

**Technology and Equipment Committee
Agency Report
Petition for Adjusted Need Determination for
One Shared Fixed Unit of Cardiac Catheterization Equipment in the
Iredell County Service Area
2022 State Medical Facilities Plan**

Petitioner:

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Request:

Iredell Health requests a special need adjustment for shared fixed cardiac catheterization equipment in the Iredell County service area in the *2022 State Medical Facilities Plan (SMFP or “Plan”)*.

Background Information:

Chapter Two of the SMFP provides that “[a]nyone who finds that the North Carolina State Medical Facilities Plan policies or methodologies, or the results of their application, are inappropriate may petition for changes or revisions. Such petitions are of two general types: those requesting changes in basic policies and methodologies, and those requesting adjustments to the need projections.” The SMFP annual planning process and timeline allow for submission of petitions for changes to policies and methodologies in the spring and petitions requesting adjustments to need projections in the summer. It should be noted that any person might submit a certificate of need (CON) application for a need determination in the Plan. The CON review could be competitive and there is no guarantee that the petitioner would be the approved applicant.

The standard methodology in the SMFP generates a need for one additional unit of fixed cardiac catheterization equipment when an existing unit of cardiac catheterization is being used at 80% capacity. The capacity of a unit of cardiac catheterization equipment is defined as 1,500 diagnostic equivalent procedures per year, with the trigger of need at 80% of capacity. One interventional cardiac catheterization procedure is valued at 1.75 diagnostic-equivalent procedures. One cardiac catheterization procedure performed on a patient age 14 or younger is valued at 2 diagnostic equivalent procedures. All other procedures are valued at 1 diagnostic-equivalent procedure. The SMFP provides an additional method for obtaining a shared fixed unit of cardiac catheterization

equipment. A service area that does not have a fixed unit of cardiac catheterization equipment has a need if the service area has a mobile unit that exceeds 80% of mobile capacity during the current year for each 8 hours per week the mobile unit is operational at the site. Capacity for a mobile cardiac catheterization unit is 300 procedures, therefore 80% of capacity for a mobile unit is 240 procedures. Application of the methodology to utilization data in the Proposed 2022 SMFP did not generate a need determination for additional fixed cardiac catheterization equipment in Iredell County. Under the standard methodology, a service area without a unit of fixed equipment may obtain a unit of shared fixed equipment if mobile cardiac catheterization procedures exceed 240 and no other cardiac catheterization service is available in the service area. Iredell Memorial Hospital (IMH) does not qualify for shared fixed equipment under the standard methodology because it already has fixed equipment.

Governor Roy Cooper's Executive Order 139 gives the Agency flexibility to modify constraints that would impair the provision of hospital care during the COVID-19 state of emergency. Under this executive order, IMH received approval to use an angiography lab for cardiac catheterization procedures. Iredell Health's current Petition requests a special need adjustment for a unit of shared fixed cardiac catheterization equipment for Iredell County in the 2022 SMFP for the following reasons: 1) to continue providing the services allowed under Executive Order 139; 2) pre-COVID growth in utilization; and 3) IMH currently has the equipment and staffing in place to support use of the angiography/vascular laboratory for cardiac catheterization.

Analysis/Implications:

Iredell Memorial Hospital (IMH) is one of three providers of cardiac catheterization services operating one of three units of fixed cardiac catheterization equipment in Iredell County. IMH has one fixed cardiac catheterization laboratory and recently purchased equipment for an angiography/vascular laboratory that can be used to perform cardiac catheterizations. The Agency, pursuant to Executive Order 139, temporarily approved IMH's use of the angiography/vascular laboratory for cardiac catheterization procedures. This approval expires 30 days after the end of the COVID-19 state of emergency and IMH must discontinue use of the second lab by that date.

The Petitioner reports that this emergency approval improved patient services, operational efficiency and quality of care. The Petitioner asserts that continued use of both laboratories will provide better scheduling of patients/doctors. The Petitioner further asserts that it will allow IMH to more efficiently utilize the operational equipment and space in the hospital.

Iredell County is currently operating with a two-unit surplus in fixed cardiac catheterization equipment. Utilization at Davis Regional Medical Center and Lake Norman Regional Medical Center has fluctuated to a great degree over the past five years, while IMH has experienced more stability (see Table 1). In addition, review of data from 2006 to 2020 shows that IMH performed substantially more weighted procedures than the other hospitals in the service area, even during times of fluctuation and the COVID-19 pandemic (Table 1, below, and Table 9V, 2016 State Medical Facilities Plan).

Table 1: Service Area Trends in Weighted Cardiac Catherization Procedures, Data Years 2016 – 2020

	2018 SMFP	2019 SMFP	2020 SMFP	2021 SMFP	Proposed 2022 SMFP	Total % Change	CAGR
Davis Regional Medical Center	229	16	9	271	130	-43.23%	-13.20%
Iredell Memorial Hospital	1,042	1,017	931	1,125	717	-31.19%	-8.92%
Lake Norman Regional Medical Center	62	69	258	405	318	412.9%	50.49%
Service Area Totals	1,333	1,102	1,198	1,801	1,165	-12.6%	-3.31%
Service Area Annual Change		-17.33%	8.71%	50.33%	-35.31%		

Source: 2017 – 2021 License Renewal Applications

Note: The data in the SMFP is two years earlier than the publication year of the SMFP.

Iredell County is having a steady growth in population. The annual change rate is 2.93% over the past four years (See Table 2). Census data from the NC Office of State Budget and Management projects that the 65 and older population of Iredell County will increase 15.85% from 2021 – 2025, compared to the 5.35% increase in the county population. Clearly, projected growth in the aging population far outstrips overall county population growth. Cardiac catheterization services are more common in the aging population, which supports the projected increase in utilization.

Table 2: Annual County Population Totals, Years 2018-2021

County	2018	2019	2020	2021	Total Percent Change	CAGR
Iredell	179,740	182,424	184,023	185,011	2.93%	0.97%

Source: State Medical Facilities Plan

Although cardiac catheterization services are available elsewhere in the county, and in relatively close proximity to IMH, the Agency does not view addition of a shared fixed unit to the IMH inventory as unnecessary duplication. Lake Norman Regional Medical Center received a CON in 2001 (F-006380-01) to designate existing angiography equipment as shared fixed cardiac catheterization equipment for use approximately two days per week. In that case and as in the current Petition, the shared fixed unit would not be expected to be used primarily for cardiac catheterization procedures. Rather, it would be available for cardiac catheterization when scheduling or other needs arise.

Agency Recommendation:

The Agency supports the standard methodology for cardiac catheterization equipment. In consideration of the factors discussed above and all information submitted by the August 11, 2021 deadline date for comments, the Agency recommends approval of the Petition for an adjusted need determination for one unit of shared fixed cardiac catheterization equipment in Iredell County, with the added stipulation that the equipment be located at Iredell Memorial Hospital.