

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: April 9, 2021

Findings Date: April 9, 2021

Project Analyst: Celia C. Inman

Team Leader: Gloria C. Hale

Project ID #: G-12015-21

Facility: Kernodle Clinic Burlington

FID #: 210087

County: Alamance

Applicant: Private Diagnostic Clinic, PLLC

Project: Develop a new diagnostic center at Kernodle Clinic to include x-ray, ultrasound, EEG, nuclear camera, DEXA, Topcon Eye Retina scanner, scrambler therapy and pulmonary function testing

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

Private Diagnostic Clinic, PLLC, hereinafter referred to as PDC or “the applicant”, proposes to develop a new diagnostic center at Kernodle Clinic Burlington (Kernodle) to include existing x-ray, ultrasound, EEG, nuclear camera, DEXA, Topcon Eye Retina scanner, scrambler therapy and pulmonary function testing equipment.

The applicant does not propose to:

- develop any beds or services for which there is a need determination in the 2021 State Medical Facilities Plan (SMFP),
- acquire any medical equipment for which there is a need determination in the 2021 SMFP, or

- offer a new institutional health service for which there are any applicable policies in the 2021 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- (2) Repealed effective July 1, 1987.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, PDC, proposes to develop a new diagnostic center at Kernodle to include existing x-ray, ultrasound, EEG, nuclear camera, DEXA, Topcon Eye Retina scanner, scrambler therapy and pulmonary function testing equipment.

In Section C.1, pages 26-27, the applicant states that Kernodle is an Alamance County-based large, multi-specialty group practice operating numerous types of medical equipment needed to support the daily clinical operations of the specialty clinics. The applicant states:

“Therefore, Kernodle Clinic has acquired various medical diagnostic equipment over the last 25 years, unaware that the North Carolina Certificate of Need Statute regulated diagnostic centers.

Through recent planning discussions, PDC leadership became aware that the costs for the existing medical diagnostic equipment at Kernodle Clinic Burlington exceeds \$500,000, and thus, requires a certificate of need for a diagnostic center. PDC is submitting this CON application in good faith, requesting Kernodle Clinic Burlington be designated at [sic] a diagnostic center.”

The proposed project involves the existing medical diagnostic equipment at Kernodle. The applicant does not project to acquire new equipment or develop new services as part of this project.

Designation as a Diagnostic Center

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.”

On page 27, the applicant provides a list of the existing equipment, date of acquisition, and its purchase price, as summarized in the following table:

Equipment	Manufacturer	Acquisition Date	Purchase Price
X-ray #1 (CR)	Konica	2/1/2009	\$128,500
X-ray #2 (DR)	Konica	12/1/2017	\$184,500
X-ray #3(DR)	Konica	3/1/2019	\$213,700
C-arm	GE	3/1/2015	\$55,200
Ultrasound #1 (Cardiac Echo)	Philips	9/21/2018	\$144,500
Ultrasound #2 (Cardiac Echo)	Philips	8/17/2017	\$156,500
Ultrasound #3 (Cardiac Echo)	Philips	8/17/2017	\$156,500
Ultrasound #4 (OBGYN)	GE	12/15/2014	\$76,700
Ultrasound #5 (MSK)	GE	9/28/2018	\$46,000
Ultrasound #6 (OBGYN)	Philips	12/28/2017	\$75,200
EEG #1	Natus	8/22/2017	\$38,400
EEG #2	Cadwell	7/31/2017	\$22,800
Nuclear Camera	Philips	2/1/2006	\$214,000
Dexa Bone Densitometer	Hologic	4/9/1996	\$82,000
Topcon Eye Retina Scanner	Topcon	7/2/2020	\$50,000
Scrambler Therapy	Delta International	7/1/2019	\$63,000
Pulmonary Function	VIASYS	1/14/2008	\$27,900
Total			\$1,735,400

In addition to the above existing equipment, it is expected that another physician will relocate his practice, which includes one ultrasound valued at \$20,650, to join Kernodle in April 2021. This will increase Kernodle’s inventory of ultrasounds to seven and the total value of diagnostic equipment to \$1,756,050, which exceeds the statutory threshold of \$500,000. Therefore, Kernodle 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 2021 SMFP does not define a service area for diagnostic centers nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant.

