Department of Health and Human Services
Division of Licensing and Regulatory Services
State House, Augusta, Maine
Preliminary Analysis

Date: **September 28, 2012**

Project: **Acquire EMMC's Dialysis Centers**

Proposal by: **DaVita/ Total Renal Care**

Prepared by: **Phyllis Powell, Assistant Director, Medical Facilities**
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Directly Affected Party: **None**

CON Recommendation: **Approval with condition**

	Proposed Per Applicant	**Revised By Applicant**	**Approval Recommended**
Estimated Capital Expenditure	$ 10,000,000	$ 17,300,000	$ 17,300,000
Maximum Contingency	$ 0	$ 0	0
Total Capital Expenditure with Contingency	$ 10,000,000	$ 17,300,000	$ 17,300,000
Third Year Incremental Operating Cost Savings	N/A	N/A	N/A

I. Abstract

A. From Applicant

"Eastern Maine Medical Center ("EMMC") has provided inpatient acute, outpatient chronic, and home based dialysis programs for many years in northern and eastern Maine. EMMC currently provides acute services at the main campus in Bangor and at outpatient chronic dialysis centers in Bangor (Union Street), Ellsworth and Lincoln. Across the industry, however, dialysis programs are increasingly operated by specialty providers who are more familiar with the unique technical, staffing, and regulatory issues involved in providing this service. EMMC spent significant time assessing the optimal way to continue to provide this essential service, and determined that the best option for the community was to partner with a national dialysis provider. Potential national providers were identified and, after extensive discussions and analysis, Total Renal Care, Inc. ("TRC"), was chosen as the best partner to continue the program and to bring their expertise to assure continuous improvement of services in a challenging regulatory environment."

"TRC is a wholly owned subsidiary of DaVita Inc. ("DaVita"), a Fortune 500® company and leading provider of kidney dialysis services in the United States for patients suffering from chronic kidney failure, also known as end stage renal disease ("ESRD"). DaVita owns or provides administrative services to over 1800 dialysis facilities in the United States, serving approximately 142,000 patients, and it also furnishes acute inpatient dialysis services in approximately 750 hospitals. In a telephone conversation with Certificate of Need ("CON") staff on or about February 2, 2012, staff expressed an interest in understanding and obtaining an assurance that TRC is not simply a "shell" or holding company for DaVita, with little assets. On the contrary, TRC generates significant cash flow from its operation of over 640 dialysis centers in 35 states and the District of Columbia. TRC holds assets worth more than $2 billion, and serves as one of DaVita's primary vehicles for acquiring and operating dialysis centers in the United States."

"Through this proposed transaction, TRC intends to acquire substantially all of the assets of EMMC relating to EMMC's outpatient dialysis business, home dialysis program, and acute inpatient dialysis treatments rendered at EMMC's main hospital campus. More specifically, TRC intends to purchase substantially all of the assets of EMMC related to: (1) the EMMC Boyd Dialysis Center, 925 Union Street, Bangor, Maine; (2) the EMMC Ellsworth Dialysis Center, 11 Short Street, Ellsworth, Maine; (3) the EMMC Lincoln Lakes Dialysis Center, 250 Enfield Road, Lincoln, Maine (hereinafter, together referred to as the "Outpatient Centers"); (4) EMMC Home Dialysis (Boyd Center), Bangor, Maine ("hereinafter, referred to as the "Home Program"); and (5) inpatient acute dialysis services at the EMMC main hospital campus (hereinafter, referred to as the "Acute Program")."

"The assets acquired by TRC at closing will include all of the tangible and intangible assets which comprise, are used, or are held out for use in connection with, or are necessary for the operation of, the dialysis services provided at the Outpatient Centers and through the Home

Program. The assets will include the tangible assets used by EMMC in connection with the Acute Program, as well as equipment leases related to any of the dialysis services. With respect to real property, TRC will enter into new real estate leases with EMMC's parent, Eastern Maine Healthcare Systems ("EMHS"), for the premises housing the Boyd Center and Ellsworth Center. TRC will either assume the existing real estate lease for the Lincoln Lakes Center or enter into a new lease for the center premises. A copy of the draft Asset Purchase Agreement, with certain confidential business information redacted or not included because the parties have not reached final terms, is attached hereto as **Exhibit 1**. Please understand that the parties continue with their due diligence and have not reached a definitive agreement with respect to key terms such as purchase price. As discussed in the Technical Assistance Meeting, TRC will update **Exhibit 1** when the parties complete their due diligence and reach a definitive agreement."

"With respect to each Outpatient Center, TRC expects to enter into a ten (10) year agreement with Northeast Nephrology, P.A., for the provision of a Medical Director, who will provide oversight and responsibility for all medical and patient care aspects of the respective Outpatient Center. TRC will be seeking licensure from the State of Maine to operate each Outpatient Center. Dialysis services provided at the Outpatient Centers and through the Home Program will be billed and provided under TRC's provider number. TRC may, in its sole discretion, accept the Outpatient Centers current provider number or it may seek new provider numbers. TRC may, in its sole discretion, accept current third party payer agreements or it may negotiate new third party payer agreements. Regardless, TRC does not expect to make significant changes to the Outpatient Centers, Home Program, or Acute Program, and patients generally will continue to receive services on a day-to-day basis in the same way that they had before the transaction."

"With respect to the Acute Program, TRC intends to enter into a services agreement ("Acute Services Agreement"), whereby TRC will provide staffing and patient service related to the Acute Program in return for a per-treatment payment from EMMC. Dialysis services provided by the Acute Program will be provided pursuant to EMMC's license and billed to third party payers under EMMC's provider number. A copy of the draft Acute Services Agreement, with certain confidential business information redacted, is attached hereto as **Exhibit 2**. Again, TRC will update **Exhibit 2** when the parties complete their due diligence and reach a definitive agreement."

