



June 2, 2015

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Executive Director  
State Health Planning & Development Agency  
100 North Union St., Suite 870  
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**RECEIVED**

**JUN 04 2015**

**STATE HEALTH PLANNING  
AND DEVELOPMENT AGENCY**

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

Dear Mr. Lambert:

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 end stage renal disease center and operation of ten (10) dialysis stations in Coffee County, Alabama, does not require our client, Bio-Medical Applications of Alabama, Inc. d/b/a Fresenius Medical Care Enterprise ("Fresenius Medical Care Enterprise"), to obtain a Certificate of Need ("CON") from the State Health Planning and Development Agency. Attached is a check for \$1,000.00 in payment for the applicable fee. 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 dialysis facility 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.

The proposed location of Fresenius Medical Care Enterprise is in Coffee County, Alabama, with the end stage renal disease treatment center to be located in Enterprise. Coffee County does not contain a Class 1, 2, or 3 municipality<sup>1</sup> and, accordingly, the Coffee 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**

<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.

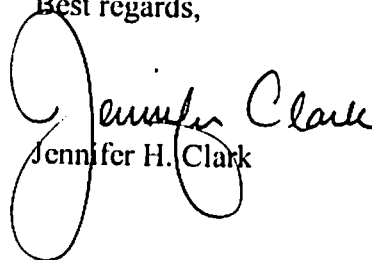
**municipality** (as such classes are defined in Section s11-40-12 and 11-40-13 or any successor provision of law) **shall not be subject to or governed by the provisions of Article 9 of Chapter 21 of Title 22** (including, without limitation, the provision of said articles which require that a certificate of need be obtained 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 § 410-2-3-.05(1)(b), a CON is not required for the proposed project.

Based upon the above, we respectfully request your determination that Fresenius Medical Care Enterprise 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. Thank you very much.

Best regards,

  
Jennifer H. Clark