DELIVERED VIA EMAIL

March 30, 2022

Ms. Micheala Mitchell, Chief
Ms. Julie Faenza, 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
Dhsr.con.comments@dhhs.nc.gov
julie. faenza@dhhs.nc.gov

Re: Comments Application for a Certificate of Need for Statesville Surgery Center to Expand Scope of Ambulatory Surgical Facility in Statesville, Iredell County, North Carolina, Project ID No. F-12183-22

Dear Ms. Mitchell and Ms. Faenza,

On behalf of Iredell Memorial Hospital, Incorporated ("Iredell Health"), thank you for the opportunity to comment on the above referenced application by Piedmont Surgical Center of Excellence, LLC ("PSCE") to expand the scope of CON F-11998-20 from a single specialty ambulatory surgery center to a multispecialty ambulatory surgery center in Statesville, Iredell County. During your review, I trust that you will consider the comments presented here.

We recognize that the State's review of the application will be based upon statutory criteria in G.S. 131E-183. A year ago, on March 15, 2021, the Agency recommended Disapproval of the original application for this project (see Attachment B). It found the application non-conforming to statutory criteria: 3, 3a, 4, 5, 6, and 18a. The Certificate was issued only upon settlement of an appeal that occurred before affected parties could intervene. The most recent progress report for that CON shows no progress, giving as the reason its desire for an increased scope. Clearly, the applicant questions whether the service area population served needs the approved surgery center. We believe that the Agency's original decision was correct, that the population does not need proposed facility and would represent unnecessary duplication of existing health service facilities in the service area. The applicant has not changed the location. It is still within a half-mile of an existing underused multispecialty surgery center in Statesville. Iredell Health's multispecialty surgery center in Statesville is also not operating at capacity, and Iredell Health just recently opened a new freestanding ambulatory surgery center in Mooresville.

The PCSE change of scope application presents no compelling argument for duplicating these expensive health care resources. It also fails to acknowledge the very real problem of staffing shortages facing all health care providers. The application claims that the request does not represent a cost overrun. We disagree. With no change in design of the facility, it requests an increase in construction and other costs

that would, in turn, increase the capital cost limit for the project from 115 to 129 percent of the original approved amount.

I have attached detailed comments to support my concerns and ask that the Agency deny this application and consider withdrawal of the original application.

Sincerely,

John Green
Chief Executive Officer

Attachments

Attachment A

Iredell Health Comments Regarding
Piedmont Center for Surgical Excellence, LLC, Project ID F-12183-22

Overview

Piedmont Center for Surgical Excellence, LLC, ("PCSE") filed a request to increase capital costs and change the scope of services at an as yet undeveloped ambulatory surgery center, identified as Statesville Surgery Center ("SSC"). Although PSCE received a certificate of need for SSC in 2021, Project ID# F-11998-20, the Agency recommended Disapproval of that CON. Issues that caused that disapproval have not changed. The applicant admits to having made no progress on that project and has made no capital expenditures. The Agency should find this application to expand its scope of services non-conforming to Review Criteria 3, 5, 6, 7, 12 and 18a.

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.

The applicant requests an increased capital expenditure to change the licensure designation of a proposed ambulatory surgery center from single specialty orthopedic to multi-specialty. One year after receiving a CON as part of a settlement with the Agency, PSCE has not yet begun to develop the project. The CON timetable called for an executed construction contract on September 1, 2021. The last progress report, (Tab 10 in the new application) attributes the delay in construction to applicant plans to file a CON for a multispecialty surgery center. However, the proposed construction project in this new CON application indicates that there will be no change in design. There must be some other reason for the delay, but F-12183-22 does not provide it.

Moreover, delaying start on the approved single specialty CON because the applicant "intends to apply for a change of scope" validates the Agency's original recommendation for disapproval and puts the applicant's commitment to the original CON settlement in question.

This new application provides insufficient information to demonstrate that the population to be served needs evenOn the original approved SSC. The current application, F-12183-22, provides no justification for most of the proposed cases. See pages 100 and 101. Orthopedic surgery cases represent 86 percent of proposed Year 3 cases (1,267 / (206 + 1267)). Yet, the application fails to confirm sufficient need for these ambulatory surgery orthopedic cases. On page 100, the application states that surgeons who will perform outpatient surgery at SSC "will continue to perform surgery at Davis Regional Medical Center ("DRMC")." The application provides no names for the orthopedic surgeons. The utilization methodology (page 106) forecasts that only 223 orthopedic surgical cases would shift from DRMC to SSC in the third project year. Yet, the application claims 1,267 orthopedic surgical cases that year (page 103).

The application indicates that more - 395 orthopedic cases - will come from a shift of forecast cases from Lake Norman Regional Medical Center in Mooresville. The application provides no information to assure the Agency that patients would travel from Mooresville to Statesville for services that are available in Mooresville. Iredell Mooresville ASC offers orthopedic surgery and has an open medical staff. Iredell Mooresville ASC opened in 2021 and is not yet operating at capacity.

Even in the unlikely event that the Lake Norman shift were to occur, the project will still be short 659 cases in Project Year 03 (1,267 – 395 – 223 = 659). As was true with the original application, the new application provides no evidence that the proposed orthopedic procedures will materialize. According to the original application, two orthopedic surgeons, Scott Brandon, MD and Bret Feldman, MD were to have provided 598 cases at SSC. However, both are on the staff of Iredell Memorial Hospital, and neither provided letters supporting this application.

The application fails to demonstrate that the population it proposes to serve needs such a large facility. The floor plan includes 17 prep and recovery beds for 1,865 surgical cases in Project Year 03. The project assumes 250 operating days. That is an average of 7.46 cases a day. If all these cases materialized, each patient would have to use more than 16 hours of prep and recovery to justify that capacity. As noted, the application does not justify all the cases. The plan includes beds that can accommodate overnight stays [2 beds with private toilets adjacent to exit in floor plan]. The application fails to demonstrate need for those beds.

The justification for adding to the construction cost is "recent increases in materials and labor" (page 79). This is clearly a request for an overrun of costs for facility plans that are unchanged from the original. By adding to an approved construction cost amount, the applicant is requesting to increase its original capital cost limit by the statutory limit of 115 percent of the amount in this new CON application. That translates to 129 percent of the original amount. The full capital expenditure requires an explanation not provided in this application.

Table 1: Impact of New Capital Cost on Project Cost Limits

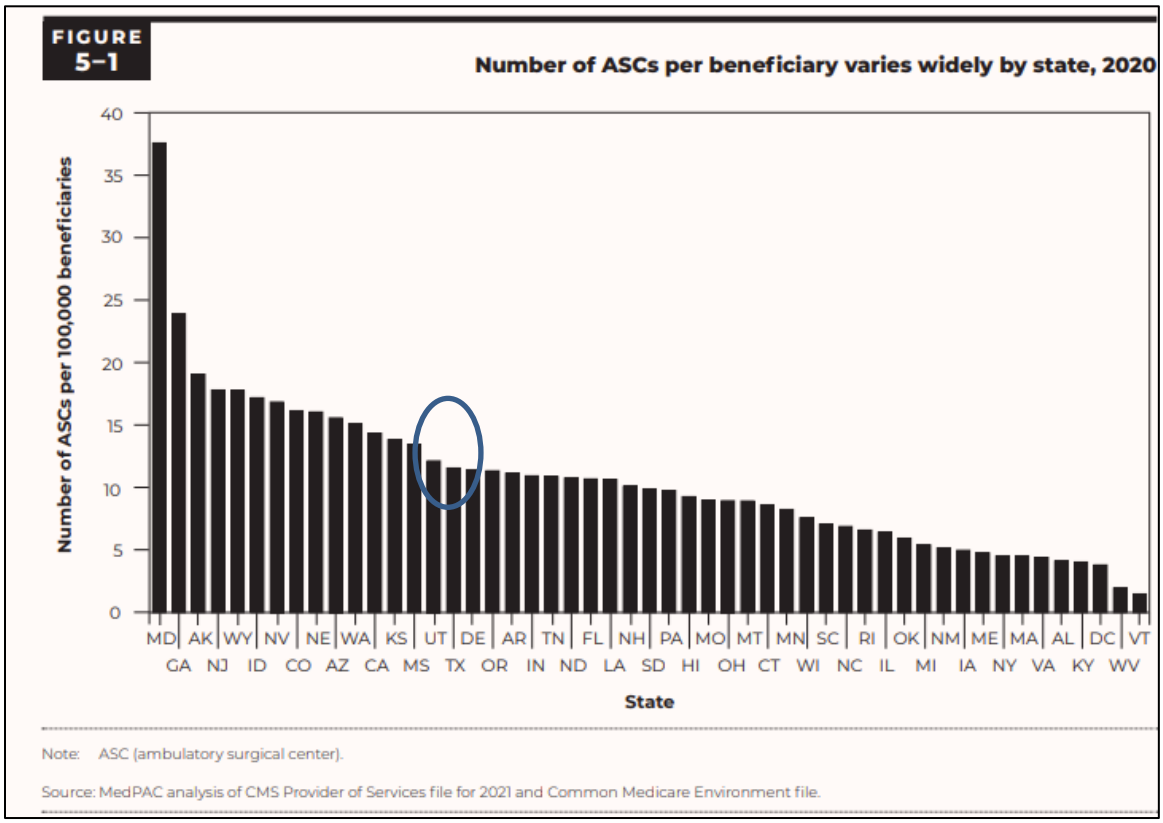
	Original	Proposed Scope Change
Requested Capital costs	$ 6,169,939	$ 6,901,999
Statutory Limit: 115% of Capital Costs	$ 7,095,430	$ 7,937,299
Percent of Original Capital Costs	115%	129%
Amount of Cost Overrun		$ 1,767,360

On page 37, the application claims that the growing population ages 45 to 64 will increase demand for surgical cases, but the table on page 37 shows that age group will add only 249 people between now and the third project year. On page 38, the application confirms that this age group represents the majority of ambulatory surgery cases.

On page 42, the application cites *MedPAC 2021 Report to Congress* Figure 5-1 showing North Carolina's ratio of ambulatory surgery centers to Medicare beneficiaries below the national average in 2019. That year, CMS public use files reported 33,331 Medicare beneficiaries in Iredell County. Even without SSC,

the Iredell County ratio is closer to the middle of the curve at 9 per 100,000. With SSC, Iredell's ratio would be 12, closer to Utah and Texas at the mid- to upper end of the curve.