"As noted briefly above, the parties determined to enter into this proposed transaction because dialysis services are specialized services that require special equipment and a willingness and ability to focus on the unique needs of ESRD patients. With the increasing financial and operational pressures on general acute care hospitals, particularly in the area of dialysis services, EMMC determined to focus more of its efforts on its core hospital functions and, with the exception of the Acute Program as described above, move away from providing dialysis services. TRC, on the other hand, focuses solely on providing care and services to ESRD patients. This allows TRC to leverage economies of scale for purchasing equipment and supplies that simply is not available to a hospital serving northern and eastern Maine. As a result, TRC is able to better absorb recent changes in Medicare reimbursement that have created financial pressures for some hospitals providing dialysis services. Regarding quality, TRC

consistently differentiates itself from other kidney care companies and surpasses national averages for clinical outcomes. TRC's clinical outcomes for dialysis have improved for the past decade, and in many key areas measuring quality dialysis care, DaVita and TRC lead the nation. In short, this transaction will benefit area patients by allowing the parties to focus on what they do best."

"The estimated capital expenditure associated with the asset purchase and real estate leases is more than ten million dollars ($10,000,000.00). We do not anticipate any incremental increase in third year operating costs, and the acquisition will not materially impact the day-to-day operations of the Outpatient Centers, Home Program, or Acute Program. Accordingly, TRC believes that this proposed acquisition should be subject to the simplified review and approval process described at 22 M.R.S.A. § 336 (3). We also note that most ESRD patients are covered by Medicare (approximately 85%). As such, we do not anticipate any material impact to MaineCare expenditures as a result of this transaction."

B. CONU Discussion

The proposed transaction is reviewable under M.R.S.A. 22§ 329 (1) Transfer of Ownership. The relevant language states that "A certificate of need from the department is required for any transfer of ownership or any acquisition of control of a health care facility. M.R.S.A. 22 § 328 (8) defines a health care facility as "a hospital, psychiatric hospital, nursing facility, kidney disease treatment center including a freestanding hemodialysis facility, rehabilitation facility, ambulatory surgical facility, independent radiological service center, independent cardiac catheterization center or cancer treatment center." The Certificate of Need Unit (CONU) determined that this project was reviewable based on information contained in a Letter of Intent filed with the department on March 5, 2012.

At a technical assistance meeting held on September 4, 2012, the applicant disclosed that the estimated capital expenditure associated with the asset purchase and the lease(s) is more than seventeen million dollars ($17,300,000). This meeting was required under Public Law 648 signed by the governor on 4/18/2012 and effective 9/30/2012. As a technical requirement, disclosure of the purchase cost is necessary to ensure that the scope of the project, if approved, is not exceeded.

II. Fit, Willing and Able

A. From Applicant

"TRC is fit, willing and able to acquire the assets of EMMC's dialysis business, including the Outpatient Centers, Home Program, and Acute Program, and provide dialysis services to the service area at the proper standard of care. DaVita is one of the nation's largest dialysis providers and a leader in delivering services to patients with chronic kidney failure and ESRD. In addition to providing high quality dialysis services, TRC and DaVita offer a variety of additional services intended to enhance the quality of care provided. Before we describe those services, we offer a summary of TRC's dialysis services and how this proposed transaction aligns with the core services TRC already provides to thousands of patients across the country. For even more information, please visit DaVita's website at: http://www.davita.com/."

A. Dialysis Services

"Hemodialysis, the most common form of ESRD treatment, is usually performed at a freestanding outpatient dialysis center, in a hospital-based outpatient center, or in the patient's home. The hemodialysis machine uses an artificial kidney, called a dialyzer, to remove toxins, fluids, and salt from the patient's blood. An outpatient hemodialysis treatment typically lasts about three and one-half hours and is usually performed three times per week. TRC proposes to acquire the assets of the Outpatient Centers, obtain all required licenses and certificates, obtain or assume provider numbers, and provide this service to the community with the same level of high quality care it provides to all of its dialysis patients across the United States."

"Some ESRD patients who are healthier and more independent may perform home-based hemodialysis through the use of a hemodialysis machine that is portable, smaller and easier to use. Patients receive training, support, and monitoring from registered nurses in outpatient dialysis centers or in centers dedicated to home dialysis. Home-based hemodialysis is typically performed with greater frequency than dialysis treatments performed in outpatient dialysis centers and on varying schedules. Peritoneal dialysis uses the patient's peritoneal or abdominal cavity to eliminate fluid and toxins and is typically performed at home. Because peritoneal dialysis does not involve going to an outpatient dialysis center three times a week for treatment, it is an alternative to hemodialysis for patients who are healthier, more independent and desire more flexibility. Peritoneal dialysis, however, is not a suitable method of treatment for many patients, including patients who are unable to perform the necessary procedures and those at greater risk of peritoneal infection. TRC proposes to acquire EMMC's assets relative to the Home Program, obtain all required licenses and certificates, obtain or assume a provider number, and provide these services to the community with the same level of high quality care it provides to all of its dialysis patients across the United States."

"Hospital inpatient hemodialysis services are required for patients with acute kidney failure resulting from trauma, patients in early stages of ESRD, and ESRD patients who require hospitalization for other reasons. Hospital inpatient hemodialysis is generally performed at the

patient's bedside or in a dedicated treatment room in the hospital, as needed. TRC proposes to manage the day-to-day operations of EMMC's inpatient dialysis service (Acute Program) through an Acute Services Agreement between TRC and EMMC. The Acute Program service will be provided and billed under EMMC's provider number. EMMC will handle all billing and TRC will be paid a management fee pursuant to the Acute Services Agreement." See **Exhibit 2**.

"Finally, although DaVita and TRC will be new to Maine, please know that DaVita currently owns and/or operates thirty-seven (37) dialysis sites in Rhode Island, Massachusetts, Connecticut, and New Hampshire. As such, DaVita already has extensive dialysis operations in New England and sees this opportunity to bring its knowledge and expertise to Maine as the next logical step in developing its northeastern dialysis network."

B. Ancillary Services and Strategic Initiatives

"As noted above, TRC and DaVita offer a variety of additional services that are intended to complement dialysis services and to enhance the quality of care provided. They include laboratory and pharmacy services, as well as disease management programs, all of which would be available to TRC dialysis patients."

