

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: February 25, 2021

Findings Date: February 25, 2021

Project Analyst: Celia C. Inman

Team Leader: Gloria C. Hale

Project ID #: J-12001-20

Facility: Duke Coley Hall Imaging

FID #: 202897

County: Orange

Applicant: Duke University Health System, Inc.

Project: Develop a diagnostic center with mammography and ultrasound equipment

REVIEW CRITERIA

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

Duke University Health System, Inc., hereinafter referred to as DUHS or “the applicant”, proposes to develop a new diagnostic center, Duke Coley Hall Imaging (Duke Coley), at 66 Vilcom Drive, Chapel Hill (Orange County) by acquiring and installing mammography and ultrasound equipment.

The applicant does not propose to:

- develop any beds or services for which there is a need determination in the 2020 State Medical Facilities Plan (SMFP),
- acquire any medical equipment for which there is a need determination in the 2020 SMFP, or
- 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- (2) Repealed effective July 1, 1987.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, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant, DUHS, proposes to develop a new diagnostic center, Duke Coley, by acquiring and installing mammography and ultrasound equipment in renovated leased space at 66 Vilcom Drive, Chapel Hill, NC. The applicant states that the location will be operated as an independent diagnostic testing facility (IDTF).

Though the applicant is inconsistent in select places in the application, stating that mobile MRI is currently contracted at the facility (Section A.4(f), page 10), fixed MRI services will be offered at the facility (Section C.11, pages 29-31, and in the Medical Director's letter of support, Exhibit I.3), the description throughout the application involves acquiring only mammography and ultrasound equipment, the architect's letter (Exhibit F.1(a)) refers to the costs of upfit to accommodate mammography and ultrasound services, the capital cost involves only mammography and ultrasound equipment, the quotes for equipment (Exhibit F.1(b)) are for only mammography and ultrasound equipment, the utilization projections involve only mammography and ultrasound services, and Form.2 Revenues and Net Income involves only mammography and ultrasound services. The line drawings (Exhibit K.2) are titled Coley Hall MRI Study, but the floor plan clearly shows only mammography and ultrasound space in the line drawings. In its "Response to Comments", the applicant states, "*To the extent that there are references to MRI services in this application, those are, as UNC recognized, typographical errors.*"¹ Thus, the Project Analyst is confident that mentions of MRI are inadvertent and do not apply to the project as proposed, though a project involving MRI may have been used as reference in developing the application under review.

Furthermore, the application refers to developing the new diagnostic center as a new IDTF (page 16) and building out space to house mammography and ultrasound services in a medical office building that is currently under development (page 53). Conversely, the applicant refers to the IDTF as existing (page 49) and states that the IDTF is certified for participation in Medicare and Medicaid and is accredited by the American College of Radiology (page 66) and refers to documentation in Exhibit O.2. The exhibits to the proposed project do not

¹ *Two recent DUHS applications for the development of mammography services were for sites at which MRI services (either fixed or mobile) were already offered, namely at Holly Springs and at Cary Parkway, and those applications were used as templates for this one. DUHS regrets any resulting typographical errors. As to the floor plans included in Exhibit K.2, the physical areas included in this application are identified in color; areas identified in gray reflect the potential for future expansion, but are not included in the scope or cost of this project.*"

include an Exhibit O.2. The applicant states in its “Response to Comments” that it will operate the newly proposed facility as an IDTF. Again, the Project Analyst is confident that mentions of the IDTF as existing are inadvertent and do not apply to the project as proposed, though a project involving an existing IDTF may have been used as reference in developing the application under review.

Designation as a Diagnostic Center

In Section C, page 16, the applicant states:

“DUHS is acquiring one unit of 3D tomosynthesis mammography equipment and one unit of ultrasound equipment and renovating space within an existing leased suite to accommodate the new equipment, creating a new diagnostic center as defined in NCGS 131E-176. Upon project completion, the diagnostic center will include the following diagnostic equipment:

- *Mammography*
- *Ultrasound*

This location will be operated as an independent diagnostic testing facility (IDTF).”

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.”

In Section Q, Form F.1a Capital Cost, the applicant states the cost to acquire the proposed mammography and ultrasound equipment, renovate the space, and install the equipment at the Duke Coley facility is \$1,720,000, which will exceed the statutory threshold of \$500,000. Therefore, Duke Coley qualifies as a diagnostic center, which is a new institutional health service, and which requires a Certificate of Need (CON).