Figure 1: MedPAC 2021 Report to Congress, Figure 5-1



In 2021, DRMC provided 1,391 ambulatory surgery cases compared to 1,555 the year before (p 105). The application calls this a temporary drop associated with the pandemic. However, cases did not drop at Lake Norman (p108). The application does not explain the discrepancy.

Condition 6 on the original Certificate of Need F-11998-20 (Tab 2) indicates that the procedure rooms "shall not be used for procedures that should be performed only in an operating room based on current standards of practice." The current CON application does not challenge this. However, this new application, F-12183-22, does not explain how the project will fit cases that justify 1.31 operating rooms (p 114) into the proposed one operating room. In fact, information about the new infection control requirements on page 44 imply that making the fit will be difficult or impossible.

On the other hand, the current application proposes only 181 pain cases for two procedure rooms. A typical pain case uses less than 30 minutes of procedure room time. The application fails to explain why a facility open 250 days a year needs two procedure rooms for 181 cases. The state may not regulate the number of procedure rooms, but the statutory criterion directs the Agency to evaluate the need for capital expenditures.

The analysis of outmigration from Iredell County on page 43 has insufficient information to distinguish Mooresville from Statesville. Mooresville is close to the Mecklenburg County line and several ambulatory surgical centers are located across the line in the Huntersville area. The application does not have enough information to determine if the reasons for outmigration to other counties is for access to ambulatory surgery facility payment structures, or for specialty services that are not available at DRMC or other facilities in Iredell County.

Access to ambulatory surgery facilities is important. That said, Statesville has two functioning, Medicare and Medicaid Certified, NC Licensed, freestanding ambulatory surgery centers - Iredell Ambulatory Surgery Center and Iredell Surgery Center - which together have five operating rooms. Table 6A of the 2022 State Medical Facilities Plan and recent license renewal applications show neither facility used to capacity (see Attachment C).

Table 2: Capacity of Licensed Iredell County Ambulatory Surgery Centers

Licensed and Certified ASC	Operating Rooms	FY2020 Surgical Hours (a)	FY2021 Surgical Hours (b)	FY2021 % Capacity (c)
Iredell Mooresville Campus ASC (AS0175) (d)	1	0	0	0%
Iredell Surgical Center (AS0050)	4	747.3	1,180 * 31min = 610.2	47%
Iredell Ambulatory Surgery Center (AS0042)	1	286	347 * 1 = 347	26%

Notes:

a. *Table 6 A p 61 2022 SMFP*
b. *License Renewal Application 2022; See Attachment C*
c. *b / 1312 hours for Group 6*
d. *Iredell Mooresville Campus began services in November 2021, which is in FY 2022*

The application failed to demonstrate that the population to be served needs the proposed facility. Hence, the project should be found non-conforming to Criterion 3.

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.

This statutory requirement does not limit inquiry to the applicant's alternatives. It directs the Agency to consider alternative methods available. As noted above, Statesville has excess capacity in existing ambulatory surgical centers, and none have closed medical staffs.

The application shows no increase in charity, Medicaid, or Medicare percentages over what is available at existing freestanding ambulatory surgery centers.

Additional capital expenditure at an unneeded ambulatory surgery center is not the least costly or most effective alternative. Thus, the project should be found non-conforming to Criterion 4.

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.

Financial and operational projections for the facility are not reasonable. Orthopedic procedures are over projected. Staffing costs and capital costs are under projected. Funding for the original project was not available at the time of the last progress report.

Without the Unsupported Orthopedic cases and their related income and expense, the project shows need for continual subsidy. It will not be financially feasible, even at unreasonably low salaries. See Attachment D row z.

Form H lists annual nursing salaries at $66,200 in FY 2023. In today's nursing shortage environment, this is too low to attract and retain quality nursing staff. Ambulatory surgery nursing salaries in Statesville today are at the high end of the range. Indeed.com, reports the salary range at $64,800 to $82,000 per year.[1] Similarly, SSC surgical tech salaries at $44,354 are too low .Indeed reports the average for surgical techs in Iredell County today is $51,613.6[2]. IMH finds it must pay more than the average to retain quality surgical tech staff. Application Form H shows PSCE proposes to pay higher salaries for clerks than surgical techs.

Proposed Capital Costs appear understated, and the application does not adequately document assumptions to support them. The project estimate in Form F.1.b translates to at Total Project Cost of $519 per square foot ($6,901,999 / 13,299[3] = $519) . This is lower than most current cost estimates for a comparable building, according to our architects, Beck Group. In today's environment, estimated Total Project Cost for a building of this size and scale, bid in 2022, is $586/ SF . If the project does not adhere to the schedule in Section P, costs could escalate another 5 percent annually. Turner Construction Cost Index reports confirm the escalation. See additional discussion in Criterion 12.

The project schedule in Section P is also unrealistic. Medicare will not certify a new surgery center until the facility demonstrates that it has provided care for patients. Typical North Carolina experience is several months delay to obtain certification. Until it has a certification visit and recommended approval, an ASC cannot care for or bill Medicaid and Medicare patients. Payor Mix and volumes in the proforma do not account for that reality and the first-year forecast may overstate cases, as a result.

Is there a problem with funding? This application and the recent Progress Report imply that PSCE cannot complete CON F-11998-20 if it does not receive approval for the proposed change in scope. The Original CON application showed support from Ortho Carolina. This application does not. The original CON called for funding to be available in January 2022 (see Tab 10). That did not occur. Financial analysis of the

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[1] https://www.indeed.com/jobs?l=Iredell%20County%2C%20NC&q=nurse&from=mobRdr&utm_source=%2Fm%2F&utm_medium=redir&utm_campaign=dt&vjk=73444a835428e5a8

[2] https://www.indeed.com/cmp/Lrs-Healthcare/salaries/Surgical-Technician/Statesville-NC#:~:text=Average%20LRS%20Healthcare%20Surgical%20Technician,which%20meets%20the%20national%20average.

[3] Square feet from original application Section K.2

parent company shows evidence of financial strain. CHS is highly leveraged and may not be willing to invest in a venture that has a questionable profitability outlook.

As of 12/31/21, according to data provided by FactSet and reported on wsj.com[4]:

- CHS had more liabilities than assets. It had a total **debt to total assets ratio of 84.26**. A ratio greater than one shows a considerable portion of the assets funded by debt, while a ratio of 0.5 or less is considered good. A high ratio indicates that a company may be putting itself at risk of defaulting on its loans. For example, in fiscal year ending 2017, Sears had a total debt to total asset ratio of 1.4085 and it filed for Chapter 11 bankruptcy in October 2018.
- CHS had a **negative** shareholders' equity of $1.37 billion. Shareholders' deficit (negative shareholders' equity) is often a bad sign. It means the company has been losing money and has lost more money than the owners have put into the company.

Moreover, as demonstrated on page 39 of the 10Q provided in Exhibit F.5.1, Tab 11, CHS primary capital source is an ABL Credit Agreement Facility, which will be due in full on April 3, 2023. CHS states,

> *"Our ability to meet the restricted covenants and financial ratios and tests in the ABL Facility and the indentures governing our outstanding notes can be affected by events beyond our control, and we cannot assure you that we will meet those tests. A breach of any of these covenants could result in a default under the ABL Facility and/or the indentures that govern our outstanding notes. Upon the occurrence of an event of default under the ABL Facility or indentures that govern our outstanding notes, all amounts outstanding under the ABL Facility and the indentures that govern our outstanding notes may become immediately due and payable and all commitments under the ABL Facility to extend further credit may be terminated."*

On page 47 of the 10Q, CHS acknowledges the

> *"…risks associated with our substantial indebtedness, leverage, and debt service obligations, including our ability to refinance such indebtedness on acceptable terms or to incur additional indebtedness, and our ability to remain in compliance with debt covenants."*

Although the 10Q assures the reader that CHS believes it will have sufficient funds to finance capital requirements through the next 12 months, the data show that the parent company must be careful with its new capital investment.

PSCE requested an extension and provided no evidence in either the Progress Report or this application that CHS, the parent company of DRMC, has yet approved the capital funding request for this project. If that is the case, the Agency should incorporate withdrawal of F-11998-20 as part of denial of F-12183-22.

PSCE claims that the increased capital cost in F-12183-22 is not a cost overrun because the total capital cost increase is less than 15 percent of the approved amount. However, there is no proposed change in the facility, and the application understates the capital cost required to construct the facility. See discussion in Criteria 3 and 12.

[4] https://www.wsj.com/market-data/quotes/CYH/financials

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 proposed project will duplicate existing freestanding ambulatory surgical capacity in Iredell County. As noted, there are three other multi-specialty freestanding ambulatory surgery centers in the county, two in Statesville. None has reached capacity. The application did not address this. The fact that this project does not meet the application form definition of a service component has no bearing on the fact that ambulatory surgery centers that provide all surgical case types proposed already exist in Iredell County in both Statesville and Mooresville. Mecklenburg, Caldwell, and Catawba also have freestanding ambulatory surgery centers that are not operating at capacity, according to the *2022 State Medical Facilities Plan*, Table 6B.

Because the project represents unnecessary and unjustified duplication of existing ambulatory surgical capacity, it should be found 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.

Section H.4 states, states "PSCE does not anticipate significant difficulties in recruiting the staff necessary to fully support this surgical services project. DRMC recruiting efforts have been successful in assuring access to the appropriate number and mix of staff" (p 72). Yet it proposes salaries for two years from now that are at the low end of current nursing and surgical tech salaries. See discussion in Criterion 5 above. On March 30, 2022, Indeed.com shows that DRMC has posted vacancy for Operating Room Nurses for the last 29 days. The application has no letters from individuals indicating willingness to work for those salary rates. Iredell County and the state of North Carolina have nursing and tech workforce shortages.

The application shows no evidence of availability of resources including health workforce and management personnel for provision of the services proposed. Hence it should be found 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 proposed project does not demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative**.** The 13.299 SF floor plan has too few operating rooms for the proposed surgical cases, too many procedure rooms for the planned pain cases, and the ratio of prep and recovery rooms to operating room (14 to 1) exceeds all planning standards. Common ratios for ambulatory surgery are, at most four to one. The standard for NC Licensure is FGI Guidelines. *FGI Guidelines for Design and Construction of Outpatient Facilities 2018 Edition* call for a minimum of one prep and one recovery room per or procedure room[5].

It is impossible to tell the applicant's real plans for this facility. The application nor the original application contained a letter from the building owner indicating that it would rent the shell building for the proposed rent amounts used in Form 3b Operating Costs.

According to the Turner Construction Cost index, non-residential construction costs are increasing. Its most recent index shows increases in every 2021 quarter. The index was up 5.16 percent in 2021.

