ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

Decision Date: May 19, 2020
Findings Date: May 19, 2020

Project Analyst: Celia C. Inman
Assistant Chief: Lisa Pittman

Project ID #: F-11857-20
Facility: Iredell Ambulatory Surgery Center
FID #: 923282
County: Iredell
Applicants: Iredell Memorial Hospital, Incorporated
Iredell Physician Network, LLC
Project: Convert specialty ambulatory surgical program to a multispecialty ambulatory surgical program

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.

NA

Iredell Memorial Hospital, Incorporated (IMH) and Iredell Physicians Network, LLC (IPN), collectively referred to as the "applicant" proposes to convert Iredell Ambulatory Surgery Center (IASC), a specialty ambulatory surgical program, to a multispecialty ambulatory surgical program. In Section C.1, page 16, the applicant states that IASC currently offers otolaryngology (ENT) surgery. The applicant proposes to add orthopedic and general surgery. This meets the requirements in Gen. Stat. 131E-176(15a) for a multispecialty ambulatory surgical program: *"A formal program for providing on a same-day basis surgical procedures for at least three of the following specialty areas: gynecology, otolaryngology, plastic surgery, general surgery, ophthalmology, orthopedic, or oral surgery."*

On page 16, the applicant further states:

> *"The proposed project will not involve construction of any new operating rooms or the relocation of any existing operating rooms. IASC will continue to have one operating room, one procedure room, and all the support spaces required to meet licensure, certification, and accreditation standards for an ambulatory surgery center."*

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 2020 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to this review.

Policies

There are no policies in the 2020 SMFP which are applicable to this review.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that this criterion is not applicable to this review.

(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 convert IASC, a specialty ambulatory surgical program, to a multispecialty ambulatory surgical program. Surgical specialties to be offered at the ambulatory surgical facility (ASF) include ENT, orthopedics, and general surgery. This meets the requirements in Gen. Stat. 131E-176(15a) for a multispecialty ambulatory surgical program.

Patient Origin

On page 51, the 2020 SMFP states, *"An operating room's "service area" is the service area in which the operating room is located. The operating room service areas are the single or*

multicounty groupings shown in Figure 6.1." In Figure 6.1, page 57 of the 2020 SMFP, Iredell County is shown as a single-county operating room (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.

In Section C.2, page 20, the applicant provides the historical patient origin data for IASC's one operating room for the last full fiscal year (FY), as summarized in the table below.

IASC Historical Patient Origin
FY2019
10/1/2018-9/30/2019

County	Patients	% of Total
Iredell	275	76.0%
Alexander	45	12.4%
Rowan	9	2.5%
Davie	8	2.2%
Catawba	7	1.9%
Wilkes	6	1.7%
Mecklenburg	4	1.1%
Yadkin	2	0.6%
Burke	2	0.6%
Vance	1	0.3%
Surry	1	0.3%
Lincoln	1	0.3%
Gaston	1	0.3%
Total	362	100.0%

Source: Application, Table C.1, page 20
Percentages and totals may not calculate/sum due to rounding

The applicant provides the projected patient origin for the IASC operating room on page 21, as summarized below.

Projected Patient Origin: IASC OR

	FY2021		FY2022		FY2023	
County	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Iredell	392	75.7%	397	75.7%	402	75.7%
Alexander	61	11.7%	62	11.7%	62	11.7%
Catawba	12	2.3%	12	2.3%	12	2.3%
Davie	12	2.3%	12	2.3%	12	2.3%
Rowan	13	2.6%	13	2.6%	14	2.6%
Wilkes	9	1.8%	9	1.8%	10	1.8%
Other*	19	3.6%	19	3.6%	19	3.6%
Total	518	100.0%	525	100.0%	531	100.0%

Source: Table C.4, page 21.
*The applicant identifies "Other" as all other NC counties and other states in its assumptions on page 26
Percentages and totals may not calculate/sum due to rounding

The applicant provides the projected patient origin for the IASC procedure room on page 22 and states that it does not expect ENT physicians to utilize the procedure room; therefore, procedure room patient origin reflects that of general and orthopedic physicians only.

