

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: July 19, 2019

Findings Date: July 19, 2019

Project Analyst: Celia C. Inman

Team Leader: Gloria C. Hale

Project ID #: F-11702-19

Facility: Iredell Mooresville Campus

FID #: 190166

County: Iredell

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

Project: Develop a new diagnostic center

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

Iredell Memorial Hospital, Incorporated (IMH) and Iredell Physician Network, LLC (IPN), collectively referred to as “the applicant”, proposes to develop a new diagnostic center, Iredell Mooresville Campus (IMC), in Mooresville, Iredell County.

The applicant will acquire and operate computed tomography (CT), 3D-mammography, x-ray and ultrasound equipment, the total cost of which will exceed the statutory threshold of \$500,000; therefore, the equipment qualifies the facility as a diagnostic center, which is a new institutional health service, which requires a Certificate of Need (CON).

N.C. Gen. Stat. 131E-176(7a) states:

“Diagnostic center” means a freestanding facility, program, or provider, including but not limited to, physicians’ offices, clinical laboratories, radiology centers, and mobile diagnostic programs, in which the total cost of all the medical diagnostic equipment utilized by the facility which cost ten thousand dollars (\$10,000) or more exceeds five hundred thousand dollars (\$500,000). In determining whether the medical diagnostic equipment in a diagnostic center costs more than five hundred thousand dollars (\$500,000), the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater.”

Policies

The proposed capital cost is greater than \$2 million, but less than \$5 million; therefore, Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities on page 31 of the 2019 SMFP is applicable to this review. Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities 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 is required to submit a plan for 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.”

In Section B.11, pages 25-26, the applicant discusses the project’s plan to assure improved energy efficiency and water conservation, stating:

“Iredell Memorial Hospital, Inc and Iredell Physician Network, LLC are committed to providing energy efficiency and sustainability.

...

The construction of Iredell Mooresville Campus will utilize energy conserving mechanical equipment and construction methods that comply with North Carolina Commercial Energy Code, as well as the latest addition of ASHRAE 90.1.

...

The design will have a water-conservation plan among its features, the plumbing system will include water saving faucets and water closets.”

In Section K.4(c), page 86, the applicant makes further references to its plan to assure improved energy efficiency and water conservation, citing the architect’s letter in Exhibit K.4.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

- the applicant does not propose to develop any new beds or services, or acquire any equipment for which there is a need determination in the 2019 SMFP, and
- the applicant adequately demonstrates that the proposal is consistent with Policy GEN-4 for the following reasons:
 - the capital cost of the proposed project is greater than \$2 million and less than \$5 million, and
 - the applicant provides a written statement in the application describing the project’s plan to assure improved energy efficiency and water conservation.

- (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 applicant proposes to develop a diagnostic center by acquiring and operating CT, mammography, x-ray and ultrasound equipment in leased space in a medical office building (MOB) in southern Iredell County. Applicant IMH will develop and own the MOB and Applicant IPN will lease space in the MOB to operate the diagnostic center. IMH is the parent company of IPN.

In Section C.1, pages 27-31, the applicant describes the proposed project and discusses the medical diagnostic equipment. The applicant states that the diagnostic center will serve urgent care and primary care patients of practices in the same MOB, as well as other outpatients who may need tests for routine monitoring or preventive care. On page 27, the applicant states:

“The diagnostic center will serve as an extension of IHS’s existing healthcare system, providing additional access to diagnostic imaging services for patients in the southern part of the county and nearby communities where access to charitable diagnostic services is inadequate.”

Designation as a Diagnostic Center

In Exhibit F.1, the applicant provides the vendor quotes for the cost of the proposed new medical diagnostic equipment which will establish the proposed diagnostic center, as shown below.

Proposed Diagnostic Equipment				
Equipment	Manufacturer/Model	#	Unit Cost	Total Cost
CT Scanner	Aquilion Lightning 160	1	\$459,142	\$459,142
	VLO-TUABASIC/LU-S.100	1	\$48,742	\$48,742
Mammography	Mammomat Revelation	1	\$398,067	\$398,067
	Breast Density License	1	\$11,400	\$11,400
Ultrasound	Accuson Sequoia	1	\$147,000	\$147,000
X-Ray	Multix Fusion Max	1	\$215,334	\$215,334
Total				\$1,279,685

The combined value of the proposed new medical diagnostic equipment, costing \$10,000 or more exceeds the statutory threshold of \$500,000; therefore, the equipment qualifies the facility as a diagnostic center, which is a new institutional health service, which requires a CON.

Patient Origin

N.C. Gen. Stat. §131E-176(24a) states, “Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.” The 2019 SMFP does not define a service area for diagnostic centers nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant. In Section C.3, page 33, the applicant defines the service area for the proposed

diagnostic center as “encompassing a 12-minute drive-time radius from the proposed diagnostic center in Mooresville”; which includes census tracts in Iredell and Catawba counties, as shown in Section Q, page 115. Facilities may also serve residents not included in their service area.

The proposed diagnostic center is a new facility and therefore has no historical patient origin. In Section C.3, pages 33-35, the applicant provides IMC’s projected patient origin for CT, x-ray, ultrasound, mammography, and the entire facility, respectively, for the first three full fiscal years (FY), as summarized in the tables below.

