

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: April 29, 2016

Findings Date: April 29, 2016

Project Analyst: Gregory F. Yakaboski

Team Leader: Lisa Pittman

Project ID #: G-11118-16

Facility: Solis Mammography Greensboro

FID #: 160013

County: Guilford

Applicant: Solis North Carolina Diagnostic Imaging & Breast Cancer Management, Inc.

Project: Develop a diagnostic center by acquiring three mammography units and one biopsy system, to replace existing mammography and diagnostic imaging equipment

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

NA

Solis North Carolina Diagnostic Imaging & Breast Cancer Management, Inc. (Solis), also referred to throughout these findings as “the applicant,” proposes to acquire three mammography units and one biopsy system, to replace existing mammography and diagnostic imaging equipment at Solis Mammography Greensboro (Solis Mammography). Solis Mammography is a freestanding outpatient imaging center located at 1126 N. Church Street, Suite 200, in Greensboro. The value of the three mammography units and one biopsy system (\$1,061,849) combined with the existing medical diagnostic equipment already being utilized by Solis Mammography, exceeds the statutory threshold for a diagnostic center of \$500,000; therefore, the acquisition of the proposed equipment requires a certificate of need.

Need Determination

There are no need determinations in the 2016 State Medical Facilities Plan (2016 SMFP) which are applicable to the acquisition of the type of equipment proposed in this application or to the establishment of a diagnostic center.

Policies

There are no policies in the 2016 SMFP which are applicable to this review.

Conclusion

In summary, the applicant does not propose to develop any beds, operating rooms, or other services or acquire equipment for which there is a need determination in the 2016 SMFP. There are no policies in the 2016 SMFP that are applicable to this review. Therefore, this criterion 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

Solis proposes to acquire three mammography units and one biopsy system to replace existing mammography and biopsy equipment at Solis Mammography. Solis Mammography is a freestanding outpatient imaging center located at 1126 N. Church Street, Suite 200, in Greensboro. The value of the three mammography units and one biopsy system (\$1,061,849) combined with the existing medical diagnostic equipment already being utilized by Solis Mammography, exceeds the statutory threshold for a diagnostic center of \$500,000; therefore, the acquisition of the proposed equipment requires a certificate of need.

Population to be Served

The 2016 SMFP does not provide a need methodology for the establishment of diagnostic centers in North Carolina. Nor does the SMFP specify a service area relative to diagnostic centers. 10A NCAC 14C .1802(3) defines the service area for diagnostic centers as *“the geographic area, as defined by the applicant, for which the proposed diagnostic center will provide services.”*

In Section III, page 49, the applicant states that the geographic service area for Solis Mammography is Guildford County.

The historical patient origin for existing Solis Mammography services for the twelve-month period ending October 2015 is provided in Section III, pages 47-48, as illustrated in the table below.

**Solis Mammography- Mammography and Biopsy Services
November 2014 – October 2015**

County	3D & 2D Mammography % of Total	Biopsy Procedures % of Total
Guilford	82.92%	79.24%
Alamance	5.14%	3.39%
Randolph	6.28%	5.79%
Forsyth	2.07%	2.79%
Rockingham	1.89%	2.79%
Davidson	0.76%	2.00%
Other NC*	0.42%	2.40%
VA	0.46%	0.80%
Other States**	0.06%	0.80%
Total	100.0%	100.00%

*Other NC Counties include Brunswick, Cabarrus, Caldwell, Caswell, Chatham, Durham, Mecklenburg, Edgecombe, Iredell, Montgomery, Moore, New Hanover, Orange, Pitt, Richmond, Rowan, Stokes, Wake, Watauga and Yadkin.

**Other States include California, Florida, Georgia, Maryland, South Carolina and West Virginia.

In Section III, pages 50-51, the applicant provides the projected patient origin for Solis Mammography services during the first two operating years following project completion, as shown in the table below.

**Solis Mammography- Mammography Services
FY2017-FY2018**

County	3D & 2D Mammography % of Total	Year One (FY2017)	Year Two (FY2018)
Guilford	82.92%	16,506	16,837
Alamance	5.14%	1,018	1,038
Randolph	6.28%	1,428	1,456
Forsyth	2.07%	339	346
Rockingham	1.89%	503	513
Davidson	0.76%	212	216
Other NC*	0.42%	95	99
VA	0.46%	81	82
Other States**	0.06%	12	12
Total	100.0%	20,193	20,598

*Other NC Counties include Brunswick, Cabarrus, Caldwell, Caswell, Chatham, Durham, Mecklenburg, Edgecombe, Iredell, Montgomery, Moore, New Hanover, Orange, Pitt, Richmond, Rowan, Stokes, Wake, Watauga and Yadkin.