1. Laboratory Services

"DaVita owns two separately incorporated, licensed, clinical laboratories specializing in ESRD patient testing ("DVA Laboratory Services"). DVA Laboratory Services provides routine laboratory tests for dialysis and other physician-prescribed laboratory tests predominantly for DaVita's network of ESRD patients throughout the United States. These tests are performed to monitor a patient's ESRD condition, including the adequacy of dialysis, as well as other medical conditions. DVA Laboratory Services utilizes a seamless information system that provides for order entry and results reporting and that communicates information to its dialysis centers regarding critical outcome indicators. The proposed transaction will allow patients of the Outpatient Centers and Home Program to access the DVA Laboratory Services."

2. Pharmacy Services

"DaVita operates a full-service pharmacy, DaVita Rx, that specializes in renal care and that helps DaVita patients adhere to their drug regimens through, for example, 24-hour access, refill reminders, flexible payment options, and access to renal vitamins at cost. The main objectives of the pharmacy are to improve clinical outcomes by facilitating increased patient compliance and to provide patients a convenient way to fill their prescription needs by delivering the prescriptions to the center where they are treated. DaVita Rx helps caregivers improve patient care by making sure kidney medications are always in stock and increases adherence to caregiver recommendations by removing typical challenges that can lead to patients deviating from their care plans. The proposed transaction will allow patients of the Outpatient Centers and Home Program to access DaVita Rx."

3. Disease Management Services

"Through VillageHealth, DaVita's sophisticated disease management program offered at all centers, DaVita provides advanced care management services to health plans and government agencies for members or employees, as appropriate, diagnosed with chronic kidney disease or ESRD. Through a combination of clinical coordination, medical claims analysis, and information technology, DaVita endeavors to assist customers and patients in obtaining superior renal health care and improved clinical outcomes, as well as helping to reduce overall medical costs. It also allows the patient, physician, and provider to coordinate care; educates and engages patients to take an active role in their health care; and focuses on patient-centric solutions to achieve results. The proposed transaction will allow patient of the Outpatient Centers and Home Program to access VillageHealth. Certain VillageHealth services also will be available to patients in the Acute Program."

C. Quality and Patient Satisfaction Recognition

"Regarding quality and the proper standard of care, TRC and DaVita have more than 41,000 employees dedicated solely to providing superior patient care. Superior care begins with superior clinical leadership. Led by some of the world's most acclaimed nephrologists, DaVita's Office of the Chief Medical Officer drives clinical quality programs at the 1,800 plus dialysis centers around the country, including all centers owned by TRC. Through continued innovation, DaVita has produced ten (10) consecutive years of improvement in the DaVita Quality Index (DQI), a benchmarking tool created by DaVita's Physician Council to measure each dialysis center's outcomes against company-wide performance."

"Through this dedication to providing high quality care, DaVita, its physician partners and its clinical care teams have achieved the following results for patients:

- According to annual patient satisfaction survey results, 96% of DaVita patients would recommend DaVita for dialysis services.
- DaVita's clinical outcomes are the best or among the best in virtually every category, including ten (10) consecutive years of continued improvement.
- In 2009, DaVita had the lowest day-90 catheter rates (the less preferred access method) among large dialysis providers, reducing the risk of hospitalization from infections and blood clots for its patients.
- Since 2006, DaVita has exceeded other providers' influenza vaccination rates by as much as 40%, and vaccinations reduce hemodialysis patients' odds of hospitalization by 7%."

"In addition, DaVita's efforts in quality and leadership in health care have been recognized by the following:

Fortune

- Recognized on the 2009 Fortune Top Companies for Leaders list, ranking 18th in North America
- Recognized among Fortune World's Most Admired Companies for the past 5 years (2006-2010)
    - Ranked #1 overall among Health Care Medical Facilities
    - Ranked #1 Health Care Medical Facility in Innovation, Use of Corporate Assets, Financial Soundness, Long-Term Investment and Quality of Products and Services"

Training Magazine

- Training Magazine's "Top 125" ranked #1 national healthcare service provider for its employee training programs.
- Honored for the seventh straight year (2005-2011) as one of the "Top 125" ranked companies of employer-sponsored workforce training and development.

American Association of Kidney Patients (AAKP)

- 2010 AAKP Medal of Excellence awarded to Allen Nissenson, MD, FACP, Chief Medical Officer of DaVita.

National Health Information Award

- 2010 National Health Information Awards for consumer health information programs and materials that address the growing needs of healthcare consumers.

Lastly, we note that DaVita is:

- The largest provider of home peritoneal dialysis (PD) in the United States
- The largest provider of home hemodialysis (HHD) in the U.S.
- The fastest-growing in-center nocturnal hemodialysis provider in the U.S.
- A pioneer of in-center self-care hemodialysis

"For more information about DaVita and its vision to be the greatest kidney care company and greatest healthcare community, please see **Exhibit 3**, which is a copy of the latest version of "Community Care: The DaVita Vision for Social Responsibility." Also, we encourage you to visit DaVita's website (http://www.davita.com), which is full of information for patients and the general public about the kidney and dialysis services provided by DaVita."

"Based on the foregoing, TRC and DaVita respectfully submit that they are fit, willing and able to acquire the assets of EMMC's dialysis business, including the Outpatient Centers, Home Program, and Acute Program, and provide dialysis services to the service area at the proper standard of care."

B. CONU Discussion

i. CON Criteria

Relevant criteria for inclusion in this section are specific to the determination that the applicant is fit, willing and able to provide the proposed services at the proper standard of care as demonstrated by, among other factors, whether the quality of any health care provided in the past by the applicant or a related party under the applicant's control meets industry standards.

ii. CON Analysis

DaVita is one of the nation's largest dialysis providers. The company is a leader (patients served annually) in delivering services to patients with chronic kidney failure and end stage renal disease (ESRD) treatment. Training Magazine's ranked DaVita as the #1 national healthcare service provider for its employee training programs. DaVita was honored for seven consecutive years (2005-2011) as one of the "Top 125" ranked companies of employer-sponsored workforce training and development. In 2012, the American Association of Kidney Patients (AAKP) awarded its Medal of Excellence to Allen Nissenson, MD, FACP, Chief Medical Officer of DaVita. In 2010, DaVita received the National Health Information Award for consumer health information programs and materials that address the growing needs of healthcare consumers.

