Delivered via Email

December 31, 2020

Ms. Martha Frisone, Chief
Ms. Celia Inman Project Analyst
Certificate of Need Section
Division of Health Service Regulation
NC Department of Health and Human Services
809 Ruggles Drive
Raleigh, North Carolina 27603

Re: Comments on Application for a Certificate of Need for Piedmont Surgical Center of Excellence, new orthopedic-only ambulatory surgical facility in Statesville, Iredell County, CON Project ID Number: F-011998-20

Dear Ms. Inman and Ms. Frisone:

On behalf of Iredell Health System, thank you for providing an opportunity to comment on the proposed Piedmont Surgical Center of Excellence application. Iredell Health System deliberated carefully before filing these comments. We understand competition and respect customer choice. However, this application fails on its merits. Moreover, if approved, this project would have a serious and negative impact on the resources of Iredell Health System. As you know, Iredell County residents own Iredell Health System. Iredell Health System is accountable to the whole county for making appropriate investments in resident health and well-being. Iredell Health System depends on the income it generates to provide services. Unfortunately, the health care payment system rewards a few specialties at the expense of others; orthopedics subsidizes primary care and obstetrics, for example.

Statesville has about 28,000 people and two freestanding ambulatory surgery facilities ("ASFs"), one owned by Iredell Health System and the other is a joint venture of Iredell Health System, Atrium, and local physicians. One of these ASFs, Iredell Surgical Center, is located only **0.5 miles away** from the applicant's proposed site and already has **four ORs that can perform orthopedic surgery.**

The key physician whose cases provide the basis for the proposed third, orthopedic-only, surgery center has privileges at the joint venture ASF. The local physicians also qualify for privileges at the Iredell Health System's wholly owned Iredell Ambulatory Surgery Center. If patient cost of care is really important to the surgeons, they could do procedures at either existing freestanding ASF tomorrow, or at Iredell Mooresville Campus ASF when it opens in 2021.

The CON application itself has numerous erroneous statements and details highlight the applicant's lack of experience with ambulatory surgical facility operations. Yet, the application budgets nothing to compensate for the lack of experience. As an experienced ASF operator, Iredell Health System can assure you that the differences between hospital and ASF operations are substantial.

We recognize that the State's Certificate of Need (CON) award for the proposed new health care facility, an ambulatory surgical facility with one relocated operating room and two procedure rooms, will be based upon the State's CON health planning objectives, as outlined in G.S. 131E-183. We have reviewed those criteria and provide remarks in the attached document to show how the application is nonconforming to at least eight of those criteria.

Sincerely,

John Green
President and CEO
Iredell Health System

David R. Green
Chair, Board of Directors
Iredell Health System

ATTACHMENTS

Comments on Piedmont Surgical Center of Excellence, LLC 1

SOSC Floor Plan 2

ATTACHMENT 1

Comments: F-011998-20, Piedmont Surgical Center of Excellence

COMPETITIVE REVIEW OF–STATESVILLE ORTHOPEDIC SURGERY CENTER [PIEDMONT SURGERY CENTER OF EXCELLENCE, LLC], [PROJ ID F-011998-20]

COMMUNITY HEALTH SYSTEMS DAVIS REGIONAL MEDICAL CENTER

OVERVIEW

Piedmont Surgery Center of Excellence, LLC's ("PSCE") application is non-conforming with statutory review criteria 3, 3(a), 4, 5, 6, 7, 12, and 18(a).

PSCE proposes to develop one operating room and two procedure rooms in a leased, new construction medical office building in Statesville, Iredell County, North Carolina. The applicant proposes to spend $6,169,139 in fixed capital to serve 1,267 patients from Iredell and other North Carolina counties by Project Year 3, October 1, 2024 through September 30, 2025. Annual operating costs for the facility are $4,712,870 in Year 3.

CON REVIEW CRITERIA

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.

Overestimated Need and Utilization

PSCE significantly overestimates the need of the population it proposes to serve. PSCE proposes an orthopedic-only ambulatory surgery facility ("ASF"). Hence, it should demonstrate the need that the population to be served has for orthopedic surgery. Instead, it identifies need based on use rates for all types of outpatient surgery; and does not even adjust these rates for cases appropriate for a freestanding ambulatory surgery center.