**Other States include California, Florida, Georgia, Maryland, South Carolina and West Virginia.

**Solis Mammography- Biopsy Procedures
 FY2017-FY2018**

County	Biopsy Procedures % of Total	Year One (FY2017)	Year Two (FY2018)
Guilford	79.24%	596	608
Alamance	3.39%	26	26
Randolph	5.79%	44	44
Forsyth	2.79%	21	21
Rockingham	2.79%	21	21
Davidson	2.00%	15	15
Other NC*	2.40%	18	18
VA	0.80%	6	6
Other States**	0.80%	6	6
Total	100.0%	752	767

*Other NC Counties include Brunswick, Cabarrus, Caldwell, Caswell, Chatham, Durham, Mecklenburg, Edgecombe, Iredell, Montgomery, Moore, New Hanover, Orange, Pitt, Richmond, Rowan, Stokes, Wake, Watauga and Yadkin.

**Other States include California, Florida, Georgia, Maryland, South Carolina and West Virginia.

On page 51, Section III, the applicant states that projected patient origin is based on its 2015 utilization percentages and no changes are expected in patient origin for the first two years following project completion.

The applicant adequately identifies the population to be served.

Analysis of Need

In Section III, pages 33-43, and in supplemental information the applicant states that the need for the proposed project is based on quantitative and qualitative factors, which are summarized below.

- Projected population growth presumes continued increases in demand for healthcare.
- Cancer incident rates support need for improved access to mammography and biopsy procedures.
- Project will enhance patient access to fast, convenient, high-quality and accurate mammograms.
- Adding tomosynthesis (3D) to digital mammography results in decreased patient call backs for additional procedures and increased cancer detection rates.
- Changes in the reimbursement for 3D mammography have increased patient access and support future growth in utilization.
- Historical Solis Mammography utilization data demonstrates increased demand for 3D mammography and high volumes of mammography procedures.
- Projected utilization at Solis Mammography meets or exceeds Diagnostic Center performance standards.

The applicant adequately demonstrates the need to develop a diagnostic center by replacing three existing mammography systems with three new mammography systems and adding biopsy equipment at the existing Solis Mammography facility.

Projected Utilization

In Section IV, page 55, the applicant provides projected utilization for mammography and biopsy services at Solis Mammography through the first three years of operation following completion of the project, as shown in the following table.

	FY2017	FY2018	FY2019
Mammography Procedures	18,684	19,057	19,438
Biopsy Procedures	752	767	783

In Section IV, page 56, the applicant provided the capacity, with assumptions, of the mammography equipment, as illustrated in the table below.

Equipment	Hours per Week	Weeks per Year	Annual Hours	Adjusted Annual Hours	Mammography Procedures/Hour	Annual Equipment Capacity per Unit (procedures)
Mammography Equipment	51.5	51	2,627	2,627	2.5	6,566

The table below illustrates at what capacity the mammography equipment is projected to operate for the first three years following project completion.

	FY2017	FY2018	FY2019
Mammography Procedures	18,684	19,057	19,438
Mammography Units	3	3	3
Mammography Procedures Per Unit (Procedures/Unit)	6,228	6,352	6,479
% of Capacity (Procedures Per Unit/ Capacity Per Unit)	94.85%	96.74%	98.67%

As shown above, for each of the first three project years following completion of the proposed project the mammography equipment is projected to operate at over 94.0% of capacity. By the third project year the applicant projects the mammography equipment to be operating at 98.67%% capacity.

The table below summarizes Solis Mammography’s historic and projected utilization of its mammography services including year over year percentage growth. The applicant projects utilization based on an annual 2.0% growth rate.

