ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

Decision Date: July 27, 2017
Findings Date: July 27, 2017

Project Analyst: Gloria C. Hale
Team Leader: Fatimah Wilson

Project ID #: F-11349-17
Facility: Carolinas Healthcare System Huntersville Surgery Center
FID #: 170239
County: Mecklenburg
Applicant: The Charlotte-Mecklenburg Hospital Authority
Project: Separately license Carolinas HealthCare System Huntersville Surgery Center, which is currently licensed as part of Carolinas HealthCare System University, as a freestanding ambulatory surgical facility

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

NA

The Charlotte-Mecklenburg Hospital Authority (CMHA) proposes to separately license Carolinas HealthCare System Huntersville Surgery Center (CHS HSC), which is currently licensed as part of CHS University, as a freestanding ambulatory surgical facility (ASF) operating under its own license. CHS HSC currently has two licensed operating rooms (ORs) and two procedure rooms. However, pursuant to a Certificate of Need (CON) issued for Project I.D. #F-11106-15, ownership of one OR will be transferred to Charlotte Surgery

Center, LLC [1] and relocated to Randolph Surgery Center. At the completion of this project and Project I.D. #F-11106-15, CHS HSC will have one licensed OR and will develop one additional procedure room for a total of three 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 2017 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to this review.

Policies

There are no policies in the 2017 SMFP which are applicable to this review. *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*, on page 33 of the 2017 SMFP, is not applicable because the capital cost of the proposed project is $355,000, which is less than $2 million.

Therefore, Criterion (1) is not applicable to this application.

(2) Repealed effective July 1, 1987.

(3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant, CMHA, proposes to separately license CHS HSC, which is currently licensed as part of CHS University, as a freestanding ASF operating under its own license. CHS HSC currently has two licensed ORs and two procedure rooms. However, pursuant to a CON issued for Project I.D. #F-11106-15, ownership of one of CHS HSC's ORs will be transferred to Charlotte Surgery Center, LLC and relocated to Randolph Surgery Center, a freestanding ASF under development. Upon relocation of the OR, CHS HSC will use the vacated space as an unlicensed procedure room and begin offering electroconvulsive therapy (ECT) procedures. Therefore, upon completion of the development of Randolph Surgery Center on January 1, 2018, CHS HSC will have one licensed OR and three unlicensed procedure rooms.

Patient Origin

[1] On March 17, 2017, Charlotte Surgery Center, LP, a co-applicant for Project I.D. #F-11106-15, became Charlotte Surgery Center, LLC, pursuant to the Agency's determination that the transaction was materially compliant with the CON issued.

On page 57, the 2017 State Medical Facilities Plan (SMFP) states, *"An operating room's service area is the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1."* In Figure 6.1, page 60 of the 2017 SMFP, Mecklenburg County is shown as a single-county operating room service area. Thus, the service area for the proposed project is Mecklenburg County. Providers may serve residents of counties not included in their service area.

In Section III.7, page 48, the applicant provides the historical patient origin for CHS HSC's ORs and procedure rooms for calendar year (CY) 2016, as follows:

CHS HSC
Historical Patient Origin, ORs and Procedure Rooms
CY2016

County	ORs Percent of Total Cases	Procedure Rooms Percent of Total Cases
Mecklenburg	58.7%	67.2%
Iredell	14.7%	7.2%
Lincoln	8.0%	3.9%
Cabarrus	6.0%	11.1%
Gaston	4.1%	4.3%
Other	8.5%*	6.3%**
Total	**100.0%**	**100.0%**

*Other category for ORs includes: Alexander, Buncombe, Catawba, Cleveland, Forsyth, Rowan, Stanly, Union, and Wilkes counties in North Carolina, as well as other states.
**Other category for procedure rooms includes: Avery, Burke, Catawba, Rowan, Stanly, Union, Wilkes, and Yadkin counties in North Carolina, as well as other states.

In Section III.6, page 47, the applicant provides the projected patient origin for CHS HSC's ORs and procedure rooms for the first two operating years (OY) of the proposed project, summarized as follows:

CHS HSC
Projected Patient Origin, OR
OY1 (CY2019) through OY2 (CY2020)

County	OY1 (CY2019) Percent of Total Cases	OY2 (CY2020) Percent of Total Cases
Mecklenburg	58.7%	58.7%
Iredell	14.7%	14.7%
Lincoln	8.0%	8.0%
Cabarrus	6.0%	6.0%
Gaston	4.1%	4.1%
Other*	8.5%	8.5%
Total	**100.0%**	**100.0%**

*Includes the counties of Alexander, Buncombe, Catawba, Cleveland, Forsyth, Rowan, Stanly, Union, and Wilkes in North Carolina and other states not specified by the applicant.

