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June 2 2020

Holly S. Hosford hhosford@bradley.com

205.521.8376



June 1, 2020

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: Fresenius Kidney Care of Florence, LLC d/b/a Fresenius Kidney Care of 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, Fresenius Kidney Care of Florence, LLC d/b/a Fresenius Kidney Care of 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 <u>not</u> contain a Class 1, 2, or 3 municipality<sup>1</sup> 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

<sup>&</sup>lt;sup>1</sup> 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 Fresenius Kidney Care of Florence, LLC d/b/a Fresenius Kidney Care of 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

Holly & Skofrl

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## 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 Fresenius Kidney Care of Florence, LLC d/b/a Fresenius Kidney Care of Florence and to the best of her information, knowledge and belief, such facts are true and correct.

Rose Wynn

Regional Vice President, Fresenius Kidney Care

(SEAL)

SUBSCRIBED AND SWORN to before me this 2 day of 1020.

Notary Public

My commission expires:

My Commission Expires:

Holly S. Hosford hhosford@bradley.com 205.521.8376



June 26, 2020

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: RV2020-019

Fresenius Kidney Care of Florence, LLC d/b/a Fresenius Kidney Care of Florence

Response to Request for Additional Information

Dear Ms. Marsal:

This letter is written in response to the Agency's June 5, 2020 letter requesting that we provide the Agency with approximate project costs, including equipment, first year annual operating, and capital costs, associated with the proposed ten (10) station kidney disease treatment center in Lauderdale County. The requested project costs are not available at this time.

Ala. Code § 22-21-278 exempts from Certificate of Need ("CON") review a kidney disease treatment center located in a Class 3, 4, 5, 6, 7, or 8 municipality which contains no more than ten hemodialysis stations. Such kidney disease treatment centers are exempt form CON review regardless of the project costs associated with establishing and operating the centers. Because Fresenius Kidney Care of Florence, LLC proposes to operate a ten (10) stations kidney disease treatment center in Lauderdale County, a county which does not have any Class 1, Class 2, or Class 3 municipalities, The proposed project is exempt from CON review, regardless of the costs of the project. Therefore, we do not believe the requested project costs are necessary for review of the Reviewability Determination Request.

We appreciate your assistance with this Reviewability Determination Request. As always, please do not hesitate to contact me if you have any questions or if we can address any further issues relating to this project.

Best regards,

Golly & Skofrl

Holly Hosford