**Section 148.82 Organ Transplant Services**

Effective for dates of outpatient services on or after July 1, 2014 and inpatient discharges on or after July 1, 2014:

a) Introduction

The Department will cover organ transplants as identified under subsection (b) that are provided to United States citizens or aliens who are lawfully admitted for permanent residence in the United States under color of law pursuant to 42 USC 1396a(a) and 1396b(v). These services must be provided by certified organ transplant centers that meet the requirements specified in subsections (c) through (g) of this Section.

b) Covered Services

1) Inpatient heart, heart/lung, lung (single or double), liver, pancreas or kidney/pancreas transplantation. Inpatient bone marrow transplants, inpatient and outpatient stem cell transplants.

2) Inpatient intestinal (small bowel or liver/small bowel) transplantation for children only (see subsection (d)(1)(H) of this Section).

3) Other types of transplant procedures may be covered when a hospital has been certified by the Department as a transplant center eligible to perform such transplants. Centers must complete the certification process established in subsection (c) and provide the necessary documentation of the number of transplant procedures performed and the survival rates.

4) Medically necessary work-up.

c) Certification Process

1) In order to be certified to receive reimbursement for transplants performed on Medical Assistance patients, the hospital must:

A) Request an application from the Bureau of Comprehensive Health Services.

B) Submit a completed application to the Department for the type of transplant for which the center is seeking certification.

C) Meet certification criteria established in subsection (d).D) Submit a detailed status report on each patient for the type of transplant for which the hospital is seeking certification. The reports must include the patient's diagnosis, date of transplant, the length of hospitalization, charges, survival rates, patient-specific transplant outcome, and complications (including cause of death, if applicable) for all transplants performed in the time frames required for the type of transplant indicated in subsections (d)(1)(C), (D), (E), (F), (G), (H), (I) or (J). To protect the privacy of patients included in this report, names of patients who are not covered under Medical Assistance are not required.

2) The Department shall notify the hospital of approval or denial of the hospital as a transplant center for Medical Assistance eligible patients.

3) In the event the Department receives a request for prior approval to provide a service from a hospital not formally certified under this Section, the Department may approve the request if it determines that circumstances are such that the health, safety and welfare of the recipient would best be served by receiving the service at that hospital. In making its determination, the Department shall take into account the ability and qualifications of the hospital and its medical staff to provide the service, the burden on the recipient's family if a certified hospital is a great distance from their home, and the urgent nature of the transplant.

4) A joint application combining the statistical data for the adult and pediatric programs from two affiliated hospitals that share the same surgeons may be submitted for review. The hospitals must meet the criteria under subsections (d)(1)(A), (B), (K), (L), (M), (N), (O), (P) and (Q), the applicable criteria under subsections (d)(1)(C), (D) or (J) and (d)(1)(R), subsections (d)(2), (3) and (4), and subsection (e) for certification and recertification.

d) Certification Criteria

1) Hospitals seeking certification as a transplant center shall submit documentation to verify that:

A) The hospital is capable of providing all necessary medical care required by the transplant patient.

B) The hospital is affiliated with an academic health center.

C) The hospital has had the transplant program for inpatient adult heart and liver transplants in operation for at least three years with 12 transplant procedures per year for the past two years and 12 cases in the three-year period preceding the most current two-year period for adult heart and liver transplants.

D) The hospital has had the transplant program for inpatient adult heart/lung and lung transplants in operation for at least three years with ten transplant procedures per year for the past two years and 10 cases in the three-year period preceding the most current two‑year period for adult heart/lung and lung transplants.

E) A hospital specializing in inpatient pediatric heart/lung and lung transplants has had a program in operation for at least three years and has performed a minimum of six transplant procedures per year for the past two years, and six procedures in the three-year period preceding the most current two-year period.

F) The hospital has had the transplant program for inpatient adult and pediatric bone marrow transplants in operation for at least two years with 12 transplant procedures per year for the past two years.

G) The hospital performing outpatient adult and pediatric stem cell transplants must be part of a certified inpatient program and must have been in operation for at least two years with at least 12 outpatient stem cell transplant procedures per year in the past two years.

H) A hospital specializing in inpatient pediatric heart or liver transplants, or both, has had a program in operation for at least three years and has performed a minimum of six transplant procedures per year for the past two years, and six procedures in the three-year period preceding the most current two-year period.

I) A hospital specializing in inpatient pediatric intestinal (small bowel or liver/small bowel) transplants has had a program in operation for at least three years and has performed a minimum of six transplant procedures per year for the past two years, and six procedures in the three-year period preceding the most current two-year period.

J) A hospital specializing in inpatient kidney/pancreas and/or pancreas transplants has had the transplant program in operation for at least three years with 25 kidney transplant procedures per year for the past two years and 25 cases in the three-year period preceding the most current two-year period, and five pancreas transplant procedures per year for the past two years and five in the three year period preceding the most current two-year period, or 12 kidney/pancreas transplant procedures per year for the past two years and 12 in the three-year period preceding the most current two-year period.

