

March 28, 2024

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Re: Comments on Competing Applications for a Certificate of Need for a fixed MRI Scanner in Carteret County; CON Project ID Numbers:

<u>Project ID</u>	<u>Name</u>
P-12478-24	Seashore Imaging, LLC
P-12495-24	EmergeOrtho, PA

Dear Mr. Yakaboski,

On behalf of Seashore Imaging, LLC, Project ID# P-12478-24, thank you for the opportunity to comment on the above referenced applications for a fixed MRI scanner in Carteret County. We understand that your time is limited, so we have focused comments on important issues in this review.

We believe that the applications submitted confirm and support the proposal from Seashore Imaging as the most qualified to address the identified need.

We understand that the State's Certificate of Need ("CON") award for the proposed fixed MRI must be based upon the statutory review criteria in G.S 131E-183 and that the Agency has discretion in choice of comparative factors when all applicants conform to the statutory review criteria.

First and foremost, the Agency should recognize that EmergeOrtho, PA's application is non-conforming to multiple statutory review criteria. Namely the EmergeOrtho application *does not demonstrate*:

- the need of the population to be served for the proposed service (Criterion 3);
- that its chosen alternative is the least costly or most-effective (Criterion 4);
- the availability of funds for capital and operating needs (Criterion 5);
- that the proposed project will not create unnecessary duplication (Criterion 6);
- that it has and will improve access by medically underserved populations (Criterion 13a and d);
- that its project will make a cost-effective contribution to competition or that competition is not important (Criterion 18a); or,
- that it meets any of the performance standards in 10A NCAC 14C .2703(a).

Attached comments provide detail and supporting documentation regarding EmergeOrtho's non-conformance to each of these eight criteria. Because both volume and financial metrics used in the EmergeOrtho application are incorrect, it would be inappropriate to use any EmergeOrtho volume or financial metrics in a comparative analysis. Such a comparison would be inherently wrong.

Even if EmergeOrtho **were conforming** the proposal is not a good choice for Carteret County. Though EmergeOrtho would technically be a new provider in the county, this application is not for a full-service fixed MRI; see detail with Criterion 4 in **Attachment A**. Its open magnet features are offset by the wide bore 83cm equipment proposed by Seashore Imaging. EmergeOrtho's 1.2 Tesla MRI scanner is a weaker magnet with lower field strength than Seashore Imaging's 1.5 Tesla. Together lower field strength and lower gradients mean exams performed on this equipment take longer to get equivalent image resolution to the 1.5 Tesla.

The proposed EmergeOrtho location is only five minutes from an existing freestanding fixed multispecialty 1.5 Tesla MRI scanner. It does nothing to improve geographic access in Carteret County.

Moreover, this application presents technical only billing; there is no physician expense. The full cost is not presented.

EmergeOrtho is an orthopedic and pain management organization. Throughout its application, it demonstrates that primary utilization of its proposed MRI will be by patients of EmergeOrtho physicians associated with these two service lines. Restricting use of standard diagnostic tools like MRI does not increase access to medically underserved populations.

On the value spectrum, EmergeOrtho proposes equipment that requires regular replacement of the helium coolant. Seashore proposes containerized helium that will last through the life of the scanner. Helium is the only element on the universal table of elements whose supply is permanently disappearing through the earth's atmosphere and into outer space.

The Seashore Imaging application, on the other hand, is both conforming to all statutory criteria and comparatively superior in program and location.

In stark contrast to EmergeOrtho, Seashore Imaging proposes a site in an underserved part of Carteret County. Seashore Imaging recognizes that the combined population growth of Carteret County and increased travel times during peak tourist season limit western Carteret County residents. Access to services in Morehead City will be increasingly difficult. Morehead City has two MRI units, one in a freestanding clinic, and one in a hospital. Western Carteret has none.

Carteret County is rural, see the maps in **Attachment H** from USDA. It has a small population base and limited capacity to absorb competitors who focus universal resources like MRI in a single specialty. Unlike urban areas where hundreds of thousands of people can support both specialized and generalized services, rural communities have a different experience and need to carefully conserve and distribute limited resources.

Seashore Imaging at Cedar Point will provide an access alternative to the two existing Morehead City MRIs. This is possible because Seashore can take advantage of shared costs and the negotiating power of its hospital owner. Seashore has a proven track record of sharing these savings with consumers through its freestanding reimbursement structure and payment adjustments. The Seashore application and the Broad Street Clinic support letter in [Attachment I](#) confirm the importance of the Cedar Point location and the community appreciation for what Seashore Imaging offers.

Seashore Imaging proposes equipment and equipment options that allow it to offer the new Cedar Point site a full range of state-of-the-art MRI scans – breast, prostate, abdomen, brain, cancer, and musculoskeletal. The proposed Seashore Imaging equipment will have more capabilities than any other MRI equipment in Carteret County or proposed by EmergeOrtho. See discussion in Criterion 4 in [Attachment A](#).

As noted in the application, Seashore Imaging is a trusted provider of imaging services in Carteret County. In addition to its ACR accredited, quality service, it is backed by the expertise of Eastern Radiologists, Inc., which employs over 20 radiologists in Eastern North Carolina. Many of them specialize in different types of MRI scan interpretations, including prostate, breast, cancers, vascular, liver, orthopedic, and neurologic issues. Eastern Radiologist, Inc.'s radiologists offer highly skilled support for persons with emerging and highly progressed chronic and acute conditions; see Section C of our application. They are also locally available for direct consultations with referring providers. Furthermore, as noted in Exhibit I.2 of our application, Seashore Imaging accepts referrals from all providers across a multitude of service lines.

Clearly there is only one good choice and only one that meets all Statutory Criteria. That is the application from Seashore Imaging, LLC.

Thank you for the time and attention you and your staff give to reviewing these important and detailed documents. Please do not hesitate to contact me should you have any questions.

Sincerely,



[Dr. Brian Kuszyk \(Mar 28, 2024 14:05 EDT\)](#)

Brian Kuszyk, MD
Seashore Imaging, LLC

Attachment(s)

ATTACHMENTS

Comments on EmergeOrtho, PA Application for a Fixed MRI in Carteret County A

Agency Correspondence Re: EmergeOrtho Application Missing Information B

Seashore Imaging Referral Data from EmergeOrtho Providers..... C

Travel Time Maps to EmergeOrtho-Morehead City D

2024 SMFP Table 15E-1, Excerpts..... E

Diagnostic Center Cost Threshold for 2024 F

Cape Fear Diagnostic Imaging, 2024 Equipment Inventory Form, Excerpts..... G

North Carolina Rural County Status Maps H

Letter of Support: Broad Street Clinic..... I

Competitive Review of – EmergeOrtho Project ID# P-12495-24

Overview

EmergeOrtho, PA (“EmergeOrtho”) proposes to acquire one new fixed Magnetic Resonance Imaging scanner (“MRI”) in response to the 2024 SMFP need determination for one new fixed MRI in Carteret County. The application proposes a 1.2 Tesla (“1.2T”) MRI scanner to be installed in a space formally used for physical therapy.

As illustrated in the following discussion, the EmERGEOrtho application is non-conforming with review criteria 1, 3, 4, 5, 6, 13a and d, 18a, and the Performance Standard in 10A NCAC 14C .2709(a).

CON Review Criteria

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, ambulatory surgery operating rooms, or home health offices that may be approved.**

Policy GEN-3

Because the 2023 SMFP has a need determination for one new fixed MRI in Carteret County, Policy GEN-3 “Basic Principles” applies. This policy reads,

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

EmergeOrtho’s application **does not meet the requirements of this policy**. The Applicant does not “document how its projected volumes incorporate these concepts in meeting the... needs of all residents in the proposed service area.” For details see discussion of Criterion 3 below.

3. **The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.**

Fails to Demonstrate Need

EmergeOrtho does not demonstrate the need of the population for the proposed service.

No Methodology

EmergeOrtho provides no methodology to support the Form C projected MRI volumes.

In an abundance of caution, the Commentor contacted the Agency to ensure that no portion of the EmergeOrtho application was missing from the copy obtained. **Attachment B** contains a copy of that correspondence confirming that the copy provided was complete as submitted.

Based on its own data in Form C.2a, in calendar year 2023, the part-time third-party mobile currently serving Carolina Center for Surgery did only 652 MR scans (p121).¹

Form C.2a Historical and Interim Medical Equipment Utilization [^] EmergeOrtho – Morehead City	Last Full FY
	F: 01/01/2023 T: 12/31/2023
Fixed X-ray (including fluoro)	
# of Units	1
# of Procedures	19,340
MRI Scanner (see Tab C)	
# of Units (mobile MRI)	1
# of Procedures	652
# of Weighted Procedures	-

¹ Per the EmergeOrtho application, orthopedic physicians previously employed by Carolina Center for Surgery are a part of the EmergeOrtho organization as of February 2024. See pages 31-33 and 70-71.

Form C claims that it will perform over 4,700 MR scans in its first year of operation (p123, Form C.2b).

Form C.2b Projected Medical Equipment Utilization upon Project Completion [^] EmergeOrtho -- Morehead City	1st Full FY	2nd Full FY	3rd Full FY
	F: 01/01/2026 T: 12/31/2026	F: 01/01/2027 T: 12/31/2027	F: 01/01/2028 T: 12/31/2028
Fixed X-ray (including fluoro)			
# of Units	1	1	1
# of Procedures	19,340	19,533	19,729
MRI Scanner (see Tab C)			
# of Units	1	1	1
# of Procedures	4,776	4,824	4,872
# of Weighted Procedures	42	42	43

Add three providers by 2026 at avg of 276 MRI per provider per year.

This is a **632.5 percent growth in proposed MRI scans between CY2023 and CY2026**. But EmergeOrtho provides no reference to the source of people that will get the additional 4,100 scans.

