

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: July 22, 2022

Findings Date: July 22, 2022

Project Analyst: Gregory F. Yakaboski

Co-Signer: Micheala L. Mitchell

Project ID #: F-12180-22

Facility: Iredell Memorial Hospital

FID #: 933284

County: Iredell

Applicant: Iredell Memorial Hospital, Incorporated

Project: Develop one shared fixed cardiac catherization lab pursuant to the 2022 SMFP need determination for a total of no more than 2 cardiac catheterization labs

REVIEW CRITERIA

G.S. 131E-183(a): The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

Iredell Memorial Hospital, Inc. (hereinafter referred to as IMH, Inc. or “the applicant”) proposes to acquire one unit of shared fixed cardiac catherization (cardiac cath) equipment pursuant to the need determination in the 2022 State Medical Facilities Plan (SMFP) for a total of no more than two cardiac cath labs at Iredell Memorial Hospital (“IMH”). Iredell Memorial Hospital is located at 557 Brookdale Drive, Statesville in Iredell County.

Background

IMH has one unit of “grandfathered” fixed cardiac cath equipment. See the IMH, Inc. 2021 Hospital License Renewal Application (LRA) in Exhibit A.1.

IMH also has an interventional angiography laboratory.

In response to the COVID-19 Emergency, the Governor of the State of North Carolina issued Executive Order 116 entitled “*DECLARATION OF A STATE OF EMERGENCY TO COORDINATE A RESPONSE AND PROTECTIVE ACTIONS TO PREVENT THE SPREAD OF COVID-19*”. Subsequently, the Governor of the State of North Carolina also issued Executive Order 139 entitled “*ADDITIONAL REGULATORY FLEXIBILITY TO MEET NORTH CAROLINAS HEALTH AND HUMAN SERVICES NEEDS*”. Pursuant to Executive Order 139, IMH applied for and received CON approval on May 20, 2020 to operate its interventional angiography laboratory equipment for cardiac cath procedures which equates to a unit of shared fixed cardiac cath equipment. This CON approval is temporary and specifically defined to last only through the “*Declared State of Emergency Executive Order 116, plus 30 days.*”

With the goal of being able to continue to use its interventional angiography laboratory equipment as a shared fixed cardiac cath laboratory IMH filed a petition in July 2021 requesting an adjusted need determination for an additional unit of shared fixed cardiac cath equipment in Iredell County. IMH’s petition was approved and the requested adjusted need determination was included in the 2022 SMFP.

IMH filed this application in response to the adjusted need determination in the 2022 SMFP.

Need Determination

The 2022 SMFP includes an adjusted need determination for one unit of shared cardiac cath equipment in the Iredell County cardiac catheterization service area specifically designated for Iredell Memorial Hospital [See Table 17A-5, page 319, 2020 SMFP]. The applicant proposes to acquire one unit of shared cardiac cath equipment to be located at Iredell Memorial Hospital. The applicant does not propose to acquire more units of shared cardiac cath equipment than are determined to be needed in the 2022 SMFP for the Iredell County cardiac catheterization service area at Iredell Memorial Hospital. Therefore, the application is consistent with the need determination.

Policies

There is one policy in the 2022 SMFP applicable to this review: Policy GEN-3: *Basic Principles*.

Policy GEN-3: *Basic Principles*, on page 30 of the 2022 SMFP, states:

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

Promote Safety and Quality

The applicant describes how it believes the proposed project will promote safety and quality in Section B(a), page 27, Section N.2, page 101; Section O, pages 103-106; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B(b), page 28; Section C.6, pages 56-58; Section L, pages 92-98; Section N.2, page 101, and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B(c), page 28; Section F, pages 71-77; Section K, pages 88-91, Section N, page 100; the applicant’s pro forma financial statements in Section Q, supplemental information and referenced exhibits. The information provided by the applicant with regard to its efforts to maximize healthcare value is reasonable and supports the determination that the applicant’s proposal will maximize healthcare value.