Projected Patient Origin CT Services

County Census Tracts	First Full FY 10/1/21-9/30/22		Second Full FY 10/1/22-9/30/23		Third Full FY 10/1/23-9/30/24	
	Patients	Percent	Patients	Percent	Patients	Percent
Iredell	1,378	88.4%	2,101	88.5%	3,025	88.5%
Catawba	180	11.6%	273	11.5%	392	11.5%
Total	1,558	100.0%	2,374	100.0%	3,417	100.0%

Projected Patient Origin X-ray Services

County Census Tracts	First Full FY 10/1/21-9/30/22		Second Full FY 10/1/22-9/30/23		Third Full FY 10/1/23-9/30/24	
	Patients	Percent	Patients	Percent	Patients	Percent
Iredell	2,055	88.4%	3,134	88.5%	4,513	88.5%
Catawba	268	11.6%	408	11.5%	585	11.5%
Total	2,324	100.0%	3,541	100.0%	5,097	100.0%

Projected Patient Origin Ultrasound Services

County Census Tracts	First Full FY 10/1/21-9/30/22		Second Full FY 10/1/22-9/30/23		Third Full FY 10/1/23-9/30/24	
	Patients	Percent	Patients	Percent	Patients	Percent
Iredell	581	88.4%	886	88.5%	1,276	88.5%
Catawba	76	11.6%	115	11.5%	165	11.5%
Total	657	100.0%	1,001	100.0%	1,441	100.0%

Projected Patient Origin 3D Mammography Services

County Census Tracts	First Full FY 10/1/21-9/30/22		Second Full FY 10/1/22-9/30/23		Third Full FY 10/1/23-9/30/24	
	Patients	Percent	Patients	Percent	Patients	Percent
Iredell	535	88.4%	827	88.4%	1,209	88.5%
Catawba	70	11.6%	108	11.5%	157	11.5%
Total	605	100.0%	935	100.0%	1,366	100.0%

Projected Patient Origin Entire Diagnostic Center

County Census Tracts	First Full FY 10/1/21-9/30/22		Second Full FY 10/1/22-9/30/23		Third Full FY 10/1/23-9/30/24	
	Patients	Percent	Patients	Percent	Patients	Percent
Iredell	4,549	88.5%	6,947	88.5%	10,023	88.5%
Catawba	594	11.6%	904	11.5%	1,299	11.5%
Total	5,143	100.0%	7,851	100.0%	11,322	100.0%

In Section C.3(c), page 35, the applicant states that the assumptions, methodology and calculations by county and modality are contained in the Need and Utilization Methodology with Form C in Section Q and Exhibit C.3. The applicant further states that the projected patient origin assumes the following:

- a proportionate distribution of demand across the service area census tracts,
- constant patterns for all three years,
- demand is proportionate to population, and
- each procedure represents a unique patient.

The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, pages 36-43, the applicant explains why they believe the population projected to utilize the proposed services needs the proposed services.

On page 36, the applicant states that the need for the proposed project is based on the following considerations:

- the charter and mission of Iredell Health System (IHS) to serve the whole of Iredell County (page 36),
- population growth within Iredell County (pages 36-38),
- traffic congestion in Iredell County (page 39),
- the age and health status of Iredell County residents (pages 40-41),
- US Preventive Service Task Force Recommendations (page 42), and
- County income levels and access for medically underserved groups (pages 39 and 42-43).

Iredell Health System Mission

In Section C.4, page 36, the applicant discusses the IHS commitment to provide health and wellness services to serve the community, acknowledging that the county’s growth and changing population centers require IHS to adjust its services to accommodate the changes.

Population Growth

On pages 36-38, the applicant states that the Iredell County population is shifting from the Statesville area in central Iredell County to southern Iredell County. The applicant further states:

“In fact, according to national demographer Claritas, from 2010 to 2019, the population in the two zip codes associated with Mooresville, 28115 and 28117, grew 22.6 percent, while the remainder of the county grew only 4.8 percent. Mooresville’s growth is not expected to slow down, with projected growth of 8.7 percent between 2019 and 2024, compared to 4.1 percent for the remainder of the county.”

Traffic Congestion

In Section C.4, page 39, the applicant discusses the traffic situation in Iredell County and states:

“Because of the traffic congestion, outpatient diagnostic services, once easily accessible at the charitable non-profit Iredell Memorial Hospital, now involve car trips that take up to 40 minutes from the center of Mooresville, and longer from South Iredell.”³

The applicant further states that to survive and maintain reasonable quality of life, Mooresville is developing as a service hub in its own right.

Age and Health Status of Iredell County

In Section C.4, page 40, the applicant states that the median age of Iredell County residents will increase from 40.98 in 2018 to 41.65 in 2024 and the percent of persons over 65 will increase from 15.7% to 17.8%.

On pages 40-41, the applicant discusses Iredell County and in particular the Mooresville area’s health status and prevention statistics from the North Carolina State Center for Health Statistics, stating that Mooresville’s health risks include:

- 14.8% of the adult population is uninsured,
- almost 29% of adults are obese,
- 17% of adults smoke,
- substance abuse deaths are 140% of the state rate, and
- rates are high at 467 and 158 per 100,000 residents in 2013-2017, for cancer and heart disease, respectively.

On page 41, the applicant states that Iredell County has higher rates of heart disease, cardiovascular, cancer and stroke deaths than the state. The applicant also notes a particular pattern of high thyroid cancer rates in southern Iredell County. In addition, the applicant states that the number of primary care physicians per 10,000 residents shows a declining supply in the state and the county.