K) The hospital has experts, on staff, in the fields of cardiology, pulmonology, anesthesiology, immunology, infectious disease, nursing, social services, organ procurement, associated surgery and internal medicine to complement the transplant team. In addition, in order to qualify as a transplant center for pediatric patients, the hospital must also have experts in the field of pediatrics.

L) The hospital has an active cardiovascular medical and surgical program as evidenced by the number of cardiac catheterizations, coronary arteriograms and open heart procedures per year for heart and heart/lung transplant candidates.

M) The hospital has pathology resources that are available for studying and reporting the pathological responses for transplantation as supported by appropriate documentation.

N) The hospital complies with applicable State and federal laws and regulations.

O) The hospital participates in a recognized national donor procurement program for organs or bone marrow provided by unrelated donors, abides by its rules, and provides the Department with the name of the national organization of which it is a member.

P) The hospital has an interdisciplinary body to determine the suitability of candidates for transplantation as supported by appropriate documentation.

Q) The hospital has blood bank support necessary to meet the demands of a certified transplant center as supported by appropriate documentation.

R) The hospital meets the applicable transplant survival rates as supported by the Kaplan-Meier method or other method accepted by the Department:

i) A one-year survival rate of 50 percent for inpatient bone marrow and inpatient and outpatient stem cell transplant patients.

ii) A one-year survival rate of 75 percent and a two-year survival rate of 60 percent for heart transplant patients.

iii) A one-year survival rate of 75 percent and a two-year survival rate of 60 percent for liver transplant patients.

iv) A one-year survival rate of 90 percent for kidney transplant and a one-year survival rate of 80 percent for pancreas transplant; or a one-year survival rate of 80 percent for kidney/pancreas transplant.

v) A one-year survival rate of 65 percent and a two-year survival rate of 60 percent for heart/lung and lung (single or double) transplant patient.

vi) A one-year survival rate of 60 percent and a two-year survival rate of 55 percent for intestinal transplants (small bowel or liver/small bowel).

2) The commitment of the hospital to support the transplant center must be at all levels as evidenced by such factors as financial resources, allocation of space and the support of the professional staff for the transplant program and its patients. The hospital must submit appropriate documentation to demonstrate that:

A) Component teams are integrated into a comprehensive transplant team with clearly defined leadership and responsibility.

B) The hospital safeguards the rights and privacy of patients.

C) The hospital has adequate patient management plans and protocols to meet the patient and hospital's needs.

3) The hospital must identify, in writing, the director of the transplant program and the members of the team as well as their qualifications. Physician team members must be identified as board certified, in preparation for board certification, or pending board certification, and the transplant coordinator's name must be submitted.

4) The hospital must provide patient selection criteria including indications and contraindications for the type of transplant procedure for which the facility is seeking certification.

e) Recertification Process/Criteria

1) The Department will conduct an annual review for certification of transplant centers. A certified center must submit documentation established under subsections (c), (d), (f) and (g) for recertification as a transplant center.

2) Survival rates of previous transplant patients must be documented prior to certification. The center must maintain patient volume in the year of certification based on previous transplant statistics.

3) The Department shall notify the hospital of approval or denial of the recertification of the hospital as a transplant center.

4) If the hospital has previously met the requirements for certification or recertification of its program under subsections (d)(1)(K), (L), (M), (N), (O), (P) and (Q) and (d)(2), (3) and (4) and the program has experienced no changes under the above subsections, as evidenced in written documentation on the hospital's application, the hospital will not be required to resubmit the same data.

5) If a center has previously met the requirements for certification or recertification of its program under subsections (d)(1) (K), (L), (M), (N), (O), (P), (Q) and (R)(i) through (R)(vi), but has performed fewer than the required number of transplants pursuant to subsections (d)(1)(C), (D), (E), (F), (G), (H), (I) or (J) as appropriate, the Department may recertify the center if it determines that the best interests of the Medical Assistance client eligible for transplant services would be served by allowing continued certification of the center. Criteria the Department may consider in making such a determination include, but are not limited to:

A) Not recertifying a center would limit the accessibility of available organs.

B) Other centers are not accepting new patients or have extensive waiting lists.

C) The distance to other eligible centers would jeopardize the client's opportunity to receive a viable organ/tissue transplant.

f) Notification of Transplant

1) The hospital must notify the Department prior to performance of the transplant procedure. The notification letter must be from a physician on the transplant team.

2) The notification must include the admission diagnosis and pre-transplant diagnosis.

3) The Department shall notify the hospital regarding receipt of the notification and provide the appropriate outcome summary forms to the hospital.

g) Reporting Requirements of Certified Transplant Center

The following documentation must be submitted within the time limits set forth in this subsection (g).

1) Outcome Summary

A) The discharge summary for each Medical Assistance patient must be received by the Department within 30 days after the patient's discharge.

B) For those Medical Assistance patients who expire, a summary must be received by the Department within 30 days after the patient's death.

2) Notification of Changes

The center must notify the Department within 30 days after any changes in its program including, but not limited to, certification criteria, patient selection criteria, members of the transplant team and the coordinator.

(Source: Amended at 38 Ill. Reg. 15165, effective July 2, 2014)