

North Carolina Department of Health and Human Services Division of Health Service Regulation

Pat McCrory Governor Aldona Z. Wos, M.D. Ambassador (Ret.) Secretary DHHS

> Drexdal Pratt Division Director

March 13, 2014

Barry Boyce 5500 N. El Carol Court Wilmington, NC 28409

No Review

Individual:

Barry Boyce

Project Description:

Open a clinic to use a Class III laser to treat chronic pain

County:

New Hanover

Dear Mr. Boyce:

The Certificate of Need Section (CON Section) received your letter of February 19, 2014 regarding the above referenced proposal. Based on the CON law in effect on the date of this response to your request, the proposal described in your correspondence is not governed by, and therefore, does not currently require a certificate of need. However, please note that 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.

Moreover, you need to contact the Construction and Acute and Home Care Licensure and Certification Sections of the Division of Health Service Regulation to determine if they have any requirements for development of the proposed project.

It should be noted that this determination is binding only for the facts represented by you. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by the Certificate of Need Section. Changes in a project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.



Certificate of Need Section

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Please contact the CON Section if you have any questions. Also, in all future correspondence you should reference the Facility I.D. # (FID) if the facility is licensed.

Sincerely,

Gregory F. Yakaboski, Project Analyst

Martha J. Frisone, Interim Chief Certificate of Need Section

cc: Medical Facilities Planning Branch, DHSR

Construction Section, DHSR (Not Hospice Home Care/ Home Health) Acute and Home Care Licensure and Certification Section, DHSR February 19, 2014

Barry Boyce 5500 N. El Carol Court Wilmington, N.C. 28409

Certificate of Needs Section 2704 Mail Service Center Raleigh, N.C. 27699-2704

Dear Mr. Yakaboski,

The purpose of this letter is to request "A No Review Letter" in order to open a business in Wilmington N.C.. The clinic will use a Class III laser with FDA regulation #890.5500. The FDA product code is ILY. Classification name is LAMP, INFARED, THERAPEUTIC HEATING. These devices are used to treat chronic pain. The cost to open the business should be under \$100,000.

I am uncertain at this time whether I will apply as a corporation or an LLC to operate under. Consultation with an attorney will determine which is best.

I hope I have covered everything we discussed on the phone. Thank you for your assistance.

Best Regards,

Barry Boyce

Cell # 540 520-6824 barry.boyce@yahoo.com

