-purpose labs are becoming more common across the country. LNRMC believes that it makes sense to include this concept within the planning methodology here in North Carolina.

As noted in the requested change, only facilities currently utilizing mobile cardiac catheterization at volumes of 200 procedures or more per year would have a need for shared equipment. This criterion encourages the continued use of mobile cardiac catheterization services between hospitals performing less than 200 procedures annually. The criterion also supports the current North Carolina

regulatory requirement that a cardiac catheterization team perform at least 200 diagnostic procedures per year (see 10 NCAC 3R .1615(a)(3)), which was established based on the American College of Cardiology/American Heart Association's recommended guidelines for cardiac catheterization laboratories.

Furthermore, LNRMC recommends limiting the need for shared equipment to those mobile cardiac catheterization sites located in service areas with no other existing fixed or mobile cardiac catheterization units. For service areas without any existing fixed cardiac catheterization equipment, there is no mechanism under the current methodology for those sites to ever develop fixed equipment. The current cardiac catheterization need methodology is based on the utilization of existing fixed catheterization equipment. Any additional equipment allocated on the basis of high utilization of existing equipment is allocated to the service area in which the existing equipment operates. Therefore, a facility, such as Lake Norman, that operates outside the service areas of existing fixed equipment will never have the opportunity to apply for fixed equipment. For service areas that have multiple mobile sites, the continued use of mobile catheterization units to serve those areas remains the best alternative. However, for service areas with no other mobile sites or fixed equipment sites, the ability to utilize shared fixed equipment at the same site is the better alternative.

Impact of Request

Based on volumes reported in the 2000 SMFP, there are only four mobile cardiac catheterization sites that meet the criteria set forth in the requested change. Although the number of sites affected by this request is not significant, the impact of the request on each of those sites is significant. Approving the request will resolve four key issues for these sites:

1. Provide a better alternative for sites that have no opportunity of ever acquiring full-time, fixed-based cardiac catheterization equipment within the service system, based on the current need methodology.
2. Provide another alternative for providers who have very limited choices among mobile cardiac catheterization vendors in North Carolina.
3. Provide another alternative for those providers who have little negotiating power to influence reasonable costs and quality service for patients, because of the limited number of choices for mobile vendors.
4. Promote more efficient utilization for providers with existing resources that could be used to improve patient care and patient convenience, without sacrificing the State's standards for high utilization of expensive equipment.

LNRMC appreciates your careful consideration of this petition. Please let us know if we can assist the Council, its committees, and the staff during the process.

Thank you very much.

Attachment 2

All responses should pertain to October 1, 2009 through September 30, 2010.

7. Specialized Cardiac Services (for questions, call 855-3865 [Medical Facilities 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	Electro-physiology 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
1. Number of Units of Fixed Equipment	1	-0-	-0-
2. Number of Procedures* Performed in Fixed Units on Patients Age 14 and younger			
3. Number of Procedures* Performed in Fixed Units on Patients Age 15 and older	77		
4. Number of Procedures* Performed in Mobile Units			

*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: _____

Number of 8-hour days per week the mobile unit is onsite: _____ 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	N/A
2. Total Annual Number of Open Heart Surgery Procedures Utilizing Heart-Lung Bypass Machine	N/A
3. Total Annual Number of Open Heart Surgery Procedures done without utilizing a Heart-Lung Bypass Machine	N/A
4. Total Open Heart Surgery Procedures (2. + 3.)	N/A
Procedures on Patients Age 14 and younger	
5. Of total in #2, Number of Procedures on Patients Age 14 & younger	N/A
6. Of total in #3, Number of Procedures on Patients Age 14 & younger	N/A

All responses should pertain to October 1, 2009 through September 30, 2010.

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	-0-	-0-	-0-	-0-
Mobile PET Scanner	1	-0-	201	201
PET pursuant to Policy AC-3				
Other Human Research PET Scanner				
Ultrasound equipment	6	1,614	3,828	5,442
Mammography equipment	3		9,987	9,987
Bone Density Equipment	1		891	891
Fixed X-ray Equipment (excluding fluoroscopic)	3	8,962	6,938	15,900
Fixed Fluoroscopic X-ray Equipment	2	685	1,293	1,978
Special Procedures/ Angiography Equipment (neuro & vascular, but not including cardiac cath.)	1	1,277	1,498	2,775
Coincidence Camera	-0-			
Mobile Coincidence Camera				
Vendor:	-0-			
SPECT	-0-			
Mobile SPECT				
Vendor:	-0-			
Gamma Camera	2	1,106	2,183	3,289
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	-0-	-0-	-0-	-0-
Mobile	1	-0-	30	30

Lithotripsy Vendor/Owner:
Stone Institute

Attachment 3

All responses should pertain to October 1, 2009 through September 30, 2010.

7. **Specialized Cardiac Services** (for questions, call 855-3865 [Medical Facilities 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	Electro-physiology 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
1. Number of Units of Fixed Equipment	1		
2. Number of Procedures* Performed in Fixed Units on Patients Age 14 and younger			
3. Number of Procedures* Performed in Fixed Units on Patients Age 15 and older	617	108	
4. Number of Procedures* Performed in Mobile Units	0	0	

*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: N/A

Number of 8-hour days per week the mobile unit is onsite: 0 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	0
2. Total Annual Number of Open Heart Surgery Procedures Utilizing Heart-Lung Bypass Machine	0
3. Total Annual Number of Open Heart Surgery Procedures done without utilizing a Heart-Lung Bypass Machine	0
4. Total Open Heart Surgery Procedures (2. + 3.)	0
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	

All responses should pertain to October 1, 2009 through September 30, 2010.

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
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