

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: August 30, 2019

Findings Date: August 30, 2019

Project Analyst: Gregory F. Yakaboski

Team Leader: Fatimah Wilson

Project ID #: F-11727-19

Facility: Iredell Mooresville Campus (ASC)

FID #: 190282

County: Iredell

Applicants: Iredell Memorial Hospital, Incorporated
Iredell Physicians Network, LLC

Project: Develop a freestanding multispecialty ambulatory surgical facility by relocating no more than one operating room from Iredell Memorial Hospital and developing one new procedure room

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency 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

The applicants, Iredell Memorial Hospital, Incorporated (IMH) and Iredell Physicians Network, LLC (IPN) propose to develop a freestanding multispecialty ambulatory surgical facility (ASF) in a new medical office building on the Iredell Mooresville Campus (IMC) by relocating no more than one operating room (OR) from IMH and developing one new procedure room (PR). The facility will be referred to throughout these findings as Iredell Mooresville ASC as a result of multiple projects being developed on this campus simultaneously.

Need Determination

The proposed project does not involve the addition of any new health service facility beds services or equipment for which there is a need determination in the 2019 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to this review.

Policies

There is only one policy in the 2019 SMFP applicable to the review.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 31 of the 2019 SMFP, states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”

The proposed capital expenditure for this project is greater than \$5 million. In Section B, pages 20-21, the applicants explain why they believe the application is consistent with Policy GEN-4. The applicants provide a written statement of their plan to assure improved energy efficiency and water conservation, including the use of LED lighting, low-flow plumbing and energy efficient mechanical system. The applicants adequately demonstrate that the application includes a written statement describing the projects plan to assure improved energy efficient and water conservation.

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion because the applicants adequately demonstrate that the proposal is consistent with Policy GEN-4.

- (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, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicants propose to develop Iredell Mooresville Campus ASC, a freestanding multispecialty ASF by relocating one OR from IMH and developing one new PR. Surgical specialties to be offered at the proposed ASF include orthopedics, ENT, podiatry, ophthalmology and general surgery.

Patient Origin

On page 55, the 2019 SMFP states, “An operating room’s service area is the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1.” In Figure 6.1, page 60 of the 2019 SMFP, Iredell County is shown as a single-county OR service area. Thus, the service area for this application is Iredell County. Facilities may also serve residents of counties not included in the service area.

While this is a new facility with no existing patient origin data, the applicants provide current patient origin data for outpatient surgery at IMH in Exhibit C.2, as show in the table below.

Current Patient Origin at IMH for Outpatient Surgical Cases: ORs

ZIP Code	2018 Fiscal Year (FY) 10/01/2017 to 9/30/2018	
	Patients	% of Total
Iredell	3,184	73.2%
Alexander	467	10.7%
Catawba	161	3.7%
Rowan	126	2.9%
Wilkes	72	1.7%
Davie	68	1.6%
Mecklenburg	67	1.5%
Other*	207	4.7%
Total	4,352	100.0%

Source: Exhibit C.2

*The applicant lists the counties and other states included in this category in Exhibit C.2.

Projected patient origin is shown in the tables below.

Projected Patient Origin: ORs

ZIP Code (County)	3 rd Full Fiscal Year (FY) 10/01/2023 to 9/30/2024	
	Patients	% of Total
28115 (Iredell)	362	35.25%
28117 (Iredell)	424	41.25%
28125 (Rowan)	26	2.55%
28673 (Catawba)	61	5.89%
28682 (Catawba)	10	0.93%
28166 (Iredell)	87	8.49%
Out of Area	58	5.66%
Total	1,028	100.0%

Source: Section C.3, page 30.

Note: Out of Area includes patients from other North Carolina counties, primarily Mecklenburg, Rowan, Cabarrus, Lincoln and Catawba, and from other states, primarily Virginia and South Carolina.

Projected Patient Origin: PRs

ZIP Code	3 rd Full Fiscal Year (FY) 10/01/2023 to 9/30/2024	
	Patients	% of Total
28115 (Iredell)	378	35.25%
28117 (Iredell)	442	41.25%
28125 (Rowan)	27	2.55%
28673 (Catawba)	63	5.89%
28682 (Catawba)	10	0.93%
28166 (Iredell)	91	8.49%
Out of Area	61	5.66%
Total	1,072	100.0%

Source: Section C.3, page 31.