³ Per Google Maps Statesville to Mooresville measured March 31, 2019

US Preventive Services Task Force Recommendations

On page 42, the applicant states that the US Preventive Services Task Force (USPSTF) recommends biennial screening for mammography for asymptomatic women ages 50 to 74 and states that for persons with symptoms or other risk factors, the frequency recommendations may be different, and screening may begin earlier for some. The applicant states that the USPSTF also recommends the following preventive screening:

- ultrasound screening for abdominal aortic aneurysm in men 65 to 75, and
- annual CT scans for adults 55 to 80 who have been heavy smokers.

County Income Levels and Access for Medically Underserved Groups

On page 39, the applicant discusses Mooresville's residents' income levels and state:

“Though the service area [poverty level] is lower than the county and state, it is important to note that almost one in ten persons in Mooresville have an income below poverty. This is masked higher average household income metric. Although the average in 2013-2017 was \$67,213, the distribution was wide and skewed towards lower incomes.

Household income employment is also a critical factor with regard to access to care. Persons with incomes above poverty often struggle harder to meet the challenge of underinsurance. Price is an access deterrent for this group.”

On page 42, the applicant states that underinsured, uninsured, and persons with special needs are more likely to face challenges with regard to access to care and the proposed diagnostic center will offer charitable services and contribute to competition. On page 43, the applicant further states that the proposed diagnostic center will:

- provide the rapidly growing service area with a second charitable non-profit alternative,
- be one of only two non-profit tax-exempt, freestanding diagnostic centers in the proposed service area,
- be accountable to IHS' Board of Trustees, which is comprised of Iredell County residents, and
- be the only diagnostic imaging center in the county that is accountable to a local, Iredell County board.

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

- Reliable data sources are used to support assertions about population growth and medical need for the proposed services.
- The applicant uses the data to make reasonable and adequately supported assumptions about service area residents' future need for the proposed services.

Projected Utilization

In Section Q, Form C, page 108, the applicant provides the projected utilization for the first three years of operation following completion of the project, as summarized in the following table.

**Iredell Mooresville Campus
 Diagnostic Center
 Form C: Utilizations**

Each Service Component	1st Full FY FY2022	2nd Full FY FY2023	3rd Full FY FY2024
CT Services			
# of Units	1	1	1
# of Scans	1,558	2,374	3,417
# of HECT Units*	2,402	3,660	5,269
X-ray Services			
# of Units	1	1	1
# of Procedures	2,324	3,541	5,097
Mammography			
# of Units	1	1	1
# of Procedures	605	935	1,366
Ultrasound			
# of Units	1	1	1
# of Procedures	657	1,001	1,441

*Based on applicant's calculations from Exhibit C.12 using DHSR 2018 Hospital License Renewal Applications (FY2017 data)

In Section Q, pages 113-133, the applicant provides the assumptions and methodology used to project utilization, as follows:

1. The new facility will be one of four hospital related diagnostic imaging providers in or adjacent to the service area.
2. The service area is composed of the census tracts within a 12-minute drive time from the proposed facility, as identified on page 115.
3. Service area population estimates are from Claritas and are the same for CT, x-ray and ultrasound. Mammography estimates include the Claritas service area female population ages 50 through 74, arrived at through interpolation.
4. Calendar and fiscal year population estimates are considered the same.
5. CT and mammography procedures are projected using North Carolina state use rates for each modality.
6. X-ray and ultrasound are projected using outpatient adjusted use rates for each modality.
7. Market share is estimated at 8%, 12%, and 17% for each modality for the first three fiscal years, respectively.

CT Services	Use Rate*	FY2022	FY2023	FY2024
Service Area Population		93,009	94,503	96,022
NC CT Use Rate	209.33/1,000			
Service Area Scans		19,470	19,782	20,100
IMC Market Share		8%	12%	17%
Total IMC CT Scans		1,558	2,374	3,417

*NC use rate is 209.33 per 1,000 population based on FY2017 data for all acute care hospitals and ambulatory surgery center in NC, as reported on 2018 Hospital License Renewal Applications

X-ray Services	Use Rate*	FY2022	FY2023	FY2024
Service Area Population		93,009	94,503	96,022
NC X-ray Use Rate	312.27/1,000			
Service Area Procedures		29,044	29,511	29,985
IMC Market Share		8%	12%	17%
Total IMC X-ray Procedures		2,324	3,541	5,097

*Use rate was calculated based on FY2018 data from Hospital License Renewal Applications (433.71 x-rays per 1,000 population), and reduced using actual IMH ratios of outpatient to inpatient x-rays, resulting in 312.27 outpatient x-rays per 1,000 population

Mammography Services	Use Rate*	FY2022	FY2023	FY2024
Service Area Population		15,859	16,346	16,861
NC Use Rate	476.51/1,000			
Service Area Scans		7,557	7,789	8,034
IMC Market Share		8%	12%	17%
Total IMC Mammography Procedures		605	935	1,366

*NC mammography use rate is 476.51 per 1,000 population based on the NC DHSR 2018 database, which contains FY2017 data as reported on licensure data

Ultrasound Services	Use Rate*	FY2022	FY2023	FY2024
Service Area Population		93,009	94,503	96,022
NC Use Rate	88.30/1,000			
Service Area Scans		8,212	8,344	8,479
IMC Market Share		8%	12%	17%
Total IMC Ultrasound Procedures		657	1,001	1,441

*Use rate was calculated based on FY2018 data from Hospital License Renewal Applications (110.37 ultrasounds per 1,000 population), and reduced using actual IMH ratios of outpatient to inpatient ultrasound procedures, resulting in 88.30 outpatient ultrasounds per 1,000 population

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

- Projected population increase and aging in the service area is expected to support ongoing diagnostic services.
- Utilization is projected for each specific diagnostic service type, applying assumptions based on state use rates for CT and mammography and adjusted outpatient use rates for x-ray and ultrasound services.