Table 3: Turner Construction Costs, 2021

Quarter	Index	% Change
4th Quarter 2021	**1,230**	**1.91**
3rd Quarter 2021	1,207	1.88
2nd Quarter 2021	1,187	1.28
1st Quarter 2021	1,172	0.09
Total		5.16

Source: https://www.turnerconstruction.com/cost-index

Turner notes in its 2021 online report – for the period before PSCE filed this project application – "There is a continual escalation in steel, copper, and aluminum prices. In addition, the supply chain disruptions have continued at unprecedented levels."

The application justifies none of the construction costs. The architect letter simply says the amount "should be sufficient." He provides no back up.

The application overestimates service volume and underestimates construction costs. The application should be found non-conforming to Criterion 12.

[5] FGI Guidelines for Design and Construction of Outpatient Facilities, 2018 Edition Section 2.1-3.2.3.7(17) p75 and 3.1-3.7.2 p98

18 a. 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.

Competition

The project proposes to add competition to the service area. However, the argument that the unbuilt project was previously approved, hence the Agency should not question its existence, does not hold up. The statement in Section G page 70 is incorrect.

> *"Therefore, any currently available OR capacity at other Iredell County facilities cannot effectively meet the need for the Statesville Surgery Center multispecialty ambulatory surgical program. "*

The assertion on page 70 that "surgical utilization at SSC us based on reasonable and supported assumptions" is also incorrect as demonstrated in Criterion 3 above.

Other freestanding ambulatory surgery centers in Iredell County offer all proposed services and more. None are full. Excess ambulatory surgery operating room capacity in the county could divide the market and cause existing facilities to fail, which would, in turn, *reduce* competition.

Cost Effectiveness

The project will require additional Anesthesia and CRNA capacity. Both resources are also in short supply. Competition for these and other staff could increase costs for all providers.

The proposed new ASC is not cost effective. The application indicates there will be no management company, but the proformas show hefty management fees of five percent (Financial Assumptions 5p 123) in addition to allocated G&A and per procedure corporate expenses. This puts management fees at 7.5 percent, which is remarkably high for a surgery center.[6] Most management fees at ASFs are three to five percent.

Access

As discussed in Criterion 3, the project's contribution to improved access will be minimal and will come at the cost of unnecessary duplication (Criterion 6).

The proposed project will not have a favorable impact on competition. Hence, it should be found non-conforming to Criterion 18a.

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[6] 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 B

NC DEPARTMENT OF
HEALTH AND HUMAN SERVICES

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

March 15, 2021

Matthew Littlejohn
171 Fairview Road
Mooresville, NC 28117

Disapproval

Project ID #:	F-11998-20
Facility:	Statesville Orthopedic Surgery Center
Project Description:	Develop a new orthopedic ASF by relocating no more than 1 OR from Davis Regional Medical Center and developing no more than two new procedure rooms
County:	Iredell
FID #:	200893

Last Date to Appeal: April 14, 2021
Required State Agency Findings: Enclosed

Dear Mr. Littlejohn:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) has disapproved the above referenced certificate of need application.

The applicant or any person aggrieved by this decision may file a petition for a contested case hearing in accordance with G.S. 150B, Article 3. This petition must be filed with the Office of Administrative Hearings, 6714 Mail Service Center, Raleigh, North Carolina 27699-6714 within thirty (30) days of the date of this decision. Effective October 1, 2009, OAH requires a filing fee with submittal of petitions for contested cases. Please direct all questions regarding this fee to the OAH Clerk's Office (919-431-3000).

G.S. 150B-23 provides that a party filing a petition must also serve a copy of the petition on all parties to the petition. Therefore, if you file a petition for a contested case hearing, you must serve a copy of the petition on the Department of Health and Human Services by mailing a copy of your petition to:

Lisa G. Corbett
Department of Health and Human Services,
Office of Legal Affairs,
Adams Building – Room 154
2001 Mail Service Center
Raleigh, North Carolina, 27699-2001

It is requested that a copy of the petition also be served on the Agency.

In accordance with G.S. 131E-188(a1), as a condition precedent to proceeding with a contested case hearing on the approval of an applicant for a certificate of need, the petitioner shall deposit a bond with the clerk of superior court where the new institutional health service that is the subject of the petition is proposed to be located. The bond shall be secured by cash or its equivalent in an amount equal to five percent (5%) of the cost of the proposed new institutional health service that is the subject to the petition,

but may not be less than five thousand dollars ($5,000) and may not exceed fifty thousand dollars ($50,000). Moreover, the applicant who received approval for the new institutional health service that is the subject of the petition may bring an action against a bond filed under this subsection in the superior court of the county where the bond was filed. Upon finding the petition for a contested case was frivolous or filed to delay the applicant, the court may award the applicant part or all of the bond filed.

Please refer to the Project ID # and Facility ID # (FID) in all correspondence.

Sincerely,

Celia C. Inman
Project Analyst

Gloria C. Hale
Team Leader

Enclosure: Required State Agency Findings

REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conforming as Conditioned
NC = Nonconforming
NA = Not Applicable

Decision Date: March 15, 2021
Findings Date: March 15, 2021

Project Analyst: Celia C. Inman
Team Leader: Gloria C. Hale

Project ID #: F-11998-20
Facility: Statesville Orthopedic Surgery Center
FID #: 200893
County: Iredell
Applicant: Piedmont Surgical Center of Excellence, LLC
Project: Develop a new orthopedic ASF by relocating no more than 1 OR from Davis Regional Medical Center and developing no more than two new procedure rooms

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.

C

Piedmont Surgical Center of Excellence, LLC, hereinafter referred to as PSCE or "the applicant" proposes to develop Statesville Orthopedic Surgery Center (SOSC), a new orthopedic ambulatory surgical facility (ASF), by relocating no more than one operating room (OR) from Davis Regional Medical Center (DRMC) and developing two new procedure rooms.

Need Determination

The proposed project does not involve the addition of any new health service facility beds services or equipment for which there is a need determination in the 2020 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to this review.

Policies

There is only one policy in the 2020 SMFP applicable to the review.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 31 of the 2020 SMFP, states:

> *"Any person proposing a capital expenditure greater than $2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.*
>
> *In approving a certificate of need proposing an expenditure greater than $5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.*
>
> *Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."*

The proposed capital expenditure for this project is greater than $5 million. In Section B, pages 14-15, the applicant explains why it believes the application is consistent with Policy GEN-4. The applicant states that it will develop a plan for energy efficiency and water conservation during the design phase of the project and will submit the plan to the Construction Section of DHSR for review and offers the following statement:

> *"The applicant will conform to the energy efficiency and water conservation rules, codes and standards implemented by the construction Section of the Division of Health Service Regulation and required by the North Carolina State Building Code. During the design of this project, the applicant will work with the project architects and engineers to assure that the latest technologies for enhanced building energy and water conservation are evaluated for the project and incorporated in the facility where most appropriate. The goal of this effort will be to maximize energy efficiency and water conservation while creating the best possible care and healing environments for patients."*

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 based on the following:

- The applicant does not propose to develop any beds, services or equipment for which there is a need determination in the 2020 SMFP.
- The applicant does not propose to add any new ORs to the inventory of ORs in Iredell County.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-4 based on the following:
    - The applicant states it will develop a plan for energy efficiency and water conservation during the design phase of the project.
    - The applicant emphasizes its commitment to identify and implement processes that improve efficiency, reduce consumption and waste, minimize environmental impact and improve the well-being of the communities served.

(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, PSCE, proposes to develop SOSC, a new orthopedic ASF, by relocating no more than one OR from DRMC and developing two new procedure rooms. DRMC is the sole member of PSCE at this time; however, the applicant states that PSCE is meant to be a future joint venture between DRMC and local physicians. The single-specialty ASF will be developed in leased space in a medical office building on Fern Creek Drive in Statesville, Iredell County.

Statesville Orthopedic Surgery Center will be part of the Community Health System (CHS) Iredell County health system, along with Davis Regional Medical Center and Lake Norman Regional Medical Center. Per the 2020 SMFP, upon completion of the proposed project, the CHS Iredell County health system would have three ambulatory ORs and 11 shared ORs, while Iredell County would have three inpatient, nine ambulatory, and 20 shared ORs (which

includes the proposed relocation of one shared OR from DRMC to a separately licensed ambulatory OR at SOSC, and the previously approved Project ID #F-11727-19 to relocate one shared OR from Iredell Memorial Hospital to an ambulatory OR at Iredell Mooresville Campus ASC).

Patient Origin

On page 51, the 2020 SMFP states, *"An operating room's 'service area' is the service area in which the room is located. The operating room service areas are the single or multicounty groupings as shown in Figure 6.1."* In Figure 6.1, page 57 of the 2020 SMFP, Iredell County is shown as a single-county OR service area. Thus, the service area for this application is Iredell County. Facilities may also serve residents of counties not included in the service area.

SOSC is a proposed facility with no existing patient origin data; however, for informational purposes, on page 20, the applicant provides DRMC's historical surgical services patient origin by county, as summarized below.

County	Last Full FY October 1, 2019-September 30, 2020	
	# of Patients	% of Total
Iredell	1,881	64.62%
Alexander	277	9.52%
Rowan	159	5.46%
Catawba	88	3.02%
Surry	80	2.75%
Wilkes	72	2.47%
Davie	59	2.03%
Caldwell	41	1.41%
Mecklenburg	40	1.37%
Cabarrus	22	0.76%
Yadkin	21	0.72%
Other NC Counties*	116	3.98%
Virginia	36	1.24%
Other States	19	0.65%
Total	**2,911**	**100.00%**

*Includes all other NC counties, each of which represents <1% of total patient origin.
Source: Section C.2, page 20, DRMC
Total may not sum due to rounding

On page 21, the applicant provides the proposed facility's projected patient origin for surgical services during the initial three full fiscal years, as summarized in the table below:

County	1st Full FY 10/1/22-9/30/23		2nd Full FY 10/1/23-9/30/24		3rd Full FY 10/1/24-9/30/25	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Iredell	634	77.11%	805	77.24%	979	77.26%
Mecklenburg	44	5.38%	57	5.43%	69	5.47%
Alexander	23	2.84%	29	2.77%	35	2.72%
Catawba	24	2.95%	31	2.95%	37	2.96%
Rowan	22	2.70%	28	2.68%	34	2.66%
Lincoln	15	1.80%	19	1.82%	23	1.84%
Other NC Counties*	55	6.69%	69	6.61%	83	6.58%
Other States	4	0.54%	5	0.53%	7	0.52%
Total	**822**	**100.00%**	**1,042**	**100.00%**	**1,267**	**100.00%**

*Includes all other NC counties, each of which represents <1% of total patient origin.
Source: Section C.3, page 21
Total may not sum due to rounding

In Section C, page 21, the applicant states:

> *"The applicant projects the SOSC patient origin based on organic growth, the projected shift of some surgical outpatients from DRMC and from LNRMC to Statesville OSC, and on the historical DRMC and LNRMC surgical services patient origins, as shown in the following tables."*

On pages 22-24 the applicant provides tables, as summarized below, that it states represent (1) the assumed projected market share of outpatient surgery patients at SOSC based on market growth (2) the projected patient origin for the shifted DRMC outpatient surgery patients (3) the projected patient origin for the shifted LNRMC outpatient surgery patients and (4) the combination of the first three tables.