Seashore Imaging is the only freestanding fixed MRI provider existing in Carteret County. A review of its 2023 referrals by provider shows that referrals from practices acquired by EmergeOrtho to Seashore Imaging equaled approximately 616 patients (see **Attachment C**). Even if the reader assumes that EmergeOrtho physicians could maintain 2023 volume through 2026, plus scans referred out, that equals only 1,268 MRI scans. The EmergeOrtho application says nothing about the people associated with the remaining 3,508 MRI scans forecast in 2026.

Does Not Demonstrate Need of the Population

Overall, this application looks more like a plan for EmergeOrtho to consolidate all MRI referrals from Carteret, Duplin, Pender, and Onslow Counties in Morehead city, than a demonstration of need for a population to be served.

EmergeOrtho asserts that need for this application is patients’ need for MRI services in freestanding versus hospital settings (see pages 37-39). The proposed EmergeOrtho location is 1.6 miles – only 5 minutes in peak summer tourism traffic – from an **existing freestanding multi-specialty fixed MRI scanner** (Seashore Imaging Morehead) that operates as a clinic. EmergeOrtho’s application does not demonstrate why patients need – or would even choose – the EmergeOrtho proposed scanner over that of an existing freestanding multi-specialty scanner.

Note the bottom of Form C.2b reads “Add three providers by 2026 at average of 276 MRI per provider per year,” (p123). This is further confirmation that the intent of the application is to serve EmergeOrtho patients only, not Carteret County. However, even that statement is unsupported.

Finally, on page 33, EmergeOrtho proposes that 65.9 percent of its EmergeOrtho-Morehead City patients will originate from “New HanoverCarteret” [sic]. While likely a typo, it is unclear from where the majority of EmergeOrtho MRI patients will originate. Does this Applicant expect a portion of patients to originate from New Hanover? If so, what percentage? How will that affect Carteret County patients?

b. **Service Component(s)** – Complete the following table for each service component included in this proposal for the facility or campus identified in Section A, Question 4.

MRI	EmergeOrtho - Morehead City					
	1st Full FY 01/01/26 to 12/31/26		2nd Full FY 01/01/27 to 01/31/27		3rd Full FY 01/01/28 to 12/31/28	
	Number of Patients	% of Total	Number of Patients	% of Total	Number of Patients	% of Total
County or geographic area such as zip code						
New HanoverCarteret	3146	65.87%	3177.46	65.87%	3209.235	65.87%
Pender	680	14.24%	686.8	14.24%	693.668	14.24%
Onslow	758	15.87%	765.58	15.87%	773.2358	15.87%
Duplin	175	3.66%	176.75	3.66%	178.5175	3.66%
Other NC Counties	12	0.25%	12.12	0.25%	12.2412	0.25%
Other States	5	0.10%	5.05	0.10%	5.1005	0.10%
Total	4776		4824		4872	

Page 33 clearly indicates that 33.8 percent of EmergeOrtho-Morehead City’s patients will originate from Duplin, Onslow, and Pender Counties. Review of the application shows that the Applicant offers no explanation why residents of these counties, or New Hanover, need the proposed MRI services, nor why they would seek them in Morehead City.

Patient Origin Flawed

Forecasting such a substantial portion patients from outside Carteret County is unreasonable. All are more than an hour from Morehead City and underutilized freestanding fixed MRI scanners are available along those travel routes.

Table 1 below shows Google Map’s estimated travel times during peak tourist season from the county seats of Duplin, Onslow, and Pender Counties to Morehead City. Coordinating maps are in [Attachment D](#).

Table 1: Estimated Travel Times from Selected County Seats to EmergeOrtho-Morehead City, June 19, 2024

Location	Travel Time to Morehead City
Kenansville, Duplin County	2+ hours
Jacksonville, Onslow County	1 hour 20 minutes
Burgaw, Pender County	2 hours

Source: Google Maps, accessed 03.13.24

Other than the freestanding discussion, EmergeOrtho provides no information addressing why residents of these counties would – or should – drive such long distances to seek care at EmergeOrtho-Morehead City.

According to Table 15E-1 of the 2024 SMFP, Onslow County has two freestanding fixed MRI scanners. Nearby New Hanover has another two, plus a third yet to be developed from the 2023 Need Determination. See **Attachment E** for detail. For some patients, utilizing those scanners would cut driving time by as much as half

EmergeOrtho provides no information to demonstrate why these MRI scanners could not absorb the projected 693 scans from Duplin, Onslow, and Pender.

Inconsistent Volume Projections

The application is not consistent about the number of projected unweighted scans. Is it 4,665 or 4,872:

- In Section L, pages 89-90, EmergeOrtho states it will provide care to 70 charity and 30 reduced cost patients in its third year of operation. Both estimations are based on multiplying the total projected third year scans by the respective charity and self-pay payor percentages.
 - $4,665 * 0.015 = 70$
 - $4,665 * 0.0063 = 30$
- Form C.2b, page “123,” reports an estimated 4,872 unweighted MR scans in the third year.

Incomplete Volume Projections

Section C.3 of the application asks applicants to complete historical and projected patient origin for the service component and the entire facility, as well as descriptions for any assumptions and methodologies used to create those projections.

On pages 31 and 32, EmergeOrtho provides the historical patient origin for the Service Component and the entire facility. Service Component was represented as CY2023 volumes for the third-party owned and operated mobile MRI hosted at EmergeOrtho Morehead City, while the entire facility included those same MRI volumes as well as all other imaging patients (x-ray and CT), see page 32.

However, on the following pages 33 and 34, EmergeOrtho does not provide the same information for projected patient origin. Question C.3b asks for projected Service Component volumes – which EmergeOrtho provides; Question C.3c asks for projected volumes of the entire facility – which EmergeOrtho does not provide.

For the Service Component, MRI, EmergeOrtho provides the following “assumptions” to support the MRI volumes,

“EmergeOrtho projects patient origin based on the historical experience of EmmergeOrtho’s Carteret-based physicians, which includes periods pre-dating EmmergeOrtho’s experience in the market, and (2) the projected shift of some Morehead City MRI patients from EmmergeOrtho’s existing leased mobile MRI unit as shown in the following tables. EmmergeOrtho assumes that the projected organic market share of MRI patients and EmmergeOrtho-Morehead City will represent the same zip codes as historically served in Morehead City.” (p32-33)

Although the application does not include the tables to which the quote alludes, the narrative **implies** that EmmergeOrtho has enough historical information from its new physicians to make informed projections for future utilization. In fact, it implies that it has data to evaluate patient patterns at the ZIP code level. However, **none of these data are included in the CON application or the exhibits.**

The Applicant does not provide the same projections for the other services provided in the entire facility – x-ray and CT. EmmergeOrtho instead responds to Questions C.3c (p33) by saying “Because EmmergeOrtho entered the Carteret County market in 2024, EmmergeOrtho does not have sufficient data to make the projections requested in this section.”

Based on this information, it would seem that EmmergeOrtho has enough data from a third-party owned and operated MRI service to make ZIP code level MRI patient origin projections but has no data regarding x-ray or CT patients – services that they own and operate.

EmmergeOrtho fails to provide any supporting documentation, methodologies, or assumptions meaning none of these projections – or lack of projections – can be confirmed.

Finally, EmmergeOrtho proposes to begin fixed MRI services in Morehead City on 09/01/2025, see Section C, p27 and Section P, page 102. However, nowhere in the application does EmmergeOrtho project the volumes of the interim or partial years 2024 and 2025.

Page 71 of the application states that EmmergeOrtho plans to terminate mobile MRI services at EmmergeOrtho-Morehead City “following implementation of the proposed fixed MRI scanner project.” This implies that contracted mobile MRI services will continue at EmmergeOrtho-Morehead City until the proposed project opens for service. Thus, there would be both an interim and a partial year of MRI volumes to report. However, neither Forms C.2a nor C.2b report these interim volumes. In fact, the only place where these volumes are recorded is on “Page 140” in the assumptions with Forms F.2 and F.3. They show constant volumes in 2024 and 2025.

On page 18 the application describes the proposed project as a Diagnostic Center. However, data to support need for this are not included.

Because of its lack of methodology and assumptions, its flawed patient origin, and inconsistent and incomplete volume projections, EmmergeOrtho should be found non-conforming to Criterion 3.

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.**

Alternatives

Status Quo

The statement on page 58 that “two existing fixed MRI scanners are in operation, but neither is a low cost, clinic-based operation,” is wrong. Seashore Imaging is a low-cost, clinic-based operation. The applicant is misinformed. Moreover, Seashore Imaging office in Morehead City is less than 5 minutes from the applicant’s proposed site.

Location

On page 59, the application states that “EmergeOrtho patients will benefit from the central and convenient location of the North 35th Street site” because Morehead City is the largest municipality and has a large concentration of health care providers.

The discussion of location alternatives overlooks the size of Morehead City. According to NCOSBM, Morehead City population was only 9,934 in 2022². NCOSBM reports 69,721 residents in Carteret County that year. The analysis of location is silent about the distribution of Carteret County residents and about the needs of the population to be served.

Patient origin in the EmergeOrtho application page 33 demonstrates that 34 percent of the expected users will come from counties west of Morehead City. See additional details in Criterion 3 above. The discussion does not address why a Morehead City location would benefit those proposed users.

The alternative locations discussion is also silent about the freestanding, clinic based, 1.5 tesla MRI that is only 5 minutes (1.6 miles) away. Morehead City has a freestanding, clinic-based MRI that accepts referrals from all providers.

The reference on page 59 to Exhibit I.2 referring providers confirms the inferences throughout this application that the intended use of this MRI is to serve patients of EmergeOrtho physicians. All referral letters are from EmergeOrtho physicians.