On application page 101, PSCE forecasts need for ambulatory surgical cases in Iredell County, but uses a statewide population-based outpatient surgical use rate to forecast cases. This is incorrect because these use rates forecast need for all outpatient surgical cases, regardless of specialty.

The PSCE need methodology does not specifically address the need for the "services proposed" – freestanding ambulatory orthopedic surgical cases -- as required by statutory criterion 3. PSCE's application broadly mentions a shift of joint surgeries (page 12), but fails to quantify the need for these cases in the local population to be served. The forecast need for surgical cases at PSCE should be based on the **much lower** statewide outpatient- orthopedic surgery and not the use rate for all multi-specialty outpatient surgery**. And, the results should be adjusted down** for cases appropriate for a freestanding ambulatory surgical center. Without these adjustments, the methodology misleads the reader. Far later in the application (at page 106), buried in a table

labeled "Project Outpatient Surgical Case Shifts," the application notes that **in the third project year, only 215 orthopedic surgery cases** that would have occurred at Davis Regional Medical Center ("DRMC") in Statesville would occur at the proposed new orthopedic-only ambulatory surgical center. With this fact alone, the application demonstrates that the size of population in need of the "mission" of providing an alternative to high-cost hospital surgery at DRMC is insufficient to support a new 13,200 SF freestanding single-specialty orthopedic ambulatory surgical facility in Statesville.

One must untangle the methodology in Section Q to discover the source of the remaining cases forecast for Year 3:

- At page 110, the application proposes 333 cases would "shift" from Lake Norman Regional Medical Center("LNRMC").
- Then one must, by deduction, discover that the remaining 719 cases (1,267 – 215 – 333 = 719 cases) would otherwise have gone Iredell Memorial Hospital or to the three freestanding multi-specialty ambulatory surgery centers already serving Iredell County.

On page 106 of the application, PSCE makes some errors in logic regarding the shift of outpatient orthopedic surgical cases from DRMC and LNRMC to the proposed Statesville Orthopedic Surgery Center ("SOSC"). These shifts are crucial to supporting the projected caseloads at SOSC.

The applicant first projects total inpatient surgical cases at DRMC by using one-fourth of the four-year CAGR calculated from the FFY2016-FFY2020 total inpatient surgical cases and projects total outpatient surgical cases by using one-third of the four-year CAGR calculated from the FFY2016-FFY2020 total outpatient surgical cases. The applicant then takes about 20 percent of the total projected outpatient surgical cases to determine outpatient orthopedic cases at DRMC and then shifts a percentage of those outpatient orthopedic cases to SOSC. The applicant projects total inpatient surgical cases at LNRMC by using the total four-year CAGR calculated from FFY2016-FFY2020 inpatient surgical cases and projects total outpatient surgical cases using one-half of the four-year CAGR calculated from FFY2016-FFY2020 outpatient surgical cases. The applicant then takes about 14 percent of the total projected outpatient surgical cases to determine outpatient orthopedic cases at DRMC and then shifts a percentage of those orthopedic cases to SOSC.

Not only is this method flawed, it is incorrect. DRMC's and LNRMC's 2018-2020 NC DHSR License Renewal Applications, indicate that outpatient orthopedic cases are declining at both hospitals. Table 1 below shows the outpatient orthopedic surgical cases at both DRMC and LNRMC declined annually --by 19 percent and 14 percent respectively.

Table 1: Outpatient Orthopedic Surgical Cases, FFY2017-FFY2019

Facility	FFY2017	FFY2018	FFY2019	CAGR
Davis Regional Medical Center	674	608	445	-19%
Lake Norman Regional Medical Center	984	726	720	-14%

Source: 2018-2020 NC DHSR License Renewal Applications

Note: CAGR Calculated by (2019 cases / 2017 cases) ^ (1/ (2019-2017))-1

LRA data for FFY 2020 are not yet publicly available and the applicant did not provide that information in the application.

Table 2 below shows the impact of using the orthopedic surgical case CAGRs from Table 1 in the application's shift methodology (page 105). The results are dramatically different. The application used the three-year CAGR for all outpatient cases to project outpatient orthopedic surgical cases at DRMC and LNRMC. Table 2 uses the recent available three-year outpatient orthopedic CAGR.

