

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: July 24, 2020

Findings Date: July 24, 2020

Project Analyst: Ena Lightbourne

Team Leader: Gloria C. Hale

Project ID #: B-11892-20

Facility: Mission Hospital

FID #: 943349

County: Buncombe

Applicant(s): MH Mission Hospital, LLLP

Project: Acquire a third da Vinci Xi Surgical System for a total of 4 da Vinci systems (3 Xi and 1 Si)

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

MH Mission Hospital, LLLP or “the applicant,” proposes to acquire a third da Vinci Xi Surgical System at Mission Hospital (Mission) for a total of 4 da Vinci systems (3 Xi and 1 Si). MH Mission Hospital, LLLP is an affiliate of HCA Healthcare, Inc (HCA).

The applicant does not propose to:

- develop any beds or services for which there is a need determination in the 2020 State Medical Facilities Plan (SMFP)
- acquire any medical equipment for which there is a need determination in the 2020 State Medical Facilities Plan (SMFP)
- offer a new institutional health service for which there are any policies in the 2020 State Medical Facilities Plan (SMFP)

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

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to acquire a third da Vinci Xi Surgical System at Mission for a total of 4 da Vinci systems (3 Xi and 1 Si).

N.C. Gen. Stat. §131E-176(24a) states, “*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2020 SMFP does not define a service area for major medical equipment, nor are there any applicable rules adopted by the Department that define the service area for major medical equipment. In Section C.4, pages 22-23, the applicant defines the service area for the proposed project. The applicant states that Mission serves patients from an 18-county area as shown in Figures 1 and 2 on page 23. Facilities may also serve residents of counties not included in the service area.

The following table illustrates current and projected patient origin.

County	Last FFY 01/01/2019-12/31/2019 (CY 2019)		3 rd FFY 10/01/2022-09/30/2023 (FY 2023)	
	# of Patients	% of Total	# of Patients	% of Total
Buncombe	227	39.5%	487	39.5%
Henderson	53	9.3%	115	9.3%
Jackson	45	7.9%	97	7.9%
Haywood	37	6.5%	80	6.5%
McDowell	32	5.6%	69	5.6%
Transylvania	24	4.2%	52	4.2%
Cherokee	21	3.7%	46	3.7%
Rutherford	16	2.8%	34	2.8%
Macon	13	2.3%	29	2.3%
Madison	13	2.3%	29	2.3%
Burke	11	1.9%	23	1.9%
Swain	11	1.9%	23	1.9%
Yancey	8	1.4%	17	1.4%
Caldwell	8	1.4%	17	1.4%
Graham	8	1.4%	17	1.4%
Polk	8	1.4%	17	1.4%
Mitchell	5	0.9%	11	0.9%
Avery	3	0.5%	6	0.5%
Other North Carolina*	3	0.5%	6	0.5%
Out of State**	27	4.7%	57	4.7%
Total	575 [573]	100.0%	1,233 [1,232]	100.0%

Source: Section C, pages 20-21

*Other NC includes: Clay County

**Out of State includes: GA, FL, SC, TN, VA

In Section C, page 22, the applicant provides the assumptions and methodology used to project its patient origin. The applicant states:

“Mission does not expect the patient origin for its surgery patients receiving robotic surgery to change as a result of this project. FY 2019 actual patient origin percentages by county for Mission’s existing 3 da Vinci surgical robots were applied to the projected da Vinci robotic surgical volume in order to project patient origin.”

The applicant’s assumptions are reasonable and adequately supported because projected patient origin is based on historical patient origin at Mission.

Analysis of Need

In Section C, pages 22-34, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services.

The applicant states that the need for the project is based on the following factors:

Service Area Definition (pages 22-23)

On page 22, the applicant states that Mission is the only provider of robotic surgery within a 50-mile radius of Buncombe County. Based on their historical patient origin, Mission serves an 18-county service area, which includes a primary service area and a secondary service area as shown in the table below.