By contrast, the Seashore Imaging application is very clear about needs of the population, location of alternative scanners in its proposed catchment area, and why Morehead City is not a good location for the next MRI scanner.

² <https://demography.osbm.nc.gov/explore/dataset/2022-standard-population-estimates/table/?disjunctive.county&disjunctive.municipality&sort=county&q=Carteret>

Equipment

This alternative discussion focuses only on the EmergeOrtho decision not to acquire 3 Tesla or extremity MRI equipment. The discussion on page 59 implies that 1.2 and 1.5 Tesla equipment are equivalent. **They are not.** Moreover, the particular 1.2 Tesla equipment proposed has significant limitations.

- The FujiFilm Velocity Open MRI uses helium cryogen to cool the magnet (Exhibit F.1 pdf p 44.)
 - Helium is the only element on the periodic table which is a non-renewable resource on Earth³. Lighter than air, it easily escapes from the earth's atmosphere.
 - Because of this shortage, most MRI manufacturers are developing scanners that require only around 7.0 liters of liquid helium compared to the more common 1,500 liters used in equipment like the proposed FujiFilm 1.2T. This new technology is commonly referred to as "zero boil off systems" because the MRI scanners do not require helium refills. Alternatively, the traditional 1,500 liter "nonzero boil off systems" require refills annually or bi-annually.
 - Unlike the zero boil off system 1.5T magnet proposed by Seashore Imaging, the Velocity Open MRI proposed by EmergeOrtho, requires helium that must be provided and installed by a vendor **and** periodically replaced through a maintenance agreement (see p 62 Cryogens in Maintenance agreement).
 - Like any scarce resource, over time, this maintenance cost will likely increase.
- Throughout the narrative and in the specifications for this equipment, it is clear that the emphasis of the proposed EmergeOrtho Morehead City is on serving the orthopedic, pain, and spine patients of EmergeOrtho practices. (See emphasis on orthopedics in the equipment discussion on page 59, in access on page 90, the practice on page 25, and services on pages 28 and 29). Please consider the following regarding the proposed Velocity Open MRI:
 - The magnet is not as strong as a 1.5T.
 - Resolution of scans for soft tissue areas like breast, prostate, and brain are not as high-quality as a 1.5T, suggesting that **if** EmergeOrtho were to perform these scans, readability would less than ideal.
 - No breast coil included which suggests inability to do breast imaging.
 - Proposal lacks a detachable table which presents a safety concern for patients on a stretcher or in a wheelchair. This is in direct contradiction to the safety policies in Exhibit O.2.2 which show that staff must be able to remove patients from the gantry table in case of cardiac arrest.
 - It has a 45cm field of view compared to Seashore Imaging's proposed Philips 55cm. This restricts the size of images able to be captured which may require taking additional images to capture all areas of interest.

³ Doctors are worried as the world is running out of helium; here is why, CNBC October 21, 2022.
<https://www.cnbc.com/healthcare/doctors-are-worried-as-the-world-is-running-out-of-helium-here-is-why-15052831.htm>

- The significant weight of the Velocity Open MRI – 29,100 pounds compared to 5,071 pounds of the Seashore Imaging Philips MRI scanner – suggests that costs to install will be very high. Equipment of this size will have sizeable freight cost (not included per the FujiFilm quote), require additional concrete on the slab to support the MRI, and likely a larger crane to install.

It is clear that the equipment is focused on orthopedics and location convenience for the Morehead City EmergeOrtho practices. The application did not demonstrate selection of the least costly or most effective alternative and should be found non-conforming to Criterion 4.

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.

Finances

This application falls short in both capital and operating cost estimates.

Fixed Capital

With regard to capital cost, Form F.1a provides no funds for purchase of an injector – which is essential to offering MRI scans involving contrast. The Applicant notes on page 61 that EmergeOrtho has access to an injector, but it does not say how far away or who else will need that injector. Without an injector on site, contrast scans will require special scheduling.

Form F.1a does not include all costs associated with the proposed equipment. According to the vendor quote in Exhibit F.1:

- “Freight added to final invoice,” PDF page 53;
- Rigging costs excluded; vendor quote on PDF page 49 limits the vendor to \$15,000 of the rigging cost and excludes a special crane or other special site adaptations. (See Criterion 4 “Equipment.”)

The letter from Mr. Brelsford in Exhibit F.2.2 is specific, limiting the dollar amount of funds he will commit to only \$1,365,172 of the \$2,786,228 total capital cost presented on Form F.1a. Mr. Brelsford does not address use of the funds proposed by Truist Bank in Exhibit F.2.

Moreover, the application contains no evidence from a third party that EmergeOrtho has access to the EmergeOrtho funds that Mr. Brelsford proposes to use. According to his letter, Mr. Brelsford is the CFO for EmergeOrtho, not an independent third party. Review of the Exhibits show no audited financials or attestation from an independent third party documenting that EmergeOrtho has access to \$1.36 million in cash or cash equivalents.

The proposed fixed capital is not sufficient for this proposed project.

Operational Projections

Operational projections and related financial proformas in this application are not based on reasonable projections.

In fact, the application provides no foundation or methodology to demonstrate how the applicant arrived at the number of proposed scans. There is no Form C Methodology. Moreover, the application provides inconsistent statements about the number of proposed scans. See differences in Year 3 between Section L, page 89 and Form C.2.b on page 128. The application provides no information to demonstrate how the applicant calculated the number of annual MRI scans proposed.

Similarly, Form C.2b mentions 19,729 x-rays. But Form F.3b in the application provides no information about x-rays. Neither C nor F forms mention the CT scans alluded to in Question C.3 on pages 32-34.

Nowhere does the application explain where x-ray and CT are located. The application does indicate that the MRI services have been provided at the Guardian Avenue address, not the proposed N 35th Street address.

The scope in Question C.1 indicates that the project will involve a contract for physics, but there are no expenses in the proforma assumptions.

The statement on page 128, "add three providers by 2026 avg if 276 MRI per provider per year" does not compute to the number of proposed scans $3 \times 276 = 828$ not 4,776.

Financial projections in Forms F.2a and F.2b are inconsistent with the Assumptions that start on page 140. Assumptions 7 and 9 show annual cost increases. Forms 2.a and 2.b show the same costs every year. Assumption 1 shows a dramatic and unexplained change in payor mix. There is no explanation of scans or revenue associated with the last four months of CY 2025. Section P Timetable shows the project will be operational September 1, 2025. Yet the procedures in CY 2025 on Assumption Note 1 show no change from CY 2024. There is no form C.2b for calendar years 2024 and 2025.

In response to question, C.1, the application says the MRI will operate 60 hours a week. Staffing assumptions for Form H do not show how proposed staffing will be adequate to cover those hours and provide paid time off. Assume 10 days of holidays, the facility will operate 50 weeks a year times 60 hours a week or 3,000 hours a year.

On page 63, the application indicates that the project will require \$50,316.75 for a three-month initial operating period. The explanation on page 64, that "cash revenue from the contracted MRI exceeds expenses...to be conservative EmergeOrtho assumed a brief initial operating expense associated with transitioning...." The transition involves a change from one day a week to 60 hours a week. The application provides no support for the calculation.

Mobile MRI Contract

EmergeOrtho claims to have mobile service through Novant Health Network (see page 59). This is not consistent with information reported to DHSR for the 2024 SMFP. Table 15E-1 page 341 says that the mobile service provided to the practice EmmergeOrtho purchased in 2023 (aka Carolina Center for Surgery) has had service from Cape Fear Diagnostic Imaging. An excerpted copy of the 2024 Equipment and Inventory Form confirming this provider is in [Attachment G](#).

Regardless of who provides the mobile service, the application does not address how long EmmergeOrtho is obligated to that contract or how much it will cost to terminate the contract. These omitted elements can change the operating cost projections.

Financial and operational projections for the project do not 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. Consequently, this application should be found non-conforming to Criterion 5.

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

Unnecessary Duplication

The application provides confusing and sometimes wrong information about approved health service providers in the service area. The response to Question G.1 refers to Exhibit G.2 for utilization of other providers. Exhibit G.2 does not exist. Exhibit G.1 has no information about MRI providers. It covers linear accelerators and lithotripters.

The response to Question G.2 indicates the proposed EmmergeOrtho MRI scans will cost consumers less than hospital scans. On page 38, the application provides a table of cost comparisons from the Blue Cross Cost Estimator. However, those data are old and appear to exclude the professional fee component for EmmergeOrtho. During this period, the professional fee was separately billed. The data should not be considered comparable in this review.

The EmmergeOrtho application claims improved geographic access, but the proposed site only 1.6 miles away from Seashore Imaging, an existing, full-service, 1.5 tesla MRI that operates a freestanding clinic-based MRI. In fact, data in Seashore Imaging records show that physicians who have recently joined EmmergeOrtho referred as many as 616 scans a year to Seashore Imaging Morehead. Clearly they know of its existence and appreciate its value. The application does not directly address implied intent to cease referring to Seashore Imaging and “shift” referrals to the proposed EmmergeOrtho equipment.

The referenced letters say only that signers will refer MRI procedures “as appropriate.” None committed to a number of referrals.

This proposed project will represent unnecessary duplication of an existing health service facility that is only 5 minutes away in peak tourist season. It proposes a freestanding charge structure that appears to exclude professional fees. Moreover, Seashore Imaging offers a wider range of services than EmergeOrtho proposes, and Seashore Imaging has capacity to provide more annual scans than have been demanded in Morehead City to date. Throughout the application, EmergeOrtho focuses only on orthopedic, pain and spine scans (Exhibit I.1, pages 25, 28-29, 40-42, 59, 90, and 96).

EmergeOrtho failed to demonstrate that it will not result in unnecessary duplication and should be found non-conforming to Criterion 6.