In Section C, page 39, the applicant states that the service area for the proposed project is Alamance County. Facilities may also serve residents not included in their service area.

In Section C.2, pages 28-30, the applicant provides the historical patient origin for the last full fiscal year (FY), CY2020, for each diagnostic modality, as summarized in the tables below. On page 28, the applicant states:

“Please note the patient origin reflects unique patient encounters. Some patients receive more than one diagnostic procedure during the fiscal year; thus, the number of unique patients is not equivalent to the number of diagnostic procedures.”

**Historical Patient Origin by Modality
 CY2020**

County	Ultrasound		X-ray/Fluoro		Nuclear Medicine		DEXA	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Alamance	1,432	75.6%	10,397	79.0%	699	80.7%	977	82.2%
Guilford	213	11.2%	1,451	11.0%	70	8.1%	100	8.4%
Caswell	50	2.6%	253	1.9%	16	1.8%	27	2.3%
Orange	34	1.8%	0	0.0%	21	2.4%	18	1.5%
Randolph	40	2.1%	291	2.2%	16	1.8%	18	1.5%
Rockingham	23	1.2%	0	0.0%	0	0.0%	0	0.0%
Durham	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Wake	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Virginia	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Other*	102	5.4%	768	5.8%	44	5.1%	48	4.0%
Total	1,894	100.0%	13,161	100.0%	866	100.0%	1,188	100.0%

Rounding has an insignificant effect on number of patients, percent and sums

*Other includes NC counties and other states with less than one percent

**Historical Patient Origin by Modality
 CY2020**

County	Topcon Retina Imaging		Scrambler Therapy		EEG		Pulmonary Function	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Alamance	362	81.5%	7	63.6%	101	71.8%	250	79.7%
Guilford	4	0.8%	1	9.1%	15	10.4%	29	9.2%
Caswell	49	11.1%	0	0.0%	5	3.5%	9	2.8%
Orange	0	0.0%	0	0.0%	2	1.6%	6	1.9%
Randolph	0	0.0%	0	0.0%	3	2.2%	5	1.6%
Rockingham	16	3.6%	0	0.0%	3	1.9%	0	0.0%
Durham	0	0.0%	1	9.1%	0	0.0%	3	1.0%
Wake	0	0.0%	0	0.0%	2	1.3%	0	0.0%
Virginia	0	0.0%	2	18.2%	0	0.0%	0	0.0%
Other*	13	3.0%	0	0.0%	10	7.3%	12	3.8%
Total	444	100.0%	11	100.0%	140	100.0%	313	100.0%

Rounding has an insignificant effect on number of patients, percent and sums

*Other includes NC counties and other states with less than one percent

On page 31, the applicant provides the historical patient origin for CY2020 for the entire facility (all diagnostic modalities), as summarized in the table below.

**Historical Patient Origin Entire Facility
 CY2020**

County	Number of Patients	Percent of Total
Alamance	14,228	79.0%
Guilford	1,872	10.4%
Caswell	415	2.3%
Orange	85	0.5%
Randolph	370	2.1%
Other*	1,046	5.8%
Total	18,017	100.0%

Rounding has an insignificant effect on number of patients, percent and sums

*Other includes Rockingham, Durham, Wake, Virginia, and less than one percent from other North Carolina counties and other states.

In Section C.3, pages 32-35, the applicant provides the projected patient origin for the first three full fiscal years (CY2022-CY2024) for each diagnostic modality. The tables below summarize the projected patient origin for each diagnostic modality for the third full fiscal year, CY2024.

