

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: August 10, 2018

Findings Date: August 10, 2018

Project Analyst: Julie M. Faenza

Section Chief: Martha J. Frisone

Project ID #: B-11500-18

Facility: Margaret R. Pardee Memorial Hospital

FID #: 943324

County: Henderson

Applicant: Henderson County Hospital Corporation

Project: Develop a new dedicated C-section operating room for a total of 11 operating rooms

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 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.

C

Henderson County Hospital Corporation (HCHC) proposes to develop a dedicated C-section operating room (OR) at Margaret R. Pardee Memorial Hospital (Pardee) for a total of 11 operating rooms (ORs) upon project completion.

#### 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 2018 State Medical Facilities Plan (SMFP). Further, the 2018 SMFP, on page 61, states:

*“Dedicated C-Section Operating Rooms’ and associated cases are excluded from the calculation of need for additional operating rooms by the standard methodology; therefore, hospitals proposing to add a new operating room for use as a ‘Dedicated C-*

*Section Operating Room' shall apply for a certificate of need without regard to the need determinations in Chapter 6 of this Plan."*

Therefore, there are no need determinations applicable to this review.

### **Policies**

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities is the only policy in the 2018 SMFP applicable to this review.

**Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities**, on page 33 of the 2018 SMFP, states:

*"Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.*

*In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.*

*Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."*

The proposed capital expenditure for this project is greater than \$2 million; therefore, Policy GEN-4 is applicable to this review. In Section B.4, page 15, the applicant states that the proposed renovation will reuse as many existing utilities as possible to avoid waste and will meet or exceed the North Carolina building code requirements for energy efficiencies and water conservation.

The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4, subject to Condition #5 found in Criterion (4).

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- 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 does not propose the addition of any new health service facility beds, services, or equipment for which there is a need determination in the 2018 SMFP.
  - The applicant adequately demonstrates that the application is consistent with all applicable policies in the SMFP.
- (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 develop a dedicated C-section OR at Pardee for a total of 11 ORs upon project completion. Currently, Pardee has 10 shared ORs. The applicant states that it currently performs C-sections and attempts to create a de facto dedicated C-section OR by not scheduling surgeries in one of its 10 shared ORs, but it is now impractical to do so.

## **Patient Origin**

On page 57, the 2018 SMFP defines the service area for ORs as “...*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.*” Thus, the service area for this facility consists of Henderson County. Facilities may also serve residents of counties not included in their service area.

In Section C, page 19, the applicant provides current and projected patient origin, as shown in the table below.

<b>Pardee Patient Origin – C-Section Cases</b>				
	<b>Historical (7/1/16 – 6/30/17)</b>		<b>OY 3 Projected (7/1/23 – 6/30/24)</b>	
<b>County</b>	<b># of Patients</b>	<b>% of Total</b>	<b># of Patients</b>	<b>% of Total</b>
Henderson	82	80.4%	164	80.4%
Transylvania	10	9.8%	20	9.8%
Polk	3	2.9%	6	2.9%
Buncombe	2	2.0%	4	2.0%
Rutherford	2	2.0%	4	2.0%
Jackson	1	1.0%	2	1.0%
Other*	2	2.0%	4	2.0%
<b>Total</b>	<b>102</b>	<b>100.0%</b>	<b>204</b>	<b>100.0%</b>

Table may not foot due to rounding.

\* Includes Pickens and Spartanburg counties in South Carolina.

In Section C, page 20, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported.

### **Analysis of Need**

In Section C, pages 20-25, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services:

- Demographics – the Henderson County population of women of child-bearing age (ages 18-44) is projected to increase at a higher rate than the overall population of Henderson County over the next 10 years (page 21).
- Best Practice – in order to conform to best practices when responding to an emergency C-section, a dedicated C-section OR is required. Without a dedicated C-section OR, the staff must wait for an available OR and change equipment in the available OR to prepare it for an emergency C-section, which may cause the hospital to fail to conform to best practices and increases the risk to mothers and babies (pages 21-22).
- Impact on Operations – while it was possible to hold open one OR for dedicated C-section use in the past, growth in utilization of the ORs means that Pardee can no longer hold open a dedicated OR for C-sections, and scheduling other surgeries in the available ORs while trying to maintain space for emergency C-sections results in schedules which are inefficient and inconvenient for both staff and patients (page 22).
- Increased Utilization – the applicant states that the number of surgical cases from FY 2015 to FY 2018 (annualized) has grown at a compound annual growth rate (CAGR) of 7.8 percent. This is due in part to increases in inpatient cases, which have longer case times, and which require greater OR capacity. The applicant also states that, based on the number of cases it has performed, and applying the 2018 SMFP OR Methodology to those cases, its total surgical hours have increased at a CAGR of 8.7 percent between FY 2015 and FY 2018. The applicant states that, using the 2018 SMFP OR Methodology, it currently demonstrates a need for 8.5 ORs, and should the 8.7 percent CAGR continue through the

end of FY 2021, Pardee will demonstrate a need for 11 ORs – more than it will have at that time even if the proposed project is approved (pages 22-24).

The information is reasonable and adequately supported for the following reasons:

- The applicant uses publicly available data to document the projected increase in population in its service area.
- The applicant uses its own historical data to demonstrate increases in historical utilization.
- The applicant uses the methodology in the 2018 SMFP combined with its own historical data to project future utilization of its ORs.

*Projected Utilization*

In Section Q, the applicant provides historical and projected utilization as illustrated in the following table.

<b>Pardee Historical and Projected Utilization – C-Section Cases</b>				
	<b>Historical (7/1/16 – 6/30/17)</b>		<b>OY 3 Projected (7/1/23 – 6/30/24)</b>	
<b>County</b>	<b># of Patients</b>	<b>% of Total</b>	<b># of Patients</b>	<b>% of Total</b>
Henderson	82	80.4%	164	80.4%
Transylvania	10	9.8%	20	9.8%
Polk	3	2.9%	6	2.9%
Buncombe	2	2.0%	4	2.0%
Rutherford	2	2.0%	4	2.0%
Jackson	1	1.0%	2	1.0%
Other*	2	2.0%	4	2.0%
<b>Total</b>	<b>102</b>	<b>100.0%</b>	<b>204</b>	<b>100.0%</b>

Table may not foot due to rounding.

\* Includes Pickens and Spartanburg counties in South Carolina.

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

- The applicant uses historical data on C-sections performed at Pardee to calculate a historical average growth rate of 9.3 percent:

<b>Pardee Historical C-Section Utilization</b>					
	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>	<b>FY 2018*</b>	<b>CAGR</b>
C-Sections	92	83	102	120	9.3%

Source: Pardee internal data

\*FY 2018 based on July 2017 – January 2018 annualized.

- The applicant then applied the 9.3 percent growth rate, beginning with the data from FY 2018, to project the number of future C-sections that will be performed at Pardee through the third full fiscal year following project completion.

<b>Pardee Historical C-Section Utilization</b>								
	<b>FY 2018*</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>CAGR</b>
C-Sections	120	131	143	157	171	187	204	9.3%

\*FY 2018 based on July 2017 – January 2018 annualized.

Projected utilization is reasonable and adequately supported for the following reasons:

- The applicant uses historical data to project future utilization.
- The applicant adequately demonstrates that a dedicated C-Section OR is needed in addition to the 10 existing shared ORs.

**Access**

In Section C.8, pages 27-28, the applicant states:

*“Pardee is committed to providing care to anyone in need and does not deny access to non-elective care because of race, sex, creed, age, handicap, financial status, or lack of medical insurance. All area residents, including low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups, will have access to the dedicated C-Section operating room as they do currently with the existing shared operating rooms that are used for C-Sections.*

*The proposed project will be designed in accordance with the latest State of North Carolina and Federal guidelines for handicapped accessibility. The project incorporates all applicable provisions of the Americans with Disabilities Act.”*

In Section L.3, page 62, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

<b>Pardee Projected Payor Mix – FY 2023</b>		
<b>Payor Source</b>	<b>Pardee Total</b>	<b>C-Section Cases</b>
Medicare	58.5%	0.0%
Medicaid	19.0%	70.6%
Commercial/Managed Care	14.2%	28.4%
Other	0.5%	0.0%
Self-Pay	7.8%	1.0%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>

The projected payor mix is reasonable and adequately supported.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- 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, eliminate, 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.