In Section C, pages 23-29, the applicant provides the assumptions and methodology used to project operating room patient origin, combining projected ENT cases (one case equals one patient) with projected general surgery and orthopedic patients. Step 4, page 28, Table C.12, miscalculates the sum of the ENT patients (Table C.10) and the general/orthopedic patients (Table C.11), resulting in a lower projection than provided in Table C.4, page 21. Table C.12 (the sum of Tables C.10 and C.11, correctly summed) results in the same figures as provided in Table C.4, page 21. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, pages 30-37, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, summarized as follows:

- Demographics of the geographic area to be served (pages 30-31, and 37);
- Access to high-quality, low-cost surgery (pages 31-34);
- Health status of service area residents (pages 35-36);
- Physician interest in serving patients at IASC (pages 33 and 37); and
- Efficient use of resources (page 38).

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

- The applicant uses clearly cited and reasonable historical and demographic data to make the assumptions with regard to identifying the population to be served, their health status, and the need for the proposed services.

- The applicant provides reasonable information to support the need for access to high quality, low cost surgical services in the service area; and cites reasonable data demonstrating the cost-effectiveness of outpatient surgery in a non-hospital based ASF.
- The applicant reasonably documents the physician interest for the surgical services to be provided at IASC through physician support letters provided in Exhibit I.3.
- The applicant reasonably demonstrates that a minimal investment to convert from a specialty ASF to a multispecialty ASF will benefit patients, physicians and the ASF, improving physician and facility efficiency and providing stability that will ultimately sustain customer friendly pricing.

Projected Utilization

In Section Q, Form C, page 93, the applicant provides the historical and projected utilization, as summarized in the following table.

Projected Operating Room and Procedure Room Utilization

Operating Rooms	**Prior Full FY2019**	**Interim FY2020**	**1st Full FY FY2021**	**2nd Full FY FY2022**	**3rd Full FY FY2023**
Dedicated Ambulatory ORs	1	1	1	1	1
Outpatient Surgical Cases*	362	368	518	525	531
Outpatient Surgical Case Time	54	54	54	54	54
Outpatient Surgical Hours	326	331	467	472	478
Group Assignment	5	5	5	5	5
Standard Hours per OR per Year	1,312	1,312	1,312	1,312	1,312
Total Surgical Hours/Standard Hours Per OR per Year	0.25	0.25	0.36	0.36	0.36
Procedure Rooms**					
Number of Rooms	1	1	1	1	1
Total Number of Procedures	0	0	24	24	24

Source: Section Q Form C, page 93
*One case equals one patient
** Existing ENT surgeons did not utilize the procedure room in FY2019 and FY2020

In Section Q, pages 98-102, the applicant provides the assumptions and methodology used to project IASC operating room and procedure room utilization, which is summarized below.

IASC Operating Room Utilization

Step 1: Determine Historical Operating Room Utilization at IASC – the applicant uses surgical case data from the facility's 2016 through 2020 ASF License Renewal Applications (LRAs), which provide its historical ENT cases only (Table 3, page 98). The applicant discusses IPN's acquisition of the facility in 2017 and the closing and re-credentialing that continued through calendar year 2019. Based on that information, the applicant states that the facility's compound average growth rate (CAGR) of 1.7% between 2015 and 2017 is the more

reasonable and conservative predictor for future IASC surgical ENT case growth than the post-acquisition one-year CAGR of 4.0% for 2018-2019.

Step 2: Project ENT OR Utilization at IASC – the applicant projects future ENT utilization by increasing historical cases by the 1.7% CAGR, as summarized below.

		2019	2020	2021	2022	2023
Historical Cases		362				
2015-2017 CAGR	1.7%					
Projected Cases			368	374	381	387

Step 3: Forecast New General Surgery and Orthopedic Surgical Cases - the applicant states that appropriate cases will be shifted from IMH to IASC in response to patient, insurer and physician requests. Based on physician letters in Exhibit I.3, the applicant assumes five general surgery and seven orthopedic cases (patients) per month will shift to IASC for a total of 144 annually (Table 5, page 100).