**Projected Patient Origin by Modality
 CY2024**

County	Ultrasound		X-ray/Fluoro		Nuclear Medicine		DEXA	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Alamance	1,667	75.6%	11,555	79.0%	840	80.7%	1,095	82.3%
Guilford	248	11.3%	1,613	11.0%	84	8.1%	112	8.4%
Caswell	58	2.6%	281	1.9%	19	1.8%	30	2.3%
Orange	40	1.8%	0	0.0%	25	2.4%	20	1.5%
Randolph	47	2.1%	323	2.2%	19	1.8%	20	1.5%
Rockingham	27	1.2%	0	0.0%	0	0.0%	0	0.0%
Durham	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Wake	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Virginia	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Other*	119	5.4%	854	5.8%	53	5.1%	54	4.1%
Total	2,204	100.0%	14,626	100.0%	1,040	100.0%	1,331	100.0%

Rounding has an insignificant effect on number of patients, percent and sums
 *Other includes NC counties and other states with less than one percent

**Projected Patient Origin by Modality
 CY2024**

County	Topcon Retina Imaging		Scrambler Therapy		EEG		Pulmonary Function	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Alamance	373	81.5%	7	63.6%	259	71.8%	844	79.7%
Guilford	4	0.8%	1	9.1%	38	10.4%	97	9.2%
Caswell	51	11.1%	0	0.0%	13	3.5%	29	2.8%
Orange	0	0.0%	0	0.0%	6	1.6%	17	1.6%
Randolph	0	0.0%	0	0.0%	8	2.2%	20	1.9%
Rockingham	16	3.6%	0	0.0%	7	1.9%	11	1.0%
Durham	0	0.0%	1	9.1%	0	0.0%	0	0.0%
Wake	0	0.0%	0	0.0%	5	1.3%	0	0.0%
Virginia	0	0.0%	2	18.2%	0	0.0%	0	0.0%
Other*	14	3.0%	0	0.0%	26	7.3%	40	3.8%
Total	457	100.0%	11	100.0%	360	100.0%	1,059	100.0%

Rounding has an insignificant effect on number of patients, percent and sums
 *Other includes NC counties and other states with less than one percent

On page 36, the applicant provides the projected patient origin for CY2024 for the entire facility (all diagnostic modalities), as summarized in the table below.

**Projected Patient Origin Entire Facility
CY2024**

County	Number of Patients	Percent of Total
Alamance	16,712	79.0%
Guilford	2,199	10.4%
Caswell	488	2.3%
Orange	99	0.5%
Randolph	435	2.1%
Other*	1,229	5.8%
Total	21,162	100.0%

Rounding has an insignificant effect on number of patients, percent and sums

*Other includes Rockingham, Durham, Wake, Virginia, and less than one percent from other North Carolina counties and other states

In Section C.3, the applicant refers to Section Q for the assumptions and methodology used to project the number of patients by county, stating that the applicant expects future patient origin to remain consistent with the historical experience at Kernodle.

The applicant's assumptions are reasonable and adequately supported based on the following:

- projected patient origin is based on the historical patient origin on the existing diagnostic modalities at the facility
- projected growth is based on the projected Alamance County population growth of 1.0%

Analysis of Need

The proposed project involves the existing medical diagnostic equipment at Kernodle. The applicant does not project to acquire new equipment or develop new services as part of this project.

In Section C.4, pages 36-41, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

- The diagnostic equipment is integral to PDC's continuum of specialty services and is necessary for the clinicians to properly diagnose patients. (pages 37-38)
- Utilization of the diagnostic equipment enables PDC to provide cost-effective services to meet patient expectations and ensure quality care. (pages 38-39)
- The service area demographics, including projected growth of the service area population, presumes continued increases in demand for healthcare. (pages 39-41)

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

- The applicant provides data to support the use of the existing diagnostic equipment to provide specialty physician services at Kernodle.

- The applicant provides utilization data regarding the historical use of the existing diagnostic equipment at Kernodle.
- The applicant provides reasonable and adequately supported information to support its assertion that the existing diagnostic equipment is needed to meet the growing population and the growing segment of residents over 65 in the service area.
- The applicant provides reasonable and adequately supported information to support its assertion that the existing diagnostic equipment is needed to meet the need for diagnostic services for the medically underserved residents in the service area.

Projected Utilization

In Section Q Form C.2a, page 94, the applicant provides the historical utilization for the existing diagnostic equipment for the last full fiscal year of operation, CY2020, and the interim full fiscal year, CY2021, as summarized in the following table.

