

DEPARTMENT OF HEALTH AND HUMAN SERVICES DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER GOVERNOR MANDY COHEN, MD, MPH SECRETARY

> MARK PAYNE DIRECTOR

RESPONSE REQUIRED

October 16, 2017

Jacquelyn Tillinger 2025 Frontis Plaza Blvd, Suite 200 Winston-Salem, NC 27103

Conditional Approval

Project ID #: G-11381-17

Facility: Digestive Health Specialists, P.A.

Project Description: Develop an ASC with one licensed GI endoscopy room in an existing

medical office building

County: Stokes FID #: 170364

Dear Ms. Tillinger:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) has conditionally approved the above referenced certificate of need application. This decision was made after a review of the applications submitted for this cycle and after consideration of the Certificate of Need Law, N.C. Gen. Stat. §131E-175 et. seq. and regulations promulgated there under, the State Medical Facilities Plan, and other applicable information. Attached to this letter are the required findings made with respect to your application. The applicant shall not proceed with the construction, offering or development of this project until the certificate of need is issued. Further, the Agency shall not issue the certificate of need until all applicable conditions of approval have been met pursuant to N.C. Gen. Stat. §131E-187(a). The conditions are as follows:

- 1. Digestive Health Specialists, P.A. shall materially comply with all representations made in the certificate of need application.
- 2. Digestive Health Specialists, P.A. shall develop an ambulatory surgery center with no more than one licensed gastrointestinal endoscopy procedure room.

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

WWW.NCDHHS.GOV TELEPHONE 919-855-3873

LOCATION: EDGERTON BUILDING • 809 RUGGLES DRIVE • RALEIGH, NC 27603 MAILING ADDRESS: 2704 MAIL SERVICE CENTER •RALEIGH, NC 27699-2704 AN EQUAL OPPORTUNITY/ AFFIRMATIVE ACTION EMPLOYER

- 3. Upon completion of the project, Digestive Health Specialists, P.A. shall be licensed for no more than one gastrointestinal endoscopy procedure room.
- 4. Digestive Health Specialists, P.A. 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.
- 5. The procedure room shall not be used for procedures that should be performed only in an operating room based on current standards of practice.
- 6. Procedures performed in the procedure room shall not be reported for billing purposes as having been performed in an operating room and shall not be reported on the facility's license renewal application as procedures performed in an operating room.
- 7. Digestive Health Specialists, P.A. 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, Digestive Health Specialists, P.A. shall not increase charges more than 5% of the charges projected in Section X 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 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, Digestive Health Specialists, P.A. 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.
- 10. Digestive Health Specialists, P.A. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to issuance of the certificate of need.

Response to the above conditions should be submitted to the Agency no later than 35 days from the date of the decision. Failure to respond within this time period may result in the Agency making a determination not to issue a certificate of need for the project referenced above.

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The conditional approval is valid only for a capital expenditure of \$60,000. If a cost overrun occurs that exceeds the approved capital expenditure amount, a new certificate of need may be required as determined by N.C. Gen. Stat. §131E-176(16)(e).

The applicant should be aware that according to the Certificate of Need law any affected person shall have thirty (30) days after the date of decision to file a petition for a contested case on this approval. Further, if you are aggrieved by the conditions of the decision you may file a petition for a contested case hearing in accordance with N.C. Gen. Stat. §150B, Article 3, as amended. This petition must be filed with the Office of Administrative Hearings, 6714 Mail Service Center, Raleigh, North Carolina 27699-6714 within thirty (30) days of the date of this decision. [Note: Effective October 1, 2009, OAH requires a filing fee with submittal of petitions for contested cases. Please direct all questions regarding this fee to OAH Clerk's Office (919-431-3000).]

N.C. Gen. Stat. §150B-23 provides that a party filing a petition must also serve a copy of the petition on all parties to the petition. Therefore, if you file a petition for a contested case hearing, you must serve a copy of the petition on the Department of Health and Human Services by mailing a copy of your petition to:

Lisa G. Corbett

Department of Health and Human Services,
 Office of Legal Affairs,
 Adams Building – Room 154
 2001 Mail Service Center
 Raleigh, North Carolina, 27699-2001

It is requested that a copy of the petition also be served on the Agency.

The certificate of need will not be issued before the completion of this 30 day period ending **November 15, 2017.** If a contested case request is received within the thirty (30) day period, the certificate will not be issued until the appeal is resolved (10A NCAC 14C .0208).

The timetable for completion of the project is the timetable outlined in the certificate of need application, unless an adjustment has been made by the Agency because the review period was extended. The timetable for this project is as follows:

1.	Financing Obtained	March 5, 2018
2.	Licensure Obtained	December 15, 2018
3.	Services Offered	January 1, 2019
4.	Medicare and/or Medicaid Certification Obtained	January 1, 2019
5.	Facility or Service Accredited	June 30, 2019
6.	Final Annual Report Due	March 31, 2021

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If the decision is appealed, the timetable set forth in this letter will be adjusted accordingly before the Certificate of Need is issued. Please contact this office if any clarification of this decision is required.

Please refer to the Project ID # and Facility ID # (FID) in all correspondence.

Sincerely,

Celia C. Inman Project Analyst Fatimah Wilson Team Leader, Certificate of Need

Attachment

cc: Construction Section, DHSR

Acute & Home Care Licensure & Certification Section, DHSR Sharetta Blackwell, Program Assistant Healthcare Planning, DHSR

CERTIFICATE OF SERVICE

I hereby certify that I have served the foregoing notice of **conditional approval** on the following person by placing a copy in an official depository of the United States Postal Service in a postage-paid, first class envelope addressed as follows:

Jacquelyn Tillinger 2025 Frontis Plaza Blvd, Suite 200 Winston-Salem, NC 27103

This the 16th day of October, 2017.

Celia C. Inman Project Analyst, Certificate of Need