

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: June 6, 2022

Findings Date: June 6, 2022

Project Analyst: Julie M. Faenza

Co-signer: Micheala Mitchell

Project ID #: F-12183-22

Facility: Statesville Orthopedic Surgery Center

FID #: 200893

County: Iredell

Applicant: Piedmont Surgical Center of Excellence, LLC

Project: Change of scope for Project ID #F-11998-20 to convert a specialty ASF to a multi-specialty ASF

REVIEW CRITERIA

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

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

NA

Piedmont Surgical Center of Excellence, LLC (hereinafter referred to as "PSCE" or "the applicant") was issued a certificate of need for Project ID #F-11998-20 on April 28, 2021 to develop Statesville Orthopedic Surgery Center (SOSC), a specialty ambulatory surgical facility (ASF), by relocating one operating room (OR) from Davis Regional Medical Center (Davis RMC) and developing two procedure rooms. According to the application for Project ID #F-11998-20, PSCE is a wholly owned subsidiary of Davis RMC. The capital expenditure for the approved project was \$6,169,939.

In this application, the applicant proposes a change of scope to develop a multispecialty ASF instead of a specialty ASF. The projected increase in capital cost is \$732,060.

The applicant does not propose to:

- develop any beds or services or acquire any medical equipment for which there is a need determination in the 2022 SMFP
- offer a new institutional health service for which there are any policies in the 2022 SMFP

Therefore, Criterion (1) 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- (2) Repealed effective July 1, 1987.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, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

NC

The applicant proposes a change of scope to Project ID #F-11998-20. Instead of proposing to relocate one OR from Davis RMC to develop a specialty ASF with two procedure rooms, the applicant proposes to develop the facility as a multispecialty ASF with two procedure rooms.

Patient Origin

On page 49, the 2022 SMFP defines the service area for ORs as “...*the single or multicounty grouping shown in Figure 6.1.*” Figure 6.1 on page 55 of the 2022 SMFP shows Iredell County as its own OR service area. Thus, the service area for this project is Iredell County. Facilities may also serve residents of counties not included in their service area.

SOSC is not an existing facility and thus has no historical patient origin to report. The following table illustrates projected patient origin.

SOSC – Projected Patient Origin – Surgical & Non-Surgical Procedures						
County	FY 1 – FFY 2024		FY 2 – FFY 2025		FY 3 – FFY 2026	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Iredell	832	69.2%	996	69.6%	1,156	69.9%
Alexander	118	9.8%	141	9.8%	163	9.9%
Catawba	73	6.1%	88	6.1%	102	6.1%
Davie	34	2.8%	40	2.8%	47	2.8%
Rowan	34	2.9%	41	2.8%	47	2.8%
Mecklenburg	17	1.4%	21	1.5%	25	1.5%
Surry	12	1.0%	12	0.8%	12	0.7%
Cabarrus	10	0.8%	13	0.9%	15	0.9%
Caldwell	8	0.7%	8	0.6%	8	0.5%
Wilkes	7	0.5%	7	0.5%	7	0.4%
Yadkin	3	0.3%	3	0.2%	3	0.2%
Other NC Counties	54	4.5%	62	4.4%	70	4.3%
Total	1,203	100.0%	1,431	100.0%	1,654	100.0%

Source: Section C, page 47

In Section C, page 48, the applicant provides the assumptions and methodology used to project its patient origin. The applicant states it updated its projected patient origin from Project ID #F-11998-20 to account for the most recent patient origin data and to provide updated patient origin projections for the additional surgical specialties. The applicant’s assumptions are reasonable and adequately supported based on the following:

- The applicant uses projections consistent with those used in its original project and updated them to include more recent data.
- The applicant states Davis RMC provided patient origin information for the surgical cases to be performed by physicians who wish to utilize SOSC.

Analysis of Need

In Section C, pages 35-45, the applicant explains why it believes there is a need to change the scope of Project ID #F-11998-20 by developing a multispecialty ASF instead of a specialty ASF, as summarized below:

- Population Growth in Iredell County: the applicant states that, according to the North Carolina Office of State Budget and Management (NC OSBM), the population of Iredell County is projected to increase at a compound annual growth rate (CAGR) of 1.28% between 2022 and 2027, higher than the state’s projected CAGR of 1.03%.
- Aging of Population: the applicant states people undergoing surgery are getting older at a faster rate than the general population, and that most surgical procedures are performed on patients aged 45 and older.
- Iredell County Health Status: the applicant states that the Robert Wood Johnson Foundation’s and the University of Wisconsin Population Health Institute’s County

Health Rankings lists Iredell County as 15th out of 100 North Carolina counties in terms of health outcomes. The applicant states there are multiple risk factors for Iredell County residents that make a multispecialty ASF more important.