Mission Hospital Service Area Definition	
Primary	Secondary
Buncombe	Madison
Henderson	Burke
Jackson	Swain
Haywood	Yancey
McDowell	Caldwell
Transylvania	Graham
Cherokee	Polk
Rutherford	Mitchell
Macon	Avery

Source: Section C, page 23

Population Trends of the Service Area (pages 23-26)

The applicant used data from the North Carolina Office of State Budget and Management (NCOSBM) to demonstrate the need based on the population growth in the service area. The applicant states that between 2020 and 2025, the primary service area is projected to grow steadily from 714,122 to 748,533, a 4.82 percent growth. The applicant states that the entire service area is projected to grow by approximately 40,000 residents over the same time period, as shown in the tables below. However, based on the Project Analyst's calculation, the NCOSBM projects a population increase of 22,591 from 2020 to 2025 for the entire service area.

2020 Service Area Population

	Age 0-17	Age 18-44	Age 45-64	Age 65+	Total
Buncombe	49,481	92,059	70,130	55,376	267,046
Henderson	21,919	33,515	31,461	32,837	119,730
Jackson	7,483	18,538	9,870	8,957	44,848
Haywood	11,379	18,182	17,705	16,547	63,813
McDowell	9,018	14,667	13,140	10,080	46,905
Transylvania	5,680	9,796	8,779	11,551	35,806
Cherokee	4,894	7,822	8,115	9,142	29,972
Rutherford	13,646	21,703	18,665	15,091	69,105
Macon	6,755	10,226	9,135	10,781	36,897
Madison	3,958	7,193	6,325	5,367	22,843
Burke	17,869	29,660	25,260	19,145	91,934
Swain	3,252	4,400	3,505	2,951	14,108
Yancey	3,353	5,730	4,944	4,767	18,794
Caldwell	16,108	26,720	23,965	16,910	83,703
Graham	1,728	2,604	2,164	2,190	8,686
Polk	3,360	5,874	5,963	6,655	21,852
Mitchell	2,741	4,887	3,952	3,678	15,258
Avery	2,687	6,106	5,185	4,057	18,035
Total	185,309	319,682	268,262	236,082	1,009,335

Source: Section C, page 24; 2019 NCOSBM

2025 Service Area Population

	Age 0-17	Age 18-44	Age 45-64	Age 65+	Total
Buncombe	49,359	96,417	72,654	63,574	282,004
Henderson	21,939	35,659	31,892	36,793	126,283
Jackson	7,639	19,872	9,901	10,009	47,421
Haywood	11,758	19,082	17,323	18,083	66,246
McDowell	8,910	15,031	12,871	11,387	48,199
Transylvania	5,841	9,944	8,880	12,622	37,287
Cherokee	4,922	8,286	8,045	10,217	31,470
Rutherford	13,707	22,227	18,238	16,572	70,744
Macon	7,111	11,084	8,950	11,734	38,879
Madison	4,085	7,465	6,368	6,129	24,047
Burke	17,736	30,871	23,699	21,293	93,599
Swain	3,143	4,271	3,155	3,031	13,600
Yancey	3,471	6,203	4,849	5,119	19,642
Caldwell	16,084	27,823	23,203	18,805	85,915
Graham	1,636	2,750	2,016	2,284	8,686
Polk	3,372	6,313	5,525	7,394	22,604
Mitchell	2,787	5,041	3,646	3,826	15,300
Avery	2,647	5,888	5,056	4,439	18,030
Total	186,147	334,227	266,271	263,311	1,049,956 [1,031,926]

Source: Section C, page 25; 2019 NCOSBM

Note: Project Analyst's calculations are in brackets

The applicant states that the 65+ population is showing the highest growth projections which is significant due to their higher use of health care resources, including minimally invasive

robotic surgery. The applicant states that the growth in demand for robotic surgery will increase with the projected service area population. Based on data from the NCOSBM, the table below demonstrates the percentage of growth across a five-year period.