CHS HSC
Projected Patient Origin, Procedure Rooms
OY1 (CY2019) through OY2 (CY2020)

County	OY1 (CY2019) Percent of Total Cases	OY2 (CY2020) Percent of Total Cases
Mecklenburg	67.2%	67.2%
Cabarrus	11.1%	11.1%
Iredell	7.2%	7.2%
Gaston	4.3%	4.3%
Lincoln	3.9%	3.9%
Other*	6.3%	6.3%
Total	**100.0%**	**100.0%**

*Includes the counties of Avery, Burke, Catawba, Rowan, Stanly, Union, Wilkes, and Yadkin in North Carolina and other states not specified by the applicant.

The applicant provides the assumptions for projected patient origin in Section III.6, page 47, stating that it does not expect any change in patient origin from historical patient origin for OR or procedure room services provided in CY2016. The applicant adequately identifies the population to be served.

Analysis of Need

In Section III.1(a) and (b) of the application, pages 27-37, the applicant describes the need for the proposed project, summarized as follows:

- The increasing demand for freestanding ambulatory surgery services due to clinical advances, including medical technology, and health insurers' efforts to contain healthcare costs (page 28).

- The high rate of historical and projected population growth in Mecklenburg County as a whole and in the Huntersville zip code area specifically as compared to other northern Mecklenburg County zip code areas (pages 32-35).

- The growth of the over 65 years of age population in Mecklenburg County as a whole and in the Huntersville zip code area as compared to other northern Mecklenburg County zip code areas (pages 35-36).

Moreover, the applicant states, on page 27, that the proposed project will not add OR capacity in Mecklenburg County, rather it will increase access to freestanding ASF capacity. The information provided by the applicant in the pages referenced above is reasonable and adequately supported.

Projected Utilization of OR

In Section III.1, pages 37-43, the applicant provides the assumptions and methodology for projecting utilization of the proposed freestanding ASF and provides its utilization projections for the first three operating years of the project in Section IV.1, page 52. The applicant projects utilization of the proposed OR as follows:

Step One:

The applicant provides historical utilization of its existing two ORs at CHS HSC in Section III.1, page 38, as follows:

CHS HSC
Historical Utilization, ORs
CY2014 through CY2016

	CY2014	CY2015	CY2016	CAGR CY2014-CY2016
Outpatient Cases	1,987	1,847	1,394	-16.2%
Total Surgical Hours*	2,981	2,771	2,091	-16.2%
Annual Growth		-7.0%	-24.5%	
OR Need**	1.59	1.48	1.12	
# of ORs	2	2	2	

*Total Surgical Hours = 1.5 hours x number of outpatient OR cases (per 10A NCAC 14C .2103 (b) (1) Performance Standards)
**OR Need = Total Surgical Hours/1,872 Standard Hours per OR per Year (per 10A NCAC 14C .2103 (b) (1) Performance Standards)

The applicant states, on page 38, that it attributes CHS HSC's historical decreases in OR utilization to the increasing availability of freestanding ASFs in Mecklenburg County and to an increase in demand for less invasive surgery that can be performed in ASFs.

Step Two:

On page 39, the applicant provides its projected utilization prior to projected shifts in surgical cases to Charlotte Surgery Center and Randolph Surgery Center, pursuant to Project I.D. #F-11106-15. The applicant states that to be conservative it keeps the number of surgical outpatient cases at the same level in CY2017 as CY2016 and utilizes one-half of the Mecklenburg County Compound Annual Growth Rate (CAGR) for outpatient surgical volume, 2.6%, to project utilization for CY2018. The 2.6% rate is used for CY2018 since the proposed project will begin July 1, 2018. For the first three operating years (OY) of the project after completion, CY2019 through CY2021, the applicant applies the Mecklenburg County CAGR for outpatient surgical volume of 5.2% to project utilization.

Step Three:

On page 40, the applicant subtracts the projected shifts in outpatient surgical cases to Charlotte Surgery Center and Randolph Surgery Center, pursuant to Project I.D. #F-11106-15, from the projected utilization calculated in Step Two for CY2017 through CY2020. In order to calculate the amount of shift for CY2021, since the third OY for Project I.D. #F-11106-15 will be CY2020, the applicant assumed that the shifted volume in surgical cases would increase by the Mecklenburg County CAGR for outpatient surgical volume of 5.2%. Projected utilization is summarized as follows:

CHS HSC
Projected OR Utilization with Shift
CY2017 through CY2021

	CY2017	**CY2018**	**CY2019**	**CY2020**	**CY2021**
Baseline # of Outpatient Cases	1,394	1,430	1,504	1,582	1,664
Shifts of Outpatient Cases		-578	-650	-722	-759
Final # of Outpatient Cases	**1,394**	**852**	**854**	**860**	**905**
Total Surgical Hours*	2,091	1,278	1,281	1,290	1,357
OR Need**	1.1	0.7	0.7	0.7	0.7
# of ORs	2	1	1	1	1

*Total Surgical Hours = 1.5 hours x Final # of Outpatient Cases (per 10A NCAC 14C .2103 (b) (1) Performance Standards)
**OR Need = Total Surgical Hours/1,872 Standard Hours per OR per Year (per 10A NCAC 14C .2103 (b) (1) Performance Standards)

The applicant states, in Section III.1, page 41, that the proposed project will begin operation on July 1, 2018. Thus, Project Year One (PY1) will be July 1, 2018 through June 30, 2019, PY2 will be July 1, 2019 through June 30, 2020, and PY3 will be July 1, 2020 through June 30, 2021. The applicant converts the projected utilization for CY2021 depicted in the table above to PY3 using the following formula:

PY3 = (CY2020 Final # of Outpatient Cases x 0.5) + (CY2021 Final # of Outpatient Cases x 0.5)
Therefore PY3 = (860 x 0.5) + (905 x 0.5), which calculates to 430 + 452.5 = 882.5.

