



State of New Jersey
DEPARTMENT OF HEALTH
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CHRIS CHRISTIE
Governor

KIM GUADAGNO
Lt. Governor

CATHLEEN D. BENNETT
Commissioner

September 28, 2016

Darrell K. Terry Sr., MHA, MPH, FACHE
Interim President & CEO
Newark Beth Israel Medical Center
201 Lyons Avenue at Osborne Terrace
Newark, New Jersey 07712
dterry@barnabashealth.org

Re: CN# FR 15-0805-07-01
Certificate of Need Application for Closure of
Kidney Transplant Surgical Service and
Continuation of Heart/Kidney Transplants
Under Heart Transplant Program
Project Cost: \$0
Expiration Date: September 28, 2021

Dear Mr. Terry:

I am approving Newark Beth Israel Medical Center's (Newark Beth or Applicant) certificate of need (CN) application for the closure of the kidney transplant surgical service by means of the consolidation of kidney transplant services at Saint Barnabas Medical Center (St. Barnabas) and the continuation of heart/kidney transplants under the Heart Transplant Program located at Newark Beth in Newark, Essex County. Newark Beth and St. Barnabas are members of the Barnabas Health System which recently merged with Robert Wood Johnson University Health System to become RWJ Barnabas Health, known as RWJ Barnabas Health throughout this letter. There are no project costs associated with this project.

The Applicant's intent upon Department CN approval is to continue to provide pre-kidney transplant evaluation and post-kidney transplant surgical follow-up, as well as perform simultaneous heart/kidney transplants under the Director of the heart transplant program. The surgical component of the kidney transplant program was previously temporarily suspended at Newark Beth and consolidated with the St. Barnabas program through an expedited review (ER) CN approval (ER 14 0305-07-01.)

On August 5, 2013 Newark Beth notified the Department of Health (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). Since transplant programs are carefully monitored and regulated by the federal as well as state government, Newark Beth notified the Centers for Medicare and Medicaid Services (CMS) and the Organ Procurement and Transplant Network (OPTN) of its intent to withdraw from the kidney transplant program as of January 1, 2014. The Department recognized this date as the suspension of Newark Beth's kidney transplant program with an expiration date effective December 31, 2015.

On February 25, 2015, the Department approved Newark Beth's CN for the temporary suspension of the kidney transplant surgical service with several conditions, including the requirement that Newark Beth file a full review CN application in order to either reopen the surgical component of its kidney transplant service, or to permanently close the kidney transplant surgical service. This full review CN to permanently close the kidney transplant surgical program satisfies this previous CN condition.

The Applicant's decision to suspend and now permanently close the kidney transplant surgical service and shift services to St. Barnabas was prompted by the decrease in Newark Beth's transplant volume over time and the goals of (1) quality patient outcomes enhancement¹ and (2) cost reduction of providing these services; thereby contributing to the orderly development and provision of adequate and effective health care delivery. Prior to the suspension of services at Newark Beth, RWJ Barnabas Health operated two kidney transplant programs located seven miles apart at Newark Beth and St. Barnabas. The transition of patients from Newark Beth to St. Barnabas occurred as part of the expedited CN approval and patients on Newark Beth'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 Newark Beth for pre-evaluation and post-transplant follow up visits has resulted in no negative impact on access for minority patients. The Applicant states that it has realized its goals of patient outcomes enhancement and cost reductions. Attached is a table indicating by race and gender how many patients received kidney transplants at Newark Beth or St. Barnabas from 2010 through August 31, 2016.

In accordance with the conditions on its ER CN approval for temporary suspension of the kidney transplant surgical service, Newark Beth has been providing a full-service satellite transplant clinic in which pre-transplant evaluation and post-

¹ To ensure quality patient outcomes, the Office of Organ Transplantation within the United States Department of Health and Human Services, Health Resources & Services Administration, monitors all transplant center quality metrics (i.e., patient and graft survival, complication rates, and return to operating room), and will suspend a program if it falls below acceptable performance. Newark Beth's kidney transplant program has never been suspended by the Office of Organ Transplantation.

transplant follow-up care are provided for those patients under care of St. Barnabas' kidney transplant program. Its parent organization, RWJ Barnabas Health, has also provided free transportation services to and from the transplant program at St. Barnabas, as well as the transplant clinic at Newark Beth, to those patients who have no other financial access to transportation. In addition, Newark Beth's heart transplant program collaborates with the St. Barnabas kidney transplant program to assess, evaluate and manage the kidney transplant aspects of simultaneous 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 Newark Beth.

Newark Beth is a fully credentialed kidney transplant center through the OPTN 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. At the time of the CN filing (August 1, 2015), there were 2 patients on the active heart/kidney transplant wait list.