DaVita is the subject of a whistleblower lawsuit alleging the company intentionally wasted an anemia drug to collect millions of dollars in extra Medicare payments. The company has denied the allegations. The Justice Department investigated the whistleblowers' claims and declined to join the suit. The plaintiffs, a former nurse and doctor for DaVita, subsequently filed an amended complaint. A federal judge in Atlanta advanced the case by refusing DaVita's request to dismiss the claims. Newspaper sources announced that a settlement had been reached in the case for $55 million dollars. This settlement has triggered a shareholder lawsuit seeking reimbursement from the company's senior management of the $55 million settlement and the $23 million in legal fees. DaVita reports that they do not believe that the physicians prescribing EPO to patients in DaVita dialysis clinics in this period did anything wrong. The government investigated these allegations and decided not to intervene.

DaVita received a subpoena from the U.S. Department of Health and Human Services over Medicaid payments it received for dialysis drugs in New York. The company said in an October 2011 news release that it would work with investigators and looked forward to resolving the inquiry.

In a criminal investigation, a federal grand jury in Denver is looking into the company's financial relationships with nephrologists. Prosecutors recently subpoenaed some of the company's executives and board members as reported in the Bangor Daily News.

Investigations, subpoenas and audits do not indicate wrongdoing. None of the claims against the company have been substantiated and no regulatory penalties have resulted.

Public Comments

A public information meeting was held on May 25, in Bangor, Maine at the Spectacular Events center. A public hearing was requested by 5 members of the public. This hearing was held on July 10, 2012 at Spectacular events. This hearing was held within 2 miles of one of the dialysis centers that is the subject of this proposal. The public comment period ended on August 9, 2012.

A significant number of comments were received and included in the record regarding the proposed transaction. A vast number of the commenters were concerned about safety and responsibilities of the centers. Specific questions from the commenters included whether the centers had access to a crash cart, the policy regarding the re-use of catheters and clinical procedures. Some of these comments were buttressed by anecdotal evidence. DaVita stated that many if not all of the medical decisions will be the responsibility of the Doctors treating the patients. Several doctors responsible for treating dialysis patients in the Bangor area testified that they would not employ the practice of catheter sterilization and re-use at these facilities. The CONU reviewed these comments with the survey and certification surveyors for the state of Maine. The conclusion was that all the specific requests regarding safety equipment and procedures to ensure proper care are included in the general conditions of participation guidelines (Centers for Medicare and Medicaid Services Guidelines that regulate the ESRD facilities). These dialysis centers are regularly reviewed for compliance as part of the ongoing licensing and certification surveys that are conducted by the State of Maine on behalf of the Centers for Medicare and Medicaid Services.

The most recent information included in this analysis comes from the second quarter conference call from DaVita management.

DaVita now reports serving approximately 150,000 patients in the United States DaVita settled the whistleblower case for $55 million plus attorney's fees and some other related expenses. DaVita reports that they do not believe that the physicians prescribing EPO to patients in DaVita dialysis clinics in this period, did anything wrong. The government investigated these allegations and decided not to intervene.

A concern for access to care was revealed when the CEO of DaVita reported that DaVita may be forced in some cases to turn away patients rather than accept new patients at unacceptable rates of reimbursement. The CEO is quoted as saying, "there remains a lot of uncertainty around the

impact of exchanges on our private patients as it does for lots of other health care service segments". The possible effects of the Affordable Care Act on reimbursement are a systemic risk for all healthcare providers currently.

Generally, according to surveyors from the Division of Licensing and Regulatory Services, DaVita provides excellent and continuously improving clinical care. As evidence, by its financial statements and related comments, DaVita continues to see steady volume growth of its services. DaVita has capability to provide integrated kidney care that significantly increases quality while decreasing costs.

iii. Conclusion

CONU recommends that the Commissioner find that the applicant is fit, willing and able to provide the proposed services at the proper standard of care as demonstrated by, among other factors, whether the quality of any health care provided in the past by the applicant or a related party under the applicant's control meets industry standards.

III. Economic Feasibility

A. From Applicant

"TRC and DaVita have the capacity to support the project financially over the useful life, in light of the rates the applicant expects to be able to charge for dialysis services. In fact, because of the economies of scale DaVita enjoys with dialysis supplies and equipment, TRC is in a better position than EMMC to support these services financially, and this is a key driver of this transaction. Further, TRC and DaVita are well-positioned financially to operate the Outpatient Centers, Home Program, and Acute Program in accordance with existing and reasonably anticipated future changes in federal, state and local licensure and other rules. TRC does not expect any material increase in patient volume at any Outpatient Center or in the Home Program, above and beyond the annual 3.5 to 4 percent increase currently experienced by dialysis providers in the normal course. See Discussion in Section IV. TRC does, however, expect to recognize some cost savings related to the large quantities in which TRC purchases dialysis equipment and supplies. Attached as **Exhibit 4** please find TRC's three (3) year financial projections for each Outpatient Center and the Home Program. Please note that **Exhibit 4** is subject to further due diligence and, if the projections change or are refined as a result, TRC will update accordingly."

"Regarding financial capacity, attached as **Exhibit 5** is DaVita's Form 10-K for the period ending December 31, 2011, and attached as **Exhibit 6** is DaVita's 2010 Annual Report. As noted earlier, TRC generates significant cash flow from its operation of over 640 dialysis centers in 35 states and the District of Columbia. TRC holds assets worth more than $2 billion, and serves as one of DaVita's primary vehicles for acquiring and operating dialysis centers in the United States. DaVita, the parent of TRC, owns or provides administrative services to over 1,800 dialysis facilities in the United States (including the over 640 owned by TRC), serving approximately 142,000 patients, and it also furnishes acute inpatient dialysis services in approximately 750 hospitals."

