STATE OF VERMONT
DEPARTMENT OF BANKING, INSURANCE, SECURITIES AND HEALTH CARE ADMINISTRATION

In re: Bio-Medical Applications of New Hampshire, Inc. Certificate of Need Application to Acquire Outpatient Dialysis Clinics from Fletcher Allen Health Care, Inc. Purchase Price: $28,633,873.00	)	**Docket No. 11-004-H**

[PROPOSED] STATEMENT OF DECISION

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I. INTRODUCTION

A. SUMMARY OF THE PROPOSED PROJECT

The applicant for this Certificate of Need ("CON") is Bio-Medical Applications of New Hampshire, Inc., a for-profit corporation and a subsidiary of Fresenius Medical Care Holdings, Inc., ["FMCNA"] which is a subsidiary of Fresenius Medical Care AG & Co. KGaA, a German corporation whose stock is traded on the New York and Frankfurt exchanges and which has an estimated enterprise value on the order of $23.4 billion. Appl. p. 18.[1] The applicant will be referred to here as Fresenius unless a particular distinction is required. Fresenius proposes to buy and operate the five outpatient renal dialysis clinics and the home dialysis services now owned by Fletcher Allen Health Care, Inc., which owns and operates Vermont's only tertiary care hospital and only academic medical center.

The five clinics are located in South Burlington, Newport, Rutland, St. Albans and Berlin. Collectively, they have 55 treatment stations and as of June 15, 2011 provided dialysis services to approximately 241 patients in the clinics, with another 26 patients receiving home dialysis. The numbers fluctuate from time to time.

There are seven outpatient dialysis clinics in Vermont, apart from one at the Veterans Administration Hospital in White River Junction. One of the seven is owned and operated by Southwestern Vermont Medical Center in Bennington and another, located in St. Johnsbury, is owned and operated by Fresenius. The transaction would end Fletcher Allen's involvement in outpatient dialysis and give Fresenius ownership of six of the seven non-VA dialysis centers.

The total cost of the acquisition is $28,633,873, which includes $2,588,873 attributed to working capital, usable inventory and adjustments at closing for prepaid items. Fletcher Allen would receive the remaining $26,045,000 as goodwill. Fresenius Medical Care Holdings, Inc. will fund the purchase and continued operations of the outpatient dialysis services.

The project is set out in full in the application and three supplemental filings by Fresenius. The record includes without limitation that which was in the record at the close of the public hearing on November 14, 2011, the hearing transcript, and anything else relied on in this decision.[2] Rule § 6(c)(1)(H) (record includes "[a]ny other materials relied upon by the Commissioner in rendering his or her decision regarding the application").[3]

B. SUMMARY OF THE DECISION

The application is denied.

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[1] Refers to the initial application, submitted June 22, 2011.

[2] An email comment from Ms. Katherine Voigt Walsh, a member of the public, was received the morning of the public hearing and distributed to all Parties. It is part of the record.

[3] "Rule" refers throughout to the Department's Rule H-2010-1, addressed to Certificates of Need.

As set out in more detail below, I find that Fresenius has not met its burden to demonstrate that the project – the proposed sale – meets the statutory requirements and I conclude that the application therefore fails as a matter of law.

Without limitation, that failure is shown by a proposed nearly four-fold increase in charges to commercial payors in just the first year of operation, an increase of nearly $6 million over current charges. This is not containing increases in costs. It would be less costly for Fletcher Allen, which claims to be losing money on its dialysis operations, to raise its charges to commercial payors by $1.8 million, which would both cover its losses and provide a surplus, based on the financial data submitted.

While Fresenius repeatedly asserts that it will maintain the current level of quality of care, to maintain is not to improve and improvement is what the statute calls for. Even as to maintaining quality, Fletcher Allen submitted sworn testimony as to its investigation of the quality of Fresenius services and set out the results as to what Fletcher Allen considered key measures. In fact, Fletcher Allen scored higher than Fresenius on every one of those key measures, leaving Fletcher Allen to point out only that Fresenius was at least above average. To sell facilities to a buyer who – by the seller's own data – scores lower on key quality measures is not an improvement, nor does it give reason to believe that the current quality standards will even be maintained. As to a less data-based measure of quality of care, Fresenius maintains that it will offer jobs to all Fletcher Allen employees at the centers, but Fresenius' own financial tables show a roughly 20% decrease in FTE nursing headcount, raising questions as to whether the patients – whose numbers are expected to increase -- will receive the same attention they have with Fletcher Allen.

As to improved access, the centers will stay where they are. The schedules and the number of dialysis stations will stay the same. Those aspects of access are unchanged. Fresenius does assert that it will promote home dialysis, which will, says Fresenius, make access to care easier for some patients. But Fresenius' own data show that over the first three years of operation the proportion of its patient count that is projected to receive home dialysis will increase by only slightly more than one-third of one percent. I find that to be no meaningful increase in access.

The principal argument for this project serving the public good is a suggestion by Fletcher Allen that it might not continue to provide dialysis services – that it cannot "at this time" commit to continuing those services for ten years. Fletcher Allen stops short of saying that it will close the centers, saying only that it can't continue to operate them at a loss. The answer to that is simple – it doesn't need to operate them at a loss. Fletcher Allen has autonomy to apportion its overall rate increases as it sees fit. That for years it hasn't apportioned those increases to cover the costs of the dialysis centers but has chosen to apportion that rate increase to other services has been a management decision by Fletcher Allen. Not incidentally, Fletcher Allen did not approach the Department seeking a solution for its stated losses on the dialysis centers, as the hospital budget statutes expressly allow.

A secondary argument for the public good is that Fletcher Allen will receive some $26 million that, says Fletcher Allen, it can use to refurbish some inpatient facilities. Fletcher Allen is a regulated non-profit. To accept its contention that it would use the $26 million for some

particular future project is to ask me to implicitly approve a CON for construction that Fletcher Allen has not submitted. There is a statutory CON process and I decline the invitation to ignore the process set out by the Legislature and to effectively give approval for a $26 million future construction project by the back door.

There is a need for dialysis services in Vermont, but the need to be evaluated here is not the need for dialysis but the need for this project – whether there is a need to sell control of the large majority of Vermont's dialysis services from a regulated, local, non-profit entity to a for-profit corporation whose finances (unlike Fletcher Allen's) are not subject to regulation by the state. I find no such need and conclude that as a matter of law Fresenius has failed to demonstrate that it has met the criteria for a Certificate of Need for this project.

II. FINDINGS OF FACT AND CONCLUSIONS OF LAW

A. PROCEDURAL BACKGROUND

Five entities were granted Interested Party status pursuant to Rule § 6(f): Fletcher Allen Health Care, Inc. the Vermont Federation of Nurses and Health Professionals, North Country Medical Center, Northwestern Medical Center and Disability Rights Vermont.

Some of the more pertinent events in the application process follow.

On February 8, 2011, the Department received a letter from Bio-Medical Applications of New Hampshire, Inc. ("Fresenius") stating its intention to purchase five outpatient dialysis facilities from Fletcher Allen Health Care, Inc. On February 15, 2011 the Department asserted jurisdiction over the project.

On June 17, 2011 and subsequently, Department staff met with Fresenius to review the application process and respond to questions about the process. Department staff also had telephone conferences with counsel for Fresenius and Fletcher Allen prior to the submission of the application.

On June 22, 2011, Fresenius filed its CON application ("**Appl.**").

Fresenius' application lacked many of the required financial tables and some tables had patently incorrect information. Notably missing from the tables was the required financial data on Fletcher Allen's operation of its dialysis clinics and home program.

On July 29, 2011, the Department sent Fresenius a letter requesting resubmission of specific financial tables and specifically noting the lack of required financial data for Fletcher Allen.

On August 15, 2011, Fresenius submitted revised financial tables to the Department. ("**Suppl. 1**"). The revised tables again lacked the required financial data on Fletcher Allen.

On August 30, 2011, the Department sent a letter to Fresenius relative to the missing financial data on Fletcher Allen's operation of the dialysis services to be sold.

On September 2, 2011, Fresenius submitted supplemental materials to the Application unrelated to the financial tables. ("**Suppl. 2**").

On September 6, 2011, Department staff met with representatives of Fresenius and Fletcher Allen to discuss the technical requirements of a CON application, including required financial data.

On September 7, 2011, the Department received a letter notifying the Department that Fresenius was in the process of working with Fletcher Allen to "develop the information regarding Fletcher Allen's current operations [sic] of the dialysis clinics . . .."