	CY2014	CY2015*	Interim CY2016	First Full CY2017	Second Full CY2018	Third Full CY2019
Mammography Procedures	19,102	17,958	18,317	18,684	19,057	19,438
		-na-	359	367	373	381
Mammography Units	3	4	3	3	3	3
Annualized Increase %	-na-	-na-	2.0%	2.0%	2.0%	2.0%

*Note: The method of calculated procedure volumes changed after CY2014. In CY2014 procedure volumes were calculated based on actual billed primary procedure codes. The 2015 procedure volumes are based on changes in CPT codes (implemented by CMS in 2015) for billed primary procedure codes and 10 months annualized data. See page 54 of the application.

The project analyst notes that even if the number of mammography procedures performed in FY 2015 remains constant the three mammography units would operate at 91.2%, which is in excess of the 80% threshold in 10A NCAC 14C .1804, as illustrated in the table below.

	FY2015
Mammography Procedures	17,958
Mammography Units	3
Mammography Procedures Per Unit (Procedures/Unit)	5,986
% of Capacity (Procedures Per Unit/ Capacity Per Unit)	91.2%

A 2% annual growth rate is a conservative projection based on Solis Mammography’s historical experience providing mammography services, projected service area population growth, and the increase in efficiency and reliability of providing mammography services. (See page 54 of the application)

In supplemental information the applicant states

“Biopsy equipment is used in conjunction with mammography equipment or ultrasound equipment when a biopsy procedure is necessary. Solis has one existing biopsy unit that is utilized with the existing ultrasound equipment. One biopsy unit was acquired with the 3D mammography unit. Consequently, biopsy equipment does not have a “stand alone” capacity calculation but instead its capacity is based on the weekly availability of the technologist and radiologist who are both present for all biopsy procedures. Scheduling capacity for 20 breast biopsy procedures per week includes 12 procedures for ultrasound biopsy and 8 for 3D mammography procedures per week.”

The following capacity calculations are based on the staffing and radiologist availability to perform biopsy procedures in conjunction with the imaging modalities:

Biopsy Equipment	
Hours/ Week Based on Technologist and Radiologist Availability	10
Weekly Biopsy Schedule Slots per Biopsy Unit	10
Appointments Adjustment (6 Percent Missed or Delayed)	94.00%
Weeks per Year	51
Annual Capacity Per Biopsy Equipment Unit	479.4

The table below summarizes Solis Mammography’s projected utilization of its biopsy services in Year 3 (CY2019) including year over year percentage growth.

Year 3 Utilization and Capacity Projections	
Total Biopsy Procedures	783
Number of Biopsy Units	2
Average Procedures per Unit	391.5
Annual Capacity Per Unit	479.4
Capacity Percentage Per Unit	81.66%

Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth. Therefore, the applicant adequately demonstrates the need for the development of a diagnostic center by acquiring the three mammography systems and biopsy equipment to replace existing mammography equipment and biopsy equipment.

Access

In Section VI.2, page 66, the applicant states, “*Solis provides patients with equal access to treatment and does not restrict services on the basis of race, religion, color, national origin, gender, age, sexual orientation, disability, medical condition, marital status, veteran status, or other improper basis.*”

In Section VI, pages 72-73 the applicant provides the projected payor mix for the entire facility and for diagnostic services only at Solis Mammography for CY2018 (the second full fiscal year of operation), as shown in the following table:

**Solis Mammography- Entire Facility
 Second Full Fiscal Year (CY2018)
 Procedures as Percent of Total Utilization**

Self Pay/ Indigent/ Charity	0.96%
Medicare/Medicare Managed Care	30.01%
Medicaid	1.19%
Commercial and Managed Care	54.44%
Other*	13.40%
Total	100.00%

*Other includes Champus PGBA, CAMPVA, Pacificare PPO, Medcost and Secure Horizons

**Solis Mammography- Diagnostic Services Only
Second Full Fiscal Year (CY2018)
Procedures as Percent of Total Utilization**

Self Pay/ Indigent/ Charity	0.96%
Medicare/Medicare Managed Care	30.01%
Medicaid	1.19%
Commercial and Managed Care	54.44%
Other*	13.40%
Total	100.00%

*Other includes Champus PGBA, CAMPVA, Pacificare PPO, Medcost and Secure Horizons

As shown in the above referenced table, 31.2% of the current and proposed payor mix is Medicare and Medicaid.

The applicant adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services.