Historical and Interim Year Utilization by Modality

Modality	CY2020	CY2021
X-ray (including Fluro)		
# of Units	4	4
# of Procedures	20,850	22,500
Nuclear Medicine		
# of Units	1	1
# of Procedures	900	1,050
Ultrasound		
# of Units	6	7
# of Procedures*	5,580	6,306 [6,246]
DEXA Bone Density		
# of Units	1	1
# of Procedures	1,250	1,360
Topcon		
# of Units	1	1
# of Procedures	444	444
Scrambler Therapy		
# of Units	1	1
# of Procedures	90	90
Pulmonary Function		
# of Units	1	1
# of Procedures	313	1,028
EEG		
# of Units	2	2
# of Procedures	140	350
Total Procedures *	29,567	33,128[33,068]

*Methodology states CY2021 ultrasound procedures at 6,246 and the table on page 94 states CY2021 ultrasound procedures at 6,306. The difference is the result of projecting only 75% of the seventh ultrasound's annual utilization of 240 to prorate for number of months after joining practice. The prorated utilization failed to get entered in the table on page 94. This is a typographical error and of no consequence.

In Section Q Form C.2b, page 95, the applicant provides the projected utilization for the existing diagnostic equipment for the first three years of operation following completion of the project, as summarized in the following table.

Projected Utilization by Modality

Modality	CY2022	CY2023	CY2024
X-ray (including Fluro)			
# of Units	4	4	4
# of Procedures	22,721	22,945	23,171
Nuclear Medicine			
# of Units	1	1	1
# of Procedures	1,060	1,071	1,081
Ultrasound			
# of Units	7	7	7
# of Procedures	6,368	6,431	6,494
DEXA Bone Density			
# of Units	1	1	1
# of Procedures	1,373	1,387	1,401
Topcon			
# of Units	1	1	1
# of Procedures	448	453	457
Scrambler Therapy			
# of Units	1	1	1
# of Procedures	91	92	93
Pulmonary Function			
# of Units	1	1	1
# of Procedures	1,038	1,048	1,059
EEG			
# of Units	2	2	2
# of Procedures	353	357	360
Total Procedures*	33,212 [33,452]	33,538 [33,784]	33,868 [34,116]

Totals may not sum due to rounding

*Applicant's total procedures are less than the individual modality procedures by 240, 246 and 248 procedures in CY2022, CY2023, and CY2024, respectively. The totals shown in [] approximate those in the applicant's table for projected procedures in its methodology on page 97. The difference appears to relate to procedures for the seventh ultrasound and is considered an insignificant error in the transfer of numbers.

In Section Q Form C Assumptions & Methodology, pages 96-98, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- CY2022-CY2024 are projected to be the first three full fiscal years for the project
- Calculate the compound annual growth rate (CAGR) from CY2017 through CY2019 for each modality and for total diagnostic procedures (7.2%)
- Though COVID affected systemwide procedure volumes, PDC anticipates the need for services in future years will return to pre-COVID levels
- PDC projects interim year CY2021 procedures for X-ray, nuclear medicine, DEXA, pulmonary function, and EEG will approximate CY2019 procedure volumes

- The scrambler therapy and topcon retina equipment was acquired in 2019 and 2020, respectively, thus CY2021 procedures will reflect the most recent CY2020 utilization
- 2021 Ultrasound procedures on the six existing units will approximate CY2019 volumes at 6,066 procedures with the seventh ultrasound joining the practice with a projected 180 procedures for a total of 6,246 procedures
- PDC projects procedures will increase based on the projected population growth for Alamance County at 1.0 percent annually
- The number of unique patients is not equivalent to the number of diagnostic procedures. PDC projects patients by modality based on the CY2020 ratio of diagnostic procedures to patients. The following table summarizes Kernodle’s ratio of procedures to patients per modality based on CY2020 data