On September 12, 2011, the Department received an email from Fresenius requesting confirmation that the 90-day review period would end on October 7, 2011.

On September 12, 2011 the Department confirmed the October 7, 2011 date as the end-date of the 90-day review period, referred to in the Rule as the "Application Closed Date."

On September 13, 2011, the Department received a question from Northwestern Medical Center for consideration by the Commissioner and on September 14, 2011, received questions from Vermont Federation of Nurses and Health Professionals for consideration by the Commissioner.

On September 19, 2011, the Department notified the Parties that the Commissioner would not request that Fresenius respond to the questions, noting instead that the Applicant possessed copies of the questions and had the burden of proof on the CON criteria, expressly leaving it to Fresenius to decide whether answers to the questions were required to meet its burden.

On October 6, 2011, the Department received a sworn statement from John R. Brumsted, M.D., Acting Chief Executive Officer of Fletcher Allen, relative to reasons Fletcher Allen planned to sell its outpatient dialysis services to Fresenius. ("**Brumsted Decl.**").

In a letter dated October 7, 2011, the Department notified Fresenius that the Application Closed Date had arrived and of the publication of a Public Notice on October 11, 2011 advising that a public hearing on the application would be held November 14, 2011.

On October 7, 2011, Fresenius filed a supplement to the Application. ("**Suppl. 3**").

On October 19, 2011, the Department provided additional information to the Parties regarding the hearing process.

On November 1, 2011, the Department issued a memorandum describing certain hearing procedures.

On November 4, 2011, the Commissioner signed a Delegation of Authority to conduct the public hearing to Clifford Peterson, General Counsel of the Department.

On November 14, 2011, the Department conducted a public hearing on the Application.

B. STANDARD OF REVIEW

Vermont's Certificate of Need laws are set out in Title 18, Sections 9431-9446. Rule H-2010-01 (the "Rule") also applies.

It is Vermont's public policy "that all new health care projects be offered or developed in a manner which avoids unnecessary duplication and contains or reduces increases in the cost of delivering services, while at the same time maintaining and improving the quality of and access to health care services, and promoting rational allocation of health care resources in the state; and that the need, cost, type, level, quality, and feasibility of providing any new health care project be subject to review and assessment prior to any offering or development." 18 V.S.A. § 9431.

Section 9437 of Title 18 provides that a CON issues *if* "the applicant demonstrates" *and* "the commissioner finds" that the statutory criteria are met. Thus it is the applicant's burden to demonstrate that the statutory criteria are met. Rule § 4(c)(3) ("It is the applicant's burden to establish that a Certificate of Need should be granted."); *accord, In re Central Vermont Medical Center, Inc.*, 174 Vt. 607, 611, 816 A.2d 531, 538 (2002).

The statutory criteria for evaluating applications are set out in 18 V.S.A. § 9437(1)-(8). The criteria are separated by "and" not "or". Thus, if a statutory criterion is applicable, it must be met. It follows that all applicable criteria must be satisfied; the decision is not one of balancing failure to meet some criteria against meeting others. If the applicant fails to meet its burden as to any one of the statutory criteria, the Department must deny the application and discussion of other criteria is unnecessary.

As part of the first statutory criterion, the applicant must satisfy each of certain requirements set out in the current Health Resource Allocation Plan ("HRAP") CON Standards. The Department specifies which HRAP CON Standards apply. The Department made that specification in a letter dated February 15, 2011, listing HRAP CON Standards Nos. 1.6, 1.7, 1.8, 3.24 and 3.27. In addition, the Department specified that the applicant had to demonstrate that it met the "Triple Aims" of the Institute of Health Improvement ("IHI"), found at pp. 10-13 of the HRAP. The applicant has the burden of proof on the HRAP Standards as it does the statutory criterion that incorporates them.

1. THE CERTIFICATE OF NEED STATUTE

The statutory criteria in 18 V.S.A. § 9437(1)-(7) apply here.[4] Therefore, Fresenius must demonstrate that each of these criteria is met:

(1) the application is consistent with the health resource allocation plan;

[4] The eighth criterion, 18 V.S.A. § 9437(8), addresses an application for the purchase or lease of new health care information technology and does not apply here.

(2) the cost of the project is reasonable, because:

(A) the applicant's financial condition will sustain any financial burden likely to result from completion of the project;

(B) the project will not result in an undue increase in the costs of medical care. In making a finding under this subdivision, the commissioner shall consider and weigh relevant factors, including:

(i) the financial implications of the project on hospitals and other clinical settings, including the impact on their services, expenditures, and charges;

(ii) whether the impact on services, expenditures, and charges is outweighed by the benefit of the project to the public; and

(C) less expensive alternatives do not exist, would be unsatisfactory, or are not feasible or appropriate;

(3) there is an identifiable, existing, or reasonably anticipated need for the proposed project which is appropriate for the applicant to provide;

(4) the project will improve the quality of health care in the state or provide greater access to health care for Vermont's residents, or both;

(5) the project will not have an undue adverse impact on any other existing services provided by the applicant;

(6) the project will serve the public good;

(7) the applicant has adequately considered the availability of affordable, accessible patient transportation services to the facility.

18 V.S.A. 9437(1)-(7).

2. JUDICIAL STANDARDS OF REVIEW

The Commissioner's decision is reviewed on appeal under 8 V.S.A. § 16 and may be disturbed only if it:

(1) was issued pursuant to unconstitutional statutory provision;
(2) was in excess of statutory authority;
(3) was issued on unlawful procedure; or
(4) is not supported by substantial evidence in the record.

8 V.S.A. § 16; *In re Central Vermont Medical Center, Inc.*, 174 Vt. 607, 608, 816 A.2d 531, 535 (2002); *Vermont State Employees' Assoc. v. Dep't of Banking, Insurance Securities and Health Care Admin.*, 183 Vt. 630, 634, 955 A.2d 504, 509 (2008) ("We must emphasize at the outset the extraordinarily narrow scope of review that we apply in this context").

"Decisions of the Commissioner are therefore presumed to be correct, valid and reasonable, absent a clear and convincing showing to the contrary." *In re Central Vermont Medical Center*, 174 Vt. at 608, 816 A.2d at 535 (affirming denial of CON). The Court also said that "[i]n general, we have granted administrative bodies a great deal of deference, both in regard to their findings of fact and to their interpretations of their governing statutes and regulations." *Id.*, 174 Vt. at 608, 816 A.2d at 535. *See*, *In re Prof'l Nurses Service* (2006 VT 112, ¶ 12, 180 Vt. 479, 485, 913 A.2d 381, 386 ("we apply a highly deferential standard to decisions by the Commissioner"). "It is altogether fitting, therefore, that the broad information-gathering process utilized by the Commissioner in CON proceedings – similar in many respects to a quasi-legislative proceeding – be given the widest possible latitude on review." *In re Prof'l Nurses Service*, 2006 VT 112, ¶ 15, 180 Vt. at 487, 913 A.2d at 387.

As to findings of fact, the Court has said, "'[W]e will not set aside an administrative agency's findings unless clearly erroneous. We view the evidence in the light most favorable to the prevailing party and exclude any modifying evidence. So long as the findings are supported by credible evidence, we will not disturb them.'" *In re Central Vermont Medical Center*, 174 Vt. at 608, 816 A.2d at 535 (citation omitted).

As to the Commissioner's interpretation of the Department's regulations, "we presume the Commissioner's interpretation of the Department's own regulations is correct and will not set aside the Commissioner's interpretation unless the challenging party can show a compelling indication of error to overcome this presumption." *Id.* at 609, 816 A.2d at 535. The Commissioner's interpretation of the Department's regulations will be upheld "So long as the Commissioner's interpretation is not arbitrary or capricious, . . ." *Id.* at 610, 816 A.2d at 537.

C. THE STATUTORY CRITERIA (18 V.S.A. § 9437(1)-(7))

The summaries of the proposal and the decision in the Introduction to this decision are incorporated by reference.

There is overlap among some of the statutory criteria. Findings of fact under the head of any particular criterion apply to other criteria as appropriate without express incorporation by reference. Because each of the criteria must be met, each of the findings and conclusions below that a criterion is not met is an independent and sufficient basis for denying the application.

1. STATUTORY CRITERION (1): THE APPLICATION IS CONSISTENT WITH THE HEALTH RESOURCE ALLOCATION PLAN

By letter dated February 15, 2011, the Department advised Fresenius that the following provisions of the Health Resource Application Plan (HRAP) applied.