Conclusion

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

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

NA

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

CA

In Section III, pages 46-47, the applicant describes the alternatives considered, which included removing the recently acquired equipment from the facility or distributing the equipment to separate locations. The applicant discusses the age and condition of the equipment replaced, the need for the new equipment and the higher cost of operating the new equipment at separate locations. After considering those alternatives, the applicant states the alternative represented in the application is the most effective alternative to meet the identified need.

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

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

- 1. Solis North Carolina Diagnostic Imaging & Breast Cancer Management, Inc. shall materially comply with all representations made in the certificate of need application and in supplemental information provided. In those instances where representations conflict, Solis North Carolina Diagnostic Imaging & Breast Cancer Management, Inc. shall materially comply with the last made representation.**
 - 2. Solis North Carolina Diagnostic Imaging & Breast Cancer Management, Inc. shall acquire no more than three Hologic Selenia Mammography Systems and one Hologic Biopsy System.**
 - 3. Solis North Carolina Diagnostic Imaging & Breast Cancer Management, Inc. shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application or that would otherwise require a certificate of need.**
 - 4. Solis North Carolina Diagnostic Imaging & Breast Cancer Management, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

Solis proposes to acquire three mammography units and one biopsy system, to replace existing mammography and diagnostic imaging equipment at Solis Mammography. Solis Mammography is a freestanding outpatient imaging center located at 1126 N. Church Street, Suite 200, in Greensboro. The value of the three mammography units and one biopsy system (\$1,061,849) combined with the existing medical diagnostic equipment already being utilized by Solis Mammography, exceeds the statutory threshold for a diagnostic center of \$500,000; therefore, the acquisition of the proposed equipment requires a certificate of need.

Capital and Working Capital Costs

On page 80, the applicant projects the total capital cost of the project will be \$1,061,849, which includes:

Equipment	\$1,047,675
Consultant Fees	\$14,174
Total	\$1,061,849

The applicant states no working capital (start-up and initial operating expenses) is required for the proposed project because no new service is being proposed and the facility is already staffed and operational. (See application page 84)

Availability of Funds

In Section VIII, page 81, the applicant states that the capital costs of the proposed project were financed by the parent company cash. The parent company of Solis is WDT Acquisition Corp. (WDT).

In Exhibit 28, the applicant provides a letter dated January 11, 2016 from Mano Mahadeva, a Director and the Treasurer of WDT which states that the invoices to purchase the three mammography units and one biopsy unit have already been paid that he is authorized to represent that adequate funds are available for any and all costs associated with the proposed project.

The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

Financial Feasibility

In the projected revenue and expense statement (Form B) provided in the pro formas and in supplemental information Solis Mammography projects revenues will exceed operating expenses in both of the first two Operating Years following completion of the proposed project, as shown in the table below.

	FY 2017 (1st Operating Year)	FY 2018 (2nd Operating Year)
Net Revenues	\$4,217,928	\$4,292,086
Total Operating Expenses	\$4,049,536	\$4,110,350
Net Profit	\$168,392	\$181,736

The assumptions used by the applicant in preparation of the pro formas are reasonable including projected utilization, costs and charges. See the financial section in the supplemental information for the assumptions used regarding costs and charges. The

discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

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

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

C

Solis proposes to acquire three mammography units and one biopsy system, to replace existing mammography and biopsy equipment at Solis Mammography. Solis Mammography is a freestanding outpatient imaging center located at 1126 N. Church Street, Suite 200, in Greensboro. The value of the three mammography units and one biopsy system (\$1,061,849) combined with the existing medical diagnostic equipment already being utilized by Solis Mammography, exceeds the statutory threshold for a diagnostic center of \$500,000; therefore, the acquisition of the proposed equipment requires a certificate of need.

The 2016 SMFP does not provide a need methodology for the establishment of diagnostic centers in North Carolina. Nor does the SMFP specify a service area relative to diagnostic centers. 10A NCAC 14C .1802 (3) defines the service area for diagnostic centers as *“the geographic area, as defined by the applicant, for which the proposed diagnostic center will provide services.”*

In Section III, page 49, the applicant states that the geographic service area for Solis Mammography is Guilford County.

The total number of mammography and biopsy systems in the service area defined by the applicant will not increase as a result of this proposal.