The information provided by the applicant is reasonable and adequately demonstrates how its proposal incorporates the concepts of quality, equitable access and maximum value for resources expended in meeting the need identified in the 2022 SMFP. Therefore, the application is consistent with Policy GEN-3.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency

- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on the following reasons:

- The applicant does not propose to acquire more units of shared fixed cardiac cath equipment than are determined to be needed in the service area.
 - The applicant proposes to acquire the shared fixed cardiac catheterization equipment for Iredell Memorial Hospital.
 - The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 based on the following reasons:
 - The applicant adequately documents how the project will promote safety and quality in the delivery of shared fixed cardiac cath in the Iredell County shared fixed cardiac cath equipment service area;
 - The applicant adequately documents how the project will promote equitable access to shared fixed cardiac cath in the Iredell County shared fixed cardiac cath equipment service area;
 - The applicant adequately documents how the project will maximize healthcare value for the resources expended; and
 - The applicant's projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the need identified in the 2022 SMFP.
- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to acquire one unit of shared fixed cardiac cath equipment pursuant to the need determination in the 2022 SMFP for a total of no more than two cardiac cath labs at Iredell Memorial Hospital.

Patient Origin

On page 310, the 2022 SMFP defines the cardiac catheterization equipment service areas as "...the Acute Care Bed Service Areas defined in Chapter 5 and shown in Figure 5.1." Figure 5.1 on page 38 shows Iredell County as a single county Acute Care Bed Service Area. Therefore, the service area is Iredell County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin for cardiac cath services at Iredell Memorial Hospital.

ZIP Code	Historical (10/1/2020)		Third Full FY of Operation following Project Completion (10/1/2024 – 9/30/2025)	
	Patients	% of Total	Patients	% of Total
28625	270	36.7%	354	31.9%
28677	173	23.5%	282	25.4%
28681	25	3.4%	45	4.1%
28115	26	3.5%	42	3.8%
28678	25	3.4%	41	3.7%
28166	29	3.9%	41	3.7%
28117	24	3.2%	38	3.4%
28634	20	2.7%	37	3.4%
27013	18	2.4%	33	3.0%
28636	21	2.8%	31	2.8%
28689	13	1.7%	17	1.5%
28660	12	1.7%	13	1.2%
27028	8	1.1%	13	1.2%
28125	4	0.5%	11	1.0%
27020	6	0.9%	10	0.9%
28687	0	0.0%	10	0.9%
28609	3	0.5%	6	0.6%
28659	5	0.7%	6	0.6%
28673	2	0.3%	5	0.4%
28697	4	0.6%	5	0.4%
27054	3	0.4%	4	0.4%
28613	4	0.5%	4	0.3%
28610	5	0.7%	4	0.3%
28654	2	0.3%	3	0.3%
28625	1	0.2%	0	0.0%
28677	33	4.5%	0	0.0%
Other ZIP codes	0	0.0%	56	5.0%
Total	735	100.0%	1,110	100.0%

Source: Tables on pages 34 & 38 of the application.

In Section C, page 40, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported based on the following:

- IMH has consistent patient origin as an established hospital.
- The applicant assumed in-migration would remain constant.
- The applicant assumed patients would grow with the rate of population for the six primary service area counties.

Analysis of Need

In Section C.4, pages 41-50, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- Need Determination in the 2022 SMFP (page 42).
- Service Area Population Growth (pages 42-45).
- Historic Use of Cardiac Cath and Angiography Procedures (pages 46-47).
- Health Status of the IMH Service Area (pages 47-49).
- Need for Operational Efficiency at IMH (page 50).

The information is reasonable and adequately supported based on the following:

- The 2022 SMFP contains an adjusted need determination for one unit of shared fixed cardiac catheterization equipment at Iredell Memorial Hospital. See Table 17A-5: *Shared Fixed Cardiac Catheterization Equipment Need Determination*, page 319 of the 2022 SMFP.
- The applicant cites a study showing cardiac cath use rates increases with age and that “*after age 49, use rates doubled in the 50-59 age group and by age 89, use rates were more than triple those of the 40-49 age group.*” The applicant identifies projected population cohorts in its primary service area and states that by 2027 there will be approximately 3,000 additional residents in the high-risk group.
- From FY2017 through FY2020 (annualized) the NC State Medical Facilities Database from 2018 based on Hospital LRAs shows a steady increase in both cardiac cath procedures and angiography procedures.
- The applicant cites that data from the NCDHHS State Center for Health Statistics regarding health and prevention data indicates that Iredell and nearby counties’ health providers will see high demand for cardiac services.
- The applicant states that the current combination of a dedicated fixed cardiac cath unit and a shared fixed cardiac cath unit has permitted tremendous operational efficiencies which have both saved IMH operating expenses, improved staff retention and allowed better schedule flexibility and/or improved operational efficiency.

Projected Utilization

In Section Q, the applicant provides historical and projected utilization, as illustrated in the following table.