Population Growth 2020 to 2025

	Age 0-17	Age 18-44	Age 45-64	Age 65+	Total
Buncombe	-0.25%	4.73%	3.60%	14.80%	5.60%
Henderson	0.10%	6.40%	1.37%	12.05%	5.47%
Jackson	2.08%	7.20%	0.31%	11.75%	5.74%
Haywood	3.33%	4.95%	-2.16%	9.28%	3.81%
McDowell	-1.20%	2.48%	-2.05%	12.97%	2.76%
Transylvania	2.83%	1.51%	1.15%	9.27%	4.14%
Cherokee	0.57%	5.93%	-0.85%	11.76%	5.00%
Rutherford	0.45%	2.41%	-2.29%	9.81%	2.37%
Macon	5.27%	8.39%	-2.03%	8.84%	5.37%
Madison	3.21%	3.78%	0.68%	14.20%	5.27%
Burke	-0.74%	4.08%	-6.18%	11.22%	1.81%
Swain	-3.35%	-2.93%	-9.99%	2.71%	-3.60%
Yancey	3.52%	8.25%	-1.92%	7.38%	4.51%
Caldwell	-0.15%	4.13%	-3.18%	11.21%	2.64%
Graham	-5.32%	5.61%	-6.84%	4.29%	0.00%
Polk	0.36%	7.47%	-7.35%	11.10%	3.44%
Mitchell	1.68%	3.15%	-7.74%	4.02%	0.28%
Avery	-1.49%	-3.57%	-2.49%	9.42%	-0.03%
Total	0.45%	4.55%	-0.74%	11.53%	4.02%

Source: Section C, page 26; 2019 NCOSBM

Robotic Surgery Is Increasingly Becoming the Standard of Care (pages 26-27)

The applicant used data from the National Institutes of Health and Intuitive Surgical Inc., a company that manufacture and market robotic products, to illustrate how robotic surgery is becoming the standard of care. Robotic surgery has grown significantly over the last 10 years with exponential growth in the last few years alone. It is estimated that annual procedure volume nationwide reached 1,229,000 last year, up from 877,000. The applicant states that the rapid growth in robotic surgery can be attributed to the improved efficiencies, recovery time, patient safety, and quality of care. The applicant expects that the demand for robotic surgery will increase, therefore the proposed project will allow the applicant to stay current with modern medicine and have the capacity to offer patients in its service area adequate access to advanced technology.

Patients are Migrating Out of the Service Area for Robotic-Appropriate Procedure (27-30)

The applicant states that residents of Buncombe County are migrating out of the county to receive services that are robotic-appropriate and across several specialties. To illustrate this trend, the applicant used data from Intuitive Surgical, Inc., as shown in the table below.

Patient Outmigration for Robotic Eligible Procedures of Buncombe County	
Specialty	2018
Colon	125
Rectal	15
Hernia	231
Hysterectomy-Malignant	42
Hysterectomy-Benign	75
Prostatectomy	45
Thoracic	21

Source: Section C. page 28

In Figure 5, page 29, the applicant provides a map illustrating da Vinci Robotic Surgery providers closest to Mission. The closest providers are approximately 50 miles away. The applicant states that the proposed project will allow Mission to continue to expand its ability to perform more robotic procedures and allow patients to stay closer to home for care.

Trends in Utilization of Mission’s Robotic Surgery Services (pages 30-32)

The applicant states that the actual volume of robotic surgery cases performed at Mission was higher than what was previously projected in the previous approved application, Project ID# B-11750-19. The scope of the project was to acquire the third da Vinci Xi system. The applicant states that it underestimated the total number of robotic surgeries by almost 35 percent, as illustrated in the table below.