Step 4: Forecast Total Surgical Cases in the IASC OR – Sum projected ENT and general/orthopedic cases

	Surgical Cases	FY2021	FY2022	FY2023
a	ENT	374	381	387
b	General and Orthopedic	144	144	144
c	Total OR Cases	518	525	531

Notes:
a. ENT cases (Step 2, Table 4)
b. General and Orthopedic cases (Step 3, Table 5)
c. Total OR cases (a.+ b.)

IASC Procedure Room Utilization

Step 5: Forecast Procedure Room Utilization – IPN acquired IASC in November 2017, closed, re-opened, and re-credentialed; as a result, no cases were performed in the procedure room during FY2019. The applicant states that based on physician letters in Exhibit I.3, it assumes that one general surgery and one orthopedic case per month would be appropriate for the procedure room, resulting in two cases per month and 24 cases annually (Table 7, page 101).

Step 6: Test for Reasonableness for the Projected Utilization at IASC - the applicant provides data in Table 8, page 102, to support the reasonableness of its projections, showing that the total annual OR and procedure room cases for general surgery and orthopedic cases is within the referral range estimate provided in the physician referral letters in Exhibit I.3 (six general surgery and eight orthopedic for a total of 14).

IMH Operating Room Impact

Step 7: Determine Historical Surgical Cases at IMH - the applicant provides the 2014-2019 inpatient and ambulatory surgical cases in Table 9, page 103, and the 2015-2019 CAGR in Table 10, as summarized below.

	Surgical Cases	FY2015	FY2016	FY2017	FY2018	FY2019	CAGR*
a	Inpatient	1,986	2,011	1,967	1,926	1,953	-0.4%
b	Ambulatory	3,953	4,066	4,210	4,352	4,449	3.0%
c	Total	5,939	6,077	6,177	6,278	6,402	1.9%

Notes:
a. Inpatient cases as reported on IMH 2016-2020 LRAs (Exhibit C.7)
b. Ambulatory cases as reported on IMH 2016-2020 LRAs (Exhibit C.7)
c. Total cases (a.+ b.)
* CAGR = (2019 cases by discipline / 2015 cases by discipline)^ (1 /(2019-2015))-1

Step 8: Project OR Surgical Cases at IMH - the applicant provides the projected IMH inpatient and ambulatory surgical cases in Table 11, page 104, growing ambulatory cases by the 2015-2019 CAGR of 3.0% and summarized below.

	Surgical Cases	Growth Factor	FY2020	FY2021	FY2022	FY2023
a	Inpatient	0.0%	1,953	1,953	1,953	1,953
b	Ambulatory	3.0%	4,582	4,720	4,861	5,007
c	Total		6,535	6,673	6,814	6,960

Notes:
a. Inpatient cases remain constant from 2019
b. Ambulatory cases increase at the 3.0% CAGR
c. Total cases (a.+ b.)

Step 9: Determine the Number of OR Cases Shifting from IMH to Iredell Health ASFs - the applicant provides Table 12, on page 105, with the projected shift in general and orthopedic OR cases to IASC in Step 4, Table 6, page 100, as summarized in Step 4 above (144 annually).

	Shift in Surgical Cases	FY2021	FY2022	FY2023
a	IASC	144	144	144
b	IMC	0	240	296
c	Total Shift in OR Cases	144	384	440

Notes:
a. Step 4, Table 6, Row b
b. IMC Utilization Methodology from Project ID #F-11727-19, Excerpt, Exhibit C.7
c. Total cases (a.+ b.)

Step 10: Estimate Remaining Number of OR Cases at IMH - the applicant provides the remaining projected OR cases at IMH after the projected shifts noted above in Table 13, page 105, as summarized below.

	Surgical Cases	FY2020	FY2021	FY2022	FY2023	Difference 2020-2023
a	Estimated OR Cases IMH- Step 8	6,535	6,673	6,814	6,960	
b	OR Cases Shifted- Step 9		144	384	440	
c	Total OR Cases at IMH	6,535	6,529	6,430	6,520	15

Notes:
a. Step 8, Table 11, Row C
b. Step 9, Table 12, Row C
c. Total cases Remaining (a.- b.)