- Cost Effectiveness of ASFs and Ambulatory Surgical Trends: the applicant states approximately 83% of surgical procedures in the United States are performed on an outpatient basis. The applicant states ambulatory surgical cases increased steadily between FFY 2014 and FFY 2019 and that based on FFY 2020 data, approximately 71.7% of all surgical utilization in North Carolina is ambulatory surgical cases. The applicant further states Medicare has been steadily increasing the number of procedures it will reimburse from ASFs and ASFs offer a lower cost option for patients. The applicant states that, according to a MedPAC report to Congress in 2021, North Carolina ranks 35th out of 51 states (including Washington D.C.) in the number of ASFs per resident.
- Outmigration of Iredell County Residents: the applicant states 35% of surgical cases performed on Iredell County residents in FFY 2020 were performed outside of Iredell County. The applicant states that this shows Iredell County surgical patients are not having their needs met by Iredell County-based providers and it means there is a need for more outpatient surgical services in Iredell County.
- Physician Support: the applicant states many local physicians support the proposal to convert the specialty ASF to a multispecialty ASF and that surgeons have written letters of support projecting to bring hundreds of cases to SOSOC. The applicant states physicians prefer the ASF setting over the hospital setting when appropriate because of enhanced productivity, more flexibility, and better patient outcomes.
- Impact of COVID-19 Pandemic: the applicant states the COVID-19 pandemic has led to increased turnaround time for surgical suites based on CDC guidelines. The applicant also states patients and families may prefer ASFs, which are outside of the hospital setting, because of the psychological impact of the pandemic and concerns about being exposed to COVID-19 in a hospital setting.

However, the information is not reasonable and adequately supported based on the following:

- Project ID #F-11998-20 was submitted for the review period beginning December 1, 2020 and received a certificate of need on April 28, 2021. This application was submitted for the review period beginning March 1, 2022. The applicant does not identify any circumstances that have changed in the 15 months between the two applications being submitted to demonstrate the need to change the scope of Project ID #F-11998-20. Much of the information submitted by the applicant in this review is the same as the information submitted by the applicant in Project ID #F-11998-20. The applicant cites the same studies (see pages 37-39 and 43) as the prior application and provides an update to the data based on the time between the prior application and the current application but does not otherwise demonstrate anything meaningful that has changed in Iredell County or the projected patient population in the last 15 months.

- In some cases, the metrics used by the applicant to demonstrate the need for the specialty ASF 15 months ago have improved since that application was submitted.
 - In Project ID #F-11998-20, Iredell County was ranked 20th in the state on the County Health Rankings. In the current application, Iredell County's health ranking has improved to 15th in the state. The applicant does not explain why an improvement in health outcomes means there is a need for a multispecialty ASF.
 - In Project ID #F-11998-20, the applicant stated that during FFY 2019, 36.24% of ambulatory surgical cases performed on Iredell County residents were performed outside of Iredell County. During FFY 2020, 35.03% of ambulatory surgical cases performed on Iredell County residents were performed outside of Iredell County. The applicant does not explain why a decrease in outmigration means there is a need for a multispecialty ASF.
 - The COVID-19 pandemic and its impact on surgical cases and access is not new – but, if anything, the impact of the pandemic has diminished, not increased. Based on data from previous SMFPs and License Renewal Applications (LRAs), outpatient surgical cases (at both hospitals and ASFs) decreased from FFY 2019- 2020, but then increased between FFY 2020-2021. In fact, of the 78 OR service areas in the state that reported any surgical cases between FFY 2019-2021, 59, or 75%, had increases in outpatient surgical cases between FFY 2020-2021. And almost half of the OR service areas with cases that rebounded between FFY 2020-2021 saw outpatient surgical cases increase higher than the number of outpatient surgical cases in FFY 2019 – for both overall outpatient surgical cases and specifically outpatient surgical cases at hospitals. Please see the Working Papers for more information. The applicant does not explain why the continued (or improved) impact of the pandemic now creates the need for a multispecialty ASF.
- The applicant does not explain how the ambulatory surgical trends it cites means there is a lack of available ambulatory surgical services in Iredell County. The applicant cites statewide data about the number of ASFs per resident and states that, according to a recent MedPAC report given to Congress, North Carolina ranks 35th out of 51 listings. However, the applicant does not explain how the statewide ranking means that Iredell County residents are lacking in available ambulatory surgical services. Based on data from NC OSBM, as of July 2020 Iredell County was estimated to have the 15th highest county population in North Carolina. However, the counties that had the 5th through 14th highest county populations each have fewer existing and approved ASFs than Iredell County. Please see the Working Papers for additional information. The applicant does not adequately explain how Iredell County residents lack access to ambulatory surgical services when they have access to more existing and approved ASFs than more populous counties.
- The applicant does not explain how outmigration of Iredell County residents for ambulatory surgical services means there is a lack of available ambulatory surgical services in Iredell County. Table 6B in the 2022 SMFP shows Iredell County has seven