IMH: Cardiac Cath-Projected

	Historical FFY 2021	Interim FFY2022*	1 st Full FY (2023)	2 nd Full FY (2024)	3 rd Full FY (2025)
# of Units**	2	2	2	2	2
Cardiac Cath Procedures: DX Equivalents***	857	1,278	1,293	1,308	1,324
Angiography Procedures: DX Equivalents***	912	1,258	1,330	1,402	1,476
Total DX Equivalents (Fixed and Shared)***	1,769	2,536	2,623	2,711	2,799

Source: Section Q, Table 13, page 126.

Note: Totals might not foot due to rounding.

*Annualized based on actual data from October 2021 – December 2021.

**Units equal the one fixed cardiac cath and the one proposed shared fixed cardiac cath (which performs both cardiac cath and angiography procedures). For FFY 2021 and FFY 2022 the units consist of one fixed cardiac cath and one angiography lab.

***Diagnostic Equivalent Procedures equals Diagnostic Procedures + [Therapeutic (Interventional) Procedures x 1.75]

In Section Q, Form C, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

Forecast Need

Step 1. Identify the Service Area using Historical IMH Cardiac Catheterization and Angiography Procedures by Zip Code (see pages 115-116).

Step 2. Define Service Area Population (see pages 116-117).

Step 3. Define the Population Use Rate for Cardiac Catheterization and Angiography in NC (see pages 118-120).

Step 4. Forecast the Need for Cardiac Catheterization and Angiography Procedures in the Service Area (see page 120).

Forecast Utilization

Step 5. Identify Historic IMH Cardiovascular Procedures by Fiscal Year (see page 121).

Step 6. Annualize IMH Cardiac Catheterization and Angiography Procedures for FY 2022 (see pages 122-123).

Step 7. Determine IMH Market Share of Procedures Needed (see page 123).

Step 8. Forecast Future IMH Cardiovascular Procedures at Constant 2022 Market Share of Estimated Service Area Need (see pages 124-125).

Step 9. Distribute Procedures to Fixed and Shared Fixed Cardiac Catheterization Equipment (see page 126).

Step 10. Test for Performance Standards (see page 127).

Projected utilization is reasonable and adequately supported based on the following:

- Population data, both historical and projected, for the service area from Claritas.
- Historic North Carolina use rates for both cardiac catheterization and angiography per 1,000 residents established from population data from the North Carolina Office of State Budget and Management (NCOSBM) and the 2019-2022 SMFP.
- The applicant's actual experience of operating its existing interventional angiography laboratory equipment for cardiac cath procedures which equates to a unit of shared cardiac catheterization unit pursuant to Executive Order 139, under which IMH applied for and received CON approval on May 20, 2020.
- The applicant made reasonable adjustments to address the COVID-19 impact on 2020 data.
- The applicant relied on historical cardiac catheterization and angiography procedure performed, including the ratio of diagnostic to therapeutic procedures, at IMH in combination with projected need to calculate market share and project utilization.
- The applicant states that two local cardiologists joined the IMH staff in 2021. Both doctors utilized cardiac catheterization and angiography services in their practice prior to joining that staff at IMH and now treat most of their patients at IMH.
- The applicant's plan to increase interventional cardiologist physician capacity at IMH in addition to extending hours on the shared equipment.
- The applicant states that IMH is now the hospital recommended by Iredell County EMS staff when patients with heart attacks do not express a preference.
- The project analyst notes that in the last year with full historical data, FFY 2021, the applicant, with one unit of fixed cardiac cath equipment and one angiography lab, performed 857 diagnostic-equivalent cardiac catheterization procedures and 912 angiography procedures. Thus, even if the applicant projected no growth in utilization from FFY 2021 through the third full fiscal year of operation following completion of the project, the number of diagnostic-equivalent cardiac cath procedures [857 / 2 units of cardiac cath equipment = 428.5] and angiography procedures [912 as all of the angiography procedures would be performed on the proposed unit of shared fixed cardiac cath equipment] exceeds the 225 or more diagnostic-equivalent cardiac catheterization and angiography procedures required by the Rule in 10A NCAC 14C .1603 (b)(3) [Performance Standards for Cardiac Catheterization Equipment and Cardiac Angioplasty Equipment].