Table 2: Outpatient Orthopedic Surgical Cases, FFY2020-FFY2025

	Facility	Fiscal Year					
		2020	2021	2022	2023	2024	2025
a	Davis Regional Medical Center	362	294	239	194	158	128
b	Lake Norman Regional Medical Center	616	527	451	385	330	282

Notes:

a) Previous Year DRMC Outpatient Orthopedic Cases * (1+ CAGR from Table 1)
b) Previous Year LNRMC Outpatient Orthopedic Cases * (1+ CAGR from Table 1)

In PSCE's third project year, FFY2025, DRMC would have 128 cases and LNRMC would have 282 cases. Table 2 shows that neither hospital would have enough outpatient orthopedic cases to support the proposed shifts to the new SOSC -- 215 cases from DRMC and 333 cases from LNRMC. Table 2 also shows that foundations for the SOSC utilization projections are unreasonable.

Failure to Demonstrate Need of Population to be Served

Even the population health status description of need bears little relationship to orthopedic surgery. The need description discusses Iredell County cardiovascular disease and stroke (page 28), which have little to do with orthopedic surgery.

The application mentions a 25-minute drive time for the population to be served; but, does not mention the number of freestanding ambulatory surgery centers that are located within that drive time. See Table 3. The map on page 55 suggests that the patients may be driving to the proposed center within a 30-minute drive time. The application provides no evidence that patients would drive from areas like Huntersville, Clemmons, and Hickory to Statesville. It ignores both other alternatives in those locations and traffic congestion on I-77 and I-40, especially when the economy is fully functioning. See Table 4. The applicant also fails to map the freestanding ambulatory surgery centers that offer orthopedic surgery inside that area.

As illustrated in the following two tables, six such centers located within a 30-mile radius have a **combined total of 13 freestanding ambulatory surgery center operating rooms that offer orthopedic surgery. All three in Iredell County are below capacity**, according to the *2020 State Medical Facilities Plan*.

Table 3: Ambulatory ORs at Freestanding ASFs within 25 Minute Drive Time

Facility Name	Location	Number of Multi-Specialty Ambulatory Surgery ORs*
Iredell Surgical Center	Statesville	4
Iredell Ambulatory Surgery Center	Statesville	1
Iredell Mooresville Campus ASC	Mooresville	1
Total		**6**

Source: 2020 SMFP, Chapter 6A
Note: * includes CON adjustments

Table 4: Additional Ambulatory ORs at Freestanding ASFs within 30 Minute Drive Time

Facility Name	Location	Number of Multi-Specialty Ambulatory Surgery ORs*
Novant Health Clemmons Outpatient Surgery	Clemmons	2
Novant Health Huntersville Outpatient Surgery	Huntersville	2
Viewmont Surgery Center	Hickory	3
Total		**7**

Source: 2020 SMFP, Chapter 6A
Note: * includes CON adjustments

See additional discussion with regard to Criteria 4 and 6 below.

Failure to Justify Need for Additional Ambulatory Surgical Facility in Iredell County

It is important to note that the application is not for relocation of one operating room. On page 7, the application clearly notes that "**the capital expenditure is required to develop a new health service facility, an ambulatory surgical facility**." Plans for the proposed SOSC ambulatory surgical facility show three functioning rooms inside a sterile core. Need for one operating room is questionable and need for the two procedure rooms is clearly not justified by the forecast utilization in Form C. The cost to operate the proposed facility will be $4.7M by the third year of operation.

Similarly, the discussion on pages 30 through 32 is about multispecialty outpatient surgery, not freestanding orthopedic ambulatory surgery. The statement on page 38 about a "new alternative for obtaining value-based outpatient surgical services in Statesville and Iredell County" is misleading. There are two such alternatives in Statesville today and three approved in Iredell County. Page 33 mentions letters from "local orthopedic surgeons," but only four of the 12 are local. The others are located in Mecklenburg County and letters from those surgeons offer only general support for the concept. In Section C.5.(b) the application discusses the importance of proximity to DRMC for surgeons who practice there. This contradicts the statement on page 110 that surgeons from LNRMC will bring patients to Statesville. Moreover, as noted above, only 215 cases in the third year, or 17 percent of the cases, would come from DRMC surgeons. It is not reasonable to spend $6.1 million on a new ambulatory surgery center that will provide only 215 local cases by the third year of operation.