13. The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

Payor mix on page 88 says "... EmergeOrtho reasonably estimates the Porters Neck MRI payor mix..." and "... because EmergeOrtho will be able to own the Porters Neck MRI...". EmergeOrtho Porters Neck is in Wilmington, New Hanover County, NC⁴. The narrative implies this is an unedited copy of a recent EmergeOrtho Porters Neck MRI CON application, not an evaluation of a proposed payor mix for the EmergeOrtho Morehead City location. At best, the Applicant fails to explain why Porters Neck would be a reasonable proxy for the payor structure of patients in Carteret County.

Because EmergeOrtho does not demonstrate "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" it should be found non-conforming to 13(a). The application provides no information about the medically underserved in the Porters Neck service area.

(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 physician.

The Applicant implies on page 42 that EmergeOrtho physicians have relationships with referring physicians in and around Carteret County. However, Exhibit I.2 includes support letters from only EmergeOrtho providers and offers no quantitative referral volumes to support the substantial increase in MRI scans projected in 2026.

⁴ <https://emergeortho.com/locations/wilmington-porters-neck/?region=coastal-region>

The application confirms intent to add revenue to EmergeOrtho rather than serve Carteret County patients. See pages 25, 29, 40, 41, 42, and 96. In each of these instances, EmergeOrtho references the types of MRI scans they expect to perform, musculoskeletal scans. It provides no clear indication that EmergeOrtho-Morehead City will be able to accommodate scans related to abdominal soft tissues, cancers, or neurological, urological, or gynecological diseases. The letters in Exhibit I.2 state "... I intend to refer patients to the proposed scanner **as appropriate...**," further suggesting that if any non-musculoskeletal MRI scans occurred at EmergeOrtho-Morehead City it would be quite by accident.

- 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 the service for which competition will not have a favorable impact.**

Competition

Cost-Effectiveness

On page 94, EmergeOrtho explains how competition from others will motivate it to be cost-effective. The cost-effectiveness argument on pages 94 and 95 depends on the accuracy of EmergeOrtho's proposed capital costs and financials. Both are wrong, see Criterion 5 above.

Access

EmergeOrtho's proposed scanner will not provide new geographic access to a freestanding fixed MRI. As detailed several places in these comments, EmergeOrtho is proposing to place the fixed MRI scanner 1.6 miles from the existing freestanding multi-specialty fixed MRI scanner at Seashore Imaging Morehead.

Not only will it duplicate services in Morehead City – see Criterion 6 above – but it will also have adverse effects on Seashore Imaging Morehead. In CY23, EmergeOrtho physicians accounted for 17.5 percent of all referrals to Seashore Imaging Morehead (see **Attachment C**). A loss of such a substantial proportion will render Seashore Imaging Morehead less cost-effective.

Because EmergeOrtho failed to demonstrate a favorable impact on competition, the Applicant had to demonstrate that competition for this service is not important. EmergeOrtho failed to demonstrate that competition is not important.

Its proposed project should therefore be found non-conforming to Criterion 18a.

CON Rules

10A NCAC 14C .2703(a) Performance Standard

According to pages 49-51 of its application, EmergeOrtho does not believe that any of the rules in 10A NCAC 14C .2703(a) apply to its application. This is wrong. Note the following:

.2703(a)(1) through (4):

EmergeOrtho claims that it has no existing or approved fixed or mobile MRI scanners in the MRI scanner service area. This is correct. According to Table 15E-1, EmergeOrtho does not own or operate any fixed or mobile scanners in Carteret County.

.2703(a)(5):

The rule asks for the application to provide “projected utilization of the MRI scanners identified in Subparagraphs (1) through (4) of the Paragraph...” – to which EmergeOrtho answers “Not applicable... EmergeOrtho does not own or operate and is not approved for any fixed MRI scanner or any mobile MRI scanners...”.

However, the Applicant failed to read the entire rule. The rule **also states**, “projected utilization of ... **the proposed fixed MRI scanner....**” Based on the fact that it submitted this application, EmergeOrtho is proposing a fixed MRI scanner in Carteret County and is therefore required to provide projected utilization.

.2703(a)(6):

Subparagraph (6) requires applicants to “provide the assumptions and methodology used to project the utilization required by Subparagraphs (5).” EmergeOrtho determined this rule “not applicable.” By failing to recognize the rule requires projected volumes for the proposed MRI scanner, it failed to provide the requested assumptions and methodologies associated with the proposed scanner.

.2703(a)(7):

Again, because EmergeOrtho apparently did not read Subparagraph (5) completely, it fails to show that the proposed fixed MRI scanner will meet the performance standard in its third project year. It instead claims Subparagraph (7) is not applicable.

The application should be found non-conforming with the performance standard.

Additional Errors

EmergeOrtho had additional errors in its application that, while they may not render the application non-conforming, they do speak to a lack of interest in this regulatory process or in Carteret County.

Diagnostic Center Threshold

On page 18 EmERGEOrtho indicates that the proposed location will be a diagnostic center. Based on existing information publicly available, EmERGEOrtho-Morehead City does not currently have diagnostic center status. The assumption presented by the application is that acquisition of the proposed freestanding fixed MRI scanner will provide diagnostic center status to EmERGEOrtho-Morehead City.

Unfortunately, this is incorrect. According to a letter from NC DHSR Chief Micheala Mitchell dated October 30, 2023, the cost threshold to create a diagnostic center is \$2,971,200. See [Attachment F](#).

Form F.1a in EmERGEOrtho's application indicates a total capital cost of \$2,762,228, almost \$200,000 shy of the threshold; and the CT and x-ray listed in Section C.3 and on Forms C.2a and b are at a different address.

The proposed project will not create a diagnostic center.

Inconsistent Pages

Review of Section Q shows an array of inconsistent page numbering. The last page of Section P is page "103." Based on instructions from the Agency, the first page of Section Q Workbooks, should then be "104." It is instead page "121." This could be considered a typo, meaning Section Q simply started on the wrong page, but then followed with the sequence accordingly. However, this is not the case. The remainder of Section Q lacks any organization, with non-sequential page numbers, repetition of some page numbers, and others skipped altogether. As noted on page 2 above in Criterion 3, the Commentor contacted the Agency, who then confirmed that the version publicly available was as submitted. (See [Attachment B](#).)

While at first this may seem insignificant, combined with the other errors detailed in the criteria above, it is actually very telling about EmERGEOrtho's commitment to this project. It suggests that EmERGEOrtho quilted this application together from multiple other sources without taking the time to evaluate the needs of MRI services for residents of Carteret County.

ATTACHMENT B

From: [DHSR.CON.Request](#)
To: [Kelly Ivey](#); [Stancil, Tiffany C](#); [DHSR.CON.Request](#)
Cc: [Jon Campbell](#)
Subject: RE: [External] P-12495-24 Application Question
Date: Tuesday, February 27, 2024 5:10:11 PM
Attachments: [image002.png](#)

I have checked 2nd copy, it is 137 pages, last section contains all pages you received. The pages are marked clearly with page #s, until that last section, they jump all over the place and some have same page #...

What you received is the total scanned copy as submitted.

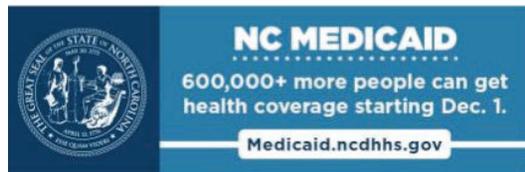
Martha Waller

Administrative Specialist 1
Division of Health Service Regulation, Certificate of Need Section North Carolina Department of Health and Human Services

Main: 919-855-3873
Office: 919-855-3885
martha.waller@dhhs.nc.gov

2704 Mail Service Center
Raleigh, NC 27699-2704

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including confidential information relating to an ongoing State procurement effort, is prohibited by law. If you have received this email in error, please notify the sender immediately and delete all records of this email.

From: Kelly Ivey <kivey@pda-inc.net>
Sent: Tuesday, February 27, 2024 5:02 PM
To: Stancil, Tiffany C <Tiffany.Stancil@dhhs.nc.gov>; [DHSR.CON.Request](#) <[DHSR.CON.Request@dhhs.nc.gov](#)>
Cc: Jon Campbell <jcampbell@pda-inc.net>
Subject: [External] P-12495-24 Application Question

CAUTION: External email. Do not click links or open attachments unless verified. Report suspicious emails with the Report Message button located on your Outlook menu bar on the Home tab.

Tiffany,

I received the scanned copy of EmergeOrtho's Carteret County MRI Application (P-12495-24) that you sent via TransferNow on Friday 2/26.

I have had a chance to review it and it looks like there is some information missing. The scanned copy of the application portion that I received has 137 pages. Can you confirm that that is the same number you have?

I think that the missing information would be in Section Q – which starts at Form C.2a, PDF page 125. I have 12 pages for Section Q.

It is plausible that they didn't include what I am looking for – but if they did and it accidentally got left out of the scan copy, I'd like to know and I'd need those missing pages.

Thanks for your help!

Kelly Ivey
kivey@pda-inc.net
919.754.0303
www.pdaconsultants.com

PDA

Take a Problem, Make it a Feature.