existing and approved facilities with ORs, all of which (except for SOSC) are multispecialty, and which have a combined total of 29 ORs. Table 6B also shows that every facility in Iredell County with ORs has a surplus of OR capacity equaling roughly half of the potentially available OR capacity. Patient origin reports and LRAs for FFYs 2020 and 2021 show that a majority of patients leaving Iredell County for Mecklenburg, Forsyth, Catawba, and Cabarrus counties – the four counties with the highest number of patients arriving from Iredell County and the counties cited by the applicant in Project ID #F-11998-20 and the current application – are receiving surgical services at hospitals, not ASFs, or are receiving surgical services such as ophthalmology or otolaryngology, services which are not proposed as part of the proposed project. The applicant does not explain why a minority of patients leaving Iredell County for ambulatory surgical services lack access to ASFs in Iredell County, particularly when every facility with ORs in Iredell County has surplus capacity.

Projected Utilization

On Form C.3b in Section Q, the applicant projects utilization for the first three fiscal years of operation following project completion, as shown in the table below.

SOSC Projected Utilization – FYs 1 – 3 (FFYs 2024 – 2026)			
	FY 1 (FFY 2024)	FY 2 (FFY 2025)	FY 3 (FFY 2026)
ORs	1	1	1
Outpatient Surgical Cases	1,022	1,250	1,473
Outpatient Case Times (minutes)	70.1	70.1	70.1
Total Surgical Hours	1,194.0	1,460.4	1,721.0
Standard Hours per OR per Year (Group 6)	1,312	1,312	1,312
Total Surgical Hours / Standard Hours per OR per Year	0.91	1.11	1.31

In the Form C Need and Utilization Assumptions and Methodology subsection of Section Q, the applicant provides the assumptions and methodology used to project utilization, as summarized below.

- The applicant projects no changes to the number of orthopedic cases projected in Project ID #F-11998-20. The applicant states the need has continued and circumstances have not changed.
- The applicant provides letters of support from physicians who indicated their willingness to perform surgical cases at SOSC in Exhibit I.3.3. The table below shows the name of the physician, their specialty, and how many cases they project to perform at SOSC in the first year following completion of the project.

Surgical Projections from Letters of Support – Exhibit I.3.3		
Name of Physician	Specialty	Projected # of Surgical Cases
Naila Rashida Frye, MD	Obstetrics/Gynecology	175
Michael Getter, MD	?	113
Lauri Givens, MD	Obstetrics/Gynecology	175
Robert Grajewski, MD	Urology	80
Michael A. Kepley, MD	Obstetrics/Gynecology	55
Timothy Leone, MD	General Surgery	120
Dale Rader, MD	?	242
Total		960

- The applicant states that, based on the physician estimates, it projects that 50 OB/GYN cases, 60 urology cases, and 90 general surgery cases will be performed at SOSC during its first operating year, and that cases will increase annually by 1.28%, the average annual growth rate for the Iredell County population projected by NC OSBM between 2022 and 2027.

The applicant’s projected utilization is summarized in the table below.