Patient Origin

N.C. Gen. Stat. §131E-176(24a) states, “*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2020 SMFP does not define a service area for 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.3, the applicant refers to Section Q for the assumptions which define the primary service area for the proposed diagnostic center as the ZIP code areas within 10-15 minutes driving time of the facility.

In Section C, pages 18-20, the applicant lists the number of patients and patient origin by ZIP codes in Orange and Durham counties of the patients it proposes to serve; thus, the service area for this facility consists of portions of Orange and Durham counties. Facilities may also serve residents not included in their service area.

The following table illustrates the projected Duke Coley patient origin for FY2024, the third year of operation, as provided in the application. The proposed diagnostic center has no historical patient origin.

**Projected Patient Origin
 Third Full FY of Operation following Project Completion
 FY2024 (7/1/23-6/30/24)***

ZIP Code	County/Town	Mammography Services		Ultrasound Services		Entire Facility	
		Patients	% of Total	Patients	% of Total	Patients	% of Total
27278	Orange/Hillsborough	247	11%	309	9%	556	9%
27510	Orange/Carrboro	90	4%	150	4%	240	4%
27514	Orange/Chapel Hill	344	15%	542	15%	886	15%
27516	Orange/Chapel Hill	239	10%	426	12%	665	11%
27517	Orange/South Chapel Hill	201	9%	303	9%	504	9%
27705	Durham/Durham	501	21%	781	22%	1,282	22%
27707	Durham/South Durham	507	22%	691	20%	1,198	20%
	Other/In-migration^	213	9%	320	9%	533	9%
	Total Projected Patients	2,342	100%	3,523	100%	5,865	100%

Totals may not sum due to rounding

Source: Section C.3, pages 18-19

*The applicant's tables incorrectly identify FY2024, the third full fiscal year following the completion of the project, as "7/1/2022-6/30/23" for mammography and ultrasound and as "7/1/2021-6/30/2022" for the entire facility. The FY2024 dates of 7/1/23-6/30/24 are consistent with what the applicant provides in its pro formas.

^In-migration is assumed to come from other ZIP codes in Orange and Durham counties and from adjacent counties and Vance County.

In Section C, page 20, the applicant refers to Section Q-Utilization Projections for the assumptions and methodology used to project its patient origin, stating:

"Please see Section Q for the specific assumptions and methodology used to project mammography and ultrasound patients to be served by the zip [sic] codes in Orange and Durham Counties and from adjacent counties."

The applicant's tables as provided on pages 18-19 of the application and summarized for FY2024 above are labeled "number of patients and percent of total patients". However, it is

obvious from analyzing the assumptions provided in Section Q-Utilization Projections that the methodology results in number of mammography and ultrasound procedures, not patients, as follows.

Projected Procedures

	1 st Full FY	2 nd Full FY	3 rd Full FY
Mammography	832	1,584	2,342
Ultrasound	1,145	2,319	3,523
Entire Facility	1,977	3,903	5,865

Number of procedures, as opposed to patients, was also used in the development of the proposed diagnostic center’s Form C Utilization and Form F.2 Revenues and Net Income. Thus, the labels on the patient origin tables provided by the applicant on pages 18-20 of the application should have been labeled “Number of Procedures” rather than “Number of Patients”, as shown below. However, the percent of total for patient origin remains valid for the services to be provided.

**Projected Patient Origin
 Third Full FY of Operation following Project Completion
 FY2024 (7/1/23-6/30/24)***

ZIP Code	County/Town	Mammography Services		Ultrasound Services		Entire Facility	
		Procedures	% of Total	Procedures	% of Total	Procedures	% of Total
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	Other/In-migration^	213	9%	320	9%	533	9%
	Total Projected Patients	2,342	100%	3,523	100%	5,865	100%

Totals may not sum due to rounding

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*The applicant’s tables incorrectly identify FY2024, the third full fiscal year following the completion of the project, as “7/1/2022-6/30/23” for mammography and ultrasound and as “7/1/2021-6/30/2022” for the entire facility.

^In-migration is assumed to come from other ZIP codes in Orange and Durham counties and from adjacent counties and Vance County.