Access to Medically Underserved Groups

In Section C.6, page 56, the applicant states: *"IMH accepts patients regardless of gender, gender preference, race, ethnicity, age, income, or disability status. ... IMH has Medicare and Medicaid certification, and provides services to both populations."*

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	2.7%
Racial and ethnic minorities	24.0%
Women	60.0%
Persons with Disabilities	100.0%
Persons 65 and older	65.0%
Medicare beneficiaries	76.6%
Medicaid recipients	1.8%

Source: Section C, page 57

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant states that by definition all users of these services have a disability.
- The applicant relied on the demographic makeup of the proposed service area and IMH's historical experience to estimate the percentage of women and racial and ethnic minorities projected to use the proposed services.
- The applicant relied on historical experience and the aging of the service area population to project the percentage of persons 65 and older.
- Medicaid, Medicare and low-income persons were based on the payor assumptions set forth in the proformas in Section Q.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

The applicant proposes to acquire one unit of shared fixed cardiac cath equipment pursuant to the need determination in the 2022 SMFP for a total of no more than two cardiac cath labs at Iredell Memorial Hospital.

In Section E, pages 68-70, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- *Maintain the Status Quo*- Maintaining the status quo would entail continuing to operate IMH's angiography laboratory as a shared fixed cardiac cath lab under Executive Order 139 which is temporary, as this is an Emergency Order which will expire. The applicant states that there is a need determination in the 2022 SMFP for one unit of shared fixed cardiac catheterization equipment for Iredell Memorial Hospital and maintaining the status quo would not meet this need determination. Therefore, the applicant determined that this alternative was a less effective alternative.
- *Return to Single Fixed Cardiac Catheterization Laboratory when COVID Emergency Ends*- The applicant states that, based both on demand for cardiac catheterization cases and angiography, a single fixed cardiac cath lab will not meet the need at IMH. In addition, many cardiac cath cases are due to a patient emergency, which, with only one cardiac cath lab, pushes scheduled cardiac procedures. Returning to a single fixed cath lab would, at a minimum, create delays in care or possibly lead to decisions to forego care, forced overtime, increased operating costs, and additional stress on a system that is already strained. Therefore, the applicant determined that this alternative was a less effective alternative.
- *Request Second Full Catheterization Laboratory*- The applicant states that there is no need determination in the 2022 SMFP for a unit of dedicated cardiac catheterization equipment. In addition, IMH does not believe that it is reasonable to project the number of diagnostic equivalent cardiac catheterization procedures by FY2025 needed to comply with the Performance Rules for an additional unit of dedicated (fixed) cardiac catheterization equipment. Therefore, the applicant determined that this alternative was a less effective alternative.
- *Move Cardiac Catheterization Suite to Ambulatory Surgery Center*- The applicant states that the level of need in the IMH service area would not support both a program in a hospital and in a free-standing ambulatory surgery center. Further, a free-standing ambulatory

surgery center would not offer emergency STEMI care. In addition, having the shared fixed cardiac catheterization equipment at the hospitals ambulatory surgery center would not meet the need in the 2022 SMFP. Therefore, the applicant determined that this alternative was a less effective alternative.

On page 68, the applicant states that its proposal is the most effective alternative because

“This alternative is the most effective and least costly of the alternatives considered. It involves no major new capital costs, no change in staff, and can be put into effect immediately upon receipt of the Certificate of Need. Patient need and physician capacity to deliver both support the request.”

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The proposed project meets the adjusted need determination in the 2022 SMFP for one unit of shared fixed cardiac cath equipment at Iredell Memorial Hospital.
- The applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Iredell Memorial Hospital, Incorporated (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application and any supplemental responses. If representations conflict, the certificate holder shall materially comply with the last made representation.**
- 2. The certificate holder shall develop no more than one unit of shared fixed cardiac catheterization equipment at Iredell Memorial Hospital pursuant to the need determination in the 2022 SMFP.**

- 3. Upon completion for the project Iredell Memorial Hospital shall be licensed for no more than one unit of fixed cardiac catheterization equipment and one unit of shared fixed cardiac catheterization equipment.**
 - 4. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. The first progress report shall be due on October 1, 2022.**
 - 5. The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
 - 6. No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, the certificate holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
 - a. Payor mix for the services authorized in this certificate of need.**
 - b. Utilization of the services authorized in this certificate of need.**
 - c. Revenues and operating costs for the services authorized in this certificate of need.**
 - d. Average gross revenue per unit of service.**
 - e. Average net revenue per unit of service.**
 - f. Average operating cost per unit of service.**
 - 7. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

The applicant proposes to acquire one unit of shared fixed cardiac cath equipment pursuant to the need determination in the 2022 SMFP for a total of no more than two cardiac cath labs at Iredell Memorial Hospital.