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

- ENT surgical cases are based on historical surgical cases projected to increase at the 2015-2017 CAGR of 1.7%.
- Based on physician letters in Exhibit I.3, the applicant assumes a reasonable number of general surgery and orthopedic cases per month will shift to IASC from IMH.
- The applicant's utilization projections are based on estimates of operating room and procedure room case volumes provided by physicians who have expressed their intention to refer surgical cases to IASC.
- Population projections and demographics reasonably support the projections.

Access

In Section C, page 45, the applicant states, *"As demonstrated in the service policy in Exhibit C.8, page 5, the facility does not restrict service on the basis of age, gender, race, sexual orientation, ethnicity, age, or ability. The facility design meets standards of the Americans with Disabilities Act. IPN has adopted IMH's charity policy for IASC, which permits persons with low incomes to qualify for discounts."* In Section L.3, page 80, the applicant projects the payor mix during the third full fiscal year of operation following completion of the project, as summarized in the following table.

Payor Source	Entire Facility	Operating Room	Procedure Room
Self-Pay	0.28%	0.28%	0.28%
Medicare*	22.65%	22.65%	22.65%
Medicaid*	43.09%	43.09%	43.09%
Insurance*	33.15%	33.15%	33.15%
Other (Workers compensation, TRICARE)	0.83%	0.83%	0.83%
Total	100.0%	100.0%	100.0%

Source: Table on page 80 of the application
*Including any managed care plans.

The projected payor mix is reasonable and adequately supported based on the following:

- The applicant states that it assumes no change in payor mix.
- The applicant states that the majority of projected cases will still be ENT and any changes in new case payor mix will not materially affect payor mix.

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 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 proposes to convert IASC, a specialty ambulatory surgical program, to a multispecialty ambulatory surgical program. The proposal does not result in the reduction, relocation, or elimination of a service. Therefore, Criterion (3a) is not application 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 convert IASC, a specialty ambulatory surgical program, to a multispecialty ambulatory surgical program.

In Section E, pages 56-58, 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 alternatives considered were:

- Maintain the Status Quo – the applicant states:

  > *"Within Iredell County, there is only one freestanding ambulatory surgery option for low-intensity general and orthopedic procedures (see Exhibit C.4, pages 2-9). With few low-cost options available, many cases are performed at the hospital. Providers are receiving increasing pressures from patients and payors for low out-of-pocket costs for these types of surgical services."*

  IASC currently has limited capacity as a specialty surgery center. Converting to multispecialty would allow IASC to keep up with the growing market and offer patients a low-cost alternative to hospital surgical services. The applicant also discusses its lack of control over operations at Iredell Surgical Center (the ASF the applicant refers to in the quote above) and its expectation that changes in service there, if any, will come slowly. Therefore, the applicant rejected this alternative as less effective.

- Build Another Ambulatory Surgery Facility – the applicant determined that there is presently insufficient demand to justify the capital cost of a new surgery center in Statesville. The applicant therefore rejected this alternative as less effective and more costly.

- Expand IASC- the applicant states that facility constraints make an expansion in square footage at the current facility difficult. Construction would unnecessarily add to the project's capital cost and could interrupt current operations. Therefore, the applicant rejected this alternative as less effective and more costly.

On page 57, the applicant states that its project as proposed is the most effective alternative because it's the least costly method to meet the demand for expanded ambulatory surgical services in a low-cost, high quality setting. The proposed project will allow IPN to increase their capacity without the burden and cost of construction. IMH will be able to shift cases appropriate for an outpatient setting to IASC, increasing IMH's capacity for more cases better suited to an inpatient setting.

The applicant provides supporting documentation in Exhibits C.4, pages 2-9.

The applicant adequately demonstrates 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 applicant provides credible information to explain why it believes 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 convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical facility by adding general surgery and orthopedic surgical services.**

3. **Upon project completion, Iredell Ambulatory Surgery Center shall be licensed for no more than one operating 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. **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.**

6. **No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, 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.

7. 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 applicant proposes to convert IASC, a specialty ambulatory surgical program, to a multispecialty ambulatory surgical program.

Capital and Working Capital Costs

In Section Q, Form F.1a, page 111, the applicant projects the total capital cost of the project as shown in the table below.

