

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 1, 2020

Findings Date: May 1, 2020

Project Analyst: Gregory F. Yakaboski

Team Leader: Gloria C. Hale

Project ID #: B-11860-20

Facility: Pardee Mobile Mammography

FID #: 200140

County: Henderson

Applicant: Pardee Imaging, LLC

Project: Develop mobile mammography services

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

Pardee Imaging, LLC (the applicant) proposes to develop a mobile mammography service and serve Henderson, Buncombe, Polk, and Transylvania counties. The applicant proposes to acquire and operate mobile mammography equipment and a mobile mammography coach, the total equipment cost of which will exceed the statutory threshold of \$500,000; therefore, the equipment qualifies the facility as a diagnostic center, which is a new institutional health service and requires a Certificate of Need (CON). The new diagnostic center (the mobile mammography service) will be known as Pardee Mobile Mammography. The applicant is wholly owned by Henderson County Hospital Corporation which does business as Margaret R. Pardee Memorial Hospital hereinafter referred to as either Pardee UNC Health Care or Pardee.

N.C. Gen. Stat. 131E-176(7a) states:

““Diagnostic center” means a freestanding facility, program, or provider, including but not limited to, physicians’ offices, clinical laboratories, radiology centers, and mobile diagnostic programs, in which the total cost of all the medical diagnostic equipment utilized by the facility which cost ten thousand dollars (\$10,000) or more exceeds five hundred thousand dollars (\$500,000). In determining whether the medical diagnostic equipment in a diagnostic center costs more than five hundred thousand dollars (\$500,000), the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater.”

Need Determination

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) nor acquire any medical equipment for which there is a need determination in the 2020 SMFP.

Policies

The applicant does not propose to offer a new institutional health service for which there are any applicable policies in the 2020 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 develop a new diagnostic center which will be comprised of a mobile mammography unit.

Designation as a Diagnostic Center

In Section C, page 24, the applicant states the proposed diagnostic center will offer a mobile mammography service. In Section C, page 28, and Section Q, Form F.1-a, the applicant provides a table showing the new medical diagnostic equipment and coach with each costing over \$10,000, which is summarized below:

| Pardee Mobile Mammography: Medical Diagnostic Equipment | | |
|--|------------------------|------------------|
| Equipment | Number of Units | Cost |
| Hologic Selenia Dimensions 3D Performance Mammography System | 1 | \$368,734 |
| Mobile Mammography Coach | 1 | \$397,000 |
| Subtotal | | |
| Other Costs* | | \$99,515 |
| Totals | | \$865,249 |

*See Form F.1a for all non-medical equipment costs.

As shown in the table above, the combined cost of the medical diagnostic equipment is more than \$500,000 and therefore a certificate of need is required to develop a diagnostic center.

Patient Origin

N.C.G.S. §131E-176(24a) states: “Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services from a health service facility.” The 2020 SMFP does not define a service area for diagnostic centers, nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant. In Section C, page 24 the applicant identifies the service area as Henderson, Polk, Buncombe and Transylvania counties. Facilities may also serve residents of counties not included in their service area.

The following table illustrates projected patient origin.

| County | First Full FY of Operation following Project Completion (7/1/2021 to 6/30/2022) | | Second Full FY of Operation following Project Completion (7/1/2022 to 6/30/2023) | | Third Full FY of Operation following Project Completion (7/1/2023 to 6/30/2024) | |
|--------------|---|---------------|--|---------------|---|---------------|
| | Patients | % of Total | Patients | % of Total | Patients | % of Total |
| Henderson | 1,658 | 82.9% | 2,487 | 82.9% | 3,316 | 82.9% |
| Polk | 104 | 5.2% | 157 | 5.2% | 209 | 5.2% |
| Transylvania | 83 | 4.2% | 125 | 4.2% | 167 | 4.2% |
| Buncombe | 69 | 3.4% | 103 | 3.4% | 138 | 3.4% |
| Other* | 85 | 4.3% | 128 | 4.3% | 171 | 4.3% |
| Total | 2,000 | 100.0% | 3,000 | 100.0% | 4,000 | 100.0% |

Source: Table on page 30 of the application.

