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:
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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.