



Fresenius Medical Care

November 12, 2010

RECEIVED

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Mr. Mike Constantino
Illinois Health Facilities & Services Review Board
525 West Jefferson Street
Springfield, IL 62761

HEALTH FACILITIES &
SERVICES REVIEW BOARD

RE: #10-066, Fresenius Medical Care Joliet
Response to opposition letter from Silver Cross Hospital and Silver Cross Renal
Center

Dear Mr. Constantino:

The data/comments contained herein are in response to Silver Cross' opposition letter dated October 29, 2010. Fresenius Medical Care questions the opposition of Silver Cross to yet another one of Fresenius Medical Care's CON applications for a facility within the Silver Cross Service area. The Joliet ESRD population is clearly growing not only according to Renal Network data, facility expansions and clinic utilizations but according to Silver Cross as it stated in its application to relocate and expand its Hospital based facility (#10-020). The Silver Cross Hospital and Renal West facilities have historically operated at a high utilization despite any new facility that Fresenius Medical Care has established in the area and despite a number of expansions of the Silver Cross facilities. Fresenius Medical Care's establishment of facilities in the HSA obviously has not had a negative impact on the Silver Cross facilities as evidenced by these continued high utilizations. This in fact attests to the ever growing ESRD population in Joliet.

Fresenius Medical Care acknowledges a miscommunication between us and the referring physician's practice, Germane Nephrology, as to the type of patient counts required for the application. We are clarifying that data within this document. Fresenius Medical Care at no time attempted to intentionally misrepresent, overstate or craft any patient data in an attempt to meet Board criteria. We are knowledgeable of the rules of the Illinois Health Facilities & Services Review Board and try to address the requirements to the best of our ability. Fresenius Medical Care submits approximately a dozen CON applications on a yearly basis and has consistently strived to maintain high standards in doing so.

Opposition 1) Silver Cross claims the application misstates Dr. Alausa's ESRD patient count at Silver Cross Facilities.

The ESRD patient count of Dr. Alausa's practice as stated in his letter were not "exaggerated". They were accurate numbers. However a misunderstanding occurred and Dr. Alausa's office reported total number of patients he had in the facilities throughout the entire year (some were counted twice if they transferred) rather than the total as of the date of December 31, 2007, 2008, 2009 and June 30, 2010 as specified in the letter. The Silver Cross patient counts were supplied to him by the Silver Cross facilities. Dr. Alausa has now revised these numbers from his internal practice data to include only those patients as of each end date. While some of the numbers match the Silver Cross records, there are three that do not and it is unclear as to whether Dr. Alausa's records are overstated or Silver Cross records are understated, however the records of each provider stand as is.

SITE	NUMBER OF IN-CENTER HEMODIALYSIS PATIENTS FOR GERMANE NEPHROLOGY	2007	2008	2009
Silver Cross Renal - West				
	Revised per Germane Neph.	18	37	38
	Per Silver Cross Records	19	28	33
	Difference	1	9	5
Silver Cross Hospital (Hospital Based Facility)				
	Revised per Germane Neph.	4	6	8
	Per Silver Cross Records	4	5	8
	Difference	0	1	0
Combined Silver Cross Facilities				
	Revised per Germane Neph.	22	43	46
	Per Silver Cross Records	23	33	41
	Difference	1	10	5

Opposition 2) Silver Cross claims the projected referrals do not meet State standards.

A correction to the patient referral numbers originally submitted in the application was submitted to the Board dated October 29, 2010. In the application, patient attrition was not accounted for. As well, for informational purposes only, the 3rd year patients were included in the application to reinforce the need for additional ESRD services and the excessive growth of ESRD in Joliet. These patients have been removed so as not to be confused with the referral requirements of the Board of patient referrals for the first two years of operation. The number of patients Dr. Alausa will refer to the Joliet facility in the first two years of operation is 107, within the State standards.