*Applicant provides full list of counties covered by “Other” on page 30.

In Section C, page 30, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported because they are based on Pardee historical patient origin for mammography services from the same counties.

Analysis of Need

In Section C, pages 31-34, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, which is summarized below:

- The need for mobile mammography services in western North Carolina due to underuse of mammography services by several medically underserved demographic groups including uninsured women, women who reside in rural areas, racial and ethnic minority women and women with lower income (see pages 31-32);
- The demographics in Henderson, Buncombe, Polk, and Transylvania counties show that breast cancer is the most frequently diagnosed cancer in these four counties and the percentage of the female population age 40 and over in these counties exceeds the state as a whole (see pages 32-33); and
- The need for mobile mammography services to be offered by Pardee Imaging which can offer state-of-the-art advanced breast diagnostic services including extensive experience providing cancer services (see pages 33-34).

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

- The applicant provides data and information regarding the incidence of breast cancer in Buncombe, Henderson, Polk and Transylvania counties, the benefits of yearly screening and early diagnosis and Pardee’s expertise in this area.
- The applicant provides population projections for the service area to support the projected need for mammography services.
- The applicant provides documentation of the current problems and issues related to increasing the utilization of mammography services by women age 40 and up in the proposed service area including access issues and provides a comprehensive strategy to provide mammography services “*on-site where they live and work*” in partnership with local businesses and physician practices.

Projected Utilization

In Section Q, Form C, the applicant provides projected utilization, as illustrated in the following table.

| | First Full FY (7/1/2021 to 6/30/2022) | Second Full FY (7/1/2022 to 6/30/2023) | Third Full FY (7/1/2023 to 6/30/2024) |
|-----------------|--|---|--|
| # of Units | 1 | 1 | 1 |
| # of Screenings | 2000 | 3000 | 4000 |

In Section Q, and in supplemental information, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The first full operating year (OY) is July 1, 2021 to June 30, 2022 which corresponds to Pardee Imaging’s fiscal year and the State Fiscal Year (SFY).

- A mammography screening is defined as a patient visiting the mammography unit one time/trip.
- The number of working weeks in each OY is 50 weeks.
- The applicant projects a ramp up in the number of days per week that the mobile mammography unit will actively be in use: OY1-2 days per week; OY2-3 days per week; and OY3-4 days per week.
- Pardee Imaging projects capacity of the mobile mammography unit as 28 screening per screening day based on a 10-hour day, 4 screenings per hour and 3 hours of the day dedicated to travel and set up [10 hours – 3 hours = 7 hours x 4 screenings per hour = 28 screenings per day]
- The applicant projected capacity for Pardee Mobile Mammography as shown in the following table.

Pardee Mobile Mammography: Projected Capacity

| | OY1 (SFY2022) | OY2 (SFY2023) | OY3 (SFY2024) |
|--|---------------|---------------|---------------|
| Screening Days per Week | 2 | 3 | 4 |
| Total # of Annual Screening Days based on 50 weeks | 100 | 150 | 200 |
| Projected 28 Screenings per Day | 28 | 28 | 28 |
| Total Screening Capacity per year | 2,800 | 4,200 | 5,600 |

In Section Q, Form C Utilization-Assumptions and Methodology, pages 3-4, the applicant then projected mammography screenings and utilization rate for the first three OY's:

- Based on estimated demand for mobile mammography services by the organizations that will be providing the host sites the applicant estimates demand for mammography screenings as 5,120 screenings annually.
- Further, again based on identified host sites and communications the applicant assumes that for each day of its operational year it will provide, on average, 20 mammography screenings per working day of the year which results in projections of 2,000, 3,000 and 4,000 mammography screenings for OY1-OY3 respectively, as shown in the table below.

