

State of North Carolina

Department of Health and Human Services
Division of Health Service Regulation

Certificate of Need

for

Project ID #: G-12301-22

FID #: 100545

ISSUED TO: Carolina Dialysis of Mebane, LLC

Pursuant to G.S. 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 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 G.S. 131E-189(a). 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 section.

SCOPE: Add no more than 2 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 dialysis stations upon completion of this project and Project ID# J-12080-21 (relocate 2 stations)/ Alamance County

CONDITIONS: See Reverse Side

PHYSICAL LOCATION: Carolina Dialysis-Mebane
1410 South Third St.
Mebane, NC 27302

CAPITAL EXPENDITURE: \$0

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: November 30, 2023

This certificate is effective as of June 8, 2023



Micheala Mitchell, Chief

Conditions for Project ID# G-12301-22

1. Carolina Dialysis of Mebane, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.
2. Pursuant to Condition 2 of the facility need methodology in the 2022 SMFP, the certificate holder shall develop no more than two additional in-center dialysis stations for a total of no more than 27 in-center (and home hemodialysis) stations at Carolina Dialysis-Mebane upon completion of this project and Project ID #J-12080-21 (relocate 2 stations).
3. Progress Reports:
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.
 - b. The certificate holder shall complete all sections of the Progress Report form.
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.
 - d. The first progress report shall be due on November 30, 2023.
4. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.

Timetable

	Milestone	Date <i>mm/dd/yyyy</i>
1	Financing Obtained	11/15/2022
2	Equipment Ordered	9/2/2023
3	Equipment Installed	11/16/2023
4	Equipment Operational	12/7/2023
5	Services Offered	12/31/2023
6	Medicare and / or Medicaid Certification Obtained	12/31/2023

State of North Carolina

Department of Health and Human Services
Division of Health Service Regulation

Certificate of Need

for

Project ID #: J-12311-23

FID #: 170324

ISSUED TO: Bio-Medical Applications of North Carolina, Inc.

Pursuant to G.S. 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 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 G.S. 131E-189(a). 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 section.

SCOPE: Relocate no more than 5 dialysis stations from FMC Briggs Avenue for a total of no more than 19 dialysis stations upon project completion/ Durham County

CONDITIONS: See Reverse Side

PHYSICAL LOCATION: Fresenius Kidney Care Eno River
4917 Old Farm Road
Durham, NC 27704

CAPITAL EXPENDITURE: \$18,750

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: November 1, 2023

This certificate is effective as of June 1, 2023



Micheala Mitchell, Chief

CONDITIONS:

1. **Bio-Medical Applications of North Carolina, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
2. **The certificate holder shall relocate no more than five in-center dialysis stations to Fresenius Kidney Care Eno River for a total of 19 in-center stations upon project completion.**
3. **Upon completion of this project, the certificate holder shall take the necessary steps to decertify five in-center dialysis stations from FMC Dialysis Services of Briggs Avenue for a total of no more than 24 in-center stations.**
4. **Progress Reports:**
 - a. **Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. **The certificate holder shall complete all sections of the Progress Report form.**
 - c. **The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. **The first progress report is due on November 1, 2023.**
5. **The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**

A letter acknowledging of and agreeing to comply with all conditions stated in the conditional approval letter was received by the Agency on May 1, 2023.

Timetable

	Milestone	Date <i>mm/dd/yyyy</i>
1	Equipment Ordered	10/04/2023
2	Equipment Installed	12/03/2023
3	Equipment Operational	12/17/2023
4	Services Offered	12/31/2023
5	Medicare and / or Medicaid Certification Obtained	12/31/2023

State of North Carolina

Department of Health and Human Services
Division of Health Service Regulation

Certificate of Need

for

Project ID #: G-11737-19

FID #: 980838

ISSUED TO: Bio-Medical Applications of North Carolina, Inc.

Pursuant to G.S. 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 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 G.S. 131E-189(a). 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 section.

SCOPE: Relocate no more than 10 dialysis stations from BMA Burlington (Alamance County) pursuant to Policy ESRD-2 for a total of no more than 54 stations upon project completion / Guilford County

CONDITIONS: See Reverse Side

PHYSICAL LOCATION: BMA of South Greensboro
622 Industrial Avenue
Greensboro, NC 27406

CAPITAL EXPENDITURE: \$0

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: December 1, 2023

This certificate is effective as of June 21, 2023



Micheala Mitchell, Chief

CONDITIONS:

- 1. Bio-Medical Applications of North Carolina, Inc. shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to Policy ESRD-2, Bio-Medical Applications of North Carolina, Inc. shall relocate no more than 10 dialysis stations from BMA of Burlington (Alamance County) to BMA of South Greensboro, for a total of no more than 54 dialysis stations at BMA of South Greensboro upon project completion.**
- 3. Upon completion of this project, Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify 10 dialysis stations at BMA of Burlington for a total of no more than 35 dialysis stations at BMA of Burlington.**
- 4. Bio-Medical Applications of North Carolina, Inc. 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 of and agreeing to comply with all conditions stated in the conditional approval letter was received by the Agency on June 27, 2023.