In its “Response to Comments”, the applicant states:

“The application’s utilization and financial pro formas were based on the procedure totals, and the patient origin tables reflect an assumption of one procedure per patient. The ratios cited by UNC Health and provided in the capacity analysis simply reflect the potential for patients with multiple procedures that could affect how many procedures could be performed (such patients requiring a longer slot). Either way, the

patient origin tables reflect the projected percentage of total patients and procedures by zip code, providing sufficient information to determine the population to be served. DUHS would note that neither mammography nor ultrasound is subject to a universal performance standard.”

Thus, the projected patient origin by procedure and by patient would be the same number.

The applicant’s assumptions, as provided in Section Q-Utilization, are reasonable and adequately supported based on the following:

- The first year of operation for the new facility will be FY2022, beginning services in July 2021. Thus, the third full fiscal year of operation is FY2024 (July 1, 2023- June 30, 2024). (page 1)
- The proposed diagnostic center will be located in ZIP code 27514 (Chapel Hill), with the primary service area consisting of ZIP codes 27278 (Hillsborough), 27510 (Carrboro), 27514 (Chapel Hill), 27516 (Chapel Hill), 27517 (South of Chapel Hill), 27705 (Durham), and 27707 (South Durham), all within a 15-minute drive time. (page 1)
- The applicant uses Sg2, a healthcare strategic planning provider nationally recognized for its expertise in market demand forecasting, to project the total mammography and ultrasound utilization in the identified ZIP codes. (page 1)
- DUHS calculates its applicable internal FY2020 volumes (July through February, annualized) for appropriate outpatient, non-emergent mammography and ultrasound procedures for patients from the identified ZIP codes and shifts a percentage of the patients to the proposed location based on convenience, payor preferences, capacity constraints at existing sites, and other factors. (pages 1-2)
- The variable shifts of volume were based on the patient’s originating ZIP code, ramping the shift to the total volume shift of 9% in the third year of operation. (pages 2-3)
- Additional market share is assumed based on increase in population, service area utilization, provider recruitment, geographic access and patient convenience, and the cost/benefit structure of the proposed IDTF structure. (pages 3-5)
- In-migration will constitute an additional 10% of procedures. (pages 5-6)
- Physician support letters confirming that the existing DUHS imaging services are highly utilized and experience capacity constraints. (Exhibit C.4(b))

Analysis of Need

In Section C.4, pages 20-25, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, stating on page 20:

“DUHS is proposing this project to increase geographic access to imaging services and to develop a new, non-hospital based option for its patients and other residents of Orange County and surrounding areas. This facility will offer ultrasound and screening mammography services, which are both essential diagnostic tools.”

The applicant further explains why the proposal is needed as summarized below:

- Ultrasound is an imaging method that uses no radiation (page20).
- Ultrasound is known as the scan of choice to evaluate pregnancy and is useful for evaluating other organs such as the bladder, gallbladder, kidneys, ovaries, thyroid, blood vessels, and other regions of interest (page 20).
- Mammography equipment is the foundation for screening and diagnostic breast imaging (page 20).
- A 3D tomosynthesis unit provides state-of-the-art services and is quickly becoming the standard of care in the community (page 20).
- Based on the historical growth in mammography utilization for DUHS facilities in Wake and Durham counties from 2017 to 2019, including a decline in 2020 due to the suspension of non-urgent procedures to address the COVID-19 emergency, and a return to prior growth in early FY2021 (pages 20-21), DUHS anticipates a continued demand for these essential screening and diagnostic tools in Wake and Durham counties, as well as in Orange County.
- The projected growth of the service area population from 2018 through 2023, leading to expected growth in demand for imaging services (pages 22-23).
- DUHS's strategic growth in both primary and specialty services and its physician recruitment in the proposed service area (pages 23-24).
- The cost and convenience benefits of an IDTF, particularly for patients with high-deductible health plans (page 24).

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

- The applicant documents the proposed medical diagnostic equipment is essential for cost effective delivery of quality care for Duke Coley patients.
- The projected growth of the service area population is based on credible information from the U.S. Census and Truven Analytics.
- The projected demand for imaging services is based on the analytics of Sg2, a healthcare strategic planning provider nationally recognized for its expertise in market demand forecasting.
- The applicant provides supporting information to document the need for the proposed imaging services in Exhibit C.4.