Note: Out of Area includes patients from other North Carolina counties, primarily Mecklenburg, Rowan, Cabarrus, Lincoln and Catawba, and from other states, primarily Virginia and South Carolina.

In Section C, pages 31-32 and in Section Q, pages 124-145, the applicants provide the assumptions and methodology used to project patient origin. The applicants assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 32-47, the applicants explain why they believe the population projected to utilize the proposed services needs the proposed services, summarized as follows:

- Mission of Iredell Health System (See application page 33)
- Population growth and aging within Iredell County, specifically the southern portion (See application pages 33-38);
- Cost effectiveness of outpatient surgery at ASF's as opposed to hospitals (See application pages 41-43);
- Health status of Iredell County residents (See application pages 39-40);

- Traffic congestion in and around Iredell County and particularly the Mooresville area (See application page 39);
- Physicians interest and referrals (See application page 47);
- The difficulty associated with Statesville ambulatory surgery locations trying to serve southern Iredell County (See application pages 44-47); and
- Historical surgical patterns at Iredell Memorial Hospital (See application page 47).

The information is reasonable and adequately supported for the following reasons:

- The applicants provide information and data to support population age trends in the proposed geographic service area showing that by 2024, 29.2 percent of the population will be in the 45-64 age range and that the 45-65 age group dominates the ambulatory surgery user profile.
- The applicants provide reasonable information to support the need for a new ASF in southern Iredell County, in order to provide services closer to home for patients and health care personnel.
- The applicants used clearly cited and reasonable historical and demographic data to make the assumptions with regard to identifying the population to be served, its growth and aging, and the need the identified population has for the proposed services.
- The applicants cited reasonable data demonstrating the cost-effectiveness of outpatient surgery in a non-hospital based ASF and the improved access to care provided by both the proposed location and the lower cost structure to be provided by the proposed ASF.
- The applicants reasonably documented outmigration trends of Iredell County residents for outpatient surgery in ASF's and the support of local physicians for the proposed ASF.

Projected Utilization

In Section Q, Form C, page 122, the applicants provide projected utilization, as illustrated in the following table.

Projected Utilization			
Operating Rooms	1st Full FY FY2022	2nd Full FY FY2023	3rd Full FY FY2024
Dedicated Ambulatory ORs	1	1	1
Outpatient Surgical Cases	1,028	1,028	1,028
Outpatient Surgical Case Time	76.6	76.6	76.6
Outpatient Surgical Hours	1,312	1,312	1,312
Group Assignment	6	6	6
Standard Hours per OR per Year	1,312	1,312	1,312
Total Surgical Hours/Standard Hours Per OR per Year	1.0	1.0	1.0

Source: Section Q, Form C.

In Section Q, pages 124-145, and the applicants provide the assumptions and methodology used to project utilization, which is summarized below.

Surgical Cases

Step 1. Identify the Geographic Area and Population to be Served by IMC (See pages 124 and 126) Based on [Envionics Analytics] and Claritas the applicants determined the projected overall population in the proposed geographic service area for the years 2019 to 2024. The service area, identified by ZIP codes, was selected to target the heavy population area of south Iredell County and, in addition, to address traffic congestion between south Iredell County and IMH in Statesville. (See pages 39 and 140)

Step 2. Project Need for Ambulatory Surgical Cases in the Geographic Area (See page 127) Using NC DHSR Hospital and AMSU Access Data bases the applicants calculated the 2017 Ambulatory Surgical Case Use Rate per 1,000, Statewide, for 2017.

Step 3. Project Need for ORs in the Geographic Area (See page 128) The applicants projected the total number of ambulatory surgical cases for the proposed service area by multiplying the overall population for each year from Step 1 by the 2017 Statewide Ambulatory Surgical Case Use Rate per 1,000 from Step #2.

Step 4. Project IMC Market Share of Need in the Geographic Area (See page 129) The applicants determined the need for ORs in the proposed service area as shown in the following table.

		2022	2023	2024
a	Ambulatory Surgical Cases*	7,209	7,324	7,441
b	Average Case Time (Hours)	1.28	1.28	1.28
c	Total Surgical Hours	9,203	9,350	9,500
d	Hours Required per OR at Group 6 Facility	1,312	1,312	1,312
e	ORs Needed in Service Area	7.01	7.13	7.24

*Calculated in Step 3.
 Source: Table on page 140.