- Market share is estimated to increase in each of the first three fiscal years, but remains below 25%. The proposed facility will be one of four providers in the service area.
- The utilization forecast for each service was validated against referral estimates from urgent care visits and physician letters in Exhibit H.4.

Access

In Section C.11, page 49, the applicant discusses access to the proposed services. The applicant states:

“Because the proposed project will be subject to the charter mandates of the applicants, it will operate with a charitable mission. ...

As demonstrated in the service policy in Exhibit C.11, the facility will not restrict service based on age, gender, race, ethnicity, age or ability.”

In Section L.1(a), pages 91-92, the applicant provides information on patients served by the IPN physicians expected to provide services in the MOB where the diagnostic center will be located, showing that 65% and 29% of current services were provided to women and persons 65 and older, respectively. The applicant states that statistics related to racial and ethnic minority data were not available.

The proposed facility is not an existing facility and therefore has no current patient information, but the applicant provides FY2018 payor mix of imaging patients served by the Iredell Health System and payor mix for patients served by the IPN physician group on page 94.

In Section L.3(b), page 96, the applicant provides the projected payor mix for the proposed diagnostic center and for each service component for the second full fiscal year of operation following completion of the project, FY2023, as summarized in the following table.

**Iredell Mooresville Campus
 Diagnostic Center
 FY2023**

Payor Source	Entire Facility	CT	Mammography	Ultrasound	X-ray
Self-Pay	7.1%	5.4%	5.4%	5.4%	5.4%
Charity Care	0.6%	3.0%	3.0%	3.0%	3.0%
Medicare*	56.2%	19.7%	19.7%	19.7%	19.7%
Medicaid *	8.3%	6.4%	6.4%	6.4%	6.4%
Insurance*	26.2%	56.5%	56.5%	56.5%	56.5%
Workers Compensation	0.8%	0.0%	0.0%	0.0%	0.0%
TRICARE	0.9%	0.0%	0.0%	0.0%	0.0%
Other (specify)	0.0%	10.0%	10.0%	10.0%	10.0%
TOTAL	100.0%	100.0%	100.0%	100.0%	100.0%

* Includes any managed care plans
 Totals may not sum due to rounding

In Section Q, page 153, the applicant states:

“These payor percentages are based on Iredell Physician Network, Mooresville based, physicians’ historical payor percentages.”

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, and
- supplemental information requested by the Agency.

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

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects 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.

NA

The applicant does not propose to reduce or eliminate a service or relocate a health service facility or health service. The applicant proposes to establish a new diagnostic center. 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 develop a diagnostic center by acquiring and operating CT, mammography, x-ray and ultrasound equipment in leased space in an MOB in southern Iredell County.

In Section E.2, pages 61-63, the applicant describes the alternatives 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 other alternatives considered were:

1. Maintain the Status Quo – the applicant states that maintaining the status quo would not address the growing need for imaging services, or for improved access to lower priced services, which may cause patients to leave the county, delay care, or go without care. Therefore, the applicant rejects the status quo, deeming it a less effective alternative.
2. Develop the Proposed Diagnostic Center in a Different Area – the applicant states that it considered developing the proposed diagnostic center close to Lake Norman, where land and development would be more costly. Also half of the county population is now concentrated in the southern portion of Iredell County; therefore, population and consumer responsiveness favor the location in Mooresville. Thus, the applicant states that developing the proposed diagnostic center in another location would be both a less effective and more costly alternative and was therefore rejected.
3. Pursue a Joint Venture with a Non-IHS Related Entity – the applicant states that if the proposed diagnostic center is accountable only to a charitable purpose organization, it will have more latitude to make decisions that favor quality and/or access and will retain IHS's charitable mission purpose. Thus, a joint venture with a non-IHS related entity would not be an effective alternative for the applicant; therefore this alternative was rejected.
4. Relocate Equipment from Iredell Memorial Hospital to IMC – the applicant determined that relocating and replacing equipment at IMH would cause disruption to services at IMH and would be more costly than purchasing new equipment for the proposed diagnostic center. Therefore, the applicant rejected this alternative.
5. Acquire Different Quantities of Medical Diagnostic Equipment – the applicant states that clinical and administrative leadership have decided that the proposed mix of medical diagnostic equipment will adequately meet the qualitative and quantitative needs of the physicians located in the MOB, as well as the projected needs of the population to be served. Therefore, a different mix or quantity of diagnostic equipment was rejected as a less effective alternative at this time.