HRAP CON STANDARD 1.6: Applicants seeking to develop a new health care project shall explain how the applicant will collect and monitor data relating to health care quality and outcomes related to the proposed new health care project. To the extent practicable, such data collection and monitoring shall be aligned with related data collection and monitoring efforts, whether within the applicant's organization, other organizations or the government.

Fresenius' response opens by digressing into an irrelevant (for this Standard) promotion of its commitment to quality, but Fresenius also addresses its internal Quality Assessment Performance Improvement (QAI) Committees, which monitor quality and outcomes. The committee includes a Clinical Manager responsible for compiling data through lab reports and internal quality audit tools. Fresenius states that quality indicators are trended and benchmarked and ranked against other clinics, areas, regions, and divisions throughout the organization and reported to the ESRD [End-Stage Renal Disease] Network[5] and to the federal CMS (Centers for Medicare & Medicaid Services) as required.

Fresenius also has Regional Quality Managers and says it is actively working with Fletcher Allen to develop a plan for the electronic exchange of patient information between the Outpatient Clinics and Fletcher Allen, including lab results, hospital discharge summaries and clinical care documents ("CCDs"). Fresenius says that discussions with Vermont Information Technology Leaders ("VITL") were planned for late summer 2011 and that it intends to contract with VITL to participate in the Vermont Health Information Exchange when it becomes available. Some of this information is somewhat off point as to how quality and outcome data is collected and is aligned with other organizations and government, or is prospective in nature. In Supplement 3, Fresenius states "In supplement to the second paragraph of its response to this Standard, the Applicant specifically incorporates by reference the QSR for the Massachusetts/New Hampshire Area for the period ending April 30, 2011, attached as Exhibit C to the Application." Exhibit C does show that Fresenius collects quality data. I find that this Standard is met.

HRAP CON STANDARD 1.7: Applicants seeking to develop a new health care project shall explain how such project is consistent with evidence-based practice. Such explanation may include a description of how practitioners will be made aware of evidence based practice guidelines and how such guidelines will be incorporated into ongoing decision making.

In response to the first part of this Standard, requiring an explanation of how the project is consistent with evidence-based practice, Fresenius quotes the National Kidney Foundation:

> The National Kidney Foundation Disease Outcomes Quality Initiative (NKF KDOQI)™ has provided evidence-based clinical practice guidelines for all stages of chronic kidney disease (CKD) and related complications since 1997. Recognized throughout the world for improving the diagnosis and treatment of kidney disease, the KDOQI Guidelines have

[5] There are 18 ESRD Networks. See http://www.esrdnetworks.org/; last accessed Nov. 30, 2011. The ESRD Network of New England "is a non-profit corporation which serves as the Medicare contractor for the New England States of Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island and Vermont." See http://www.networkofnewengland.org/; last accessed Nov. 30, 2011.

changed the practices of numerous specialties and disciplines and improved the lives of thousands of kidney patients.

Appl. p. 16.

The CMS Conditions for Coverage for end-stage renal disease (ESRD) provide what CMS describes as "the minimum health and safety rules" that participating dialysis facilities must meet.[6] There is no evidence that Fresenius is not meeting CMS standards (which it must). CMS references the KDOQI adequacy guidelines as "the current evidence-based professionally accepted clinical practice standards" while not explicitly mentioning the KDOQI guidelines in the final rule. 73 Fed. Reg. at 20401 (April 15, 2008). CMS also allows, however, the use of "an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis that would allow for future advances in dialysis adequacy measurement." 42 CFR § 494.90(a)(1).

In Supplement 3 Fresenius notes that the Medical Director Agreement entered into between it, Fletcher Allen and the Fletcher Allen employed physicians who will oversee the Outpatient Clinics specifically requires that:

> The Company shall operate the Facilities with the care, skill, prudence and due diligence that the Company uses in its operation and management of other similarly situated outpatient renal dialysis centers with an academic affiliation, in accordance with industry standards for outpatient renal dialysis services (including the NFK-KDOQI Clinical Practice Guidelines and any similar national standards promulgated in the future), and in accordance with the standards of care and quality required by the Medical Directors.

Suppl. 3 at p. 3 (emphasis by Fresenius). I find that Fresenius meets CMS standards and that if the project were to be approved Fresenius would follow the KDOQI guidelines; the first part of this Standard is met.

As to the second part of this Standard, the communication of evidence-based guidelines and how they are incorporated in decision-making, Fresenius states (Appl. pp. 16-17):

> FMCNA [Fresenius Medical Care North America] evidence based practices are communicated by the Medical Department to Medical Directors through:
>
> - Regular Medical Director newsletters
> - Medical Director Symposiums
> - Regular Medical Advisory Board meetings
>
> The Medical Director is responsible for ensuring evidence based practice within his/her clinic, and for oversight of other physicians with privileges at the clinic.

[6] https://www.cms.gov/cfcsandcops/13_esrd.asp; last accessed Nov. 30, 2011.

Many FMCNA clinics also participate in the **DOPPS - (Dialysis Outcomes and Practice Patterns Study)**

- The DOPPS is a prospective, longitudinal, observational study of hemodialysis patients and facilities in twelve countries. Based on national, representative samples of dialysis facilities and patients, the goal of the study is to determine which hemodialysis practice patterns are associated with the best patient outcomes, with adjustment for a wide range of patient case-mix characteristics.

While Fresenius clinics around the world may participate in the international effort that is DOPPS, there is no mention as to whether any of the Vermont centers would participate in DOPPS were the project to be approved. While a number of U.S. persons are involved in DOPPS, DOPPS' list of "experts in nephrology in each of our DOPPS countries" does not list the U.S. among those countries.[7] I discount the applicant's discussion of DOPPS.

Based on the legal requirement to meet CMS conditions for coverage and on the statement that if the project were approved Fresenius would adhere to KDOQI guidelines, and the statements on internal communications set out above, I find this Standard is met.

HRAP CON STANDARD 1.8: Applicants seeking to develop a new health care project shall demonstrate, as appropriate, that the applicant has a comprehensive evidence-based system for controlling infectious disease.

In response, Fresenius states:

> FMCNA is committed to preventing and controlling infectious disease in our clinics. FMCNA's UltraCare Program represents our commitment to deliver excellent care to patients through innovative programs, the latest technology, continuous quality improvement and a focus on superior customer service. UltraCare is delivered by highly trained staff and demonstrated through dedication, leadership and compassion by every team member, every day.

Appl. at p. 17.

This is not to the point. UltraCare® is a branding and marketing label, not an infection control practice: "UltraCare® is Fresenius Medical Care's unique approach to patient care. It is based on the mission of delivering excellent medical care to patients through innovative and efficient programs, the latest technology, continuous quality improvement and a focus on superior customer service."[8]

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[7] http://www.dopps.org/investigators.aspx; last accessed Nov. 30, 2011.

[8] http://www.ultracare-dialysis.com/FreseniusMedicalServices/FreseniusMedicalCareDialysisCenters.aspx; last accessed Nov. 30, 2011.

Fresenius goes on to say, however, that "FMCNA has comprehensive and exhaustive evidence based practice infection control policies and procedures. . . . based, in part on the following accepted CDC recommendations and guidelines" which it then lists. It also says that

> Outcome based results of infection control practices are benchmarked against all other FMCNA clinics. This data is also reported to the ESRD Network and CMS.
>
> Infection control practices, policies and procedures are reviewed and monitored by each clinic QAI Committee, who tracks analysis of infection rates, as well as regular internal infection control audits. Responsibility for infection control in each clinic lies with the QAI Committee and the Medical Director who is the leader of the QAI Committee.

Id.

Fresenius notes that under the Medical Director Agreement with Fletcher Allen and with respect to the outpatient clinics, the Medical Director will be accountable for oversight of infection control issues and ensuring adherence to infection control policies and procedures. Suppl. 3 at p. 3. I find that Fresenius has met this Standard.

> **HRAP CON STANDARD 3.24: An applicant shall disclose potential financial conflicts of interest between hospitals and physicians and an equipment purchase.**

Fresenius states that there are no financial conflicts between hospitals and physicians implicated by the proposed acquisition. The acquisition includes the dialysis equipment and supplies at each site but that is a minor portion of the purchase price. No conflicts of interest as to the equipment purchase have been disclosed and I find no evidence of such conflicts. I find this Standard is met.