Medical Equipment	$4,375
Non-Medical Equipment	$10,000
Consultant Fees	$65,000
Contingency	$7,938
Total	**$87,313**

In Section Q, page 111, the applicant provides the assumptions used to project the capital cost.

In Section F, page 61, the applicant projects there will be no start-up costs or initial operating expenses because the ASF is an ongoing operation.

Availability of Funds

In Section F, page 59, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	Iredell Physician Network, LLC	Iredell Memorial Hospital, Incorporated	Total
Loans	$	$	$
Accumulated Reserves or OE*	$	$87,313	$87,313
Bonds	$	$	$
Other	$	$	$
Total Financing	$	$87,313	$87,313

* OE = Owner's Equity

Exhibit F.2 contains a letter dated February 17, 2020 from the Chief Financial Officer of Iredell Memorial Hospital, Incorporated and Iredell Physician Network, LLC stating IMH's intent to provide up to $150,000 to convert IASC to a multispecialty ASF. The Exhibit also contains the IMH balance sheet, as of September 30, 2019 showing more than $5 million in cash, $30 million in current assets and $141 million in total net assets.

Financial Feasibility

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Forms F.2 for the operating room and the procedure room, the applicant projects that revenues will exceed operating expenses in each of the three full fiscal years following completion of the project for both the operating room cases and the procedure room cases, as shown in the tables below.

	FY2021	FY2022	FY2023
Operating Room Cases	518	525	531
Total Gross Revenues (Charges)	$2,495,907	$2,577,069	$2,661,021
Total Net Revenue	$726,112	$749,724	$774,147
Average Net Revenue per Case	$1,402	$1,428	$1,458
Total Operating Expenses (Costs)	$633,681	$647,995	$666,994
Average Operating Expense per Case	$1,223	$1,234	$1,256
Net Income	$92,431	$101,729	$107,153

	FY2021	FY2022	FY2023
Procedure Room Cases	24	24	24
Total Gross Revenues (Charges)	$54,640	$55,897	$58,269
Total Net Revenue	$54,640	$55,897	$58,269
Average Net Revenue per Case	$2,277	$2,329	$2,428
Total Operating Expenses (Costs)	$29,337	$29,636	$30,133
Average Operating Expense per Case	$1,222	$1,235	$1,256
Net Income	$25,304	$26,261	$28,136

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
- 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 costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the 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 convert IASC, a specialty ambulatory surgical program, to a multispecialty ambulatory surgical program.

On page 51, the 2020 SMFP states, *"An operating room's "service area" is the service area in which the operating room is located. The operating room service areas are the single or multicounty groupings shown in Figure 6.1."* In Figure 6.1, page 57 of the 2020 SMFP, Iredell County is shown as a single-county operating room 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.

The following table combines information identifying the existing and approved inpatient (IP), outpatient (OP), and shared operating rooms located in Iredell County, and the inpatient and outpatient case volumes for each provider, from pages 63 and 75 of the 2020 SMFP.

	IP ORs	OP ORs	Shared ORs	Excluded C-Sec, Trauma, Burn	CON Adjust-ments	IP Surgery Cases	OP Surgery Cases	Group
Davis Regional Medical Center	1	0	5	-1	0	345	1,538	4
Lake Norman Regional Medical Center	1	2	7	-1	0	1,726	5,421	4
Iredell Ambulatory Surgery Center	0	1	0	0	0	0	348	5
Iredell Mooresville Campus ASC*	0	0	0	0	+1	0	0	
Iredell Surgical Center	0	4	0	0	0	0	1,309	5
Iredell Memorial Hospital*	1	0	10	-1	-1	1,760	4,352	4
Total Iredell County ORs	**3**	**7**	**22**	**-3**				

Source: 2020SMFP, page63 and 75
*CON Adjustment for Project ID #F-11727-19 (relocate one OR from IMH to develop IMC ASC)

As the table above shows, there are currently only two ambulatory surgical facilities in Iredell County.

