**Preliminary Analysis**

**Date: October 18, 2013**

**Project**: **Acquisition of Control through purchase of Dialysis Services Program located at Maine General Medical Center in Waterville, Maine.**

**Proposal by: Dialysis Clinic, Inc.**

**Prepared by: Phyllis Powell, Assistant Director, Medical Facilities**

**Larry Carbonneau, Manager, Health Care Oversight**

**Richard S. Lawrence, Senior Health Care Financial Analyst**

**Directly Affected Party None**

**Certificate of Need Recommendation: Approved**

 **Proposed Approved**

 **Per Applicant** **CON**

Estimated Capital Expenditure $ 3,000,000 $ 3,000,000

Maximum Contingency $ 0 $ 0

Total Capital Expenditure with Contingency $ 3,000,000 $ 3,000,000

Pro-Forma Marginal Operating Costs $ 261,833 $ 261,833

# I. Abstract

1. **From Applicant**

“Dialysis Clinic, Inc. (DCI) desires to purchase the existing dialysis program at Maine General Medical Center, Thayer Campus, 149 North Street, Waterville, Maine 04901. This application requests a change of ownership. The existing dialysis program at Maine General Medical Center (MGMC) has fourteen (14) dialysis stations and operates six (6) days a week. Pending Certificate of Need Unit (CONU) approval DCI will assume ownership of the MGMC program in Waterville on January 1, 2014. No changes are planned in location or available stations, although the chronic program is nearing capacity at this time. The service area will remain primarily in Kennebec County. If approved the DCI clinic in Waterville will continue to serve those patients in Kennebec County who have been identified in the existing Certificate of Need (CON) for MGMC.”

“DCI operates a 12 station dialysis facility in Skowhegan located at 27 Research Drive, Skowhegan, Maine 04976 and a 12 station In-center and Home dialysis program in Belfast located at 125 Northport Ave., Suite 101, Belfast, Maine 04915.”

“The change of ownership will not impact service delivery. The local Medical Director and DCI will provide clinical oversight for the facility. Nephrologists at MGMC will continue to fulfill the role of Medical Director. DCI believes that it can improve the facility’s financial performance while billing in accordance with the rates established by CMS. State and Federal government finances will not be affected.”

“The purchase price is estimated to be $3,000,000.00 including assets of the dialysis program at MGMC. The final price may vary slightly to account for the existing inventory of supplies and employee benefits.”

1.

**B. CONU Comments**

This transaction is subject to certificate of need review per 22 M.R.S.A §329 which states that a certificate of need from the department is required for any transfer of ownership or acquisition under lease or comparable arrangement or through donation or any acquisition of control of a health care facility under lease, management agreement or comparable arrangement or through donation that would have required review if the transfer or acquisition had been by purchase, except in emergencies when that acquisition of control is at the direction of the department.

# II. Fit, Willing and Able

**A. From Applicant**

“Dialysis Clinic, Inc. (DCI) is fit, willing and able to acquire the assets of Maine General Medical Center’s dialysis services business, including outpatient and home program dialysis services. DCI will provide dialysis services to the residents of the greater Waterville area at the current MGMC location.”

“DCI operates 210 outpatient dialysis clinics in 27 states. The Company provides inpatient dialysis services to more than 100 hospitals. The experience DCI has gained through clinical operations in each program is relevant to every facility with which DCI is affiliated. DCI has a reputation for delivering exceptional outcomes and meeting both CMS and State guidelines.”

“The most recent (2012) USRDS (United States Renal Data System) survey confirms the commitment to patient care which has been part of the Company’s mission since 1971. Below is a summary of the findings.”

“DCI continues to have the lowest Standard Hospitalization Ratio (SHR) — in 2010, 10 percent lower than those of the other Large Dialysis Organizations (LDOs).”

“For 2010, by unit affiliation among the LDOs, DCI continues to have the lowest ratios for both hospitalization and mortality.”

“Since 2009 DCI has provided dialysis services at the lowest cost to CMS.”

“In Maine, DCI began operations in 2003 in Skowhegan and subsequently in Belfast in 2006. The local team of caregivers is familiar with CMS and State of Maine licensure requirements and by continuing to meet the guidelines has demonstrated a commitment to patient care and safety.”