> **HRAP CON STANDARD 3.27: Applications for kidney-dialysis of non-acute patients shall not be granted absent a showing that such service shall be provided through an academic medical center or the applicant will be able to provide comparable quality and continuity of care, either directly or through a formal relationship with a tertiary medical center.**

Since the service would no longer be provided through an academic medical center the first clause does not apply. The second clause requires a showing by the applicant that it will be able to provide comparable quality and continuity of care, either directly by Fresenius or through a formal relationship with a tertiary medical center. Fresenius points to its contract with Fletcher Allen to provide Medical Director services, constituting a formal relationship with a tertiary medical center.

That leaves the Standard's requirement that the applicant will be able to provide comparable quality and continuity of care. I find that the continuity criterion is met – the clinics' locations, hours, and number of dialysis stations will not change. Appl. pp. 12, 13.

As to comparable quality, Dr. John Brumsted, Acting Chief Executive Officer of Fletcher Allen, testified at the public hearing in this matter that, in his opinion, the quality assurance standards used by Fresenius were comparable to those used by Fletcher Allen, as were the clinical outcomes. Tr. 29.[9] What is "comparable" is – as Dr. Brumsted indicated in his testimony – a matter of opinion. Dr. Brumsted's Declaration shows that on each of what Fletcher Allen considers key indicators Fletcher Allen's quality is actually superior to Fresenius'. In addition, the required financial data provided in Supplement 3 shows that Fresenius plans an FTE staff reduction in the first year of more than 20% compared to Fletcher Allen's latest actual data. Suppl. 3, Table 9. The evidence is that this reduction will in turn reduce the quality of care. *See* the application for Interested Party Status of the Vermont Federation of Nurses and Health Professionals at 2 and the testimony of Mr. Dennis DeBevec at the public hearing; tr. 67-68. I find that Fresenius has not demonstrated that the quality of care that it would provide would be comparable to that provided by Fletcher Allen.

This Standard as written, however, only requires a showing that the applicant "will be able" to provide comparable quality of care. Considering its vast financial resources, Fresenius is presumably "able" to provide comparable care.

I find that this HRAP Standard, given the "will be able" wording, is met.

HRAP INCORPORATION OF IHI TRIPLE AIMS: improving the individual experience of care, improving the health of populations, and reducing the per capita costs of care for populations

Fresenius was required to address the so-called Triple Aims of the Institute of Healthcare Improvement, incorporated in the HRAP (at pp. 11-13). 18 V.S.A. § 9440(b)(1). The triple aims and Fresenius' responses are set out below.

1. Improving the individual experience of care

Under this Aim, Fresenius set out bullet points:

- Our ability to provide high quality care for those suffering from chronic renal failure is based on a unified team approach, led by excellent nephrologists and dedicated practice staff members, also extending to the dialysis patient and their support group. As caregivers, we share the responsibility for each individual patient with our affiliated physicians.
- BMA-NH will operate the Outpatient Clinic with protocols that require no reuse of artificial kidneys (medical disposables).
- Planned expansion of home dialysis programs, thereby reducing travel for home patients
- Integrated care management
- Integrated pharmacy services

[9] Refers to the transcript of the November 14, 2011 public hearing in this matter, which is part of the record pursuant to Rule § 6(c)(1)(J).

- Will institute individualized Thrive with UltraCare programs for patients receiving services at the Outpatient clinics

Appl. at p. 14.

What is missing is demonstration that Fresenius will *improve* the individual experience of care. "Improvement" requires comparison, which is lacking. For example, Fresenius says their protocols require no reuse of artificial kidneys, but does not say whether Fletcher Allen is reusing artificial kidneys, that such reuse lowers the individual experience of care, and that not reusing artificial kidneys will result in an improvement in the patient experience. The same criticism applies to the "unified team approach," "integrated care management," "integrated pharmacy services," and "individualized Thrive with UltraCare programs." Absent a comparison to how Fletcher Allen is caring for patients, there is no basis for finding that these programs will improve the patient experience.

I also note that some of the things advanced by Fresenius may simply be standard of care for any dialysis facility certified to treat Medicare and Medicaid patients. For example, the "unified team approach" appears to be the "interdisciplinary team" required by CMS. *See, e.g.*, 42 CFR §§ 494.80, 494.90.

Fresenius does say that it plans to expand home dialysis programs, thereby reducing travel for some patients. This might indeed improve the individual experience, but the statement is contradicted by statistical projections Fresenius provides elsewhere. Fresenius projects having 274 patients in its first year of operation and 292 in its third year. Appl. Exh. 1A. In Fresenius' first year 29 patients would be in the home program, 10.58394% of its total patient count. In the third year, it would have only 32 patients in the home program, 10.9589% of its patient count. The projected increase in the proportion of its patients on home dialysis is therefore only 0.37496%. I regard this increase of a little more than one-third of one percent not to be an "expansion of home dialysis programs" and not evidence of improvement in the individual experience of care.

In Supplement 3, Fresenius incorporates in response to this Aim a patient survey in which 93% of respondents were satisfied with the care they received and describes the survey as "evidence of the Applicant's proven track record of improving the individual experience of care for patients." Suppl. 3 at p. 2; *see* Appl. p. 10, ¶ 8. Again, however, there is no comparative data to show a "record of improving the individual experience" or of relative patient satisfaction at Fletcher Allen. The survey, itself only a snapshot and not evidence of improvement even at Fresenius, is not evidence that the individual experience would improve at these clinics after the proposed acquisition.

There is also the survey's inherent problem in not addressing whether the patients who responded have any basis for comparison, a point made at the public hearing by Mr. DeBevec, a dialysis patient who had been treated at both Fletcher Allen and Fresenius centers and who found the Fletcher Allen experience superior. Tr. 35-37, 66-68.

In spite of taking the opportunity to respond to Mr. DeBevec at the hearing, Fresenius did not in fact address whether the survey respondents had a basis for comparing their experience to that at Fletcher Allen. Tr. 36-37. I find the survey results of no value in determining whether the patient experience would improve after the acquisition.

Mr. DeBevec also testified that on the basis of his experience at both Fletcher Allen and Fresenius dialysis clinics, he found the Fresenius clinic understaffed. Tr. 66-67. "They never were able to take time to talk with you, take care of anything, do anything that you didn't have taken care of. . . . and so those staffing ratios and the ability to do those things I think were incredibly important . . .." Tr. 67. As discussed above, the data produced by Fresenius shows that it plans a 20% reduction in staffing in the first year.

Nothing in Fresenius' response to the first of the Triple Aims demonstrates that Fresenius' acquisition of Fletcher Allen's outpatient dialysis program would improve the patient experience and I find that Fresenius has not met the standard for the first Triple Aim.

2. Improving the health of populations

Fresenius offers the following bullet points:

- BMA-NH will utilize state of the art dialysis technology at the outpatient clinics, which is not currently provided at the Outpatient Clinics, including: AMP (adequacy monitoring program), OLC (online clearance), DiaSafe (provides ultrapure dialysate), Autoflow (optimizes dialysis flow for each individual patient), and Poly sulfone (non reuse artificial kidneys with increased bio-compatibility)
- Will make available industry leading staff and patient education programs, including chronic kidney disease (CKD) programs
- Will make available TOPS (Treatment Options Programs) for patient and public education
- Individualized care management

Appl. at pp. 14-15.

In the first bullet Fresenius does state that it will do things not done currently, providing a summary list of procedures and materials. Some of those appear to bear names applied by Fresenius to proprietary products, such as the DiaSafe filter[10] or brand names given to internal procedures, such as TOPS.[11] Others are positive terms without content, such as "industry leading" and "individualized care". Without disparaging these products or programs, what is lacking is any demonstration that these will *improve* the health of populations compared to the

[10] http://www.msmedicals.in/diasafe-filter.html; last accessed Nov. 30, 2011.

[11] http://www.ultracare-dialysis.com/FreseniusMedicalServices/TreatmentOptionsProgram.aspx; last accessed Nov. 30, 2011 (Fresenius website). Although Fresenius capitalizes "Poly sulfone" implying it is proprietary, the term polysulfone is generic and refers to a family of polymers. *See* "Chem 421: Introduction to Polymer Chemistry – Aromatic Addition-Elimination Polymerization" at http://chem.chem.rochester.edu/~chem421/aromaddnelim.htm; last accessed Nov. 30, 2011.

present Fletcher Allen programs and the technology Fletcher Allen uses.[12] I find that Fresenius has not demonstrated that it will improve the health of populations compared to Fletcher Allen's program and has therefore not met the standard of the Second Triple Aim. I also note that there is evidence that the acquisition would *not* improve the health of populations, discussed in detail under Statutory Criterion 4, below.