In Section III, page 51, the applicant provides a list by name and location of all existing facilities that operate mammography services in the project service area, Guilford County, as illustrated in the table below:

Facility	Location	County
Green Valley OB GYN	719 Green Valley Rd Ste 201, Greensboro	Guilford
Greensboro OB/GYN Associates	510 N. Elam Ave Ste 101, Greensboro	Guilford
High Point Regional Hospital	601 N Elm St, High Point	Guilford
The Womans Hospital of Greensboro	801 Green Valley Rd, Greensboro	Guilford
Solis Women's Health Radiology Associates of North Carolina	1126 N Church St Ste 200, Greensboro	Guilford
Piedmont Comprehensive Womens Center	1814 Westchester Dr Ste 200, High Point	Guilford
High Point Surgery Center	600 N Lindsay St, High Point	Guilford
Physicians for Women of Greensboro	802 Green Valley Rd. Ste 300, Greensboro	Guilford
The Breast Center of Greensboro Imaging	1002 N Church St Ste 401, Greensboro	Guilford
Cone Health Day Surgery Center	1127 N Church St, Greensboro	Guilford
Cone Health Med Center High Point Imaging	2630 Willard Dairy Rd, High Point	Guilford
Premier Imaging	4515 Premier Dr, Ste 101, High Point	Guilford
Greensboro OB/GYN Associates	510 N. Elam, Ste 101, Greensboro	Guilford

However, the applicant correctly notes that there is no publically available data which provides sufficient information to determine if the similar medical diagnostic equipment was operating at 80.0% of the maximum number of procedures that the equipment is capable of performing for the twelve month period immediately preceding the submittal of the application.

The discussions regarding analysis of need, alternatives and competition found in Criteria (3) (4) and (18a), respectively, are incorporated herein by reference.

The applicant adequately demonstrates that the proposed project would not result in the unnecessary duplication of existing or approved mammography and biopsy services in the proposed service area. Consequently, the application is conforming to this criterion.

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

C

Solis Mammography's mammography and biopsy services are open Monday, Wednesday and Friday 7:00-4:30; Tuesday and Thursday 7:00-5:00 and alternating Saturday's 8-12:00. In Section VII, pages 74-75, the applicant states that it staffs 6.0 Full Time Equivalent (FTE)

mammography technologists and that the replacement equipment will not result in the addition of any FTEs as it has already been acquired and is in operation. In Section VII.8, page 77, the applicant identifies Margaret Bertrand, M.D., as the Medical Director for Solis Mammography. Exhibit 6 contains a copy of a letter from Dr. Bertrand expressing her interest in continuing as the Medical Director for the facility. In Section VII.7, page 76, the applicant states, *“the board-certified radiologists with Solis Women’s Health Radiology Associates of North Carolina P.C. provide the professional mammography reading services.”* Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in the pro forma financial statements. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section II.2, page 15, the applicant describes the ancillary and support services that will be provided by the facility. Exhibit 5 contains a copy of the management agreement. Exhibit 22 and 23 contain copies of letters from other health care providers and the community, respectively, expressing support for the proposed project. In Section V.2, page 58, the applicant states,

“The applicant provides outpatient imaging services and does not admit patients to their facility. The proposed project involves no surgery or endoscopy procedures.”

The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

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

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the

HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

- (i) would be available under a contract of at least 5 years duration;
- (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

NA

- (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 VI, page 71, the applicant provides the projected payor mix for the entire facility and for diagnostic only services at Solis Mammography for CY2015 (the last full fiscal year of operation), as shown in the following table:

**Solis Mammography- Entire Facility
 Last Full Fiscal Year (CY2015)
 Procedures as Percent of Total Utilization**

Self Pay/ Indigent/ Charity	0.96%
Medicare/Medicare Managed Care	30.01%
Medicaid	1.19%
Commercial and Managed Care	54.44%
Other*	13.40%
Total	100.00%

*Other includes Champus PGBA, CAMPVA, Pacificare PPO, Medcost and Secure Horizons

**Solis Mammography- Diagnostic Services Only
 Last Full Fiscal Year (CY2015)
 Procedures as Percent of Total Utilization**

Self Pay/ Indigent/ Charity	0.96%
Medicare/Medicare Managed Care	30.01%
Medicaid	1.19%
Commercial and Managed Care	54.44%
Other*	13.40%
Total	100.00%

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The United States Census Bureau¹ provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant's service area.

