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VIA U.S. MAIL

Illinois Health Facilities and Services Review Board
525 West Jefferson Street, 2nd Floor
Springfield, Illinois 62761
Attention: Courtney Avery, Administrator

***Re: Certificate of Need Project 19-022
Austin Dialysis at Loretto
Response to Opposition Letter***

RECEIVED

OCT 02 2019

**HEALTH FACILITIES &
SERVICES REVIEW BOARD**

Dear Ms. Avery:

This letter replies to the comments submitted by Maple Avenue Kidney Center ("MAKC") in its opposition letter dated September 4, 2019, and thereafter posted on the website of the Health Facilities and Services Review Board ("State Board"). The opposition letter raises six points, all of which are incorrect or misleading. On behalf of Austin Dialysis at Loretto, LLC ("Applicant"), a response to each argument is provided below.

(1) State Board Data Shows Insufficient Need in HSA 6

The first argument posed by MAKC, that Health Service Area 6 ("HSA 6") only shows a need for 5 additional in-center hemodialysis stations and, therefore, the State Board should oppose the Applicant's project seeking approval for a 12-station dialysis center, is now moot. The State Board recently published a new Inventory of Health Care Facilities and Services and Need Determination ("Inventory") and, therein, included new ESRD facility station need projections for HSA 6 through 2022. The revised Inventory identifies a need for an additional 80 dialysis stations in HSA 6, clearly showing that a 12-station dialysis center is not an unreasonable request in a traditionally underserved part of Chicago.

(2) Using CKD Patients Based on Hospital Admissions is Improper

The second argument posed by MAKC illustrates an imperfection in the State Board's rules. The Applicant correctly points out that the Applicant's CON permit application justifies need for the project based on hospital data pertaining to patients with chronic kidney disease ("CKD") that have received services at the hospital rather than the more traditional historical data coming from a nephrologist in private practice. This raises two important points of consideration. First, MAKC fails to address how this review criterion does not take into account a hospital hiring a new nephrologist with no historical case data.

Second, MAKC does not explain how difficult it is to find an established nephrologist in the City of Chicago or elsewhere who has not, long ago, agreed to an affiliation with the two big business dialysis—that is, Fresenius and DaVita. The Applicant approached several nephrologists and the result was not favorable.

In the present case, the Applicant first attempted the traditional route and met with several nephrologists in the area surrounding the hospital. Some were not interested in a relationship with the hospital. Others wanted unreasonable shares in the business. Many were already affiliated with Fresenius and DaVita. After several delays in the project due to ongoing efforts to secure a reasonable relationship with a nephrologist or nephrology group, the Applicant decided to take another route. The Applicant chose to hire or otherwise contract with one or more new, unaffiliated nephrologists to provide this service line and is prepared to present a cogent argument to the State Board regarding its need data at the upcoming State Board meeting in October.

In sum, the Applicant frequently sees that there is a growing need for dialysis stations in one of Chicago's poorest, medically underserved communities. The Applicant's observations are bolstered by the State Board's new hemodialysis station need data recently published in the revised Inventory (i.e., a need for 80 more stations). Therefore, the Applicant is asking the State Board to consider alternative data based on hospital admissions because it is the best it can do when existing nephrologists are joined in closed-shop relationships with Fresenius and DaVita or demand unrealistic shares in the joint venture business.

(3) Use of Hospital Data Violated HIPAA

Next, MAKC incorrectly argues that the Applicant used hospital data in a manner that violates the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). MAKC argues that the Applicant's in-house dialysis medical director, Rajani Kosuri, M.D., "possibly" violated HIPAA when she "reviewed the records of the ESRD patients belonging to other nephrologists and agrees that the patients need dialysis" when she was neither the patients' "nephrology service provider at the hospital or in her private practice." The Applicant takes exception to a project opponent raising claims that "possibly" violate the law. MAKC should have consulted with a healthcare attorney before making claims about alleged violations of law. Such actions are irresponsible and possibly libelous.