Capital and Working Capital Costs

In Section Q, Form F.1a, page 128, the applicant projects the total capital cost of the project, as shown in the table below.

Site Costs	\$0
Construction Costs	\$0
Miscellaneous Costs (Contingency)	\$150,000
Total	\$150,000

In Section F.1, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The unit of shared fixed cardiac cath equipment is already in-place and operational as such the proposed project requires no capital cost at this time.
- The unit of shared fixed cardiac cath equipment is currently operating under a waiver, the proposed project is only for a certificate of need for permanent use of the operational program.
- The contingency costs are a safeguard for any unexpected additional costs.

In Section F.3, page 73, the applicant states that there will be no start-up costs or initial operating expenses as the unit of cardiac cath equipment is already existing and operation. The cardiac cath equipment is currently operating under an EO 139 waiver granted in 2021.

Availability of Funds

In Section F.2, page 71, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing

Type	Iredell Memorial Hospital	Total
Loans	\$	\$
Cash and Cash Equivalents, Accumulated reserves or OE *	\$150,000	\$150,000
Bonds	\$	\$
Other (Specify)	\$	\$
Total Financing	\$150,000	\$150,000

* OE = Owner's Equity

Exhibit F.2 contains a letter dated February 10, 2022 from the Chief Financial Officer of Iredell Memorial Hospital, Incorporated documenting that Iredell Memorial Hospital has sufficient cash reserves and would make the funds available to cover the capital costs of the

proposed project. In supplemental information, the applicant provided documentation from the most recent Audited Financial Statement Balance Sheet of Iredell Memorial Hospital, Incorporated demonstrating that as of September 30, 2021, the applicant had \$136.2 million in cash reserves. The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- Documentation in supplemental information from the most recent Audited Financial Statement Balance Sheet of Iredell Memorial Hospital, Incorporated demonstrating that as of September 30, 2021, the applicant had \$136.2 million in cash reserves.
- A letter in Exhibit F.2, dated February 10, 2022, from the Chief Financial Officer of Iredell Memorial Hospital, Incorporated documenting that Iredell Memorial Hospital has sufficient cash reserves and would make the funds available to cover the capital costs of the proposed project.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2b, the applicant projects that revenues will exceed operating expenses in the first three full fiscal years following completion of the project, as shown in the table below.

	1st Full Fiscal Year	2nd Full Fiscal Year	3rd Full Fiscal Year
Total Procedures*	2,623	2,711	2,799
Total Gross Revenues (Charges)	\$50,463,920	\$51,948,683	\$53,447,869
Total Net Revenue	\$10,593,071	\$10,903,487	\$11,216,918
Average Net Revenue per Procedure	\$4,039	\$4,022	\$4,008
Total Operating Expenses (Costs)	\$6,467,905	\$6,866,783	\$7,162,377
Average Operating Expense per Procedure	\$2,466	\$2,533	\$2,559
Net Income	\$4,125,165	\$4,036,704	\$4,054,541

*Procedures = Diagnostic Equivalent Procedures from both the Fixed and Shared Labs.

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Projected charges and revenues are reasonable and adequately supported.
- Projected operating expenses are reasonable and adequately supported.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
 - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to acquire one unit of shared fixed cardiac cath equipment pursuant to the need determination in the 2022 SMFP for a total of no more than two cardiac cath labs at Iredell Memorial Hospital.

On page 310, the 2022 SMFP defines the cardiac catheterization equipment service areas as “...the Acute Care Bed Service Areas defined in Chapter 5 and shown in Figure 5.1.” Figure 5.1 on page 38 shows Iredell County as a single county Acute Care Bed Service Area. Therefore, the service area is Iredell County. Facilities may also serve residents of counties not included in their service area.

According to Chapter 17 of the 2022 SMFP, there are three facilities with cardiac cath equipment located in Iredell County. Information about each facility is shown in the table below.