Pardee Mobile Mammography: Projected Screenings and Projected Utilization Rate

| | | OY1 (SFY2022) | OY2 (SFY2023) | OY3 (SFY2024) |
|---|--|---------------|---------------|---------------|
| a | Screening Days per Week | 2 | 3 | 4 |
| b | Total # of Annual Screening Days based on 50 weeks | 100 | 150 | 200 |
| c | Projected 20 Screenings per Day | 20 | 20 | 20 |
| d | Total Projected Screenings per year | 2,000 | 3,000 | 4,000 |
| e | Screening Capacity | 2,800 | 4,200 | 5,600 |
| f | Projected Utilization (d/e = f) | 71% | 71% | 71% |

To further support projected utilization, in Section Q, Form C, and in supplemental information the applicant analyzed overall demand and current mammography screenings in the proposed service area.

- Since annual screening mammograms are recommended for all women beginning at the age of 40, the applicant calculated the female population age 40 and over in the proposed service area based on data from the North Carolina Office of State Budget and Management (NCOSBM) as illustrated in the table below.

Female Population Age 40 and Over in the Service Area

| | 2020 | 2024 | CAGR |
|--------------|----------------|----------------|-------------|
| Henderson | 38,134 | 40,162 | 1.3% |
| Buncombe | 76,717 | 81,985 | 1.7% |
| Transylvania | 12,127 | 12,738 | 1.2% |
| Polk | 7,249 | 7,447 | 0.7% |
| Total | 134,227 | 142,332 | 1.5% |

Source: NCOSBM, Exhibit C.4-5.

In Section G.1, page 57, and in supplemental information the applicant identifies only one other provider of mobile mammography services in the propose service area, Invision Diagnostics, and further states that it is not aware of any public data source that provides an inventory of existing or approved mobile mammography units. In Section G.2, and in supplemental information the applicant states that it is unaware of any public source, such as the SMFP or license renewal applications, which provide total annual utilization for either Invision Diagnostics or other mobile mammography providers.

In supplemental information the applicant identified the fixed mammography units in the proposed service area from the 2020 License Renewal Applications (LRA's).

| | # of Units | Procedures/Screenings |
|--------------------------------|------------|-----------------------|
| Henderson County | | |
| AdventHealth Hendersonville | 1 | 3,991 |
| Pardee Memorial Hospital | 1 | 18,920 |
| Henderson County Total | 2 | 22,911 |
| Buncombe County | | |
| Mission Hospital | 7 | 41,130 |
| Polk County | | |
| St. Lukes Hospital | 1 | 1,389 |
| Transylvania County | | |
| Transylvania Regional Hospital | 1 | 3,376 |
| Total | 11 | 68,806 |

Source: 2020 License Renewal Applications

If women age 40 and over total 134,227 in 2020 and total possible mammography screenings at fixed mammography units totaled 68,806 in the 2020 LRA's, that leaves a potential patient base of approximately 65,421 in need of annual mammography screenings in the proposed service area. Even then, factoring women age 40 and over who receive annual mammography screenings from the other mobile mammography unit operating in the service area based on

the above factors there is significant demand for the proposed mobile mammography services far in excess of Pardee Mobile Mammography’s projected utilization.

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

- Projected utilization is based on population data from NCOSBM and historical data regarding mammography screenings in the proposed service area from LRA’s.
- The applicant projects reasonable “ramp up” times and screenings based on the number of existing fixed and mobile mammography units in the proposed service area, the number of women age 40 and over in the service area, a group for whom annual mammography screenings are recommended, increasing awareness of the services by the providers and patients in the community over the time period, and capacity of the mobile mammography unit based on Pardee’s experience and research.
- In Exhibit I.2, the applicant provides copies of letters of support for the proposed project which support the applicant’s intent to increase its utilization, in part, through community partnerships and increased knowledge of screening availability.
- The applicant provides reasonable and adequately supported information to justify the need for the mobile mammography service.

