

CERTIFICATE OF NEED
DEPARTMENT STAFF PROJECT SUMMARY, ANALYSIS & RECOMMENDATIONS
Request to Close Kidney Transplant Surgical Service and Continuation of
Heart/Kidney Transplants Under Heart Transplant Program

Facility Name: Newark Beth Israel Medical Center CN #: FR 150805-07-01

Applicant Name: Barnabas Health Total Project Cost: None

Location: Newark (Essex County) Equity Contribution: N/A

Project Description:

Transplantation is a specialty health care service requiring full Certificate of Need (CN) review which is regulated by the Department of Health (Department) under the Transplantation Services CN regulations (N.J.A.C. 8:33Q.) Kidney transplantation is a highly specialized regional service for which the demand is a function of the number of eligible patients on the waiting list and the number of available live and cadaver kidneys.

Newark Beth Israel Medical Center (NBI or Applicant) filed a full review CN application to permanently close its kidney transplant surgical service but to continue to provide heart/kidney transplants under the heart transplant program at NBI. The applicant's intent upon Department CN approval is to continue to provide pre-transplant evaluation and post-kidney transplant surgical follow-up, as well as perform heart/kidney transplants under the Director of the heart transplant program. The surgical component of the program was previously suspended at NBI and consolidated with the Saint Barnabas Medical Center (St. Barnabas) program through an expedited review CN approval.

In March 2014, NBI filed an expedited review CN for the temporary suspension of kidney transplant surgical services, which the Department approved effective through December 31, 2015. A condition of approval required NBI to submit a full review CN for permanent closure or the reopening of the kidney transplant surgery service by September 3, 2015. This full review CN to permanently close the surgical program satisfies this previous CN condition.

On August 5, 2013, NBI notified the Department of its intent to suspend the surgical component of the kidney transplant program and its wish to maintain the CN in a state of suspension for a period of up to two years in accordance with N.J.A.C. 8:33-3.2(a). NBI's intent was to transfer surgical services of the program to its member hospital, St. Barnabas, which is a high volume program located seven miles from NBI, that shared common administrative and surgical teams. NBI also intended to maintain pre-transplant evaluation and post-transplant follow-up care on its campus.

Transplant programs are carefully monitored at the federal level by the Centers for Medicare and Medicaid Services (CMS) and the Health Resources and Services Administration (HRSA) under the National Organ Transplant Act (NOTA), which called for an Organ Procurement and Transplantation Network (OPTN) to be created and run by a private, non-profit organization under federal contract. United Network for Organ Sharing

(UNOS) is the federal contracting agency that collects data from all transplant sites in the United States. Because transplant programs are regulated by federal as well as state government, NBI notified CMS and UNOS of its intent to withdraw from the kidney transplant program effective January 1, 2014. The Department recognized this date as the beginning of the program's two-year suspension, which expired December 31, 2015.

In accordance with the conditions on its expedited review (ER) CN approval for temporary suspension, NBI has been providing a full-service satellite transplant clinic in which pre-transplant evaluation and post-transplant follow-up care are provided for those patients under care of St. Barnabas' kidney transplant program. Its parent organization, Barnabas Health, has also provided free transportation services to and from the transplant programs at St. Barnabas, as well as the transplant clinic at NBI, to those patients who have no other financial access to transportation. In addition, NBI's heart transplant program collaborates with the St. Barnabas kidney transplant program to assess, evaluate and manage the kidney transplant aspects of heart/kidney transplant recipients. St. Barnabas' kidney transplant Medical Director or designee serves as the Medical Director of kidney transplant for the heart/kidney transplant program at NBI. The applicant intends to continue to provide pre-transplant evaluation and post-transplant follow-up care at a full-service satellite transplant clinic; free transportation services to and from the transplant programs at St. Barnabas and the transplant clinic at NBI for patients without financial access; and the collaboration among the Medical Directors of the St. Barnabas and the NBI transplant programs upon CN approval to permanently close the kidney transplant surgical service.

Applicant's Justification of Need:

The applicant's decision to suspend and now permanently close the kidney transplant program and shift services to St. Barnabas was prompted by the decrease in NBI's transplant volume over time and the goals of (1) quality patient outcomes enhancement and (2) cost reduction of providing these services; thereby contributing to the orderly development and provision of adequate and effective health care delivery.

