

Guidance and Instructions for General Hospitals Seeking to Certify Transplant Program(s) Requiring a Limited Review Application

Introduction

Prior to starting up a Kidney, Adult Heart, Pediatric Heart and/or Liver solid organ transplant and bone marrow transplant programs general hospitals must submit and gain approval of a Certificate of Need (CON) application that undergoes a full review by the Department of Health (DOH) and the Public Health and Health Planning Council (PHHPC).

Prior to starting up of a lung, pancreas, intestine and/or vascularized composite allograft (VCA) transplant programs, general hospitals are required to submit and gain approval of a Limited Review Application (LRA) from the Department.

In addition to gaining Department approval of a CON/LRA application, all solid organ and VCA transplant programs must attain approval from the Health Resources and Services Administration's (HRSA) Organ Procurement and Transplantation Network (OPTN) contractor, currently the United Network for Organ Sharing (UNOS), prior to start up. Kidney, heart, lung, liver, pancreas and intestine programs require Centers for Medicare and Medicaid Services (CMS) certification in order to receive Medicare reimbursement. Adult and pediatric pancreas and intestine programs may be Medicare approved, with no independent survey activity, if the programs operate as a component of a Medicare approved kidney or liver transplant program, respectively.

Instructions for Completing and Submitting an LRA for Lung, Pancreas, Intestine or Vascularized Composite Allograft (VCA) Transplant Services

Each hospital seeking to provide lung, pancreas, intestine, and/or VCA transplant services must submit a Limited Review Application (LRA). This application is necessary for those proposed projects which are subject to a limited review pursuant to 10 NYCRR 710.1(c)(5)-(7). The LRA consists of a cover sheet and the tabs and schedules listed below as applicable:

General Tab	Data entry done online
Executive Summary Tab	Data entry done online
Sites Tab	Data entry done online
LRA Cover Sheet	LRA Cover Sheet
Schedule LRA 2	Total Project Cost
Schedule LRA 3	Proposed Plan for Project Financing
Schedule LRA 4	Environmental Assessment
Schedule LRA 5	Space & Construction Cost Distribution
Schedule LRA 6	Architectural and Engineering Requirements
Schedule LRA 7	Proposed Operating Budget
Schedule LRA 8	Staffing
Schedule LRA 10	Impact on Operating Certificate (uploaded as N/A)
Schedule LRA12	Assurances

Submit the application via the New York State Electronic Certificate of Need system (NYSECON), along with information and documentation necessary to support the proposal. Information and instructions can be found at: <http://www.health.ny.gov/facilities/cons/nysecon/>.

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PLEASE NOTE: Not all the schedules listed above will need to be completed. The responses given on the cover sheet will determine which schedules to complete. Below are instructions for completing schedules that require modified or specific information when applying for lung, pancreas, intestine or VCA transplant services. Please complete ALL schedules that are required in accordance with the LRA application instructions adding additional information if specific instructions are provided below.

General Tab

The general tab provides a high-level summary of the application. This is where the applicant completes general information about the applicant, the proposal, and the project contact and alternate contact information.

Executive Summary Tab

This is a narrative summary giving an overview of the project. This should include where proposed services will be provided, e.g., hospital, street address, building, etc.; the type of transplant service the facility is seeking to add, why the facility is seeking to add the service; description of the need for the service and population it will serve, and what the project entails, e.g. construction, purchase of moveable equipment, etc.

Sites Tab (Previously LRA Schedule 10: Impact on Operating Certificate)

Please complete the sites tab as directed. Include in your site proposal summary the location(s), and, where appropriate, the number of rooms/beds, hours of operation, etc., where transplant patients will receive care, including but not limited to pre-op, operative, post-op ICU, step-down, floor and clinic locations. Additionally, through the Services button, you must indicate which transplant service(s) you are requesting.

LRA Schedule 7: Proposed Operating Budget

Complete the form per instructions. Since Medicare will not reimburse the first ten lung transplants, please include how your facility will manage lack of reimbursement for these services.

LRA Schedule 8: Staffing

Please include all healthcare provider and support staff required in order to gain UNOS approval of the program when completing this form, including but not limited to: primary physician, primary surgeon, other program medical and surgical providers, anesthesia, program administrator(s), program coordinator(s), pharmacy, mental health and social work, financial coordinator(s), quality assurance and data manager(s), etc.