Timetable

	Milestone	Date <i>mm/dd/yyyy</i>
1	Financing Obtained	07/16/2023
2	Drawings Completed	04/17/2024
3	Equipment Ordered	09/24/2024
4	Equipment Installed	12/13/2024
5	Equipment Operational	12/27/2024
6	Building/Space Occupied	12/01/2024
7	Medicare and/or Medicaid Certification Obtained	12/31/2024
8	Facility or Service Accredited	12/31/2024

State of North Carolina

Department of Health and Human Services
Division of Health Service Regulation

Certificate of Need

for

Project ID #: G-11744-19

FID #: 190319

ISSUED TO: Total Renal Care of North Carolina, LLC

Pursuant to G.S. 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 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 G.S. 131E-189(a). 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 section.

SCOPE: Develop a new 10-station dialysis facility by relocating no more than 7 stations from Reidsville Dialysis (Rockingham County) and no more than 3 stations from Burlington Dialysis (Alamance County) pursuant to Policy ESRD-2, and develop a home training and support program / Guilford County

CONDITIONS: See Reverse Side

PHYSICAL LOCATION: Central Greensboro Dialysis
2437 Randleman Road
Greensboro, NC 27406

CAPITAL EXPENDITURE: \$3,079,575

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: December 1, 2023

This certificate is effective as of June 21, 2023



Micheala Mitchell, Chief

CONDITIONS:

1. **Total Renal Care of North Carolina, LLC shall materially comply with all representations made in the certificate of need application.**
2. **Pursuant to Policy ESRD-2, Total Renal Care of North Carolina, LLC shall develop a new kidney disease treatment center to be known as Central Greensboro Dialysis by relocating no more than 7 dialysis stations from Reidsville Dialysis (Rockingham County) and no more than 3 stations from Burlington Dialysis (Alamance County).**
3. **Total Renal Care of North Carolina, LLC shall install plumbing and electrical wiring through the walls for no more than 10 dialysis stations which shall include any isolation stations.**
4. **Total Renal Care of North Carolina, LLC shall take the necessary steps to decertify 7 dialysis stations at Reidsville Dialysis for a total of no more than 24 dialysis stations at Reidsville Dialysis upon completion of this project.**
5. **Total Renal Care of North Carolina, LLC shall take the necessary steps to decertify 3 dialysis stations at Burlington Dialysis for a total of no more than 13 dialysis stations at Burlington Dialysis upon completion of this project.**

A letter acknowledging of and agreeing to comply with all conditions stated in the conditional approval letter was received by the Agency on December 20, 2019.

Timetable

Milestone		Date <i>mm/dd/yyyy</i>
1	Drawings Completed	04/02/2024
2	Construction/Renovation Contract Executed	05/03/2024
3	50% of Construction/Renovation Completed	08/14/2024
4	Construction/Renovation Completed	11/06/2024
5	Equipment Operational	11/13/2024
6	Building/Space Occupied	11/20/2024
7	Services Offered	01/01/2025
8	Medicare and/or Medicaid Certification Obtained	01/01/20254

State of North Carolina

Department of Health and Human Services
Division of Health Service Regulation

Certificate of Need

for

Project ID #: J-11739-19

FID #: 170520

ISSUED TO: Bio-Medical Applications of North Carolina, Inc.

Pursuant to G.S. 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 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 G.S. 131E-189(a). 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 section.