Projected Utilization

In Section Q Form C Utilization, the applicant provides the projected utilization for the mammography and ultrasound equipment for the first three years of operation following completion of the project, as summarized in the following table.

**Duke Coley Hall Imaging
 Projected Utilization**

	1st Full FY 7/1/21-6/30/22	2nd Full FY 7/1/22-6/30/23	3rd Full FY 7/1/23-6/30/24
Mammography			
# Units	1	1	1
# Procedures	832	1,584	2,342
Ultrasound			
# Units	1	1	1
# Procedures	1,145	2,319	3,523

In Section Q, pages 1-6, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

Step 1: The applicant identifies the service area for the proposed equipment as the Orange and Durham County ZIP Code areas within a 10 to 15-minute driving time from the facility.

Step 2: The applicant uses projections from Sg2 for total projected utilization in the identified ZIP codes for the two modalities.

Step 3: The applicant projects the percentage shift of outpatient, non-emergent mammography and ultrasound patients from existing DUHS sites of service to the proposed site, based on geographic location, preferences of payers and patients for IDTF over hospital-based services, growth in the referral network, Medicaid reimbursement changes, and the backlog and capacity constraints of the existing sites.

Step 4: The applicant projects additional patient volume based on increases in the service area population, physician recruitment, increased geographic access and patient convenience, and the cost-savings associated with the IDTF setting. The new shares were estimated by ZIP code reflecting proximity to the proposed site, with the ZIP code of the proposed facility anticipated to have the greatest increase in share. These projections were calculated based on volumes projected by Sg2 in Step 2.

Step 5: The applicant projects 10% additional patient volume based on in-migration from areas outside the Zip code areas identified as the primary service area, which the applicant states is consistent with DUHS experience at other imaging sites of service.

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

- Projected utilization is based on outpatient, non-emergent historical experience of DUHS mammography and ultrasound equipment at its existing sites of service in Wake and Durham counties.
- Exhibit C.4(a) contains copies of letters from physicians expressing support for the proposed project and their intention to refer patients.
- Projected population increases in the service area are expected to support increase in the utilization of diagnostic imaging services such as mammography and ultrasound.

Access to Medically Underserved Groups

In Section L.3, page 61, the applicant provides the estimated payor percentage for the following medically underserved groups at the proposed diagnostic center, as shown in the following table.

Medically Underserved Groups	Percentage of Total Services
Self-Pay	0.73%
Charity care persons	2.31%
Medicare beneficiaries	33.25%
Medicaid recipients	4.17%

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant assumes a baseline reflecting the existing payor mix for the existing patients originating from the identified ZIP codes within the categories projected to shift to the proposed facility.
- Future payor mix is adjusted to account for the anticipated shift in the population from managed care payors to Medicare as the population ages.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written Comments
- Response to Comments

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 describes the extent to which all residents, including underserved groups, are likely to have access to the proposed services 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, ... persons [with disabilities], 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, DUHS, proposes to develop a new diagnostic center, Duke Coley, by acquiring and installing mammography and ultrasound equipment in renovated leased space at 66 Vilcom Drive, Chapel Hill, NC. The applicant states that the location will be operated as an IDTF.

In Section E, page 38, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Offering no new imaging services – the applicant states this alternative would be less effective because not providing local imaging services would not provide the efficiencies and patient convenience created by having imaging located in the new medical office building.
- Develop the imaging services at a different location – the applicant states that this alternative would not allow Duke to achieve the operating efficiencies and savings achieved by adding imaging services to a medical office building under development. In addition, the proposed location provides convenient highway access to patients throughout the county.
- Relocate existing equipment – the applicant states that its other imaging equipment is well-utilized and necessary to support services at the existing locations. Also, the expense of moving used equipment is not necessarily cost-effective.

In Section C, page 38, the applicant states that its proposal is the most effective alternative because DUHS can maintain its current offerings and ensure ongoing access during the ramp-up of the proposed project, with the ability to take its older existing equipment at other locations out of service rather than replacing them at the end of their useful life, if in the future utilization shifts more aggressively than anticipated.