For the reasons that follow, I am approving, with conditions, the application submitted for the closure of the kidney transplant surgical service by means of the consolidation of kidney transplant services at St. Barnabas and the continuation of simultaneous heart/kidney transplants under the Heart Transplant Program located at Newark Beth. My decision to approve this CN application is consistent with the recommendation of the State Health Planning Board (SHPB), which unanimously recommended approval of CN# 15-0805-07-01 at its June 2, 2016 meeting. In reaching this decision, I considered the CN application for the closure of the kidney transplant surgical service and the continuation of heart/kidney transplants under the Heart Transplant Program located at Newark Beth, completeness questions and responses, the public hearing transcript, written comments and exhibits, Department staff recommendations and SHPB recommendations. The referenced materials are incorporated and made a part of this final decision.

Public Hearing

As part of the review process, the SHPB is required to hold at least one public hearing in Newark Beth's service area within 30 days of the application being declared complete by the Department. A public hearing was held on May 12, 2016 from 6:00 pm until 8:00 pm, at St. John's Community Baptist Church in Newark, NJ. Approximately 7 people attended the meeting, of which 4 were Barnabas Health 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 transplant program and that overall quality and cost savings exceed the slight inconvenience of having transplant surgery occurring seven miles away. There were no

community members present. No additional information was requested of the Applicant or Department.

Applicant's Concerns Regarding Certain Conditions

During the SHPB's June 2, 2016 meeting, the Chief of the Renal and Pancreas Transplant Program, Dr. Shamkant Mulgaonkar, raised concern about Condition 2 proposed in the Staff Recommendations, which required that "RWJ Barnabas Health shall provide free transportation services to and from the transplant program at St. Barnabas as well as the transplant clinic at Newark Beth 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." Dr. Mulgaonkar stated there was no need for patients to be transported from St. Barnabas to the transplant clinic and that the requirement is more burdensome than other transplant programs experience. The members of the SHPB discussed the Applicant's concerns regarding Condition 2 and approved an edit to the language to state that "RWJ Barnabas Health shall provide **or arrange for** free transportation services..."

After the SHPB meeting, the Applicant contacted the Department and recommended the following language change to Condition 2: "Newark Beth Israel Medical Center ~~RWJ Barnabas Health~~ shall ~~provide~~ **arrange** free transportation services **for Newark area residents** to and from the transplant program at St. Barnabas as well as the transplant clinic at Newark Beth to those patients who have no ~~other financial~~ access to transportation **or the financial means to obtain access**. Any change to this condition shall be requested at least 120 days prior to implementation, and require prior written approval from the Department."

I am in agreement with the SHPB recommendation in that the kidney transplant surgical service will be at St. Barnabas not at Newark Beth. The reference to RWJ Barnabas Health, is therefore appropriate. I am not in agreement with the Applicant's request to limit Condition 2 to "Newark area residents." I find that there is no definition of "Newark area resident" and, more importantly, transplant services are regional in nature and if a patient needs help with transportation to all the services involved with transplantation, then it should not matter where they live. For these reasons, I am approving Condition 2 as stated herein.

Analysis

The standards I am compelled to use in evaluating this application are set forth in statutory criteria (N.J.S.A. 26:2H- et seq.) and in regulations (N.J.A.C. 8:33, 8:33Q and 8:43G). I must be satisfied that the project submitted by Newark Beth is consistent with those requirements. N.J.S.A. 26:2H-8, as well as N.J.A.C. 8:33-4.9(a), provides for the

issuance of a certificate of need only where the action proposed in the application for such certificate is necessary to provide required health care in the area to be served, can be economically accomplished and maintained, will not have an adverse economic or financial impact on the delivery of health services in the region or statewide, and will contribute to the orderly development of adequate and effective health care services. In making such determinations, I must take into consideration the following: a) the availability of services which may serve as alternatives or substitutes; b) the need for special equipment and services in the area; c) the possible economies and improvement in services to be anticipated from the operation of joint central services; d) the adequacy of financial resources and sources of present and future revenues; e) the availability of sufficient manpower in several professional disciplines and f) such other factors as may be established by regulation.

As to the specifics of this application, N.J.S.A. 26:2H-8(a) requires that I consider the availability of facilities or services, which may serve as alternatives or substitutes. I note that St. Barnabas, which offers kidney transplantation services, is located within seven miles of Newark Beth. 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.