C

The applicant proposes to develop a dedicated C-section OR at Pardee for a total of 11 ORs upon project completion.

In Section E, pages 37-38, 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
- Develop a New Dedicated C-Section OR on the Second Floor

On page 38, the applicant states that its proposal is the most effective alternative because it needs the dedicated C-section OR to most effectively and efficiently provide care to its patients and locating the new dedicated C-section OR on the first floor in the surgical services suite is the most cost-effective and efficient option.

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 criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- 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 for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Henderson County Hospital Corporation shall materially comply with all representations made in the certificate of need application.**
- 2. Henderson County Hospital Corporation shall develop one new dedicated C-section operating room at Margaret R. Pardee Memorial Hospital.**
- 3. Upon completion of the project, Margaret R. Pardee Memorial Hospital shall be licensed for no more than one dedicated C-section operating room and no more than 11 total operating rooms.**
- 4. Henderson County Hospital Corporation shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section F of the application and that would otherwise require a certificate of need.**
- 5. Henderson County Hospital Corporation shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.**

6. **No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Henderson County Hospital Corporation 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.**
  7. **Henderson County Hospital Corporation 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 develop a dedicated C-section OR at Pardee for a total of 11 ORs upon project completion.

**Capital and Working Capital Costs**

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

<b>Pardee Capital Costs</b>	
<b>Item</b>	<b>Cost</b>
Construction/Renovation Contract	\$2,551,000
Architect/Engineering Fees	\$556,000
Medical Equipment	\$2,159,000
Non-Medical Equipment	\$204,000
Financing Costs	\$150,000
Interest During Construction	\$230,000
<b>Total</b>	<b>\$5,850,000</b>

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

In Section F, page 41, the applicant projects that there will be no start-up costs or initial operating costs since Pardee is already providing this type of service.

**Availability of Funds**

In Section F, page 40, the applicant states that the entire capital cost will be funded through a loan. Exhibit F.2 contains a letter from a senior vice president at First Citizens Bank, expressing interest in financing a loan for the expected project cost.

**Financial Feasibility**

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.4, the applicant projects that operating expenses will exceed revenues in the first three operating years of the project, as shown in the table below.

<b>Pardee Revenues and Operating Expenses – C-Section Services</b>			
	<b>1<sup>st</sup> FFY FY 2022</b>	<b>2<sup>nd</sup> FFY FY 2023</b>	<b>3<sup>rd</sup> FFY FY 2024</b>
Total # of C-Sections	171	187	204
Total Gross Revenues (Charges)	\$3,674,736	\$4,135,498	\$4,654,034
Total Net Revenue	\$453,544	\$510,413	\$574,411
Average Net Revenue per C-Section	\$2,652	\$2,729	\$2,816
Total Operating Expenses (Costs)	\$1,539,489	\$1,604,482	\$1,677,458
Average Operating Expense per C-Section	\$9,003	\$8,580	\$8,223
Net Income	(\$1,085,945)	(\$1,094,069)	(\$1,103,047)

The applicant also provides the projections for revenues and operating expenses for the entire hospital on Form F.3. In the projections for the entire hospital, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

<b>Pardee Revenues and Operating Expenses – Entire Hospital</b>			
	<b>1<sup>st</sup> FFY FY 2022</b>	<b>2<sup>nd</sup> FFY FY 2023</b>	<b>3<sup>rd</sup> FFY FY 2024</b>
Total Gross Revenues (Charges)	\$840,983,336	\$883,032,503	\$927,184,128
Total Net Revenue	\$282,557,312	\$296,685,178	\$311,519,437
Total Operating Expenses (Costs)	\$276,890,444	\$288,596,760	\$300,810,455
Net Income	\$5,666,868	\$8,088,418	\$10,708,981

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
- Remarks made at the public hearing
- 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 demonstrates that the capital cost is 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 develop a dedicated C-section OR at Pardee for a total of 11 ORs upon project completion.