SOSC Summary of Projected Utilization – FYs 1-3 (FFYs 2024-2026)			
Surgical Case Specialties	FY 1 (FFY 2024)	FY 2 (FFY 2025)	FY 3 (FFY 2026)
Orthopedics (based on F-11998-20)	822	1,042	1,267
Obstetrics/Gynecology (1.28% growth rate)	50	51	52
Urology (1.28% growth rate)	60	61	62
General Surgery (1.28% growth rate)	90	91	92
Total Surgical Cases	1,022	1,250*	1,473

*The applicant appears to have inadvertently made a typo in transposing some numbers from Project ID #F-11998-20 to this application. According to the findings for Project ID #F-11998-20, the applicant projected to perform 1,042 orthopedic surgical procedures, which would make the total surgical cases with the additional specialties add up to 1,245. However, this apparent error does not meaningfully impact the analysis or outcome of the review.

However, projected utilization is not reasonable and adequately supported based on the following:

- The applicant provides letters of support from seven physicians who state they anticipate performing surgery on patients at SOSC during the first year following project completion. However, the applicant’s projected utilization only includes five of the seven physicians. The applicant provides no explanation in the application as submitted to explain why certain physicians are included in utilization projections and others aren’t. Further, the letters do not list the physician’s specialty, so it is impossible to determine what surgical specialty the other two physicians will provide.
- The applicant does not explain the assumptions behind the projected number of cases from the newly proposed specialties for each of the first three years following project completion. The applicant states the projections are reasonable because in Project ID #F-11998-20, it provided research suggesting 50% of outpatient surgeries are appropriate

for ASFs. However, the applicant does not explain how it made the projections in the first place, especially when the physician letters state they plan to perform all of the projected cases at SOSC.

Further, the applicant did not reduce the physician projections by 50%. The applicant projects 12.3% of physician-projected obstetrics/gynecology cases, 75% of physician-projected urology cases, and 75% of physician-projected general surgery cases will be performed at SOSC in the first year following project completion. The applicant provides no information in the application to explain the assumptions behind these projections.

Access to Medically Underserved Groups

In Section C, page 51, the applicant states:

“All Iredell County residents (plus residents of other counties), including low income persons, racial and ethnic minorities, women, [disabled] persons, [persons aged 65 and older], Medicare and Medicaid beneficiaries, and other underserved groups, will have access to the ASF, as clinically appropriate. PSCE is committed to providing services to all persons regardless of race, ethnicity, gender, age, religion, creed, disability, national origin, or ability to pay. Outpatient surgical services will be available to all persons listed above, and including the medically indigent, the uninsured and the underinsured.”

In Section C, page 51, the applicant provides the estimated percentage of patients it projects to serve in its third full fiscal year of operation, for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	9.7%
Racial and ethnic minorities	18.6%
Women	48.8%
Persons with disabilities	9.0%
Persons 65 and older	28.8%
Medicare beneficiaries	37.6%
Medicaid recipients	5.3%

Source: Davis RMC internal records, US Census Bureau

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

- The applicant provides a statement that it will provide access to the proposed services for underserved groups.
- The applicant provides a copy of the Davis RMC non-discrimination policy it will use at SOSC in Exhibit C.8.7.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is not conforming to this criterion for all the reasons described above.

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

NA

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

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

NC

The applicant proposes a change of scope to Project ID #F-11998-20. Instead of proposing to relocate one OR from Davis RMC to develop a specialty ASF with two procedure rooms, the applicant proposes to develop the facility as a multispecialty ASF with one OR and two procedure rooms.

In Section E, pages 57-58, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need:

- Maintain the Status Quo: The applicant states maintaining the status quo would result in continued outmigration of Iredell County patients and would not contribute as broadly to lower-cost patient care as a multispecialty ASF. The applicant determined this was not an effective alternative.

- Add Additional OR Inventory at SOSC: The applicant states it is not necessary to add an additional OR at SOSC to accommodate the addition of specialties to SOSC. The applicant determined this was not an effective alternative.
- Develop an Additional ASF in Statesville: The applicant states developing an additional ASF in Statesville would be more expensive and not necessary to accommodate additional surgical specialties. The applicant determined this was not an effective alternative.

However, the applicant does not adequately demonstrate that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The applicant does not demonstrate the need for the proposed project, or that projected utilization is reasonable and adequately supported. The discussions about analysis of need and projected utilization found in Criterion (3) are incorporated herein by reference. A project that is not necessary and which cannot provide reasonable and adequately supported utilization projections is not the most effective alternative to meet the need.
- The applicant does not demonstrate that the financial feasibility of the proposal is reasonable and adequately supported. The discussion regarding financial feasibility found in Criterion (5) is incorporated herein by reference. If the applicant cannot demonstrate that developing the project is financially feasible, the applicant cannot demonstrate the proposed alternative is the most effective alternative to meet the need.
- The applicant does not demonstrate that the proposed project is not an unnecessary duplication of existing or approved health service capabilities or facilities. The discussion about unnecessary duplication found in Criterion (6) is incorporated herein by reference. A project that is unnecessarily duplicative cannot be the most effective alternative to meet the need.
- The applicant does not provide credible information to explain why it believes the proposed project is the most effective alternative.
- The application is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be an effective alternative to meet the need.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is not conforming to this criterion for the reasons stated above. Therefore, the application is denied.