Generally, under HIPAA, a person's protected health information ("PHI") may be used and disclosed by health care professionals and providers only with the person's express written authorization. However, there are some exceptions to this general rule. A notable exception is the "Treatment, Payment, or Health Care Operations" exception. Under the third element of this exception, physicians and health care providers may use and disclose a person's PHI in order to "conduct healthcare business and to perform functions that support business activities." These activities include, but are not limited to, quality assessment activities, employee review activities, training of staff, and conducting or arranging for other business activities such as population-based activities relating to improving health (i.e., establishing a new service line to combat kidney disease in a majority minority community that has historically demanded dialysis treatments when compared with the population as a whole). The "health care operations" exception allows health care providers to review and use data to determine if a new service line, such as in-center dialysis care, is needed. Importantly, HIPAA's "minimum necessary standard" provides that a covered entity, such as Loretto, make reasonable efforts to limit the use and release of PHI to the minimum

necessary to accomplish the intended purpose of the request. Loretto met this standard by redacting patient names and other identifying information from the data set it used for this CON permit application.

(4) Loretto Hospital, as a Not-For-Profit, Can't Enter the Joint Venture as Proposed

As with the prior point, MAKC should have consulted with a competent legal counsel with actual knowledge of tax law. MAKC, citing federal IRS Revenue Ruling 98-15, claimed that Loretto, a co-applicant, cannot have “zero control” over a joint venture entity and delineates several points in support of this position, including: (a) Loretto as a nonprofit must have control of the entity; (b) the benefit to the community must explicitly be put ahead of the partnership’s profitability; and (c) that Rev. Rul. 98-15 can be applied to an outpatient dialysis joint venture arrangement even though the ruling applied to a hospital joint venture arrangement. MAKC concluded that the proposed arrangement may jeopardize Loretto’s tax exempt status. *However, MAKC’s opposition relies on irrelevant tax law!*

A not-for-profit health care organization that is qualified for a federal tax exemption under Section 501(c)(3) may permissibly engage in a joint venture (“JV”) with for-profit parties without putting its tax exemption at risk, so long as the joint venture structure meets certain parameters. Joint ventures involving tax exempt health care organizations fall into one of two categories: (a) “ancillary” joint ventures; and (b) “whole-entity” joint ventures. The joint venture arrangement between Loretto and Austin Dialysis falls under the prior category—ancillary JVs. The revenue ruling cited by MAKC cites the federal IRS’ opinion concerning whole-entity JVs.

An ancillary JV, like the one proposed in the CON permit application, is one that involves an insubstantial portion of the exempt entity’s assets and activities, such as ventures to create ambulatory surgery centers, acquire and operate new medical technologies, and arrangements to establish an in-center ESRD facility. In the alternative, a whole-entity JV arises when a tax exempt entity contributes all or a substantial portion of its assets and operations to a JV entity in partnership with a for-profit entity that contributes cash and/or assets. Ancillary JVs are, by far, the more common type of JV.

All JVs, whether ancillary or whole-entity, must be organized in a manner that ensures that the exempt organization will not effectively subsidize the for-profit participant in the venture, in order to avoid private inurement and/or an impermissible level of private benefit. Specifically, (a) each JV party must receive an interest in the JV that is proportionate to the value of the party’s contributions; (b) payments to participants or their affiliates for goods and services to the JV must be at arm’s length and at fair market value; and (c) the terms of the JV agreement must not put the exempt organization’s assets at risk to the benefit on any for-profit participant.

In the Applicant’s case, co-applicant Loretto will ultimately end up getting a major benefit, albeit, its interest will grow over time as it acquires interests in the JV entity through waived rent payments, which will always be fair market value. The joint venture operating agreement will give Loretto equal seats on the board of managers and include a requirement to follow the hospital’s charity care policies. These contractual terms will protect Loretto’s tax exempt status.