Modality	CY2020 Patients	CY2020 Procedures	Ratio Procedure:Patient
X-ray (including Fluro)	13,161	20,850	1.58
Nuclear Medicine	1,894	5,580	2.95
Ultrasound	866	900	1.04
DEXA Bone Density	1,188	1,250	1.05
Topcon	444	444	1.00
Scrambler Therapy	11	90	8.18
Pulmonary Function	313	313	1.00
EEG	140	140	1.00
Total Procedures	18,017	29,567	1.64

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

- Projected utilization is based on Kernodle’s historical experience on the existing diagnostic modalities.
- Beginning the projected utilization based on pre-pandemic volume is reasonable and conservative given the facility’s utilization during the fourth quarter of 2020 was representative of pre-pandemic volumes.
- Projected population increases in the service area are expected to support an increase in the utilization of diagnostic services.
- Applying the Alamance County population growth rate of 1.0% to project future utilization is reasonable because 80% of the patients originate from Alamance County and 1% is conservative compared to the applicant’s 2-year CAGR of 7.2%.
- Letters of support in Exhibit I.2 support the increase in nuclear medicine procedures following the CY2019 decline.

Access to Medically Underserved Groups

In Section C.6, page 46, the applicant provides the estimated percentage for each medically underserved group to be served at Kernodle in CY2024, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	2.8%
Racial and ethnic minorities	23.2%
Women	65.3%
Persons with Disabilities*	
The elderly	49.9%
Medicare beneficiaries	49.9%
Medicaid recipients	5.7%

*PDC does not retain data on the number of disabled patients; however, disabled persons have not and will not be denied access to the applicant's diagnostic services

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 states its commitment to the health and well-being of all patients
- PDC has historically provided care and services to medically underserved populations
- The applicant states, on page 46, that PDC does not discriminate based on income, race, ethnicity, creed, color, age, religion, national origin, gender, physical or mental handicap, sexual orientation, ability to pay, or any other factor that would classify a patient as underserved
- The applicant states, on page 46, that PDC will continue to be accessible by any patient having a clinical need for diagnostic services

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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 all the reasons described above.

- (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.

C

The applicant, PDC, proposes to develop a new diagnostic center at Kernodle to include existing x-ray, ultrasound, EEG, nuclear camera, DEXA, Topcon Eye Retina scanner, scrambler therapy and pulmonary function testing equipment.

In Section E, pages 54-55, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the status quo – the applicant states that this is not an effective alternative because the value of the existing diagnostic equipment at Kernodle exceeds \$500,000, which requires a certificate of need for a diagnostic center.
- Decommission medical diagnostic equipment in use at Kernodle – the applicant states that the drastic alternative of decommissioning existing diagnostic equipment at Kernodle that exceeds \$500,000 would unnecessarily deny access to needed services for tens of thousands of patients receiving care at Kernodle. The existing diagnostic equipment is essential for the physician clinics to continue providing the necessary care to their patients in a cost-effective and efficient manner.

In Section E, page 54, the applicant states:

“The presence of the existing medical diagnostic equipment in the physician clinics at Kernodle Clinic Burlington is critical to a provider’s ability to give a patient a same-day diagnosis, rule out a diagnosis, or schedule the next step in a patient’s course of care. Therefore, the medical diagnostic equipment at Kernodle Clinic Burlington is needed to promptly meet patients’ diagnostic needs and reduce unnecessary visits to the emergency department.”

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 other statutory and regulatory review criteria. Therefore, the application can be approved.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

1. **Private Diagnostic Clinic, PLLC (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 center with existing diagnostic 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.**
 - c. **The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. **Progress reports shall be due on the first day of every third month. The first progress report shall be due on October 1, 2021. The second progress report shall be due on January 1, 2022 and so forth.**
4. **The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
5. **No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, the certificate holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
 - a. **Payor mix for the services authorized in this certificate of need.**

- b. **Utilization of the services authorized in this certificate of need.**
- c. **Revenues and operating costs for the services authorized in this certificate of need.**
- d. **Average gross revenue per unit of service.**
- e. **Average net revenue per unit of service.**
- f. **Average operating cost per unit of service.**

7. **The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**

(5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant, PDC, proposes to develop a new diagnostic center at Kernodle to include existing x-ray, ultrasound, EEG, nuclear camera, DEXA, Topcon Eye Retina scanner, scrambler therapy and pulmonary function testing equipment.