The applicants project a market share for the service area of 15%, 20% and 24% respectively for OY1-OY3.

		2022	2023	2024
a	Ambulatory Surgical Cases*	7,208	7,324	7,441
b	Projected Market Share	15%	20%	24%
c		1,081	1,465	1,786

Source: Tables on pages 140-141.

As stated in Section Q, page 129, projected market share was based on:

- Physician referrals. In Exhibit I.3, the applicant provides physician letters of support with estimated referrals totaling between 2,316 and 2,424 surgical cases and between 2,040 and 2,280 pain cases by the 2024 (OY3). In the third project year 2,316 surgical cases (the lower end of the estimated referrals) represents a

market share of 31% whereas the applicants are only projecting a market share of 24% in the third project year.

- Lower market share in year one to be more conservative.
- Applicants experience.

Step 5. Project Utilization at Iredell Mooresville ASC with In-migration (*See page 130*)

The applicants project some in-migration from outside the proposed service area. The applicants keep this constant at 6.0% for the first three project years.

		2022	2023	2024
a	Ambulatory Surgical Cases based on Market Share	1,081	1,465	1,786
b	Projected Market Share	6.0%	6.0%	6.0%
c		1,150	1,558	1,900

Source: Table on page 141.

In Section Q, page 130, the applicants state that the projected in-migration market share of 6% is conservative based on the 2019 License Renewal Application of Lake Norman Regional Medical Center which had 18% of their patients coming in from just Mecklenburg. In addition, to be conservative, the applicants kept the percentage of in-migration constant.

Step 6. Project Operating Rooms Needed for Iredell Mooresville ASC, 2022-2024 (*See page 131*)

		2022	2023	2024
a	Ambulatory Surgical Cases*	1,150	1,558	1,900
b	Average Case Time (Hours)	1.28	1.28	1.28
c	Total Surgical Hours	1,469	1,989	2,426
d	Hours Required per OR at Group 6 Facility	1,312	1,312	1,312
e	ORs Needed in Service Area	1.12	1.52	1.85

Source: Table on page 131.

Step 7. Determine Allocation of Cases to Operating Room and Procedure Room (*See page 132*)

		2022	2023	2024
a	Ambulatory Surgical Cases at IMC	1,150	1,558	1,900
b	Pain Cases to Procedure Rooms	200	200	200
c	OR Cases	1,028	1,028	1,028
d	Procedure Room Cases	323	731	1,072

Source: Table on page 132.

In Section Q, page 132, the applicants state that an algorithm was created to determine the number of cases that will go to either the OR or the PR. The process is described in detail on page 132. Furthermore, the applicants made the following assumptions:

- All pain management cases go to the procedure room.
- Pain management cases will stay constant at 200 cases through 2024.
- Fill operating room to 75% capacity.
- Iredell Mooresville ASC has policies approved by the board and medical staff to use the procedure room for surgical cases.

Step 8. Justify OR at Iredell Mooresville ASC After Allocation of Cases (*See page 133*)

		2022	2023	2024
a	Ambulatory Surgical Cases*	1,028	1,028	1,028
b	Average Case Time (Hours)	1.28	1.28	1.28
c	Total Surgical Hours	1,312	1,312	1,312
d	Hours Required per OR at Group 6 Facility	1,312	1,312	1,312
e	ORs Needed in Service Area	1.0	1.0	1.0

Source: Table on page 133.

*From Row a of Table in Step 7.

Procedure Room Cases

In Section Q, the applicants provide projected procedure room utilization, as illustrated in the following table.

Projected Utilization			
Procedure Rooms	1st Full FY FFY2022	2nd Full FY FFY2023	3rd Full FY FFY2024
# of Procedure Rooms	1	1	1
Total Procedures*	323	731	1,072

*From Row “d” in Table from Step 7. In Section Q, page 132, the applicants state that an algorithm was created to determine the number of cases that will go to either the OR or the PR. The process is described in more detail on page 132.

Projected utilization is reasonable and adequately supported for the following reasons:

- Patients and third-party payors pay less for the same procedure performed at an ASF than one done on an outpatient basis in a hospital-based OR.
- There are no other non-hospital licensed ASF’s in the projected geographic service area.
- Projected surgical case growth is supported by projected population growth.
- The applicants have letters of support from local physicians projecting case referrals in excess of the number of cases projected by the applicants.