SCOPE: Relocate no more than 2 dialysis stations from Southwest Wake Dialysis (Wake County) pursuant to Policy ESRD-2 for a total of no more than 12 stations upon the completion of this project and Project I.D. #J-11435-17 (develop FKC West Johnson by relocating 10 existing stations from FMC Stallings Stations) / Johnston County

CONDITIONS: See Reverse Side

PHYSICAL LOCATION: Fresenius Kidney Care West Johnston
55 E. Malibu Dr.
Garner, NC 27529

CAPITAL EXPENDITURE: \$18,900

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: December 1, 2023

This certificate is effective as of June 21, 2023



Micheala Mitchell, Chief

CONDITIONS:

- 1. Bio-Medical Applications of North Carolina, Inc. shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to Policy ESRD-2, Bio-Medical Applications of North Carolina, Inc. shall relocate no more than 2 dialysis stations from Southwest Wake Dialysis (Wake County) to Fresenius Kidney Care West Johnston.**
- 3. Bio-Medical Applications of North Carolina, Inc. shall install plumbing and electrical wiring through the walls for no more than 12 dialysis stations upon completion of this project and Project I.D. #J-11435-17, which shall include any isolation stations.**
- 4. Upon completion of this project, Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify 2 dialysis stations at Southwest Wake County Dialysis for a total of no more than 32 dialysis stations at Southwest Wake County Dialysis.**
- 5. Bio-Medical Applications of North Carolina, Inc. 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 of and agreeing to comply with all conditions stated in the conditional approval letter was received by the Agency on June 27, 2023.

Timetable

	Milestone	Date <i>mm/dd/yyyy</i>
1	Drawings Completed	04/17/2024
2	Construction / Renovation Contract(s) Executed	07/01/2024
3	25% of Construction/Renovation Completed	07/31/2024
4	50% of Construction/Renovation Completed	08/30/2024
5	75% of Construction/Renovation Completed	09/29/2024
6	Construction/Renovation Completed	10/29/2024
7	Equipment Ordered	09/29/2024
8	Equipment Installed	12/13/2024
9	Equipment Operational	12/27/2024
10	Building / Space Occupied	12/27/2024
11	Services Offered	12/31/2024
12	Medicare and/or Medicaid Certification Obtained	12/31/2024

State of North Carolina

Department of Health and Human Services
Division of Health Service Regulation

Certificate of Need

for

Project ID #: J-11743-19

FID #: 170420

ISSUED TO: Total Renal Care of North Carolina, LLC

Pursuant to G.S. 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 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 G.S. 131E-189(a). 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 section.

SCOPE: Develop a new 10-station dialysis facility by relocating no more than 5 stations from Forest Hills Dialysis (Wilson County) and no more than 5 stations from Wilson Dialysis (Wilson County)/ Johnston County

CONDITIONS: See Reverse Side

PHYSICAL LOCATION: Clayton Dialysis
2196 Hwy 42
Clayton, NC 27520

CAPITAL EXPENDITURE: \$3,173,246

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: December 1, 2023

This certificate is effective as of June 21, 2023



Micheala Mitchell, Chief

CONDITIONS:

- 1. Total Renal Care of North Carolina, LLC shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to Policy ESRD-2, Total Renal Care of North Carolina, LLC shall develop a new kidney disease treatment center to be known as Clayton Dialysis by relocating no more than 5 dialysis stations from Forest Hills Dialysis (Wilson County) and no more than 5 stations from Wilson Dialysis (Wilson County).**
- 3. Total Renal Care of North Carolina, LLC shall install plumbing and electrical wiring through the walls for no more than 10 dialysis stations which shall include any isolation stations.**
- 4. Total Renal Care of North Carolina, LLC shall take the necessary steps to decertify 5 dialysis stations at Forest Hills Dialysis for a total of no more than 21 dialysis stations at Forest Hills Dialysis upon completion of this project and Project I.D. #L-11438-17.**
- 5. Total Renal Care of North Carolina, LLC shall take the necessary steps to decertify 5 dialysis stations at Wilson Dialysis for a total of no more than 32 dialysis stations at Wilson Dialysis upon completion of this project, Project I.D. #L-11438-17, and Project I.D. #L-11591-18.**

A letter acknowledging of and agreeing to comply with all conditions stated in the conditional approval letter was received by the Agency on December 20, 2019.

Timetable

Milestone		Date <i>mm/dd/yyyy</i>
1	Drawings Completed	04/02/2024
2	Construction / Renovation Contract(s) Executed	05/03/2024
3	50% of Construction / Renovation Completed	08/14/2024
4	Construction / Renovation Completed	11/06/2024
5	Equipment Operational	11/13/2024
6	Building / Space Occupied	11/20/2024
7	Services Offered	01/01/2025

CONDITIONS:

- 1. The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation (herein after “the certificate holder”) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall develop a new cancer center by relocating an existing medical oncology treatment center to a new location, acquiring, replacing, and relocating an existing radiation oncology treatment center with one linear accelerator and one CT simulator, and combining the two treatment centers in a new location.**
- 3. Upon project completion, Cone Health Cancer Center – Asheboro will be licensed for no more than one linear accelerator and no more than one CT simulator.**
- 4. The certificate holder shall not acquire as part of this project any equipment that is not included in the project’s proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
- 5. The certificate holder shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.**
- 6. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. The first progress report shall be due on October 1, 2023.**
- 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, the certificate holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
 - a. Payor mix for the services authorized in this certificate of need.**
 - b. Utilization of the services authorized in this certificate of need.**
 - c. Revenues and operating costs for the services authorized in this certificate of need.**
 - d. Average gross revenue per unit of service.**
 - e. Average net revenue per unit of service.**
 - f. Average operating cost per unit of service.**
- 8. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**

A letter acknowledging of and agreeing to comply with all conditions stated in the conditional approval letter was received by the Agency on June 14, 2023.

Timetable

	Milestone	Date
1	Drawings Completed	8/31/2023
2	Construction / Renovation Contract(s) Executed	9/15/2023
3	25% of Construction / Renovation Completed (25% of the cost is in place)	12/15/2023
4	50% of Construction / Renovation Completed	3/1/2024
5	75% of Construction / Renovation Completed	6/1/2024
6	Construction / Renovation Completed	8/31/2024
7	Equipment Ordered	2/27/2024
8	Equipment Installed	8/15/2024
9	Equipment Operational	9/1/2024
10	Building / Space Occupied	9/1/2024
11	Licensure Obtained	10/1/2024
12	Services Offered (required)	10/1/2024
13	Medicare and / or Medicaid Certification Obtained	11/15/2024
14	Facility or Service Accredited	2/15/2025
15	First Annual Report Due	1/1/2026

State of North Carolina

Department of Health and Human Services
Division of Health Service Regulation

Certificate of Need

for

Project ID #: J-12321-23

FID #: 230128

ISSUED TO: Raleigh NC Endoscopy ASC, LLC
Amsurg Holdings, Inc.

Pursuant to G.S. 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 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 G.S. 131E-189(a). 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 section.

SCOPE: Develop a new ASF with no more than three GI endoscopy rooms upon project completion / Wake County

CONDITIONS: See Reverse Side

PHYSICAL LOCATION: Raleigh Endoscopy Center-Holly Springs
2061 Ralph Stephens Road
Holly Springs, NC 27540

CAPITAL EXPENDITURE: \$6,300,000

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: November 1, 2023

This certificate is effective as of June 22, 2023



Micheala Mitchell, Chief

CONDITIONS:

1. Raleigh NC Endoscopy ASC, LLC, and Amsurg Holdings, Inc., (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.
2. The certificate holder shall develop an ASF, Raleigh Endoscopy Center-Holly Springs, with no more than three GI endoscopy rooms in Holly Springs.
3. Upon project completion, Raleigh Endoscopy Center-Holly Springs shall be licensed for no more than three GI endoscopy rooms.
4. The certificate holder shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.
5. Prior to issuance of the Certificate of Need, the certificate holder shall provide the Agency with documentation that an effort has been made to accommodate the clinical needs of the health professional training programs in the area at Raleigh Endoscopy Center – Holly Springs.
6. Progress Reports:
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.
 - b. The certificate holder shall complete all sections of the Progress Report form.
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.
 - d. The first progress report shall be due on November 1, 2023.
7. The certificate holder 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.
8. For the first three years of operation following completion of the project, the certificate holder 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.
9. No later than six months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, the certificate holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:
 - a. Payor mix for the services authorized in this certificate of need.
 - b. Utilization of the services authorized in this certificate of need.
 - c. Revenues and operating costs for the services authorized in this certificate of need.
 - d. Average gross revenue per unit of service.

(J-12321-23 Con't)

- e. Average net revenue per unit of service.
 - f. Average operating cost per unit of service.
10. The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.
 11. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.

A letter acknowledging of and agreeing to comply with all conditions stated in the conditional approval letter was received by the Agency on June 1, 2023.