Mission CY 2019 Annualized vs Actual Robotic Surgery Volume			
	Annualized CY 2019*	Actual CY 2019	% Difference
Inpatient	130	202	55.4%
Outpatient	296	371	25.3%
Total	426	573	34.5%

Source: Section C, page 30, Mission Hospital Internal Data
 *Calculated from internal data in Project ID# B-11750-19

The applicant states that the growth in robotic surgeries in CY 2019 can be attributed to the two replacement Xi units that became operational in 2019. In Figure 8, page 31, the applicant demonstrates the growth in robotic surgeries at Mission by comparing the percentage of growth from CY 2016 to CY 2018 to the percentage of growth from CY 2018 to CY 2019. Mission experienced a 48.83 percent growth from CY 2018 to CY 2019 as opposed to a -3.27 percent growth in the prior three years.

Growth in Physicians Trained in Robotic Surgery and Recruitment (pages 32-34)

The applicant states that Mission has taken several steps in meeting the growing need for a surgical staff trained in robotic surgery. This effort included training their general surgeons on robotic surgery and recruiting several surgeons already trained in robotic assisted minimally invasive surgery who will require capacity to perform procedures on an Xi. In addition, Mission is in the process of recruiting a robotic-trained hernia surgeon and a hepatobiliary

surgeon who will require access to the robot. The applicant states that the proposed project will allow Mission to accommodate its established and newly recruited physicians who are trained to use the da Vinci System, therefore meeting the growing demand for this expertise.

The information is reasonable and adequately supported based on the following:

- The applicant provides data showing the growth in robotic surgery and the trend in it becoming the standard of care.
- The applicant’s proposal is in response to service area residents migrating outside the service area to receive robotic-appropriate procedures.
- The applicant relies on growth trends and historical utilization to justify the need.

Projected Utilization

In Section Q, Page 81, the applicant provides historical and projected utilization, as illustrated in the following table. The applicant presented its projections for the first three years of the project as FY 2021 (10/01/2020-9/30/2021), FY 2022 (10/01/2021-9/30/2022), and FY 2023 (10/01/2022-9/30/2023).

Historical and Projected Utilization of da Vinci Units					
	Prior FY FY 2019	Interim FY FY 2020	1st FY FY 2021	2nd FY FY 2022	3rd FY FY 2023
# of Units	2	3	4	4	4
# of Procedures	464	929	1,123	1,191	1,233

In Section C, pages 34-37, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

Step 1: Compare Projected 2019 Volume to Actual 2019 Volume

In its projections in the previously approved application, Project ID# B-11750-19, the applicant projected an annualized volume of 411 cases during the interim year (FY 2019) and 261 cases during partial interim year (10/1/2019-3/31/2020), based on the data available to Mission at the time of filing the application through June 30, 2019 and its two existing da Vinci units. The applicant states that Mission actually experienced 464 cases during the interim year (FY 2019) and 411 cases during partial interim year (10/1/2019-3/31/2020). Based on the comparative of the projected 2019 volume and the actual 2019 volume and the year-to-date FY 2020 volume, the applicant projects a baseline of 822 cases (411 for six months).

Step 2: Restate Projected Utilization for the Three da Vinci Robots to align with New Projected Years

In Section Q, Form C, of the previously approved application, Project ID# B-11750-19, the applicant presented its projected utilization for the first three project years as PY1 4/1/2020-3/31/2021, PY2 4/1/2021-3/31/2022, and PY3 4/1/2022-3/31/2023. For this project, the applicant projects the second Xi unit to come online October 1, 2020 and projects the first three

project years as FY 2021-FY 2023. The applicant restates its projected utilization by aligning a half of each project year to align with its restated fiscal years, as illustrated in the table below.

Align prior projections with Fiscal Years				
Restated Projections from Project ID# B-11750-19 for Fiscal Years	Interim	PY 1	PY 2	PY 3
	FY 2020 Projection	FY 2021	FY 2022	FY 2023
Fiscal Years Ending 9/30	672	900	1,041	1,104
<i>FY 2020 = Q1-Q2 FY 2020 (261) + ½ of PY1 (821/2 = 411) = 672</i>				
<i>FY 2021 ½ of PY1 (821/2 = 411) + ½ of PY2 (978/2 = 489) = 900</i>				
<i>FY 2022 = ½ of PY2 (978/2 = 489) + ½ of PY3 (1,104/2 - 552) = 1,041</i>				
<i>FY 2023 = Held constant to match PY3 at 1,104</i>				

Source: Section C, page 35

Step 3: Determine incremental Volume of Newly Trained and Recently Onboarded Physicians on the Proposed Xi Robot

The applicant projects that physician volume will ramp up with staggered start dates over the remainder of FY 2020. Its projection is based on conversation with each physician, their historical patient base, and letters of support. The applicant projects a total incremental volume of 192 cases in FY 2020-2021.