Access

In Section C, page 62, the applicants state, “As demonstrated in the service policy in Exhibit C.8, the facility will not restrict service on the basis of age, gender, race, sexual orientation ethnicity, age, or ability. The facility will be designed to meet standards of the Americans with Disabilities Act. It will have a charity policy consistent with the sample in Exhibit L.4, which

permits persons with low incomes to quality for discounts.” In Section L, page 110, the applicants project the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table.

Payor Category	Operating Room Services as a Percent of Total	Procedure Room Services as a Percent of Total
Medicaid*	6.0%	6.0%
Medicare*	30.0%	30.0%
Charity Care	2.0%	2.0%
Self-Pay	4.0%	4.0%
Insurance*	56.0%	56.0%
Other (WC, TRICARE)	2.0%	2.0%
Total	100.0%	100.0%

Source: Table on page 110 of the application

*Including any managed care plans.

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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 applicants adequately identify the population to be served.
- The applicants adequately explain why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicants project the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

- (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, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

C

The applicants propose to develop Iredell Mooresville ASC, a freestanding multispecialty ASF, by relocating one OR from IMH and developing one new PR.

The proposed project involves relocating one of the 10 existing ORs at IMH in Statesville to develop a freestanding multispecialty ASF, Iredell Mooresville Campus in Mooresville. Both Statesville and Mooresville are within the Iredell County Operating Room Service Area.

In Section D, page 69, the applicants explain why they believe the needs of the population presently utilizing the services to be reduced, eliminated or relocated will be adequately met following completion of the project. On page 69, the applicants state:

“The 2019 SMFP shows a projected surplus of 0.6 ORs at Iredell Memorial Hospital by 2021. Should this materialize, the move will not affect patient access. Should surgical demand at Iredell Memorial Hospital increase, the hospital can serve patients by developing an additional procedure room with associated board and medical staff-approved policies for use of that room for surgical cases. This approach is approved by the DHSR Licensure Section in response to the 2015 Kirshbaum ruling.”

In Section Q, page 145, the applicants provide projected utilization for IMH as illustrated in the following table.

		2022	2023	2024
a	Ambulatory Cases	4,565	4,645	4,751
b	Hours per Ambulatory Cases Actual FY18	1.6	1.6	1.6
c	Total Ambulatory Surgical Hours	7,320	7,449	7,620
d	Inpatient Cases	1,942	1,942	1,942
e	Hours per Inpatient Case Actual FY18	2.66	2.66	2.66
f	Total Inpatient Surgical Hours	5,161	5,161	5,161
g	Total Inpatient and Ambulatory Hours	12,482	12,610	12,781
h	Hours Required per OR at Group 4 Facility	1,500	1,500	1,500
i	ORs Justified at IMH by State Performance Hours	8.32	8.41	8.52
j	ORs Justified at IMH Rounded	8	8	9

Source: See Table on page 145 of the application.

In Section Q, pages 143-145, the applicants provide the assumptions and methodology used to project utilization, which is summarized below.

- Calculate the Annual Percent Change from 2014-2019 for both ambulatory and inpatient surgical cases at IMH. (See table on page 143)
- Determine the Average Annual Change Rate (AACR) for both ambulatory and inpatient surgical cases at IMH which is 0.0% for inpatient cases and 2.8% for ambulatory surgery cases. (See table on page 143)
- Project Future Inpatient and Ambulatory Surgical Cases at IMH from 2020 to 2024 using the AACRs determined in the previous step. (See table on page 144)
- Subtract out the Proposed Annual Shift of Ambulatory Surgical Cases from IMH to the proposed ASF, Iredell Mooresville ASC for the first three project years. (See tables on pages 144-145)

The needs of the patients currently served by IMH will be adequately met by the nine ORs which will remain at IMH.