On page 63, the applicant states that the project, as proposed, is the most effective alternative to best enable IHS to meet the needs of all of the population of Iredell County including the proposed diagnostic center service area. The applicant further states that the decision on

alternatives was vetted through medical staff leadership, IPN physicians practicing in the Mooresville area, and IHS' Board of Directors and Board of Trustees.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the identified need for the following reasons:

- The application is conforming to all statutory criteria.
- The applicant provides credible information to explain why the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- application, and
- 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 Physician Network, LLC shall materially comply with all representations made in the certificate of need application and any supplemental responses. In the event that representations conflict, Iredell Memorial Hospital, Incorporated and Iredell Physician Network, LLC shall materially comply with the last made representation.**
- 2. Iredell Memorial Hospital, Incorporated and Iredell Physician Network, LLC shall develop a new diagnostic imaging center with computed tomography, X-ray, ultrasound and mammography diagnostic equipment.**
- 3. Iredell Memorial Hospital, Incorporated and Iredell Physician 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.**
- 4. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Iredell Memorial Hospital, Incorporated and Iredell Physician 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.

5. **Iredell Memorial Hospital, Incorporated and Iredell Physician 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 applicant proposes to develop a diagnostic center by acquiring and operating CT, mammography, x-ray and ultrasound equipment in leased space in an MOB in southern Iredell County.

Capital and Working Capital Costs

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

**Iredell Mooresville Campus
Capital Cost**

	IMH	IPN	Total
Site Prep/Construction Costs/ Renovation/ Landscaping	\$1,668,927	\$1,118,000	\$2,786,927
Architect/Engineering Fees	\$94,250	\$262,400	\$356,650
Medical Equipment	\$0	\$1,286,083	\$1,286,083
Non-medical Equipment and Furniture	\$57,400	\$202,200	\$259,600
Consultant Fees/Other	\$128,809	\$180,000	\$308,809
Total	\$1,949,386	\$3,048,683	\$4,998,069

In Section F.1, page 65, and Section Q, the applicant provides the assumptions used to project the capital cost. See Exhibit F.1 for documentation on vendor quotes and construction related costs. IPN will lease space within the new MOB developed by IMH. IPN will incur the tenant upfit costs. See Exhibit K.5 for a copy of the lease agreement.

In Section F, pages 68-69, the applicant projects that start-up costs will be \$151,761 and initial operating expenses will be \$162,851 for a total working capital of \$314,613. In Section Q, page 158, the applicant provides the assumptions used to project the working capital needs of the project.

Availability of Funds

In Section F, page 66, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	IMH	IPN	Total
Loans	\$1,949,386	\$3,048,683	\$4,998,069
Accumulated reserves or OE *	\$0	\$0	\$0
Bonds	\$0	\$0	\$0
Other (Specify)	\$0	\$0	\$0
Total Financing **	\$1,949,386	\$3,048,683	\$4,998,069

* OE = Owner's Equity.

**Total financing should equal line 14 in Form F.1a Capital Cost.

In Section F, page 69, the applicant states that the working capital needs of the project will also be funded through loans.

See Exhibit F.2 for BB&T's documentation of available funding on behalf of IMH and IPN for the project's capital and working capital costs respectively. The exhibit also contains a letter from IMH's COO and IPN's Sole Manager committing to develop the project with the BB&T funding. Exhibit F.4 contains a copy of Iredell Memorial Hospital, Incorporated's 2018 audited financials.

Financial Feasibility

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project for the proposed IMC diagnostic modalities and for the Iredell Health System as a whole. In Form F.4, pages 141-142, the applicant projects that expenses exceed revenues for the diagnostic center in the first two operating years. Revenues exceed expenses for the diagnostic center beginning in the third operating year, as summarized in the table below.

**Iredell Mooresville Campus
 Diagnostic Center**

	1st Full FY FY2022	2nd Full FY FY2023	3rd Full FY FY2024
Total Procedures*	5,144	7,851	11,321
Total Gross Revenues (Charges)	\$3,870,111	\$5,961,787	\$8,674,245
Total Contractual Adjustments	\$3,121,567	\$4,818,108	\$7,023,649
Total Net Revenue	\$748,544	\$1,143,679	\$1,650,596
Average Net Revenue per Procedure	\$145.52	\$145.67	\$145.80
Total Operating Expenses (Costs)	\$975,597	\$1,166,908	\$1,197,297
Average Operating Expense per Procedure	\$190	\$149	\$106
Net Income	(\$227,052)	(\$23,230)	\$453,299

*Total Procedures include CT, x-ray, ultrasound and mammography

Source: Section Q Form F.4

Totals may not sum due to rounding

In Form F.3, page 140, the applicant projects that revenues will exceed operating expenses for the IHS system as a whole in each of the first three full fiscal years of the project, as summarized in the table below.

Iredell Health System

	1st Full FY FY2022	2nd Full FY FY2023	3rd Full FY FY2024
Total Gross Patient Revenues (Charges)	\$625,376,041	\$641,529,288	\$658,621,461
Total Contractual Adjustments	\$440,428,701	\$452,019,316	\$464,342,784
Total Net Revenue	\$184,947,340	\$189,509,972	\$194,278,677
Other Revenue	\$1,927,362	\$1,946,636	\$1,966,102
Total Revenue	\$186,874,702	\$191,456,607	\$196,244,779
Total Operating Expenses (Costs)	\$184,794,829	\$188,593,051	\$192,355,805
Net Income	\$2,079,873	\$2,863,556	\$3,888,974

Totals may not sum due to rounding

Source: Section Q Form F.3

The assumptions used by the applicant 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, and
- exhibits to the application.

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 and working capital costs are based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
 - 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 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 applicant proposes to develop a diagnostic center by acquiring and operating CT, mammography, x-ray and ultrasound equipment in leased space in an MOB in southern Iredell County.