(1) SOSC Patient Origin of Market Growth Ambulatory Surgery Patients

County	1st Full FY 10/1/22-9/30/23		2nd Full FY 10/1/23-9/30/24		3rd Full FY 10/1/24-9/30/25	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Iredell	414	90.00%	530	89.98%	647	89.99%
Mecklenburg	10	2.15%	13	2.15%	16	2.15%
Alexander	9	1.95%	11	1.95%	14	1.95%
Catawba	7	1.42%	8	1.42%	10	1.42%
Rowan	5	1.08%	6	1.08%	8	1.08%
Lincoln	3	0.74%	4	0.74%	5	0.74%
Davie	2	0.41%	2	0.41%	3	0.41%
Wilkes	1	0.32%	2	0.32%	2	0.32%
Yadkin	1	0.29%	2	0.29%	2	0.29%
Cabarrus	1	0.28%	2	0.28%	2	0.28%
Surry	1	0.24%	1	0.24%	2	0.24%
Other NC counties	4	0.79%	5	0.79%	6	0.79%
Other States	2	0.35%	2	0.35%	3	0.35%
Total	**460**	**100.02%**	**589**	**100.00%**	**719**	**100.01%**

Totals may not sum due to rounding

(2) SOSC Patient Origin of Shifted DRMC Patients

County	1st Full FY 10/1/22-9/30/23		2nd Full FY 10/1/23-9/30/24		3rd Full FY 10/1/24-9/30/25	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Iredell	98	64.62%	118	64.62%	139	64.62%
Alexander	14	9.52%	17	9.52%	21	9.52%
Rowan	8	5.46%	10	5.46%	12	5.46%
Catawba	5	3.02%	6	3.02%	7	3.02%
Surry	4	2.75%	5	2.75%	6	2.75%
Wilkes	4	2.47%	5	2.47%	5	2.47%
Davie	3	2.03%	4	2.03%	4	2.03%
Caldwell	2	1.41%	3	1.41%	3	1.41%
Mecklenburg	2	1.37%	2	1.37%	3	1.37%
Cabarrus	1	0.76%	1	0.76%	2	0.76%
Yadkin	1	0.72%	1	0.72%	2	0.72%
Other NC counties	6	3.98%	7	3.98%	9	3.98%
Other States	3	1.89%	3	1.89%	4	1.89%
Total	**151**	**100.00%**	**182**	**100.00%**	**215**	**100.00%**

Totals may not sum due to rounding

(3) SOSC Patient Origin of Shifted LNRMC Patients

County	1st Full FY 10/1/22-9/30/23		2nd Full FY 10/1/23-9/30/24		3rd Full FY 10/1/24-9/30/25	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Iredell	122	57.95%	157	57.95%	193	57.95%
Mecklenburg	32	15.28%	41	15.28%	51	15.28%
Catawba	13	6.24%	17	6.24%	21	6.24%
Lincoln	11	5.29%	15	5.29%	18	5.29%
Rowan	9	4.28%	12	4.28%	14	4.28%
Cabarrus	4	2.07%	6	2.07%	7	2.07%
Gaston	3	1.27%	3	1.27%	4	1.27%
Other NC counties	16	7.52%	20	7.52%	25	7.52%
Total	**211**	**99.90%**	**270**	**99.90%**	**333**	**99.90%**

Totals may not sum due to rounding

(4) SOSC Combined Patient Origin of Ambulatory Surgery Patients

County	1st Full FY 10/1/22-9/30/23		2nd Full FY 10/1/23-9/30/24		3rd Full FY 10/1/24-9/30/25	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Iredell	634	77.11%	805	77.24%	979	77.26%
Mecklenburg	44	5.38%	57	5.43%	69	5.47%
Alexander	23	2.84%	29	2.77%	35	2.72%
Catawba	24	2.95%	31	2.95%	37	2.96%
Rowan	22	2.70%	28	2.68%	34	2.66%
Lincoln	15	1.80%	19	1.82%	23	1.84%
Other NC counties	55	6.69%	69	6.61%	83	6.58%
Other States	4	0.54%	5	0.53%	7	0.52%
Total	**822**	**100.00%**	**1,042**	**100.00%**	**1,267**	**100.00%**

Totals may not sum due to rounding

The concept of physicians who perform surgical services at DRMC and LNRMC being able to shift surgical cases from DRMC and LNRMC by referring patients to SOSC could be a reasonable concept because the three facilities have the same overall parent organization, Community Health Systems (CHS).

However, the applicant's assumptions as provided in the methodology are not reasonable and are not adequately supported based on the following analysis:

- The applicant does not provide a basis for the assumed percentage for patient origin by county for the market growth segment of the projected ambulatory surgical patients to be applied to SOSC. Nor does the applicant tie (or differentiate) all ambulatory surgical patients to (or from) the orthopedic only surgical patients at SOSC. Thus, that assumption is unsupported. (Section C, page 22).
- The applicant does not provide the basis for the number of ambulatory surgery patients to be shifted from DRMC (up to 40%) and LNRMC (up to 30%), other than experience and discussion with surgeons; therefore, the assumption is not supported by specific data that is noted as consistent with referrals or shifts within the CHS Iredell health

system. Nor does the applicant tie (or differentiate) all ambulatory surgical patients to (or from) the orthopedic only surgical patients at SOSC.

- The applicant assumes the county percentages for total ambulatory surgical patient origin as historically served at DRMC and LNRMC (Section C, page 23), the facilities from which the applicant proposes to shift orthopedic ambulatory surgical patients, to be the same percentages that would apply to orthopedic "only" ambulatory surgical patients for SOSC. The applicant does not provide supporting data to support that assumption. In fact, orthopedic "only" ambulatory surgical cases for DRMC and LNRMC has not been increasing at the same rate as their total ambulatory surgical cases.

Furthermore, the total projected number of patients at SOSC, as provided in the tables on pages 22-24 and above, and based on the assumptions provided, is not reasonable and is not supported by the assumptions used to project utilization of surgical patients at the proposed single-specialty orthopedic ambulatory surgery facility based on the following:

- The reasonableness of the market growth of ambulatory surgery patients used to project the number of orthopedic surgery patients treated at SOSC could not be determined, as no data was provided to support the projected numbers of patients and origin (Section C, page 22).
- The tables in the methodology clearly provide data related to all outpatient surgical services (Section C, page 23), not outpatient orthopedic surgical services.

Analysis of Need

In Section C.4, pages 24-35, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 24, the applicant states that the need for the proposed project is based on and supported by the following:

- Projected population growth and aging of Iredell County (pages 25-27)
- Iredell County health status (pages 27-29)
- Cost effectiveness of outpatient surgery at ASFs versus hospitals (pages 29-33)
- Outmigration of Iredell county residents for outpatient surgery (page 33)
- Physician interest and community support (page 33)
- COVID-19 impact (pages 33-34)

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

- The applicant provides credible information regarding the growth and aging of the Iredell County population but fails to tie it to a need for the relocation of one OR from DRMC to SOSC to be used exclusively for orthopedic surgical services.
- The applicant provides information and data to show that Iredell County residents will continue to need access to surgical services based on health status related to cardiovascular disease, stroke, cancer incidence, diabetes, and obesity, but fails to tie these health status issues to the need for services at the proposed orthopedic ASF.

- The applicant provides data documenting that during FY2019, 36.24% of ambulatory surgery cases performed on Iredell County residents were performed outside of Iredell County, but fails to tie the outmigration of all Iredell County ambulatory surgical cases to the need for orthopedic only surgical services at the proposed ASF.
- The applicant provides data that supports the increased safety of performing surgical cases in freestanding ambulatory settings away from the potential exposure to hospital inpatients who may have COVID-19; however, at this point in time, the COVID-19 anomaly may not be a reasonable factor on which to base future surgical need.

Projected Utilization

In Section Q Form C Utilization, the applicant provides projected utilization at SOSC, as summarized in the following table.

	1ST FULL FY FY2023	2ND FULL FY FY2024	3RD FULL FY FY2025
OPERATING ROOMS			
Dedicated Ambulatory ORs	1	1	1
Outpatient Surgical Cases	882	1,042	1,267
Outpatient Surgical Case Time	71.2	71.2	71.2
Outpatient Surgical Hours	976 [1,047]	1,236	1,504
Group Assignment	6	6	6
Standard Hours per OR per Year	1,312	1,312	1,312
Total Surgical Hours/Standard Hours Per OR per Year	0.74[.80]	0.94	1.15
PROCEDURE ROOMS			
Number of Procedure Rooms	2	2	2
Total Number of Procedures	181	181	181

Source: Section Q Form C. Surgical hours as provided in Form C and above differ slightly from the hours provided on page 103 of Section Q Utilization Assumptions and Methodology. The Project Analyst's corrections are in brackets.

In Section Q, pages 101-112, the applicant provides the assumptions and methodology used to project surgical utilization in the CHS health system. In Section Q, pages 101-103, the applicant provides the assumptions and methodology for the projected surgical utilization at the proposed SOSC facility, which are summarized below.

Surgical Cases at SOSC

Step 1: the applicant provides the projected population for Iredell County through 2025.

Step 2: the applicant projects the need for ambulatory surgery cases in Iredell County based on the annual outpatient surgical cases per the North Carolina population from 2014 through 2019 at 64.89/1,000 population. Applying the 64.89 cases per 1,000 population results in the following projected ambulatory surgical cases (not just orthopedic surgical cases) for Iredell County residents.