Step 4: Combine Historical Growth that Exceeded Prior Projections with incremental Physicians

To move forward with its updated projections for this project, the applicant combines its actual historical growth, which exceeded its prior projections, and the incremental case volumes for new physicians, as demonstrated in Step 1 and Step 2. The applicant projects 929 cases in interim FY 2020 which exceeds its prior projections by 258 cases, as demonstrated in the table below.

Updated Projections for April 2020 CON	Interim	PY 1	PY 2	PY 3
	FY 2020 Annualized	FY 2021	FY 2022	FY 2023
Restated Projections from Project ID# B-11750-19 for Fiscal Year	672	900	1,041	1,104
Projected Utilization with 4 th da Vinci Robot	929	1,123	1,191	1,233
Variance from original CON [Reflects faster volume ramp up than projections (+150) and Incremental Physician Volume (+192)]	258	223	150	129

Source: Section C, page 36

Step 5: Calculate the Projected Utilization as a Percentage of Capacity

Assumptions:

- Hours available: 240 days x 8 hours / day = 1,920 hours
- Case time: 3.45 hours per case + 0.69 hours turnover = 4.13 total hours per case

- Maximal Capacity: 1,920 hours / 4.13 hours per case = 465 cases per year per unit x 4 units = 1,860
- Optimal Capacity: 80% capacity (1,860 x 80%) = 1,488 cases /4 units = 372 cases per unit

The table below illustrates that Mission will reach 88.2 percent of capacity in FY 2020 on two units and one additional unit set to go online October 1, 2020. The applicant projects that Mission will reach 82.9 percent capacity in FY 2023 with four da Vinci units.

Projection Utilization and Capacity				
	Interim FY 2020	1st FFY FY 2021	2nd FFY FY2022	3rd FFY FY 2023
Projected Utilization with 4 th da Vinci Robot	929	1,123	1,191	1,233
Capacity per Unit	372	372	372	372
Units	2.8	4	4	4
Total Surgical Capacity	1,053	1,488	1,488	1,488
Projected Program Utilization	929	1,123	1,191	1,233
Projected Percent of Capacity	88.2%	75.5%	80.0%	82.9%

Source: Section C, page 36

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

- The applicant’s utilization projections are supported by the historical utilization of the existing da Vinci units and the projected growth in physicians trained in robotic surgery at Mission.
- The applicant provided adequate support for the growing trends in utilization of robotic surgery services at Mission.
- The applicant provides adequate support for the increase in incremental projections.

Access

In Section C, page 42, the applicant states:

“Mission’s proposed da Vinci Robot will meet all requirements of the North Carolina Building Code, the Americans with Disabilities Act, any other applicable federal accessibility laws, and any local accessibility ordinances.

...

Women will have equal access to all services and are proposed to make up approximately 60 percent of patients seen at the proposed facility, which is consistent with previously- experienced patient demographics. Handicapped persons and the elderly population will be accommodated through design of the lab, as required by applicable licensure requirements. Consistent with historical data, the elderly population is expected to make up approximately 42 percent of the patients treated at Mission. Mission does not discriminate against any persons, including racial and ethnic minorities.

...

Mission already demonstrates its service to all patients, regardless of gender, race, or ability to pay, by being one of the leading providers of indigent and charity care to patients seeking services in the region.”

In Section L, page 69, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table.