Capital and Working Capital Costs

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

Project Capital Cost	
Consultant Fees	\$ 50,000
Total	\$50,000

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

- The project involves no new equipment or services
- The project involves no construction or renovation
- The consultant fees reflect the fees to develop and submit the CON application

In Section F, page 56, the applicant states that the project involves existing diagnostic equipment with minimal capital expenditure associated with the CON submittal. The letter from PDC's CFO in Exhibit F.2 documents PDC's intent to cover the anticipated \$50,000 in capital cost with cash reserves.

On page 58, the applicant states that the project does not involve any working capital.

Availability of Funds

In Section F, page 56, the applicant states that the capital cost will be funded as shown in the table below.

Type	PDC
Loans	\$0
Accumulated reserves or OE *	\$50,000
Bonds	\$0
Other (Specify)	\$0
Total Financing	\$50,000

* OE = Owner’s Equity.

Exhibit F.2 contains a copy of a letter dated January 19, 2021 from the Senior Vice President for First Citizens Bank documenting the availability of enough funds to cover the anticipated \$50,000 in capital cost.

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

- The PDC CFO confirms PDC’s intention to fund the project
- First Citizens Bank documents the availability of adequate funds

Financial Feasibility

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2 Revenues and Net Income, the applicant projects that revenues will exceed operating expenses in each of the three full fiscal year of operation following completion of the proposed project, as shown in the table below.

Kernodle Clinic Burlington Diagnostic Services			
	1st Full FY CY2022	2nd Full FY CY2023	3rd Full FY CY2024
Total Procedures	33,454	33,783	34,115
Total Gross Revenues (Charges)	\$11,476,657	\$11,821,341	\$12,176,376
Total Net Revenue	\$3,657,232	\$3,767,072	\$3,880,210
Average Net Revenue per Procedure	\$109	\$112	\$114
Total Operating Expenses (Costs)	\$2,561,317	\$2,624,987	\$2,690,445
Average Operating Expense per Procedure	\$77	\$78	\$79
Net Income	\$1,095,916	\$1,142,085	\$1,189,765

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 2020 actual gross charge by payor for each modality with price increases of 2% annually
- Contractual adjustments are derived from the adjustments experienced in CY2020
- Expenses are based on historical expenses
- FTEs and salaries are based on current staffing and projected to average annual salary increases of 2.5%
- 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

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

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

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

C

The applicant, PDC, proposes to develop a new diagnostic center at Kernodle to include existing x-ray, ultrasound, EEG, nuclear camera, DEXA, Topcon Eye Retina scanner, scrambler therapy and pulmonary function testing equipment.

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 2021 SMFP does not define a service area for diagnostic centers nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant. In Section C, page 39, the applicant states that the service area for the proposed project is Alamance County. Facilities may also serve residents not included in their service area.

In Section G.1, page 64, the applicant states:

“PDC reviewed the Healthcare Planning and Certificate of Need Section’s website to determine any existing or approved diagnostic centers in Alamance County. However, PDC was unable to identify any such facilities. To PDC’s knowledge, utilization data for medical diagnostic equipment located in diagnostic centers is not collected by any state agency or regulatory body.”

On page 64, the applicant summarizes the number of units and utilization of similar medical diagnostic equipment located at Alamance Regional Medical Center (ARMC), as reported on ARMC’s 2020 License Renewal Application (LRA).

In Section G.2, page 65, the applicant explains why it believes its proposal would not result in an unnecessary duplication of existing or approved diagnostic centers in Alamance County. The applicant states:

“The proposed project is needed to maintain access to Kernodle Clinic Burlington’s established and well-utilized diagnostic services. No other provider can meet the identified need. While other imaging services are available in the area, Kernodle Clinic enjoys a long history of nearly three decades providing diagnostic services in Alamance County. The proposed project will not result in the development of new services; instead, it will ensure access to the existing high-quality diagnostic 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 2021 SMFP for diagnostic centers.
- The proposal would not result in an increase in any regulated imaging services.
- The project involves existing diagnostic equipment and does not result in an increase in the inventory of diagnostic equipment in the service area.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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, PDC, proposes to develop a new diagnostic center at Kernodle to include existing x-ray, ultrasound, EEG, nuclear camera, DEXA, Topcon Eye Retina scanner, scrambler therapy and pulmonary function testing equipment.