- (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.

NC

The applicant proposes a change of scope to Project ID #F-11998-20. Instead of proposing to relocate one OR from Davis RMC to develop a specialty ASF with two procedure rooms, the applicant proposes to develop the facility as a multispecialty ASF with two procedure rooms.

Capital and Working Capital Costs

On Form F.1b in Section Q, the applicant provides a summary of the capital cost approved in Project I.D. #F-11998-20, the changes proposed in this application, and the new projected capital cost, as shown in the table below.

Comparison of Capital Expenditures			
	Project I.D. #F-11998-20	New Proposed	New Total
Construction/Renovation Contracts	\$3,200,000	\$430,000	\$3,630,000
Architect/Engineering Fees	\$150,000	\$0	\$150,000
Medical Equipment	\$2,124,443	\$262,856	\$2,387,299
Non-Medical Equipment/Furniture	\$358,000	\$0	\$358,000
Consultant Fees	\$187,496	\$39,204	\$226,700
Contingency	\$150,000	\$0	\$150,000
Total	\$6,169,939	\$732,060	\$6,901,999

In Section F, page 65, the applicant states that this application is not a cost overrun because the cost is not expected to exceed 115% of the capital cost approved in Project ID #F-11998-20, and that the slight increases in costs are due to the need to acquire additional surgical instrumentation and updated construction costs.

On Form F.1b, the applicant provides the assumptions used to project the capital cost and provides supporting documentation in Exhibits F.5.2 and F.5.3. The applicant appears to have underreported the projected capital cost of the proposed project by \$169,777, based on an analysis of the itemized list of medical equipment in Exhibit F.5.2. Please see the Working Papers for additional information. However, the underreported capital expenditure does not impact the outcome of these findings.

The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant provides an itemized list of medical equipment and costs in Exhibit F.5.2.

- The applicant provides a signed letter from an architect in Exhibit F.5.3, documenting the expected construction cost of \$3,360,000.

In Section F, page 67, the applicant projects start-up costs of \$72,214 and initial operating costs of \$617,029 for a total projected working capital cost of \$689,243, an increase of \$129,243 over the total projected working capital cost of \$560,000 approved in Project ID #F-11998-20. Immediately following Form H in Section Q, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

- The applicant identifies the individual components of the projected startup expenses and the expected timeframe for the startup period.
- The applicant explains the assumptions used in projecting the initial operating expenses and shows the calculations used to arrive at the total.

Availability of Funds

In Section F, pages 66-67, the applicant states the capital and working capital costs for the proposed project will be funded with cash reserves.

In Exhibit F.5.1, the applicant provides a letter dated January 10, 2022, from the president of Davis RMC, the sole member of PSCE, which states Davis RMC will commit to funding up to \$9 million for the development of the proposed project. Exhibit F.5.1 also contains a letter dated January 3, 2022, from the manager of PSCE, which commits to using the funding provided by Davis RMC for the development of the proposed project.

The applicant also provides a copy of Community Health System's Form 10-Q document filed with the United States Securities and Exchange Commission for the quarter ending September 30, 2021 in Exhibit F.5.1. Community Health Systems is the parent company of Davis RMC. According to the Form 10-Q, as of September 30, 2021, Community Health Systems had adequate cash and cash equivalents available to fund the proposed project.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- The applicant provides documentation from Davis RMC and PSCE committing to funding the proposed project and allocating the funding for the proposed project to the development of the proposed project.
- The applicant provides adequate documentation of the availability of cash and cash equivalents it proposes to use in the development of the proposed project.