ATTACHMENT C

EmergeOrtho Provider Referrals to Seashore Imaging, CY2023

Provider	Practice	Referrals
BATES, THOMAS	EmergeOrtho-Morehead City-Guardian Ave	143
BEDARD, SARAH E	EmergeOrtho-Morehead City-Guardian Ave	77
CAMPBELL, GARLON	EmergeOrtho-Morehead City-N 35th Street	15
CHAANINE, KAREN	EmergeOrtho-Morehead City-Guardian Ave	19
COLES, ROBERT E	EmergeOrtho-Morehead City-Guardian Ave	79
FRANTZ, EARL A	EmergeOrtho-Morehead City-Guardian Ave	51
GUIRGUES, ASHRAF	EmergeOrtho-Morehead City-Guardian Ave	77
HUBER, STEVEN J	EmergeOrtho-Morehead City-Guardian Ave	86
JOHNSON, TAYLOR	EmergeOrtho-Morehead City-Guardian Ave	4
RAMSEY, RANDLE	EmergeOrtho-Morehead City-Guardian Ave	3
SPAKE, JORDAN	EmergeOrtho-Morehead City-Guardian Ave	1
WERTMAN, GARY	EmergeOrtho-Morehead City-Guardian Ave	16
WERTMAN, GARY V	EmergeOrtho-Morehead City-Guardian Ave	32
WILLEY, LAUREN	EmergeOrtho-Morehead City-Guardian Ave	13

Total CY23 EmergeOrtho Referrals 616

Total MR Scans Performed at Seashore Imaging Morehead CY23 3,517
 EmergeOrtho Physician Referrals as a Percent of Total 17.5%

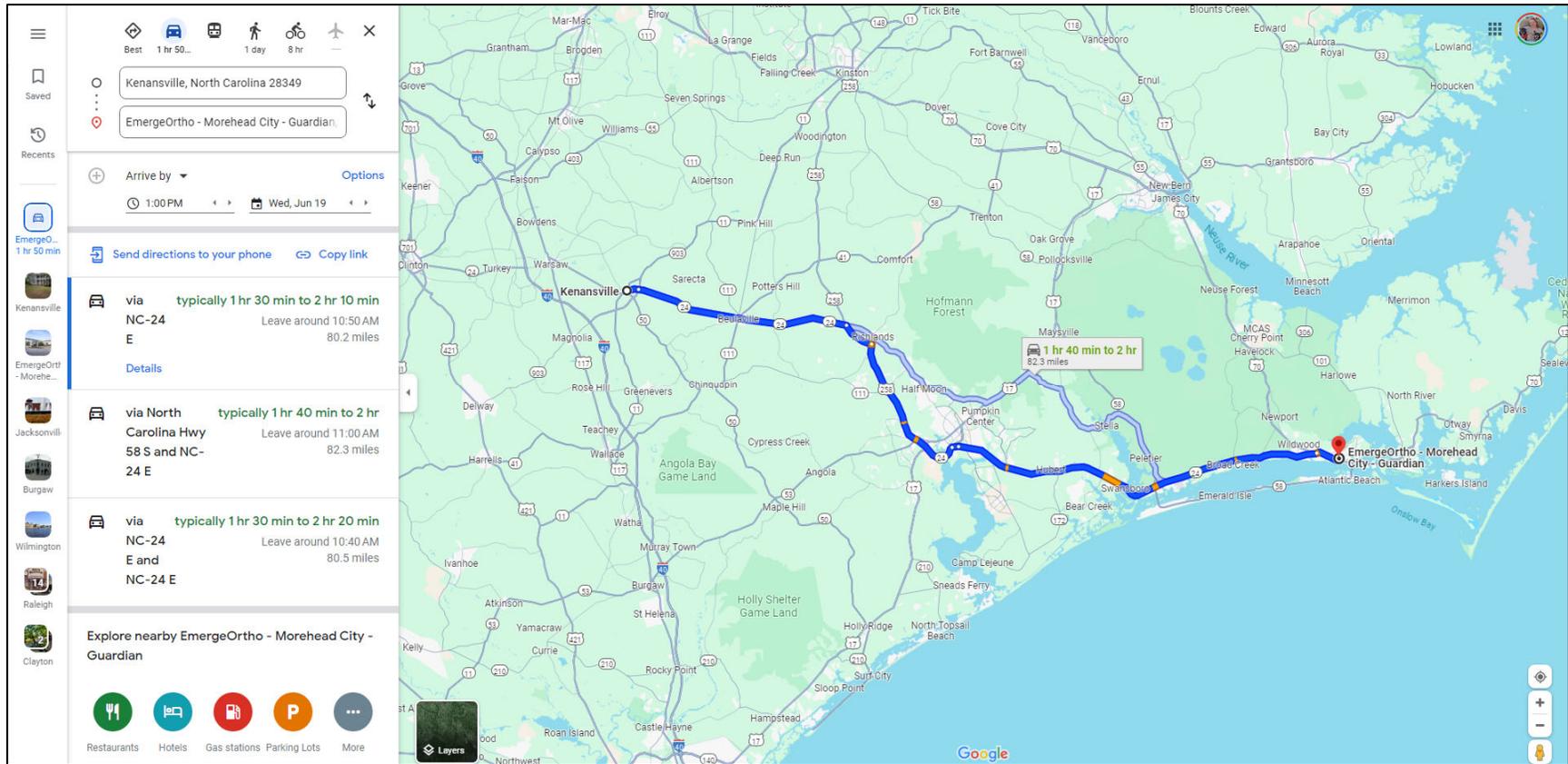
Sources:
 Seashore Imaging internal data provided by Heather Emery 03.07.24
 Seashore Imaging Fixed MRI Application Form C.2a
<https://emergeortho.com/coastal-region/locations/>

ATTACHMENT D

All sources Google Maps based on a 1pm arrival time on Wednesday June 19th, 2024. Data accessed 03.14.24

Travel Time from County Seats to EmergeOrtho-Morehead City

Kenansville, Duplin County



Jacksonville, Onslow County

Best 1 hr 16 hr 4 hr 23

o Jacksonville, North Carolina
o EmergeOrtho - Morehead City - Guardian

Options
Arrive by 1:00 PM Wed, Jun 19

Send directions to your phone Copy link

via NC-24 typically 50 min to 1 hr 20 min
E Leave around 11:40 AM
41.3 miles
Details

via North Carolina Hwy 58 S and NC-24 E typically 1 hr to 1 hr 20 min
Leave around 11:40 AM
49.3 miles

Explore nearby EmergeOrtho - Morehead City - Guardian

Restaurants Hotels Gas stations Parking Lots More

Layers

Google

Burgaw, Pender County

Best 1 hr 40... 1 day 8 hr

Burgaw, North Carolina 28425

EmergeOrtho - Morehead City - Guardian

Arrive by 1:00 PM Wed, Jun 19

Send directions to your phone Copy link

via NC-53 E and NC-24 E typically 1 hr 25 min to 2 hr
Leave around 11:00 AM 75.6 miles

via NC-53 E typically 1 hr 40 min to 2 hr 10 min
Leave around 10:50 AM 84.9 miles

Explore nearby EmergeOrtho - Morehead City - Guardian

Restaurants Hotels Gas stations Parking Lots More

1 hr 25 min to 2 hr
75.6 miles

Layers

Travel Time from County Seats to Wilmington

Kenansville, Duplin County

Best 1 hr 5 min 21 hr 6 hr

Kenansville, North Carolina 28349

Wilmington, North Carolina

Arrive by 1:00 PM Wed, Jun 19

Send directions to your phone Copy link

via I-40 E typically 55 min to 1 hr 20 min
Leave around 11:40 AM
57.3 miles

Details

Explore Wilmington

- Restaurants
- Hotels
- Gas stations
- Parking Lots
- More

Wilmington 1 hr 5 min

Kenansville

Wilmington

Emergence - Morehe...

Jacksonville

Burgaw

Raleigh

Clayton

Jacksonville, Onslow County

Best 1 hr 10 min

20 hr 5 hr

○ Jacksonville, North Carolina

○ Wilmington, North Carolina

Arrive by 1:00 PM Wed, Jun 19

Send directions to your phone Copy link

via Hwy 17 typically 1 hr to 1 hr 40 min
S/N US 17 Leave around 11:20 AM 53.6 miles
[Details](#)

via NC-53 W and I-40 E typically 1 hr to 1 hr 30 min
Leave around 11:30 AM 57.8 miles

Explore Wilmington

- Restaurants
- Hotels
- Gas stations
- Parking Lots
- More

Wilmington 1 hr 10 min

Jacksonville

Wilmington

Kenansville

Emergent - Morehe...

Burgaw

Raleigh

Clayton

1 hr to 1 hr 30 min 57.8 miles

1 hr to 1 hr 40 min 53.6 miles

Google

Burgaw, Pender County

Best 40 min 10 hr 2 hr 40

Burgaw, North Carolina 28425

Wilmington, North Carolina

Arrive by 1:00 PM Wed, Jun 19

Send directions to your phone Copy link

- via I-40 E** typically 30-50 min
Leave around 12:10 PM 28.6 miles
- via US-117 S** typically 30-55 min
Leave around 12:05 PM 25.9 miles
- via I-40 E and Military Cutoff Rd** typically 35 min to 1 hr
Leave around 12:00 PM 33.7 miles

Explore Wilmington

- Restaurants
- Hotels
- Gas stations
- Parking Lots
- More

Bladen County North Carolina 34.496595, -78.267065

Travel Time from County Seats to Jacksonville

Kenansville, Duplin County

Best 50 min 14 hr 3 hr 25

Kenansville, North Carolina 28349

Jacksonville, North Carolina

Arrive by 1:00 PM Wed, Jun 19

Send directions to your phone Copy link

- via NC-24 E and US-258 S typically 45 min to 1 hr 38.0 miles
Leave around 12:00 PM
Details
- via NC-24 E typically 45 min to 1 hr 5 min 38.3 miles
Leave around 11:55 AM
- via NC-111 S typically 45 min to 1 hr 5 min 37.5 miles
Leave around 11:55 AM