Projected Ambulatory Surgical Cases Needed by Iredell County Residents

	FY2020	FY2021	FY2022	FY2023	FY2024	FY2025
Use Rate	64.89	64.89	64.89	64.89	64.89	64.89
Population	184,023	186,665	189,308	191,951	194,595	197,238
Cases	11,942	12,113	12,285	12,456	12,628	12,799

Step 3: the applicant projects the need for ambulatory operating rooms in Iredell County based on the average case time of 1.19 hours for Group 6 facility standard hours per operating room. Based on the applicant's methodology, the above ambulatory surgical cases for Iredell County residents and the need for ambulatory operating rooms is for all types of ambulatory surgeries, not just orthopedic surgeries.

Projected Need for Ambulatory Surgical ORs in Iredell County Residents

	FY2020	FY2021	FY2022	FY2023	FY2024	FY2025
Ambulatory Surgical Cases	11,942	12,113	12,285	12,456	12,628	12,799
Average Case Time	1.19	1.19	1.19	1.19	1.19	1.19
Total Surgical Hours	14,211	14,415	14,619	14,823	15,027	15,231
Groups 6 Standard Hrs/OR	1,312	1,312	1,312	1,312	1,312	1,312
Ambulatory ORs Needed	10.8	11.0	11.1	11.3	11.5	11.6

Step 4: the applicant projects the market share of Iredell County outpatient surgery for SOSC at 6.0% in FY2023, 7.5% in FY2021 and 9.0% in FY2025, stating that the percentages are reasonable given SOSC is a new ASF that will ramp up utilization during the initial three project years. The applicant states, *"This results in a projection of 1,152 (12,799 *.09) orthopedic outpatient surgery cases on Iredell County residents in FFY2025."*

Projected SOSC Market Share of Iredell County Ambulatory Surgical Need

	FY2023	FY2024	FY2025
Iredell County Outpatient Surgical Cases	12,456	12,628	12,799
SOSC Market Share	6.0%	7.5%	9.0%
SOSC Share of Iredell County Surgical Cases	747	947	1,152

The applicant's statement and the table above clearly shows that the applicant projects SOSC with a market share ramping up to 1,152 ambulatory orthopedic surgical cases or 9.0% of total Iredell County ambulatory surgical cases. The applicant does not provide data to support why the relocated OR for orthopedic surgeries only, which after project completion would be one of nine existing and/or approved ambulatory ORs and 20 existing shared ORs in Iredell County, would merit 9.0% (1,152 orthopedic surgical cases) of the total ambulatory surgical cases for Iredell County residents.

In Section E, page 52, the applicant provides data on Iredell County surgical services showing that orthopedic surgeries composed 17.0% of total surgeries performed in Iredell County in FY2019. Applying that percentage to the Iredell County total outpatient surgical cases from the table in Step 4 above shows the following projected Iredell County outpatient orthopedic surgical cases.

Projected Iredell County Ambulatory Orthopedic Surgical Need

	FY2023	FY2024	FY2025
Iredell County Outpatient Surgical Cases	12,456	12,628	12,799
Orthopedic Cases as a Percent of Total Surgical Cases (17%)	2,118	2,147	2,176

The applicant's projected 1,152 outpatient orthopedic surgical cases for Iredell County residents at SOSC would represent 52.9% (1,158/2,176) of the total number of outpatient orthopedic surgical cases to be performed in Iredell County. This is not a reasonable assumption when there are eight other existing or approved ambulatory ORs and 20 shared ORs in the county.

Step 5: the applicant projects SOSC utilization from in-migration at 10% and states that is reasonable based on DRMC and LNRMC in-migration of 53% and 35%, respectively, for ambulatory surgery, but provides no data to support that in-migration of orthopedic surgical cases is the same as the in-migrations of all outpatient surgical cases.

	FY2023	FY2024	FY2025
SOSC Iredell County Outpatient Surgical Cases	747	947	1,152
In-Migration at 10%	75	95	115
SOSC Total Outpatient Surgical Cases	822	1,042	1,267

Step 6: the applicant projects the number of operating rooms needed for SOSC based on the number of projected orthopedic surgical cases and the operating room methodology in the 2020 SMFP.

	FY2023	FY2024	FY2025
SOSC Total Outpatient Orthopedic Surgical Cases	822	1,042	1,267
Average Case Time	1.19	1.19	1.19
Total Surgical Hours	978	1,240	1,508
Groups 6 Standard Hours/OR	1,312	1,312	1,312
ORs Needed	0.75	0.94	1.15
ORs Needed Rounded per Applicant	1.00	1.00	2.00
ORs Needed Rounded per Conventional Rounding	1.00	1.00	1.00

Totals may not sum due to rounding

The table above shows, based on the steps for projecting utilization as outlined by the applicant, pages 101-103, the methodology projects the need for one OR based on 1,267 total outpatient orthopedic surgical cases.

Procedure Room Cases at SOSC

In Section Q, page 104, the applicant anticipates the performance of interventional pain management (IPM) procedures in the two procedure rooms. To project the number of IPM procedures, the applicant assumes a shift of 30% and 25% of the IPM procedures performed at DRMC and LNRMC, respectively, resulting in 181 procedures held constant for the initial three years of operation.

Davis Regional Medical Center Projected Utilization

In Section Q, pages 105-108, the applicant provides the methodology for projecting need for ORs at DRMC based on the projected utilization at DRMC, upon project completion with the relocation of one OR and the projected shift of patients to SOSC.

In the steps provided by the applicant on pages105-107, the applicant provides the DRMC total inpatient and outpatient surgical cases from FY2014 through FY2020, along with inpatient and outpatient compound annual growth rates (CAGR) covering several different time frames. The applicant utilizes the four-year (FY2016-FY2020) inpatient and outpatient CAGRs of 9.03% and 9.94%, respectively, on which to base its projected increase in utilization. The applicant states intent to use a 2.26% annual increase (1/4 the 9.03% CAGR) for inpatient cases and a 3.31% annual increase (1/3 of 9.94% CAGR) for outpatient cases, which results in the projected surgical cases as summarized below.

Projected DRMC Surgical Cases

	Annual Increase	FY2021	FY2022	FY2023	FY2024	FY2025
Total Inpatient Surgical Cases	2.26%	633	647	662	677	692
Total Outpatient Surgical Cases	3.31%	2,368	2,446	2,527	2,611	2,698
Total Surgical Cases		3,001	3,094	3,189	3,288	3,390

The applicant does not explain why the precise percentages for inpatient and outpatient annual increases were chosen or provide any supporting documentation for the choices.

In the next step, the applicant assumes a ratio of 19.96% for outpatient orthopedic surgical cases as a percent of total DRMC surgical cases based on 2019 and 2020 DRMC experience, resulting in 538 outpatient orthopedic surgical cases, of which the applicant proposes to shift 40% (215) to SOSC's one OR, leaving only 60% of the orthopedic surgical cases for the remaining four shared ORs at DRMC. Thus, the applicant proposes to perform 40% of DRMC's outpatient orthopedic surgical cases in 20% of the available ORs. The applicant does not provide a basis for the decision of shifting 40% of the cases to SOSC, other than experience of DRMC and discussions with surgeons. Furthermore, the applicant makes an assumption that orthopedic outpatient surgical cases will increase at the same rate as total outpatient surgical cases. There is no evidence to support this assumption. In fact, surgical case data from the DRMC License Renewal Applications (LRAs) reveals the following information.

	FY2014	**FY2015**	**FY2016**	**FY2017**	**FY2018**	**FY2019**	**FY2020**	**4Yr CAGR**	**6Yr CAGR**
Orthopedic Cases	502	510	643	674	608	445	507	-6%	**0%**
Ambulatory Cases	1308	1356	1569	2,215	1,538	1,410	1,555	0%	**3%**

Source: 2015- 2021 DRMC LRAs

As the table above shows, orthopedic surgical cases at DRMC have not had a positive increase over the last several years and in fact the CAGR for 2016 through 2020 was a negative 6%.

On page 108, the applicant provides the projected OR need at DRMC after the relocation of one OR and the shift of patients to SOSC, as summarized below.

Projected DRMC OR Need

	FY2021	FY2022	FY2023	FY2024	FY2025
Total Inpatient Surgical Cases	633	647	662	677	692
Average Inpatient Case Time*	1.442	1.442	1.442	1.442	1.442
Total Inpatient Surgical Hours	913	933	955	976	998
Total Outpatient Surgical Cases	2,368	2,446	2,376	2,429	2,482
Average Outpatient Case Time*	1.440	1.440	1.440	1.440	1.440
Total Outpatient Surgical Hours	3,410	3,523	3,422	3,497	3,574
Total Combined Surgical Hours	4,322	4,456	4,376	4,473	4,572
Groups 4 Standard Hours/OR	1,500	1,500	1,500	1,500	1,500
ORs Needed	2.88	2.97	2.92	2.98	3.05
ORs Needed Rounded per Applicant	3.0	3.0	3.0	3.0	4.0
ORs Needed Rounded per Conventional Rounding	3.0	3.0	3.0	3.0	3.0

*Proposed 2021 SMFP, Table 6B [2020 SMFP, Table 6B] in hours
Totals may not sum due to rounding

Lake Norman Regional Medical Center Projected Utilization

In Section Q, pages 109-112, the applicant provides the methodology for projecting need for ORs at LNRMC based on the projected utilization at LNRMC, upon project completion and the projected shift of patients to SOSC.

In the steps provided by the applicant on pages 109-111, the applicant provides the LNRMC total inpatient and outpatient surgical cases from FY2014 through FY2020, along with inpatient and outpatient compound annual growth rates (CAGR) covering several different time frames. The applicant utilizes the four-year (FY2016-FY2020) inpatient and outpatient CAGRs of 1.79% and 5.25%, respectively, on which to base its projected increase in utilization. The applicant states intent to use the 1.79% CAGR as the annual increase for inpatient cases and a 2.63% annual increase (1/2 of 5.25% CAGR) for outpatient cases, which results in the projected surgical cases as summarized below.

Projected LNRMC Surgical Cases

	Annual Increase	FY2021	FY2022	FY2023	FY2024	FY2025
Total Inpatient Surgical Cases	1.79%	1,960	1,996	2,031	2,068	2,105
Total Outpatient Surgical Cases	2.63%	7,241	7,432	7,627	7,827	8,033
Total Surgical Cases		9,202	9,427	9,658	9,895	10,138

Totals may not sum due to rounding

The applicant does not explain why the precise percentages for annual increases were chosen or provide any supporting documentation for the choices.

