



NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

ROY COOPER • Governor
KODY H. KINSLEY • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

November 17, 2023

Ruth Marler, Chief Operating Officer/ Chief Nursing Officer – UNC Health Johnston
Ruth.marler@unchealth.unc.edu

No Review

Record #: 4315
Date of Request: November 13, 2023
Facility Name: UNC Health Johnston-Clayton Campus
FID #: 061348
Business Name: Johnston Memorial Hospital Authority
Business #: 1053
Project Description: Develop a procedure room in space vacated by relocation of a GI endoscopy room
County: Johnston

Dear Ms. Marler:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence regarding the project described above. Based on the CON law in effect on the date of this response to your request, the project as described is not governed by, and therefore, does not currently require a certificate of need. If the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

This determination is binding only for the facts represented in your correspondence. If changes are made in the project or in the facts provided in the correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office.

Please do not hesitate to contact this office if you have any questions.

Sincerely,

[Handwritten signature of Cynthia Bradford]

Cynthia Bradford
Project Analyst

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



Micheala Mitchell  
Chief

cc: Acute and Home Care Licensure and Certification Section, DHSR



November 7, 2023

**VIA ELECTRONIC MAIL**

Ms. Micheala Mitchell, Chief  
Ms. Cynthia Bradford, Project Analyst  
Healthcare Planning and Certificate of Need Section  
Division of Health Service Regulation  
2704 Mail Service Center  
Raleigh, NC 27699-2704  
[Micheala.Mitchell@dhhs.nc.gov](mailto:Micheala.Mitchell@dhhs.nc.gov)  
[Cynthia.Bradford@dhhs.nc.gov](mailto:Cynthia.Bradford@dhhs.nc.gov)

**RE: No Review Determination Request**

Facility: Johnston Health  
FID #: 061348  
County: Johnston

Dear Ms. Mitchell and Ms. Bradford:

Pursuant to N.C. Gen. Stat. §§ 131E-176(16)b Johnston Health Services Corporation d/b/a UNC Health Johnston (hereinafter referred to as UNC Health Johnston) requests a no review determination regarding the development of an unlicensed procedure room at UNC Health Johnston - Clayton Campus.

**Background**

On September 29, 2015 Johnston Health Services Corporation and Johnston Health Endoscopy Services, LLC were awarded a Certificate of Need (CON) for Project ID #J-11033-15, to develop a new ambulatory surgical center (ASC), by relocating one existing GI endoscopy room from UNC Health Johnston - Clayton Campus to Johnston Health Endoscopy Services, LLC and developing a new GI endoscopy room for a total of no more than two gastrointestinal endoscopy rooms upon project completion.

**“SCOPE: Develop a new licensed ambulatory surgical center with two GI endoscopy rooms in Clayton by relocating one GI endoscopy room from Johnston Health Clayton and developing a new GI endoscopy room/Johnston County”**

Subsequently, a cost overrun and change in scope CON was awarded pursuant to Project ID #J-11721-19. This CON addressed increased costs, a change in location and new ownership for Project ID #J-11033-15. Please see Attachment A for copies of the CONs issued on September 29, 2015 and October 1, 2019.

**Request**

As development of Johnston Health Endoscopy Services nears completion, UNC Health Johnston is planning to convert the space which will be vacated by relocating the GI endoscopy room to a procedure room. The capital costs associated with converting the GI endoscopy room at UNC Health Johnston - Clayton Campus to a procedure room once the GI endoscopy room has been relocated to Johnston Health

Endoscopy Services will be well below the \$4 million threshold specified in N.C. Gen. Stat. §§ 131E-176(16)b. As such UNC Health Johnston requests a no review determination by the Agency.

As you know, a Certificate of Need is not needed to add a procedure room. North Carolina also does not have any licensure regulations concerning use of procedure rooms. The Certificate of Need Section in the past has issued material compliance determinations that permit an increase in the number of procedure rooms compared to the number approved by a Certificate of Need, where the associated capital expenditure does not exceed that permitted by the Certificate of Need. See, e.g. March 9, 2020 Material Compliance Determination issued to Western Carolina Surgery Center to add four procedure rooms (Attachment B). More recently, on August 2, 2023, the Certificate of Need Section issued a No Review Determination to Metrolina Vascular Access Care for adding one procedure room to an ambulatory surgical facility (Attachment C).