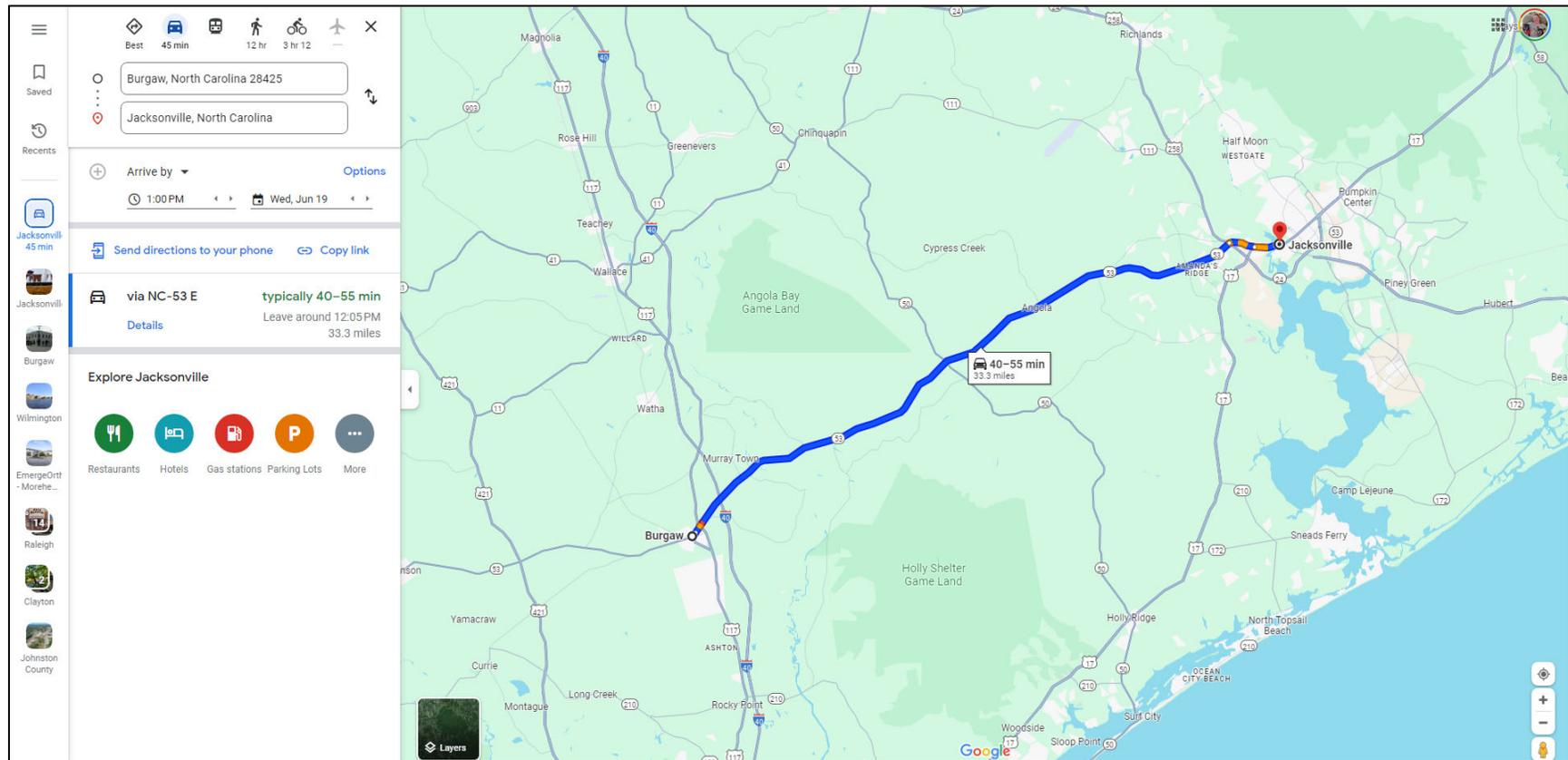
Explore Jacksonville

- Restaurants
- Hotels
- Gas stations
- Parking Lots
- More

Layers

Google

Burgaw, Pender County



Jacksonville is the county seat of Onslow County so no drive time was generated.

Table 15E-1: MRI Fixed and Mobile Procedures by MRI Service Area with Tiered Thresholds and Fixed Equivalents

A	B	C	D	E	F	G	H	I	J	K	L
Service Area	Service Type	CON #	Service Site (Provider/Owner)	Fixed Magnet	Fixed Equiv	Total MRI Scans	Base Outpatient	Complex Outpatient	Base Inpatient	Complex Inpatient	Adjusted Total
Mecklenburg				30	33.24	145,859					176,530
Mitchell	Hospital Fixed	D-006866-03	Blue Ridge Regional Hospital	1	1.00	1,345	854	421	34	36	1,502
Mitchell				1	1.00	1,345					1,502
Montgomery	Mobile	J-007008-04	First Health Montgomery (Troy) Memorial Hospital (Foundation Health Mobile Imaging)	0	0.20	368	295	73	0	0	383
Montgomery				0	0.20	368					383
Moore	Hospital Fixed	H-005602-97; H-006846-03; H-007097-04	FH Moore Regional Hospital	3	3.00	12,449	9,335	1,626	1,234	254	14,088
Moore	Freestanding Fixed	H-008365-09	First Health Southern Pines (Firsthealth of the Carolinas)	1	1.00	1,241	942	299	0	0	1,304
Moore	Freestanding Fixed	H-006845-03	Pinehurst Surgical Clinic PA	1	1.00	5,359	4,862	497	0	0	5,464
Moore				5	5.00	19,049					20,857
Nash	Hospital Fixed	L-005908-98	Nash Hospitals Inc.	2	2.00	6,260	3,272	1,283	1,391	314	8,022
Nash	Mobile	Legacy	Boice Willis Clinic (Insight Imaging)	0	0.09	429	244	185	0	0	468
Nash				2	2.09	6,689					8,491
New Hanover	Hospital Fixed		No Service Site	1	1.00	0	0	0	0	0	0
New Hanover	Hospital Fixed	O-006212-00	New Hanover Regional Medical Center - Main Campus	2	2.00	8,726	1,885	1,807	2,843	2,191	13,892
New Hanover	Hospital Fixed		NHNHRMC Health & Diagnostics - Medical Mall	1	1.00	2,117	1,048	1,069	0	0	2,344
New Hanover	Hospital Fixed		Novant Health New Hanover Orthopedic Hospital	1	1.00	5,726	2,490	3,094	94	48	6,513
New Hanover	Freestanding Fixed		2023 Need Determination	1	1.00	0	0	0	0	0	0
New Hanover	Freestanding Fixed	O-007259-05	EmergeOrtho (EmergeOrtho P.A.)	1	1.00	4,886	4,393	493	0	0	4,991
New Hanover	Freestanding Fixed	O-011063-15	Wilmington Health, PLLC (Wilmington Health)	1	1.00	4,195	2,531	1,664	0	0	4,548
New Hanover	Mobile		No Service Site	0	0.00	0	0	0	0	0	0
New Hanover	Mobile	Legacy	Delaney Radiologists (Insight Imaging)	0	0.54	2,714	1,977	737	0	0	2,870
New Hanover	Mobile	O-007254-05	Delaney Radiologists (Porter's Neck Imaging)	0	0.71	3,546	1,145	2,401	0	0	4,055
New Hanover	Mobile	O-007254-05	Delaney Radiologists (Porter's Neck Imaging)	0	0.14	683	683	0	0	0	683
New Hanover	Mobile	Legacy	EmergeOrtho-Wilmington Porters Neck (Rayus Radiology)	0	0.38	1,880	1,738	142	0	0	1,910
New Hanover	Mobile	Legacy	New Hanover Regional (Alliance HealthCare Services)	0	0.03	142	63	79	0	0	159
New Hanover	Mobile	O-007001-04	New Hanover Regional-Scotts Hill (Alliance HealthCare Services)	0	0.47	2,337	1,124	1,213	0	0	2,594
New Hanover	Mobile		NHNHRMC Health & Diagnostics - Brunswick Forest	0	0.21	1,073	544	529	0	0	1,185

Table 15E-1: MRI Fixed and Mobile Procedures by MRI Service Area with Tiered Thresholds and Fixed Equivalents