I also find that the requirement at N.J.S.A. 26:2H-8(b) to consider the need for special services or equipment within the area is not needed as the project relates to the regionalization and consolidation of existing services. With respect to N.J.S.A. 26:2H-8(c) regarding the possible economies and improvement in services, I find the requirement is met due to the consolidation of kidney transplant surgeries at St. Barnabas, which is the largest volume provider in the State having performed 297 kidney transplants in 2015. The Applicant states 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 since the temporary closure at Newark Beth. 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 Newark Beth.

N.J.S.A. 26-2H-8(d) requires consideration of the adequacy of financial resources and sources of present and future revenues. The application involves consolidation of existing services and the reduction of duplicative services and overall expenses which enhances RWJ Barnabas Health's financial results. With respect to N.J.S.A. 26:2H-8(e), regarding the availability of sufficient manpower in the several professional disciplines, the proposed project involves the regionalization and consolidation of existing services, therefore I am satisfied that this criterion is met since there will be no need for additional staff.

N.J.S.A. 26:2H-8(f) requires consideration of such other factors as may be established by regulation; therefore, I have taken into consideration the applicable administrative rules governing the services subject of full review (i.e., N.J.A.C. 8:33-1.1 et seq.). Newark Beth is in compliance with the access requirements set forth at N.J.A.C. 8:33-4.10(a) in that it states it provides care to all patients regardless of their ability to pay and is dedicated to removing artificial health care barriers for all New Jerseyans. Newark Beth also states that it complies with all State and Federal laws that preclude any health care provider from discriminating against low income persons, minorities and disabled individuals. In addition, Newark Beth states that since the temporary closure on January 1, 2014, it has not seen evidence that access to kidney 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 at St. Barnabas continues to facilitate and coordinate pre-transplant testing for both transplant recipients and living donors at both St. Barnabas and Newark Beth hospitals and clinics for patient convenience. Transportation has not been an obstacle for patients because RWJ Barnabas Health has been providing and will continue to provide free transportation services to and from the transplant program at St. Barnabas as well as the transplant clinic at Newark Beth 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 a 31.8% increase in the percentage of minority patients that have received transplants between 2011 and 2014. The Department verified this data and the accuracy of the applicant's statements. In addition, the Department found that the applicant demonstrated overall improvements in quality metrics (i.e., patient and graft survival, complication rate, return to the operating room) between 2012 when the two kidney transplant programs existed, and 2014 when the programs consolidated.

I find that Newark Beth has provided an appropriate project description, which includes information as to the total project cost, operating costs and revenues, services affected, equipment involved, source of funds, utilization statistics, and justification for the proposed project (N.J.A.C. 8:33-5.3(a)(1)); assurance that all residents of the area, particularly the medically underserved, will have access to services (N.J.A.C. 8:33-5.3(a)(2)); and has demonstrated a track record of substantial compliance with the Department's licensing standards (N.J.A.C. 8:33-5.3(a)(3)). Furthermore, I also find that Newark Beth has satisfied all applicable planning and licensing regulations pertaining to transplantation services (N.J.A.C. 8:33Q and 8:43G), specifically related to personnel and physical plant requirements as well as institutional commitment.

Approval with Conditions

Based on the foregoing, I am approving Newark Beth's application for permanent closure of its kidney transplant surgical service, and consolidation of kidney transplant

services at St. Barnabas. I also approve Newark Beth's continued ability to perform simultaneous heart/kidney transplants at Newark Beth subject to the following conditions:

1. Newark Beth shall provide a full-service satellite transplant clinic 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 written approval from the Department.
2. RWJ Barnabas Health shall provide or arrange for free prompt transportation services to and from the transplant program at St. Barnabas as well as the transplant clinic at Newark Beth to those patients who have no access to transportation or the financial means to obtain access. Any change to this condition shall be requested at least 120 days prior to implementation, and require written approval from the Department.
3. Newark Beth's heart transplant program shall collaborate with the St. Barnabas kidney transplant program to assess, evaluate and manage the kidney transplant aspects of simultaneous 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 Newark Beth.
4. Patient medical records related to Newark Beth'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. Within ten days of receipt of this letter, Newark Beth shall inform the Department's Certificate of Need and Healthcare Facility Licensure Program (CNHFL) of which entity within RWJ Barnabas Health retains ownership of these records, the location of the records and how they may be accessed by patients or authorized representatives. RWJ Barnabas Health shall also document to the Department that the entity retaining ownership of these medical records has acquired data breach insurance which protects all of these records. Such documentation shall be forwarded to CNHFL within ten days of receipt of this letter. Newark Beth shall also provide information on its website regarding the location of these records and how they may be accessed by patients or authorized representatives.
5. RWJ Barnabas Health shall report to the CNHFL Program concerning the status of all of the conditions referenced within the time frames noted in the conditions.
6. RWJ Barnabas Health shall file a licensing application with the CNHFL Program to execute the closure of the kidney transplant program at Newark Beth.