UNC Health Johnston does not foresee any need to expend capital to utilize the former GI endoscopy room as a procedure room, as the room will be in use until its license is transferred to the new ASC. Based on the foregoing information, UNC Health Johnston respectfully requests that you confirm in writing that the development of a procedure room at UNC Health Johnston - Clayton Campus in space vacated by the relocation of a GI endoscopy room is not subject to CON review.

Should you have any questions or need additional information, please do not hesitate to call me at (919) 938-7383 or contact me via email at [ruth.marler@unchealth.unc.edu](mailto:ruth.marler@unchealth.unc.edu). I look forward to your response.

Sincerely,



Ruth Marler, MPH, BSN, RN  
Chief Operating Officer/Chief Nursing Officer  
UNC Health Johnston

Enclosures

# STATE OF NORTH CAROLINA

*Department of Health and Human Services  
Division of Health Service Regulation*

## **CERTIFICATE OF NEED**

for

**Project ID #J-11033-15**

**FID #150206**

**ISSUED TO: Johnston Health Services Corporation and  
Johnston Health Endoscopy Services, LLC  
509 N Bright Leaf Blvd.  
Smithfield, NC 27577**

Pursuant to G.S. 131E-175, the North Carolina Department of Health and Human Services hereby authorizes the person or persons named above (the "certificate holder") to develop the certificate of need project identified above. The certificate holder shall develop the project in a manner consistent with the representations in the project application and with the conditions contained herein and shall make good faith efforts to meet the timetable contained herein, as documented by the periodic progress reports required by 10A NCAC 14C .0209. The certificate holder shall not exceed the maximum capital expenditure amount specified herein during the development of this project, except as provided by G.S. 131E-176(16)e. The certificate holder shall not transfer or assign this certificate to any other person except as provided in G.S. 131E-189(c). This certificate is valid only for the scope, physical location, and person(s) described herein. The Department may withdraw this certificate pursuant to G.S. 131E-189 for any of the reasons provided in that law.

**SCOPE: Develop a new licensed ambulatory surgery center with two GI endoscopy rooms in Clayton by relocating one GI endoscopy room from Johnston Health Clayton and developing a new GI endoscopy room/ Johnston County**

**CONDITIONS: See Reverse Side**

**PHYSICAL LOCATION: Johnston Health Endoscopy Services, LLC  
11626 Highway 70 West  
Clayton, NC 27520**

**MAXIMUM CAPITAL EXPENDITURE: \$822,451**

**TIMETABLE: See Reverse Side**

**FIRST PROGRESS REPORT DUE: March 1, 2016**

This certificate is effective as of the 29<sup>th</sup> day of September, 2015

  
Shelley Carraway, Chief

**CONDITIONS:**

1. Johnston Health Services Corporation and Johnston Health Endoscopy Services, LLC shall materially comply with all representations made in the certificate of need application.
2. Johnston Health Services Corporation and Johnston Health Endoscopy Services, LLC shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application and that would otherwise require a certificate of need.
3. Johnston Health Services Corporation and Johnston Health Endoscopy Services, LLC shall relocate the existing gastrointestinal endoscopy room from Johnston Health Clayton to Johnston Health Endoscopy Services, LLC, and develop a new ambulatory surgical facility with no more than two gastrointestinal endoscopy rooms upon project completion.
4. Johnston Health Services Corporation shall take the necessary steps to delicense the existing gastrointestinal room at Johnston Health Clayton upon project completion.
5. Prior to issuance of the certificate of need, Johnston Health Endoscopy Services, LLC shall provide the agency with the documentation of an agreement to transfer and accept referrals of GI endoscopy patients from a hospital where physicians utilizing the facility have practice privileges.
6. Johnston Health Services Corporation and Johnston Health Endoscopy Services, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.

A letter acknowledging acceptance of and agreeing to comply with all conditions stated in the conditional approval letter was received by the Healthcare Planning and Certificate of Need Section, Division of Health Services Regulation on September 29, 2015.