Cardiac Cath Equipment – Iredell County					
Facility	# of Units	# of Diagnostic Procedures	# of Interventional Procedures	2020 Weighted Total Procedures	Machines Required (80% util.)
Davis Regional Medical Center	1	130	0	130	0.11
Iredell Memorial Hospital	1	507	120	717	0.60
Lake Norman Regional Medical Center	1	201	67	318	0.27
Total	3	838	187	1,165	1

Source: 2022 SMFP, Table 17A-1, page 312, and Table 17A-3, page 317

In Section C.4, page 42, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved shared fixed cardiac cath equipment services in Iredell County. The applicant states:

“The Cardiac Catheterization methodology in the 2022 State Medical Facilities Plan uses reported utilization of existing cardiac catheterization equipment to determine a need for additional equipment within a service area. According to the methodology, Iredell County has a surplus of fixed cardiac catheterization units. However, ‘[i]n response to a petition, The State Health Coordinating Council approved the adjusted need determination for one Shared Fixed Cardiac Catheterization Equipment designated for Iredell Memorial Hospital.’ (page 319).”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- There is an adjusted need determination in the 2022 SMFP for the proposed unit of shared fixed cardiac catheterization equipment at Iredell Memorial Hospital.
- The applicant adequately demonstrates that the proposed unit of shared fixed cardiac catheterization equipment is needed in addition to the existing or approved units of shared fixed cardiac catheterization equipment in the service area.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
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- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

The applicant proposes to acquire one unit of shared fixed cardiac cath equipment pursuant to the need determination in the 2022 SMFP for a total of no more than two cardiac cath labs at Iredell Memorial Hospital.

In Section Q, Form H, page 136, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff
	(1/21/2022)	3rd Full Fiscal Year (10/1/2024 – 9/30/2025)
Registered Nurses	5.80	6.80
Medical Director	0.06	0.06
Director of Nursing	1.00	1.00
Radiology Technologists	5.00	7.00
Other (Certified Nursing Asst.)	1.00	1.00
TOTAL	13.0	16.0

Note: Totals might not foot due to rounding.

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b. In Sections H.2 and H.3, pages 82-84, and Exhibit H.3, the applicant describes the methods to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the information provided in Section H, pages 82-84, Section Q, Form H and Exhibit H.3, as described above.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

The applicant proposes to acquire one unit of shared fixed cardiac cath equipment pursuant to the need determination in the 2022 SMFP for a total of no more than two cardiac cath labs at Iredell Memorial Hospital.

Ancillary and Support Services

In Section I.1, page 85, the applicant identifies the necessary ancillary and support services for the proposed services. On page 85, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1.

In Exhibit I.1, the President & CEO of Iredell Health System states:

“As President & Chief Executive Officer of IMH, I am responsible for the overall daily operations of the hospital, including the proposed cardiac services. I can attest to the availability of all ancillary and support services necessary for the proposed project.”

The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

Coordination

In Section I.2, page 86, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the information provided in Section I.2, page 86, and Exhibit I.2, as described above.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

The applicant does not propose to construct any new space or renovate any existing space. Therefore, Criterion (12) is not applicable to this review.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 92, the applicant provides the historical payor mix during the last Full FY (10/1/2020 to 9/30/2021) for Iredell Memorial Hospital, as shown in the table below.

Iredell Memorial Hospital

Payor Category	Percent of Total Patients Served
Self-Pay	4.71%
Charity Care	0.57%
Medicare*	55.69%
Medicaid*	8.89%
Insurance*	26.69%
Other (Tricare, VA, WC, MedCost)	3.45%
Total	100.00%

Source: Table on page 92 of the application.

*Including any managed care plans.

In Section L, page 93, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	60.20%	50.60%
Male	39.78%	49.4%
Unknown	0.02%	n/a
64 and Younger	61.73%	81.90%
65 and Older	38.27%	19.1%
American Indian	0.10%	0.40%
Asian	0.58%	2.50%
Black or African American	18.78%	9.40%
Native Hawaiian or Pacific Islander	0.02%	0.00%
White or Caucasian	75.17%	80.50%
Other Race	3.90%	4.80%
Declined / Unavailable	1.45%	n/a

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

- Responses to comments
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and persons with disabilities to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.2 , pages 94-95, the applicant states that Iredell Memorial Hospital is: *"a CMS certified hospital and therefore subject to EMTALA rules ... furthermore IMH is subject to compliance with Internal Revenue Service Section 501(r) and all requirements imposed by the Affordable Care Act."* The applicant states that it is in full compliance with these requirements.

In Section L, page 95, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L, page 96, and supplemental information, the applicant projects the following payor mix for both Iredell Memorial Hospital overall and for cardiac cath

and angiography services during the third full fiscal year of operation following completion of the project, as shown in the tables below.

Iredell Memorial Hospital: All Services

Payor Category	Percent of Total Patients Served
Self-Pay	4.71%
Charity Care	0.57%
Medicare*	55.69%
Medicaid*	8.89%
Insurance*	26.69%
Other (Tricare, VA, WC, MedCost)	3.45%
Total	100.00%

Source: Table on page 96 of the application.