Financial Feasibility

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

Revenues and Operating Expenses – SOSC			
	1st Full FY FFY 2024	2nd Full FY FFY 2025	3rd Full FY FFY 2026
Total Surgical Cases/Procedures	1,203	1,431	1,654
Total Gross Revenues (Charges)	\$14,424,031	\$17,928,005	\$21,494,444
Total Net Revenue	\$4,947,286	\$6,150,308	\$7,374,775
Total Net Revenue per Test	\$4,112	\$4,298	\$4,459
Total Operating Expenses (Costs)	\$4,447,226	\$5,063,677	\$5,676,753
Total Operating Expenses per Test	\$3,697	\$3,539	\$3,432
Net Income/(Loss)	\$500,060	\$1,086,630	\$1,698,022

The assumptions used by the applicant in preparation of the pro forma financial statements are provided immediately following Form H in Section Q. However, the applicant does not demonstrate that the financial feasibility of the proposal is reasonable and adequately supported because projected utilization is not based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference. Therefore, projected revenues and operating expenses, which are based in part on projected utilization, are also questionable.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is not conforming to this criterion because the applicant does not adequately demonstrate sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

NC

The applicant proposes a change of scope to Project ID #F-11998-20. Instead of proposing to relocate one OR from Davis RMC to develop a specialty ASF with two procedure rooms, the applicant proposes to develop the facility as a multispecialty ASF with one OR and two procedure rooms.

On page 49, the 2022 SMFP defines the service area for ORs as “...the single or multicounty grouping shown in Figure 6.1.” Figure 6.1 on page 55 of the 2022 SMFP shows Iredell County as its own OR service area. Thus, the service area for this project is Iredell County. Facilities may also serve residents of counties not included in their service area.

Table 6B on pages 74-75 of the 2022 SMFP shows Iredell County has seven existing and approved hospitals and ASFs offering ambulatory surgical services. Information about each of the facilities is shown in the table below.

Iredell County ORs – Hospitals & ASFs					
Facility	Hospital/ASF	Specialty*	Location	ORs**	(Surplus)/Deficit
Davis Regional Medical Center	Hospital	NA	Statesville	4	(2.32)
Iredell Memorial Hospital	Hospital	NA	Statesville	9	(1.55)
Lake Norman Regional Medical Center	Hospital	NA	Mooresville	9	(4.66)
Iredell Ambulatory Surgery Center	ASF	Multi	Statesville	1	(0.81)
Iredell Mooresville Campus ASC***	ASF	Multi	Mooresville	1	(1.00)
Iredell Surgical Center	ASF	Multi	Statesville	4	(3.44)
Statesville Orthopedic Surgery Center***	ASF	Single	Statesville	1	(1.00)
Total				29	(14.78)

*The CON statutes designate ASFs as “specialty” or “multispecialty” – there is no “single specialty” ASF. “Single” is a simplification used for clarity.

**Number of ORs in Adjusted Planning Inventory

***This is a facility which is approved but not yet operational at the time of data collection for the 2022 SMFP.

As shown in the table above, every facility with ORs in Iredell County has a surplus of OR capacity. The total surplus OR capacity in Iredell County is approximately half of the total available OR capacity.

In Section G, page 70, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved diagnostic center services in Iredell County. The applicant states:

“The proposed project does not include addition of any operating rooms to the existing licensed OR inventory in Iredell County, nor does it increase the OR inventory at Statesville Surgery Center.”

However, the applicant does not adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- The applicant does not demonstrate why Iredell County needs additional multispecialty ASFs.

Table 6B in the 2022 SMFP shows Iredell County has seven existing and approved facilities with ORs, all of which (except for SOSC) are multispecialty, and which have a combined total of 29 ORs. Table 6B also shows that every facility in Iredell County with ORs has a surplus of OR capacity equaling roughly half of the potentially available OR capacity. The applicant provides no information in the application as submitted to explain why additional expenditures are needed to convert an approved but not yet developed specialty ASF to a multispecialty ASF, particularly with the level of surplus OR capacity in Iredell County.

- The applicant does not demonstrate the need for the proposed project, or that projected utilization is reasonable and adequately supported. The discussions about analysis of need and projected utilization found in Criterion (3) are incorporated herein by reference. A project that is not necessary and which cannot provide reasonable and adequately supported utilization projections cannot demonstrate that the project is not an unnecessary duplication of existing or approved services in the service area.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is not conforming to this criterion for all the reasons described above.

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

C

The applicant proposes a change of scope to Project ID #F-11998-20. Instead of proposing to relocate one OR from Davis RMC to develop a specialty ASF with two procedure rooms, the applicant proposes to develop the facility as a multispecialty ASF with one OR and two procedure rooms.