3. Reducing the per capita costs for care of populations

Fresenius offers only two bullet points under this heading:

- FMCNA manufactures all disposables, dialysis supplies and dialysis machines, resulting in a reduced cost of delivery and a high quality of care.
- FMCNA's participation experience, through its subsidiary, Fresenius Health Partners (FHP), in a CMS ESRD Disease Management Demonstration Project and its recent efforts to work with the Center for Medicare and Medicaid Innovation (CMMI) demonstrates its commitment to identifying ways to continue to reduce the cost of caring for the ESRD population while improving patient outcomes.

The first point goes to vertical integration, which Fresenius has and which likely reduces *its* costs compared to those of dialysis centers that must purchase supplies and equipment from companies such as Fresenius. It does not address overall per capita costs, which include such elements as Fresenius' profits, nor does it consider the costs to those who pay for health care.

The second point only says that Fresenius is committed, as one would expect in a business enterprise, to reducing costs. Fresenius does not demonstrate that these efforts, taken together with Fresenius' plans to turn losses to profits, would reduce per capita costs to the payors, or to those who pay insurance premiums, or to the society at large.

In light of Fresenius' plan, laid out in the final of the three sets of financial tables submitted in support of the application, to increase payments by commercial payors from roughly $2 million now paid to Fletcher Allen to more than $7.8 million to be paid to Fresenius in its first year of operation, the evidence is that there will be a dramatic increase in per capita costs when seen at the payor level, rather than at Fresenius' income and expense statement level. *See* Suppl. 3, Table 6B "Revenue Source Projections – Project Only". It is a truism that there's no free lunch. Commercial payors include insurers and self-insured employers. To increase almost four-fold in one year the costs to commercial payors means costs will rise for those who bear the ultimate cost burden – Vermonters and their employers. This is not a decrease in per capita costs.

[12] Another example of a failure to provide comparative information allowing a demonstration of improvement is this statement from Supplement 3: "The Applicant does not, nor will it, mandate thresholds for discontinuing treatment for patients who miss treatments, cancel appointment or are non-compliant with care plans. Similarly, the Applicant will not impose treatment run time limitations or "turn away" patients requiring longer run times." Suppl. 3 at p. 5. There is no evidence that Fletcher Allen does not have a similar approach.

Fresenius asks for consideration under this heading of its encouragement of home dialysis to "reduce the per capita cost of care." Suppl. 3 at p. 2. Fresenius' own projection of an insignificant increase in its patient mix of those on home dialysis has been dealt with elsewhere in this decision and I do not find that will reduce the per capita cost of health care. Any per capita reduction that might be achieved from that increase of one-third of one percent would be swallowed by the nearly four-fold increase in charges to commercial payors.

Fresenius has called attention in its application and in testimony at the public hearing to a CMS demonstration project in which it participated and which, it says, showed per capita costs could be reduced. Appl. pp. 10-11; Tr. 18-21. Fresenius says that if the demonstration project were extrapolated to Vermont, "that would lead to an annual payer savings of approximately one million dollars." Tr. 21. This begs the question of whether payors would actually receive the benefit of those cost savings. Fresenius is a for-profit corporation with an understandable incentive to keep as much of such savings for itself as it could manage. Even if the full $1 million in claimed savings went to the commercial payors, however, it would be dwarfed by the size of the increase in charges to those same payors – an *increase* reduced from $5.8 million dollars to $4.8 million dollars is still an increase. "Savings" as a 12.9% discount off a nearly four-fold increase in charges to $7.8 million is not a reduction in per capita costs.

Fresenius' arguments as to how per capita costs *might* be reduced are contradicted by its own financial projections. The application shows a Fletcher Allen patient count of 267 as of June 15, 2011. Fletcher Allen had "latest actual" total operating expenses for its outpatient dialysis services of $11,998,141. Suppl. 3, Table 3B. Taking the patient count as applying throughout the "latest actual" year, Fletcher Allen had a per capita cost of care of $44,937. Fresenius shows a patient count of 274 for its first year of operation. Appl. Exh. 1A. It shows a total operating expense for that year of $14,998,085. Suppl. 3, Table 3B. That is a per capita cost of $54,738, an increase of 21.8% in per capita cost of care over Fletcher Allen's.

I find that the third of the Triple Aims, to reduce per capita costs, is not met.

2. STATUTORY CRITERION (2): THE COST OF THE PROJECT IS REASONABLE, BECAUSE:

(A) the applicant's financial condition will sustain any financial burden likely to result from completion of the project;

Fresenius is a large multinational company. The application has 85 pages of press and analyst's reports of Fresenius' financial success and future earning capacity, much of it optimistic about future earnings growth. The acquisition will be guaranteed by the parent company, which will provide funding for the clinics. Appl. p. 1. The parent company (which would provide the cash and fund the clinics) may issue bonds. Appl., Notes to Financial Tables, note 7. I find that the applicant can sustain the financial burden likely to result from the acquisition and this subcriterion is met.

(B) the project will not result in an undue increase in the costs of medical care. In making a finding under this subdivision, the commissioner shall consider and weigh relevant factors, including:

(i) the financial implications of the project on hospitals and other clinical settings, including the impact on their services, expenditures, and charges;

Fletcher Allen has represented that it has in the past and will continue to lose money if it continues to own and operate its outpatient dialysis services. Appl. p. 19; Brumsted Decl. ¶¶ 6-7. Fresenius says its acquisition of the clinics will relieve the hospital of that burden and provide Fletcher Allen with an infusion of capital. Appl. p. 19. In Supplement 3, Fresenius asks that consideration be given here to Dr. Brumsted's Declaration. Suppl. 3 at p. 4.[13]

I find no evidence in the record that the project will have a financial impact on the regional and community hospitals where the clinics are located. This subcriterion is met, but it is only a subpart of the requirement that "the project will not result in an undue increase in the costs of medical care."

(ii) whether the impact on services, expenditures, and charges is outweighed by the benefit of the project to the public; and

Fresenius' entire response to this subpart is:

> The patients will be the same as those currently serviced by the Outpatient Clinics or other dialysis centers. The majority of these patients are enrolled in Medicare, Medicaid, or commercial insurances. There will be no change in services. Fees for dialysis are set by CMS, or by contract with commercial insurances. FMCNA has existing national and regional contracts in place with most insurers. Rates are subject to arms length negotiation and vary depending on specific plan benefits set forth by the insurer or self-insured employer, as the case may be.

Appl. p. 19.

This requires more extensive discussion.

Fresenius submitted significantly incomplete financial tables with its application. The Department's financial tables for this CON application required actual results for the latest completed year, the current budgeted figures, and projected figures for the first three years of the project. These data are to be broken down further to show the financial picture for the project as a stand-alone, and for the institution with and without the project. 18 V.S.A. § 9440(b)(1) and

[13] Fresenius also asks us to consider Supplement 2 under this heading. Supplement 2 is a deck of PowerPoint slides described by Fresenius as "background on the ESRD Payment System and Reimbursement Structure under Medicare." Sept. 2, 2011 letter from Anne E. Cramer to Donna Jerry. It is not clear how this addresses the impact of the sale on hospitals' services, expenditures, and charges. In any case, costs and other financial considerations as to Fletcher Allen are addressed in detail elsewhere in this decision.

Feb. 15, 2011 letter to Anne E. Cramer from Donna Jerry. This allows the Department, by comparing figures, to analyze the financial impact of the project.

In its application Fresenius failed to provide any financial projections at all for Bio-Medical of New Hampshire with or without the project. It limited its figures to financial projections only for the operations to be acquired from Fletcher Allen and then presented those same figures for Bio-Medical of New Hampshire as a whole, contrary to reality. Some required tables were completely blank.

Most significant, however, are the requirements for the latest actual figures and for the budget figures for the current year, that is, for Fletcher Allen's operation of its outpatient dialysis services. Fresenius failed to submit *any* figures whatever for the latest actual and current budgeted Fletcher Allen dialysis operations. Because the application lacked any financial data for Fletcher Allen's operations that could provide a comparison to the first three years of operation under Fresenius' ownership, it was impossible to determine the financial implications of the project, including increases in health care costs.