Finally, in regard to JV governance, majority control of a JV governance by the exempt organization is not absolutely required. It is, however, a highly favorable factor in establishing that profit motives do not subvert the exempt organization's charitable mission. That said, an exempt organization that lacks formal voting control of the JV entity to ensure control of major decisions should have another mechanism to ensure that the JV will operate to further the exempt organization's charitable purpose (e.g., the tax exempt organization retains powers over certain major actions).

In this matter, the Applicant's attorney will draft JV documents consistent with the laws affecting ancillary JVs and will include a clear statement of purpose that indicates that the JV will be operated in a manner consistent with the exempt organization's charitable purpose. The governing documents will also reflect that the for-profit partners recognize and understand that the operations of the JV entity will not be conducted in a manner solely designed to maximize profits.

(5) Applicant Failed to Notify MAKC About Filing a CON Permit Application

MAKC infers that the applicant wrongfully "failed to inform the facility that they were applying for a CON." Again, the law has changed regarding notice to existing providers and is a moot point to raise in an opposition letter.

MAKC was not required to receive notice from the Applicant that it was submitting a CON permit application for this project. MAKC is likely remembering an outdated CON review criterion, which required a CON permit applicant to send an impact letter to every affected provider in the project's geographic service area. However, the State Board eliminated this requirement many years ago.

(6) Area ESRD Facilities Are Underutilized

In its final point, MAKC argues that the State Board should deny this application because nearby ESRD facilities are underutilized, including MAKC, which has a 56.48% utilization rate that is well below the State Board 80% utilization standard.

In regard to MAKC's complaint about its ESRD facility being underutilized, it is true that its dialysis center is underperforming the expectations they set when applying for their CON permit. MAKC should look internally and determine why its nephrologists failed to satisfy the State Board's utilization standards even though at the time they applied for a permit its nephrologists certified that the target utilization standard would be met within two years of operation.

The Applicant, however, does not want to suggest that the State Board should not consider utilization data. It is legitimate for the State Board to examine existing ESRD facilities within the geographic service area and see to what extent existing ESRD facilities are utilized. It is relevant to the discussion. However, it is also reasonable to ask the question "why are existing facilities not at capacity?" There are many answers to this question.

While all of the existing ESRD facilities in the Applicant's geographic service area are not at capacity according to the State Board's 80% utilization standard, there are important facts to consider:

- There are seven ESRD facilities owned by Fresenius, five of which are operating below 80% utilization.
- When Fresenius comes before the State Board, they always claim that their centers will achieve capacity. In most cases, they don't. Is it possible that Fresenius' strategy is to keep many facilities below 80% to drive away possible competition? Maybe. But it's also possible that Fresenius' inability to achieve the 80% utilization rate at all of its facilities is because their forecasting model is too aggressive, which results in building centers that are too large for the particular community at its present population count. For example, Fresenius Kidney Care Congress, a rather large center with 30 stations, is presently utilized at 56%. Take away several stations and this center reaches the 80% utilization standard.
- The Applicant believes that Fresenius should be asked to account for their inability to meet the utilization standards and that system wide underutilization should not be held against applicants unaffiliated with big business dialysis companies.
- Furthermore, of the six facilities not at capacity, two are over 70% utilized and two more have utilization rates in the upper 60th percentiles. Thus, these four centers appear to be approaching the State Board's 80% utilization standard.

Conclusion

The Applicant believes that this project will have a great impact on the Austin neighborhood and other surrounding communities, many of which fall within federally-designated medically underserved areas and health professional shortage areas. The Applicant's project site is centered in an area with high levels of poverty and where notable health disparities and outcomes have been reported. Moreover, HSA 6 now shows a need for 80 more dialysis stations. Despite MAKC's attempt to raise doubts about this project, the need for more dialysis stations in the Austin neighborhood is quite clear. The Applicant is looking forward to presenting this project to the State Board on October 22, 2019.

Please let me know if you have questions. Thank you for your attention to this matter.

Sincerely yours,



Joseph Hylak-Reinholtz
Legal Counsel for Applicant

Enclosures