The applicant calculates operating room need, on page 41, as follows:

CHS HSC PY3
OR Utilization

	PY3
Outpatient OR Cases	882
Total Surgical Hours*	1,323
OR Need**	0.71
# of ORs	1

*Total Surgical Hours = 1.5 hours x # of Outpatient OR Cases (per 10A NCAC 14C .2103 (b) (1) Performance Standards)
**OR Need = Total Surgical Hours/1,872 Standard Hours per OR per Year (per 10A NCAC 14C .2103 (b) (1) Performance Standards)

As shown in the table above, the applicant projects CHS HSC will perform 882 outpatient surgical cases in one outpatient surgical OR in PY3. Based on the performance standards required in 10A NCAC 14C .2103 (b)(1), the number of ORs required would be one.

Projected utilization of the applicant's one proposed OR is based on reasonable and adequately supported assumptions. Therefore, the applicant adequately demonstrates the need for one OR at the proposed ASF.

Projected Utilization for Procedure Rooms

In Section III.1, pages 41-43, the applicant provides the projected utilization for its three proposed procedure rooms, including assumptions and methodology, as follows:

Step One:

The applicant provides its historical utilization for CHS HSC's two existing procedure rooms, CY2014 through CY2016, and provides its projected *"baseline"* procedure room utilization, CY2017 through CY2021, on page 42, summarized as follows:

CHS HSC Historical Utilization, CY2014-CY2016,
and Projected Baseline Utilization, CY2017-CY2021*

	CY2014	**CY2015**	**CY2016**	**CY2017**	**CY2018**	**CY2019**	**CY2020**	**CY2021**
Number of Procedures	268	213	513	513	526	554	582	612

*The applicant provides historical and projected utilization based on calendar years to be consistent with CHS HSC fiscal year data, as stated in Section III.1, page 37.

The applicant states, on page 42, that utilization of CHS HSC's procedure rooms will grow at the same rate that CHS HSC's OR utilization will due to the same factors, namely, increasing demand for outpatient surgery, population growth, the benefits of a freestanding ASF, and the impact of potential physician ownership. Therefore, to be conservative the applicant keeps the utilization of CHS HSC's procedure rooms level from CY2016 through CY2017, increases utilization by one-half the Mecklenburg County CAGR for outpatient surgical volume, 2.6%, for CY2018 due to a July 1, 2018 project start date, then increases utilization annually by 5.2%, the Mecklenburg County CAGR for outpatient surgical volume, for the first three OYs of the project after completion, CY2019 through CY2021.
Step Two:

The applicant states, on page 42, that it will begin to offer ECT procedures at CHS HSC after one existing OR is relocated to Randolph Surgery Center, pursuant to Project I.D.#F-11106-15, and the vacated space is converted to an unlicensed procedure room. The applicant states that based on an analysis of historical volumes and provider coverage, it will perform eight ECT procedures per day for a total of 2,000 ECT procedures per year (8 x 250 days per year = 2,000). The growth in utilization for ECT procedures is projected to be consistent with those projected for OR volume, therefore the applicant applies the Mecklenburg County CAGR for outpatient surgical volumes of 5.2% each year.

The table below illustrates projected utilization for the three proposed procedure rooms, combining the projected *"baseline"* procedure room utilization and the projected ECT procedure utilization for CY2018 through CY2021:

CHS HSC Projected Utilization, Procedure Rooms

	CY2018	**CY2019**	**CY2020**	**CY2021**
Other Procedures*	526	554	582	612
ECT Procedures	2,000	2,104	2,212	2,327
Total Procedures	**2,526**	**2,657**	**2,795**	**2,939**

*Other Procedures represent *"baseline"* procedure room utilization.

Projected utilization of the applicant's three proposed procedure rooms is based on reasonable and adequately supported assumptions. Therefore, the applicant adequately demonstrates the need to develop one additional procedure room at the proposed ASF.