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority	% Persons in Poverty	% < Age 65 with a Disability	% < Age 65 without Health Insurance
Guilford	14%	53%	48%	18%	7%	18%
Alamance	16%	52%	34%	18%	10%	20%
Randolph	16%	51%	20%	17%	10%	21%
Forsyth	14%	53%	42%	20%	7%	17%
Rockingham	18%	52%	27%	19%	14%	18%
Davidson	17%	51%	19%	17%	12%	18%
Statewide	15%	51%	36%	17%	10%	15%

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

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

¹ <http://www.census.gov/quickfacts/table>

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

C

In Section VI.11, pages 70-71, that applicant states, “*Solis Mammography has had no obligation to provide uncompensated care.*” In Section VI.2, page 66, the applicant states, “*Solis provides patients with equal access to treatment and does not restrict services on the basis of race, religion, color, national origin, gender, age, sexual orientation, disability, medical condition, marital status, veteran status or other improper basis.*”

In Section VI., page 70, the applicant states that “*No civil rights complaints have been filed against Solis during the past five years.*” Therefore, application is conforming to this criterion.

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

C

In Section VI, pages 72-73 the applicant provides the projected payor mix for the entire facility and for only diagnostic services at Solis Mammography for CY2018 (the second full fiscal year of operation), as shown in the following table:

**Solis Mammography- Entire Facility
Second Full Fiscal Year (CY2018)
Procedures as Percent of Total Utilization**

Self Pay/ Indigent/ Charity	0.96%
Medicare/Medicare Managed Care	30.01%
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Total	100.00%

*Other includes Champus PGBA, CAMPVA, Pacificare PPO, Medcost and Secure Horizons

As shown in the above referenced table, 31.2% of the payor mix is Medicare and Medicaid. In Section VI.2, page 66, the applicant states, “*Solis provides patients with equal access to treatment and does not restrict services on the basis of race, religion, color, national origin, gender, age, sexual orientation, disability, medical condition, marital status, veteran status, or other improper basis.*”

The applicant demonstrates that medically underserved populations would have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section V.2(d), pages 58-59, Section VI.9, page 70 and Exhibit 22 the applicant describes the range of means by which a person will have access to Solis Mammography’s services. The applicant adequately demonstrates that it will provide a range of means by which a person can access the diagnostic imaging services. Therefore, the application is conforming to this criterion

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

C

In Section V.1, page 57, the applicant describes how the facility will accommodate the clinical needs of area health professional training programs, as follows:

“Solis Mammography is willing to establish a clinical training program with Guilford Technical Community College.”

Exhibit 26 contains a copy of a letter and email from Solis Mammography to the Department Chair of Radiography at Guildford Technical Community College stating its willingness to establish a clinical training agreement.

The information provided is reasonable and adequately supports a determination that the application is conforming to this criterion.

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

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Solis proposes to acquire three mammography units and one biopsy system, to replace existing mammography and diagnostic imaging equipment at Solis Mammography. Solis Mammography is a freestanding outpatient imaging center located at 1126 N. Church Street, Suite 200, in Greensboro. The value of the three mammography units and one biopsy system (\$1,061,849) combined with the existing medical diagnostic equipment already being utilized by Solis Mammography, exceeds the statutory threshold for a diagnostic center of \$500,000; therefore, the acquisition of the proposed equipment requires a certificate of need.

The 2016 SMFP does not provide a need methodology for the establishment of diagnostic centers in North Carolina. Nor does the SMFP specify a service area relative to diagnostic centers. 10A NCAC 14C .1802 (3) defines the service area for diagnostic centers as *“the geographic area, as defined by the applicant, for which the proposed diagnostic center will provide services.”*

In Section III, page 49, the applicant states that the geographic service area for Solis Mammography is Guilford County.

In Section III, page 51, the applicant provides a list by name and location of all existing facilities that operate mammography services in the project service area, Guilford County, as illustrated in the table below:

Facility	Location	County
Green Valley OB GYN	719 Green Valley Rd Ste 201, Greensboro	Guilford
Greensboro OB/GYN Associates	510 N. Elam Ave Ste 101, Greensboro	Guilford
High Point Regional Hospital	601 N Elm St, High Point	Guilford
The Womans Hospital of Greensboro	801 Green Valley Rd, Greensboro	Guilford
Solis Women's Health Radiology Associates of North Carolina	1126 N Church St Ste 200, Greensboro	Guilford
Piedmont Comprehensive Womens Center	1814 Westchester Dr Ste 200, High Point	Guilford
High Point Surgery Center	600 N Lindsay St, High Point	Guilford
Physicians for Women of Greensboro	802 Green Valley Rd. Ste 300, Greensboro	Guilford
The Breast Center of Greensboro Imaging	1002 N Church St Ste 401, Greensboro	Guilford
Cone Health Day Surgery Center	1127 N Church St, Greensboro	Guilford
Cone Health Med Center High Point Imaging	2630 Willard Dairy Rd, High Point	Guilford
Premier Imaging	4515 Premier Dr, Ste 101, High Point	Guilford
Greensboro OB/GYN Associates	510 N. Elam, Ste 101, Greensboro	Guilford

However, the applicant correctly notes that there is no publically available data which provides sufficient information to determine if the similar medical diagnostic equipment was operating at 80.0% of the maximum number of procedures that the equipment is capable of performing for the twelve month period immediately preceding the submittal of the application.

In supplemental information, the applicant discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services.

The information in the application is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need to acquire the proposed replacement equipment and become a diagnostic center and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that Solis Mammography will continue to provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.

- The applicant adequately demonstrates Solis Mammography will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

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

C

In Section II.7, pages 19-29, and Exhibit 10 the applicant describes the methods used by Solis Mammography to insure and maintain quality care including stating that Solis Mammography has not had any penalties or licensure limitations imposed and that Solis is in full compliance with the radiation safety requirements for the North Carolina Regulations for Protection against Radiation. The information provided by the applicant is reasonable and supports the determination that the applicant 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.

C

The application is conforming to all applicable Criteria and Standards for Diagnostic Centers promulgated by 10A NCAC 14C Section .1800. See discussion below.

SECTION .1800 - CRITERIA AND STANDARDS FOR DIAGNOSTIC CENTERS

10A NCAC 14C .1804 PERFORMANCE STANDARDS

An applicant proposing to establish a new diagnostic center or to expand an existing diagnostic center shall provide:

- (1) *documentation that all existing health service facilities providing similar medical diagnostic equipment and services as proposed in the CON application in the defined*

diagnostic center service area were operating at 80% of the maximum number of procedures that the equipment is capable of performing for the twelve month period immediately preceding the submittal of the application;

- C- The applicant is proposing to acquire three mammography units and one biopsy system, to replace existing mammography and biopsy equipment. In Section II, pages 27-29 and in Section III, page 51, the applicant identifies other health service facilities that operate or have been approved to operate similar medical diagnostic equipment. However, the applicant correctly notes that there is no publically available data which provides sufficient information to determine if the similar medical diagnostic equipment was operating at 80.0% of the maximum number of procedures that the equipment is capable of performing for the twelve month period immediately preceding the submittal of the application.
- (2) *documentation that all existing and approved medical diagnostic equipment and services of the type proposed in the CON application are projected to be utilized at 80% of the maximum number of procedures that the equipment is capable of performing by the fourth quarter of the third year of operation following initiation of diagnostic services;*
- C- In Section II, pages 28-30, the applicant states that due to the lack of publically available data, the applicant cannot determine if the existing and approved medical diagnostic equipment and services of the type proposed in this CON application are projected to be utilized at 80% of the maximum number of procedures that the equipment is capable of performing by the fourth quarter of the third year of operation following initiation of diagnostic services. In Section IV, pages 54-56, and in supplemental information the applicant documents that the Solis Mammography's mammography and biopsy services will be utilized at 80% of the maximum number of procedures that the equipment is capable of performing by the fourth quarter of the third year of operation following initiation of diagnostic services. The applicant projects utilization of the mammography and biopsy services at 98.68% and 81.6% respectively of capacity in Project Year 3 (CY2019).
- (3) *documentation that the applicant's utilization projections are based on the experience of the provider and on epidemiological studies; and*
- C- In Section II, page 30, Section III, pages 37-41, Exhibit 25 and in supplemental information, the applicant documents that its utilization projections are based on its experience providing mammography and biopsy services at Solis Mammography and on epidemiological studies. See also Section III.1 of the application.
- (4) *all the assumptions and data supporting the methodologies used for the projections in this Rule.*

- C- In Section III.1, Section IV, Exhibits 16-18 and supplemental information, the applicant provides all the assumptions and data supporting the methodologies used to project utilization.