On Form H in Section Q, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as shown in the table below.

Proposed Staffing in FTEs – SOSC – FYs 1-3 (FFYs 2024-2026)			
Position	FY 1 – FFY 2024	FY 2 – FFY 2025	FY 3 – FFY 2026
Registered Nurses	3.50	4.00	4.40
Director of Nursing	1.00	1.00	1.00
Surgical Technicians	1.75	2.00	2.00
Administrator/CEO	1.00	1.00	1.00
Business Office	1.00	1.00	1.00
Clerical	1.00	1.00	1.00
Receptionist	1.00	1.00	1.00
Scheduler	1.00	1.00	1.00
Total FTEs	11.25	12.00	12.40

The assumptions and methodology used to project staffing are provided immediately following Form H in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted on Form F.3b in Section Q. In Section H, page 72, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant projects staffing based on the experience of Davis RMC and Community Health Systems (the parent company of Davis RMC).
- The applicant adequately explains the need for additional staffing compared with projections in Project ID #F-11998-20.
- The applicant projects adequate operating expenses for the staff it proposes on Form H.
- Project ID #F-11998-20 was conforming with this criterion and the applicant proposes no changes in the application as submitted which would affect that determination.

Conclusion

The Agency reviewed the:

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

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

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and

support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

The applicant proposes a change of scope to Project ID #F-11998-20. Instead of proposing to relocate one OR from Davis RMC to develop a specialty ASF with two procedure rooms, the applicant proposes to develop the facility as a multispecialty ASF with one OR and two procedure rooms.

Ancillary and Support Services

In Section I, pages 74-75, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, pages 74-75, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.3.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant provides documentation of the availability of the necessary ancillary and support services.
- The applicant is relying on Davis RMC, an established provider, to assist in providing necessary ancillary and support services.

Coordination

In Section I, page 75, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.3.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- While SOSOC is not an existing facility, the applicant's parent company, Davis RMC, has existing relationships with other local health care and service providers.
- The applicant provides documentation of local health care and community support in Exhibit I.3.2.

Conclusion

The Agency reviewed the:

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

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

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

NA

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

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

NA

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

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

NA

The applicant does not propose to construct any new space or renovate any existing space beyond what was previously approved in Project ID #F-11998-20. Therefore, Criterion (12) is not applicable to this review.

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

C

Project ID #F-11998-20 was conforming with this criterion and the applicant proposes no changes in the application as submitted which would affect that determination. Therefore, the application is conforming to this criterion.

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

C

Project ID #F-11998-20 was conforming with this criterion and the applicant proposes no changes in the application as submitted which would affect that determination. Therefore, 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 85, 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 shown in the table below.

SOSC Projected Payor Mix FFY 2026		
Payment Source	% of Total Patients	% of Surgical Patients
Self-Pay	2.21%	2.31%
Medicare*	37.60%	36.08%
Medicaid*	5.28%	5.49%
Insurance*	51.07%	52.31%
Workers Compensation	3.30%	3.21%
Other (Other government)	0.54%	0.60%
Total	100.00%	100.00%

*Including any managed care plans

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 2.21% of total services and 2.31% of surgical services will be provided to self-pay patients, 37.6% of total services and 36.08% of surgical services to Medicare patients, and 5.28% of total services and 5.49% of surgical services to Medicaid patients.

In Section L, page 85, the applicant states that charity care is included under the self-pay category.

On pages 85-86, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The applicant projects the adjustments to the payor mix based on Davis RMC's historical payor mix for the surgical specialties proposed to be added.
- Project ID #F-11998-20 was conforming with this criterion and the applicant proposes no changes in the application as submitted which would affect that determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

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

C

Project ID #F-11998-20 was conforming with this criterion and the applicant proposes no changes in the application as submitted which would affect that determination. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes a change of scope to Project ID #F-11998-20. Instead of proposing to relocate one OR from Davis RMC to develop a specialty ASF with two procedure rooms, the applicant proposes to develop the facility as a multispecialty ASF with one OR and two procedure rooms.

In Section M, page 88, the applicant states the proposed project does not involve any changes to the information provided in the application for Project ID #F-11998-20.

Project ID #F-11998-20 was conforming with this criterion and the applicant proposes no changes in the application as submitted which would affect that determination. 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 a change of scope to Project ID #F-11998-20. Instead of proposing to relocate one OR from Davis RMC to develop a specialty ASF with two procedure rooms, the applicant proposes to develop the facility as a multispecialty ASF with one OR and two procedure rooms.