Payor Source	Robotic Surgery Services as Percent of Total
Self-Pay	4.3%
Medicare**	36.9%
Medicaid**	4.7%
Insurance**	51.9%
Other (Worker's Comp, TRICARE, Agency, Champus)	2.1%
Total	100.0%

**Including managed care plans

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

- Payor mix is based on the most recent actual experience at Mission.
- The projected payor source for robotic surgery services is consistent with historical trends.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

(3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will

be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

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

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

CA

The applicant proposes to acquire a third da Vinci Xi Surgical System at Mission for a total of 4 da Vinci systems (3 Xi and 1 Si).

In Section E, page 49, 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 that this alternative was not feasible due to the scheduling difficulties and capacity constraints on the existing two da Vinci Xi surgical systems. In addition, this alternative does not address the issue of limited access to services by service area residents. The applicant states that Buncombe County patients are leaving the area and traveling approximately 50 miles for robotic surgery.

Updating da Vinci Si Robotic Surgical System-The applicant states that this alternative was neither cost-effective nor feasible. The applicant states that retaining the Si is important because it provides the ability for physicians to provide access for their patients to robotic surgery until they are trained to perform procedures on the Xi. In addition, upgrading the system instead of bringing in a fourth system would not accomplish Mission's goal to expand capacity for continued growth in robotic surgery.

Acquire a Third da Vinci Xi Robotic Surgical System-The applicant states that this alternative was cost-effective, efficient, and forward-thinking. The applicant states that acquiring a third da Vinci Xi Surgical System will allow Mission to accommodate the rapidly growing demand from patients and newly credentialed surgeons, provide access to robotic surgery capacity to new recruits, and improve its competitive position in western North Carolina.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The application is conforming to all statutory and regulatory review criteria.

- The alternative will meet the need for additional capacity to perform robotic surgeries at Mission.
- The alternative is more cost-effective and convenient for patients and medical staff.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. MH Mission Hospital, LLLP shall materially comply with all representations made in the certificate of need application.**
 - 2. MH Mission Hospital, LLLP shall acquire no more than one da Vinci Xi Surgical System at Mission Hospital for a total of 4 da Vinci systems (3 Xi and 1 Si).**
 - 3. MH Mission Hospital, LLLP shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
 - 4. No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, MH Mission Hospital, LLLP shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
 - a. Payor mix for the services authorized in this certificate of need.**
 - b. Utilization of the services authorized in this certificate of need.**
 - c. Revenues and operating costs for the services authorized in this certificate of need.**
 - d. Average gross revenue per unit of service.**
 - e. Average net revenue per unit of service.**
 - f. Average operating cost per unit of service.**
 - 5. MH Mission Hospital, LLLP shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of

the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to acquire a third da Vinci Xi Surgical System at Mission for a total of 4 da Vinci systems (3 Xi and 1 Si).

Capital and Working Capital Costs

In Section Q, page 84, the applicant projects the total capital cost of the project, as shown in the table below.

Capital Costs	
Medical Equipment	\$1,636,931
Consultant Fees	\$35,000
Total	\$1,671,931

In Section Q, page 84, the applicant provides the assumptions used to project the capital cost.

In Section F, page 53, the applicant states that there will be no start-up or initial operating expenses since the proposed project involves the expansion of an existing space.

Availability of Funds

In Section F, page 52, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing		
Type	MH Mission Hospital, LLLP	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$147,181	\$147,181
Bonds	\$0	\$0
Other (Capital Lease)	\$1,524,750	\$ 1,524,750
Total Financing	\$ 1,671,931	\$ 1,671,931

* OE = Owner's Equity

Exhibit F-2.1 contains a letter dated April 10, 2020 from the CFO of HCA, an affiliate of Mission, documenting its intention to provide funding for the project through an inter-company loan from accumulated reserves and through a capital lease for the capital needs of the proposed project. Exhibit F-2.2 contains the audited consolidated financial statements of HCA, which show that as of December 31, 2019, HCA had \$621 million in cash and cash equivalents, \$45,058 million in total assets.