In the next step, the applicant assumes a ratio of 13.82% for outpatient orthopedic surgical cases as a percent of total LNRMC surgical cases based on 2019 and 2020 LNRMC experience, resulting in 1,110 outpatient orthopedic surgical cases in FY2025, of which the applicant proposes to shift 30% (333) to SOSC's one OR, leaving 70% of the orthopedic surgical cases for the two ambulatory ORs and seven shared ORs at LNRMC. Thus, the applicant proposes to perform 30% of LNRMC's outpatient orthopedic surgical cases in 10% of the available ORs. The applicant does not provide a basis for the decision of shifting 30% of the cases to SOSC, other than experience of LNRMC and discussions with surgeons. Again, the applicant makes an unsupported assumption that LNRMC's orthopedic outpatient surgical cases would increase at the same rate as its total outpatient surgical cases.

On page 112, the applicant provides the projected OR need at LNRMC after the shift of patients to SOSC, as summarized below.

Projected LNRMC OR Need

	FY2021	FY2022	FY2023	FY2024	FY2025
Total Inpatient Surgical Cases	1,960	1,996	2,031	2,068	2,105
Average Inpatient Case Time*	2.050	2.050	2.050	2.050	2.050
Total Inpatient Surgical Hours	4,019	4,091	4,164	4,239	4,315
Total Outpatient Surgical Cases	7,241	7,432	7,416	7,557	7,700
Average Outpatient Case Time*	1.067	1.067	1.067	1.067	1.067
Total Outpatient Surgical Hours	7,724	7,927	7,910	8,061	8,213
Total Combined Surgical Hours	11,743	12,018	12,075	12,299	12,528
Groups 4 Standard Hours/OR	1,500	1,500	1,500	1,500	1,500
ORs Needed	7.83	8.01	8.05	8.20	8.35
ORs Needed Rounded per Applicant	8.0	9.0	9.0	9.0	9.0
ORs Needed Rounded per Conventional Rounding	8.0	8.0	8.0	8.0	8.0

*Proposed 2021 SMFP, Table 6B [2020 SMFP, Table 6B] in hours
^2020 SMFP OR Methodology for health systems with 10 or more ORs
Totals may not sum due to rounding

The projected utilization for SOSC is not reasonable and adequately supported based on the following:

- The applicant's methodology in Section Q, pages 101-103, for projecting utilization at SOSC does not provide data to support why SOSC, a relocated OR for orthopedic surgeries only, which after project completion would be one of nine existing and/or approved ambulatory ORs and 20 existing shared ORs in Iredell County, would merit 9.0% (1,152 surgical cases) of the total ambulatory surgical cases in Iredell County at an orthopedic only ASF.
- The applicant's methodology does not provide data to support the projected 1,152 outpatient orthopedic surgical cases for Iredell County residents at SOSC, which would represent 52.9% (1,158/2,176) of the total number of outpatient orthopedic surgical cases to be performed in Iredell County, when there are eight other existing or approved ambulatory ORs and 20 shared ORs in the county.

Access to Medically Underserved Groups

In Section C.8, page 41, the applicant states:

> *"All Iredell County residents (plus residents of other counties), including low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, Medicare and Medicaid beneficiaries, and other underserved groups, will have access to the ASF, as clinically appropriate. The applicant 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."*

The proposed facility has no historical data on access but provides the FY20220 DRMC patient demographics on page 83, which includes providing care to the elderly and racial and ethnic groups.

In Section L, page 86, the applicant provides the estimated payor percentages for SOSC for the following medically underserved groups to be served in FY2025, as summarized below.

Medically Underserved Groups	Percentage of Total Patients
Self-Pay	1.23%
Medicare beneficiaries	41.87%
Medicaid recipients	14.04%

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.

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.

NC

The applicant proposes to relocate one operating room from DRMC to the proposed new ASF.

In Section D, pages 46-50 and in Section Q, the applicant explains why it believes the needs of the population presently utilizing the OR to be relocated will be adequately met following completion of the project. On page 46, the applicant states:

> *"Following reduction of one OR, DRMC will be licensed for five operating rooms. According to the 2020 SMFP, DRMC currently has a surplus of 3.07 ORs; therefore, according to the SMFP, DRMC will continue to have a surplus of ORs following relocation of one OR to the new ASF. The proposed project will not diminish any patient's ability to obtain surgical services at DRMC, as the hospital will continue to have sufficient ORs on its licensed* [sic] *to meet projected need in the near term."*

In Section Q, the applicant provides the projected need for ORs at DRMC based on the projected utilization at DRMC, upon project completion with the relocation of one OR and the projected shift of patients to SOSC, as summarized in the table below.

Projected DRMC OR Need

	FY2021	FY2022	FY2023	FY2024	FY2025
Total Inpatient Surgical Cases	633	647	662	677	692
Average Inpatient Case Time*	1.442	1.442	1.442	1.442	1.442
Total Inpatient Surgical Hours	913	933	955	976	998
Total Outpatient Surgical Cases	2,368	2,446	2,376	2,429	2,482
Average Outpatient Case Time*	1.440	1.440	1.440	1.440	1.440
Total Outpatient Surgical Hours	3,410	3,523	3,422	3,497	3,574
Total Combined Surgical Hours	4,322	4,456	4,376	4,473	4,572
Group 4 Standard Hours/OR	1,500	1,500	1,500	1,500	1,500
ORs Needed	2.88	2.97	2.92	2.98	3.05

*Proposed 2021 SMFP, Table 6B [2020 SMFP, Table 6B] in hours
Totals may not sum due to rounding

As shown in the table above, the applicant demonstrates that the needs of the population presently served will be met adequately after the relocation of one OR to SOSC, leaving four shared ORs at DRMC.

In Section Q, the applicant provides the assumptions and methodology used to project utilization, which is summarized below:

- the applicant identifies the historical inpatient and outpatient surgical volume at DRMC
- the applicant projects an inpatient surgical volume increase of 2.26% annually
- the applicant projects an outpatient surgical volume increase of 3.31% annually

- the applicant projects the shift of outpatient orthopedic surgical volume to SOSC at 30%, 35% and 40% during the first through third project years, respectively

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

- the applicant provides no supporting data for the differences in the choice of the percentages for annual increases in surgical volume
    - inpatient surgical volume is increased at 2.26% annually, or one-quarter of the four-year CAGR
    - outpatient surgical volume is increased at 3.31% annually, or one-third of the four-year CAGR
- the applicant provides no supporting data, other than DRMC experience, for the percentages of outpatient surgical volume to be shifted from DRMC; an unsupported shift of 40% of outpatient orthopedic surgical volume is unreasonable considering DRMC will have four remaining shared ORs in which outpatient orthopedic surgical cases can be performed

In Section D.5, page 50, the applicant refers to Exhibit C.8 for the non-discrimination policy. The policy states:

> *"This provider complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. This provider does not exclude people or treat them differently because of race, color, national origin, age, disability or sex."*

The applicant adequately demonstrates that the needs of medically underserved groups that will continue to use surgical services at DRMC will be adequately met following completion of the project for the following reasons:

- DRMC projects adequate operating room capacity to meet the needs of the population presently served
- DRMC's non-discrimination policy commits to serving all people in need of service

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 stated above.

(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 to develop a new ASF, by relocating no more than one OR from DRMC and developing two new procedure rooms.

In Section E, pages 51-56, 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. The alternatives considered were:

- Maintain the status quo – the applicant states this alternative is not effective because Iredell County residents need additional access to freestanding surgical services and lower cost surgical services.
- Develop two ORs in the separately licensed ASF – the applicant determined that one OR would be sufficient to accommodate the anticipated outpatient surgical cases.
- Develop a multi-specialty ASF – the applicant states that a single-specialty ASF would be more efficient and less resource-intensive that a multi-specialty center.
- Develop a single-specialty ASF focused on other than Orthopedics – the applicant determined that orthopedic surgeries composed 17% of the FY2019 Iredell County outpatient surgery cases, second only to ophthalmology.
- Develop the ASF in a different geographic location – the applicant states that no other location in Iredell County would be a more effective location that the proposed location, 2.4 miles from DRMC, in close proximity to surgeons and physician clinics, and near the interchange of Interstate 77, Interstate 40 and U.S. Highway 64.
- Develop SOSC as proposed, with one OR relocated from DRMC – the applicant states that the proposed alternative is an example of healthcare providers seeking to promote efficient, cost-effective solutions that maximize existing resources rather than unnecessarily duplicating existing services.

On page 56, the applicant states that its proposal is the most effective alternative because it best meets the need for additional value-based surgical services in Iredell County.

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 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

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 to develop a new ASF, by relocating no more than one OR from DRMC and developing two new procedure rooms.

Capital and Working Capital Costs

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

Proposed Capital Cost

Construction Costs	$3,200,000
Medical Equipment	$2,124,443
Miscellaneous Costs	$845,496
Total	**$6,169,939**

In Sections F and Q, the applicant provides the assumptions used to project the capital cost, stating that the costs are based on architect estimates and DRMC's experience in developing operating rooms. Exhibit F contains supporting documentation.

In Section F, pages 59-60, the applicant projects that start-up costs will be $60,000 and initial operating expenses will be $500,000 for a total working capital of $560,000. On pages 59-60, and Section Q, the applicant provides the assumptions and methodology used to project the working capital needs of the project.

Availability of Funds

In Section F, page 58, the applicant states that the capital cost will be funded as shown below in the table.

Sources of Capital Cost Financing

Type	PSCE
Loans	$0
Accumulated reserves or OE *	$6,169,939
Bonds	$0
Other (Specify)	$0
Total Financing	**$6,169,939**

* OE = Owner's Equity.

In Section F, page 60, the applicant states that the working capital needs of the project will be funded, as shown in the following table.

Sources of Financing for Working Capital

	Type	Amount
(a)	Loans	$0
(b)	Cash or Cash Equivalents, Accumulated Reserves or OE	$560,000
(c)	Lines of credit	$0
(d)	Bonds	$0
(e)	**Total ***	**$560,000**

In Section F, page 61, the applicant states that PSCE will fund the proposed project using cash reserves.

Exhibit F.2(a) contains a copy of a letter dated November 13, 2020 from the Manager, Piedmont Surgery Center of Excellence, LLC expressing its intent to fund the capital costs of the project with cash reserves from the $8 million investment by DRMC, currently the sole member of PSCE. The exhibit also contains a letter from the President of DRMC stating its intent to invest up to $8 million in PSCE for the capital and working capital costs of the project. Exhibit F.2 contains a copy of the audited financial statements for Community Health Systems, Inc., the parent company of DRMC, which indicate it had cash and cash equivalents of $1,823 million as of September 30, 2020.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2, the applicant projects that revenues will exceed operating expenses in each of the first three full fiscal years of operation following completion of the proposed project, for the surgical operating room and for the ASF as a whole, as shown in the tables below.

