



RICK SCOTT
GOVERNOR

ELIZABETH DUDEK
SECRETARY

September 25, 2012

Bernardo B. Fernandez, M.D.
Authorized Representative for
Cleveland Clinic Florida Health System Nonprofit Corporation
d/b/a Cleveland Clinic Hospital
3100 Weston Road
Weston, Florida 33331

RE: CON Action Number 10151

Dear Dr. Fernandez:

Since the Agency did not receive a challenge to the Notice of Intent to Issue Certificate of Need Number 10151, the Notice of Intent to Issue becomes the final Agency action regarding Certificate of Need Number 10151.

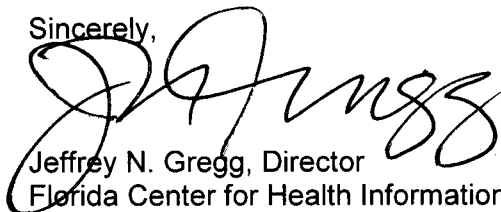
Enclosed is Certificate of Need Number 10151 authorizing Cleveland Clinic Florida Health System Nonprofit Corporation to establish an adult kidney transplantation program at Cleveland Clinic Hospital in Broward County, District 10, Organ Transplantation Service Area 4.

The issuance of this certificate does not resolve any licensure issues either pending or resulting from the issuance of this certificate.

Rule 59C-1.013(3), Florida Administrative Code, states that a report to the Agency must be filed annually after licensure or operation assessing compliance with any condition placed on this certificate of need. Any questions regarding such reporting should be directed to Mr. James B. McLemore of our staff at (850) 412-4401.

If there is any change in the project scope or cost, which would require certificate of need review, you are to notify this office immediately.

Sincerely,



Jeffrey N. Gregg, Director
Florida Center for Health Information and Policy Analysis

Enclosure

cc: Broward Regional Health Planning Council, Inc.
Bureau of Health Facility Regulation, Hospital & Outpatient Services Unit





STATE OF FLORIDA
AGENCY FOR HEALTH CARE ADMINISTRATION

CERTIFICATE OF NEED

Under the provisions of the "Health Facility and Services Development Act" (Sections 408.031-.045, Florida Statutes (Supp 1992), AND Chapter 59C-1, Florida Administrative Code), the Agency for Health Care Administration certifies the need for this project.

APPLICANT:
Cleveland Clinic Florida Health System Nonprofit Corporation
d/b/a Cleveland Clinic Hospital
3100 Weston Road
Weston, Florida 33331

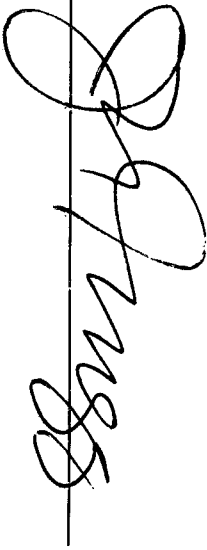
NUMBER: 10151
PROJECT COST: \$795,118
ISSUE DATE: September 25, 2012
TERMINATION DATE: March 24, 2014
REVISED TERMINATION DATE:

COUNTY: Broward **DISTRICT:** 10 **SUBDISTRICT:** OTSA 4

PROJECT DESCRIPTION: Establish an adult kidney transplantation program at Cleveland Clinic Hospital.

CONDITIONS: See Attachment.

FORM 1793, APRIL 1993

 _____ DATE: 9/25/12

CONDITIONS
CERTIFICATE OF NEED NUMBER 10151
CLEVELAND CLINIC FLORIDA HEALTH SYSTEM NONPROFIT CORPORATION
ESTABLISH AN ADULT KIDNEY TRANSPLANTATION PROGRAM
AT CLEVELAND CLINIC HOSPITAL

1. Paired Donation Program: The applicant will become an active member of the Paired Donation Network within its first year of the Program's operation. Paired kidney donation is a procedure that allows individuals who wish to give a kidney to their loved one, but cannot because they are incompatible (they have the wrong blood type or their loved one has immunity to their kidney). In paired donation, the donor and recipient are matched with another incompatible donor/recipient pair and the kidneys are exchanged between the pairs.
2. Whole Slide Imager: The applicant will install a whole slide imager to have real time consults with the Ohio campus pathologists when reading biopsies. This would commence with initiation of the program. The applicant has budgeted \$100,000 to purchase a whole slide imager which is included in project costs on Schedule 1. The transplant center at the Ohio campus is completely digitized, which means that with the use of whole slide digital imaging, a biopsy can be read anywhere in the world. Whole slide digital imaging uses computerized technology to scan and convert pathology specimen glass slides into digital images which are then accessible for viewing using a computer monitor and viewing software. The digital slides (images) are maintained in an information management system that allows for archival and intelligent retrieval. Computerized image analysis tools can be used with digital slides to perform objective quantification measures for special stains and tissue analysis. Digital pathology is an image based information environment that supports the management of information generated from digital slides for use in education, diagnostics, publications and research.
3. Video Conferencing: The applicant will perform the transplant with a live video conferencing feed to the Jagelman Conference Center for training and education of its residents, fellows and other medical students, subject to patient consent, once a year for the first two years, increasing to quarterly by year three.
4. Electronic Medical Record: Cleveland Clinic Hospital will maintain its electronic medical record system and integrated software systems which currently include EpicCare, eCleveland Clinic, DrConect and MyChart.

