

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, Lung 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 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 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 initial certification survey activity, only when these programs operate in a transplant center with Medicare approved kidney or liver transplant program, respectively.

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

Each hospital seeking to provide 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 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., transplant center name, 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 movable 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. If Medicare does not reimburse the first transplants, please include how your facility will manage/cover lack of reimbursement for these services.

LRA Schedule 8: Staffing

Please include all healthcare provider and support staff required in order to gain OPTN 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), physician(s) and surgeon(s) as well as a description of program staffing identifying:

- responsibilities of clinical staff members relative to patient care and quality assurance performance improvement activities, e.g., nurse practitioners/physician assistants, transplant coordinator(s), nursing, pharmacy, social work, living donor advocate(s) when applicable, 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 step-down unit, etc.