A	B	C	D	E	F	G	H	I	J	K	L
Service Area	Service Type	CON #	Service Site (Provider/Owner)	Fixed Magnet	Fixed Equiv	Total MRI Scans	Base Outpatient	Complex Outpatient	Base Inpatient	Complex Inpatient	Adjusted Total
New Hanover	Mobile		Novant Health Scotts Hill	0	0.56	2,788	1,314	1,474	0	0	3,101
New Hanover				8	11.04	40,813					48,845
Onslow	Hospital Fixed		Onslow Memorial Hospital, Inc.	1	1.00	3,624	1,000	2,196	108	320	4,537
Onslow	Freestanding Fixed	P-008326-09	Coastal Diagnostic Imaging (Jacksonville Diagnostic Imaging)	1	1.00	3,812	3,094	718	0	0	3,964
Onslow	Freestanding Fixed	P-007324-05	Coastal Diagnostic Imaging (Jacksonville Diagnostic Imaging)	1	1.00	3,297	2,610	687	0	0	3,443
Onslow	Mobile	Legacy	Diagnostic Imaging Partners (Insight Imaging)	0	0.21	1,071	755	316	0	0	1,138
Onslow				3	3.21	11,804					13,082
Orange	Hospital Fixed		University of North Carolina Hospitals at Chapel Hill, DBA UNC Hospitals	9	9.00	36,216	18,392	10,310	4,833	2,681	45,363
Orange	Freestanding Fixed	J-12141-21	Raleigh Radiology Chapel Hill	1	1.00	0	0	0	0	0	0
Orange	Freestanding Fixed		Wake Radiology (Chapel Hill Diagnostic Imaging)	1	1.00	2,476	1,272	1,204	0	0	2,731
Orange	Mobile		UNC Eastowne Medical Office (Alliance HealthCare Services)	0	0.17	864	288	576	0	0	986
Orange	Mobile	Legacy	UNC Hospital- Hillsborough Campus (Alliance HealthCare Services)	0	0.55	2,740	1,379	1,361	0	0	3,029
Orange	Mobile		UNC Hospital Imaging & Spine Center (Alliance HealthCare Services)	0	0.29	1,454	650	804	0	0	1,625
Orange	Mobile		University of North Carolina Hospitals at Chapel Hill, DBA UNC Hospitals	0	0.99	4,929	3,048	1,649	6	226	5,537
Orange				11	13.00	48,679					59,271
Pasquotank	Hospital Fixed	R-007623-06	Sentara Albemarle Medical Center	1	1.00	4,395	2,643	1,003	512	237	5,292
Pasquotank	Mobile	R-007623-06	Sentara Albemarle Medical Center	0	0.40	1,972	1,492	439	30	11	2,102
Pasquotank			2022 Need Determination	1	1.00	0	0	0	0	0	0
Pasquotank/Camden/Currituck/Perquimans				2	2.40	6,367					7,394
Pender	Mobile	Q-006884-03	Pender Memorial Hospital (Alliance HealthCare Services)	0	0.01	25	12	13	0	0	28
Pender	Mobile	O-007001-04	Pender Memorial Hospital (Alliance HealthCare Services)	0	0.41	767	432	329	2	4	843
Pender				0	0.42	792					871
Person	Hospital Fixed		Person Memorial Hospital - Reginald Harris Annex	1	1.00	288	22	241	2	23	367
Person				1	1.00	288					367
Pitt	Hospital Fixed	Q-005898-98; Q-006709-02; Q-007658-06; Q-008671-11	ECU Medical Center	4	4.00	13,946	3,645	2,429	3,593	4,279	22,199
Pitt	Freestanding Fixed		2023 Need Determination	1	1.00	0	0	0	0	0	0
Pitt	Freestanding Fixed		ECU Physicians MRI (Brody School of Medicine at East Carolina University)	1	1.00	4,279	2,880	1,399	0	0	4,576



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor

KODY H. KINSLEY • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

Date October 30, 2023

To: Certificate of Need Interested Parties

From: Micheala L. Mitchell
Section Chief, Healthcare Planning and Certificate of Need

Re: Adjustment to Cost Thresholds (Revised)

Pursuant to G.S. §§131E-176 (7a); (14o); (16)b and (22a), the Department of Health and Human Services, Division of Health Service Regulation is required to adjust the certificate of need (CON) cost threshold amounts for the development of diagnostic centers, new institutional health services and for the acquisition of major medical and replacement equipment using the Medical Care Index (MCI) of the Consumer Price Index published by the U.S. Department of Labor on September 30 for the 12-month period preceding September 1.

The percentage change in the MCI from August 31, 2022 to August 31, 2023 is -0.96%. Accordingly, the new CON cost threshold amounts for the above-referenced services and equipment are as follows:

New Institutional Health Service- \$3,961,600

Diagnostic Centers- \$2,971,200

Major Medical Equipment- \$1,980,800

Replacement Equipment-\$2,971,200

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603

MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704

<https://info.ncdhhs.gov/dhsr/> • TEL: 919-855-3873

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER



Registration and Inventory of Medical Equipment
Mobile Magnetic Resonance Imaging Scanners
January 2024

Instructions

This is the legally required "Registration and Inventory of Medical Equipment" (G.S. 131E-177) for mobile magnetic resonance imaging (MRI) scanners. Please complete all sections of this form and return to Healthcare Planning by Friday, January 26, 2024.

- 1. Submit one completed Registration and Inventory form per MRI scanner.
2. Complete and sign the form
3. Return the form by one of two methods:
a. Email a scanned copy to DHSR.SMFP.Registration-Inventory@dhhs.nc.gov.
b. Mail the form to Andrea Emanuel, Healthcare Planning, 2704 Mail Service Center, Raleigh, NC 27699-2704.

If you have questions, call Andrea Emanuel in Healthcare Planning at (919) 855-3954 or email DHSR.SMFP.Registration-Inventory@dhhs.nc.gov.

Section 1: Contact Information

- 1. Full legal name of corporation, partnership, individual, or other legal entity that acquired the equipment by purchase, donation, lease, transfer, or comparable arrangement:

Cape Fear Diagnostic Imaging, LLC (MQ15 Mobile)
(Legal Name)

- 2. Address of the corporation, partnership, individual, or other legal entity that acquired the equipment:

3480 Preston Ridge Road Ste# 600
(Street and Number)

Alpharetta GA 30005 (770) 300-0101
(City) (State) (Zip) (Phone Number)

- 3. Chief Executive Officer or approved designee who is certifying the information in this registration form:

Kelly A. Israel Sr. Mgr. Development & Mobile Ops
(Name) (Title)

3480 Preston Ridge Road, Suite 600 Alpharetta GA 30005
(Street and Number) (City) (State) (Zip)

(770) 300-0101 kisrael@medquestmail.com
(Phone Number) (Email)

- 4. Information Compiled or Prepared by: Kelly Israel
(Name)

(678) 992-7235 kisrael@medquestmail.com
(Phone Number) (Email)



Section 2: Equipment and Procedures Information

Reporting Period: 10/01/2022 – 9/30/2023 Other time period: _____

Do not make extra copies of this page if the entity has multiple MRIs. Submit a complete, separate R&I form for each scanner.

(Please make additional copies of this page as needed for additional Service Sites.)

For DHSR Planning Use Only:	
Manufacturer/Tesla	GE /1.5T
Model number	23X
Open or closed (including open bore) scanner	<input type="checkbox"/> Open <input checked="" type="checkbox"/> Closed
Serial or I.D. Number	R5786
Date of acquisition	
Purchase price (if purchased)	
Certificate of Need Project ID (or Legacy)	O-6434-01 <input type="checkbox"/> Legacy
Certificate holder, as listed on Certificate of Need	Cape Fear Diagnostic Imaging, LLC
If equipment went to only 1 site, is it permanently parked at that site?	<input type="checkbox"/> Parked <input type="checkbox"/> Not Parked
	Service Site Number <u> 2 </u>
Service Site Information: Please include all the information requested for each location.	Service Site <u>Carolina Center for Surgery (CC4S)</u> Address <u>3714 Guardian Avenue, Ste#E</u> City: <u>Morehead City</u> Zip <u>28557</u> County <u>Carteret</u>
Procedures*: - with Contrast or Sedation - without Contrast/ Sedation -Total inpatient/outpatient	Inpatient: with: _____ w/out: _____ Total: _____ Outpatient: with: <u> 0 </u> w/out: <u> 680 </u> Total: <u> 680 </u>
Total Number of Procedures	Total: <u> 680 </u>
For each day of the week, enter the number of hours the scanner is in operation.	<u> </u> Sunday <u> </u> Thursday <u> 8 </u> Monday <u> </u> Friday <u> </u> Tuesday <u> </u> Saturday <u> </u> Wednesday
Total number of hours in operation for reporting period	416 Hours

*An **MRI procedure** is defined as a single discrete MRI study of one patient (single CPT coded procedure). An MRI study means one or more scans relative to a single diagnosis or symptom. **The total number of procedures should be equal to or greater than the total number of patients reported on the MRI Patient Origin Table on page 3 of this form.**

Name of entity that acquired the equipment (from page 1) Cape Fear Diagnostic Imaging, LLC (MQ15 Mobile)



Section 4: Certification and Signature

The undersigned Chief Executive Officer or approved designee certifies the accuracy of the information contained on all pages of this form.

Signature _____ *Kelly A Israel* _____

Print Name _____ Kelly A. Israel _____

Date signed _____ January 26, 2024 _____

Note: Healthcare Planning and Certificate of Need may request CPT codes for MRI procedures if further clarification is needed.

Please complete all sections of this form and return to Healthcare Planning by **Friday, January 26, 2024**.