In terms of goal 1, the applicant states that since the consolidation, its regional program has seen a 1% decline in mortality from 3% to 2%; and a 4% decline in graft failures for kidney transplants from 6% to 2%. Quality metrics for readmission, return to operating room (OR), and complications for the regionalized program in 2014 were at or below expected measures. Goal 2 involving cost reduction was also realized in that the regional program has seen a savings of \$2.1 million in operational costs and cost avoidances in the first year of operation of the regionalized service. Consolidating services avoided the need to duplicate services at both hospitals and the costs necessary to maintain a required full-time physician for the surgical component at NBI. Additionally, two FTEs were reassigned to other NBI Departments. The applicant states that it has realized its goals of patient outcomes enhancement and cost reductions.

Prior to the suspension of services at NBI, Barnabas Health operated two kidney transplant programs located seven miles apart at NBI and St. Barnabas. The transition of patients from NBI to St. Barnabas occurred as part of the expedited CN approval and patients on NBI's transplant wait list were absorbed into St. Barnabas' wait list according to patient preference. As part of the consolidation, the applicant states that the decision to maintain the bulk of patient care time at NBI for pre-evaluation and post-transplant follow up visits has resulted in no negative impact on access for minority patients. NBI patients from its primary service area have been successfully transferred to St. Barnabas' program as documented by the increase in the number of patients evaluated and transplants among minorities at St. Barnabas. Between 2011 and 2014, transplants among Black patients increased by 31.8% and between 2014 and the first half of 2015, transplants increased by 45.6%. Of the 1,580 candidates on St. Barnabas' kidney transplants wait list on August 14, 2015, 39% were Black, 15% Hispanic, 10% Asian, and 36% White. In terms of payer status, kidney transplantation is skewed towards a specific End Stage Renal Disease (ESRD) population with high Medicare coverage. Government payers, Medicare and Medicaid, represented over 85% of transplants at NBI in 2013. Payer data suggests these cases have readily migrated to St. Barnabas as governmental payers were 70% of payer mix in 2013 and 72% in 2014 at St. Barnabas.

The applicant states that there is sufficient access at other kidney transplant programs in New Jersey to meet the needs of the State. Besides the consolidated program at St. Barnabas, there are three other kidney transplant programs in the State (Hackensack University Medical Center, Robert Wood Johnson University Medical Center and Our Lady of Lourdes Medical Center.) There are also 17 programs in New York State and 18 programs in Pennsylvania. The applicant states that in 2013, 49 New Jersey residents received kidney transplants in New York and 101 received transplants in Pennsylvania. The applicant states that there is sufficient capacity at St. Barnabas to accommodate the NBI cases with 47% remaining operating room capacity. Also, St. Barnabas was licensed for 4 additional operating rooms in April 2016, which further enhances capacity for the expanded program.

NBI is a fully credentialed kidney center through UNOS for simultaneous heart/kidney transplants. The St. Barnabas kidney transplant team would continue to assess and clinically manage patients with the heart transplant team for this low volume of specialized patients. The vast majority of these patients are at NBI awaiting a heart transplant and are too ill to be moved. There were only 3 heart/kidney transplant cases performed during 2012 and 2013 combined. Since the temporary closure of NBI's kidney transplant surgical program in 2014, NBI has listed 12 patients for heart/kidney transplants and performed 4 heart/kidney transplants between January 1, 2014 and August 1, 2015. At the time of the CN filing (August 1, 2015), there were 2 patients on the active heart/kidney transplant wait list.

Applicant's Statement of Compliance with Statutory and Regulatory Requirements:

The applicant has stated the following to demonstrate its compliance with statutory criteria set forth in the Health Care Facilities Planning Act, as amended, at N.J.S.A. 26:2H-1 et seq., and N.J.A.C. 8:33-1.1 et seq. as follows:

1. Availability of facilities or services, which may serve as alternatives or substitutes:

The applicant states that there is sufficient capacity at other providers of transplant services. St. Barnabas is located within seven miles of NBI. There are also other kidney transplant programs within New Jersey at Hackensack University Medical Center, Our Lady of Lourdes Medical Center and Robert Wood Johnson University Hospital, as well as programs in New York and Pennsylvania which serve as substitutes for this highly specialized service.