Silver Cross also raises the issue of Section 1110.1430(b)(3)(B)(iii) of the Board's rules stating that physician anticipated referrals **cannot exceed** the physician's historical caseload. While this rule is applied to ESRD, it is generally written with hospitals in mind. The Board is aware that the trend in prevalence of ESRD is continually on the rise as evidenced even by Dr. Alausa's increased patient counts at the Silver Cross facilities from 2007-2009 and as evidenced also by the fact that Silver Cross has expanded its Renal West facility by 12 stations in 2006 and is now expanding its Hospital based facility, yet utilizations still remain continually over target utilization. In the Silver Cross most recent application, #10-020, to relocate and

expand by five stations the Hospital based facility, they state on page 147, "While the referrals for the two newest physicians exceed their historical case load right now, it is anticipated that their referral volumes for in-center hemodialysis will increase quickly as they continue to absorb some of the practice's existing and **growing patient load** and provide coverage for patient once seen by Dr. Kathpalia." It seems according to Silver Cross it is reasonable that future referrals will rise due to the experienced increase in ESRD patients.

Opposition 3) Silver Cross claims the ESRD referrals indicated in the application are inconsistent with The Renal Network patient data

As seen in the chart below, and given the revised patient referral numbers submitted by the applicant, there has been above average ESRD growth in the Joliet area. Silver Cross mistakenly stated the additional 110 ESRD patients for the zip codes below were over a three and a half year period and considered this modest, although 28% growth. The time period is actually only two and a half years and, the yearly growth has been 6%, 10% and 10% for just the first 6 months of 2010. The overall State average for the same time period was 3%, 3% and 1%.

Patients identified in the application for the zip codes below will not begin dialysis until after the facility is operational in 2013. Expected patient referrals are not unreasonable given historic growth of the area.

ZIP CODE	ESRD PATIENTS BY ZIP CODE*				APPLICANT'S ANTICIPATED ESRD REFERRALS 2013 (Yr 1)**	APPLICANT'S ANTICIPATED ESRD REFERRALS 2014 (Yr 2)**	GROWTH		
	AS OF 12/31/07	AS OF 12/31/08	AS OF 12/31/09	AS OF 06/30/10			08 vs 07	09 vs 08	10 vs 09
60403	8	11	18	24	14	16	38%	64%	33%
60404	6	8	11	10	2	6	33%	38%	-9%
60410	5	5	5	6	3	11	0%	0%	20%
60421	7	9	9	9	7	8	29%	0%	0%
60431	13	20	19	17	4	4	54%	-5%	-11%
60432	62	65	68	65	6	7	5%	5%	-4%
60433	30	33	35	42	12	12	10%	6%	20%
60435	62	68	69	77	7	8	10%	1%	12%
60436	24	27	27	37	15	5	13%	0%	37%
60441	41	33	33	33	9	17	-20%	0%	0%
60442	3	3	7	9	4	9	0%	133%	29%
60446	34	28	40	42	4	7	-18%	43%	5%
60451	24	24	17	20	9	8	0%	-29%	18%
60481	11	11	12	12	2	11	0%	9%	0%
60543	19	21	25	25	4	5	11%	19%	0%
60544	34	34	39	41	7	6	0%	15%	5%
60564	9	13	14	17	4	5	44%	8%	21%
60585		1	4	4	4	4	-	300%	0%
60586	2	5	8	14	4	3	150%	60%	75%
TOTALS	394	419	460	504	121	152	6%	10%	10%

*The Renal Network per Silver Cross Opposition Letter

**Referrals for first two years of operation per patient referral corrections letter submitted to Board October 29, 2010

Illinois	ESRD PATIENTS*				GROWTH		
	12/31/07	12/31/08	12/31/09	06/30/10	08 vs 07	09 vs 08	10 vs 09
	15,268	15,659	16,122	16,245	3%	3%	1%

*ESRD patient census for Illinois obtained from The Renal Network

Opposition 4) Silver Cross claims the application incorrectly asserts that there has been a decline in services in the service area.

On page 39 of the application the applicant does not state that there has been a decline in services in the service area, but rather the region, which is referring to specifically Joliet. While services (stations) themselves have not declined, these station additions have not brought down the utilization rates in the area which is in effect a decline in availability or services. As well, when evaluating an application the entire Health Service Area is not evaluated but rather the facilities within 30 minutes travel time. The Board approved all additional stations added in the area in recent years and hence felt the 45 approved stations mentioned by Silver Cross (some of which were Silver Cross stations) were necessary. As an attestation to the growth/need in the 30 minute zone, there have actually been 64 stations added to this same area since 2006.