Access

In Section C, pages 40-41, the applicant states,

“Pardee Imaging 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 proposed diagnostic center.”

In Section L, page 72, 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 Category | Mammography Services as Percent of Total |
|-----------------------|---|
| Self-Pay | 24.8% |
| Medicare* | 9.5% |
| Medicaid* | 37.1% |
| Insurance* | 28.6% |
| Total | 100.0% |

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- 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 develop a new diagnostic center which will be comprised of a mobile mammography unit.

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 this option would not meet the need within the proposed service area for improved access to mammography screenings. Therefore, this is not an effective alternative.

- Develop a Fixed Mammography Unit- The applicant states this option would not address the regional travel barriers which especially impact medically underserved women who cannot travel to Henderson limiting their access to mammography screenings. Therefore, this is not an effective alternative.

On page 49, the applicant states that its proposal is the most effective alternative because the mobile mammography unit would increase access of medically underserved women to mammography screenings throughout the proposed service area.

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

- The application is conforming to all statutory and regulatory review 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
- Supplemental information requested 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. Pardee Imaging, LLC shall materially comply with all representations made in the certificate of need application and any supplemental responses. In the event that representations conflict, Pardee Imaging, LLC shall materially comply with the last made representation.**
- 2. Pardee Imaging, LLC shall develop a diagnostic center consisting of one mobile mammography unit.**
- 3. Pardee Imaging, LLC, as part of this project, shall not acquire any equipment that is not included in the project's proposed capital expenditures in Section Q, Form F.1a of the application and that would otherwise require a certificate of need.**
- 4. The acquisition of the mobile mammography unit shall constitute development of a mobile diagnostic program and shall not result in the creation of a diagnostic center located at any of the host sites.**

5. **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, Pardee Imaging, LLC 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.**

6. **Pardee Imaging, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to insurance 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 new diagnostic center which will be comprised of a mobile mammography unit.

Capital and Working Capital Costs

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

| | |
|---------------------|------------------|
| Site Costs | \$85,000 |
| Construction Costs | \$0.00 |
| Miscellaneous Costs | \$780,249 |
| Total | \$865,249 |

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

In Section F, page 52, the applicant projects that start-up costs will be \$19,814 and initial operating expenses will be \$29,721 for a total working capital of \$49,535. On pages 52-53, the applicant provides the assumptions and methodology used to project the working capital needs of the project.

Availability of Funds

In Section F, page 50, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing

| Type | Pardee Imaging | Total |
|---|------------------|------------------|
| Loans | \$0 | \$0 |
| Accumulated reserves or OE* of Pardee | \$113,249 | \$113,249 |
| Bonds | \$0 | \$0 |
| Other (Pardee Hospital Foundation Contribution) | \$752,000 | \$752,000 |
| Total Financing | \$865,249 | \$865,249 |

* OE = Owner's Equity

In Section F, page 53, the applicant states that the working capital needs of the project will be funded, as shown in the table below.

| Sources of Financing for Working Capital | | Amount |
|--|--|-----------------|
| (a) | Loans | \$0 |
| (b) | Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity | \$49,535 |
| (c) | Lines of credit | \$0 |
| (d) | Bonds | \$0 |
| (e) | Total | \$49,535 |

Exhibit F.2-1 contains a copy of a letter dated February 17, 2020 from the Chief Financial Officer of Pardee UNC Health Care which states that *“Pardee will be responsible for the capital costs and working capital needs of the project. ... Pardee expects to receive donations and grants from charitable organizations in the amount of \$725,000 through a contribution from the Pardee Hospital Foundation. Pardee will fund the balance of the project cost... and working capital needs through accumulated cash reserves. Pardee is committed to funding the entirety of the project capital costs and working capital needs with existing accumulated reserves if needed.”*

In supplemental information the applicant provided a copy of a letter dated April 14, 2020 from the President and CEO of Pardee Imaging, LLC which states, *“Upon receipt of the funds from Pardee, Pardee Imaging, LLC will use those funds to develop the proposed project.”*

Exhibit F.2-1 also contains a copy of Pardee's audited financial statements showing cash and cash equivalents of \$16.2 million and net total assets of \$117.6 million as of June 30, 2019. Therefore, the applicant demonstrated adequate availability of funds.