On page 104, the application proposes to "shift" 64 pain cases from DRMC and 117 from LNRMC. That amounts to less than one pain case per day; yet, the application requests two procedure rooms for the pain cases. The 181 pain cases do not justify the capital cost associated with building a new health service facility sized for pre- and post-recovery for these additional procedure rooms. This argument could similarly apply to Criterion 12.

The application fails to note that Iredell Mooresville Campus ASF (CON No. F-011727-19) will be in service by the time the proposed Statesville Orthopedic Surgery Center ("SOSC") opens and Iredell Mooresville Campus ASF will offer orthopedic surgery. As discussed later in Criteria 4 and 6, existing local freestanding ambulatory surgical facilities can provide orthopedic surgery and can clearly absorb and provide the lower-cost freestanding ambulatory surgical facility cases as an alternative to either DRMC or LNRMC.

In addition, careful review of the floor plans shows what appears to be two overnight patient rooms, but the budget and narrative are silent on use of or need for these rooms. See Attachment 2 showing the floor plan with the space dedicated to overnight rooms.

PSOC's CON application selectively borrowed language from other freestanding ambulatory surgery facility CON applications without first determining if the facts match. They do not.

Because PSCE failed to demonstrate need of the population to be served for a new orthopedic-only freestanding ASF in Statesville, it is non-conforming to Criterion 3.

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.

The application makes no attempt to quantify the impact of relocation of one operating room from DRMC on the needs of the population to be served. All such discussion is generic and high level. It does not discuss what happens to patients in Mooresville when a surgeon from LNRMC leaves to do surgery in Statesville.

As such the application is non-conforming to Criterion 3a.

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.

The application is based on a misleading statement of need. It cites 36 percent outmigration from Iredell County, failing to note that much of this outmigration occurs in the Mooresville area. It does not adjust for orthopedic surgery. This demonstrates another of the application's errors in logic.

The application proposes to draw patients from Mooresville to Statesville. On this topic, the application provides no supporting evidence to show that patients will bypass a large urban area that offers the same proposed services to seek services in a smaller, distant community. Statesville's population is only 27,528. No physician letters propose to bring patients from Mooresville or Mecklenburg County to Statesville. Patient origin calculations are not based on orthopedic surgery.

The application shows **no support from patients.** The application implies that hospitals, specifically DRMC and LNRMC, can direct where patients get care. Hospitals cannot admit patients to certified ambulatory surgery centers. Only credentialled practitioners– in this case orthopedic specialists -- can admit. It is even questionable that pain specialists could be credentialled in a center licensed only for orthopedic surgery.

The total capital expenditure for this project is $6.1M or **$6.1M per operating room.** By any standard, this is high.

The argument for an orthopedic-only center has random notes about surgical cases. The table on page 54 shows that, in all of Iredell County, in 2019, only 2,245 outpatient cases were orthopedic. If only half of those were appropriate for a freestanding center, as determined in the footnote on page 110[1] then, to achieve PSCE's case count objective, the proposed center would have **to attract 100 percent of all freestanding orthopedic surgery cases performed in Iredell County.** The application provides no information to demonstrate that the proposed SOSC could achieve this.

This proposal **does not represent the least costly or most effective alternative** and is adding to an already saturated market for outpatient surgical services; see further discussion under Criteria 3 and 6.

Because it does not represent the least costly or most cost-effective option for freestanding ambulatory orthopedic surgical services, the application is non-conforming to Criterion 4.

[1]14 Things to know about total joint replacements and ASCs for 2020, Becker's ASC Review, Jan 2020 https://www.beckersasc.com/orthopedics-tjr/14-things-to-know-about-total-joint-replacements-and-ascs-for-2020.html

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.

PSCE provides an unsupported payor mix projection for the entire facility. Justification for the proposed third project year payor mix for the entire facility begins on page 86. Table 5 below compares SOSC's third project year Medicaid projection to actual FY2019 information from NC DHSR ASC License Renewal Application forms for four other orthopedic-only ASC's in North Carolina. It shows that SOSC's Medicaid projection is much higher than similar facilities currently in operation.