**TIMETABLE:**

Contract Award	_____	January 1, 2016
25% Completion of Construction	_____	April 1, 2016
50% Completion of Construction	_____	July 1, 2016
Completion of Construction	_____	September 15, 2016
Occupancy/Offering of Service	_____	October 1, 2016



# STATE OF NORTH CAROLINA

*Department of Health and Human Services  
Division of Health Service Regulation*

## **CERTIFICATE OF NEED**

for

**Project ID #: J-11721-19**

**FID #: 150206**

**ISSUED TO: Johnston Health Endoscopy Services, LLC  
Johnston Health Services Corporation**

Pursuant to N.C. Gen. Stat. § 131E-177(6), the North Carolina Department of Health and Human Services hereby authorizes the person or persons named above (the "certificate holder") to develop the certificate of need project described below. The certificate holder shall develop the project in a manner consistent with the representations in the application and with the conditions contained herein and shall make good faith efforts to meet the timetable contained herein, as documented by the periodic progress reports required by 10A NCAC 14C .0209. The certificate holder shall not exceed the maximum capital expenditure amount specified herein during the development of this project, except as provided by N.C. Gen. Stat. § 131E-176(16)e. The certificate holder shall not transfer or assign this certificate to any other person except as provided in N.C. Gen. Stat. § 131E-189(c). This certificate is valid only for the scope, physical location, and person(s) described herein. The Department may withdraw this certificate pursuant to N.C. Gen. Stat. § 131E-189 for any of the reasons provided in that section.

**SCOPE:** Cost overrun and change of scope for Project I.D. #J-11033-15 (develop an ambulatory surgical facility with two gastrointestinal endoscopy rooms) involving a change in location and new ownership / Johnston County

**CONDITIONS:** See Reverse Side

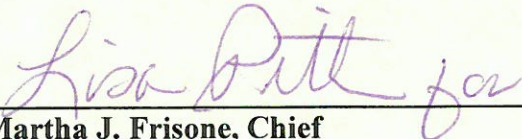
**PHYSICAL LOCATION:** Johnston Endoscopy Center  
Parcel 05G03004C, Highway 42  
Clinton, NC 27520

**MAXIMUM CAPITAL EXPENDITURE:** \$2,895,494

**TIMETABLE:** See Reverse Side

**FIRST PROGRESS REPORT DUE:** December 30, 2019

This certificate is effective as of October 1, 2019

  
\_\_\_\_\_  
Martha J. Frisone, Chief



**CONDITIONS:**

1. Johnston Health Endoscopy Services, LLC and Johnston Health Services Corporation shall materially comply with the representations in this application and the representations made in Project I.D. #J-11033-15. Where representations conflict, Johnston Health Endoscopy Services, LLC, and Johnston Health Services Corporation shall materially comply with the last made representation.
2. Johnston Health Endoscopy Services, LLC and Johnston Health Services Corporation shall develop Johnston Endoscopy Center by relocating no more than one gastrointestinal endoscopy room from Johnston Health Clayton to Johnston Endoscopy Center and by developing no more than one new gastrointestinal endoscopy room.
3. Upon completion of this project, Johnston Endoscopy Center shall be licensed for no more than two gastrointestinal endoscopy rooms.
4. Johnston Health Endoscopy Services, LLC and Johnston Health Services Corporation shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Sections F and Q of the application and that would otherwise require a certificate of need.
5. Johnston Health Endoscopy Services, LLC and Johnston Health Services Corporation shall receive accreditation from the Joint Commission for the Accreditation of Healthcare Organizations, the Accreditation Association for Ambulatory Health Care, or a comparable accreditation authority within two years following licensure of the facility.
6. For the first three years of operation following completion of the project, Johnston Health Endoscopy Services, LLC and Johnston Health Services Corporation shall not increase charges more than 5% of the charges projected in Section Q of the application without first obtaining a determination from the Healthcare Planning and Certificate of Need Section that the proposed increase is in material compliance with the representations in the certificate of need application.
7. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Johnston Health Endoscopy Services, LLC, and Johnston Health Services Corporation 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.
8. Johnston Health Endoscopy Services, LLC and Johnston Health Services Corporation 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.

A letter acknowledging acceptance of and agreeing to comply with all conditions stated in the conditional approval letter was received by the Agency on September 10, 2019.