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.

| | 1 st FFY | 2 nd FFY | 3 rd FFY |
|---|---------------------|---------------------|---------------------|
| Total Procedures (Screenings) | 2,000 | 3,000 | 4,000 |
| Total Gross Revenues (Charges) | \$1,390,314 | \$2,148,036 | \$2,949,969 |
| Total Net Revenue | \$467,189 | \$721,807 | \$991,282 |
| Average Net Revenue per Procedure (Screening) | \$234 | \$241 | \$248 |
| Total Operating Expenses (Costs) | \$361,376 | \$514,612 | \$628,745 |
| Average Operating Expense per Procedure (Screening) | \$181 | \$172 | \$157 |
| Net Income | \$105,814 | \$207,195 | \$362,537 |

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
- Supplemental information requested by the Agency

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 and working capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working 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 new diagnostic center which will be comprised of a mobile mammography unit.

N.C.G.S. §131E-176(24a) states: “Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services from a health service facility.” The 2020 SMFP does not define a service area for diagnostic centers, nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant. In Section C, page 24 the applicant identifies the service area as Henderson, Polk, Buncombe

and Transylvania counties. Facilities may also serve residents of counties not included in their service area.

In Section G.1, page 57, and in supplemental information the applicant identifies only one other provider of mobile mammography services in the propose service area, Invision Diagnostics, and further states that it is not aware of any public data source that provides an inventory of existing or approved mobile mammography units. In Section G.2, and in supplemental information the applicant states that it is unaware of any public source, such as the SMFP or license renewal applications, which provide total annual utilization for either Invision Diagnostics or other mobile mammography providers.

In supplemental information, the applicant identified the fixed mammography units in the proposed service area from the 2020 License Renewal Applications.

| | # of Units | Procedures |
|--------------------------------|------------|---------------|
| Henderson County | | |
| AdventHealth Hendersonville | 1 | 3,991 |
| Pardee Memorial Hospital | 1 | 18,920 |
| Henderson County Total | 2 | 22,911 |
| Buncombe County | | |
| Mission Hospital | 7 | 41,130 |
| Polk County | | |
| St. Lukes Hospital | 1 | 1,389 |
| Transylvania County | | |
| Transylvania Regional Hospital | 1 | 3,376 |
| Total | 11 | 68,806 |

Source: 2020 License Renewal Applications

In Section G, page 57, and supplemental information, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved mammography services in the proposed service area. The applicant states,

“The mobile mammography services proposed in this application are needed to ensure that residents of Henderson, Buncombe, Polk, and Transylvania counties have adequate access to this vital diagnostic screening tool. The residents of each of these counties currently have access to fixed mammography services; however, as noted previously, despite such access, mammography services remain underused by several medically underserved demographic groups, including uninsured women, women with lower incomes, racial and ethnic minority women, and women who reside in rural areas. Further, while residents of Henderson, Buncombe, Polk, and Transylvania counties have very limited access to a mobile mammography service serving western North Carolina, that service is based out of Charlotte. Given the geography and demographics of western North Carolina, access to a single mobile provider is simply not adequate, particularly one that is based more than 100 miles and nearly two hours drive time from Hendersonville.”