SOSC Surgical Services (OR)

	1st Full Fiscal Year	2nd Full Fiscal Year	3rd Full Fiscal Year
Total Surgical Cases	822	1,042	1,267
Total Gross Revenues (Charges)	$ 12,339,854	$ 15,793,657	$ 19,401,898
Total Net Revenue	$ 3,893,769	$ 4,983,597	$ 6,122,157
Average Net Revenue per Case	$ 4,737	$ 4,783	$ 4,832
Total Operating Expenses (Costs)	$ 3,344,522	$ 3,909,773	$ 4,433,141
Average Operating Expense per Case	$ 4,069	$ 3,752	$ 3,499
Net Income	$ 549,247	$ 1,073,824	$ 1,689,016

SOSC ASF

	1st Full Fiscal Year	2nd Full Fiscal Year	3rd Full Fiscal Year
Total Gross Revenues (Charges)	$ 12,627,449	$16,084,128	$ 19,695,274
Total Net Revenue	$ 3,984,518	$ 5,075,253	$ 6,214,730
Total Operating Expenses (Costs)	$ 3,604,131	$ 4,183,633	$ 4,712,870
Net Income	$ 380,388	$ 891,620	$ 1,501,860

The applicant also provides a separate Form F.2 for the procedure rooms, showing that operating expenses exceed revenues for the procedure rooms by less than $200,000 in each of the first three fiscal years. The shortfall is more than covered each year by the net income from surgical services, resulting in the net income for the facility, as shown above.

However, the assumptions used by the applicant in preparation of the pro forma financial statements are not reasonable because the projected utilization is not based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization found in Criterion (3) which is incorporated herein by reference.

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 not conforming to this criterion for the reasons stated 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 to develop a new ASF, by relocating no more than one OR from DRMC and developing two new procedure rooms.

On page 51, the 2020 SMFP states, *"An operating room's 'service area' is the service area in which the room is located. The operating room service areas are the single or multicounty groupings as shown in Figure 6.1."* In Figure 6.1, page 57 of the 2020 SMFP, Iredell County is shown as a single-county OR service area. Thus, the service area for this application is Iredell County. Facilities may also serve residents of counties not included in the service area.

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

Facilities	# of Planning Inventory ORs	Projected OR Deficit/Surplus (-)
Davis Regional Medical Center	5	-3.07
Lake Norman Regional Medical Center	9	-2.36
Iredell Ambulatory Surgery Center	1	-0.74
Iredell Mooresville Campus ASC	1	-1.00
Iredell Surgical Center	4	-3.41
Iredell Memorial Hospital	9	-1.50

Source: 2020 SMFP, Table 6B, page 75

In Section G, page 64, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved surgical services in the Iredell County OR service area. The applicant states:

> *"The proposed project will not result in unnecessary duplication of existing or approved facilities in Iredell County. The proposed project does not include addition of operating rooms to the existing licensed OR inventory in Iredell County. Rather, PSCE proposes to relocate one existing licensed OR from DRMC to develop a new ASF and better utilize the existing licensed OR inventory within Iredell County."*

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 because the applicant does not adequately demonstrate that the proposed ASF is needed in the service area. See the discussion regarding projected utilization found in Criterion (3) which is incorporated herein by reference.

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 not conforming to this criterion based on 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

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

Position	Projected FTE Staff
	FY2025
Registered Nurses	4.0
Surgical Technicians	2.0
Administrator	1.0
Director of Nursing	1.0
Business Office	1.0
Receptionist	1.0
Scheduler	1.0
Business Office Manager	1.0
TOTAL	**12.0**

The applicant states that it bases its assumptions and methodology to project staffing on DRMC's experience in offering surgical services.

Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H, pages 67-68, 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.

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 the reasons stated above.

(8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section I, page 70, the applicant states that the following ancillary and support services are necessary for the proposed services and explains how each will be made available:

- Surgical services
- Medical direction
- Perioperative services
- Sterile Processing
- Anesthesiology
- Pathology
- Pharmacy
- Medical Records
- Business Office
- Materials Management
- Housekeeping and laundry

The applicant provides supporting documentation in Exhibit I.1.

In Section I, pages 71-73, the applicant describes its efforts to develop relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

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

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

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

NA

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

(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

(11) Repealed effective July 1, 1987.

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

C

The applicant proposes to develop a new ASF, by relocating no more than one OR from DRMC and developing two new procedure rooms.

In Section K, page 75, the applicant states that the project involves constructing 13,200 square feet of new space. Line drawings are provided in Exhibit K.2.

On pages 78-81, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site. Supporting documentation is provided in Exhibit K.4. The site appears to be suitable for the proposed ASF based on the applicant's representations and supporting documentation.

On pages 75-76, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal to relocate the OR and provides supporting documentation in Exhibit F.1, based on the following:

- The architect based the SOSC design and construction cost on a detailed review of the project, and upon published construction costing data and the architect's experience designing similar projects
- The assumptions for the project capital costs are based on knowledge, experience and expertise of the architect, contractor, and DRMC and CHS

On page 76, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services, based on the following:

- The applicant states that ASFs provide cost-effective care that can moderate healthcare costs for the patient, government and third-party payors
- The applicant states that this project will not increase the charges or projected reimbursement for the proposed services

On pages 76-77, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

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 the reasons stated above.

(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

The applicant proposes to develop a new ASF, by relocating no more than one OR from DRMC; therefore, there is no historical data. For informational purposes, in Section L, page 84, the applicant provides the historical payor mix during FY2020 for DRMC, as shown in the table below.

Payor Category	DRMC Surgical Services as Percent of Total
Self-Pay	2.37%
Medicare*	39.33%
Medicaid*	19.79%
Insurance*	36.00%
Workers Compensation	0.89%
TRICARE	0.27%
Other (other Government)	1.34%
Total	**100.00%**

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

In Section L, page 83, the applicant provides the following comparison for surgical services at DRMC and the service area.

	Percentage of Total Patients Served by DRMC Surgical Services during the Last Full FY	Percentage of the Population of the Service Area
Female	58.3%	50.8%
Male	41.6%	49.2%
Unknown	0.0%	0.0%
64 and Younger	69.4%	83.8%
65 and Older	30.6%	16.2%
American Indian	0.1%	0.5%
Asian	0.2%	2.8%
Black or African-American	18.1%	12.3%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	79.9%	76.3%
Other Race	0.0%	8.0%
Declined / Unavailable	1.7%	0.0%

The Agency reviewed the:

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

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

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, pages 84-85, the applicant states that though DRMC has no such obligations, DRMC does not discriminate based on race, ethnicity, creed, color, sex, age, religion, national origin, handicap, or ability to pay; and SOSC will have the same policy.

In Section L, page 85, the applicant states that during the last five years no patient civil rights access complaints have been filed against DRMC or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

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

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

(c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L, page 86, 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.

Payor Category	SOSC Surgical Services as Percent of Total FY2025
Self-Pay	1.23%
Medicare*	41.87%
Medicaid*	14.04%
Insurance*	39.90%
Workers Compensation	1.10%
TRICARE	0.39%
Other (other Government)	1.47%
Total	**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 1.23% of total services will be provided to self-pay patients, 41.87% to Medicare patients and 14.04% to Medicaid patients.

On page 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 bases the projected payor mix on a combination of the historical payor mixes of DRMC orthopedic outpatient surgical cases and LNRMC orthopedic outpatient surgical cases.
- The applicant states its belief that future payor mix will be consistent with historical, barring changes occurring due to healthcare reform, Medicaid expansion, and other policy initiatives relative to payor categories.

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 based on the reasons stated 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

In Section L, page 89, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

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

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

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

C

In Section M, page 90, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M.2.

Conclusion

The Agency reviewed the:

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

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

(15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.

(18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

NC

The applicant proposes to develop a new ASF, by relocating no more than one OR from DRMC and developing two new procedure rooms.

On page 51, the 2020 SMFP states, *"An operating room's 'service area' is the service area in which the room is located. The operating room service areas are the single or multicounty groupings as shown in Figure 6.1."* In Figure 6.1, page 57 of the 2020 SMFP, Iredell County is shown as a single-county OR service area. Thus, the service area for this application is Iredell County. Facilities may also serve residents of counties not included in the service area.

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

Facilities	# of Planning Inventory ORs	Projected OR Deficit/Surplus (-)
Davis Regional Medical Center	5	-3.07
Lake Norman Regional Medical Center	9	-2.36
Iredell Ambulatory Surgery Center	1	-0.74
Iredell Mooresville Campus ASC	1	-1.00
Iredell Surgical Center	4	-3.41
Iredell Memorial Hospital	9	-1.50

Source: 2020 SMFP, Table 6B, page 75

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 91, the applicant states:

> *"The proposed Statesville OSC will promote competition in the service area because it will enable DRMC to better meet the needs of its existing patient population, and to ensure timely provision of and convenient access to high quality, cost-effective outpatient surgical services for residents of Iredell County and surrounding communities."*

Regarding the impact of the proposal on cost effectiveness, in Section N, pages 91-92, the applicant states:

> *"The applicant is designing the planned ASF as a lower charge, lower reimbursement facility. ASFs provide cost-effective care that can reduce costs for the patient, government, and third-party payors."*

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 93, the applicant states:

> *"The applicant will adhere to the highest standards and quality of care, consistent with the high standard that DRMC has sustained throughout its history of providing surgical care."*

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, pages 93-94, the applicant states:

> *"Statesville OSC 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 Section L and C of the application and any exhibits.

However, the applicant does not adequately demonstrate the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant does not adequately demonstrate: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.

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 not conforming to this criterion based on the reasons stated above.

(19) Repealed effective July 1, 1987.

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

C

In Section Q Form A Facilities, the applicant identifies the hospital facilities providing surgical services located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of two hospitals located in North Carolina.