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

Position	Current FTE Positions	Projected FTE Positions
	CY2020	CY2022-CY2024
Operations Manager	1.0	1.0
Radiology Technologist	12.0	12.0
Receptionist	1.0	1.0
Medical Records	1.0	1.0
TOTAL	15.0	15.0

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 66-67, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs.

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

- FTE positions are based on CY2020 staffing at Kernodle
- Staffing is based on expected volume with minimum staffing requirements

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant, PDC, proposes to develop a new diagnostic center at Kernodle to include existing x-ray, ultrasound, EEG, nuclear camera, DEXA, Topcon Eye Retina scanner, scrambler therapy and pulmonary function testing equipment.

Ancillary and Support Services

In Section I, page 68, the applicant identifies the necessary ancillary and support services for the proposed diagnostic center services. On pages 68-69, the applicant explains how each ancillary and support service is made available at Kernodle. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- Kernodle clinic Burlington has provided diagnostic services for many years and currently has in place all ancillary and support services necessary to support the existing medical diagnostic equipment.
- The applicant states that each of the services will continue to be provided upon receipt of the CON.
- Housekeeping, security, and maintenance are provided via third parties.
- Registration and administration will continue to be provided directly by existing staff positions within various physician clinics where the equipment is located.

Coordination

In Section I, page 68-69, the applicant describes its existing and proposed relationships with other local health care and social service providers, stating that the Kernodle Clinic Burlington physicians have extensive relationships with physicians, healthcare providers, and social service providers in Alamance County and the surrounding communities which will continue into the future, and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- Kernodle Clinic's existing relationships which were established during the 70 years it has been operating in the Alamance County healthcare community
- Support letters in Exhibit I.2

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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.

NA

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

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as

medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... 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;

C

In Section L, page 74, the applicant provides the historical payor mix during CY2020 for the diagnostic services involved in the proposed project, as shown in the table below.

**Kernodle Clinic Burlington
 CY2020**

Payor Category	Clinic Services as Percent of Total
Self-Pay	2.8%
Charity Care	Included in Self-Pay
Medicare*	69.1%
Medicaid*	5.7%
Insurance*	18.6%
Workers Compensation	1.8%
Other (TRICARE and other govt)	2.0%
Total	100.0%

*Including any managed care plans

In Section L, page 75, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility during CY2020	Percentage of the Population of the Service Area*
Female	65.3%	50.8%
Male	34.7%	49.2%
Unknown		
64 and Younger	50.1%	83.5%
65 and Older	49.9%	16.5%
American Indian	0.1%	1.3%
Asian	0.7%	5.9%
Black or African-American	16.9%	13.4%
Native Hawaiian or Pacific Islander	0.1%	0.2%
White or Caucasian	79.2%	60.1%
Other Race	1.6%	
Declined / Unavailable	1.4%	

* The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the county.

The Agency reviewed the:

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

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

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

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 76, the applicant states that the facility has no such obligations.

In Section L, page 76, the applicant states that during the last 18 months preceding the application deadline, no patient civil rights access complaints have been filed against the facility.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, pages 77-80, the applicant projects the payor mix for the individual diagnostic services and the entire facility during the third full fiscal year of operation following completion of the project. On page 77, the applicant provides the proposed payor mix for the entire facility, as shown in the table below.

**Kernodle Clinic Burlington
CY2024**

Payor Category	Clinic Services as Percent of Total
Self-Pay	2.8%
Charity Care	Included in Self-Pay
Medicare*	69.1%
Medicaid*	5.7%
Insurance*	18.6%
Workers Compensation	1.8%
Other (TRICARE and other govt)	2.0%
Total	100.0%

*Including any managed care plans

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 2.8% of total services will be provided to self-pay and charity care patients, 69.1% to Medicare patients and 5.7% to Medicaid patients.