In supplemental information the applicant states,

“Based on Pardee Memorial Hospital’s (Pardee) experience, the majority of fixed mammography scans are performed as part of screening mammography scans (approximately 75 percent based on Pardee’s experience) with the remaining 25 percent performed as part of other diagnostic scans or biopsies. Thus, some portion of the 68,806 scans identified above are not screening mammograms. As shown in its Form C Utilization – Assumptions and Methodology, Pardee Imaging estimates that currently more than 134,000 women in these same counties require annual screening mammograms, or nearly two times the number of total mammograms provided in 2019.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based because the applicant adequately demonstrates that the proposed mobile mammography unit is needed in addition to the existing or approved mammography services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- 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, Form H, the applicant provides the projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

| Position | Projected FTE Staff | | |
|-------------------------|---|---|---|
| | 1 st Full Fiscal Year (7/1/21 to 6/30/22) | 2 nd Full Fiscal Year (7/1/22 to 6/30/23) | 3 rd Full Fiscal Year (7/1/23 to 6/30/24) |
| Radiology Technologists | 1.00 | 1.50 | 2.00 |
| Scheduler/Driver | 0.50 | 0.75 | 1.00 |
| TOTAL | 1.50 | 2.25 | 3.00 |

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 59-60, the applicant describes the methods to be used to recruit or fill new positions and its proposed

training and continuing education programs. In supplemental information the applicant identifies Dr. Scott Prechter as the proposed medical director.

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
- Supplemental information requested 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 61, the applicant states that the following ancillary and support services are necessary for the proposed services:

- Image interpretation
- Quality improvement
- Payor contracting
- Marketing
- Human resources
- Billing and collections

On page 61, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1.

In Section I, pages 61-63, the applicant describes its efforts to develop relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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:
- would be available under a contract of at least 5 years duration;
 - would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - would cost no more than if the services were provided by the HMO; and
 - 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 or renovate any existing 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

The applicant is wholly owned by Pardee. The proposed project involves the development of a new health service facility, thus there is no historical data. For comparison, in Section L, page 71, the applicant provides the historical payor mix for Pardee during the last full fiscal year (7/1/2018 to 6/30/2019) for fixed mammography services, as shown in the table below.

| Payor Category | Mammography Services as Percent of Total |
|-----------------------------------|---|
| Self-Pay | 1.4% |
| Medicare* | 55.5% |
| Medicaid* | 1.4% |
| Insurance* | 36.5% |
| Other (Other Govt, Worker's Comp) | 5.3% |
| Total | 100.0% |

Source: Table on page 71 of the application.

*Including any managed care plans.

The proposed project involves the development of a new health service facility. In Section L, page 70, the applicant provides the following comparison based on the last full fiscal year for Pardee as a whole.

| | Percentage of Total Patients Served by the Facility or Campus during the Last Full FY | Percentage of the Population of the Service Area |
|-------------------------------------|---|--|
| Female | 61.6% | 52.0% |
| Male | 38.4% | 48.0% |
| Unknown | 0.0% | 0.0% |
| 64 and Younger | 44.4% | 74.2% |
| 65 and Older | 55.6% | 25.8% |
| American Indian | 0.2% | 0.7% |
| Asian | 0.2% | 1.3% |
| Black or African-American | 3.1% | 3.4% |
| Native Hawaiian or Pacific Islander | 0.0% | 0.2% |
| White or Caucasian | 88.2% | 92.5% |
| Other Race | 2.2% | 1.9% |
| Declined / Unavailable | 6.0% | 0.0% |

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

The applicant does not own or operate an existing facility but states, on page 72, that Pardee has not been notified of any civil rights access complaints filed against it or any related entities within the past five years.

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

| Payor Category | Mammography Services as Percent of Total |
|-----------------------|---|
| Self-Pay | 24.8% |
| Medicare* | 9.5% |
| Medicaid* | 37.1% |
| Insurance* | 28.6% |
| Total | 100.0% |

Source: Table on page 72 of the application.

*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 24.8% of total services will be provided to self-pay patients, 9.5% to Medicare patients and 37.1% to Medicaid patients.

On pages 72-73, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the proposed mobile mammography unit's anticipated route and days of service at clinics, businesses and other locations by type based on Pardee's historical experience.

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.5, page 73, 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, page 74, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M.1.