Table 5: Comparison of SOSC Project Year 03 Payor Mix Projection to Similar Facilities in North Carolina

Payor	Proposed Statesville Orthopedic Surgery Center**	Mallard Creek Surgery Center	Triangle Orthopaedics Surgery Center***	Orthopaedic Surgery Center of Asheville***	Raleigh Orthopaedic Surgery Center
Self-Pay	1.23%	5.92%	0.75%	0.62%	0.58%
Charity	0.00%	1.23%	0.45%	0.08%	0.16%
Medicare*	41.87%	16.16%	15.03%	41.85%	14.22%
Medicaid*	**14.04%**	**5.70%**	**4.21%**	**3.59%**	**0.94%**
Commercial Insurance	39.90%	62.71%	72.07%	52.53%	84.09%
Worker's Compensation	1.10%	0.00%	0.00%	0.00%	0.00%
Tricare	0.39%	0.00%	0.00%	0.00%	0.00%
Other	1.47%	8.28%	7.49%	1.33%	0.00%
Total	100.0%	100.0%	100.0%	100.0%	100.0%
Total Cases	1,267	2,754	2,682	3,897	5,513

Source: Page 86 of application and 2020 NC DHSR ASC License Renewal Applications

* *includes managed care plans*
** *Self-Pay and Charity combine at Statesville Orthopedic Surgery Center*
*** *Other at Triangle Orthopaedics Surgery Center and Orthopaedic Surgery Center of Asheville includes workers comp, liability insurance, TriCare*

Table 5 shows SOSC's projected Medicaid percent is at least fourteen times higher than Raleigh Orthopedic Surgery Center. SOSC's projected Medicaid percentage is also three times those of Triangle Orthopaedics Surgery Center and Orthopaedic Surgery Center of Asheville.

The application provides no description of any planned initiatives that would cause it to reach 14 percent Medicaid. Moreover, PSCE bases the Medicaid percentage on the hospital outpatient departments ("HOPD") at DRMC and LNRMC and not on its proposed freestanding ambulatory surgery eligible orthopedic surgery cases, or those of other orthopedic ASFs. There is no evidence in the application that the Medicaid percentages for the HOPD setting will apply to a freestanding orthopedic-only ASF setting. The payer mix discrepancies alone raise questions

about the reasonableness of the financial proformas. The unrealistic forecasts of utilization described in Criterion 3 above make the financial projections unreasonable.
Considering the information above, the application provides unreasonable assumptions which would affect both the cost and the quantity of service proposed and the resulting income statement and is therefore non-conforming to Criterion 5.

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

The application makes several incorrect statements regarding ambulatory surgery in the service area. For example, on pages 64 and 65, the application notes,

> *"The proposed project will not result in unnecessary duplication of existing or approved facilities in Iredell County".*
>
> *"The proposal to establish a freestanding ASC for local surgeons and patients cannot be duplicated by any other Iredell County facility."*

There are two multi-specialty freestanding ambulatory surgical facilities in Statesville. Both can offer orthopedic surgery. The application does not mention this. Nor does the application mention that one of the "local surgeons" who provided a letter of support for the project has privileges at Iredell Surgical Center, a licensed and certified ambulatory surgical facility that is located only **0.5 miles** from the proposed site.

Form C forecasts 1,267 cases in the third project year and implies that these will come from DRMC and LNRMC "shift.". In fact, as noted in the discussion of Criterion 3, only 548 cases would come from the "shift." Nonetheless, hospitals cannot schedule ASF cases. Surgeons alone do this. The project provides little local support from local orthopedic surgeons. The surgeon proposing the largest number of surgeries does few procedures at DRMC. Scott Brandon, MD is a hand surgeon and does most of his outpatient cases at Iredell Memorial Hospital. The same is true of Brett Feldman, MD. **The letters from these two do not indicate that either surgeon presently does surgery at DRMC or LNRMC.** The historical pattern of their surgeries suggests that estimates in the letters appear inflated. See Table 6.