In Section K, pages 53-54, the applicant discusses the proposed project and states building out space to house mammography and ultrasound services in a medical office building under development that will house other medical services, including an ambulatory surgery center,

achieves operational and economic efficiencies compared to developing a new medical office building to house imaging services only, or to developing each modality in separate facilities; and allows for shared waiting areas and other overhead space. The applicant states that the project as proposed provides a cost-effective plan to meet clinical needs and patient satisfaction.

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

- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all statutory and regulatory review criteria.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to comments

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. **Duke University Health System, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
2. **The certificate holder shall develop a new diagnostic imaging center by acquiring mammography and ultrasound equipment, as designated in the application.**
3. **Progress Reports:**
 - a. **Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. **The certificate holder shall complete all sections of the Progress Report form.**

Duke Coley Capital Cost

Construction Costs	\$630,000
Medical Equipment*	\$ 526,000
Miscellaneous Costs	\$ 564,000
Total	\$1,720,000

*Medical equipment includes Mammography (\$342,800) and Ultrasound (\$182,982)

In Section Q, following the pro forma financial statements, the applicant provides the assumptions used to project the capital cost. Exhibit F contains supporting documentation. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- Building construction, permitting, and contingency items are based on the letter from the Architect in Exhibit F.1(a).
- Medical equipment is based on the mammography and ultrasound equipment quotes in Exhibit F.1(b).
- Other costs are based on DUHS experience developing similar projects.

In Section F, pages 40-42, the applicant does not list any working capital or initial operating expenses and states that the proposed facility will be operated as part of the Duke University Health System and will not have separate financial statements. The funding letter in Exhibit F.2(a) documents availability of more than \$1M in excess of projected capital costs to cover any operating expenses before services are offered and/or until revenues exceed expenses.

Availability of Funds

In Section F, page 39, the applicant states that the capital cost will be funded as shown below in the table.

Sources of Capital Cost Financing

Type	DUHS
Loans	\$0
Accumulated reserves or OE *	\$1,720,000
Bonds	\$0
Other (Specify)	\$0
Total Financing	\$1,720,000

* OE = Owner's Equity.

As stated above, the applicant does not project working capital or initial operating expenses as the proposed facility will be operated as a part of DUHS. Thus, any start-up costs and any initial operating expenses, if incurred, will be funded by DUHS.

Exhibit F.2(a) contains a copy of a letter dated November 12, 2020 from the Senior Vice President and Chief Financial Officer for DUHS expressing its intention to fund the capital costs and any other associated costs of the project with accumulated reserves, documenting availability of more than \$1 million in excess of the projected capital cost of the project.

Exhibit F.2(b) contains a copy of the audited financial statements for DUHS which indicate it had cash and cash equivalents of \$157 million as of June 30, 2020.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project based on the following:

- The DUHS CFO confirms DUHS’s intention to fund the project.
- DUHS’s audited financial statements confirm adequate accumulated reserves to fund the project.

Financial Feasibility

The applicant provides separate pro forma financial statements for the first three full fiscal years of operation following completion of the project for DUHS, Duke Coley Hall Imaging (diagnostic services), mammography only services, and ultrasound only services. In Form F.2 Revenues and Net Income, the applicant projects that revenues will exceed operating expenses in each of the third full fiscal year of operation following completion of the proposed project for Duke Coley’s diagnostic services, as shown in the table below.

Duke Coley Diagnostic Services

	1st Full FY 7/1/21- 6/30/22	2nd Full FY 7/1/22- 6/30/23	3rd Full FY 7/1/23- 6/30/24
Total Procedures (mammography and ultrasound)	1,977	3,903	5,865
Total Gross Revenues (Charges)	\$679,327	\$1,358,703	\$2,076,350
Total Net Revenue	\$289,014	\$576,734	\$879,626
Average Net Revenue per Procedure	\$146	\$148	\$150
Total Operating Expenses (Costs)	\$688,083	\$767,503	\$807,069
Average Operating Expense per Procedure	\$348	\$197	\$138
Net Income	(\$399,070)	(\$190,768)	\$72,557

Furthermore, Form F.2 for DUHS shows a net income in excess of \$100 million in each of the three project years. The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Procedure gross charges are based on IDTF CDM Charge Master provided by Revenue Management effective date July 1, 2020.
- The applicant bases expenses on historical expenses for similar DUHS projects.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

- The applicant adequately demonstrates that the capital is based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant, DUHS, proposes to develop a new diagnostic center, Duke Coley, by acquiring and installing mammography and ultrasound equipment in renovated leased space at 66 Vilcom Drive, Chapel Hill, NC.

