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September 17, 2020

RV2020-027
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Sep 17 2020

STATE HEALTH PLANNING AND
DEVELOPMENT AGENCY

Via Electronic Filing
(shpda.online@shpda.alabama.gov)

Ms. Emily Marsal, Esq.
Executive Director
State Health Planning and Development Agency
100 North Union Street, Suite 870
Montgomery, Alabama 36104

Re: Bio-Medical Applications of Alabama, Inc. d/b/a Fresenius Kidney Care Florence
Request for Reviewability Determination

Dear Ms. Marsal:

The purpose of this letter is to request your determination, pursuant to Section 401-1-7-.02 of the Alabama Certificate of Need Program Rules & Regulations ("Regulations"), that the proposed establishment of a new kidney disease treatment center and operation of ten (10) stations in Lauderdale County, Alabama, does not require our client, Bio-Medical Applications of Alabama, Inc. d/b/a Fresenius Kidney Care Florence ("Fresenius"), to obtain a Certificate of Need ("CON") from the State Health Planning and Development Agency. In order to assist with this determination, we offer the following information:

Pursuant to Ala. Code § 22-21-278, a kidney disease treatment center located in a Class 3, 4, 5, 6, 7, or 8 municipality, as defined by Ala. Code § 11-40-12(a), which contains no more than ten (10) freestanding hemodialysis stations is not subject to CON review. However, this exemption from the CON program does not apply to a kidney disease treatment center located in a Class 4, 5, 6, 7, or 8 municipality if such municipality, or any part of such municipality, is located in a county in which a Class 1, 2, or 3 municipality, or any part thereof, is located. *See* Ala. Admin. Code r. 410-2-3-.05(1)(b).

The proposed location of the clinic to be developed by Fresenius is in Lauderdale County, Alabama, with the kidney disease treatment center to be located in Florence. Lauderdale County does **not** contain a Class 1, 2, or 3 municipality¹ and, accordingly, this Lauderdale County proposal meets the exemption criteria set forth in Ala. Code § 22-21-278, which provides, in pertinent part, as follows:

(b) Notwithstanding any existing law to the contrary, **any kidney disease treatment center that contains no more than ten freestanding hemodialysis units and that is located in a Class 3, 4, 5, 6, 7 or 8 municipality** (as such classes are defined in Sections 11-40-12 and 11-40-13 or any successor provision of law) **shall not be subject to or governed by the provisions of Article 9 of Chapter 21 of Title 22** (including, without limitation, the provision of said articles which require that a certificate of need be obtained

¹ As defined by Section 11-40-12(a), a Class 1 municipality is a city with a population of 300,000 inhabitants or more; a Class 2 municipality is a city with a population of not less than 175,000, and not more than 299,999 inhabitants; and a Class 3 municipality is a city with a population of not less than 100,000, and not more than 174,999 inhabitants.

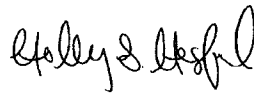
from the State Health Planning and Development Agency as a condition precedent to the offering or development of new institutional health services).

(c) The provisions of subsection (b) shall not apply to a kidney disease treatment center located in a Class 4, 5, 6, 7 or 8 municipality if such municipality or any part thereof is located in a county in which a Class 1, 2 or 3 municipality or any part thereof is located. [emphasis added]

Therefore, pursuant to Ala. Code § 22-21-278 and Ala. Admin. Code r. 410-2-3-.05(1)(b), the proposed clinic is not subject to CON review. Due to this exemption, a CON is not required for the proposed project.

Based upon the above, we respectfully request your determination that Bio-Medical Applications of Alabama, Inc. d/b/a Fresenius Kidney Care Florence is exempt from CON review and is not required to obtain a CON in order to complete the project as described in this letter. We appreciate your consideration of this request, and welcome the opportunity to address any questions regarding this matter. Pursuant to the agency's Temporary Agency Operating Procedures, the applicable filing fee will be submitted electronically through the vendor portal. Thank you very much.

Best regards,



Holly S. Hosford

Affirmation of Requesting Party:

The undersigned, being first duly sworn, hereby makes oath or affirms that she, as the Regional Vice President of Fresenius Kidney Care for the Tennessee Valley Region, has knowledge of the facts in the attached Reviewability Determination Request for Bio-Medical Applications of Alabama, Inc. d/b/a Fresenius Kidney Care Florence and to the best of her information, knowledge and belief, such facts are true and correct.

Rose Wynn RVP
Rose Wynn
Regional Vice President, Fresenius Kidney Care

(SEAL)

SUBSCRIBED AND SWORN to before me this 15th day of Sept, 2020.

John W. Clark
Notary Public
My commission expires: _____

JOHN W. CLARK, IV
Notary Public, Alabama State At Large
My Commission Expires Nov. 18, 2022