In Section D, page 73, the applicants state, “*Because IMH will continue to serve its geographic area population according to its charitable mission and the needs of prescriptions of the SMFP, the relocation of one operating room from Statesville to Mooresville will have no effect on low-income persons, racial and ethnic minorities, or other medically underserved populations.*”

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

- The applicants utilized historical cases from IMH
- The applicants calculated AACRs based on accepted Agency practice.
- Projected inpatient and ambulatory cases at IMH were based on applying the calculated AACR to historical surgical cases at IMH.
- The applicants were conservative with respect to projecting inpatient surgical cases by showing no growth when the AACR would have shown negative growth which would have resulted in lower projected surgical hours at IMH.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the applicants adequately demonstrate that:

- The needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion.
- The project will not adversely impact the ability of underserved groups to access these services following project completion.

- (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 applicants propose to develop Iredell Mooresville ASC, a freestanding multispecialty ASF by relocating one OR from IMH and developing one new PR.

In Section E, pages 75-80, the applicants describe the alternatives considered and explain 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 – The applicants state that the Mooresville area ZIP codes defined as the geographic service area to be served have no ambulatory surgical facilities, that the deficiency of available, reasonably priced ambulatory surgical care in the Mooresville area has led to significant outmigration of Iredell residents and that maintaining the status quo would not address the growing need for freestanding ASF services, or for improved access to lower priced ambulatory services. Therefore, the applicants rejected this alternative as more costly and less effective.
- Relocate a Different Number of Rooms or From a Different Location – IMH currently has 10 ORs. The applicants determined that IMH will need 9 ORs to meet the needs of its population in 2024, the third full fiscal year of the proposed project. Relocating an OR from Iredell Ambulatory Surgical Center (IASC) would have necessitated shutting down IASC as it only has one OR. The applicants do not have control of any additional ORs as they are minority shareholders in Iredell Surgical Center. Therefore, the applicants rejected this alternative as less effective.
- Develop the Project in a Different Area- The applicants considered developing the proposed ASF closer to Lake Norman however, development costs and land costs are more expensive closer to Lake Norman and would not address the fact that half of the Iredell County population is now located in the southern portion of Iredell County. Therefore, the applicants rejected this alternative as less effective and more costly.
- Pursue a Joint Venture- A joint venture was considered however, no compelling reasons to enter into a joint venture were forthcoming so this alternative was rejected as less effective.

On page 80, the applicants state that its proposal is the most effective alternative because it's the best method to meet the demand for expanded surgical services in Mooresville in a low-cost, high quality setting it represents and the best use of the applicants' surgical resources.

The applicants provide supporting documentation in Exhibits C.4 and C.5.

The applicants adequately demonstrate that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The application is conforming to all statutory and regulatory review criteria.
- The applicants provide credible information to explain why they believe the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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 and Iredell Physicians Network, LLC shall materially comply with all representations made in the certificate of need application.**
- 2. Iredell Memorial Hospital, Incorporated and Iredell Physicians Network, LLC shall develop a freestanding multispecialty ambulatory surgical facility by relocating no more than one operating room from Iredell Memorial Hospital and developing one procedure room.**
- 3. Upon project completion, Iredell Mooresville Campus ASC shall be licensed for no more than one operating room and one procedure room.**
- 4. Iredell Memorial Hospital, Incorporated and Iredell Physicians Network, LLC 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.**
- 5. Iredell Mooresville Campus ASC shall receive accreditation from the Joint Commission for the Accreditation of Healthcare Organizations, the Accreditation Association for Ambulatory Health Care or a comparable accreditation authority within two years following licensure of the facility.**
- 6. For the first three years of operation following completion of the project, Iredell Memorial Hospital, Incorporated and Iredell Physicians Network, LLC shall not increase charges more than 5% of the charges projected in Section Q of the application without first obtaining a determination from the Healthcare Planning and Certificate of Need Section that the proposed increase is in material compliance with the representations in the certificate of need application.**
- 7. The procedure rooms shall not be used for procedures that should be performed only in an operating room based on current standards of practice.**
- 8. Procedures performed in the procedure rooms shall not be reported for billing purposes as having been performed in an operating room and shall not be reported on the facility's license renewal application as procedures performed in an operating room.**
- 9. Iredell Memorial Hospital, Incorporated and Iredell Physicians Network, LLC shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.**

10. 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, Iredell Memorial Hospital, Incorporated and Iredell Physicians Network, LLC 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.**

11. Iredell Memorial Hospital, Incorporated and Iredell Physicians Network, LLC 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.

C

The applicants propose to develop Iredell Mooresville ASC, a freestanding multispecialty ASF by relocating one OR from IMH and developing one new PR.