This evidenced growth of ESRD is not "attempted crafted arguments" as Silver Cross states, but based on factual data and is the reality of the situation. The chart below shows area utilization and station additions in the past four years.

RENAL NETWORK PATIENTS/STATIONS															
Facility	AS OF 12/31/06			AS OF 12/31/07			AS OF 12/31/08			AS OF 12/31/09			AS OF 9/30/10		
	Patients	Util	Stations	Patients	Util	Stations	Patients	Util	Stations	Patients	Util	Stations	Patients	Util	Stations
Silver Cross Hospital	92	110%	14	87	104%	14	88	105%	14	87	104%	14	89	78%	19
Fresenius Lockport	-	-	-	-	-	-	-	-	-	-	-	-	-	-	12
Sun Health	75	83%	15	74	82%	15	67	66%	17	58	57%	17	56	55%	17
Silver Cross West	110	63%	29	134	77%	29	143	82%	29	162	93%	29	151	87%	29
Fresenius Mokena	-	-	-	-	-	12	20	28%	12	30	42%	12	43	60%	12
Fresenius Orland Park	91	95%	16	89	93%	16	82	85%	16	72	75%	16	76	70%	18
Fresenius Plainfield	-	-	-	-	-	-	-	-	12	1	1%	12	46	64%*	12
Fresenius Bolingbrook	100	98%	17	99	97%	17	95	93%	17	96	80%	20	121	84%	24

STATION ADDITIONS

Silver Cross Hospital	5 additional stations permitted July 2010, will not be operational until December 2012
Fresenius Lockport	12 Station facility permitted December 2009, will not be operational until late 2011, reaching 80% 2013
Sun Health	2 Station addition operational 2008
Silver Cross West	12 Station addition operational 2006
Fresenius Mokena	12 Station facility approved February 2007, operational March 2008, did not reach 80% target within Board standards
Fresenius Orland Park	2 Station addition operational September 2010
Fresenius Plainfield	12 Station facility approved February 2008, operational December 2009
Fresenius Bolingbrook	3 Station addition approved Jan 09 - operational Dec 09. 4 Station addition approved Sept 10, not yet operational

*Fresenius Plainfield is now at 72% utilization with 52 patients as of November 10, 2010. (See attached patient list)

In fact in #10-020, which was just heard before this Board 4 months ago, Silver Cross stated repeatedly the growing demand for dialysis services.

Below are excerpts from #10-020:

Page 122 – "Relocation and expansion of the existing facility on the new campus will improve access for Silver Cross' current and projected dialysis patients, provide operational efficiencies and **meet the needs of the growing and aging population in the area.**"

Page 122 – "Three nephrologists have been added to the hospital's medical staff within the last twelve months. Two of these newest nephrologists joined the hospital's primary nephrology group – Northeast Nephrology Consultants – **a practice that has rapidly grown from three to five physicians. The group added these physicians partially in response to growing patient demand for dialysis treatment.**"

Page 123 – “The proposed facility will address the needs of a **growing and aging population**. According to Nielsen Claritas data, Silver Cross Hospital’s designated service area is projected to grow from an estimated population of 801,234 in 2009 to 908407 by 2014 – **an increase of more than 100,000 people or a growth rate of 13.4% over the next five years**. According to the same Nielsen Claritas data, the fastest growing segment of the population is projected to be among those **over the age of 65** (+28% over the next five years), followed by those between the ages of 45 and 64 years of age (+18% over the next five years).”

Page 124 - “According to one source, chronic renal failure and **end-stage renal disease affects roughly 2 out of 1,000 people in the United States**. **Assuming that holds true in the area’s target population, it could be estimated that another 200 area residents may need dialysis services over the next five years alone**. Adding 5 stations to the hospital’s existing 14-station facility will provide more capacity to address the **growing demand for dialysis services**.”

Page 124 – “The expanded facility will be located in Will County – **where the largest numbers of dialysis patients currently reside and where the need appears to be the greatest**.”

Page 124-125 – “Combined, these diseases accounted for just under half (or 47%) of all deaths in Will County. **Based on this mortality data, it would appear that the population of Will County is at high risk for developing ESRD**.”