"TRC will pay the purchase price out of readily available funds, and the purchase is not subject to any financing contingencies. TRC's current earnings are not expected to be materially impacted by this proposed transaction."

"Regarding rates, most ESRD patients are eligible for Medicare and/or Medicaid coverage and TRC and DaVita will of course accept Medicare and Medicaid payment rates. To the extent some patients may have commercial health insurance, TRC, at its sole discretion, may assume the current agreement with EMMC or negotiate a new agreement. Regardless, TRC and DaVita respectfully submit that they have the capacity to support the project financially over the useful life, in light of the rates the applicant expects to be able to charge for dialysis services and are well-positioned financially to operate the Outpatient Centers, Home Program, and Acute Program in accordance with existing and reasonably anticipated future changes in federal, state and local licensure and other rules." See **Exhibits 5** and **6**.

B. CONU Discussion

i. CON Criteria

Relevant criteria for inclusion in this section are specific to the determination that the economic feasibility of the proposed services is demonstrated in terms of the:

- Capacity of the applicant to support the project financially over its useful life, in light of the rates the applicant expects to be able to charge for the services to be provided by the project; and

- The applicant's ability to establish and operate the project in accordance with existing and reasonably anticipated future changes in federal, state and local licensure and other applicable or potentially applicable rules.

ii. CON Analysis

In 1972, the US Congress passed legislation authorizing the End Stage Renal Disease (ESRD) program under Medicare. Section 299I of Public Law 92-603 extended Medicare coverage to Americans if they had stage five chronic kidney disease (CKD) and were otherwise qualified under Medicare's work history requirements. The program's launch was July 1, 1973. Previously only those over 65 could qualify for Medicare benefits. This entitlement is nearly universal, covering over 90% of all US citizens with severe CKD according to a 2006 report on payment sources for dialysis.

The Medicare Secondary Payer (MSP) provision of the ESRD program (also known as the ESRD Coordination Period) was enacted as part of the Omnibus Budget Reconciliation Act of 1981. MSP provides for a coordination of benefits period between Medicare and private health insurance plans for individuals entitled to Medicare solely on the basis of ESRD. If an individual is entitled to Medicare because of ESRD and is covered by an Employer Group Health Plan (EGHP), the EGHP is the first payer (primary) for the first thirty months.

Medicare's unit of payment is one composite rate per dialysis treatment. This is described as a bundled payment. Although different equipment, supplies, and labor are needed for hemodialysis and peritoneal dialysis, the current system does not differentiate payment based on dialysis method, location (home or in center) or equipment used.

The composite rate is intended to cover all operating and capital costs that efficient providers would incur in furnishing dialysis in outpatient facilities or in beneficiaries' homes. Medicare caps its payments to facilities at an amount equal to three dialysis sessions per week. Although home dialysis may be given more frequently it is not fully reimbursed by Medicare.

The analysis of the economic feasibility is hampered by DaVita’s reluctance to provide full documentation at this time of its financial plans for the facilities. The criterion however is “whether the applicant has the capacity to support the project financially over its useful life, in

light of the rates the applicant expects to be able to charge for the services to be provided by the project". Since the services provided are of such limited scope and the reimbursement is concentrated (estimated 85% Medicare), CONU is relying on reference to the size of the DaVita operations and its considerable financial resources in making the assumption that DaVita can maintain services. DaVita is larger and has more financial resources available to it than does EMMC.

The DaVita subsidiary TRC will pay the purchase price out of readily available funds making the purchase not subject to any financing contingencies.

DaVita reported net operating revenues of $6.982 billion for 2011, with operating income being $1.131 billion or 16% of revenues.

DaVita has provided financial pro-formas for the operating facilities that they contend are trade secrets. Upon consultation with the Attorney General's office, CONU will not disclose in this document the actual forecasted information. CONU can say that the financial pro-formas indicate the ability for DaVita (TRC) to operate the facilities and DaVita has the capacity to financial support the facilities based on the rates they expect to receive for performing the services expected to be provided.

Changing Laws and Regulations

CONU staff is not aware of any imminent or proposed changes in laws and regulations that would impact the project, except for the federal health care reform. The impact of the health reform is not yet determinable. DaVita/TRC presently has the organizational strength to adjust to reasonable changes in laws and regulations.

The CMS model for reimbursement includes bundling many of the dialysis services into a payment bundle. DaVita reported that oral drugs will be added to the bundle in 2014 at a currently unknown rate. New models of care such as Accountable Care Organizations (ACOs) and changing affiliation models for physicians like employment by hospitals may decrease the earning potential of the individual facilities.

v. Conclusion

CONU recommends that the Commissioner determine that the applicant has met their burden to demonstrate: (1) the capacity of the applicant to support the project financially over its useful life, in light of the rates the applicant expects to be able to charge for the services to be provided by the project; and (2) the applicant's ability to establish and operate the project in accordance with existing and reasonably anticipated future changes in federal, state and local licensure and other applicable or potentially applicable rules.

IV. Public Need

A. From Applicant

"This project involves the purchase of assets and operation of three (3) outpatient dialysis centers, a home dialysis program, and the operation of an acute inpatient dialysis program at EMMC. Thus, this is not a new project or new service, but the continuation of dialysis services currently provided and needed in the respective communities. The continuation of these services will address kidney disease specifically. Through education and outreach, however, TRC and DaVita expect to impact outcomes and quality in a positive way by giving patients the tools they need to understand the role that diet, lifestyle, and nitration play in kidney function; by educating patients on how to reduce risk factors related to kidney disease, for example, diabetes and hypertension; and by creating a community through live and on-line patient discussion groups, message boards, and support groups, where patients can share their experiences and learn from each other in a supportive environment."