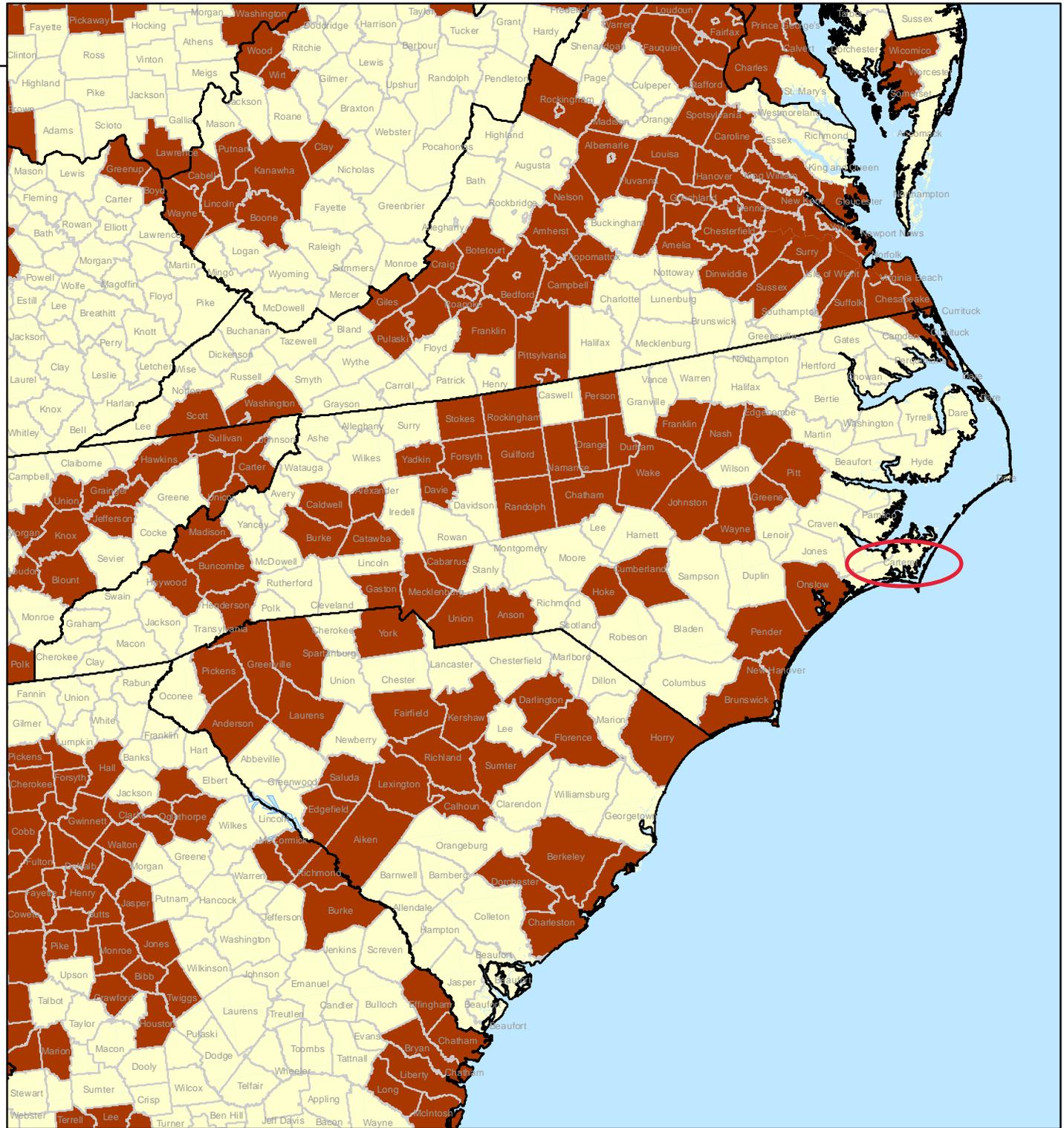
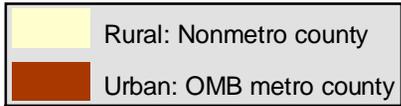
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Name of entity that acquired the equipment (from page 1) _____ Cape Fear Diagnostic Imaging, LLC (MQ15 Mobile) _____

North Carolina

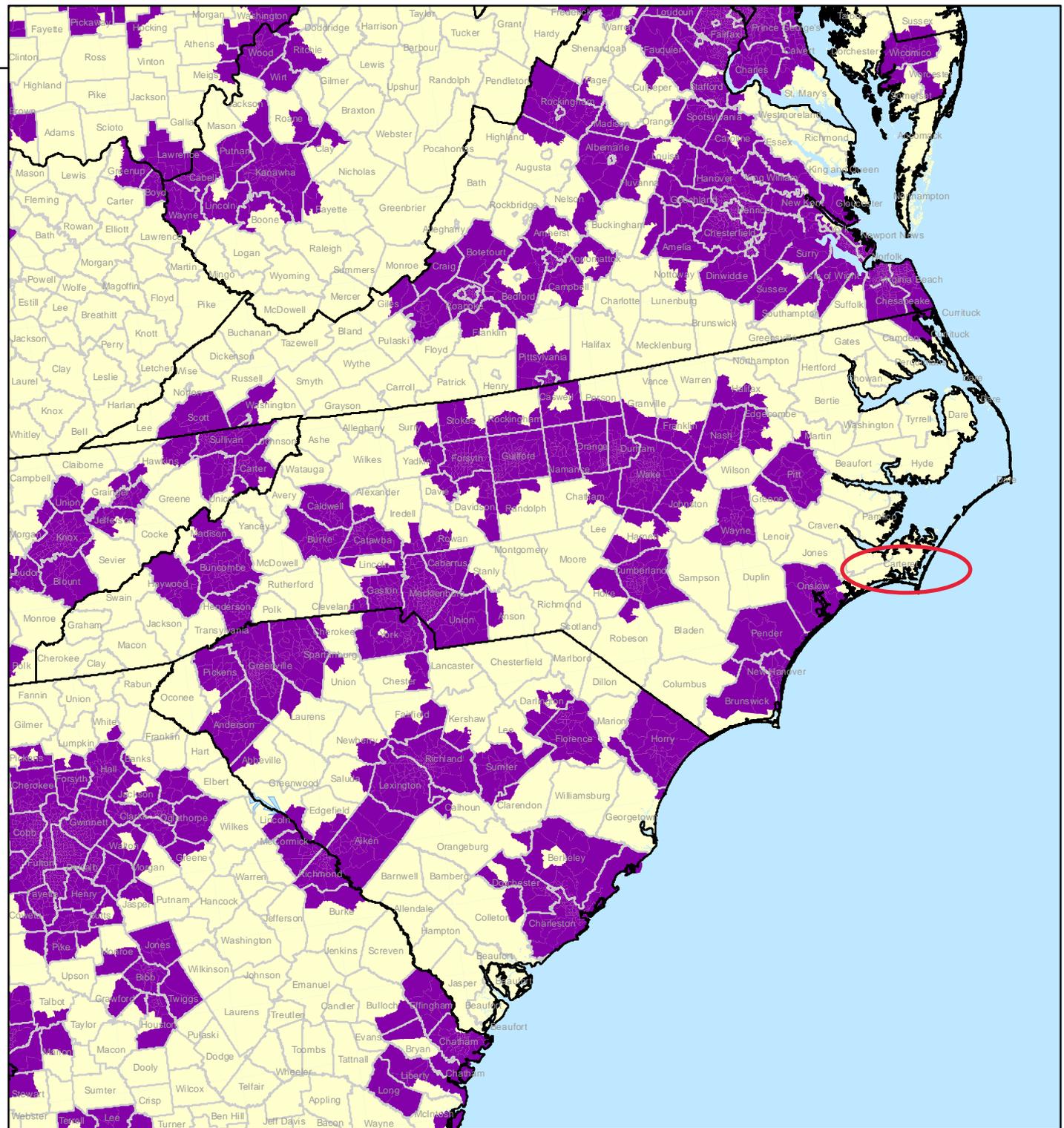
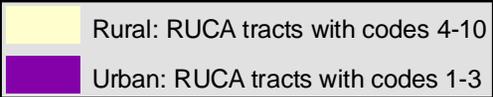
Rural definition based on Office of Management and Budget (OMB) metro counties



For more information on definitions, see documentation

North Carolina

Rural definition based on Economic Research Service Rural-Urban Commuting Areas (RUCA)



For more information on definitions, see documentation

More About Census Summary File 3

The primary source of data for building rural definitions and the associated socioeconomic indicators was Census Summary File 3. Specifically, we used summary level 85. Summary level 85 gives census data for the intersection of States-Counties-Places/Remainder-Tract-Urban/Rural. We needed to use summary level 85 in order to identify the portions of Census Places that were also part of Urban Areas.

In the case of the Census Place-based definitions, Census Urban Area-based definitions, and the Business and Industry (B&I) Loan Program definition, we were able to designate an observation as "rural" based on SF3 geographic identifiers. For the OMB-based definition, we merged a file identifying metro/nonmetro counties into SF3, matching by a county ID number. For the RUCA-based definition, we merged a file identifying tracts by RUCA code into SF3, matching by a tract ID number.

For more information, contact: [John Cromartie and Shawn Bucholtz](#)

https://www.ers.usda.gov/webdocs/DataFiles/53180/25587_NC.pdf?v=0

ATTACHMENT I

Date: March 15, 2024

Ms. Michaela Mitchell, Chief
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, NC 27699-2704

Re: Letter of Support for Seashore Imaging, LLC's Application for a new fixed MRI Scanner

Dear Ms. Mitchell:

I am writing this letter to express my full support for Seashore Imaging, LLC's certificate of need application to acquire a new fixed MRI scanner in a new diagnostic center in Cedar Point, Carteret County, in response to the need determination in the *2024 State Medical Facilities Plan*.

My name is Paul Woodard M.D. and I am the Vice Chairman of the Board of Broad Street Clinic. The Broad Street Clinic is a private non-profit, free health clinic serving the adult residents of Carteret County and surrounding areas. Our mission is to provide access to medical care for the uninsured low-income population in our community. The Clinic is open Monday through Thursday, with Monday and Tuesday mornings open to patients who can be seen by our volunteer Doctors, Nurse Practitioners, and Nurses.

As a non-profit organization who works primarily with medically underserved communities, relationships with other area providers are important to our sustainability. We need access to other services – like diagnostic imaging – to ensure our patients get the care they need.

In Carteret County, there is only one freestanding outpatient MRI service location – Seashore Imaging East in Morehead City. Seashore Imaging provides high-quality, low-cost services to my patients. The only other MRI service provider available is at Carteret Health, also in Morehead City. While the hospital does provide quality imaging services, it is not an ideal alternative for outpatients who can be appropriately served at a lower-cost freestanding facility.

Furthermore, due to traffic constraints created by a growing population and frequently exacerbated by our large tourist season, traveling to Morehead City is becoming increasingly cumbersome. As a result, western Carteret County areas like Cedar Point, Cape Carteret, Bogue, and Swansboro need their own retail, dining, transportation, and healthcare services.

Seashore Imaging is a trusted and vital partner for imaging services in our community. Its foresight to develop a location closer to residents in western Carteret County is both welcomed and encouraged. I urge the State of North Carolina to approve this project. Thank you for the opportunity to provide my support.

Sincerely,



Paul R. Woodard M.D.

Vice Chairman, the Board of Directors of the Broad Street Clinic