Timetable

Milestone		Date <i>mm/dd/yyyy</i>
1	Financing Obtained	10/1/23
2	Drawings Completed	10/1/23
3	Construction / Renovation Contract(s) Executed	11/1/23
4	25% of Construction / Renovation Completed (25% of the cost is in place)	2/1/24
5	50% of Construction / Renovation Completed	5/1/24
6	75% of Construction / Renovation Completed	8/1/24
7	Construction / Renovation Completed	11/1/24
8	Equipment Ordered	10/1/23
9	Equipment Installed	11/15/24
10	Equipment Operational	11/15/24
11	Building / Space Occupied	12/1/24
12	Licensure Obtained	12/15/24
13	Services Offered	1/1/25
14	Medicare and / or Medicaid Certification Obtained	4/1/25
15	Facility or Service Accredited	6/1/25
16	First Annual Report Due* (only for non-ESRD decisions)	3/31/26

State of North Carolina

Department of Health and Human Services
Division of Health Service Regulation

Certificate of Need

for

Project ID #: J-12328-23

FID #: 230129

ISSUED TO: Duke University Health System, Inc.

Pursuant to G.S. 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 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 G.S. 131E-189(a). 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 section.

SCOPE: Develop a diagnostic center with mammography and ultrasound / Wake County

CONDITIONS: See Reverse Side

PHYSICAL LOCATION: Duke Imaging Garner
130 Timber Drive East
Garner, NC 230129

CAPITAL EXPENDITURE: \$2,422,000

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: November 1, 2023

This certificate is effective as of June 6, 2023



Micheala Mitchell, Chief

CONDITIONS:

1. Duke University Health System, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.
2. The certificate holder shall develop a new diagnostic center with mammography and ultrasound imaging equipment in a medical office building to be developed in Garner.
3. Progress Reports:
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.
 - b. The certificate holder shall complete all sections of the Progress Report form.
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.
 - d. The first progress report shall be due on November 1, 2023.
4. The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.
5. No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, the certificate holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:
 - a. Payor mix for the services authorized in this certificate of need.
 - b. Utilization of the services authorized in this certificate of need.
 - c. Revenues and operating costs for the services authorized in this certificate of need.
 - d. Average gross revenue per unit of service.
 - e. Average net revenue per unit of service.
 - f. Average operating cost per unit of service.
7. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.

A letter acknowledging of and agreeing to comply with all conditions stated in the conditional approval letter was received by the Agency on May 8, 2023.

Timetable

Milestone		Date <i>mm/dd/yyyy</i>
1	Drawings Completed	05/08/2023
2	Construction / Renovation Contract(s) Executed	11/01/2023
3	25% of Construction / Renovation Completed (25% of the cost is in place)	12/01/2023
4	50% of Construction / Renovation Completed	02/01/2024
5	75% of Construction / Renovation Completed	04/01/2024
6	Construction / Renovation Completed	06/01/2024
7	Equipment Operational	07/01/2024
8	Services Offered	07/01/2024
9	Medicare and / or Medicaid Certification Obtained	10/01/2024
10	Facility or Service Accredited	10/01/2024
11	First Annual Report Due* (only for non-ESRD decisions)	09/30/2025

State of North Carolina

Department of Health and Human Services
Division of Health Service Regulation

Certificate of Need

for

Project ID #: J-12329-23

FID #: 923421

ISSUED TO: Duke University Health System, Inc.

Pursuant to G.S. 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 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 G.S. 131E-189(a). 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 section.

SCOPE: Acquire no more than one CT scanner for a total of no more than five CT scanners/ Wake County

CONDITIONS: See Reverse Side

PHYSICAL LOCATION: Duke Raleigh Hospital
3400 Wake Forest Road
Raleigh, NC 27609

CAPITAL EXPENDITURE: \$4,151,000

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: December 1, 2023

This certificate is effective as of June 27, 2023



Micheala Mitchell, Chief

CONDITIONS:

1. Duke University Health System, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.
2. The certificate holder shall acquire no more than one fixed CT scanner for a total of no more than five fixed CT scanners, including three fixed CT scanners to be located at Duke Raleigh Hospital, and two fixed CT scanners located at outpatient clinics.
3. Progress Reports:
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.
 - b. The certificate holder shall complete all sections of the Progress Report form.
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.
 - d. The first progress report shall be due on December 1, 2023.
4. The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.
5. No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, the certificate holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:
 - a. Payor mix for the services authorized in this certificate of need.
 - b. Utilization of the services authorized in this certificate of need.
 - c. Revenues and operating costs for the services authorized in this certificate of need.
 - d. Average gross revenue per unit of service.
 - e. Average net revenue per unit of service.
 - f. Average operating cost per unit of service.
6. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.

A letter acknowledging of and agreeing to comply with all conditions stated in the conditional approval letter was received by the Agency on June 20, 2023.

Timetable

Milestone		Date <i>mm/dd/yyyy</i>
1	Construction / Renovation Completed	11/30/2023
2	Services Offered	01/01/2024
3	First Annual Report Due	10/01/2025