"According to the latest annual report from the United States Renal Data System, at the end of 2009, the ESRD program in the United States was treating 571,414 dialysis and transplant patients, which was a 4.0 percent increase from 2008. There were 116,395 new cases of ESRD reported, which is 3.5 percent more than in 2008 and the largest increase since 2000. TRC expects the annual rate of increase in the use of ESRD services to remain at around 3.5 to 4 percent, particularly in light of the increase in incidence of contributing factors, such as diabetes and hypertension, with perhaps some slightly higher increases in Maine, reflecting the generally older population in Maine. In fact, the data from EMMC, which we used in our financial projections, demonstrates that growth is trending up at about 4.4% across all chronic programs. See also **Exhibit 4**."

"Regarding access in terms of potential financial barriers, almost all dialysis patients have some form of third party payer, in most cases Medicare. Thus, TRC expects that it would see few patients at the Outpatient Centers or through the Home Program who are not able to pay for the services. TRC is nevertheless committed to caring for all patients, regardless of their ability to pay, and will meet all legal obligations to provide uncompensated care. The patient access policies of EMMC would apply to patients in the Acute Care Program."

"Regarding access in terms of physical capacity, currently the EMMC Boyd Dialysis Center at 925 Union Street, Bangor, Maine, services one-hundred-fourteen (114) patients with twenty-one (21) stations; the EMMC Ellsworth Dialysis Center at 11 Short Street, Ellsworth, Maine, services forty-eight (48) patients with twelve (12) stations; and the EMMC Lincoln Lakes Dialysis Center at 250 Enfield Road, Lincoln, Maine, services thirty-one (31) patients with eight (8) stations. This represents a utilization percentage of 74% across all programs assuming three shifts, with the Boyd Dialysis Center at 90.5% of capacity. This information is presented graphically below."

Current Utilization

	Bangor (Boyd)	Ellsworth	Lincoln Lakes
# of Patients	114	48	31
# of Stations	21	12	8
Days of Operation	6	6	6
# of Patient Shifts	3/day	2/day	2/day
Capacity	90.5%	100% (66.7% for 3 shifts)	96.9% (64.6% for 3 shifts)

"Therefore, while we do not anticipate barriers to access on account of patient ability to pay for services, we do project access issues related to capacity in the very near future. In anticipation of this eventuality, we have discussed internally and with EMMC the possibility of opening a new center in Dover-Foxcroft, Maine. TRC understands that EMMC submitted a letter of intent related to making this service available in Dover-Foxcroft in or about 2008, and received a not subject to review letter from CON in response in late 2008. Because of impending capacity issues and the relatively large number of patients who currently travel fairly long distances from this area (in excess of 35 miles), TRC is evaluating the feasibility of expanding services to this area of Maine."

"Regarding quality and health status indicators, as discussed above, DaVita has produced ten (10) consecutive years of improvement in the DaVita Quality Index (DQI), a benchmarking tool created by DaVita's Physician Council to measure each dialysis center's outcomes against company-wide performance. Through this dedication to providing high quality care, DaVita, its physician partners and its clinical care teams have achieved the following results for patients:

- According to annual patient satisfaction survey results, 96% of DaVita patients would recommend DaVita for dialysis services.
- DaVita's clinical outcomes are the best or among the best in virtually every category, including ten (10) consecutive years of continued improvement.
- In 2009, DaVita had the lowest day-90 catheter rates (the less preferred access method) among large dialysis providers, reducing the risk of hospitalization from infections and blood clots for its patients.
- Since 2006, DaVita has exceeded other providers' influenza vaccination rates by as much as 40%, and vaccinations reduce hemodialysis patients' odds of hospitalization by 7%."

"TRC expects to see similar quality outcomes and patient satisfaction in its operation of the Outpatient Centers, Home Program, and Acute Program."

B. CONU Discussion

i. CON Criteria

Relevant criteria for inclusion in this section are specific to the determination there is a public need for the proposed services as demonstrated by certain factors, including, but not limited to:

- Whether, and the extent to which, the project will substantially address specific health problems as measured by health needs in the area to be served by the project;
- Whether the project will have a positive impact on the health status indicators of the population to be served;
- Whether the services affected by the project will be accessible to all residents of the area proposed to be served; and
- Whether the project will provide demonstrable improvements in quality and outcome measures applicable to the services proposed in the project.

ii. CON Analysis

The applicant has demonstrated that there is an ongoing need for the services. There are currently 193 patients receiving dialysis treatment at the three operational centers.

The applicant has demonstrated a commitment to improving the health status of its patients by including a description of several of the health status indicators it measures and will benchmark against these facilities. These health status indicators included 87% of all patients in 2010 achieved an albumin level of 3.5 or better. Albumin is the main protein of plasma; it binds water, calcium, sodium and potassium, hormones, and drugs (including barbiturates) - its main function is to regulate the osmotic pressure of blood. Levels below 3.5 are considered low and can lead to edema. Another indicator of improved health status is based on patient's catheter use rates. DaVita reported that the use of catheter's decreased to 17.5% of patients in its most recent data available. This rate of use, according to DaVita, is the lowest in the history of the company.

DaVita has indicated that they would accept all the patients' currently on dialysis and were considering adding services in the Dover-Foxcroft area if warranted. A concern regarding access to care was reported when the CEO identified that DaVita "may be forced in some cases to turn away patients rather than accept new patients at unacceptable rates, there remains a lot of uncertainty around the impact of exchanges on private patients as it does for lots of other health care service segments." (Source: Transcript of 2nd Quarter Financial Investors Conference Call – available on DaVita's financial investment public comment webpage).