Table 6: History of Outpatient Surgery at IMH for Key PSOE Surgeons

Physician	Specialty	Outpatient Cases at IMH				Cases Forecast SOSC Year 1	Increase
		2017	2018	2019	2020		
Scott Brandon	Shoulder, Elbow, Hand	288	278	290	268	418	155%
Dale Rader	Arthroscopy of major joints, sports medicine, hip/knee replacement, hand	32	22	27	18	132	530%
Michael Getter	Spine, general orthopedics	0	0	0	0	57	100%
Brett Feldman*	Foot and ankle	113	114	113	147*	180	159%
Total						**787**	

*Absorbed cases from a retired surgeon in 2020. Source: IMH Physician cases per IMH Internal Data, Accessed Dec 18, 2020,

In fact, letters and forecasts in Exhibit I.2 are vague about where supporting physicians currently do surgical cases. Surgeons from OrthoCarolina in Charlotte provide letters of support, but carefully avoid mention of any proposed number of surgeries. None of these surgeons practices in Statesville. None have offices in Statesville, none show intent to put an office in Statesville, and none provide evidence of patients from the Statesville area. Why would patients from Charlotte, where there are multiple freestanding ASFs, agree to fight traffic on I-77 to get surgery in Statesville? The application carefully sidesteps that question. Support letters in Exhibit I.2 from physicians are template letters that include the following remarks:

> *"The proposed project is needed to improve access to surgical services and cost-effective ambulatory surgical services…I am confident that the proposed project will help orthopedic patients receive cost effective care in a facility dedicated to orthopedic ambulatory surgery…The proposed new ASC will have a different charge structure from Davis Regional Medical Center's existing hospital-based surgical services. This **may** [emphasis added] offer… a lower cost alternative…."*

The careful wording, most likely developed by the applicant, suggests some hesitation on the part of the applicant that the proposed facility will offer a lower cost alternative. There is good reason for such hesitation. See discussion in Criterion 7 regarding lower cost alternative.

On page 16 of the application, PSCE proposes to perform outpatient spine surgical cases. PSCE provides a letter from one spine specialist, Dr. Michael Getter in Exhibit I.2. However, two surgeons provide the majority of spine cases in Statesville, Dr. Peter Miller, and Dr. Alex Seldomridge. Both perform cases at Iredell Memorial Hospital and neither have supported this project. Dr. Ben Garrido does many of the spine procedures for LNRMC and the application contains no support letter from him. The application is missing support from Dr. Mark Williamson, who also does spine cases at DRMC.

We also looked at ASF ORs per 100,000 residents in Statesville. Statesville is a saturated market for ASF ORs. See Table 7 below. Statesville today has more than **three times the national average.**

Table 7: Comparison of ASF ORs per 100,000 Residents

Region	# ORs in ASFs	Population	ORs per 100,000 Residents
	a	b	c
Statesville, 2020	5	27,528	18.2
United States, 2017	17,400	328,239,523	5.3

Notes and Sources:

a. 2020 SMFP Table 6A, pages 67-68, Column E, Ambulatory ORs, MedPac, "Report to the Congress: Medicare Payment Policy", March 2020, Chapter 5, p. 148 for US data

b. U.S. Census Quick Facts, population estimates, July 1, 2019; accessed 12.22.2020

*c. a / b * 100,000*

For all these reasons, the application is non-conforming to Criterion 6.

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.

SOSC proposes only orthopedic surgery, and, judging from the listed surgeons, the medical staff can provide only some orthopedic surgery. The application lists the following orthopedic subspecialties: foot and ankle, joint replacement, hand and shoulder and elbow, spine, sports medicine trauma, pediatric orthopedic surgery, and orthopedic oncology. Table 8, lists the physicians that will practice at the proposed SOSC. None specializes in pediatric orthopedic surgery or orthopedic oncology. The application fails to demonstrate evidence of surgical capacity to provide its proposed cases.

Table 8: Physician Letters of Support for SOSC Project

Physician Name	Practice	Specialty
Scott Brandon	Piedmont Healthcare	Shoulder, Elbow, and Hand
Dale Rader	Davis Medical Group	Arthroscopy of major joints, sports medicine, hip/knee replacement, hand
Michael Getter	Davis Medical Group	Spine, general orthopedics
Brett Feldman	Piedmont Healthcare	Foot and ankle
Charles Sikes	OrthoCarolina	Hip and knee
Rodney Stanley	OrthoCarolina	Shoulder and elbow, sports medicine
Bradley Winter	OrthoCarolina	Sports medicine, shoulder
Scott Smith	OrthoCarolina	Hip and knee, shoulder and elbow, sports medicine
William Bryan Jennings	OrthoCarolina	Sports medicine, trauma, knee shoulder, hip and knee, shoulder, and elbow
Bruce Cohen	OrthoCarolina	Foot and ankle
William Geideman	OrthoCarolina	Foot and ankle
William Craig	OrthoCarolina	Shoulder and elbow, knee, sports medicine
Michael Burchell*	Carolina Specialty Care, PA	Anesthesiology, pain management
David Eichman*	East Carolina Anesthesia Associates, PLLC	Anesthesiology, pain management