On page 57, the 2018 SMFP defines the service area for ORs as “...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.” Thus, the service area for this facility consists of Henderson County. Facilities may also serve residents of counties not included in their service area.

The operating room inventory of Henderson County is shown in the table below.

<b>Henderson County Operating Room Inventory – 2018 SMFP (10/1/15 – 9/30/16)</b>				
<b>Facility</b>	<b>Inpatient ORs</b>	<b>Shared ORs</b>	<b>Dedicated C-Section ORs</b>	<b># of C-Sections</b>
Park Ridge Health	1	6	1	154
Pardee	0	10	0	119
<b>Total</b>	<b>1</b>	<b>16</b>	<b>1</b>	<b>273</b>

In Section G, pages 46-47, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dedicated C-section OR services in Henderson County. The applicant states:

*“Pardee currently performs C-Sections in its shared operating rooms, but given the growth in its overall surgical case volume, this practice creates scheduling challenges and inefficiencies. The need for a dedicated C-Section room at Pardee is largely*

*qualitative in nature. As a community hospital serving its community, it is critical that Pardee ensure the availability of an operating room that is equipped specifically to perform C-Sections at all times, particularly in urgent and emergent situations. No other provider can meet this internal need at Pardee to provide the best care specifically for its patients; as such, the dedicated C-Section room at Pardee will not duplicate the dedicated C-Section room located at Park Ridge Health, which is utilized to meet the specific needs of its patient population.”*

The applicant adequately demonstrates that the proposal will not result in an unnecessary duplication of existing or approved services in the service area because the applicant adequately demonstrates that the proposed dedicated C-section OR is needed in addition to the existing or approved ORs and dedicated C-section ORs in Henderson County.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- 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 for 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, Form H, the applicant provides current and projected staffing for the proposed services. The applicant does not project any staffing changes as a result of the development of the dedicated C-section operating room.

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4, which is found in Section Q. In Section H, pages 48-49, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 49, the applicant identifies the current Chair of the Department of Surgery and the Chair of the Department of Obstetrics and Gynecology. In Exhibit H.4, the applicant provides letters from the Chairs indicating their support for the proposed services. In Section H, page 49, the applicant describes its physician recruitment plans.

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
- Remarks made at the public hearing
- 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 for the reasons stated above.

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

C

In Section I, page 51, the applicant states that the following ancillary and support services are necessary for the proposed services:

- Laboratory services
- Anesthesia services
- Pre- and post-operative services

On page 51, the applicant adequately explains how it already provides these ancillary and support services and provides supporting documentation in Exhibit I.1.

In Section I, pages 51-53, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2.

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

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- 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.

- (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.

C

In Section K, page 55, the applicant states that the project involves renovating 3,600 square feet of existing space. Line drawings are provided in Exhibit C.1.

On page 56, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal, and why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

On page 56, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- 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.

- (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 61, the applicant provides the historical payor mix for the proposed services during FY 2017, as shown in the table below.

<b>Pardee Historical Payor Mix – FY 2017</b>		
<b>Payor Source</b>	<b>Pardee Total</b>	<b>C-Section Cases</b>
Medicare	58.5%	0.0%
Medicaid	19.0%	70.6%
Commercial/Managed Care	14.2%	28.4%
Other	0.5%	0.0%
Self-Pay	7.8%	1.0%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>

Source: Pardee internal data

In Section L, pages 60-61, the applicant provides the following comparison.

	<b>Percentage of Total Patients Served by Pardee during FY 2017</b>	<b>Percentage of the Population of the Service Area</b>
Female	52.5%	51.5%
Male	47.5%	48.5%
Unknown	--	--
64 and Younger	50.5%	74.5%
65 and Older	49.5%	25.5%
American Indian	0.1%	0.5%
Asian	0.1%	1.2%
Black or African-American	4.2%	3.5%
Native Hawaiian or Pacific Islander	0.0%	0.2%
White or Caucasian	89.9%	87.7%
Other Race	2.9%	7.0%
Declined / Unavailable	2.7%	--

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- 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, page 61, the applicant states that it is not obligated to provide any such care.