**TIMETABLE:**

1. Drawings Completed \_\_\_\_\_ November 22, 2019
2. Construction / Renovation Contract(s) Executed \_\_\_\_\_ December 20, 2019
3. 25% of Construction / Renovation Completed  
(25% of the cost is in place) \_\_\_\_\_ April 27, 2020
4. 50% of Construction / Renovation Completed \_\_\_\_\_ June 9, 2020
5. 75% of Construction / Renovation Completed \_\_\_\_\_ July 21, 2020
6. Construction / Renovation Completed \_\_\_\_\_ September 15, 2020
7. Equipment Ordered \_\_\_\_\_ January 20, 2020
8. Equipment Installed \_\_\_\_\_ October 1, 2020
9. Equipment Operational \_\_\_\_\_ November 1, 2020
10. Building / Space Occupied \_\_\_\_\_ December 1, 2020
11. Licensure Obtained \_\_\_\_\_ December 15, 2020
12. Services Offered (required) \_\_\_\_\_ January 1, 2021
13. Medicare and / or Medicaid Certification Obtained \_\_\_\_\_ March 15, 2021
14. Facility or Service Accredited \_\_\_\_\_ May 15, 2021
15. First Annual Report Due \_\_\_\_\_ April 1, 2022



NC DEPARTMENT OF  
**HEALTH AND  
HUMAN SERVICES**

ROY COOPER • Governor  
MANDY COHEN, MD, MPH • Secretary  
MARK PAYNE • Director, Division of Health Service Regulation

March 9, 2020

Denise Gunter  
[Denise.gunter@nelsonmullins.com](mailto:Denise.gunter@nelsonmullins.com)

**Material Compliance Approval**

Project ID #: B-11520-18  
Facility: Western Carolina Surgery Center  
Project Description: Develop a new multispecialty ambulatory surgical facility with one operating room and three procedure rooms by relocating one operating room from Fletcher Hospital, Incorporated d/b/a AdventHealth Hendersonville  
County: Henderson  
FID #: 180265

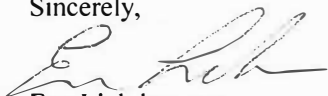
Dear Ms. Gunter:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) has determined that the change proposed in your letter of February 26, 2020 is in material compliance with representations made in the application. These changes include change in the site location and add four additional procedure rooms for a total of seven procedure rooms. However, you should contact the Agency's Construction, and Acute and Home Care Licensure and Certification Sections to determine if they have any requirements pertinent to the proposed change.

It should be noted that the Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this office and a separate determination.

If you have any questions concerning this matter, please feel free to contact this office. Please refer to the Project ID # and Facility ID # (FID) in all correspondence.

Sincerely,

  
Ena Lightbourne  
Project Analyst

  
Martha J. Frisone  
Chief

cc: Construction Section, DHSR  
Acute and Home Care Licensure and Certification Section, DHSR

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



Denise M. Gunter  
T 336.774.3322 F 336.774.3372  
denise.gunter@nelsonmullins.com

RECEIVED BY HEALTHCARE PLANNING & CON FEB 26 2020  
NELSON MULLINS RILEY & SCARBOROUGH LLP  
ATTORNEYS AND COUNSELORS AT LAW

380 Knollwood Street | Suite 530  
Winston-Salem, NC 27103  
T 336.774.3300 F 336.774.3299  
nelsonmullins.com

February 26, 2020

**Via Electronic Mail**

Martha J. Frisone, Chief  
North Carolina Department of Health and Human Services  
Division of Health Service Regulation  
Healthcare Planning and Certificate of Need Section  
809 Ruggles Drive  
Raleigh, North Carolina 27603

Re: Material Compliance Request  
Summit Health Partners, LLC  
Henderson County  
HSA I  
Project I.D. # B-11520-18  
FID # 180265

Dear Ms. Frisone:

Pursuant to N.C. Gen. Stat. §§ 131E-181 and 189, I am writing on behalf of Summit Health Partners, LLC ("Summit") to request a material compliance determination. In this request, Summit seeks to relocate its ambulatory surgery center ("ASC") to a different site in Henderson County and to add four additional procedure rooms, for a total of seven procedure rooms.

On June 5, 2019, the Agency issued a CON to Summit to develop an ASC with one OR and three procedure rooms by relocating one OR from Fletcher Hospital, Incorporated d/b/a AdventHealth Hendersonville "AHH"). The location identified in the CON is 1151 Naples Road, Hendersonville, North Carolina 28792 (the "Original Site"). The maximum capital expenditure for the CON is \$9,732,464. The CON is attached to this letter as **Exhibit A**.