Capital and Working Capital Costs

In Section Q, Form F.1a, page 146, the applicants projects the total capital cost of the project as shown in the table below.

Site Costs	\$906,880
Construction Costs	\$6,761,630
Miscellaneous Costs	\$4,125,459
Total	\$11,793,969

In Section Q, the applicants provide the assumptions used to project the capital cost.

In Section F, page 86, the applicants project that start-up costs will be \$294,507 and initial operating expenses will be \$693,307 for a total working capital of \$992,814. In Section Q, the applicants provide the assumptions and methodology used to project the working capital needs of the project.

Availability of Funds

In Section F, page 84, the applicants state that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	Iredell Memorial Hospital, Incorporated	Iredell Physician Network, LLC	Total
Loans	\$4,211,183	\$7,582,786	\$11,793,969
Total Financing	\$4,211,183	\$7,582,786	\$11,793,969

* OE = Owner's Equity

In Section F, page 87, the applicants state that the working capital needs of the project will be funded as shown in the table below.

Sources of Financing for Working Capital		Amount
(a)	Loans	\$992,814
(b)	Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	\$
(c)	Lines of credit	\$
(d)	Bonds	\$
(e)	Total *	\$992,814

Exhibit F.2 contains a letter dated June 14, 2019 from the Senior Vice President of Branch Banking and Trust Company (BB&T) stating that, *“Over the past several years Branch Banking and Trust Company (“BB&T) has had the privilege of working closely with Iredell Memorial Hospital, Incorporated and Iredell Physician Network, LLC. ... I also understand that the two companies intend to finance the surgery center upfits and working capital required for the ambulatory surgery center project with a loan in the amount of approximately \$10 million. Of that, approximately \$8.5 million would be associated with the ambulatory surgery upfits and equipment, and \$1.5 million associated with the ambulatory surgery center working capital. ... BB&T believes the proposed loan is financeable.”* Exhibit F.2 also includes a letter dated June 12, 2019 from the Chief Financial Officer of Iredell Memorial Hospital, Incorporated stating that, *“As an official of Iredell Memorial Hospital, Incorporated and Iredell Physician Network, LLC, I have the authority to commit funds in the amount of \$12 million from BB&T for the purpose of developing at the Iredell Mooresville Campus, a new ambulatory surgery center in Mooresville, North Carolina.”*

Financial Feasibility

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

	1 st Full Fiscal Year	2 nd Full Fiscal Year	3 rd Full Fiscal Year
Total Cases (Both OR and Procedure Room)	1,351	1,759	2,100
Total Gross Revenues (Charges)	\$6,117,592	\$9,461,837	\$11,766,890
Total Net Revenue	\$2,253,450	\$3,448,465	\$4,275,042
Average Net Revenue per Case	\$1,668	\$1,960	\$2,036
Total Operating Expenses (Costs)	\$2,734,901	\$3,177,957	\$3,380,566
Average Operating Expense per Case	\$2,024	\$1,807	\$1,610
Net Income	(\$481,451)	\$270,509	\$894,476

The assumptions used by the applicants in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicants adequately demonstrate that the capital and working capital costs are based on reasonable and adequately supported assumptions.
- The applicants adequately demonstrate availability of sufficient funds for the capital and working capital needs of the proposal.
- The applicants adequately demonstrate sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

- (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 applicants propose to develop Iredell Mooresville ASC, a freestanding multispecialty ASF by relocating one OR from IMH and developing one new PR.

On page 55, the 2019 SMFP states, “An operating room’s service area is the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1.” In Figure 6.1, page 60 of the 2019 SMFP, Iredell County is shown as a single-county OR service area. Thus, the service area for this review consists of Iredell County. Facilities may also serve residents of counties not included in the service area.

The following table identifies the existing and approved ORs in the Iredell County Operating Room Service Area.

Facilities	# of ORs	Projected OR Deficit/Surplus (-)
Davis Regional Medical Center	5	-2.13
Lake Norman Regional Medical Center	9	-1.76
Iredell Head Neck and Ear**	1	-0.63
Iredell Surgical Center	4	-3.41
Iredell Memorial Hospital	10	-2.52

Source: 2019 SMFP, Table 6B, page 78

** (now Iredell Ambulatory Surgery Center)

In Section G, pages 92-93, the applicants explain why it believes its proposal would not result in the unnecessary duplication of existing or approved ambulatory surgical services in Iredell County Operating Room Service Area. The applicants state:

“As defined in chapter 6 of the SMFP, “service area” is considered to be the entirety of Iredell County. However, when considering duplication of the service of existing health service facilities, the applicants note that the geographic area population to be served by the proposed Iredell Mooresville Campus ASF is significantly narrower. The proposed facility will serve primarily residents of southern Iredell County Mooresville and nearby zip codes, as explained thoroughly in Section C of this application.