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5. Hispanic Outreach to Enhance Organ Donation and Transplantation Services: The applicant will enhance awareness and educate the Hispanic community on the importance of organ donation and benefits of transplantation. To accomplish this, the applicant will:
 - a. Either host or attend a minimum of six community outreach events per year where it will provide transplant education, organ donation information from Life Alliance and other useful informative material, in both Spanish and English. This will begin immediately at the start-up of the program.
 - b. The applicant will provide public service announcements on both Spanish and English radio stations in the south Florida market that will educate listeners on the importance of organ donation.
 - c. The applicant will meet regularly with Life Alliance and assist Life Alliance in meeting with families of minorities.

6. Establish a Donor Council: The applicant will establish a donor council consisting of an ethicist, nurses and others. The goal of the donor council will be to further enhance organ donation and awareness initiatives aimed at patients, families and employees of the hospital and to assure optimal communication and referral practices with the organ procurement organization (OPO) as a donor hospital. This is indicative of the hospital's desire to be a donor hospital as much as a transplant hospital.

7. Shared Appointments: The applicant will develop a shared appointment program for end stage renal disease and make this shared appointment program available to all. Shared appointments are two or more patients with similar or same diagnosis or evaluative plan or treatment plan(s) scheduled to be seen by the same physician(s) and clinicians together. This alleviates anxiety, the feeling of aloneness and provides a structure for support. Shared appointments will be provided to all patients and scheduled accordingly.

8. Support Group for End Stage Renal Disease, Renal Transplant Candidates & Recipients: The applicant will host regularly scheduled support groups for patients who have either been diagnosed with end stage renal disease, undergoing evaluation for transplant candidacy, awaiting a kidney transplant or have received a kidney transplant.

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9. Establish a Transplant Recipient International Organization (TRIO) Chapter: TRIO is an independent not-for-profit international organization committed to improving the quality of life of transplant recipients, candidates, their families and donor family members. The applicant will establish the first local chapter of TRIO to service its members in the areas of donor awareness, transplant education, support for patients and caregivers, and patient advocacy. The applicant will make space on the Weston campus if the group wants to use it. This TRIO chapter will be established during the first year of the kidney transplant program.

10. Staff Education:
 - a. Community Continuing Medical Education: The applicant will offer two additional Grand Rounds with transplant topics, annually, as part of its surgical series, open to all health care professionals within the community.
 - b. Certified Transplant Coordinators and Transplant Nurses: 100 percent of Cleveland Clinic Hospital's transplant coordinators and transplant nursing staff will become certified according to their areas of specialty within the first two years of serving in that capacity.
 - c. Nurse Orientation: All (not just transplant) new nurses at Cleveland Clinic Hospital, as part of their orientation, will have a one day orientation to transplant. Topics to be covered will include but are not limited to organ donation, overall transplant evaluation and eligibility and organ specific education. All existing nurses at Cleveland Clinic Hospital will be provided an orientation to transplantation and the transplant program within 12 months of initiating the transplant programs at the hospital.
 - d. Brain Death Training: All Cleveland Clinic Florida staff and residents will go through formal training for determination of brain death. This training is necessary so that staff members can accurately and efficiently determine death by neurological criteria brain death. This is important for the finality of the diagnosis, the need of family members to grieve and make final arrangements, and to procure organs and tissues for transplantation.
 - e. General Surgery Residents will Rotate Through Transplant Services: All general surgery residents at Cleveland Clinic Hospital will rotate through the transplant service as part of the general surgery residency curriculum.

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11. Financial Commitment:

- a. Financial Coordinator Education and Development: The applicant will commit to funding a membership for each of its transplant financial coordinators in the Transplant Financial Coordinators Association (“TFCA”). TFCA is a national, non-profit organization with a mission to coordinate the dissemination of useful information related to transplant finance. The goal is to assure that accurate financial information is provided to patients and their families in a compassionate and tactful manner. Membership in TFCA will provide the transplant financial coordinators with access to continuing education and networking opportunities with their peers from across the country. In addition to membership, support will include attendance at the annual TFCA conference. This will assure that the hospital’s transplant financial coordinators are knowledgeable about transplant-related financial issues and serve as effective advocates for patients and their family members.
- b. Insurance Coverage: The lack of insurance coverage for transplant will not in itself be the reason to deny a transplant. Each patient referred for a transplant will be immediately assigned to a transplant financial coordinator. The financial coordinator will work with patients and family members to research insurance coverage, provide estimates of out-of-pocket costs and, if necessary, help patients explore the use of organizations such as the National Foundation for Transplants for fund raising. The availability of insurance coverage and/or personal financial resources can be a factor in the decision of whether a patient is an appropriate candidate for transplant, as it relates to the overall psycho-assessment and the ability to comply with post-transplant clinical requirements.