“MGMC has a reputation for quality patient outcomes in its dialysis program. DCI operates 210 dialysis clinics, a dedicated renal laboratory, a renal pharmacy, three organ procurement organizations (OPOs), hospital services in more than 100 locations, an office of Clinical Research, and a robust proprietary medical information system (Darwin). Collectively, the resources and the commitment exist to produce patient outcomes of the highest quality.”

1. **CONU Discussion**

**CON Standard**

The relevant standard for inclusion in this section is 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.

If the applicant is a provider of health care services that are substantially similar to those services being reviewed and is licensed in the State, the requirements of this paragraph are deemed to have been met if the services previously provided in the State by the applicant are consistent with applicable licensing and certification standards.

**CON Analysis**

Dialysis Clinic, Inc. (DCI) plans to purchase the assets of Maine General Medical Centers dialysis unit located in Waterville, Maine. In order to assess the applicants’ ability to operate the Waterville facility in accordance with industry standards the CONU obtained the most recent Federal and State surveys pertaining to DCI operations in Belfast and Skowhegan. The Skowhegan facility received no State deficiencies during its July 31, 2013 survey and no Federal deficiencies during its Re-Certification survey conducted on December 7-8, 2011. The Belfast facility received two State deficiencies during its’ May 29, 2013 survey. Expired medication was in stock and blood spills were not disinfected properly. A plan of correction was received by the Department of Health and Human Services, Division of Licensing and Regulatory Services on July 1, 2013.These deficiencies were corrected immediately. No Federal deficiencies were noted during its’ November 8-9, 2011 Re-Certification survey.

**Deeming of Standard**

As provided for at 22 M.R.S. § 335 (7)(B), if the applicant is a provider of health care services that are substantially similar to those services being reviewed and is licensed in the State, the applicant is deemed to have fulfilled the requirements of this standard if the services provided in the State by the applicant during the most recent 3-year period are of similar size and scope and are consistent with applicable licensing and certification standards.

**Conclusion**

CONU recommends that the Commissioner find that the applicant has met their burden to show that the applicant is fit, willing and able.

# III. Economic Feasibility

**A. From Applicant**

“The acquisition of the dialysis services of MGMC has been carefully reviewed for financial feasibility and sustainability. Projections were modeled to consider changes in Federal, State and private reimbursement as well as fluctuations in the cost to provide quality dialysis services. DCI will fund the purchase price with internal cash reserves without need for external financing.”

“Dialysis Clinic, Incorporated (DCI) currently operates 210 dialysis clinics in 27 states. The proposed facility will become an adjunct to existing services offered in Skowhegan (2003) and Belfast (2006). Members of the local and Corporate management support team are familiar with, and operate within, the guidelines for end-stage renal disease (ESRD) clinics in the State of Maine. The DCI Administrator for the MGMC clinic is presently responsible for facility operations in two existing units owned and operated by DCI in Skowhegan and Belfast. Through its experience in Maine DCI has developed policies and procedures that comply with both Federal (CMS) and State of Maine licensure regulations. The DCI compliance, education and quality management departments provide support to the local team of caregivers to aid in meeting current and evolving regulations.”

**B. CONU Discussion**

**CON Standard**

The relevant standards 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.If the applicant is a provider of health care services that are substantially similar to those services being reviewed and is licensed in the State, the applicant is deemed to have fulfilled the requirements. This is allowable if the services provided in the State by the applicant during the most recent 3-year period are of similar size and scope and are consistent with applicable licensing and certification standards.

**CON Analysis**

In 1972, the US Congress passed legislation authorizing the End Stage Renal Disease (ESRD) program under [Medicare](http://en.wikipedia.org/wiki/Medicare_%28United_States%29). Section 299I of Public Law 92-603 extended Medicare coverage to Americans if they had [stage five chronic kidney disease (CKD)](http://en.wikipedia.org/wiki/Chronic_kidney_disease) 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](http://en.wikipedia.org/wiki/Chronic_kidney_disease) 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.

In order to determine the ability of the applicant to support the project financially over its useful life CONU obtained copies of Dialysis Clinic, Inc. September 30, 2012 consolidated financial statements. The applicant plans to pay $3,000,000 for the assets of Maine General Medical Centers dialysis operations located in Waterville, Maine. This will not require any borrowing since Dialysis Clinic, Inc. has over $200,000,000 in cash and cash equivalents on its balance sheet. CONU reviewed current income statements and projected income statements for the Waterville operations. Dialysis Clinic, Inc. is predicting profitable operations in both year 2 and year 3 of this project. In the event that the results of operations fall short of expectations the applicant has sufficient financial resources to operate the Waterville facility.