Since the time the CON was issued, Summit has found a new site for the ASC in Henderson County. The new site is 30 Airport Park Road, Fletcher, NC 28732 (the "New Site"). Like the Original Site, the New Site is also located in Henderson County. As



Martha J. Frisone  
February 26, 2020  
Page 2

shown in **Exhibit B** to this letter, the New Site is 5.4 miles from the Original Site. The New Site offers a number of advantages for patients and providers as compared to the Original Site:

- The New Site will accommodate options for providers to co-locate services such as clinic and physical therapy space.
- The New Site is more visible and more accessible off the main highway in the area, I-26.
- The New Site is also more accessible to the growing population in the northern part of Henderson County.
- The New Site's easy access from I-26 is more convenient for many of the providers who are expected to use the ASC. Many of these providers maintain multiple practice locations and live in Buncombe County.

As such, a site that affords better access for both patients and providers is ideal, and consistent with the purposes of the CON Law and the SMFP. See N.C. Gen. Stat. § 131E-175(3a); see also N.C. Gen. Stat. § 131E-183(a)(1) and Policy GEN-3 in the SMFP. The Department has previously approved location changes of similar or greater distances. See, e.g., **Exhibit C** (approving relocation of dialysis facility 7.8 miles from original site) and **Exhibit D** (approving relocation of adult care home 19 miles from original site).

Physicians have enthusiastically supported Summit's project, and for that reason, Summit believes four additional procedure rooms, for a total of seven procedure rooms, are needed to accommodate expected volumes. Developing the additional procedure rooms concurrently with the OR and the originally-approved procedure rooms instead of waiting until after the facility opens is more efficient and less disruptive to the ongoing operations of the ASC. Thus, if this material compliance letter is approved, the ASC will consist of one OR relocated from AHH and seven procedure rooms.

At the New Site, Summit will be a tenant in a building owned by a third party. Summit will renovate space in the building. The capital costs to develop the ASC at the New Site, as shown on **Exhibit E**, are \$8,833,875 and therefore significantly lower than the maximum capital expenditure of \$9,732,464 shown in **Exhibit A**.

Summit further represents that there will be no increase in patient charges as a result of changing locations and adding four additional procedure rooms. Summit also represents that there will be no change in the scope of services approved for the ASC. While the New Site affords greater access for patients, the patient population that is likely to use the ASC is not expected to change.

N.C. Gen. Stat. § 131E-189(b) allows the Agency to withdraw the CON if Summit fails to develop the service in a manner consistent with the representations made in the

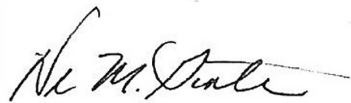
Martha J. Frisone  
February 26, 2020  
Page 3

application or with any conditions that were placed on the CON. Summit will not be operating the project in a manner that is materially different from the representations made in the application, nor in a manner that is inconsistent with any of the conditions that were placed on the CON.

Accordingly, Summit respectfully requests that the CON Section issue a material compliance determination that it be allowed to relocate the project to the New Site and add four additional procedure rooms, for a total of seven procedure rooms.



Thank you for your time and consideration. Please let me know if you have any questions or need any other information.

Sincerely,






A handwritten signature in black ink, appearing to read "Denise M. Gunter", with a long horizontal flourish extending to the right.

Denise M. Gunter

Enclosures

-  8. Use the right 2 lanes to take exit 40 for NC-280 toward Asheville/Arden  
0.2 mi
-  9. Keep left at the fork, follow signs for Brevard and merge onto NC-280 W/New Airport Rd  
180 ft

**Continue on NC-280 W/New Airport Rd to your destination in Fletcher**

-  10. Merge onto NC-280 W/New Airport Rd  
2 min (0.4 mi)  
0.3 mi
-  11. Turn left onto Airport Park Rd  
0.1 mi
-  12. Turn left  
33 ft
-  13. Turn right  
 Destination will be on the left  
69 ft

### 30 Airport Park Rd

Fletcher, NC 28732

These directions are for planning purposes only. You may find that construction projects, traffic, weather, or other events may cause conditions to differ from the map results, and you should plan your route accordingly. You must obey all signs or notices regarding your route.





NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

ROY COOPER • Governor
KODY H. KINSLEY • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

August 2, 2023

Marcus C. Hewitt
mhewitt@foxrothschild.com

No Review

Record #: 4246
Date of Request: July 14, 2023
Facility Name: Metrolina Vascular Access Care
FID #: 180517
Business Name: Metrolina Vascular Access Care, LLC
Business #: 2942
Project Description: Add one procedure room to an ambulatory surgical facility
County: Mecklenburg

Dear Mr. Hewitt:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence regarding the project described above. Based on the CON law in effect on the date of this response to your request, the project as described is not governed by, and therefore, does not currently require a certificate of need. If the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

This determination is binding only for the facts represented in your correspondence. If changes are made in the project or in the facts provided in the correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office.