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Failure to satisfy the aforementioned conditions of approval may result in sanctions, including license suspension, monetary penalties and other sanctions in accordance with N.J.S.A. 26:2H-1 et seq. and all other applicable requirements. Acceptance of these conditions will be presumed unless written objections are submitted to the Department within 30 days of receipt of this letter. Upon receipt of such objections, this approval will be deemed suspended and the project shall be re-examined in light of the objections. All the above conditions shall also apply to any successor organization to RWJ Barnabas Health, which may acquire Newark Beth and/or St. Barnabas within five years from the date of CN approval.

Any approval granted by this Department relates to certificate of need and/or licensing requirements only and does not imply acceptance by a reimbursing entity. Issues involving reimbursement are solely between the facility and the third party payer. The Department is neither a party to such matters nor an arbiter of disputes between the parties.

We look forward to working with you and helping you to provide a high quality of care to your patients. If you have any questions concerning this certificate of need, please do not hesitate to telephone Mr. John Calabria, Director, Division of Certificate of Need and Licensing at (609) 292-8773.

Sincerely,

A handwritten signature in black ink, appearing to read 'Cathleen D. Bennett', written in a cursive style.

Cathleen D. Bennett
Commissioner

c: J. Calabria, DOH

**NEWARK BETH ISRAEL MEDICAL CENTER AND SAINT BARNABAS MEDICAL CENTER
ALL KIDNEY TRANSPLANT VOLUME BY RACE/ETHNICITY (2010-2016)**

(Temporary suspension of the NBI kidney transplant program was effective January 1, 2014.)

Year	White			Black			Hispanic			Other			Total Minority			Total Cases		
	M	F	Total	M	F	Total	M	F	Total	M	F	Total	M	F	Total	M	F	Total
2010	8	2	10	35	22	57	9	5	14	16.1%	3	6	47	30	77	55	32	87
2011	11	4	15	27	20	47	8	4	12	14.8%	4	7	39	27	66	50	31	81
2012	8	3	11	19	18	37	12	8	20	28.6%	1	2	32	27	59	40	30	70
2013	2	1	3	21	9	30	5	5	10	21.3%	4	4	30	14	44	32	15	47
2014*	2	0	2	1	0	1	0	0	0	0.0%	0	0	1	0	1	3	0	3
2015*	2	0	2	1	0	1	0	0	0	0.0%	0	0	1	0	1	3	0	3
2016*	2	0	2	0	1	1	0	0	0	0.0%	0	0	0	1	1	2	1	3

*Heart/kidney transplant cases only

St. Barnabas

Year	White			Black			Hispanic			Other			Total Minority			Total Cases		
	M	F	Total	M	F	Total	M	F	Total	M	F	Total	M	F	Total	M	F	Total
2010	64	32	96	30	25	55	21	18	39	19.4%	9	2	60	45	105	124	77	201
2011	90	29	119	27	17	44	16	11	27	13.0%	8	9	51	37	88	141	66	207
2012	83	33	116	37	24	61	17	12	29	13.1%	10	5	64	41	105	147	74	221
2013	81	33	114	41	18	59	19	17	36	15.5%	14	10	74	45	119	155	78	233
2014	75	37	112	38	20	58	29	20	49	20.5%	10	10	77	50	127	152	87	239
2015	70	46	116	57	42	99	26	20	46	15.5%	21	15	104	77	181	174	123	297
2016	60	22	82	40	23	63	16	12	28	15.1%	7	6	63	41	104	123	63	186

Combined

Year	White			Black			Hispanic			Other			Total Minority			Total Cases		
	M	F	Total	M	F	Total	M	F	Total	M	F	Total	M	F	Total	M	F	Total
2010	72	34	106	65	47	112	30	23	53	18.4%	12	5	107	75	182	179	109	288
2011	101	33	134	54	37	91	24	15	39	13.5%	12	12	90	64	154	191	97	288
2012	91	36	127	56	42	98	29	20	49	16.8%	11	6	96	68	164	187	104	291
2013	83	34	117	62	27	89	24	22	46	16.4%	18	10	104	59	163	187	93	280
2014	77	37	114	39	20	59	29	20	49	20.2%	10	10	78	50	128	155	87	242
2015	72	46	118	58	42	100	26	20	46	15.3%	21	15	105	77	182	177	123	300
2016	62	22	84	40	24	64	16	12	28	14.8%	7	6	63	42	105	125	64	189

2016 YTD August 31, 2016

Source: UNOS