Under the law the review period could have ended then and the application would have been rejected as incomplete. At any time "within 90 days of receipt of an application" I could have advised Fresenius that "the application review period is complete notwithstanding the absence of information." Rule § 4(d)(2). Under Rule § 4(c)(3) "A Certificate of Need application shall be denied if the applicant has failed to provide all necessary information required to review the application." The Department was under no obligation to ask Fresenius to submit a complete application. Rule § 4(e)(3) ("If the applicant fails to provide sufficient information in the application to justify a Certificate of Need, the Department is under no obligation to seek additional information"); *In re Central Vermont Medical Center, Inc.*, 174 Vt. 607, 611, 816 A.2d 531, 538 (2002) (Department has no burden to seek additional information).

Nonetheless, by letter dated July 29, 2011, the Department asked Fresenius to submit proper and complete financial tables and specifically cited the failure to include financial data for Fletcher Allen's operation of the clinics.

Fresenius submitted a revised set of tables on August 15, 2011. These again included *no* data whatever as to the latest actual and current budgeted figures for the dialysis operations under Fletcher Allen's ownership.

Fresenius claimed in its cover letter that it "does not have that information available to it." *See* Aug. 15, 2011 letter from Anne E. Cramer. Fresenius also claimed that it "cannot make representations with regard to the current or past operations of these clinics under Fletcher Allen's ownership." *Id.*

As to Fresenius' claim that it "does not have that information available to it," it would be extraordinary that on a corporate acquisition in excess of $28 million the buyer's due diligence did not include examining the finances of the seller's operations.

It is equally odd that with an expressed desire to make a cash sale for $28 million Fletcher Allen could not or would not make such data available to Fresenius. The Certificate of Need procedures allow the submission of data received from others, and the verification required to accompany submitted data expressly allows reliance on data from others. Alternatively, nothing would have prevented Fresenius attaching an affidavit from Fletcher Allen that provided the missing financial data or from Fletcher Allen as an Interested Party simply supplying it.

Fresenius also claimed in its August 15 letter that Fletcher Allen makes different (but unidentified) accounting assumptions than does Fresenius. There is, however, no barrier to adjusting assumptions to provide comparative data, especially with a willing buyer and a willing seller, both of them substantial operations with sophisticated accounting departments.

After two critically incomplete submissions of financial data, it is difficult to avoid the conclusion that one or the other of the parties to the transaction did not want to provide financial data on Fletcher Allen's operation of the clinics.

Rather than reject the application at that point as incomplete, however, at Fresenius' request the Department's General Counsel, then-Deputy Commissioner for Health Care Administration Georgia Maheras, and Department staff met with counsel and executives from both Fresenius and Fletcher Allen on September 6, 2011 to discuss the technical requirements of the CON program, including the required financial tables. *See* Rule § 6(d)(2)(A).

On October 7, 2011, Fresenius submitted a third supplement to its application. This third supplement included "latest actual" figures for Fletcher Allen's dialysis services but not its "current budgeted" figures.

Because the application continues to lack required current budgeted figures for the five clinics and the home program, it remains incomplete and is denied on that independent and sufficient ground.

Incomplete as they are, the figures that were finally submitted invite further investigation.

First, they show that Fresenius adjusted some of its data to conform to Fletcher Allen's system, thus solving the alleged problem of different accounting assumptions that Fresenius had pointed to in its August 15, 2011 letter. Suppl. 3, note on Table 3B.

The "latest actual" tables in Supplement 3 show that Fletcher Allen lost $1,616,128 on its outpatient dialysis operations. Suppl. 3, Table 3B. They also show that Fletcher Allen had net patient revenue from these operations for the "latest actual" year of $10,382,013, and had revenues on these operations from commercial payors (*i.e.*, not Medicare or Medicaid) of $2,007,380. Suppl. 3, Table 6B.

The tables also show that, in stark contrast, Fresenius projects a profit in the first year of its operation of $1,172,606 (Table 3B), a jump in net patient revenue in the first year to $16,170,691 and revenues from commercial payors of $7,769,338. The data can be summarized in tabular form:

	Latest Actual Fletcher Allen	Fresenius Year 1
(Loss)/Profit[14]	(1,616,128)	1,172,606
$ Change in first year of acquisition		+ 2,788,734
Net Patient Revenue	10,382,013	16,170,691
% Change in first year of acquisition		+55.8%
Commercial Payors	2,007,380	7,769,338
Fresenius charges to commercial payors as a multiple of Fletcher Allen charges to commercial payors		3.87x

Fresenius plans to increase net patient revenues in its first year by roughly $5.8 million, and that will come from commercial payors, whose charges will increase by roughly $5.8 million to $7.8 million, nearly four times what commercial payors paid Fletcher Allen in the last year for which figures are provided.

This subcriterion calls for weighing this increase in cost against the benefit of the acquisition to the public. The clinics would continue to operate in the same places, with no additional stations and on the same schedules as before, so there is no benefit to the public there. Appl. p. 13. Comparative improvements in quality and access are discussed elsewhere in this decision and found lacking. Staffing levels would be reduced, evidence that the individual patient experience would deteriorate.

As shown above in the discussion of the third of the Triple Aims, per capita cost of care will increase significantly. The argument that the sale is necessary to provide for the continued operation of the clinics is addressed in detail elsewhere and rejected. Costs to commercial payers, predictably to fall on employers and individuals through premium increases, would increase nearly four-fold. Vermonters would pay for this acquisition, not Fresenius.

Fresenius argues that Fletcher Allen will benefit by a $26 million capital infusion. That infusion is addressed elsewhere in this decision, but the argument that this is a public benefit proves too much: the same argument could be used to support selling any part of any non-profit hospital to any for-profit corporation. It is not an argument for a general public benefit when the hospital is a solvent going concern such as Fletcher Allen.

I find that the negative impact on services, expenditures and charges from the project are not outweighed by any benefit to the public. This subcriterion is not met.

(iii) less expensive alternatives do not exist, would be unsatisfactory, or are not feasible or appropriate;

Fresenius implies that sale is the only way to address the losses on the outpatient dialysis operations. Appl. p. 19. This is not the case.

[14] Fresenius' profit is after annual attributions of the cost of acquisition.

Fletcher Allen could raise its dialysis rates to commercial payors sufficiently to cover its losses, *i.e.*, by $1.6 million, or by $1.8 million to provide a 2% surplus (based on Fletcher Allen's latest actual figures), without imposing the $5.8 million increase Fresenius intends to impose in just the first year of operation. It is simply not correct to say that Fletcher Allen is "unable to operate [the outpatient dialysis program] on a break-even basis" or to suggest that rates would have to rise to Fresenius' projected level to reduce or eliminate Fletcher Allen's losses. *Cf.* Brumsted Decl. ¶¶ 15(d), 16(c); tr. 34.

Fletcher Allen is not compelled to take a loss on its outpatient dialysis services. Each year this Department grants Fletcher Allen a certain overall percentage rate increase, calculated across all its services. How to apportion that overall increase among the hospital's services is then a management decision. Fletcher Allen could decide to raise its rates substantially on services that are increasing in volume or decreasing in cost to maximize the financial return, while not raising rates on services where volume and costs are relatively fixed, such as outpatient dialysis. These are management decisions, not economic inevitabilities, nor do they mean that Fletcher Allen itself is operating at a loss, which it is not.[15] On September 26, 2011 Fletcher Allen announced results for the first two quarters of its fiscal year, showing $9.1 million in net income (in spite of any losses on dialysis), $2.5 million above budget.[16] Operating expenses were below budget by $11.1 million.

No argument has been advanced in any material submitted by Fresenius or Fletcher Allen as to why Fletcher Allen could not (and did not) raise its dialysis charges to commercial payors by $1.8 million. There is no evidence presented of any barrier to Fletcher Allen raising its rates to commercial payors for dialysis services. Fletcher Allen's Spencer Knapp testified simply that as to "raising prices . . . we don't want to." Rather, Mr. Knapp testified, the sale is an "easy basis" on which to eliminate the losses on dialysis. Tr. 78, lines 21-24. Fletcher Allen doesn't want to raise its dialysis rates, yet it is willing for the sake of $26 million to let Fresenius nearly quadruple those rates, to a level far beyond what it would take to cover Fletcher Allen's losses.

Fletcher Allen's claim that it can no longer sustain losses on outpatient dialysis is not persuasive. In addition to raising its rates it could also simply carry on as it is, generating net income above its budget projections. That, too, would be a less expensive, satisfactory, and feasible alternative to this sale. The hospital budget process would still allow this non-profit $950 million/year charitable institution to earn a reasonable overall surplus.