Page 186 – “On the surface, it might appear that there is capacity in the target service area to accommodate projected demand for dialysis: however, this analysis does not take into account several key factors.”

One would have to surmise that if the above statements were true just four months ago, that they would still be applicable today. The only major changes to dialysis services in the area since July would be that #10-020 was approved for a five station addition with 54 projected new referrals, the Fresenius Plainfield facility went from 50% utilization to 72%, Fresenius Orland Park added 2 stations to reduce high historical utilization, and Fresenius Medical Care Bolingbrook, despite being approved for 4 additional stations, remains above 80%. None of these changes show that there is any additional capacity in the area.

Opposition 5) Silver Cross claims the application fails to address the fact that the service area has existing capacity.

The application does include a certification on page 79, that the facility is expected to achieve and maintain the 80% target utilization as set forth by 77 ILL. Adm. Code 1100 for the category of service. It appears the point Silver Cross is attempting to make is that none of the Fresenius Medical Care facilities in the area have met this utilization target and/or are not able to maintain the target utilization. The chart below shows the actual facility utilization utilizing the 3rd Quarter data that the Board uses in reviewing ESRD projects. **There is in fact only one Fresenius facility in the area that should be at target that is not.** That is the Fresenius Mokena facility which became operational in 2008. This facility has failed to meet target utilization within two years per the Board's rules. However, the application at issue pertains to the Joliet area (although the Mokena facility is within 30 minutes per the Board's rules). The Mokena facility is 14 miles away and does not serve the residents of Joliet, nor does Dr. Alausa practice in Mokena.

Facility	AS OF 9/30/10			Comments
	Patients	U/I	Stations	
Silver Cross Hospital	89	78%	19	This utilization includes 5 stations that will not be operational for 2 more years.
Fresenius Lockport	-	-	12	Facility will not be operational until late 2011, patients from a separate referral source than Dr. Alausa
Sun Health	56	55%	17	Facility has until late 2013 to reach 80% target utilization
Silver Cross West	151	87%	29	Underutilized since 2008 and addition of 2 stations
Fresenius Mokena	43	60%	12	Over 80% utilization standard
Fresenius Orland Park	76	70%	18	Did not reach target utilization as expected, 15 more patients to reach 80%
Fresenius Plainfield	46	64%	12	Historic high utilization, two stations added Sept. 2010 to alleviate high utilization
Fresenius Bolingbrook	121	84%	24	Now at 72% utilization (Nov. 2010) after being open just 11 months
				Historic high utilization, two stations added Sept. 2010, still over 80%.

After years of high utilization, the Fresenius Orland Park facility has only recently dropped below 80%. The facility has two additional stations that just became operational in September to address historical high utilization. This is why it has briefly dipped below 80% but we anticipate this will not last for long.

The historically over utilized Fresenius Bolingbrook facility, despite the addition of 7 stations in the last year (4 are not yet operational), is still above 80%.

The Fresenius Plainfield facility (of which Dr. Alausa is the Medical Director), after being operational only 9 months (as of the 3rd quarter Renal Network data) is at 64% utilization, again attesting to the growth of ESRD in the Joliet area. Fresenius Medical Care patient tracking system now shows a total of 52 in-center hemodialysis patients for a utilization of 72% after only 11 months of operation (see attached patient list). It appears the extensive growth predictions of the ESRD population in #10-020 are correct.

The only other Fresenius facility in the area is Fresenius Lockport, which will not be operational for another year. In the application for that facility, Southwest Nephrology Associates identified 78 patients who would be referred to it in the first two years of operation. Silver Cross in its application #10-020 used that data in support of its facility expansion. **Page 186** – Referencing the Fresenius Lockport and DaVita Palos Park facilities patient referrals to reach 80% by the end of the second year of operation; *“These two facilities were approved for 12 stations each, but are not expected to be completed and operational until late 2011. Because these two projects received permits from the Illinois Health Facilities & Services Review Board, it can only be assumed that each facility adequately justified the need for stations and*

provided enough supporting documentation to demonstrate their ability to meet the State's target occupancy levels two years after opening." "If their projections hold true, then each of these facilities would be considered "fully utilized" according to the Illinois Health Facilities & Services Review Board criteria and would not have enough capacity to accommodate projected demand." In sum, Fresenius Lockport has until late 2013 to achieve 80% target utilization.