Access

In Section VI.2, pages 61-62, the applicant states its commitment to provide services to all persons in need of medical care regardless of race, sex, creed, age, national origin, handicap, or ability to pay in full. In Exhibit 22 the applicant provides a copy of Union West Surgery Center's Charity and Financial Assistance Policy which the applicant states will be used as a model for CHS HSC's financial policies. In Section VI.12, page 67, the applicant reports that 31.9% of CHS HSC's OR services were provided to Medicare or Medicaid recipients in CY2016. In Section VI.12, page 68, the applicant reports that 85.2% of its services provided in its two procedure rooms in CY2016 were provided to Medicare

or Medicaid recipients. In Section VI.14, the applicant projects that the percentage of OR services at CHS HSC to be provided to Medicare or Medicaid recipients will remain at 31.9% for CY2020. For procedures other than ECT, the applicant projects that 85.2% will be reimbursed by Medicare or Medicaid. Lastly, for ECT procedures only, the applicant projects that 31.6% will be reimbursed by Medicare or Medicaid. The applicant adequately demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for the project and adequately demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services. Therefore, the application is conforming to this criterion.

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

NA

The applicant does not propose a reduction or elimination of a service, rather it proposes to convert CHS HSC, an existing outpatient surgery center, to a freestanding ASF and add one unlicensed procedure room.

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

CA

In Section III.8, page 49, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the Status Quo – The applicant states that it rejected the status quo because by not converting to an ASF, patients and third party payors would continue to pay higher charges as an outpatient surgery center on CHS University's license. In addition, the applicant states that CHS HSC does not perform intensive outpatient surgical cases requiring easy access to needed hospital services, therefore there is no added benefit to patients. Thus, this alternative is not the most effective alternative.

- Construct a new ASF at another location - The applicant states that this alternative would be cost-prohibitive and would not have the advantage of sharing common services such as janitorial, security, and other related expenses. Therefore, this is not the most effective alternative.

After considering these alternatives, the applicant states the proposed project will allow for *"the continued provision of a high quality continuum of outpatient services that offers lower charges, convenient access, and separation from more intensive inpatient services where patients are often sicker."* In addition, the applicant states that the proposed project will allow for a potential joint venture with physicians. Therefore, the proposed project is the most effective alternative to meet the identified need.

Furthermore, the application is conforming or conditionally conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that the proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions.

1. **The Charlotte-Mecklenburg Hospital Authority shall materially comply with all representations made in the certificate of need application.**

2. **The Charlotte-Mecklenburg Hospital Authority shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application or that would otherwise require a certificate of need.**

3. **The Charlotte-Mecklenburg Hospital Authority shall develop an ambulatory surgical facility that shall be licensed for no more than one ambulatory surgical operating room upon completion of this project and Project I.D. #F-11106-15.**

4. **The Charlotte-Mecklenburg Hospital Authority shall develop no more than one room in the facility that meets licensure requirements for an operating room under the ambulatory surgical facility rules upon completion of this project and Project I.D. #F-11106-15.**

5. **Carolinas HealthCare System Huntersville Surgery Center shall meet all criteria to receive accreditation of the ambulatory surgical facility from JCAHO, AAAHS or a comparable accreditation authority within two years following completion of the facility.**

6. **Following completion of this project, Carolinas HealthCare System University shall reduce the number of licensed operating rooms operated under its license**

by one, such that at the completion of this project and Project I.D. #F-11106-15, Carolinas HealthCare Systems University shall not be licensed for more than eight operating rooms, including seven shared operating rooms, one dedicated C-section operating room, and one gastrointestinal endoscopy room.

7. **The procedure rooms shall not be used for procedures that should be performed only in an operating room based on current standards of practice.**

8. **Procedures performed in the minor procedure rooms shall not be reported for billing purposes as having been performed in an operating room and shall not be reported on the hospital's license renewal application as procedures performed in an operating room.**

9. **The Charlotte-Mecklenburg Hospital Authority shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to issuance of the certificate of need.**

(5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

CMHA proposes to separately license CHS HSC, which is currently licensed as part of CHS University, as a freestanding ASF operating under its own license. CHS HSC currently has two licensed ORs and two procedure rooms. However, pursuant to a CON issued for Project I.D. #F-11106-15, one OR will be relocated from CHS HSC to Randolph Surgery Center. At the completion of this project and Project I.D. #F-11106-15, CHS HSC will have one licensed OR and will develop one additional procedure room for a total of three procedure rooms.

Capital and Working Capital Costs

In Section VIII.1, page 79, the applicant states the total capital cost is projected to be as follows:

CHS HSC
Project Capital Cost

Capital Cost Category	Total
Construction Costs	$250,000
Consultant Fees, inc. Architect and Engineering	$80,000
Other	$25,000
TOTAL CAPITAL COST	**$355,000**

In Section IX.1, page 84, the applicant states there will be no start up or initial operating expenses for the project since the facility is currently operational.