...

This proposal will not result in the unnecessary duplication of existing ambulatory surgery services in the service area. The projected surplus of operating rooms among Statesville area facilities does not reflect the limited access to ambulatory surgical facilities in the Mooresville area, the high cost of surgical care in that area, or the outmigration for ambulatory surgery.”

The applicants adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The proposal would not result in an increase in ORs in the Iredell County Operating Room Service Area.
- The applicants adequately demonstrate that the proposed ASF is needed in addition to the existing or approved ASF's in Iredell County.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

- 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 for the reasons stated 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

In Section Q, Form H Staffing- Facility, page 168, the applicants provide projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Projected FTE Staff
	3rd Full Fiscal Year (10/01/2023 to 9/30/2024)
Registered Nurses	6.23
Surgical Technicians	3.12
Housekeeping	2.08
Administrator	0.25
Other (non-health professionals)	1.04
TOTAL	12.72

The assumptions and methodology used to project staffing are provided in Sections H and Q. Adequate costs for the health manpower and management positions proposed by the applicants are budgeted in Form 3, which is found in Section Q. In Section H.2 and H.3, page 95, the applicants describe the methods used to be used to recruit or fill new positions and its proposed training and continuing education programs. In Section I, page 98, the applicants identify the proposed medical director. In Exhibit I.3, page 17, the applicants provide a letter from the proposed medical director indicating an interest in serving as medical director for the proposed services.

The applicants adequately demonstrate the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

In Section I, pages 96-97, the applicants state that the following ancillary and support services are necessary for the proposed services:

- Pre and Post Anesthesia, Recovery
- Anesthesia
- Extended Recovery
- Sterile Processing
- Medical Records
- Pathology
- Housekeeping
- Materials Management
- Laundry Service
- Medical Direction
- Business Office

On pages 96-97, the applicants adequately explain how each ancillary and support service is or will be made available and provides supporting documentation in Exhibits I-2 and I-3.

In Section I, page 97, the applicants describe the existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits I.2 and I.3.

The applicants adequately demonstrate that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 applicants do 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 applicants do 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.

- (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

Neither of the applicants is 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.

C

In Section K, page 101, the applicants state that the project involves up fitting 14,171 square feet of a medical office building (MOB) currently under construction. In Section K, page 104, the applicants state that IMH, the parent company, will develop and own the MOB and Iredell Physicians Network, LLC will lease space on the first floor of the building to operate the proposed ASF. Line drawings are provided in Exhibit K.1.

On pages 102-103, the applicants adequately explain how the cost, design and means of construction represent the most reasonable alternative for the proposal and provides supporting documentation in Exhibit K.1.

On page 103, the applicants adequately explain why the proposal will not unduly increase the costs to the applicants of providing the proposed services or the costs and charges to the public for the proposed services and provides supporting documentation in Section Q.

On page 103, the applicants identify any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit K.4.

On pages 104-106, the applicants identify the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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.

- (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 handicapped persons, 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

IMC is currently not an existing facility. The OR for the proposed ASF is to be relocated from IMH, which is one of the applicants. In Section L, page 108, the applicants provide the historical payor mix during the last full fiscal year (10/01/2017 to 9/30/2018) for the operating rooms and procedure rooms at IMH, as shown in the table below.

Payor Category	Operating Room Services as a Percent of Total	Procedure Room Services as a Percent of Total
Medicaid*	11.2%	2.1%
Medicare*	46.9%	55.1%
Charity Care	1.0%	0.0%
Self-Pay	3.4%	3.3%
Insurance*	34.7%	34.4%
Workers Compensation	0.9%	2.7%
TRICARE	0.6%	2.4%
Other (Medcost, VA)	1.3%	0.0%
Total	100.0%	100.0%

Source: Table on page 110 of the application

*Including any managed care plans.