N.C.G.S. §131E-176(24a) states, “*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2019 SMFP does not define a service area for diagnostic centers nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant. In Section C.3, page 33, the applicant defines the service area for the proposed diagnostic center as “*encompassing a 12-minute drive-time radius from the proposed diagnostic center in Mooresville*”; which includes census tracts in Iredell and Catawba counties, as shown in Section Q, page 115. Facilities may also serve residents not included in their service area.

In Section G.1, page 73, the applicant identifies the providers of similar hospital and outpatient imaging services within the applicant’s defined service area, as shown below.

Provider	CT	3D Mammography	X-ray	Ultrasound
Novant Health Imaging Mooresville	x			x
Novant Health Breast Imaging Center Langtree (Mooresville)		x		
Lake Norman Regional Medical Center/Lake Norman Imaging Center	x	x	x	x
Charlotte Radiology Mooresville Breast Center		x		

Source: 2018 Hospital License Renewal Applications, DHSR and internet search

In Section G, page 74, the applicant states:

“Total annual utilization for diagnostic centers is not available from a public source such as the SMFP or North Carolina license renewal applications. Hospital license renewal forms have limited information for imaging modalities and data for CT do not

separate inpatient from outpatient services. The following table presents available DHSR Hospital License Renewal form information for FY2018.”

Provider	CT	3D Mammography	X-ray	Ultrasound
Novant Health Imaging Mooresville	Not Available	Not Available	Not Available	Not Available
Novant Health Breast Imaging Center Langtree (Mooresville)	Not Available	Not Available	Not Available	Not Available
Lake Norman Regional Medical Center/Lake Norman Imaging Center	9,967	6,369	2,747	3,225
Charlotte Radiology Mooresville Breast Center	Not Available	Not Available	Not Available	Not Available

Source: 2019 DHSR LRAs; CT is outpatient and inpatient combined

In Section G.3, page 75, the applicant explains why it believes the proposal would not result in an unnecessary duplication of existing or approved diagnostic centers in the proposed service area. The applicant states:

“This proposal will not result in unnecessary duplication of existing diagnostic imaging services in the service area. . . . As Section C of this application demonstrates, population growth in Iredell County, and specifically the southern portion, combined with health status and increasing demand for outpatient healthcare services, will sustain need for additional capacity in the proposed service area.”

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

- The applicant uses reasonable assumptions to project the need for services in the proposed service area.
- The applicant uses reasonable assumptions to project the proposed utilization in the service area and in the proposed facility.
- The applicant adequately demonstrates that the proposed diagnostic center is needed in addition to the existing and/or approved diagnostic centers in the service area.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- 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 above stated reasons.

- (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, the applicant provides projected full-time equivalent (FTE) positions for the proposed services for the first three operating years, as shown in the table below.

**Iredell Mooresville Campus
Proposed Diagnostic Center Staffing**

Position	FY2022 FTE	FY2023 FTE	FY2024 FTE
X-ray Technologists	0.9	0.9	0.9
CT Technologists	0.9	0.9	0.9
Ultrasound Technologists	0.5	0.5	0.5
Mammography Technologists	0.5	0.5	0.5
Clerical	0.9	0.9	0.9
Other (Administrator)	0.5	0.5	0.5
TOTAL	4.2	4.2	4.2

In Section H.1, page 76, and in Section Q, the applicant discusses the assumptions and methodology used to determine staffing needs. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4 and Form H, which are found in Section Q. In Section H.2 and H.3, pages 76-77, the applicant describes IHS's experience and process for recruiting and retaining staff and its proposed training and continuing education programs. In Section H.4, pages 77-78, the applicant discusses physician coverage needed for the project and the physician base that will be practicing at the MOB where the diagnostic center will be located. On page 77, the applicant identifies Joseph Tritico, M.D. as the proposed Medical Director. Dr. Tritico's letter expressing support and willingness to serve as Medical Director at the proposed diagnostic center is included in Exhibit H.4. The applicant provides letters of support and referral documentation in Exhibit H.4. Additional letters of support were submitted to the Agency during the public comment period.

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

Conclusion

The Agency reviewed the:

- application, and
- 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.1, pages 80-81, the applicant states that the following ancillary and support services are necessary for the proposed services and explains how the services will be made available:

- administration,
- finance and billing,
- medical records,
- housekeeping,
- scheduling,
- pharmacy,
- radiology, and
- physics.

In Section I, pages 81-82, the applicant states that IHS intends to develop the MOB and urgent care simultaneous with the development of the proposed diagnostic center, which will provide referral and support to the proposed diagnostic center. Associated costs are included in the allocated overhead in the pro forma assumptions. The applicant further states that IMH and IPN are established providers in the service area and have existing relationships with local health care and social services providers. Exhibit H.4 contains physician letters of support. Exhibit I.2 contains hospital and community letters of support. Additional letters of support were submitted to the Agency during the public comment period.

Conclusion

The Agency reviewed the:

- application, and
- 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 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.

C

The applicant proposes to develop a diagnostic center by acquiring and operating CT, mammography, x-ray and ultrasound equipment in leased space in an MOB in southern Iredell County.

In Section K.1, page 84, the applicant states that the diagnostic center portion of the new MOB involves 6,560 square feet of space within the existing MOB. Exhibit K.1 contains the site plan and line drawings.

In Section K.4(a), page 85, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal and provide supporting documentation in Section Q and Exhibit K.1.