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[15] The direct loss from the dialysis operations is not known. Fletcher Allen shows a "latest actual" operating expense for its outpatient dialysis services of roughly $12 million, of which nearly half, $5.9 million, is "other" for which it offers no breakdown. Suppl. 3, Table 3B. It is not possible to know how much of the $5.9 million is a function of central cost allocation and not a direct expense of operating the dialysis services. The method of allocation of central costs can increase apparent costs to an operating unit and thus show a "paper loss" for that unit that is greater than the loss would be if only direct costs were considered or if a different method were used for central cost allocation.

[16] September 26, 2011 Fletcher Allen Press Release: "Fletcher Allen Releases FY 2011 Year-to-Date and Second Quarter Financial Results."

I find that less expensive alternatives do exist, are satisfactory, and would be feasible. This subcriterion is not met.

I further find that the project would result in an undue increase in the cost of medical care and that the cost of the project is unreasonable. This criterion is not met.

3. STATUTORY CRITERION (3): THERE IS AN IDENTIFIABLE, EXISTING, OR REASONABLY ANTICIPATED NEED FOR THE PROPOSED PROJECT WHICH IS APPROPRIATE FOR THE APPLICANT TO PROVIDE.

Fresenius points out that as of June 15, 2011, the Outpatient Clinics provided dialysis services to two hundred and forty-one patients and home dialysis services were being provided to another twenty-six patients. "The Outpatient Clinics provide essential services to patients suffering from end stage renal disease (ESRD). [Fresenius'] acquisition of the Outpatient Clinics will assure that these individuals continue to receive high quality, cost effective care." In Supplement 3, Fresenius incorporated by reference its Capacity and Project Utilization Tables, attached as Exhibit 1 to the Notes to Financial Tables filed with the Application and the October 6, 2011 statement by Dr. Brumsted.

To focus on the fact that Vermonters need dialysis services misses the point. The project is not the provision of dialysis services. The project is a change of ownership of those services, and there is little in the application materials addressing the need for a change of ownership. Only two things appear.

First, there is the suggestion that Fletcher Allen may discontinue these services. In his declaration, Dr. Brumsted says "we determined that the financial performance of the Dialysis Clinics could not be improved sufficiently to avoid a continuing loss, without reducing service levels either by limiting patient access, reducing staff levels, or both. We do not wish to take any of these actions." Brumsted Decl. ¶ 3. As discussed above, this ignores the possibility that Fletcher Allen might raise its rates to commercial payors, which it did not do for many years. Brumsted Decl. ¶ 16(c). As shown above, it would not have to raise them to Fresenius' level to cover losses and even produce a surplus. If such a rate increase for dialysis would have created problems elsewhere in the Fletcher Allen system, it could come to the Department for relief. *See*, Act 128 of 2010, Sec. 20(a)(3)(B) and (c); 18 V.S.A. 9456(f). It has not done so.

Dr. Brumsted states that under the Asset Purchase Agreement with Fresenius, the latter commits to keeping the clinics open for ten years, a commitment "that Fletcher Allen would not be able to make itself." Brumsted Decl. ¶ 15(a). There is no explanation as to why Fletcher Allen cannot make that commitment. If Fletcher Allen intends to close the dialysis clinics, it has a responsibility to say so. Since it hasn't said so, it presumably has no such plans.

I also note that at the public hearing on November 14, 2011, both Dr. Brumsted and Spencer Knapp, Fletcher Allen's General Counsel, qualified their language to simply say that a 10-year commitment was not one Fletcher Allen could make "at this time" and "today". Tr. 32; 77. This would be consistent with having, in fact, no plans to close the dialysis clinics. Indeed, nowhere

in the record is there a statement by Fletcher Allen that it will close the clinics if this CON application is not approved.

At the public hearing Mr. DeBevec confronted the closure issue. "I'm tempted to ask the question what happens if we don't do the Fresenius thing, and does that mean that Dr. Brumsted is going to drop the dialysis units." Tr. 67-68. Neither Dr. Brumsted nor Fletcher Allen's other representative, Spencer Knapp, chose to respond. Fresenius' claim that the acquisition would "immediately extend the lifespan of the Outpatient Clinics by at least ten years" supposes that they are about to be closed. Suppl. 3 at p. 4. There is no record evidence for that supposition.

I disregard this suggestion about closure. This project is not needed in order to keep the clinics open and the home program operating; there is no testimony or submission by Fletcher Allen to the contrary. As noted, there are available solutions to Fletcher Allen's claimed losses on its dialysis operations (themselves ambiguous given the repeated failure to produce current budget figures for those operations as part of the required financial tables).

Fletcher Allen also says that it could use the proceeds of the sale to refurbish inpatient rooms. Brumsted Decl. ¶ 15(f). This is asking for tacit approval of an expenditure that is hypothetical. To base approval of this CON application on Fletcher Allen's suggestion that it might use the $26 million for some particular project is to ask the Department to implicitly approve now a construction CON for Fletcher Allen when Fletcher Allen has not applied for such a CON. There is a statutory CON process. I decline the invitation to bypass the process set out by the Legislature and effectively give approval by the back door to an Interested Party's $26 million future construction project. Fletcher Allen's desire to spend money in the future is not evidence of a need for this project.

I find there is no identifiable, existing or reasonably anticipated need for the sale of the outpatient dialysis services to Fresenius. This criterion is not met.

4. STATUTORY CRITERION (4): THE PROJECT WILL IMPROVE THE QUALITY OF HEALTH CARE IN THE STATE OR PROVIDE GREATER ACCESS TO HEALTH CARE FOR VERMONT'S RESIDENTS, OR BOTH.

The criterion's terms are clear, the project must *improve*, not simply maintain, the quality of health care or provide *greater*, not simply the same access, or both. I will take those requirements in order.

In spite of the requirement to demonstrate that the project *will improve* quality, both Fresenius and Fletcher Allen simply say that current quality will be maintained or, at best, offer conclusory statements that quality might (not *will*) improve. For example:

> "This acquisition . . . allows for the continuation of the delivery of high quality dialysis services" Appl. p. 2.
>
> "quality of care . . . comparable to the care currently provided" Suppl. 3, p. 5.

"continue to receive high quality" Appl. p. 19.

"continued high quality . . . continued quality levels" Brumsted Decl. ¶ 15(a)

"[Fresenius] will provide . . . dialysis services at a high quality" Appl. p. 20.

"FMCNA is able to improve quality of dialysis care" Appl. p. 20.

As discussed above under the quality criteria of the Triple Aims, Fresenius fails to provide comparative information that would show actual improvement over Fletcher Allen.

In the face of Fresenius' failure to demonstrate that quality will improve under its operations, Dr. Brumsted offered the results of Fletcher Allen's investigation as to comparative quality. Dr. Brumsted points out that the study of comparative quality was based on a selection of Fresenius clinics that were determined to closely resemble the characteristics of the Fletcher Allen clinics. Brumsted Decl. ¶ 11.

On each of the quality measures for which Dr. Brumsted offered data, Fresenius scored lower than Fletcher Allen, sometimes by small margins, sometimes by more significant margins. The evidence, in other words, is that not only would quality not improve, but it would go down compared to what Fletcher Allen offers.

According to Dr. Brumsted, hemoglobin measurement is a main indicator of long-term survivability for dialysis patients, and for this reason it was one of the quality measurements Fletcher Allen chose to assess. Brumsted Decl. ¶ 11(b). Dr. Brumsted states that the desired range of Hemoglobin for dialysis patients is 10 to 12 g/dL. Based on CMS reported data, 91% of Fletcher Allen's patients were within this desired range, while only 83% of Fresenius' patients were within the desired range. Brumsted Decl. ¶ 11(b). Extrapolating from this to the 267 patients reported as of June, 2011, only 24 Fletcher Allen patients fell out of the desired range, whereas 45 patients – nearly twice as many – would be out of the desired range under Fresenius. This would not be an improvement in quality.