As stated previously the applicant currently operates two dialysis programs in Belfast and Skowhegan and is familiar with the regulatory environment in the State of Maine. CONU is unaware of any proposed changes to regulations that would adversely affect Dialysis Clinic, Inc. operations.

**Conclusion**

CONU recommends that the Commissioner determine that the applicant has demonstrated that the project is economically feasible.

# IV. Public Need

**A. From Applicant**

“Acquisition of the dialysis services program of MGMC by DCI does not include the provision of any new service. The project is a change of ownership and the continuation of dialysis services currently provided by MGMC to residents in the Waterville area. DCI will continue to offer home and facility / in-center based dialysis services.”

“DCI believes strongly in the benefits of chronic kidney disease education and the coordination of care across providers. Through education DCI intends to help patients become more familiar and engaged in their care and subsequently more wise health care consumers with an emphasis on kidney disease.”

“Heath measures and outcomes for dialysis patients are addressed below. Improvements in a patient’s health status may be measured by patient satisfaction scores, prolonged renal function and delayed onset of end-stage renal disease (ESRD), well managed blood sugar, controlled hypertension, and transplantation to name a few.”

“The DCI facilities in Belfast and Skowhegan exceed the Company goal for patient satisfaction. The most recent satisfaction surveys indicate that 84% and 85% of the patient respondents rated the clinics as very good or excellent respectively.”

“Patient functional status is assessed using the Short Form 36 (SF-36) Health Survey. The questionnaire contains 36 items that measure eight dimensions: physical functioning, role limitations due to physical problems; social functioning, bodily pain, general mental health, role limitations due to emotional problems, vitality, and general health perceptions. Results are analyzed and reported quarterly.”

“The DCI Clinic Report Card patient satisfaction survey is a tool designed to assess the patient's perception about the care they receive, and to evaluate the interpersonal aspects of patient care. The questionnaire addresses the following issues: patient autonomy; patient education; staff concern, support, and professionalism; scheduling; and overall quality of care and services.”

“MGMC and DCI have active chronic kidney disease (CKD) education and care coordination programs. DCI is committed to continuing and growing the program at MGMC in Waterville. Within DCI CKD education means: 1) Three (3) times more patients begin dialysis treatments with a fistula in place (For most patients the preferred type of access. Patients with a catheter are more prone to infections.); 2) Almost six (6) times more patients receive their first treatment via their fistula; 3) As many as ten (10) times more patients choose a home based modality / therapy. Care coordination focuses on patients who are at high risk of hospital admission or readmission. Patients most likely to be admitted / readmitted to a hospital are: 1) Patients with a catheter; 2) Patients with a dual diagnosis of congestive heart failure (CHF) and Stage V chronic kidney disease (CKD); Patients within their initial 120 days since initiation of dialysis.”

“Each month a clinical Report Card is created for every DCI facility. The Report Card tracks 12 key clinical indicators which are trended and benchmarked against DCI goals. Report Card data is reviewed by each clinic in monthly quality meetings (QAPI). In addition, Corporate level support is provided by a team of registered nurses with extensive experience in chronic kidney disease.”

“The DCI clinic will serve persons with chronic kidney disease who reside in the greater Waterville area. Quality dialysis care will be provided, without discrimination, to all patients.”

“MGMC has a reputation for quality patient outcomes in its dialysis program. DCI operates 210 dialysis clinics, a dedicated renal laboratory, a renal pharmacy, three organ procurement organizations (OPOs), hospital services in more than 100 locations and an office of Clinical Research. Collectively, the resources and the commitment exist to produce patient outcomes if the highest quality.”

“The most recent (2012 – which used 2010 data) USRDS (United States Renal Data System) survey confirms the commitment to patient care which has been part of the Company’s mission since 1971. Below is a summary of the findings.”

“DCI continues to have the lowest Standard Hospitalization Ratio (SHR) — in 2010, 10 percent lower than those of the other Large Dialysis Organizations (LDOs).”