On page 86, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services and provide supporting documentation in Section Q and Exhibit F.1.

On page 86, the applicant identifies the architect's letter in Exhibit K in addressing applicable energy saving features that will be incorporated into the construction plans.

On pages 87-89, the applicant identifies the proposed site and provides information on 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, and
- exhibits to the application.

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

In Section L.1(a), page 91, the applicant discusses payor mix and states that the proposed diagnostic center is not an existing health service facility and therefore has no historical payor mix.

On page 94, the applicant provides the historical payor mix for both IMH and the IPH Mooresville physicians expected to provide services in the MOB where the diagnostic center will be located, as summarized in the tables below.

**Iredell Memorial Hospital
 FY2018**

Payor Source	Entire Facility	CT	Mammography	Ultrasound	X-ray
Self-Pay	3.3%	4.1%	3.7%	5.5%	2.4%
Charity Care	4.1%	3.8%	2.4%	9.0%	6.0%
Medicare*	49.3%	56.4%	49.3%	35.7%	52.6%
Medicaid *	4.7%	5.1%	1.5%	5.0%	7.9%
Insurance*	34.9%	27.5%	42.3%	44.1%	27.5%
Workers Compensation	2.4%	2.4%	0.0%	0.3%	3.0%
TRICARE	0.6%	0.5%	0.7%	0.4%	0.6%
Other (Liability)	0.7%	0.1%	0.0%	0.0%	0.0%
TOTAL	100.0%	100.0%	100.0%	100.0%	100.0%

* Includes any managed care plans
 Totals may not sum due to rounding

**IPN Mooresville Physicians
 FY2018**

Payor Source	Entire Facility
Self-Pay	10.2%
Charity Care	3.0%
Medicare*	19.7%
Medicaid *	6.4%
Insurance*	55.5%
Workers Compensation	0.0%
TRICARE	0.0%
Other	5.3%
TOTAL	100.0%

* Includes any managed care plans
 Totals may not sum due to rounding

On pages 91-92, the applicant provides demographical information on the IPN physicians expected to provide services in the MOB where the diagnostic center will be located and provide the following comparison.

	Percentage of Total Patients Served by the IPN Physicians during the Last Full FY	Percentage of the Population of Iredell County	Percentage of the Population of the Service Area
Female	65.0%	50.8%	50.3%
Male	35.0%	49.2%	49.7%
Unknown	Not Available	Not Available	Not Available
64 and Younger	71.0%	84.1%	85.2%
65 and Older	29.0%	15.9%	14.8%
American Indian	Not Available	0.4%	0.3%
Asian	Not Available	2.7%	3.3%
Black or African-American	Not Available	12.1%	7.3%
Native Hawaiian or Pacific Islander	Not Available	0.0%	0.1%
White or Caucasian	Not Available	78.7%	84.5%
Other Race	Not Available	3.8%	2.1%
Declined / Unavailable	Not Available	Not Available	Not Available

The Agency reviewed the:

- application, and
- exhibits to the application.

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 Iredell County and in the applicant’s proposed 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

The proposed facility is not an existing facility. Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 95, the applicant states it has no obligation.

In Section L.2(c-d), page 95, the applicant states that there have been no patient civil rights equal access complaints filed against IPN or IMH or any other related entity in the past five years.

The Agency reviewed the:

- application, and
- 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.3(b), page 96, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

**Iredell Mooresville Campus
 Diagnostic Center
 FY2023**

Payor Source	Entire Facility	CT	Mammography	Ultrasound	X-ray
Self-Pay	7.1%	5.4%	5.4%	5.4%	5.4%
Charity Care	0.6%	3.0%	3.0%	3.0%	3.0%
Medicare*	56.2%	19.7%	19.7%	19.7%	19.7%
Medicaid *	8.3%	6.4%	6.4%	6.4%	6.4%
Insurance*	26.2%	56.5%	56.5%	56.5%	56.5%
Workers Compensation	0.8%	0.0%	0.0%	0.0%	0.0%
TRICARE	0.9%	0.0%	0.0%	0.0%	0.0%
Other (specify)	0.0%	10.0%	10.0%	10.0%	10.0%
TOTAL	100.0%	100.0%	100.0%	100.0%	100.0%

* Includes any managed care plans
 Totals may not sum due to rounding

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 7.1% and 0.6% of total diagnostic services at the facility will be provided to self-pay and charity care patients. Also, the applicant projects that 56.2% and 8.3% of total diagnostic services will be provided to Medicare and Medicaid patients, respectively.

In Section Q, page 153, regarding the above payor mix, the applicant states:

“These payor percentages are based on Iredell Physician Network, Mooresville based, physicians’ historical payor percentages.”

The projected payor mix is reasonable and adequately supported for the following reasons:

- the projected payor mix is based on the historical payor mix for the services at IMH and IPN during FY2018, and

- the applicant adequately demonstrates that medically underserved populations will have access to the proposed services.

The Agency reviewed the:

- application, and
- 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.5, page 97, the applicant describes the range of means by which a person will have access to the proposed services.

The Agency reviewed the:

- application, and
- 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 98, the applicant describes 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.

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the applicant adequately demonstrates 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 applicant proposes to develop a diagnostic center by acquiring and operating CT, mammography, x-ray and ultrasound equipment in leased space in an MOB in southern Iredell County.