Availability of Funds

In Section VIII.3, page 80, the applicant states that the total project capital costs will be funded by the accumulated reserves of CHS. In Exhibit 24, the applicant provides a letter dated May 15, 2017, from the Chief Financial Officer of CHS, which states that the capital costs of $355,000 will be funded by accumulated reserves of CHS. Exhibit 25 contains a copy of the financial statements for CHS for the years ending December 31, 2015 and December 31, 2014. For the year ending December 31, 2015, CHS had $173,812,000 in cash and cash equivalents, $7,792,619,000 in current assets, and $3,934,979,000 in total net assets. The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

Financial Feasibility

The applicant provided pro forma financial statements for the first three fiscal years of operation following completion of the project. In the pro forma financial statement (Forms B and C), the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below:

CHS HSC
Projected Revenue and Expenses

	OY1 CY2019	OY2 CY2020	OY3 CY2021
Total Cases (OR and Procedure Rooms)	3,511	3,655	3,844
Total Gross Revenue (Charges)	$21,682,197	$23,262,469	$25,201,003
Deductions from Gross Revenues	$15,208,142	$16,338,319	$17,699,842
Total Net Revenue	$6,474,054	$6,924,150	$7,501,161
Average Net Revenue per Case	$1,844	$1,894	$1,951
Total Operating Expenses (Costs)	$6,024,703	$6,344,008	$6,707,302
Average Operating Expense per Case	$1,716	$1,736	$1,745
Net Income	**$449,352**	**$580,142**	**$793,858**

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the financial section of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project. Furthermore, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

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

C

CMHA proposes to separately license CHS HSC, which is currently licensed as part of CHS University, as a freestanding ASF operating under its own license. CHS HSC currently has two licensed ORs and two procedure rooms. However, pursuant to a CON issued for Project I.D. #F-11106-15, one OR will be relocated from CHS HSC to Randolph Surgery Center. At the completion of this project and Project I.D. #F-11106-15, CHS HSC will have one licensed OR and will develop one additional procedure room for a total of three procedure rooms.

On page 57, the 2017 SMFP states, *"An operating room's service area is the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1."* In Figure 6.1, page 60 of the 2017 SMFP, Mecklenburg County is shown as a single-county operating room service area. Thus, in this application, the service area is Mecklenburg County. Providers may serve residents of counties not included in their service area.

The following table identifies the number of existing and approved outpatient (OP), inpatient (IP) and shared ORs located in Mecklenburg County, and the number of OP and IP surgical cases for each provider as reported in Table 6A, pages 61-72, of the 2017 SMFP.

Operating Room Inventory, Mecklenburg County

	OP ORs	IP ORs	Shared ORs	OP Surgery Cases	IP Surgery Cases
Randolph Surgery Center*	0	0	0	0	0
Presbyterian Hospital Mint Hill*	0	0	0	0	0
Charlotte Surgery Center	7	0	0	8,792	0
Carolina Center for Specialty Surgery	2	0	0	1,704	0
SouthPark Surgery Center	6	0	0	10,022	0
Novant Health Ballantyne Outpatient Surgery	2	0	0	946	0
Novant Health Huntersville Outpatient Surgery	2	0	0	1,903	0
Matthews Surgery Center	2	0	0	1,887	0
Mallard Creek Surgery Center	2	0	0	1,874	0
Novant Health Presbyterian Medical Center	6	6	34	20,138	7,911
Carolinas HealthCare System Pineville	0	3	9	4,444	2,824
Carolinas Medical Center	11	10	41	21,593	21,242
Carolinas HealthCare System University	2	1	9	6,845	1,019
Novant Health Matthews Medical Center	0	2	6	3,768	1,341
Novant Health Huntersville Medical Center	0	1	5	3,258	1,291

*Both Randolph Surgery Center and Presbyterian Hospital Mint Hill are under development.

The applicant proposes to license CHS HSC, currently operating under the license of CHS University, as a freestanding ASF. CHS HSC has two licensed ambulatory surgical ORs, however, pursuant to Project I.D. #F-11106-15, one OR at CHS HSC will be relocated to Randolph Surgery Center. Therefore, the applicant does not propose to increase the inventory of ORs in the service area. The applicant adequately demonstrates that the projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved ORs in Mecklenburg County. Therefore, the application is conforming to this criterion.

(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 Sections VII.1 and VII.2, page 71, the applicant provides the historical (CY2016) and projected OY2 (CY2020) staffing, respectively, for CHS HSC as follows:

CHS HSC
Historical and Projected Staffing

Position	Current Number of Full-Time Equivalent (FTE) Positions CY2016	Projected Number of FTE Positions to be Added	Total Projected Number of FTE Positions OY2, CY2020
Professional Health Care Administrators	1.00	0.00	1.00
Registered Nurses (RNs)	10.63	1.47	12.10
Certified RN Anesthetists (CRNAs)	1.50	0.62	2.12
Surgical Technicians	1.13	0.00	1.13
All 'non-health professionals' and 'technical' personnel	1.23	0.00	1.23
TOTAL	**15.49**	**2.09**	**17.58**

In Section VII.3, page 72, and Section VII.7, page 75, the applicant describes its resources and procedures for recruiting and retaining staff. Exhibit 7 contains a copy of a letter from Mark Ellis, M.D., expressing his interest in continuing to serve as the Medical Director for CHS HSC. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