In Section G, page 67, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved ambulatory surgical services in the Iredell County operating room service area. The applicant states:

> *"This project does not involve an addition of operating rooms in the service area; it involves conversion of a single to a multi-specialty ambulatory surgery program. IASC is an existing and operational ambulatory surgical program. The project does not introduce new operating rooms to the service area, but it will increase freestanding ambulatory surgery center access.*
>
> *As defined in chapter* [Chapter] *6 of the SMFP, "service area" is the entirety of Iredell County. The facility serves, and will continue to serve, primarily residents of Iredell and Alexander counties (88 percent). Iredell and Alexander counties have only one multi-specialty freestanding ambulatory surgical program, Iredell Surgical Center."*

The applicant further states that Iredell Surgical Center (ISC) has excess capcity and though IMH has a small percentage ownership in ISC, it has no control or direct role in operations; therefore, IMH's leadership and physicians have limited influence on scheduling, equipment availability, or improvements for the facility. By contrast, IASC is owned and operated by IPN, a fully owned subsidiary of IMH. The applicant states that all other multispecialty outpatient operating rooms in northern Iredell County are hospital-based and subject to hospital-based pricing, which is generally higher than freestanding ambulatory surgery programs. The applicant provides documentation in Exhibit C.4.

The applicant further states that Iredell Mooresville Campus ASC is approved for a new multispecialty ambulatory surgery program in southern Iredell County, but it is not expected to draw patients from northern Iredell and Alexander counties.

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 proposal would not result in an increase in ORs in the Iredell County operating room service area.
- The applicant adequately demonstrates that the proposed conversion to multispecialty 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, pages 125-126, the applicant provides projected full-time equivalent (FTE) positions for the proposed services, as illustrated in the following table.

Projected FTE Positions
FY2021-FY2023

OR Registered Nurses	0.52
Surgical Technicians	0.52
RN Coordinator	0.86
PACU RN	0.68
Sterile Processing RN	0.50
Medical Records	0.64
TOTAL	**3.72**

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 applicant are budgeted in Section Q Form F.3, page 123. In Section H.2 and H.3, page 70, the applicant describes the methods used to recruit or fill new positions and its training and continuing education programs. In Section I, page 73, the applicant identifies the medical director as Dr. Alan Deddens. In Exhibit I.3, page 9, the applicant provides a letter from Dr. Deddens, indicating his intent to continue to serve as medical director for the proposed services.

The applicant adequately demonstrates 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, page 71, the applicant provides a table listing the necessary ancillary and support services and how they will be provided. The list includes the following:

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

The applicant adequately explains how each ancillary and support service is/will be made available in Table I.1, page 71, and provides supporting documentation in Exhibit I.

In Section I, page 72, the applicant describes 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 applicant adequately demonstrates 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 applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

(10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

(i) would be available under a contract of at least 5 years duration;
(ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
(iii) would cost no more than if the services were provided by the HMO; and
(iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

(11) Repealed effective July 1, 1987.

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

NA

The applicant proposes to convert IASC, a specialty ambulatory surgical program, to a multispecialty ambulatory surgical program. The applicant does not propose any new construction or renovation. Thus, Criterion (12) is not applicable to this review.

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and 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

Section L, page 79, the applicant provides the historical payor mix during the last full fiscal year (FY2019) for the operating and procedure rooms at IASC, as summarized in the table below.

Payor Source	Entire Facility	Operating Room	Procedure Room **
Self-Pay	0.28%	0.28%	N/A
Medicare*	22.65%	22.65%	N/A
Medicaid*	43.09%	43.09%	N/A
Insurance*	33.15%	33.15%	N/A
Other (Workers compensation, TRICARE)	0.83%	0.83%	N/A
Total	100.0%	100.0%	N/A

Source: Table on page 79 of the application
*Including any managed care plans.
**No cases were performed in the procedure room in FY2019

In Section L, page 78, the applicant provides a comparison of the FY2019 population of Iredell and Alexander counties, as summarized below, and states that it does not maintain demographic data on patients.

	Percentage of the Population of Iredell County*	Percentage of the Population of Alexander County*
Female	50.8%	49.1%
Male	49.2%	50.9%
64 and Younger	84.1%	80.0%
65 and Older	15.9%	20.0%
American Indian	0.6%	0.5%
Asian	2.7%	1.0%
Black or African-American	12.3%	5.9%
Native Hawaiian or Pacific Islander	0.1%	0.0%
White or Caucasian	75.8%	90.8%
Other Race	8.5%	1.8%

*The percentages can be found online using the United States Census Bureau's QuickFacts which is at: https://www.census.gov/quickfacts/fact/table/US/PST045218 . Just enter in the name of the county.