In Section O, page 97, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care have occurred at either of these facilities, though a complaint investigation by CMS resulted in standard-level deficiencies related to ED Assessment at DRMC. DRMC is currently compliant. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, an EMTALA incident occurred at LNRMC, and the facility was back in compliance at the time of review. 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 facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

Attachement C

Surgical and Non-Surgical Cases

A. Surgical Cases by Specialty Area - Enter the number of surgical cases performed only in licensed operating rooms by surgical specialty area in the chart below. Count each patient undergoing surgery as one case regardless of the number of surgical procedures performed while the patient was having surgery. Categorize each case into one specialty area – the total number of surgical cases is an unduplicated count of surgical cases. **Please do not include abortion procedures on this table. Count all surgical cases performed only in licensed operating rooms. The total number of surgical cases must match the total number of patients listed in the Patient Origin Table on page 11.**

Surgical Specialty Area	Cases
Cardiothoracic	0
General Surgery	0
Neurosurgery	0
Obstetrics and GYN	0
Ophthalmology	0
Oral Surgery/Dental	0
Orthopedics	1
Otolaryngology	346
Plastic Surgery	0
Podiatry	0
Urology	0
Vascular	0
Other Surgeries (specify)	0
Other Surgeries (specify)	0
Total Surgical Cases Performed Only in Licensed ORs (must match total on page 11)	347

B. Number of surgical procedures performed in unlicensed Procedure Rooms 0

C. Non-Surgical Cases by Category - Enter the number of non-surgical cases by category in the table below. Count each patient undergoing a procedure or procedures as one case regardless of the number of non-surgical procedures performed. Categorize each case into one non-surgical category – the total number of non-surgical cases is an unduplicated count of non-surgical cases. **Count all non-surgical cases, including cases receiving services in operating rooms or in any other location.**

Non-Surgical Category	Cases
Endoscopies OTHER THAN GI Endoscopies	0
Performed in Licensed GI Endoscopy Room	0
NOT Performed in Licensed GI Endoscopy Room	0
Other Non-Surgical Cases	0
Pain Management	15
Cystoscopy	0
YAG Laser	0
Other (specify)	0

D. Average Operating Room Availability and Average Case Times:

For questions regarding this page, please contact Healthcare Planning at 919-855-3865.

Based on **your facility's** experience, please complete the table below by showing the averages for all licensed operating rooms in your facility. Healthcare Planning uses this data in the operating room need methodology. **Average case times should be calculated, not estimated.** When reporting case times, be sure to include set-up and clean-up times.

Average Hours per Day **Routinely** Scheduled for Use Per Room*	Average Number of Days per Year **Routinely** Scheduled for Use	Average Case Time ** in **Minutes** for Ambulatory Cases
7	208	60

* Use only Hours per Day **routinely** scheduled when determining the answer. Example:

A facility has 3 ORs: 2 are routinely scheduled for use 8 hours per day, and 1 is routinely scheduled for use 9 hours per day.

2 rooms	x	8 hours	=	16 hours
1 room	x	9 hours	=	9 hours
		Total hours per day		25 hours

25 hours divided by 3 ORs
= **8.3 Average Hours per day Routinely Scheduled for Use Per Room**

** **Case Time = Time from Room Set-up Start to Room Clean-up Finish**. Definition 2.4 from the "Procedural Times Glossary" of the AACD, as approved by ASA, ACS, and AORN. *NOTE: This definition includes all of the time for which a given procedure requires an OR. It allows for the different duration of Room Set-up and Room Clean-up Times that occur because of the varying supply and equipment needs for a particular procedure.*

Reimbursement Source

PRIMARY PAYER SOURCE	NUMBER OF CASES
Self Pay	5
Charity Care	0
Medicare*	126
Medicaid*	134
Insurance*	97
Other (Specify)	0
TOTAL	362

* Including any managed care plans.

Surgical and Non-Surgical Cases

A. Surgical Cases by Specialty Area - Enter the number of surgical cases performed only in licensed operating rooms by surgical specialty area in the chart below. Count each patient undergoing surgery as one case regardless of the number of surgical procedures performed while the patient was having surgery. Categorize each case into one specialty area – the total number of surgical cases is an unduplicated count of surgical cases. **Please do not include abortion procedures on this table. Count all surgical cases performed only in licensed operating rooms. The total number of surgical cases must match the total number of patients listed in the Patient Origin Table on page 11.**

Surgical Specialty Area	Cases
Cardiothoracic	
General Surgery	22
Neurosurgery	
Obstetrics and GYN	
Ophthalmology	888
Oral Surgery/Dental	
Orthopedics	141
Otolaryngology	106
Plastic Surgery	
Podiatry	23
Urology	
Vascular	
Other Surgeries (specify)	
Other Surgeries (specify)	
Total Surgical Cases Performed Only in Licensed ORs (must match total on page 11)	1180

B. Number of <u>surgical</u> procedures performed in unlicensed Procedure Rooms Ø

C. Non-Surgical Cases by Category - Enter the number of non-surgical cases by category in the table below. Count each patient undergoing a procedure or procedures as one case regardless of the number of non-surgical procedures performed. Categorize each case into one non-surgical category – the total number of non-surgical cases is an unduplicated count of non-surgical cases. **Count all non-surgical cases, including cases receiving services in operating rooms or in any other location.**

Non-Surgical Category	Cases
Endoscopies OTHER THAN GI Endoscopies	N/A
Performed in Licensed GI Endoscopy Room	
NOT Performed in Licensed GI Endoscopy Room	
Other Non-Surgical Cases	
Pain Management	
Cystoscopy	
YAG Laser	
Other (specify)	

D. Average Operating Room Availability and Average Case Times:

For questions regarding this page, please contact Healthcare Planning at 919-855-3865.

Based on **your facility's** experience, please complete the table below by showing the averages for all licensed operating rooms in your facility. Healthcare Planning uses this data in the operating room need methodology. **Average case times should be calculated, not estimated.** When reporting case times, be sure to include set-up and clean-up times.

Average Hours per Day **Routinely** Scheduled for Use Per Room*	Average Number of Days per Year **Routinely** Scheduled for Use	Average Case Time ** in **Minutes** for Ambulatory Cases
4	201	~~40~~ 31

* Use only Hours per Day **routinely** scheduled when determining the answer. Example:

A facility has 3 ORs: 2 are routinely scheduled for use 8 hours per day, and 1 is routinely scheduled for use 9 hours per day.

2 rooms	x	8 hours	=	16 hours
1 room	x	9 hours	=	9 hours
		Total hours per day		25 hours

25 hours divided by 3 ORs
= **8.3 Average Hours per day Routinely Scheduled for Use Per Room**

**** Case Time = Time from Room Set-up Start to Room Clean-up Finish**. Definition 2.4 from the "Procedural Times Glossary" of the AACD, as approved by ASA, ACS, and AORN. *NOTE: This definition includes all of the time for which a given procedure requires an OR. It allows for the different duration of Room Set-up and Room Clean-up Times that occur because of the varying supply and equipment needs for a particular procedure.*

Reimbursement Source

PRIMARY PAYER SOURCE	NUMBER OF CASES
Self Pay	22
Charity Care	0
Medicare*	857
Medicaid*	35
Insurance*	265
Other (Specify) Workers Comp	1
TOTAL	1180

* Including any managed care plans.

Attachement D

Statesville Surgery Center
Calculation of Net Income with Orthopedic Surgical Cases Limited to Shifts from DRMC and LNRMC

		Project Year 1 FFY 2024	Project Year 2 FFY 2025	Project Year 3 FFY 2026
	Calculation of non-shifted orthopedic surgery cases			
	Orthopedic cases as originally filed (pg 100)	822	1,042	1,267
	Less Orthopedic cases shifted from DRMC (pg 106)	(163)	(193)	(223)
	Less Orthopedic cases shifted from LNRMC (pg 109)	(256)	(325)	(395)
a	Total Orthopedic cases not shifted ("unsupported")	403	524	649
	Calculation of non-shifted orthopedic net revenue			
b	*Orthopedic surgery average charge (pg 123)*	*$ 15,160*	*$ 15,463*	*$ 15,772*
c	Gross revenue unsupported orthopedic cases	$ 6,109,480	$ 8,102,612	$ 10,236,028
d	Less Bad Debt (1% of gross revenue; pg 123)	$ (61,095)	$ (81,026)	$ (102,360)
e	*Wt average contractual percentage (pg 123)*	*64.2%*	*64.2%*	*64.2%*
f	Less Contractual adjustment unsupported orthopedics	$ (3,920,849)	$ (5,199,970)	$ (6,569,121)
g	Net revenue of unsupported orthopedics	$ 2,127,537	$ 2,821,616	$ 3,564,546
	Adjustment for expenses based on cases or revenue			
h	*Medical Supplies per surgical case (pg 123)*	*$ 1,193*	*$ 1,229*	*$ 1,266*
i	Medical Supplies unsupported orthopedic cases	$ 480,912	$ 644,064	$ 821,634
j	*Drugs per case (pg 123)*	*$ 231*	*$ 238*	*$ 245*
k	Drugs on unsupported orthopedic cases	$ 92,984	$ 124,534	$ 158,869
l	*Equip Maintenance per case (pg 123)*	*$ 30*	*$ 31*	*$ 32*
m	Equip Maintenance on unsupported orthopedic cases	$ 12,090	$ 16,192	$ 20,658
n	*Insurance per case (pg 123)*	*$ 45*	*$ 47*	*$ 48*
o	Insurance on unsupported orthopedic cases	$ 18,272	$ 24,471	$ 31,223
p	*Management Fee % of net revenue (pg 123)*	*5%*	*5%*	*5%*
q	Management Fee on unsupported orthopedic cases	$ 106,377	$ 141,081	$ 178,227
r	*Other OH/G&A % of net revenue (pg 123)*	*2.5%*	*2.5%*	*2.5%*
s	Other OH/G&A on unsupported orthopedic cases	$ 53,188	$ 70,540	$ 89,114
t	*Allocated Corp Exp per case (pg 123)*	*$ 108*	*$ 111*	*$ 115*
u	Allocated Corp Exp on unsupported orthopedic cases	$ 43,584	$ 58,368	$ 74,466
v	Total expense adjustment on unsupported orthopedic cases	$ 807,408	$ 1,079,250	$ 1,374,191
w	**OR net income on non-shifted orthopedic cases**	$ 1,320,129	$ 1,742,366	$ 2,190,355
	Calculation of entire facility net income without non-shifted orthopedic cases			
x	OR net income as filed (Form F.2b OR; pg 116)	$ 695,388	$ 1,291,884	$ 1,911,164
w	Less OR net income on unsupported orthopedic cases (above)	$ (1,320,129)	$ (1,742,366)	$ (2,190,355)
y	Plus procedure room net loss (Form F.2b PR; pg 117)	$ (195,328)	$ (205,254)	$ (213,142)
z	Entire facility net income without unsupported orthopedic cases	$ (820,069)	$ (655,736)	$ (492,333)

Calculations

c	a x b
d	c x 1%
e	wt avg of orthopedic surgery payor mix and outpatient surgery contractual adjustment percentages
f	c x e
g	c - d - f
i	a x h
k	a x j
m	a x l
o	a x n
q	g x p
s	g x r
u	a x t
v	i + k + m + o + q + s + u
w	g - v
z	x - w - y