*Including any managed care plans.

Iredell Memorial Hospital: Cardiac Cath and Angiography Services

Payor Category	Percent of Total Patients Served
Self-Pay	1.3%
Charity Care	0.8%
Medicare*	76.1%
Medicaid*	1.8%
Insurance*	19.0%
Other (Tricare, VA, WC, MedCost)	0.8%
Total	100.0%

Source: Table on page 96 of the application.

*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 1.3% of total cardiac cath and angiography services will be provided to self-pay patients, 0.8% to charity care patients, 76.1% to Medicare patients and 1.8% to Medicaid patients.

On page 96, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the historical payor mix data from FY2021 for cardiac cath services at IMH.

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- Written comments
- Responses to comments
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section L.5, page 98, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

The applicant proposes to acquire one unit of shared fixed cardiac cath equipment pursuant to the need determination in the 2022 SMFP for a total of no more than two cardiac cath labs at Iredell Memorial Hospital.

In Section M.1, page 99, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- The applicant maintains a close relationship with Mitchell Community College.
- The applicant also works with both Blue Ridge Community College and Catawba College.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (15) Repealed effective July 1, 1987.
 - (16) Repealed effective July 1, 1987.
 - (17) Repealed effective July 1, 1987.
 - (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to acquire one unit of shared fixed cardiac cath equipment pursuant to the need determination in the 2022 SMFP for a total of no more than two cardiac cath labs at Iredell Memorial Hospital.

On page 310, the 2022 SMFP defines the cardiac catheterization equipment service areas as “...the Acute Care Bed Service Areas defined in Chapter 5 and shown in Figure 5.1.” Figure 5.1 on page 38 shows Iredell County as a single county Acute Care Bed Service Area. Therefore, the service area is Iredell County. Facilities may also serve residents of counties not included in their service area.

According to Chapter 17 of the 2022 SMFP, there are three facilities with cardiac cath equipment located in Iredell County. Information about each facility is shown in the table below.

Cardiac Cath Equipment – Iredell County					
Facility	# of Units	# of Diagnostic Procedures	# of Interventional Procedures	2020 Weighted Total Procedures	Machines Required (80% util.)
Davis Regional Medical Center	1	130	0	130	0.11
Iredell Memorial Hospital	1	507	120	717	0.60
Lake Norman Regional Medical Center	1	201	67	318	0.27
Total	3	838	187	1,165	1

Source: 2022 SMFP, Table 17A-1, page 312, and Table 17A-3, page 317

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 100, the applicant states:

“IMH expects CON approval to have a positive impact or a at least a neutral effect on competition in the service area for several reasons:

- *The second laboratory has already been operating in a shared fixed cardiac catheterization capacity and has not negatively affected competition in the service area.*
- *Utilizing the second laboratory in a shared fixed cardiac catheterization capacity is more cost effective for IMH, which ultimately benefits patients and increases accessibility of procedures in the service area.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 100, the applicant states:

“By using both cardiac catheterization and angiography functions ... IMH saved 15 to 20 minutes between cases ... reducing overtime and producing a cost savings of about \$175,000 a year. ... Retaining the shared fixed cardiac catheterization lab will enable IMH to respond quickly to STEMI patients, conceivably reducing the length of hospital stay post-procedure by as much as two to three days.”

See also Sections C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 101, the applicant states:

“Recruiting highly qualified cardiac catheterization physicians and techs is difficult. Today, IMH schedules tech and nursing staff on overlapping shifts that cover 11-12 hours a day, 7 AM to 5 PM, even with two units in service. It is more difficult to recruit staff to work a regular later schedule and take STEMI calls. With sudden loss of flexibility in schedules, IMH risks losing physicians, nurses and tech staff, all of which are in short supply nationally and are heavily recruited. Without the requested adjustment... Eight cardiologists will be forced to schedule all cardiac catheterization procedures in one room. Staff will be required to work overtime. Patients will compete for daylight appointments and scheduled cases will be moved for emergencies.

See also Sections C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 101, the applicant states:

“IMH does not discriminate against any class of patient based on age, sex, religion, race, handicap, ethnicity, or ability to pay.”

See also Section L and C of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services and the applicant's record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on all the reasons described above.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

The applicant proposes to acquire one unit of shared fixed cardiac cath equipment pursuant to the need determination in the 2022 SMFP for a total of no more than two cardiac cath labs at Iredell Memorial Hospital.