Another important measure presented by Dr. Brumsted is the "Standardized Hospitalization Ratio" or SHR, "which measures the expected number of hospitalized days per year for dialysis patients as compared to the actual days hospitalized." *Id.* at ¶ 11(d). Fletcher Allen's dialysis clinics had a lower average ratio (0.57) than Fresenius (0.97). *Id.* The ratio is derived from calculations that account for differences in patient mix and compare expected outcome to actual outcome.[17] The ratio is calculated to "reflect the number of hospitalization 'events' for the patients at a facility, relative to the number of hospitalization events that would be expected based on overall national rates and the characteristics of the patients at that facility."[18] "The degree to which the facility's SHR varies from 1.00 is a measurement of the degree to which the overall hospitalization rate at that facility is greater than (SHR>1.00) or less than (SHR<1.00) the national hospitalization rate for patients with the same characteristics as those in the

[17] *Technical Notes on the Standardized Hospitalization Ratio (SHR) For the Dialysis Facility Reports,* The University of Michigan Kidney Epidemiology and Cost Center (July 2011) at 2.
[18] *Id.*

facility."[19] Thus if the expected number of hospitalization events at a facility is 100 and that is the actual number of hospitalization events, the ratio is 1.00.[20] For Fresenius, if the patient characteristics indicated 100 hospitalization events, there would be 97. If Fletcher Allen's patient characteristics indicated 100 hospitalization events, however, there would be only 57. This indicates that Fletcher Allen does a significantly better job of reducing the days its patients spend in the hospital.[21,22]

One measure of how well a patient dialyzes is the Urea Reduction Rate (URR). KDOQI and CMS guidelines require the URR to be 65% or greater. Fletcher Allen achieved an overall average of 98% within this range while the Fresenius rate for the sites sampled was 97%. Brumsted Decl. ¶ 11(c).

The composite "all patient" death rate for Fletcher Allen was 22.2 deaths per 100 patient years, while the rate for the Fresenius sites sampled was 22.3 deaths per patient years.[23] *Id.* at ¶ 11(a).

Some of the quality data presented by Dr. Brumsted indicate only a slight difference between Fletcher Allen and Fresenius, though the differences are unfavorable to Fresenius. Other data, however, such as the "main indicator," hemoglobin, and the hospitalization ratio show Fresenius in a distinctly unfavorable light compared to Fletcher Allen. None of the data show Fresenius providing quality that would be an improvement on the quality provided by Fletcher Allen.

I find that turning the clinics over to Fresenius would not improve the quality of care. Indeed, extending the data presented by Fletcher Allen to the clinics in question, the quality would deteriorate. Fresenius' conclusory statements about "maintaining" quality are cast into doubt by the Brumsted Declaration. Fresenius' forward-looking statements about being "able to improve" (a truism applicable to any enterprise) do not amount to a demonstration that the sale *will*

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[19] *Id.*

[20] *Id.* at 11.

[21] "hospitalization events" may be calculated either as admissions or as days of hospitalization. *Id.* at 3. Fletcher Allen apparently chose days of hospitalization.

[22] The result Fletcher Allen found is consistent with a recent study finding hospitalization days per patient-year statistically and significantly higher among for-profit dialysis providers. Lee, D.K.K., G. Chertow, S. Zenios, "Reexploring Difference among For-Profit and Nonprofit Dialysis Providers," Health Services Research 45: 633-646 (June, 2010).

[23] In its application for Interested Party status the Vermont Nurses Federation cited a 2002 study finding mortality rates significantly higher at for-profit dialysis facilities. In Supplement 3, Fresenius countered with a 2006 study which Fresenius quotes as finding that "'[s]urvival among patient in for-profit units was similar to not-for-profit units." Suppl. 3 at p. 6 and Exh. J. Yet a very recent study did find a significantly higher mortality hazard at the largest for-profit chains than at non-profit chains. Yi Zhang, et al. (2011) "The Effect of Dialysis Chains on Mortality among Patients Receiving Hemodialysis," Health Services Research 46: 747-767 (first published online Dec. 9, 2010), abstract at http://onlinelibrary.wiley.com/doi/10.1111/j.1475-6773.2010.01219.x/abstract, last accessed Nov. 26, 2011. The issue is troubling but cannot be resolved here.

improve the quality of dialysis services in Vermont. The actual data presented indicate that quality would deteriorate.

As to greater access to health care there is little to be said. The clinics and their operations will stay the same. The only argument for greater access is the proposition that Fresenius will encourage home dialysis. Appl. p. 20. Based on Fresenius' own statistical projections, I rejected that argument in connection with the first of the Triple Aims.

I find the applicant has not demonstrated that the proposed sale would improve the quality of health care in Vermont or provide greater access to health care for Vermonters.

5. STATUTORY CRITERION (5): THE PROJECT WILL NOT HAVE AN UNDUE ADVERSE IMPACT ON ANY OTHER EXISTING SERVICES PROVIDED BY THE APPLICANT.

Fresenius points out that as a part of its overall operations in North America, the local subsidiary, BMA-NH, has access to extensive resources. The relevant side of that coin is that these five clinics and the home dialysis program are a very small part of Fresenius' worldwide operations and by their small scale can have no undue impact on other services provided by the applicant. I find this acquisition would not adversely impact any existing Fresenius or BMA-NH services.

6. STATUTORY CRITERION (6) THE PROJECT WILL SERVE THE PUBLIC GOOD.

The Rule provides in Section 5(c) certain factors which "may be relevant" in determining whether a project will serve the public good:

> (1) The project will help meet the needs of medically underserved groups and the goals of universal access to health services.
> (2) The project will help facilitate the implementation of the Blueprint.
> (3) The applicant has demonstrated it has analyzed the impact of the project on the Vermont healthcare system and the project furthers effective integration and coordination of health care services.
> (4) The project is consistent with current health care reform initiatives, at the state and federal level.

Remembering that the project is not the provision of dialysis services but a corporate transaction selling the control of those services, I find factor (1) is irrelevant; the groups to be served will remain the same, as will access. Fresenius says it will not turn indigent patients away, but offers no comparison to Fletcher Allen's practices. Suppl. 3 at p. 5. Factor (2) is not met; while Fresenius has testified that it welcomes the Blueprint for Health,[24] Fletcher Allen as a local hospital is at least equally well placed to facilitate implementation of the Blueprint. Fresenius says it supports the Blueprint's goals and that its "delivery of care follows the Institute of Healthcare Improvement ('IHI') Triple Aims." Suppl. 3 at p. 9. Fresenius' failure as to the

[24] Title 18 V.S.A., chapter 13.

Triple Aims is addressed elsewhere in this decision. As to factor (3), the project cannot be said to further effective integration of health care services since it alienates ownership of part of those services. While Fresenius points to continuing clinical oversight by Fletcher Allen, this at best maintains a status quo and does not "further" integration. Suppl. 3 at p. 9. Factor (4) is not met since the project is inconsistent with Act 48 of 2011, which calls among other things for containment of overall costs and growth in health care spending, mechanisms for containing all system costs, and for reducing costs that do not contribute to efficient, high-quality health services or improve health outcomes. 18 V.S.A. § 9371, *passim*. Nothing in Fresenius' response to this factor negates the findings on costs and quality in this decision. Suppl. 3 at p. 9-10.[25] The suggestion on closure of the clinics as an issue for continued access has already been dismissed. The arguments on the public good presented by Dr. Brumsted in his Declaration (¶ 15) and by Mr. Knapp (tr. 77-78) have been addressed elsewhere in this decision, as have matters of cost, quality and access.

I find that Fresenius has not demonstrated that the proposed sale will serve the public good and that the project will not serve the public good. This criterion is not met.

7. STATUTORY CRITERION (7): THE APPLICANT HAS ADEQUATELY CONSIDERED THE AVAILABILITY OF AFFORDABLE, ACCESSIBLE PATIENT TRANSPORTATION SERVICES TO THE FACILITY.

In the application, Fresenius states that "[t]here will be no changes in the location of the Outpatient Clinics. This acquisition should have no particular impact on the existing public transportation infrastructure." Appl. p. 20. In Supplement 3, Fresenius adds that "The Applicant is legally prohibited from providing transportation services to patients. However, the Outpatient Clinics will continue to work with patients to arrange and coordinate transportation, as required by Conditions for Coverage for End-Stage Renal Disease 42 C.F.R. § 494.1 et seq., through their social services departments." Suppl. 3 at p. 10. I find that the project would have no impact on existing transportation services and that Fresenius has adequately considered the availability of patient transportation services.

III. CONCLUSION

On the findings of fact and conclusions of law set out above, I find that the applicant has not demonstrated that the project meets the legal criteria for a Certificate of Need and find that the project does not meet those criteria. Accordingly, the application is denied.

_____, 2011

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Stephen W. Kimbell, Commissioner

[25] Although not focused on dialysis services, one review of the scholarly literature found that nonprofits do better on both cost and quality than do for-profit providers. Rosenau, P.V. and S.H. Linder, "Two Decades of Research comparing For-profit and Nonprofit Health Provider Performance in the United States," Social Science Quarterly 84: 219-241 (June, 2003).