In Section L, page 62, 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.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- 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.

- (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 62, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

<b>Pardee Projected Payor Mix – FY 2023</b>		
<b>Payor Source</b>	<b>Pardee Total</b>	<b>C-Section Cases</b>
Medicare	58.5%	0.0%
Medicaid	19.0%	70.6%
Commercial/Managed Care	14.2%	28.4%
Other	0.5%	0.0%
Self-Pay	7.8%	1.0%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>

Source: Pardee internal data

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 7.8 percent of total services will be provided to self-pay patients, 58.5 percent to Medicare patients, and 19 percent to Medicaid patients.

On page 62, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based entirely on the historical payor mix.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- 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.

- (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 63, the applicant adequately describes the range of means by which patients will have access to the proposed services.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- 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.

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

C

In Section M, page 64, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.1.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- Information which was publicly available during the review and used by the Agency

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 develop a dedicated C-section OR at Pardee for a total of 11 ORs upon project completion.

On page 57, the 2018 SMFP defines the service area for ORs as “...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.” Thus, the service area for this facility consists of Henderson County. Facilities may also serve residents of counties not included in their service area.

The operating room inventory of Henderson County is shown in the table below.

<b>Henderson County Operating Room Inventory – 2018 SMFP (10/1/15 – 9/30/16)</b>				
<b>Facility</b>	<b>Inpatient ORs</b>	<b>Shared ORs</b>	<b>Dedicated C-Section ORs</b>	<b># of C-Sections</b>
Park Ridge Health	1	6	1	154
Pardee	0	10	0	119
<b>Total</b>	<b>1</b>	<b>16</b>	<b>1</b>	<b>273</b>

In Section N, pages 65-66, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality, and access to the proposed services. On pages 65-66, the applicant states:

*“...Pardee elected to develop the dedicated C-section room in the most cost effective way possible by locating it in newer construction within the existing surgical services suite. The proposed co-location of the C-Section room with the existing surgical services suite will also obviate the need for duplicative space and support services, further enhancing the cost effectiveness of the proposed project.*

*...The development of a dedicated C-Section room will ensure that the hospital always has an operating room available that is equipped and set up specifically for C-Section, thus enhancing the quality of care provided, particularly for patients in need of an urgent or emergent C-Section and for mothers who fail to progress with labor. ...*

...

*...in FY 2017, more than 70 percent of C-Sections performed at Pardee were performed on Medicaid recipients. The proposed project will increase access for Pardee’s women’s and children’s patients, specifically dedicated C-Section services, regardless of the patient’s payor source.”*

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits).
- Quality services will be provided (see Section O of the application and any exhibits).
- Access will be provided to underserved groups (see Section L of the application and any exhibits).

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- 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 for the reasons stated above.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

According to its 2018 License Renewal Application (LRA), Pardee is managed by UNC Hospitals at Chapel Hill (UNC). UNC or a related entity owns, operates, or manages nine hospitals in North Carolina.

In Section O, pages 72-73, the applicant states that, during the 18 months immediately preceding the submittal of the application, there was one incident related to quality of care at Pardee. The applicant states that all of the problems have been corrected and that it is now operating in compliance with all Medicare Conditions of Participation. 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 three UNC-affiliated facilities, including Pardee, and one facility is awaiting results of an EMTALA investigation. 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 nine facilities, the applicant provides 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 develop a new dedicated C-section OR. The Criteria and Standards for Surgical Services and Operating Rooms, which are promulgated in 10A NCAC 14C .2100, are not applicable to this review because the applicant does not propose to:

- Develop a new ambulatory surgical facility.
- Develop a new campus of an existing facility.
- Develop a new hospital.
- Convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program.

- Add a specialty to a specialty ambulatory surgical program.
- Increase the number of ORs which are not dedicated C-section ORs in the facility or in the service area.
- Increase the number of dedicated C-section ORs in a facility which already has at least one dedicated C-section OR.