On page 49, the 2022 SMFP defines the service area for ORs as “...*the single or multicounty grouping shown in Figure 6.1.*” Figure 6.1 on page 55 of the 2022 SMFP shows Iredell County as its own OR service area. Thus, the service area for this project is Iredell County. Facilities may also serve residents of counties not included in their service area.

Table 6B on pages 74-75 of the 2022 SMFP shows Iredell County has seven existing and approved hospitals and ASFs offering ambulatory surgical services. Information about each of the facilities is shown in the table below.

Iredell County ORs – Hospitals & ASFs					
Facility	Hospital/ASF	Specialty*	Location	ORs**	(Surplus)/Deficit
Davis Regional Medical Center	Hospital	NA	Statesville	4	(2.32)
Iredell Memorial Hospital	Hospital	NA	Statesville	9	(1.55)
Lake Norman Regional Medical Center	Hospital	NA	Mooresville	9	(4.66)
Iredell Ambulatory Surgery Center	ASF	Multi	Statesville	1	(0.81)
Iredell Mooresville Campus ASC***	ASF	Multi	Mooresville	1	(1.00)
Iredell Surgical Center	ASF	Multi	Statesville	4	(3.44)
Statesville Orthopedic Surgery Center***	ASF	Single	Statesville	1	(1.00)
Total				29	(14.78)

*The CON statutes designate ASFs as “specialty” or “multispecialty” – there is no “single specialty” ASF. “Single” is a simplification used for clarity.

**Number of ORs in Adjusted Planning Inventory

***This is a facility which is approved but not yet operational at the time of data collection for the 2022 SMFP.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 90, the applicant states:

“This change of scope project...does not involve any changes to the impact of enhanced competition on the cost effectiveness, quality and access by medically underserved groups from what was stated in the previously approved application.”

Regarding the impact of the proposal on cost effectiveness, in Section N, pages 90-92, the applicant states:

“This change of scope project will make lower cost surgery more broadly available to credentialed surgeons and their patients....

...

The change of scope project expands access with minimal capital investment, and the proforma financial statements demonstrate the facility can sustain as a lower cost, high quality surgery setting.”

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

Regarding the impact of the proposal on quality, in Section N, page 92, the applicant states:

“Statesville Surgery Center will be dedicated to providing excellent care for patients, and to creating a safe work environment for practitioners and staff. SSC will be dedicated to ensuring quality care and patient safety through compliance with all applicable licensure and certification standards established for ambulatory surgical facilities.”

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 93, the applicant states:

“This change of scope project...will improve and broaden access to outpatient surgical services for all patients, including medically underserved groups. Statesville Surgery Center is committed to providing services to all persons, regardless of race, ethnicity, gender, age, religion, creed, disability, national origin, or ability to pay.”

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

However, the applicant does not adequately demonstrate the proposal would have a positive impact on cost-effectiveness because the applicant does not adequately demonstrate:

- the need the population to be served has for the proposal. The discussion regarding demonstration of need found in Criterion (3) is incorporated herein by reference;
- that the proposal would not result in an unnecessary duplication of existing and approved health services. The discussion regarding unnecessary duplication found in Criterion (6) is incorporated herein by reference; and
- that projected revenues and operating costs are reasonable. The discussion regarding projected revenues and operating costs found in Criterion (5) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is not conforming to this criterion based on all the reasons described above.

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

The applicant proposes a change of scope to Project ID #F-11998-20. Instead of proposing to relocate one OR from Davis RMC to develop a specialty ASF with two procedure rooms, the applicant proposes to develop the facility as a multispecialty ASF with one OR and two procedure rooms.

On Form O in Section Q, the applicant identifies facilities with ORs located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identified two hospitals in North Carolina.

In Section O, page 96, the applicant states that during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care which resulted in a finding of immediate jeopardy. According to the files in the Acute and Home Care Licensure and Certification Section, DHR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care occurred in & (#) 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 both hospitals, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

NA

The Criteria and Standards for Surgical Services and Operating Rooms promulgated in 10A NCAC 14C .2100 were not applicable to Project ID #F-11998-20 because that project did not propose to add new ORs to the existing OR inventory in Iredell County. The current proposal also does not propose to add new ORs to the existing OR inventory in Iredell County. Therefore, there are no administrative rules applicable to this review.