(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 Sections II.1 and II.2, pages 16-17, the applicant states that the existing services provided at CHS HSC, including laboratory and pathology, radiology, pharmacy consulting, anesthesia and support services, will continue to be provided. Exhibit 4 contains a letter from the President of CHS University documenting that necessary ancillary and support services will continue to be available at CHS HSC. In Section V.2, page 56, the

applicant states that CHS HSC, currently operated under the license of CHS University, has established transfer agreements with several healthcare facilities and that as a freestanding ASF that is owned by CHS, patients at CHS HSC will continue to be transferred under these agreements as needed. Exhibit 18 contains a list of CHS' current transfer agreements and a letter from the President of CHS University expressing a commitment to continue accepting transfers from CHS HSC. Exhibit 19 contains copies of letters from physicians who have privileges at CHS HSC indicating support for the proposed project. The applicant adequately demonstrates that necessary ancillary and support services will continue to be available and that the proposed services will be coordinated with the existing healthcare system. Therefore, 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

(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.

NA

The applicant proposes to convert CHS HSC from a hospital-based outpatient surgery center to a separately licensed ASF using existing space and, as stated in Section XI.6, page 91, will upgrade wall ratings only.

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

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In Section VI.12, pages 67-68, the applicant reports the following payor mix for CHS HSC's OR surgical cases and procedure room cases for CY2016, as follows:

Payor Category	OR Surgical Cases as Percent of Total*	Procedure Room Cases as Percent of Total
Self Pay/Indigent/Charity	0.9%	0.1%
Medicare/Medicare Managed Care	20.0%	48.8%
Medicaid	11.9%	36.4%
Commercial Insurance/ Managed Care	66.2%	14.3%
Other**	1.1%	0.4%
Total	**100.0%**	**100.0%**

*Total may not foot due to rounding.
**Includes worker's compensation and other government payors.

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the service area, Mecklenburg County, and statewide.

Percent of Population						
County	**% 65+**	**% Female**	**% Racial & Ethnic Minority***	**% Persons in Poverty****	**% < Age 65 with a Disability**	**% < Age 65 without Health Insurance****
Mecklenburg	10%	52%	51%	15%	6%	19%
Statewide	15%	51%	36%	17%	10%	15%

Source: http://www.census.gov/quickfacts/table, 2014 Estimate as of December 22, 2015.
*Excludes *"White alone"* who are *"not Hispanic or Latino"*
***"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable…The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."*

However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

The applicant demonstrates that it currently provides adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

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

C

In Section VI.11, page 67, the applicant states that it has no obligations to provide uncompensated care and that it will have financial policies in place to assist uninsured patients to pay for services. Exhibit 22 contains a copy of Union West Surgical Center's financial policies which will be used as a model for CHS HSC.

In Section VI.10, page 66, the applicant states that no civil rights access complaints have been filed against any affiliated entity of CHS in the last five years. 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 VI.14, pages 68-69, the applicant projects the following payor mix for its OR surgical cases, procedure cases other than ECT, and ECT procedures during OY2 (CY2020):

Payor Category	OR Surgical Cases as Percent of Total*	Procedure Room Cases Excluding ECT as Percent of Total	Procedure Room ECT Cases as Percent of Total
Self Pay/Indigent/Charity	0.9%	0.1%	0.7%
Medicare/Medicare Managed Care	20.0%	48.8%	22.8%
Medicaid	11.9%	36.4%	8.8%
Commercial Insurance/ Managed Care	66.2%	14.3%	67.7%
Other**	1.1%	0.4%	0.0%
Total	**100.0%**	**100.0%**	**100.0%**

*Total may not foot due to rounding.
**Includes worker's compensation and other government payors.

In Section VI.14, page 69, the applicant states that its projected payor mix for OR surgical cases and procedure room cases excluding ECT is based on historical payor mix for these cases in CY2016. The applicant states, on page 69, that the projected payor mix for ECT cases is based on historical payor mix for CHS ECT patients. The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

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

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In Section VI.9, page 65, the applicant states that CHS HSC's services will be accessed through referral by physicians with privileges at CHS HSC. The applicant further states that persons who self-refer or whose physicians do not have privileges at CHS HSC will be referred to a physician with privileges at CHS HSC for consideration for services. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to the proposed services. Therefore, the application is conforming to this criterion.

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

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In Section V.1, pages 54-55, the applicant states that CHS has extensive relationships with health professional training programs at various educational institutions, including Cabarrus College of Health Sciences, Carolinas College of Health Sciences, and Presbyterian School of Nursing among others. The applicant states, on page 55, that CHS HSC and all of CHS' facilities will continue to be available as clinical sites for training programs upon completion of the project. 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.

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CMHA proposes to separately license CHS HSC, which is currently licensed as part of CHS University, as a freestanding ASF operating under its own license. CHS HSC currently has two licensed ORs and two procedure rooms. However, pursuant to a CON issued for Project I.D. #F-11106-15, CHS HSC will have one OR upon completion of this project and Project I.D. #F-11106-15, and will develop one additional procedure room for a total of three procedure rooms.