Source: Exhibit I.2, Internet Searches
*Drs. Michael Burchell and David Eichman do not specialize in orthopedic surgery

The applicant proposes to manage the project. DRMC is the sole applicant member. However, the application provides no evidence of its experience operating a surgery center. For experience, the application cites DRMC experience operating a hospital. No information in the application shows that DRMC has experience operating an ambulatory surgical facility. In fact, on page 11, the application emphasizes the importance of DRMC's membership in the "North Carolina Hospital Association."

Page 66 of the application notes staffing is based on DRMC's extensive experience in offering surgical services in Statesville. All that experience is hospital experience. Page 67 of the application notes experience recruiting hospital staff. Page 70 of the application notes that DRMC will provide billing. Yet the application notes in multiple places that hospital billing differs from ambulatory surgery billing.

The application talks about providing a more cost-effective operation, but the financials indicate otherwise. The staffing plan in Form H does not separate the OR from procedure rooms, so it is difficult to tell how the proposed facility will operate. The facility seems top heavy on administration, proposing the same number of administrative staff as clinical staff. The form indicates that the cost of administrative staff exceeds the cost of clinical staff – a ratio of about 5 to 3. Yet the application is quick to note that ambulatory surgery centers and hospitals have very different payment systems. The application clearly demonstrates that the applicant is unprepared to operate an ambulatory surgery center and has not planned for appropriate manpower and management personnel.

For all these reasons, the application is non-conforming to Criterion 7.

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.

The application does not demonstrate that cost, design, and means of construction proposed represent the most reasonable alternative. It does not discuss these items. The letter from the developer in Exhibit K.4 does not include the rent amount. Nor does it indicate that water, power, and sewer at the site are adequate to support the proposed facility. Hence, it is impossible to evaluate the reasonableness of the rent or the project timeline.

The equipment list in Exhibit F.1 suggests intent to equip two rooms as operating rooms. (OR Surgical Suite). The program suggests and the equipment list supports, intent to offer spine surgery. But the list excludes a spine surgery operating room table. Costs appear underestimated; and the contingency of 2.5 percent (Form F.1a) provides little margin for error.

Forecasts of annual utilization are overstated. Hence projected capital cost associated with construction, approximately $4M for upfits alone, is not the most reasonable alternative for serving the overestimated 215 orthopedic surgery cases that would otherwise be served at DRMC (discussion under Criterion 3). In fact, if developed, the likely project result will be less efficient ASFs in Iredell County. Then, "costs to the public for providing health services by other persons" will increase. It is well known that the US health care payment system is lopsided; revenue from orthopedic surgical procedures supports other cases.

For all these reasons, the application is non-conforming to Criterion 12.

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 the service for which competition will not have a favorable impact.

The proposed project will not have a positive impact on competition. As demonstrated in Criterion 3, SOSC will provide far more capacity than Statesville can support and, as a result, could render existing and approved ambulatory surgical facilities less cost effective.