“By unit affiliation among the LDOs, DCI continues to have the lowest ratios for both SHR and Standard Mortality Ratio (SMR).”

“Since 2009 DCI has provided dialysis services at the lowest cost to CMS. Through the Corporate office a Medical Information System (MIS) is used by all DCI facilities. This computer system represents a valuable research tool and also serves to enhance clinical operations. The MIS allows for laboratory, research and patient treatment information to be compiled from the different disciplines to provide a complete picture of the care given to the patient. The MIS also contains programs in urea kinetic modeling, for both hemodialysis and peritoneal therapies, and a nutritional information section to assist dietitians.”

“DCI recognizes that a transplant is the best option for many patients. The Company dedicates a significant portion of its resources to furthering the transplantation of kidneys for its patients. To this end, the Corporation operates independent organ procurement agencies in Nashville, Tennessee; Albuquerque, New Mexico; and Sacramento, California.”

1. **CONU Discussion**

**CON Standard**

The relevant standard 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.

**CON Analysis**

The applicant has demonstrated that there is an ongoing need for the services by providing utilization data for the Skowhegan, Belfast and Waterville locations. DCI provides in-center hemodialysis to 34 patients in Skowhegan. 21 patients get in-center hemodialysis treatment and 3 patients receive peritoneal dialysis in Belfast. The current operations of Maine General Dialysis Services in Waterville provide in-center hemodialysis to 45 patients. The home program provides peritoneal dialysis to 6 patients and home hemodialysis to 4 patients. Dialysis Clinic, Inc. believes that patient growth will remain consistent with the national average given the historical utilization data of their Maine owned clinics.

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. 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. As stated by the applicant positive impacts on the health status indicators of the population to be served are, prolonged renal function and delayed onset of end-stage renal disease (ESRD), well managed blood sugar, controlled hypertension, and transplantation.

The acquisition of the Waterville dialysis operations will not affect the accessibility of services. The facility will continue to provide dialysis services in a manner that is convenient to patients in the greater Waterville area.

The applicant has described numerous benchmarks and quality assurance measures it uses to monitor patients’ treatment results. Continuing to provide needed services in the Waterville area will provide demonstrable improvements in quality and outcome measures.

**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 in conjunction with the recommended condition.

# V. Orderly and Economic Development

**A. From Applicant**

“The application seeks approval for a change of ownership of an existing dialyis program and its affiliated services. DCI anticipates that it will bring efficiencies to the dialysis services currently offered by MGMC. State and local competing demands for health care services will not be impacted.”

“No increase in cost is associated with the services of this project and therefore no additional State funds will be required per patient.”

“DCI encourages and pursues efficient methods and less costly options to provide dialysis care. Developing treatment options and equipment, particularly in home based therapies, show promise for care which is preferred by many patients, provides exceptional outcomes and is less resource intensive than traditional in-center dialysis.”

“The DCI Supply Department negotiates national agreements for medications and medical supplies for all 210 DCI clinics. Effective purchasing strategies and the thoughful use of supplies are critical to sustainability.”

“Transplantation may be the best outcome for most dialysis patients. Recognizing that a shortage of organs, which are available for transpantation, exists the DCI healthcare team emphasizes strategies to prolong renal function and delay the onset of end-stage renal disease (ESRD).”

**B. CONU Discussion**

**CON Standard**

The relevant standard 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.

**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. The majority of these services are paid for by Medicare. Only 9.05% of services at the Belfast and Skowhegan location and 4% of the services at the Waterville location are reimbursed through MaineCare. There should not be any increased utilization of these services because this purchase involves continuation of existing services and does not involve the addition of any new services.

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.

**Conclusion**

The Certificate of Need Unit 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.

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# VI. Outcomes and Community Impact

**A. From Applicant**

“Medical Director Services will be provided by MGMC. DCI plans for the existing clinical team members to continue to provide care to the patients and the community they know well. DCI is committed to transplantation, early education for patients with chronic kidney disease (to delay or negate the need for dialysis), and the coordination of care in an effort to minimize hospital admissions and readmissions.”

“The DCI QM program is built around the principles contained in the Joint Commission for Accreditation of Health Care Organizations (JCAHO) modified l0-step model (structure) and Deming's Total Quality Management model for CQI (process). Specific areas addressed include: identification of patient needs, measurement of quality, setting goals, creating the means for achieving continuous quality improvement and learning from past experiences, evaluating cost-effectiveness, developing and maintaining information systems and databases, and establishing information-driven decision making (Couch, 1991).”