Please do not hesitate to contact this office if you have any questions.

Sincerely,

[Handwritten signature of Michael J. McKillip]

Michael J. McKillip
Team Leader

[Handwritten signature of Micheala Mitchell]

Micheala Mitchell
Chief

cc: Acute and Home Care Licensure and Certification Section, DHSR

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



Fox Rothschild LLP  
ATTORNEYS AT LAW

434 Fayetteville Street  
Suite 2800  
Raleigh, NC 27601  
Tel 919.755.8700 Fax 919.755.8800  
www.foxrothschild.com

MARCUS C. HEWITT  
Direct No: 919.755.8776  
Email: MHewitt@Foxrothschild.com

July 14, 2023

Via Email to: [lisa.pittman@dhhs.nc.gov](mailto:lisa.pittman@dhhs.nc.gov)

Lisa Pittman, Assistant Chief, Certificate of Need  
North Carolina Department of Health and Human Services,  
Division of Health Service Regulation, Healthcare Planning  
and Certificate of Need Section

Dear Ms. Pittman:

Our firm represents Fresenius Vascular Care d/b/a Azura Vascular Care (“Azura”). Azura and Metrolina Vascular Access Care, LLC opened an ambulatory surgical facility (the “Vascular ASC”) in Charlotte in 2022 with one licensed operating room and one procedure room, pursuant to the CONs awarded for project ID numbers F-11612-18 (ASC CON) and F-12019-21 (cost overrun/change of scope CON). Copies of the two CONs are attached as **Exhibits 1 and 2**, respectively. The Center was licensed effective April 29, 2022 and was certified by CMS effective June 15, 2022 (See CMS Certification Letter attached as **Exhibit 3**<sup>1</sup>). In accordance with the terms of its CON, Azura will submit reports to the Agency detailing the Vascular ASC’s payor mix, utilization, revenues and operating costs for three years (see letter dated May 15, 2023, attached as **Exhibit 4**).

Since the Vascular ASC opened approximately fifteen months ago, utilization of its OR and procedure room have grown dramatically, and additional capacity is already needed to address scheduling and operational issues. Accordingly, Azura now plans to increase the capacity of the Vascular ASC by converting 300 square feet of existing space for use as a second procedure room.

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<sup>1</sup> The CMS letter dated 8/30/22 identifies the effective date of the CMS certification as 6/15/22.

Lisa Pittman  
July 14, 2023  
Page 2

As you know, procedure rooms are not specifically regulated under the CON Act. Moreover, as described below, the addition of a procedure room would not involve any other new institutional health service. Accordingly, Azura requests the Agency confirm that no CON is required.

**An additional procedure room is not a change as defined in N.C. Gen. Stat. § 131E-76(16)e**

A CON is required for a change to a project that required a CON, if the change is proposed before the project is complete or within one year after completion. N.C. Gen. Stat. § 131E-176(16)e. “Change” is defined as either an increase of more than 15% of the approved capital expenditure or the addition of a health service.

Section 131E-176 does not apply to the addition of a procedure room to the Vascular ASC. First, the facility was licensed, certified by CMS and in material compliance with the representations in its CON application as of June 15, 2022. (See letter attached as **Exhibit 3**). Therefore, the project has been complete pursuant to N.C. Gen. Stat. § 131E-181(d) for more than a year.

Second, the addition of a procedure room will not exceed the approved capital cost by more than 15%. The total capital expenditure for which the Vascular ASC was approved was initially \$2,900,000 (See **Exhibit 1**, CON for Project ID F-11612-18), and was later increased to \$4,100,000 in June 2021 (See **Exhibit 2**, CON for Project ID F-12019-21). Despite the \$4,100,000 approved capital expenditure, Azura was able to develop the Vascular ASC for much less, because anticipated increases due to the pandemic did not materialize, and because the center was new construction that came in significantly under budget. The total capital cost incurred to develop the facility date is \$2,351,442.16, made up of the following:

- Capital costs totaling \$2,147,194.74 documented in Azura’s progress report dated June 1, 2022 (copy attached as **Exhibit 5**) and
- A subsequent invoice for \$204,247.42 provided to the Agency by email on March 13, 2023 (copy attached as **Exhibit 6**).