Other concerns of limiting access of a similar nature were expressed at the Public Hearing. There was no evidence to indicate a difference in operating procedures employed by DaVita compared to any other dialysis provider. Much concern was expressed regarding the national scope of

DaVita operations. DaVita is a national company, but it is expected that a significant level of local control will be exercised over the facilities. Local staff have expressed their support for this transaction. There are no legally binding assurances, however; that this local control will be maintained. Opponents to this transaction, express grave concern about the loss of local control. To that end, and to ensure that public input is respected it is being recommended that DaVita develop a Patient Support Board (PSB). This board would be tasked with reviewing, on a regular basis, the clinical operations at the ESRD facilities. The "board" would be made up of patients of the facilities, family members, clinicians and DaVita representatives. It would be expected that any issues regarding patient complaints and service issues be addressed by this board. DaVita will be required to develop, sponsor and report activities of the board to the CONU for three years once this project is commenced. The proposed condition to be included is:

DaVita will provide CONU, 15 days before the project is commenced, the plans for the development of a Patient Support Board, describing its responsibilities, proposed meeting schedule and other pertinent information. An approved summary of Board activities will be forwarded to CONU within 60 days of each board meeting. This Patient Support Board will be required to meet at least quarterly for the first three years following commencement of this project.

v. Conclusion

CONU recommends that the Commissioner find that the applicant has met their burden to show that there is a public need for the proposed project.

V. Orderly and Economic Development

A. From Applicant

"The parties have not finalized a purchase price for the assets, but the purchase price will be more than $10 million, with the funds being retained by EMMC and used to further its mission. As such, the impact on total healthcare expenditures of purchasing the assets of the Outpatient Centers, Home Program, and Acute Program is not material. TRC intends to make some minimal capital improvements in the form of signage, painting, IT upgrades and minor renovations in the first year of operation. TRC does not project, however, a material increase to third year operating costs."

"TRC does not anticipate any increase in volume or increased service as a result of the proposed transaction, above and beyond the annual 3.5 to 4 percent increase currently experienced by dialysis providers in the normal course. As such, revenues and expenses are not expected to materially change as it relates to this project. TRC does anticipate some reduced cost for supplies, on an ongoing basis, and equipment, when it becomes necessary to replace equipment. Funding for the asset purchase will be through TRC equity. As a result, there will be no financing costs associated with this proposed transaction. Other than capital outlay, no additional cash burden to TRC shall be incurred for the proposed project."

"The impact on MaineCare funds will not be material because the vast majority of ESRD patients are covered by Medicare and, other than the annual increase currently experienced by dialysis providers in the normal course, there is no anticipated volume increases or service increases above current utilization levels."

"While research and technological advances in equipment have improved the lifestyle of patients living with ESRD, TRC is not aware of any replacement technology or service delivery mechanism that would offer a less costly alternative to dialysis services as outlined in Section II."

B. CONU Discussion

i. CON Criteria

Relevant criteria for inclusion in this section are specific to the determination that the proposed services are consistent with the orderly and economic development of health facilities and health resources for the State as demonstrated by:

- The impact of the project on total health care expenditures after taking into account, to the extent practical, both the costs and benefits of the project and the competing demands in the local service area and statewide for available resources for health care;

- The availability of state funds to cover any increase in state costs associated with utilization of the project's services; and

- The likelihood that more effective, more accessible or less costly alternative technologies or methods of service delivery may become available.

ii. CON Analysis

The services proposed in this project are highly specialized and are conducted at specialized facilities. Total health care expenditures are not expected to increase as a result of this transaction. The need for these services is definite and measurable. Current utilization of these services, and the specificity of the services make the continuation and availability of these services a necessary component of health care.

State funds should not be materially impacted by this transaction. There should not be any increased utilization of these services because of this proposed transaction.

There is research into alternatives to dialysis because of the cost and the fact that dialysis necessarily restricts patients by the need to be at dialysis centers three times a week for a significant time period. Kidney transplantation is a viable alternative but the number of kidney transplants is considerably less than the number of patients needing dialysis. A review of other alternatives indicated that some research into transplantable artificial kidneys was ongoing but successful prototypes were years away from being viable.

To date, the parties have not finalized a purchase price for the assets, but the purchase price will be more than $10 million. This interferes with the ability of the CONU to make a recommendation regarding the project in its full scope as certain portions of the agreement between the parties are not subject to the Certificate of Need statute or rules and therefore needs to be excluded from the purchase price when calculating the capital expenditures for this project. Because of this the CONU will not be able without the scope of the transaction being fully revealed to the public. This preliminary analysis, however; is constructed by analyzing the individual standards required in the statute. To that end CONU, concludes that the applicant meets this criteria.

v. Conclusion

CONU recommends that the Commissioner find that the applicant has met its burden to demonstrate that the proposed project is consistent with the orderly and economic development of health facilities and health resources for the State.

VI. Outcomes and Community Impact

A. From Applicant

"As a result of the Transaction, the Outpatient Centers' current and prospective patients are expected to benefit. Most importantly, DaVita is a clinical leader in the dialysis field, and its efforts are led by some of the world's most acclaimed nephrologists. DaVita has developed a sophisticated set of protocols for handling patient care that it intends to implement at the Outpatient Centers, Home Program, and Acute Program. DaVita's clinical outcomes are the best or among the best in all key patient metrics, with ten (10) years of continuous improvement."

"In addition to its highly qualified clinical staff (which includes physicians, nurses, patient care technicians, and emergency service providers), DaVita and TRC employ several specialists who provide support services to patients, and they include dieticians, social workers, travel planners, and insurance specialists. DaVita also offers access to a 24-hour call center through which patients can request any assistance needed to address physical, emotional, and financial needs."

"Further, as mentioned above, DaVita offers a variety of ancillary services and programs that are intended to enhance patient care and the patients would gain access to these services following the transaction. Such services include specialized laboratory services, convenient and affordable pharmacy services, and disease management programs."

"Regarding the impact on existing service providers, there are no unrelated1 existing providers within thirty-five (35) miles of the Outpatient Centers. Therefore, TRC does not anticipate any impact on the volume or quality of care delivered by existing service providers. See Exhibit 7, which is a map depicting the Outpatient Center and Acute Program service sites and location of other service providers."

B. CONU Discussion

i. Criteria

Relevant criteria for inclusion in this section are specific to the determination that the project ensures high-quality outcomes and does not negatively affect the quality of care delivered by existing service providers.

ii. CON Analysis

The applicant has demonstrated that they can ensure high-quality outcomes through the significant level of health indicators that they measure as discussed in prior sections. Existing service providers would not be impacted by this proposal in that they are significantly distant from the facility locations under review in this project.