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 develop a new diagnostic center which will be comprised of a mobile mammography unit.

N.C.G.S. §131E-176(24a) states: “*Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services from a health service facility.*” The 2020 SMFP does not define a service area for diagnostic centers, nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant. In Section C, page 24 the applicant identifies the service area as Henderson, Polk, Buncombe

and Transylvania counties. Facilities may also serve residents of counties not included in their service area.

In Section G.1, page 57, and in supplemental information the applicant identifies only one other provider of mobile mammography services in the propose service area, Invision Diagnostics, and further states that it is not aware of any public data source that provides an inventory of existing or approved mobile mammography units. In Section G.2, and in supplemental information the applicant states that it is unaware of any public source, such as the SMFP or license renewal applications, which provide total annual utilization for either Invision Diagnostics or other mobile mammography providers.

In supplemental information the applicant identified the fixed mammography units in the proposed service area from the 2020 License Renewal Applications (LRA's).

| | # of Units | Procedures |
|--------------------------------|------------|---------------|
| Henderson County | | |
| AdventHealth Hendersonville | 1 | 3,991 |
| Pardee Memorial Hospital | 1 | 18,920 |
| Henderson County Total | 2 | 22,911 |
| Buncombe County | | |
| Mission Hospital | 7 | 41,130 |
| Polk County | | |
| St. Lukes Hospital | 1 | 1,389 |
| Transylvania County | | |
| Transylvania Regional Hospital | 1 | 3,376 |
| Total | 11 | 68,806 |

Source: 2020 License Renewal Applications

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 75, the applicant states:

“...the proposed project is expected to enhance competition in the service area by promoting cost effectiveness, quality, and access to diagnostic services.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 75, the applicant states:

“The proposed mobile mammography service will offer low-cost services as a means to increase use among the uninsured and underinsured.”

Regarding the impact of the proposal on quality, in Section N, pages 75-76, the applicant states:

“...as a hospital managed by UNCHCS, Pardee, and ultimately its wholly-owned subsidiary, Pardee Imaging, also will benefit from the experience of UNC Hospitals as well as the experience of Rex Hospital ... in providing mobile mammography services. ... UNC Hospitals and Rex Hospital have seen the benefits of their mobile mammography efforts in their quality metrics- over a six month period, physician clinics utilizing those mobile units

saw an average of 7.1 percent increase in breast cancer screening rates, compared to a 2.8 percent increase across the rest of the physician clinics. UNC hospitals and Rex Hospital have reported that patients enjoy the convenience of scheduling, navigating, parking, and staff and location familiarity associated with the mobile mammography service.”

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 76, the applicant states:

“Pardee Imaging has identified three groups of medically underserved women to target with its proposed mobile mammography service-working women, women who maybe uninsured or underinsured, and women in more distant and rural areas. Pardee Imaging is committed to working in partnership with local businesses and physician practices to bring mammography services to these medically underserved women- on-site where they live and work.”

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, 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
- Supplemental information provided by the applicant
- 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.

- (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, page 77, the applicant states, *“The facility proposed in this application-Pardee Mobile Mammography- is not an existing facility, but rather a new diagnostic center facility. As a wholly-owned subsidiary of Pardee, Pardee Mobile Mammography, will adhere to*

Pardee's existing quality policies. Pardee has in place several policies to ensure quality of care, including Quality Management, Utilization Review, and Risk Management plans. Pardee also participates in the National Database of Nursing Quality Indicators Program." On pages 77-80, the applicant sets forth examples of Pardee's commitment to providing quality patient care.

The applicant is wholly owned by Margaret R. Pardee Memorial Hospital. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision no incidents related to quality of care occurred in Margaret R. Pardee Memorial Hospital. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section, DHSR Section and considering the quality of care provided at Margaret R. Pardee Memorial Hospital, 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 develop a mobile mammography service which will be a diagnostic center. There are no administrative rules that are applicable to proposals for a mobile mammography service or a diagnostic center.