In Section Q, Form O, page 137, and supplemental information, the applicant identifies the hospitals and ambulatory surgical centers located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of four of these types of facilities located in North Carolina.

In Section O, page 106, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care resulting in a finding of immediate jeopardy occurred at any of these facilities. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care occurred in none of these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all four of these facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The application is conforming with all applicable Criteria and Standards for Cardiac Catheterization Equipment and Cardiac Angioplasty Equipment promulgated in 10A NCAC 14C .1600. The specific criteria are discussed below.

10A NCAC 14C .1603 PERFORMANCE STANDARDS

(a) An applicant proposing to acquire fixed cardiac catheterization equipment pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:

- (1) identify the existing fixed cardiac catheterization equipment owned or operated by the applicant or a related entity and located in the proposed fixed cardiac catheterization equipment service area;
- (2) identify the approved fixed cardiac catheterization equipment owned or operated by the applicant or a related entity and located in the proposed fixed cardiac catheterization equipment service area;
- (3) provide projected utilization of the cardiac catheterization equipment identified in Subparagraphs (1) and (2) of this Paragraph and the proposed fixed cardiac catheterization equipment during each of the first three full fiscal years of operation following completion of the project;
- (4) provide the assumptions and methodology used to project the utilization required by Subparagraph (3) of this Paragraph; and
- (5) project that the cardiac catheterization equipment identified in Subparagraphs (1) and (2) of this Paragraph and the proposed fixed cardiac catheterization equipment shall perform 900 or more diagnostic-equivalent cardiac catheterization procedures per unit

of cardiac catheterization equipment during the third full fiscal year of operation following completion of the project.

- NA- The applicant does not propose to acquire fixed cardiac catheterization equipment pursuant to a need determination in the 2022 State Medical Facilities Plan.

- (b) An applicant proposing to acquire shared fixed cardiac catheterization equipment pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:
 - (1) provide projected utilization of the proposed shared fixed cardiac catheterization equipment during each of the first three full fiscal years of operation following completion of the project;

 - C- In Section Q, Form C.2b, the applicant provides projected utilization of the proposed shared fixed cardiac catheterization equipment during each of the first three full fiscal years of operation following completion of the proposed project.
 - (2) provide the assumptions and methodology used to project the utilization required by Subparagraph (1) of this Paragraph; and

 - C- In Section Q, pages 115-127, the applicant provides the assumptions and methodology used to project utilization of the proposed shared fixed cardiac catheterization equipment during each of the first three full fiscal years of operation following completion of the proposed project.
 - (3) project that the proposed shared fixed cardiac catheterization equipment shall perform 225 or more diagnostic-equivalent cardiac catheterization and angiography procedures during the third full fiscal year of operation following completion of the project.

 - C- Upon completion of the proposed project IMH will have one unit of fixed cardiac catheterization equipment and one unit of shared fixed cardiac catheterization equipment. In Section Q, the applicant projects that the two units of cardiac catheterization equipment shall perform 1,324 diagnostic-equivalent cardiac catheterization and 1476 angiography procedures during the third full fiscal year of operation following completion of this proposed project which exceeds the 225 procedures required by this Rule.

- (c) An applicant proposing to acquire mobile cardiac catheterization equipment pursuant to a need determination in the State Medical Facilities Plan in effect as of the first day of the review period shall:
 - (1) identify the existing mobile cardiac catheterization equipment owned or operated by the applicant or a related entity that provides cardiac catheterization services at host sites located in the proposed mobile cardiac catheterization equipment service area;
 - (2) identify the approved mobile cardiac catheterization equipment owned or operated by the applicant or a related entity that will provide cardiac catheterization services at host sites located in the proposed mobile cardiac catheterization equipment service area;
 - (3) provide projected utilization of the cardiac catheterization equipment identified in Subparagraphs (1) and (2) of this Paragraph and the proposed mobile cardiac catheterization equipment during each of the first three full fiscal years of operation following completion of the project;

- (4) provide the assumptions and methodology used to project the utilization required by Subparagraph (3) of this Paragraph; and
 - (5) project that the cardiac catheterization equipment identified in Subparagraphs (1) and (2) of this Paragraph and the proposed mobile cardiac catheterization equipment shall perform 225 or more diagnostic-equivalent cardiac catheterization procedures per unit of cardiac catheterization equipment during the third full fiscal year of operation following completion of the project.
- NA-** The applicant does not propose to acquire mobile cardiac catheterization equipment pursuant to a need determination in the 2022 State Medical Facilities Plan.