N.C.G.S. §131E-176(24a) states, “*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2019 SMFP does not define a service area for diagnostic centers nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant. In Section C.3, page 33, the applicant defines the service area for the proposed diagnostic center as “*encompassing a 12-minute drive-time radius from the proposed diagnostic center in Mooresville*”; which includes census tracts in Iredell and Catawba counties, as shown in Section Q, page 115. Facilities may also serve residents not included in their service area.

In Section G.1, page 73, the applicant identifies the providers of similar hospital and outpatient imaging services within the applicant’s defined service area, as shown below.

Provider	CT	3D Mammography	X-ray	Ultrasound
Novant Health Imaging Mooresville	x			x
Novant Health Breast Imaging Center Langtree (Mooresville)		x		
Lake Norman Regional Medical Center/Lake Norman Imaging Center	x	x	x	x
Charlotte Radiology Mooresville Breast Center		x		

In Section G, page 74, the applicant states:

“Total annual utilization for diagnostic centers is not available from a public source such as the SMFP or North Carolina license renewal applications. Hospital license renewal forms have limited information for imaging modalities and data for CT do not

separate inpatient from outpatient services. The following table presents available DHSR Hospital License Renewal form information for FY2018.”

Provider	CT	3D Mammography	X-ray	Ultrasound
Novant Health Imaging Mooresville	Not Available	Not Available	Not Available	Not Available
Novant Health Breast Imaging Center Langtree (Mooresville)	Not Available	Not Available	Not Available	Not Available
Lake Norman Regional Medical Center/Lake Norman Imaging Center	9,967	6,369	2,747	3,225
Charlotte Radiology Mooresville Breast Center	Not Available	Not Available	Not Available	Not Available

Source: 2019 DHSR LRAs; CT is outpatient and inpatient combined

In Section N, pages 99-101, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 99, the applicant states that the proposed diagnostic center will be one of only two non-profit freestanding diagnostic centers in the proposed service area. The applicant further states:

“A new freestanding competitor backed and lead by Iredell Health System will provide market competition to keep prices at the only other freestanding competitor, Novant Health, low.

...

Competition will work both ways. As a new market entrant, the proposed diagnostic center must outperform others to attract and retain patients.”

The applicant adequately describes 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), and
- 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, and
- 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 A.2(e), page 2, the applicant states that Iredell Memorial Hospital, Incorporated is the parent company of Iredell Physician Network, LLC.

In Section O.3, page 104, the applicant states that neither it, nor any related entities, own, operate or manage any diagnostic centers in North Carolina. Iredell Memorial Hospital, Incorporated operates IMH in Statesville, North Carolina. The applicant states that IMH is certified by CMS for Medicare and Medicaid participation; and has been in good standing and full compliance for the 18 months immediately preceding the submission of this application. 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, there were no incidents related to quality of care at IMH. 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 IMH, 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.

C

The applicant proposes to develop a diagnostic center by acquiring and operating CT, mammography, x-ray and ultrasound equipment in leased space in an MOB in southern Iredell County.

The Criteria and Standards for Diagnostic Centers promulgated in 10A NCAC 14C .1800 were repealed. The Criteria and Standards for Major Medical Equipment promulgated in 10A NCAC 14C .3100 were repealed. However, the Criteria and Standards for Computed Tomography

Equipment promulgated in 10A NCAC 14C .2300 are applicable to this review. The specific criteria are discussed below.

SECTION .2300 – CRITERIA AND STANDARDS FOR COMPUTED TOOGRAPHY EQUIPMENT

10A NCAC 14C .2300 PERFORMANCE STANDARDS

An applicant proposing to acquire a CT scanner shall demonstrate each of the following:

(1) *each fixed or mobile CT scanner to be acquired shall be projected to perform 5,100 HECT units annually in the third year of operation of the proposed equipment;*

-C- In Section C.12, page 53, the applicant projects that the CT scanner will perform 5,269 HECT units in the third year of operation (FY2024). This exceeds the minimum of 5,100 HECT units annually in the third year of operations as required by 10A NCAC 14C .2303. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

(2) *each existing fixed or mobile CT scanner which the applicant or a related entity owns a controlling interest in and is located in the applicant's CT service area shall have performed at least 5,100 HECT units in the 12 month period prior to submittal of the application; and*

-NA- In Section C.12, page 53, the applicant states that neither the applicant, nor any related entities, own controlling interest in an existing CT scanner located within the proposed IMC CT service area.

For information purposes only, the applicant demonstrates that IMH met the required standard by performing 26,626 HECT units on its two fixed CT scanners in the last 12 months. This exceeds the minimum of 5,100 HECT units per scanner in the 12-month period prior to the application submittal, as required by 10A NCAC 14C .2303. Details of the calculation are presented in Exhibit C.12.

(3) *each existing and approved fixed or mobile CT scanner which the applicant or a related entity owns a controlling interest in and is located in the applicant's CT service area shall be projected to perform 5,100 HECT units annually in the third year of operation of the proposed equipment.*

-NA- In Section C.12, page 53, the applicant states that neither the applicant, nor any related entities, own controlling interest in an existing CT scanner located within the proposed IMC CT service area.

For information purposes only, the applicant demonstrates that IMH will meet the required standard by performing a projected 26,121 HECT units on its two fixed CT scanners in the project's third year of operation (FY2024). This exceeds the minimum

of 5,100 HECT units per scanner in the third year of operation as required by 10A NCAC 14C .2303. Details of the calculation are presented in Exhibit C.12.