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 the first three operating years of the project, as shown in the table below.

Mission da Vinci Surgical Services	1st FFY FY 2021	2nd FFY FY 2022	3rd FFY FY 2023
Total Procedures	1,123	1,191	1,233
Total Gross Revenues (Charges)	\$60,189,878	\$64,472,846	\$67,413,912
Total Net Revenue	\$23,659,317	\$25,342,858	\$26,498,926
Average Net Revenue per Procedure	\$21,068	\$21,279	\$21,491
Total Operating Expenses (Costs)	\$9,772,918	\$10,265,984	\$10,527,808
Average Operating Expense per Procedures	\$8,703	\$8,620	\$8,538
Net Income	\$13,886,399	\$15,076,873	\$15,971,118

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on the following:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

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

C

The applicant proposes to acquire a third da Vinci Xi Surgical System at Mission for a total of 4 da Vinci systems (3 Xi and 1 Si).

N.C. Gen. Stat. §131E-176(24a) states, “Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives

services from a health service facility.” The 2020 SMFP does not define a service area for major medical equipment, nor are there any applicable rules adopted by the Department that define the service area for major medical equipment. In Section C.4, pages 22-23, the applicant defines the service area for the proposed project. The applicant states that Mission serves patients from an 18-county area as shown in Figures 1 and 2 on page 23. Facilities may also serve residents of counties not included in the service area.

In Section G, page 57, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved robotic surgical services in the 18-county service area. The applicant states:

“...there will be no unnecessary duplication of services because there are no other providers in the service area that offer the same service components proposed in this application. The closest robotic surgery facilities are Franklin Woods Community Hospital and Johnson City Medical Center Hospital. Both of these facilities are approximately 50 miles away in Johnson City, TN and are not in the proposed service area. It is imperative that Mission have sufficient robotic surgery capacity both to meet the standard of efficacious care and also to meet its duty as the regional tertiary provider that patients throughout western North Carolina rely on for their specialty care.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the applicant adequately demonstrates that Mission is the only provider of robotic surgery services in the service area and that the robotic surgery services are needed in addition to the existing or approved services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

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

C

In Section Q, page 87, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff
	(As of 12/31/2019)	2nd Full Fiscal Year (FFY 2022)
Register Nurses	3.0	4.0
Surgical Technicians	3.0	4.0
Aides/Orderlies (Surgical Assistant)	3.0	4.0
TOTAL	9.0	12.0

The assumptions and methodology used to project staffing are provided in Section Q, Form H. 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.2 and H.3, pages 58 and 59, respectively, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section I, page 61, the applicant identifies the current medical director. In Exhibit I-3.1, the applicant provides a letter from the medical director indicating an interest in continuing to serve as medical director for the proposed services. In Exhibits H-3 and I-2, the applicant provides supporting documentation.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section I.1, page 60, the applicant states that Mission is an existing quaternary and tertiary provider and a provider of robotic surgery, as such, the hospital currently has all necessary ancillary and support services in place, including but not limited to pharmacy, laboratory, medical supplies, and any subsequent diagnostic or therapeutic follow-up procedures required.

In Section I.2, page 60, the applicant states that Mission is the only hospital of its kind in its service area and other hospitals in the region frequently refer their patients to Mission. The

applicant states that Mission has a transfer agreement among hospitals in Western North Carolina 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, and
- exhibits to the application.

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

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

NA

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

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

NA

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

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

NA

The applicant does not propose to construct any new space. Therefore, Criterion (12) is not applicable to this review.

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

C

In Section L, page 68, the applicant provides the historical payor mix during CY 2019 for the proposed services, as shown in the table below.

Mission Hospital Historical Payor Mix CY 2019	
Payor Source	Robotic Surgery Services as Percent of Total
Self-Pay	4.3%
Medicare**	36.9%
Medicaid**	4.7%
Insurance**	51.9%
Other (Worker's Comp, TRICARE, Agency, Champus)	2.1%
Total	100.0%

**Including managed care plans

In Section L, page 67, the applicant provides the following comparison.