2. The need for special equipment or services in the area:

The applicant states that as the proposed project relates to the regionalization and consolidation of existing services, there is no need for additional special equipment or services.

3. The adequacy of financial resources and sources of present and future revenues:

The applicant states that the project allows for the reduction of service duplication and that overall expenses were reduced or avoided by approximately \$2.1 million in the first year of consolidation. The applicant states that these savings will enhance financial results within the current reimbursement environment thereby enhancing Barnabas Health's ability to provide a quality program for the local community and region.

4. The availability of sufficient manpower in the several professional disciplines:

The applicant states that as the project relates to the regionalization and consolidation of existing services, there is no need for additional staff.

5. Will not have an adverse economic or financial impact on the delivery of health care services in the region or statewide and will contribute to the orderly development of adequate and effective health care services:

The applicant states that since the temporary closure on January 1, 2014, it has not seen evidence that access to transplantation has been compromised. The applicant continues to operate a full service satellite at NBI for pre-transplant

evaluation and out-patient follow-up care. The regional program continues to facilitate and coordinate pre-transplant testing for both recipients and donors at local facilities for patient convenience. Transportation has not been an obstacle for patients because St. Barnabas is easily accessible via public transportation and 60% of the patients from the area are Medicaid beneficiaries who have access to transportation assistance. In addition, Barnabas Health will provide free transportation services to and from the transplant program at St. Barnabas as well as the transplant clinic at NBI to those patients who have no other financial access to transportation. There has not been a decrease in pre-transplant evaluations of patients from the greater Newark area and there were increases in pre-transplant evaluations of patients beyond the greater Newark area. St. Barnabas has seen an increase in the percentage of minority patients evaluated between 2011 and 2014.

Public Hearings:

The State Health Planning Board held a public meeting at **St. John's Community Baptist Church in Newark, NJ on Thursday, May 12, 2016**. Approximately 7 people attended the meeting, of which 3 were Saint Barnabas representatives. The Chief of the Renal and Pancreas Transplant Program, Dr. Shamkant Mulgaonkar, provided both oral and written testimony which summarized the application and stated there have been positive outcomes that have occurred with the consolidation of the kidney program and that overall quality and cost savings exceed the slight inconvenience of having transplant surgery occurring 7 miles away. There were no community members present. No additional information was requested of the Applicant or Department.

Track Record:

Department staff have not identified any track record violations in the past 12 months to warrant denial of this application.

Department Staff Analysis:

The minimum volume standard for kidney transplant programs is 25 procedures (N.J.A.C. 8:33Q.) Both programs exceeded this requirement with St. Barnabas being the largest volume provider in the State, having performed 297 transplants in 2015. NBI's kidney transplant volume was 87 cases in 2010 and 47 in 2013 (43% decline). St. Barnabas's kidney transplant volume was 201 in 2010 and 297 in 2015 (47% increase.)

The minimum volume standard for heart transplant programs is 12 procedures annually (N.J.A.C. 8:33Q). NBI maintains one of the two New Jersey heart transplant programs and performed 57 of the 71 heart transplants in the State in 2015. Robert Wood Johnson University Hospital (RWJUH) is the other New Jersey program which performed 14 heart transplants in 2015. NBI maintains the infrastructure needed to perform heart/kidney transplants when necessary.

NEW JERSEY KIDNEY TRANSPLANTS BY PROGRAM

	2015	2014	2013	2012	2011	2010
All Centers	420	335	371	394	432	437
Our Lady of Lourdes	40	29	29	23	26	20
Robert Wood Johnson UH	61	47	54	72	78	87
Hackensack UMC*	16	17	8	6*	40	42
Saint Barnabas MC	297	239	233	221	207	201
University**	3	0	2	2	0	0
Newark Beth Israel***	3	3	47	70	81	87

*Hackensack's license was suspended by HHS; but reinstated May 16, 2013

**University kidney only as combined transplant with liver

***NBI reports heart/kidney transplants in each separate organ category since there is no heart/kidney category.

Source: UNOS

The Department reviewed distance and travel time to alternate kidney transplant programs as well as their volume to estimate capacity. The Department finds that based on the capacity of the other programs in New Jersey, there are adequate alternatives to serve as substitutes for NBI's program. Since transplantation is a regional service, the Department finds the distance to these alternative providers to be reasonable.