In closing I want to thank the Board and Staff for their time and attention to this matter and apologize for any inconvenience and/or confusion that may have occurred due to the miscommunication that occurred between Fresenius Medical Care and the referring physician's office during the compiling of the application for Fresenius Medical Care Joliet.

Sincerely,

A handwritten signature in cursive script that reads "Lori Wright".

Lori Wright
Senior CON Specialist

Date: 11/10/2010
Time: 3:47 pm

BMA PLAINFIELD JV

Page: 3

Patient List by Modality

Modality: Hemodialysis Supervision and Setting: In-Unit Staff-Assisted

Acct No.	Patient	MRN	DOB	Admit Date	Attending Doctor
A	, A			03/26/2010	MORUFU ALAUSA
B	, T			02/01/2010	MORUFU ALAUSA
B				02/12/2010	MOHAMMAD SHAFI
B	, T			07/07/2010	MOHAMMAD SHAFI
E	, D			11/06/2010	MORUFU ALAUSA
C	, G			08/16/2010	MORUFU ALAUSA
D	, C			02/01/2010	MORUFU ALAUSA
E	, L			08/30/2010	MORUFU ALAUSA
E				10/18/2010	MORUFU ALAUSA
E	, P			02/01/2010	DAVID SCHLIEBEN
F	, M			02/01/2010	MORUFU ALAUSA
G	, R			02/05/2010	HUMA ROHAIL
G	, G			05/11/2010	MORUFU ALAUSA
G	, E			10/23/2010	MORUFU ALAUSA
H	, P			04/02/2010	QUAN WANG
J	, T			07/20/2010	MORUFU ALAUSA
J	, L			02/01/2010	MOHAMMAD SHAFI
J	, F			02/19/2010	MORUFU ALAUSA
J	, M			09/27/2010	DAVID MCFADDEN
K	, G			10/12/2010	TERESA MAJKA-KRAVETS
K	, C			02/01/2010	MORUFU ALAUSA
L	, K			09/13/2010	NAILA AHMED
L	, D			02/01/2010	HUMA ROHAIL
M	, K			08/13/2010	MORUFU ALAUSA
M	, I			05/05/2010	MORUFU ALAUSA
M	, J			08/19/2010	HUMA ROHAIL
M	, P			02/08/2010	MORUFU ALAUSA
M	, L			10/25/2010	MORUFU ALAUSA

Date: 11/10/2010
Time: 3:47 pm

BMA PLAINFIELD JV
Patient List by Modality

Modality: Hemodialysis Supervision and Setting: In-Unit Staff-Assisted

Acct No.	Patient	MRN	DOB	Admit Date	Attending Doctor
M	, T			08/30/2010	HUMA ROHAIL
M				08/17/2010	MORUFU ALAUSA
M	, S			09/27/2010	MORUFU ALAUSA
M	, H			11/04/2010	MORUFU ALAUSA
O	, J			02/01/2010	MORUFU ALAUSA
P	, A			02/01/2010	HUMA ROHAIL
P	, V			02/01/2010	HUMA ROHAIL
P	, W			06/02/2010	MORUFU ALAUSA
P	, H			02/01/2010	MORUFU ALAUSA
P	, B			09/04/2010	NAILA AHMED
P	, M			06/26/2010	MORUFU ALAUSA
R	, J			02/01/2010	MORUFU ALAUSA
S	, S			05/13/2010	HUMA ROHAIL
S	, D			03/05/2010	BEATA KIESEL
S	, S			09/21/2010	MORUFU ALAUSA
S	, B			05/03/2010	MORUFU ALAUSA
S	, G			02/01/2010	MORUFU ALAUSA
S	, J			09/07/2010	MORUFU ALAUSA
T	, D			10/29/2010	MORUFU ALAUSA
V	, D			07/01/2010	HUMA ROHAIL
W	, B			08/25/2010	MORUFU ALAUSA
W	, J			07/28/2010	MORUFU ALAUSA
W	, J			02/01/2010	MORUFU ALAUSA
W	, J			10/26/2010	MORUFU ALAUSA

Hemodialysis In-Unit Staff-Assisted subtotal: 52