

JOSH STEIN • Governor

DEVDUTTA SANGVAI • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

September 12, 2025

Jack G. Clifford

Jack.g.clifford@gmail.com

No Review

Record #: 4911

Date of Request: September 3, 2025 Business Name: Jack G. Clifford

Business #: 3986

Project Description: Develop an outpatient clinic offering Enhanced External Counterpulsation (EECP)

therapy only

County: Buncombe

Dear Mr. Clifford:

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 representation in your request and 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. As a reminder, it is unlawful to offer or develop a new institutional health service without first obtaining a certificate of need. The Department reserves the right to impose sanctions, including civil penalties and the revocation of a license, upon any entity that offers or develops a new institutional health service without first obtaining a certificate of need.

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

Sincerely,

Ena Lightbourne Project Analyst

Micheala Mitchell

Micheala Witchell

Chief

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

From: Mitchell, Micheala L

To: Stancil, Tiffany C

Subject: FW: [External] Certificate of Need Determination Request – Proposed EECP Clinic

Date: Wednesday, September 3, 2025 4:24:20 PM

Tiffany,

Would you mind logging and assigning this to Ena?

Thank you.

Micheala

Micheala Mitchell, JD

NC Department of Health and Human Services

Division of Health Service Regulation

Section Chief, Healthcare Planning and CON Section
809 Ruggles Drive, Edgerton Building
2704 Mail Service Center

Raleigh, NC 27699-2704

Office: 919 855 3879

Micheala.Mitchell@dhhs.nc.gov

From: Mitchell, Micheala L

Sent: Wednesday, September 3, 2025 4:23 PM **To:** 'Jack Clifford' < jack.g.clifford@gmail.com>

Subject: RE: [External] Certificate of Need Determination Request - Proposed EECP Clinic

Mr. Clifford,

We've received and are reviewing your determination request. One of our project analysts will be in touch with you if he or she has additional questions regarding your request. Please allow us 10-15 business days to reply.

Thank you,

Micheala

Micheala Mitchell, JD

NC Department of Health and Human Services

Division of Health Service Regulation

Section Chief, Healthcare Planning and CON Section
809 Ruggles Drive, Edgerton Building
2704 Mail Service Center

Raleigh, NC 27699-2704

Office: 919 855 3879

Micheala.Mitchell@dhhs.nc.gov

From: Jack Clifford < <u>jack.g.clifford@gmail.com</u>> Sent: Wednesday, September 3, 2025 4:17 PM

To: Mitchell, Micheala L < Micheala. Mitchell@dhhs.nc.gov >

Subject: [External] Certificate of Need Determination Request – Proposed EECP Clinic

You don't often get email from jack.q.clifford@gmail.com. Learn why this is important

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Dear Certificate of Need Section,

I am writing to request a formal determination of whether my proposed project requires a Certificate of Need (CON) under North Carolina General Statute §131E-175 et seq.

Project Description:

I plan to establish a small outpatient clinic that will exclusively provide Enhanced External Counterpulsation (EECP) therapy for patients. The service will be delivered using FDA-approved EECP devices (Class II medical devices).

Key Project Details:

- Location: Asheville, NC
- Facility Type: Standalone outpatient clinic (not affiliated with a licensed hospital, ASC, or diagnostic center)
- Services Provided: EECP therapy only
- Equipment: EECP system(s), estimated cost per unit: approximately \$30,000 (well below the current capital expenditure threshold for CON review)
- Beds/Rooms: No inpatient beds; therapy provided in an outpatient setting only
- Other Services: No diagnostic imaging, surgical, or acute care services will be offered

Based on my review of the applicable statutes and rules, it appears that EECP does not fall within the list of regulated services or capital expenditure thresholds that typically require CON approval. However, I respectfully request an official determination from DHSR confirming whether a Certificate of Need is required for this project.

Thank you for your time and consideration. Please let me know if additional details or documentation are needed to complete your review.

Sincerely,
Jack Clifford

jack.g.clifford@gmail.com
321 423 2829 (Cell)

Jack Clifford
jack.g.clifford@gmail.com
321 423 2829 (Cell)

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