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 in 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.3, the applicant refers to Section Q for the assumptions which define the primary service area for the proposed diagnostic center as the ZIP code areas within 10-15 minutes driving time of the facility.

In Section C, pages 18-20, the applicant lists the patient origin by ZIP code in Orange and Durham counties for procedures provided to the patients it proposes to serve; thus, the service area for this facility consists of portions of Orange and Durham County. Facilities may also serve residents not included in their service area.

In Section G.1, page 45, the applicant states, “*There is no listing of existing and approved diagnostic centers that provide mammography or ultrasound maintained by the state.*” The

applicant provides the American College of Radiology's list of facilities that are either accredited or have accreditation in progress within 10 miles of ZIP code 27514, as follows:

- Wake Radiology Diagnostic Imaging (27514)
- UNC Hospitals NC Cancer Hospital (27514);
- UNC Hospitals Imaging and Spine Center (27517)
- UNC Hospitals-Hillsborough (27278)
- Duke University Hospital – Patterson Place (27707)

The applicant states that the above facilities may or may not be diagnostic centers. On pages 45-56, the applicant also provides the mammography and ultrasound procedures reported by Duke University Hospital and UNC Hospitals on their 2020 license renewal applications (LRAs).

In Section G.3, page 46, the applicant explains why it believes its proposal would not result in an unnecessary duplication of existing or approved diagnostic centers in Orange County. The applicant states:

“The population in Chapel Hill and surrounding areas is growing quickly and the demand for imaging services is growing with it, as set forth in response to Section C. DUHS does not currently have any outpatient imaging services in Orange County. In addition, there are limited options for non-hospital based services in the area. As the population grows and ages, and as that population also faces insurance network limitations, providing access to cost-effective services and choice of providers will be essential. This project will therefore not unnecessarily duplicate any existing imaging services in the service area. Moreover, as set forth in letters from providers supporting the project are [sic] attached at Exhibit C.4(b), DUHS's existing imaging services are highly utilized and this project is needed to address capacity constraints for existing services.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- There is not a need determination in the 2020 SMFP for diagnostic centers.
- The proposal would not result in an increase in any regulated imaging services.
- The applicant adequately demonstrates that the proposed diagnostic center is needed in addition to the existing or approved diagnostic centers in the service area to meet the identified need.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

- Responses to comments
- 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 above stated reasons.

- (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

The applicant, DUHS, proposes to develop a new diagnostic center, Duke Coley, by acquiring and installing mammography and ultrasound equipment in renovated leased space at 66 Vilcom Drive, Chapel Hill, NC.

In Section Q Form H, the applicant provides the projected full-time equivalent (FTE) positions for the proposed diagnostic (mammography and ultrasound) services at Duke Coley, as shown in the table below.

Position	Projected FTE Positions
	2nd Full FY 7/1/22-6/30/23
Radiology Technologist	1.12
Ultrasound/Mammography Supervisor	0.28
Patient Service Associate	0.28
Financial Care Counselor	1.12
Sonographer	1.12
Imaging Manager	0.11
TOTAL	4.03

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H, pages 47-48, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs. In Exhibit H, the applicant provides supporting documentation.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- FTE positions provided by DUHS Radiology Ambulatory Director based on a review of the anticipated volumes by year and current staffing models at other DUHS outpatient imaging locations.
- DUHS is a major employer in the Triangle area and has historically been able to recruit and retain clinical and non-clinical personnel.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

The applicant, DUHS, proposes to develop a new diagnostic center, Duke Coley, by acquiring and installing mammography and ultrasound equipment in renovated leased space at 66 Vilcom Drive, Chapel Hill, NC.

Ancillary and Support Services

In Section I, page 49, the applicant states that the following ancillary and support services are necessary for the proposed services:

- Business office/registration
- Medical records
- Administration
- Materials management
- Quality control
- Clinical engineering
- Laundry/housekeeping

On page 49, the applicant adequately explains how each ancillary and support service will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- All ancillary services will be provided by DUHS employed staff, with the exception of laundry/housekeeping provided pursuant to third party contracts.
- Financial counseling will be onsite.