[1] The Ellsworth Outpatient Center is approximately twenty-five (25) miles from the EMMC Acute Program.

iii. Conclusion

CONU recommends that the Commissioner find that the applicant has met their burden to demonstrate that this project will ensure high-quality outcomes and does not negatively affect the quality of care delivered by existing service providers.

VII. Service Utilization

A. From Applicant

"This transaction involves the purchase of assets and operation of existing dialysis programs currently owned and operated by EMMC. TRC does not anticipate or project any increase in patient volume and service utilization of dialysis services at the Outpatient Centers, Home Program, or Acute Program, above and beyond the annual 3.5 to 4 percent increase currently experienced by dialysis providers in the normal course."

"As noted in Section IV above, according to the latest annual report from the United States Renal Data System, at the end of 2009, the ESRD program in the United States was treating 571,414 dialysis and transplant patients, which was a 4.0 percent increase from 2008. There were 116,395 new cases of ESRD reported, which is 3.5 percent more than in 2008 and the largest increase since 2000. TRC expects the rate of increase in the use of ESRD services to remain at around 3.5 to 4 percent, particularly in light of the increase in incidence of contributing factors, such as diabetes and hypertension, with perhaps some slightly higher increases in Maine, reflecting the generally older population in Maine. The data from EMMC, which we used in our financial projections, demonstrates that growth is trending up at about 4.4% across all chronic programs. See also **Exhibit 4**. This growth is not a function of this transaction because, unlike some other services that may be subject to inappropriate utilization, such as diagnostic services, ESRD patients obtain the treatment because they have no choice."

"We do believe that currently, the EMMC ESRD population receives home treatment at a fairly low percentage to overall patients, and believe TRC can increase the number of patients receiving treatments at home. This, however, is a shift in treatment delivery and will not result in less overall service utilization."

B. CONU Discussion

i. CON Criteria

Relevant criterion for inclusion in this section are specific to the determination that the project does not result in inappropriate increases in service utilization, according to the principles of evidence-based medicine adopted by the Maine Quality Forum.

ii. CON Analysis

There are no opportunities to increase service utilization in this program due to the unique nature of the service. Accordingly, the project (acquisition of ERSD services) does not result in inappropriate increases in service utilization.

iii. Conclusion

CONU recommends that the Commissioner find that the applicant has met their burden to demonstrate that the project does not result in inappropriate increases in service utilization, according to the principles of evidence-based medicine adopted by the Maine Quality Forum.

VIII. Timely Notice

A. From Applicant

TRC filed its letter of intent on March 1, 2012. A Technical Assistance meeting was held on March 14, 2012. TRC will work with the Department to schedule a public informational meeting. The parties expect to close the transaction consistent with Article III of the Asset Purchase Agreement. See **Exhibit 1**.

B. CONU Discussion

Letter of Intent filed:	March 5, 2012
Technical Assistance meeting held:	March 14, 2012
CON application filed:	April 11, 2012
CON certified as complete:	April 11, 2012
Public Information Meeting Held:	May 25, 2012
Public Hearing Held:	July 10, 2012
Public comment period ended:	August 9, 2012

IX. CON Findings and Recommendations

Based on the preceding analysis, including information contained in the record, the CONU recommends that the Commissioner make the following findings and recommendations subject to the conditions below:

A. That the applicant is fit, willing and able to provide the proposed services at the proper standard of care as demonstrated by, among other factors, whether the quality of any health care provided in the past by the applicant or a related party under the applicant's control meets industry standards.

B. The economic feasibility of the proposed services is demonstrated in terms of the:

1. Capacity of the applicant to support the project financially over its useful life, in light of the rates the applicant expects to be able to charge for the services to be provided by the project; and

2. The applicant's ability to establish and operate the project in accordance with existing and reasonably anticipated future changes in federal, state and local licensure and other applicable or potentially applicable rules;

C. The applicant has demonstrated that there is a public need for the proposed services as demonstrated by certain factors, including, but not limited to;

1. The extent to which the project will substantially address specific health problems as measured by health needs in the area to be served by the project;

2. The project has demonstrated that it will have a positive impact on the health status indicators of the population to be served;

3. The project will be accessible to all residents of the area proposed to be served; and

4. The project will provide demonstrable improvements in quality and outcome measures applicable to the services proposed in the project;

D. The applicant has demonstrated that the proposed services are consistent with the orderly and economic development of health facilities and health resources for the State as demonstrated by:

1. The impact of the project on total health care expenditures after taking into account, to the extent practical, both the costs and benefits of the project and the competing demands in the local service area and statewide for available resources for health care;

2. The availability of State funds to cover any increase in state costs associated with utilization of the project's services; and

3. The likelihood that more effective, more accessible or less costly alternative technologies or methods of service delivery may become available was demonstrated by the applicant;

In making a determination under this subsection, the commissioner shall use data available in the state health plan under Title 2, section 103, data from the Maine Health Data Organization established in chapter 1683 and other information available to the commissioner. Particular weight must be given to information that indicates that the proposed health services are innovations in high quality health care delivery, that the proposed health services are not reasonably available in the proposed area and that the facility proposing the new health services is designed to provide excellent quality health care.

E. The applicant has demonstrated that the project ensures high-quality outcomes and does not negatively affect the quality of care delivered by existing service providers;

F. The applicant has demonstrated that the project does not result in inappropriate increases in service utilization, according to the principles of evidence-based medicine adopted by the Maine Quality Forum.

CON RECOMMENDATION: For all the reasons contained in this preliminary analysis and based upon information contained in the record, CONU recommends that the Commissioner determine that this project should be **approved with the following condition:**

1. DaVita will provide CONU, 15 days before the project is commenced, the plans for the development of a Patient Support Board, describing its responsibilities, proposed meeting schedule and other pertinent information. An approved summary of Board activities will be forwarded to CONU within 60 days of each board meeting. This Patient Support Board will be required to meet at least quarterly for the first three years following commencement of this project.