The Agency previously acknowledged these capital expenditures by letter dated May 15, 2023 (see **Exhibit 4**).

The estimated cost to convert the existing space to a second procedure room totals \$388,000, as shown below. Based on this estimate, Azura estimates that the total capital expenditure, including expenditures already made plus the cost to add a second procedure room, would total only \$2,739,442.16, which is less than the originally approved capital cost of \$2,900,000.00.





Lisa Pittman  
July 14, 2023  
Page 3

Total Sq Ft	300
\$ / Sq Ft	500

<b>Buildout</b>	<b>150,000</b>
A&E Fees	25,000
Medical Equip.	180,000
Contingency	22,500
Development Fee	10,500
<b>Total Project Cost</b>	<b>388,000</b>

Third, Azura does not propose the addition of any surgical specialties or any other health service that the Vascular ASC does not already provide. Therefore, the addition of a second procedure room would not be a change within the meaning of Section 131E-176(16)e.

**An additional procedure room does not include any other New Institutional Health Services.**

The proposed addition of a second procedure room does not otherwise constitute a new institutional health service. Among other things:

- The estimated capital expenditure to add a second procedure room is only \$388,000. Therefore, N.C. Gen. Stat. § 131E-176(16)b does not apply.
- The total estimated cost of medical equipment is only \$180,000. Therefore, there is no acquisition of major medical equipment, and N.C. Gen. Stat. § 131E-176(16)p does not apply.
- The addition of a second procedure room does not involve the construction, development, establishment, increase in the number, or relocation of an operating room. Therefore, N.C. Gen. Stat. § 131E-176(16)u does not apply.

**An additional procedure room is not inconsistent with the conditions on the CONs.**

Finally, the addition of a second procedure room is materially consistent with the conditions on the CONs for the project. Among other things:

- The Vascular ASC will continue to focus on vascular access procedures for patients with end stage renal disease.
- The Vascular ASC will not be licensed for more than one operating room.



Lisa Pittman  
July 14, 2023  
Page 4

- The additional procedure room will not be used for procedures that should be performed only in a licensed operating room based on current standards of practice.
- The additional procedure room would not result in any increase in the facility's charges.

For the reasons described above, please confirm that the addition of a second procedure room at the Vascular ASC is not subject to CON review. We look forward to your response, and please let us know if you have questions or would like to discuss.

Best regards,

FOX ROTHSCHILD LLP

A handwritten signature in blue ink, appearing to read 'Marcus C. Hewitt', written over a light blue horizontal line.

Marcus C. Hewitt

Enclosures

**Exhibits:**

- 1 - CON for F-11612-18 (ASC CON)
- 2 - CON for F-12019-21 (cost overrun)
- 3 - CMS Certification Letter
- 4 - 5/15/23 Letter acknowledging capital costs
- 5 - 6/1/22 Progress Report
- 6 - 3/13/23 email with copy of additional invoice for \$204,247.42

**From:** [Waller, Martha K](#)  
**To:** [Stancil, Tiffany C](#)  
**Cc:** [Mitchell, Micheala L](#); [Kim Meymandi](#); [Bradford, Cynthia L](#)  
**Subject:** FW: [External] Johnston Health Clayton No Review Determination Request  
**Date:** Monday, November 13, 2023 9:00:32 AM  
**Attachments:** [Johnston Health Clayton No Review Determination Request.pdf](#)

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Tiffany, for you....

### *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](mailto:martha.waller@dhhs.nc.gov)

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**From:** Kim Meymandi <KimMeymandi@ascendient.com>

**Sent:** Monday, November 13, 2023 8:57 AM

**To:** Mitchell, Micheala L <Micheala.Mitchell@dhhs.nc.gov>; Bradford, Cynthia L <cynthia.bradford@dhhs.nc.gov>

**Cc:** Waller, Martha K <martha.waller@dhhs.nc.gov>

**Subject:** [External] Johnston Health Clayton No Review Determination Request

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Good morning-

I hope you all had a nice relaxing weekend. Attached is a No Review determination request submitted on behalf of our client Johnston Health Clayton. Please let me know if you have any questions or concerns.

Thanks much,

Kim

**Kim Meymandi | SENIOR CONSULTANT**

[kimmeymandi@ascendient.com](mailto:kimmeymandi@ascendient.com) | 919.226.1712 | [linkedin](#) | [www.ascendient.com](http://www.ascendient.com)



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