- Other services will be handled centrally by existing DUHS departments who provide services at DUHS's existing IDTF.
- Professional services, including interpretations, will continue to be provided by radiologist members of the Private Diagnostic Clinic, PLLC.
- Duke radiologists will rotate through to provide any necessary on-site medical coverage.

Coordination

In Section I, page 50, the applicant describes this IDTF as part of DUHS's efforts to develop relationships with other local health care and social service providers and provides supporting documentation in a DUHS link² and in physician support letters in Exhibit C.4(b).

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The proposed IDTF will be part of DUHS, which includes inpatient acute care, outpatient surgery, psychiatric, and rehabilitation services, primary care, home health and hospice services.
- Duke Health primary care, specialty care, and ambulatory surgery will be provided in the same medical building.
- DUHS works closely with the Private Diagnostic Clinic, PLLC, the Duke Health faculty practice which provides a full range of specialty physician services across the Triangle.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

- (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.

²https://corporate.dukehealth.org/sites/default/files/2020-05/WEB_MKT-1824_2019%20Community%20Benefit%20Report_final_0.pdf#:~:text=Duke%20University%20Health%20System%20Report%20on%20Community%20Benefit.,for%20the%20people%20and%20communities%20of%20North%20Carolina

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.

- (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.

C

The applicant, DUHS, proposes to develop a new diagnostic center, Duke Coley, by acquiring and installing mammography and ultrasound equipment in renovated leased space at 66 Vilcom Drive, Chapel Hill, NC in a medical office building currently under development.

In Section K, page 53, the applicant states that the project involves renovating 2,500 square feet in a medical office building under development that will house other medical services, including an ambulatory surgery center. Line drawings are provided in Exhibit K.2.

On pages 54-55, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site. Supporting documentation is provided in Exhibit

K.4. The site appears to be suitable for the proposed diagnostic center based on the applicant's representations and supporting documentation.

On pages 53-54, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- Building out space to house mammography and ultrasound services in a medical office building under development that will house other medical services, including an ambulatory surgery center, achieves operational and economic efficiencies compared to developing a new medical office building to house imaging services only, or to develop each modality in separate facilities.
- Consolidating multiple services in one location allows for shared waiting areas and other overhead space.
- DUHS worked with the architects to develop a cost-effective plan to meet clinical needs and patient satisfaction and believes the proposed plan to be the most reasonable and cost-effective alternative.

On page 54, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- Establishing a new non-hospital-based imaging site provides a potentially lower-cost alternative for patients and payors.
- The capital cost of the project will not affect the contracted rates for private payors or the fee schedule for government payors.
- DUHS has concluded that any costs incurred to develop and operate the center are necessary and appropriate to provide critical screening and diagnostic services for patients in the area.

On page 54, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit F.1(a).

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

(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 ... persons [with disabilities], 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;

NA

The proposed diagnostic center will be a new service at a DUHS IDTF; thus, it has no historical payor mix.

- (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 ... persons [with disabilities] to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

NA

The proposed diagnostic center will be a new service at a DUHS IDTF; thus, it has no past performance.

- (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 61, the applicant projects the payor mix for the proposed services during the third full fiscal year (July 1, 2023-June 30, 2024) of operation following completion of the project, as shown in the table below.

Duke Coley Hall Imaging Payor Mix
 As a Percent of Total Services

Payor Category	Entire Facility or Campus	Ultrasound	Mammography
Self-Pay	0.73%	1.09%	0.18%
Charity Care	2.31%	3.21%	0.96%
Medicare*	33.25%	32.61%	34.21%
Medicaid*	4.17%	6.34%	0.91%
Insurance*	59.09%	56.18%	63.46%
Workers Compensation	0.03%	0.04%	0.00%
TRICARE	0.28%	0.31%	0.23%
Other (Specify)	0.15%	0.22%	0.05%
Total	100.00%	100.00%	100.00%

*Including any managed care plans

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 0.73% of total services will be provided to self-pay patients, 2.31% to charity care patients, 33.25% to Medicare patients and 4.17% to Medicaid patients.