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

(b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and 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, pages 79-80, the applicant states:

> *"Both IPN and IMH 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 80, the applicant states 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 applicant 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 80, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as summarized in the table below.

Payor Source	Entire Facility	Operating Room	Procedure Room
Self-Pay	0.28%	0.28%	0.28%
Medicare*	22.65%	22.65%	22.65%
Medicaid*	43.09%	43.09%	43.09%
Insurance*	33.15%	33.15%	33.15%
Other (Workers compensation, TRICARE)	0.83%	0.83%	0.83%
Total	100.0%	100.0%	100.0%

Source: Table on page 80 of the application
*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that less than 1.0% of total services will be provided to self-pay patients, 23% to Medicare patients and 43% to Medicaid patients.

In Section L, page 81, the applicant provides 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:

- The applicant assumes no change in payor mix from the historical payor mix.
- The majority of the cases will still be ENT, and any changes in new case payor mix will not materially affect payor mix.

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 81, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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 83, 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.

Conclusion

The Agency reviewed the:

- Application
- 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 convert IASC, a specialty ambulatory surgical program, to a multispecialty ambulatory surgical program.

On page 51, the 2020 SMFP states, *"An operating room's "service area" is the service area in which the operating room is located. The operating room service areas are the single or multicounty groupings shown in Figure 6.1."* In Figure 6.1, page 57 of the 2020 SMFP, Iredell County is shown as a single-county operating room 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.

The following table identifies the existing and approved inpatient, outpatient, and shared operating rooms located in Iredell County, and the inpatient and outpatient case volumes for each provider, from pages 63 and 75 of the 2020 SMFP.

	IP ORs	OP ORs	Shared ORs	Excluded C-Section, Trauma, Burn	CON Adjust-ments	IP Surgery Cases	OP Surgery Cases	Group
Davis Regional Medical Center	1	0	5	-1	0	345	1,538	4
Lake Norman Regional Medical Center	1	2	7	-1	0	1,726	5,421	4
Iredell Ambulatory Surgery Center	0	1	0	0	0	0	348	5
Iredell Mooresville Campus ASC*	0	0	0	0	+1	0	0	
Iredell Surgical Center	0	4	0	0	0	0	1,309	5
Iredell Memorial Hospital*	1	0	10	-1	-1	1,760	4,352	4
Total Iredell County ORs	**3**	**7**	**22**	**-3**				

Source: 2020SMFP, page63 and 75
*CON Adjustment for Project ID #F-11727-19 (relocate one OR from IMH to develop IMC ASC

In Section N, pages 84-86, 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. The applicant states:

> *"The proposed project will make IASC one of two freestanding multi-specialty ambulatory surgery centers in the Statesville area. The charge structure for freestanding ASFs is lower than for a hospital-based surgical setting for the same procedure. As described in Section C.4, IASC has the lowest cost ENT procedures across the board. With the addition of new specialties, IASC will have better capacity to foster market competition by keeping out-of-packet costs to patients low. Approval of this CON application will increase IASC's competitive role in the proposed service area.*
>
> …
>
> *The proposed project will be a cost-effective investment for the applicants. The facility is designed and staffed to support a low-charge, low-reimbursement structure.*

…

IASC has CMS Medicare and Medicaid certification for payment providing yet more oversight, and maintaining a high bar for competition.

…

The location, ADA compliant building design, and willingness to accept Medicare, Medicaid, hardship patients, and uninsured will all increase access for patients and promote competition in the proposed service area. More than 60 percent of patients are Medicare and Medicaid beneficiaries."

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 C, F, N and Q of the application and any exhibits)
- Quality services will be provided (see Sections C, N, and O of the application and any exhibits)
- Access will be provided to underserved groups (see Sections L and N 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 92, the applicant identifies the hospitals and surgery centers located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of four facilities, including IASC and IMH.

In Section O, page 88, the applicant states 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 applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all three facilities, the applicant provides 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 applicant does 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.