On page 57, the 2017 SMFP states, *"An operating room's service area is the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1."* In Figure 6.1, page 60 of the 2017 SMFP, Mecklenburg County is shown as a single-county OR service area. Thus, the service area for this facility consists of Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing and approved OP, IP and shared ORs located in Mecklenburg County, and the number of OP and IP cases for each provider.

OR Inventory, Mecklenburg County

Facility	OP ORs	IP ORs	Shared ORs	OP Surgery Cases	IP Surgery Cases
Randolph Surgery Center*	0	0	0	0	0
Presbyterian Hospital Mint Hill*	0	0	0	0	0
Charlotte Surgery Center	7	0	0	8,792	0
Carolina Center for Specialty Surgery	2	0	0	1,704	0
SouthPark Surgery Center	6	0	0	10,022	0
Novant Health Ballantyne Outpatient Surgery	2	0	0	946	0
Novant Health Huntersville Outpatient Surgery	2	0	0	1,903	0
Matthews Surgery Center	2	0	0	1,887	0
Mallard Creek Surgery Center	2	0	0	1,874	0
Novant Health Presbyterian Medical Center	6	6	34	20,138	7,911
Carolinas HealthCare System Pineville	0	3	9	4,444	2,824
Carolinas Medical Center	11	10	41	21,593	21,242
Carolinas HealthCare System University	2	1	9	6,845	1,019
Novant Health Matthews Medical Center	0	2	6	3,768	1,341
Novant Health Huntersville Medical Center	0	1	5	3,258	1,291

*Both Randolph Surgery Center and Presbyterian Hospital Mint Hill are under development.

The applicant proposes to convert a hospital-based outpatient surgical center to a freestanding ASF. Currently operating under the license of CHS University, CHS HSC has two ambulatory surgical ORs. Pursuant to Project I.D. #F-11106-15, one ambulatory surgical OR from CHS HSC will be relocated to Randolph Surgery Center. Therefore, the applicant does not propose to increase the inventory of ORs in the service area.

In Section V.7, pages 59-60, the applicant discusses how any enhanced competition in the service area will promote cost-effectiveness, quality and access to the proposed services. The proposed project will foster competition by enhancing quality and accessibility of surgical services while containing costs. The applicant states that quality will be enhanced in the freestanding ASF because it will provide for greater physician productivity due to faster turnaround time between cases, greater flexibility in scheduling, and more consistent nurse staffing. In addition, the applicant states that access will be improved since CHS HSC will become one of two freestanding multispecialty surgical ASFs in Huntersville, thereby fostering competition. Moreover, the applicant states, on page 60, that the proposed project will be cost effective since CHS HSC will be providing surgical care at a lower cost in a lower intensity setting with no other hospital-based expenses and the proposed project makes use of an existing, operational outpatient surgical facility.

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information in the application is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on the cost-effectiveness,

quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need for the project and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates it will provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant demonstrates that it will provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (3) and (13) are incorporated herein by reference.

The application is conforming to this criterion.

(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 Exhibit 2, the applicant provides a listing of all healthcare facilities owned, managed or leased by CMHA in North Carolina. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, five facilities were found to be out of compliance with one or more Medicare conditions of participation and two of those were found to be out of compliance with Medicare conditions of participation more than once within the 18 months immediately preceding the submission of the application through the date of the decision. related to quality of care. As of the date of this decision, the problems have been corrected. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all 24 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.

(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.

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The application is conforming with all applicable Criteria and Standards for Surgical Services and Operating Rooms promulgated in 10A NCAC 14C .2100. The specific criteria are discussed below:

SECTION .2100 – CRITERIA AND STANDARDS FOR SURGICAL SERVICES AND OPERATING ROOMS

10A NCAC 14C .2103 PERFORMANCE STANDARDS

(a) In projecting utilization, the operating rooms shall be considered to be available for use five days per week and 52 weeks a year.

-C- In Section II.10, page 22, the applicant states that CHS HSC is projected to operate five days per week and 52 weeks a year.

(b) A proposal to establish a new ambulatory surgical facility, to establish a new campus of an existing facility, to establish a new hospital, to increase the number of operating rooms in an existing facility (excluding dedicated C-section operating rooms), to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall:

(1) demonstrate the need for the number of proposed operating rooms in the facility which is proposed to be developed or expanded in the third operating year of the project based on the following formula: {[(Number of facility's projected inpatient cases, excluding trauma cases reported by Level I or II trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and C-section rooms, times 3.0 hours) plus (Number of facility's projected outpatient cases times 1.5 hours)] divided by 1872 hours} minus the facility's total number of existing and approved operating rooms and operating rooms proposed in another pending application, excluding one operating room for Level I or II trauma centers, one operating room for facilities with designated burn intensive care units, and all dedicated open heart and C-section operating rooms or demonstrate conformance of the proposed project to Policy AC-3 in the State Medical Facilities Plan titled "Exemption From Plan Provisions for Certain Academic Medical Center Teaching Hospital Projects;" and

(2) The number of rooms needed is determined as follows:

(A) in a service area which has more than 10 operating rooms, if the difference is a positive number greater than or equal to 0.5, then the need is the next highest whole number for fractions of 0.5 or greater and the next lowest whole number for fractions less than 0.5; and if the difference is a negative number or a positive number less than 0.5, then the need is zero;

(B) in a service area which has 6 to 10 operating rooms, if the difference is a positive number greater than or equal to 0.3, then the need is the next highest whole number for fractions of 0.3 or greater and the next lowest

whole number for fractions less than 0.3, and if the difference is a negative number or a positive number less than 0.3, then the need is zero; and

(C) in a service area which has five or fewer operating rooms, if the difference is a positive number greater than or equal to 0.2, then the need is the next highest whole number for fractions of 0.2 or greater and the next lowest whole number for fractions less than 0.2; and if the difference is a negative number or a positive number less than 0.2, then the need is zero.

-C- The Mecklenburg County OR service area has more than 10 ORs. In Section II.10, page 24, and in Section III.1, page 41, the applicant provides a table showing the projected utilization for the proposed facility for project year (PY) 3, July 1, 2020 through June 30, 2021, which is shown below:

CHS HSC
Projected Utilization, PY3

	PY 3 7/1/2020 - 6/30/2021
Projected Outpatient Surgery Cases	882
Weighted Outpatient Hours (1.5 hours per case)	1,323
ORs needed at 1,872 hours per room	0.71
Total ORs Needed	1

Projected utilization, which is based on reasonable and adequately supported assumptions, supports the need for one OR. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

(c) A proposal to increase the number of operating rooms (excluding dedicated C-section operating rooms) in a service area shall:

(1) demonstrate the need for the number of proposed operating rooms in addition to the rooms in all of the licensed facilities identified in response to 10A NCAC 14C .2102(b)(2) in the third operating year of the proposed project based on the following formula: {[(Number of projected inpatient cases for all the applicant's or related entities' facilities, excluding trauma cases reported by Level I or II trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and C-section rooms, times 3.0 hours) plus (Number of projected outpatient cases for all the applicant's or related entities' facilities times 1.5 hours)] divided by 1872 hours} minus the total number of existing and approved operating rooms and operating rooms proposed in another pending application, excluding one operating room for Level I or II trauma centers, one operating room for facilities with designated burn intensive care units, and all dedicated open heart and C-Section operating rooms in all of the applicant's or related entities' licensed facilities in the service area; and

(2) The number of rooms needed is determined as follows:

(A) in a service area which has more than 10 operating rooms, if the difference is a positive number greater than or equal to 0.5, then the need is the next

highest whole number for fractions of 0.5 or greater and the next lowest whole number for fractions less than 0.5; and if the difference is a negative number or a positive number less than 0.5, then the need is zero;

(B) in a service area which has 6 to 10 operating rooms, if the difference is a positive number greater than or equal to 0.3, then the need is the next highest whole number for fractions of 0.3 or greater and the next lowest whole number for fractions less than 0.3, and if the difference is a negative number or a positive number less than 0.3, then the need is zero; and

(C) in a service area which has five or fewer operating rooms, if the difference is a positive number greater than or equal to 0.2, then the need is the next highest whole number for fractions of 0.2 or greater and the next lowest whole number for fractions less than 0.2; and if the difference is a negative number or a positive number less than 0.2, then the need is zero.

-NA- The applicant does not propose to increase the number of ORs in the service area.

(d) An applicant that has one or more existing or approved dedicated C-section operating rooms and is proposing to develop an additional dedicated C-section operating room in the same facility shall demonstrate that an average of at least 365 C-sections per room were performed in the facility's existing dedicated C-section operating rooms in the previous 12 months and are projected to be performed in the facility's existing, approved and proposed dedicated C-section rooms during the third year of operation following completion of the project.

-NA- The applicant does not propose to develop an additional dedicated C-section OR.

(e) An applicant proposing to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall:

(1) provide documentation to show that each existing ambulatory surgery program in the service area that performs ambulatory surgery in the same specialty area as proposed in the application is currently utilized an average of at least 1,872 hours per operating room per year, excluding dedicated open heart and C-Section operating rooms. The hours utilized per operating room shall be calculated as follows: [(Number of projected inpatient cases, excluding open heart and C-sections performed in dedicated rooms, times 3.0 hours) plus (Number of projected outpatient cases times 1.5 hours)] divided by the number of operating rooms, excluding dedicated open heart and C-Section operating rooms; and

(2) demonstrate the need in the third operating year of the project based on the following formula: [(Total number of projected outpatient cases for all ambulatory surgery programs in the service area times 1.5 hours) divided by 1872 hours] minus the total number of existing, approved and proposed outpatient or ambulatory surgical operating rooms and shared operating rooms in the service area. The need is demonstrated if the difference is a positive number greater than or equal to one, after the number is rounded to the next highest number for fractions of 0.50 or greater.

-NA- The applicant does not propose to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program.

(f) The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this Rule.

-C- The applicant provides documentation of its assumptions and provides data supporting its methodology in Section III.1 (b), pages 37-41, of the application.