Please include the CVs of program director(s) and physicians and a description of program staffing identifying:

- responsibilities of clinical staff members relative to patient care and quality assurance performance improvement, e.g., nurse practitioners/physician assistants, nursing, pharmacy, social work, etc.;
- how clinical staff will attain and maintain competency in their roles and responsibilities related to care of these transplant patients and;
- the number of providers per provider type and patient as the patient moves through the system receiving care, e.g., 1:1 nurse patient ratio in ICU; 2-3:1 in stepdown unit, etc.

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Other

A Program Description, including the following information must be uploaded into the Application Tab under "Other."

1. Description of: why this project/service is needed; the population it will serve; whether the program will serve adult, pediatric or both patient groups; the number of projected evaluations, waitlisting's and transplants in years 1, 2, 3 of the project and the methodology used to project these numbers; whether and/or by whom the patients to be served by this new program are currently having their needs met; the impact of the project on other providers of the service in the area; and whether the proposed project plans to provide care to all patients regardless of ability to pay.
2. Description of the oversight and management of the proposed program including: the facility's commitment to the program and an organizational chart depicting the structure of the program and indicating in it the people who fill the UNOS required positions, the role of the transplant administrator, the relationship of the proposed program to other organ transplant programs in the applicant facility, the surgery and quality management departments, hospital leadership and the rest of the facility.
3. Description of how patients will move through the system from when an inquiry is made, to potential candidate evaluation, patient listing and monitoring, pre-op, inpatient transplant, outpatient follow-up and care and availability of program staff to respond to emergencies.
4. Detailed description of the transplant program's quality assurance performance improvement (QAPI) plan and program. Please include: QAPI structure and processes, frequency of meetings and who participates in them when quality indicators and adverse events are reviewed, the quality metrics the program will be tracking, how and how often quality indicator metrics are reported out to staff, facility leadership and the Board, and process(es) for assuring adherence to OPTN data collection and reporting requirements.
5. The following policies/procedures:
 - Infection Control: Hospital Policy and IC Policy specific to transplant patients.
 - Patient Selection: Process, including involvement of interdisciplinary team, frequency of meetings, criteria used, and party responsible for the final decision.
 - Organ Offer and Acceptance: Policy, process, procedure used to receive, review and accept organ offers, and criteria utilized.
 - Patient Management: immunosuppression policies and management; involvement of the interdisciplinary team in patient evaluation, care, and rounds; off hour and weekend coverage.
6. Description of how facility is/will comply with state (NYCRR 10, Part 405) and federal regulations (CMS) as well as OPTN policies specific to the transplant services requested.

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Pre-opening Review

The following Policies and Procedures will be required to be uploaded for review once the LRA is approved and referred to the Regional Office:

Documents, Policies and Procedures
Organizational Chart of the new program and its relationship with other transplant programs, the surgery department, hospital and quality leadership and the rest of the hospital.
Description of program administration and oversight including but not limited to the role of physician directors, other program leadership positions, i.e. transplant administrator(s), transplant coordinators and other key positions.
Description of the plan for patient care of those seeking transplant evaluation, those waitlisted by the program, those admitted for transplantation, and living donation when applicable, and post-hospital discharge recipient, donor when applicable, care.
Patient, and living donor where applicable, selection criteria and process.
Plan for nurse staffing, competencies expected and training plan.
Hospital and Transplant Service Specific Infection Control Policy.
Plan and Processes for Quality Assurance Performance Improvement.
Plan for review and acceptance of organ offers.
Emergency Preparedness Policy

Initial Survey Requirements

Once the LRA has been approved, the project will be referred to the Regional Office of the Division of Hospitals and Diagnostic and Treatment Centers. Approval from the Regional Office for the new service will be based on the review of policies and procedures and environmental checklists, that are uploaded through the NYSECON system. If the LRA involves construction, then in addition to a review of these materials, an on-site survey will be conducted by staff from the Division of Hospitals and Diagnostic and Treatment Centers. Final approval will be contingent upon meeting all requirements.

Initial Certification and Recertification Survey Requirements

Certification and recertification requirements are detailed in the CMS State Operations Manual for Transplant Services. Initial certification and re-certification surveys are unannounced.

Complaints

Complaints about transplant services will be reviewed and triaged according to established policies and procedures. A determination will be made as to the whether an on-site survey will be performed to investigate the complaint.