In Section L, page 108, the applicants provide 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	61.12%	50.8%
Male	38.88%	49.2%
Unknown	Na	Na
64 and Younger	61.43%	84.1%
65 and Older	38.5%	15.9%
American Indian	0.1%	0.4%
Asian	0.3%	2.7%
Black or African-American	19.0%	12.1%
Native Hawaiian or Pacific Islander	0.0%	0.0%
White or Caucasian	77.3%	78.7%
Other Race	3.3%	3.8%
Declined / Unavailable	Na	na

The Agency reviewed the:

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

Based on that review, the Agency concludes that the applicants adequately document the extent to which medically underserved populations currently use the applicants existing services in comparison to the percentage of the population in the applicants 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 handicapped persons 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, page 109, the applicants state

“The applicant and Iredell Memorial Hospital both involve ownership or membership by a 501(c)(3) corporation. As such, both have an obligation to a charitable mission. IMH is a CMS certified hospital, and subject to EMTALA rules.

IMH is in full compliance with CMS certification for Medicare and Medicaid, and by extension in compliance with EMTALA requirements. IMH is also in full compliance with IRS regulations for its 501(c)(3) status.”

In Section L, page 109, the applicants state that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicants or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

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 110, the applicants project the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below.

Payor Category	Operating Room Services as a Percent of Total	Procedure Room Services as a Percent of Total
Medicaid*	6.0%	6.0%
Medicare*	30.0%	30.0%
Charity Care	2.0%	2.0%
Self-Pay	4.0%	4.0%
Insurance*	56.0%	56.0%
Other (WC, TRICARE)	2.0%	2.0%
Total	100.0%	100.0%

Source: Table on page 110 of the application

*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicants project that 4.0% of total services will be provided to self-pay patients, 2.0% to charity care patients, 30.0% to Medicare patients and 6.0% to Medicaid patients.

In Section Q, the applicants provide the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- It is based on a shift of cases from IMH and IMC is projected to have all of the surgical specialties that IMH currently offers;
- The payor mix is based on a review of IMH historical surgery payor mix adjusted for the differences in the Mooresville area.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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, page 111, the applicants adequately describe the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

In Section M, page 112, the applicants describe the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M.2.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicants adequately demonstrate that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

- (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 applicants propose to develop Iredell Mooresville ASC, a freestanding multispecialty ASF by relocating one OR from IMH and developing one new procedure room.

On page 55, the 2019 SMFP states, “*An operating room’s service area is the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1.*” In Figure 6.1, page 60 of the 2019 SMFP, Iredell County is shown as a single-county OR service area. Thus, the service area for this review consists of Iredell County. Facilities may also serve residents of counties not included in the service area.

The following table identifies the existing and approved ORs in the Iredell County Operating Room Service Area.

Facilities	# of ORs	Projected OR Deficit/Surplus (-)
Davis Regional Medical Center	5	-2.13
Lake Norman Regional Medical Center	9	-1.76
Iredell Head Neck and Ear**	1	-0.63
Iredell Surgical Center	4	-3.41
Iredell Memorial Hospital	10	-2.52

Source: 2019 SMFP, Table 6B, page 78

** (now Iredell Ambulatory Surgery Center)

In Section N, page 113, the applicants describe the expected effects of the proposed services on competition in the service area and discuss how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 113, the applicants state

“The proposed ambulatory surgical facility will be the only non-profit freestanding surgery center in the Mooresville area. A new freestanding competitor backed and lead by Iredell Health System will provide market competition to keep prices at nearby facilities lower. The competitive option for consumers and others for whom price is a concern should also work to contain prices for outpatients at the local hospitals. ...

The proposed project represents a distinctive approach that will enhance the quality of surgical care available in the region in multiple ways. ...

The facility will accept patients without regard to source of payment and has plans to provide charity for medical necessity.”

The applicants adequately describe the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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 for the reasons stated 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

In Section Q, Form A, page 121, the applicants identify the hospitals and surgery centers located in North Carolina owned, operated or managed by the applicants or a related entity. The applicant identifies a total of three of this type of facilities located in North Carolina.

In Section O, page 117, the applicants state that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in none 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 applicants and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all three 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.
- (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.

NA

The applicants do not propose to increase the number of operating rooms in the service area, therefore, the criteria and standards for surgical services and operating rooms do not apply.