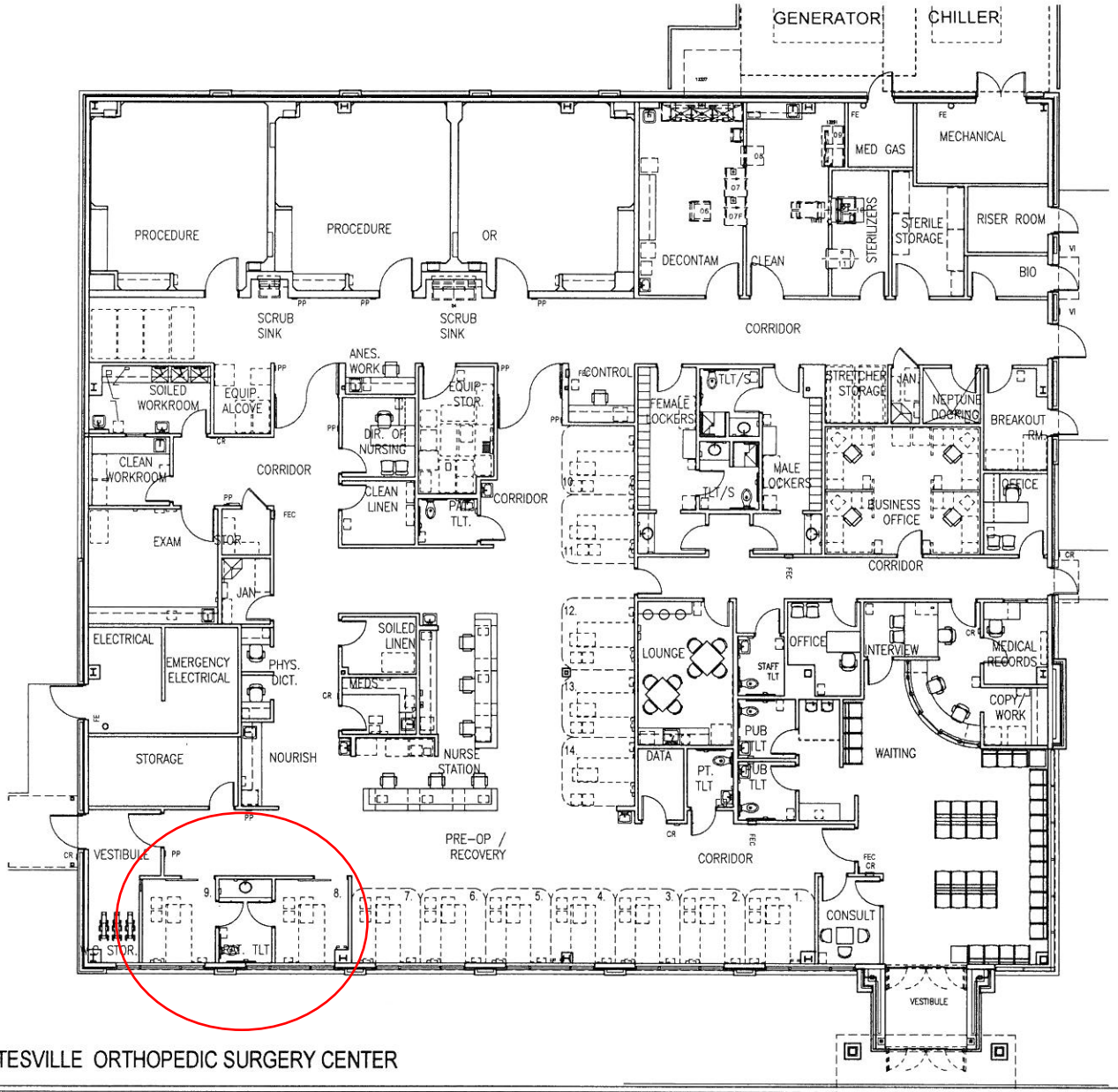
The proposed new ASF is not cost effective, itself. See discussion on administrative costs in Criterion 7. The application indicates there will be no management company, but the proformas show hefty management fees of five percent (Assumption 5, Form F.1a) in addition to allocated G&A and per procedure corporate expenses to an unknown party. This puts management fees in the neighborhood of eight percent, which is very high for a surgery center.[2] Most of the management fees at ASFs are between three to five percent.

Because PSCE's application will not have favorable impact on cost effectiveness, the application is non-conforming to Criterion 18a.

[2] 10 things to know about ASC management fees. Becker's ASC Review (2018) https://www.beckersasc.com/benchmarking/10-things-to-know-about-asc-management-fees.html?em=cboyd@pda-inc.net&oly_enc_id=1083J0218356B0F

ATTACHMENT 2

Floor Plan with Overnight Rooms Circled



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DAVIS STOKES COLLABORATIVE P.C.

DSC ARCHITECTS

10/23/2020

STATESVILLE ORTHOPEDIC SURGERY CENTER

STATESVILLE, NC

CONCEPT PLAN