“The DCI QM structure and process is evaluated on an ongoing basis. The areas reviewed include team participation (QM Minutes), establishing indicator criteria and goals, and data quality and analysis. The effectiveness of the program is evaluated using benchmarking techniques comparing DCI aggregate data to national benchmarks (NKF Kidney Disease Outcomes Quality Initiative (K/DOQI), CMSIESRD Network Clinical Performance Measures (CPM), and the US Renal Data Systems (USRDS)), assessment of functional status and patient satisfaction.”

“The facility-specific QM programs monitor clinical indicators including adequacy of dialysis, anemia, nutrition, osteodystrophy, CV risk factors, morbidity and mortality. Technical indicators for water treatment, dialyzer reprocessing and equipment maintenance are monitored and reviewed.”

“The corporate QM program monitors these quality indicators as individual clinic data and as corporate-wide composite data. Adequacy of dialysis is monitored by tracking prescribed and delivered dialysis dose (spKtN), urea reduction ratio (URR), and hours on dialysis. Nutritional indicators include serum albumin, normalized protein catabolic rate (nPCR), and body mass index (BMI). Anemia is monitored by tracking calculated hematocrit, hemoglobin, iron, ferritin, total iron binding capacity (TIBC), transferrin, % transferrin saturation, and EPO dose. Osteodystrophy indicators include calcium, adjusted calcium (corrected for serum albumin), phosphorus, calcium-phosphorous product, alkaline phosphatase, and parathyroid hormone. Cardio-vascular (CV) risk factor indicators include cholesterol, triglycerides, and pre- and post- dialysis blood pressure (BP) control. The average systolic, diastolic, and mean arterial blood pressures are calculated, and antihypertensive medications are tracked.”

“Quality indicators followed for peritoneal dialysis patients include laboratory data for adequacy, anemia, nutrition, osteodystrophy, CV risk factors, peritonitis and exit site infection rates, and outcomes. Corporate QM calculates standardized mortality ratios (SMR), and Kaplan-Meier survival curves annually.”

“The proposed facility is intended to provide dialysis services in a manner that is convenient to patients and continues to meet a demonstrated demand for dialysis services in Waterville and the surrounding area. The proposed change of ownership is unlikely, and is not intended, to have any negative consequence on the quality of care delivered by existing providers.”

**CONU Discussion**

**CON Standard**

The relevant standard 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.

**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.

**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**

“The acquisition of the dialysis services program at MGMC will not result in an inappropriate Increase in the utilization of services.”

“The clinic nephrologist and Medical Director determine the most clinically advantageous treatment regimen for each patient. Most dialysis patients receive three (3) treatments each week. Fewer require more frequent treatments if determined to be clinically necessary by the patient’s nephrologist. Nationally less than 10% of dialysis patients choose a home based treatment option some of which may require more than three (3) treatments per week. High rates of diabetes and hypertension will likely continue to contribute to an annual incident ESRD growth rate of three to four percent (3 – 4%).”

“CMS (Centers for Medicare and Medicaid Services) requires that each patient receive education about his or her dialysis treatment and modality options. Patient education and choice is an important factor in controlling the utilization of services.”

“While we endeavor to serve patients who require dialysis treatments the clinical team at DCI believes a system which promotes education, encourages transplantation, prolongs existing renal function and emphasizes modality choice will provide exceptional patient outcomes at the lowest cost to Federal and State agencies.”

**B. CONU Discussion**

**CON Standard**

The relevant standard 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 as established in Title 24-A, section 6951, when the principles adopted by the Maine Quality Forum are directly applicable to the application.

**CON Analysis**

This project involves continuation of existing dialysis services and no addition of new health services. Due to the unique and specialized nature of the services provided there would be little opportunity for inappropriate increases in service utilization.

**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. Timeline

Letter of Intent filed: June 17, 2013

Technical Assistance meeting held: Waived

CON application filed: August 1, 2013

CON certified as complete: August 1, 2013

Public information meeting held: Waived

Public hearing held N/A

Close of Public Record August 31, 2013

# 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.** 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;

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

**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.