**Table 1
 Distance from Newark Beth Israel Medical Center
 to Other Kidney Transplant Programs**

Provider/Location	Distance from Newark Beth Israel Medical Center (miles)	Travel times from Newark Beth Israel Medical Center
Saint Barnabas Medical Center Livingston, NJ	8.6 mi	21 min
Hackensack University Med Center Hackensack, NJ	20.7 mi	31 min
Robert Wood Johnson University Hospital New Brunswick, NJ	28.6 mi	35 min
Our Lady of Lourdes Med Center Camden, NJ	71.3 mi	1 hr. 15 min
NY Presbyterian/Columbia New York, NY	24.0 mi	37 min
Mount Sinai Hospital New York, NY	28.4 mi	54 min
NY University MC New York, NY	18.2 mi	45 min
Hospital of Univ. of Pennsylvania Philadelphia, PA	93.4 mi	1 hr. 32 min
Thomas Jefferson Hospital Philadelphia, PA	88.5 mi	1 hr. 34 min

Source: Google Map

Adequacy of financial resources and sources of present and future revenues

According to audited financial statements for the fiscal year ending 12/31/2014, Barnabas Health, Inc., of which NBI is a member, is in good financial standing. The closure of the kidney transplant surgical services will not require additional financial resources.

Staff Recommendations

Department staff recommends approving NBI’s CN application to request permission to permanently close its surgical component of the kidney transplant program and continue to provide heart/kidney transplants under the heart transplant program at NBI.

Reasons:

The application meets statutory (N.J.S.A. 26:2H-1 et seq.) and regulatory (N.J.A.C. 8:33-3.2) criteria requirements for termination/discontinuance of a certificate of need regulated service. The kidney transplant surgical program has consolidated at St. Barnabas over the past several years through the temporary closure of the program and patients have been transitioned appropriately. Barnabas Health obtained approval from CMS and UNOS prior

to the temporary suspension of the program. NBI has been providing pre-transplant evaluations and post-follow up care to transplant patients in its service area and transportation has been provided as needed. The Department accepts the applicant's statements that there are adequate alternative programs and sufficient capacity at alternative programs and that access to care is being provided. The Department has found no evidence of a negative impact on access to services. In terms of the heart/kidney program, NBI in collaboration with St Barnabas' kidney transplant program has the infrastructure in place to properly treat and care for this highly specialized patient population.

Conditions:

1. Barnabas Health shall provide a full-service satellite transplant clinic at NBI's campus in which pre-transplant evaluation and post-transplant follow-up care will be provided for those patients under care of St. Barnabas' kidney transplant program. Clinic hours shall be consistent with patient demand. Any change to this condition shall be requested at least 120 days prior to implementation, and require prior written approval from the Department.
2. Barnabas Health shall provide free transportation services to and from the transplant program at St. Barnabas as well as the transplant clinic at NBI to those patients who have no other financial access to transportation. Any change to this condition shall be requested at least 120 days prior to implementation, and require prior written approval from the Department.
3. NBI's heart transplant program shall collaborate with the St. Barnabas kidney transplant program to assess, evaluate and manage the kidney transplant aspects of heart/kidney transplant recipients. St. Barnabas' kidney transplant Medical Director or designee shall serve as the Medical Director of kidney transplant for the heart/kidney transplant program at NBI.
4. Patient medical records related to NBI's closed kidney transplant service shall be maintained in accordance with N.J.S.A. 8:26:8-5 et seq. and N.J.A.C. 8:43G-15.1 following completion of the aforementioned closure. NBI shall inform the Department of the location of these records and how they may be accessed by the public. NBI shall provide this information on its website.
5. Barnabas Health shall report to the Department's Office of Certificate of Need and Healthcare Facility Licensure (CNHFL) concerning the status of all of the conditions referenced within the time frames noted in the conditions.
6. Barnabas Health shall file a licensing application with the CNHFL Program to execute the closure of the kidney transplant program at NBI.