On page 80, 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 because the applicant assumes the projected payor mix will be consistent with the CY2020 payor mix for the respective diagnostic services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

In Section L, page 81, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

The applicant proposes to develop a new diagnostic center at Kernodle to include existing x-ray, ultrasound, EEG, nuclear camera, DEXA, Topcon Eye Retina scanner, scrambler therapy and pulmonary function testing equipment.

In Section M, page 83, 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:

“PDC recognizes the importance and value that local health training programs add to the medical community. PDC has existing relationships with a wide variety of health professional training programs in the community.”

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:

- The applicant provides a listing of professional training programs with which it has an existing relationship.
- PDC serves as the faculty practice plan for Duke University and PDC physicians hold academic appointments at the Duke University School of Medicine.
- PDC practices provide opportunities for training medical students and residents.
- PDC facilities, including Kernodle Clinic Burlington, will continue to be available for students training in clinical health services, as needed.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for 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, PDC, proposes to develop a new diagnostic center at Kernodle to include existing x-ray, ultrasound, EEG, nuclear camera, DEXA, Topcon Eye Retina scanner, scrambler therapy and pulmonary function testing equipment.

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 2021 SMFP does not define a service area for diagnostic centers nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant. In Section C, page 39, the applicant states that the service area for the proposed project is Alamance County. Facilities may also serve residents not included in their service area.

In Section G.1, page 64, the applicant states:

“PDC reviewed the Healthcare Planning and Certificate of Need Section’s website to determine any existing or approved diagnostic centers in Alamance County. However, PDC was unable to identify any such facilities. To PDC’s knowledge, utilization data for medical diagnostic equipment located in diagnostic centers is not collected by any state agency or regulatory body.”

On page 64, the applicant summarizes the number of units and utilization of similar medical diagnostic equipment located at Alamance Regional Medical Center (ARMC), as reported on ARMC’s 2020 License Renewal Application (LRA).

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 85, the applicant states:

“The project will enable PDC to continue meeting its existing patient population’s needs and ensure more timely provision of and convenient access to outpatient medical diagnostic imaging services for all area residents. PDC assumes no adverse effect on current medical diagnostic services providers in Alamance County, as PDC physicians have been longtime existing providers of these medical diagnostic services in Alamance County.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 85, the applicant states:

“The diagnostic services located at Kernodle Clinic Burlington contribute to cost-effective patient care because the services have a typically lower charge structure than hospital-based diagnostic services. Given the current economic uncertainty, it is

essential to consider lower-cost alternatives and the benefits that cost savings will have for health care recipients.

The project involves no new equipment or services. The proposed project requires no incremental staffing. The project will not increase the cost of diagnostic services for PDC patients.”

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 85, the applicant states that PDC is dedicated to ensuring quality and patient safety and will continue to maintain the highest standards and quality of care, consistent with the standards that it has sustained throughout its years of providing patient care in Alamance County.

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 86, the applicant states:

“The proposed project will improve access to non-hospital based diagnostic services to underserved. Groups. PDC is a participant Medicare and Medicaid provider serving the elderly and medically indigent populations in Alamance County and surrounding communities.

...

. . . PDC has historically provided care and services to medically underserved populations. PDC does not discriminate based on income, race, ethnicity, creed, color, age, religion, national origin, gender, physical or mental handicap, sexual orientation, ability to pay, or any other factor that would classify a patient as underserved. PDC will continue to have a policy to provide all 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. Diagnostic services at Kernodle Clinic Burlington will be available to and accessible by any patient having a clinical need for those services.”

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 its 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

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 O 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 eight of this type of facility located in Durham and Wake counties.

In Section O, page 90, the applicant states:

"PDC has never had its Medicare or Medicaid provider agreement terminated. PDC's operational diagnostic centers have provided quality care and operated in compliance with Medicare Conditions of Participation during the 18 months immediately preceding submission of the application. Diagnostic centers are not licensed facilities; therefore, there are no Division of Health Service Regulation licensure requirements."

After reviewing and considering information provided by the applicant and considering the quality of care provided at all nine 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 with existing diagnostic 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.