On page 61, the applicant provides the assumptions and methodology used to project payor mix during the first three years of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- DUHS assumes a baseline reflecting the existing payor mix for those existing patients originating from the identified ZIP codes.
- Future payor mix was then adjusted to account for the anticipated shift in the population from managed care payors to Medicare as the population ages, with an annual shift of 3.8% in FY2021 and FY2022, held constant thereafter.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

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

C

In Section L, page 62, 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
- Written comments
- Responses to comments

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

The applicant, DUHS, proposes to develop a new diagnostic center, Duke Coley, by acquiring and installing mammography and ultrasound equipment in renovated leased space at 66 Vilcom Drive, Chapel Hill, NC.

In Section M, page 63, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and states:

“DUHS also provides training opportunities for radiology technician students in the area. Students from UNC, Wake Tech, Johnston Community College and other local training programs may be rotated through this proposed facility pursuant to existing training agreements.”

The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- Duke provides a five-year combined residency and fellowship program in diagnostic Radiology that accepts 12 residents per year.
- Second year students at the Duke University School of Medicine are required to take a radiology rotation as part of their core curriculum.
- Duke radiologists read scans from throughout the system, including outpatient sites such as IDTFs, thus students and residents are anticipated to participate in the radiology interpretations at the proposed location.
- DUHS has existing training programs, including radiology technicians, and will extend training opportunities to the proposed site.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

- Written comments
- Responses to comments

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

- (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, DUHS, proposes to develop a new diagnostic center, Duke Coley, by acquiring and installing mammography and ultrasound equipment in renovated leased space at 66 Vilcom Drive, Chapel Hill, NC.

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 in 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.3, the applicant refers to Section Q for the assumptions which define the primary service area for the proposed diagnostic center as the ZIP code areas within 10-15 minutes driving time of the facility. Facilities may also serve residents not included in their service area.

In Section C, pages 18-19, the applicant lists the patient origin by ZIP code in Orange and Durham counties of the patients it proposes to serve; thus, the primary service area for this facility consists of portions of Orange and Durham counties, with in-migration from other Orange and Durham ZIP codes and adjacent counties.

In Section G.1, page 45, the applicant states, “*There is no listing of existing and approved diagnostic centers that provide mammography or ultrasound maintained by the state.*” The applicant provides the American College of Radiology’s list of facilities that are either accredited or have accreditation in progress within 10 miles of ZIP code 27514, as follows:

- Wake Radiology Diagnostic Imaging (27514)

- UNC Hospitals NC Cancer Hospital (27514);
- UNC Hospitals Imaging and Spine Center (27517)
- UNC Hospitals-Hillsborough (27278)
- Duke University Hospital – Patterson Place (27707)

The applicant states that the above facilities may or may not be diagnostic centers. On pages 45-56, the applicant also provides the mammography and ultrasound procedures reported by Duke University Hospital and UNC Hospitals on their 2020 license renewal applications (LRAs).

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 64, the applicant states:

“This project will benefit competition by creating a new outpatient/non-hospital based imaging services provider in Orange County. This new center will expand provider choice for patients, particularly those in Orange County and surrounding areas.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 64, the applicant states:

“This project will create a new, non-hospital based imaging site, DUHS’s first in this part of Orange County. The proposed IDTF structure typically has lower reimbursement than hospital facilities and is more cost effective for many payor and patients depending on their plan terms.”

See also Sections C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 64, the applicant states that DUHS is committed to delivering high-quality care at all its facilities and will continue to maintain the highest standards and quality of care, consistent with the standards that DUHS has sustained throughout its illustrious history of providing patient care.

See also Sections C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 65, the applicant states:

“As previously stated, DUHS will continue to have a policy to provide services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.”

See also Section L and C of the application and any exhibits.

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, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrates: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services and DUHS's record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to comments

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 Form A Facilities, the applicant identifies the like facilities located in North Carolina and owned, operated or managed by the applicant or a related entity. The applicant identifies a total of four of this type of facility located in Wake and Durham counties.

In Section O, page 67, the applicant states that, during the 18 months immediately preceding the submittal of the application, it is not aware of any incidents, regarding quality care at any of the four diagnostic centers. After reviewing and considering information provided by the applicant and considering the quality of care provided at all four facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NA

The applicant proposes to develop a new diagnostic center, Duke Coley Hall Imaging, by acquiring mammography and ultrasound equipment.

The Criteria and Standards for Diagnostic Centers were repealed, effective March 16, 2017. The project does not involve any other regulated medical diagnostic equipment for which there are applicable Criteria and Standards. Therefore, there are no performance standards applicable to this review.