MH Mission Hospital Robotic Surgery Department	Percentage of Total Patients Served by the Robotic Surgery Department during CY 2019	Percentage of the Population of the Service Area
Female	71.16%	51.31%
Male	28.84%	48.69%
Unknown	0.00%	0.00%
64 and Younger	66.51%	76.72%
65 and Older	33.49%	23.28%
American Indian	0.00%	1.33%
Asian	0.47%	1.26%
Black or African-American	6.05%	4.40%
Native Hawaiian or Pacific Islander	0.00%	0.12%
White or Caucasian	90.23%	87.59%
Other Race	1.40%	5.31%
Declined / Unavailable	1.86%	0.00%

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

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

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.2, page 68, the applicant states that Mission has no obligation in regard to uncompensated care, community service and access to care by minorities and persons with disabilities.

In Section L, page 68, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 69, 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.

Mission Hospital Projected Payor Mix FY 2023	
Payor Source	Robotic Surgery Services as Percent of Total
Self-Pay	4.3%
Medicare**	36.9%
Medicaid**	4.7%
Insurance**	51.9%
Other (Worker's Comp, TRICARE, Agency, Champus)	2.1%
Total	100.0%

**Including managed care plans

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 4.3% of total services will be provided to self-pay/charity care patients, 36.9% to Medicare patients and 4.7% to Medicaid patients.

On page 69, 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 because it is based on Mission's historical payor mix.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion 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 70, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section M, pages 71-72, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall

demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to acquire a third da Vinci Xi Surgical System at Mission for a total of 4 da Vinci systems (3 Xi and 1 Si).

N.C. Gen. Stat. §131E-176(24a) states, “*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2020 SMFP does not define a service area for major medical equipment, nor are there any applicable rules adopted by the Department that define the service area for major medical equipment. In Section C.4, pages 22-23, the applicant defines the service area for the proposed project. The applicant states that Mission serves patients from an 18-county area as shown in Figures 1 and 2 on page 23. Facilities may also serve residents of counties not included in the service area.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 73, the applicant states:

“The proposed project will not impact competition in the proposed service area. Mission is the only surgical department to offer minimally invasive robotic surgical procedures in Buncombe County.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 73, the applicant states:

“As a larger percentage of surgery is performed robotically with MIS techniques, more patients can experience reduced lengths of inpatient stay and even shift from inpatient to outpatient surgery. This will increase the cost effectiveness of surgery services and enhance patient quality of care.”

Regarding the impact of the proposal on quality, in Section N, page 73, the applicant states:

“The proposed project will foster cost containment and improve quality of care through improved efficiency of robotic surgery with the proposed advanced technology.

...

As a larger percentage of surgery is performed robotically with MIS techniques, more patients can experience reduced lengths of inpatient stay and even shift from inpatient to outpatient surgery. This will increase the cost effectiveness of surgery services and enhance patient quality of care.”

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 73, the applicant states:

“...the addition of a third da Vinci Xi Robot will provide Mission the flexibility to meet current and future demands for all kinds of advanced care and ensure that its patients will continue to have readily available access to comprehensive services.

...

Mission will continue to serve a large percentage of medically underserved patients based on its historical experience and existing policies and procedures.”

Considering all the information in the application, the applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on:

- Cost-effectiveness (see Sections C, F, K, N and Q of the application and any exhibits)
- Quality (see Sections C, N and O of the application and any exhibits)
- Access to medically underserved groups (see Sections C, L and N of the application and any exhibits)

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on 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, the applicant identifies the hospitals located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of eight of this type of facility located in North Carolina.

In Section O, page 76, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents of immediate jeopardy occurred in any of these facilities. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care occurred in one of these facilities. However, the facility was back in compliance February 20, 2019. 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 eight 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.

NA

The applicant proposes to acquire a third da Vinci Xi Surgical System. There are no administrative rules that are applicable to this proposal.