**Section 1110.245 Kidney Transplantation**

a) Introduction

1) This Section applies to projects involving the following category of service: Kidney Transplantation. Applicants proposing to establish or modernize this category of service shall comply with the applicable subsections of this Section, as follows:

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| PROJECT TYPE | REQUIRED REVIEW CRITERIA |
| Establishment of Services or Facility | (b)(1)  | − | Planning Area Need – 77 Ill. Adm. Code 1100 (formula calculation ) |
|  | (b)(2)  | − | Planning Area Need – Service to Planning Area Residents |
|  | (b)(3)  | − | Planning Area Need – Service Demand − Establishment of Category of Service |
|  | (b)(4)  | − | Planning Area Need − Service Accessibility |
|  | (c)(1)  | − | Unnecessary Duplication of Services |
|  | (c)(2)  | − | Maldistribution |
|  | (c)(3)  | − | Impact of Project on Other Area Providers |
|  | (e)  | − | Staffing Availability  |
|  | (f)  | − | Surgical Staff |
|  | (g)  | − | Support Services |
|  | (h)  | − | Performance Requirements |
|  | (i)  | − | Assurances |
| Category of Service Modernization | (d)(1)  | − | Deteriorated Facilities |
|  | (d)(2) & (3)  | − | Documentation |
|  | (d)(4)  | − | Occupancy |
|  | (h)  | − | Performance Requirements |

2) If the proposed project involves the replacement of a facility or service onsite, the applicant shall comply with the requirements listed in subsection (a)(1) (Category of Service Modernization) plus subsection (i) (Assurances).

3) If the proposed project involves the relocation of an existing facility or service, the applicant shall comply with the requirements of subsection (a)(1) (Establishment of Services or Facility), as well as requirements in Section 1110.30 (Discontinuation) and Section 1110.230(j) (Relocation of Facilities).

4) If the proposed project involves the replacement of a facility or service (onsite or new site), the number of beds shall be replaced on a 1:1 basis. If the applicant proposes to add beds to the replacement service or facility, the applicant shall also comply with the requirements listed in subsection (a)(1) for "Expansion of Existing Services".

b) Planning Area Need − Review Criterion

The applicant shall document that the proposed category of service is necessary to serve the planning area's population, based on the following:

1) 77 Ill. Adm. Code 1100 (Formula Calculation)

No formula need for this category of service has been established.

2) Service to Planning Area Residents

Applicants proposing to establish this category of service shall document that the primary purpose of the project will be to provide necessary health care to the residents of the area in which the proposed project will be physically located (i.e., the planning or geographical service area, as applicable), for each category of service included in the project.

3) Service Demand – Establishment of Category of Service

The establishment of this category of service is necessary to accommodate the service demand experienced annually by the existing applicant facility over the latest 2-year period, as evidenced by historical and projected referrals, or, if the applicant proposes to establish a new hospital, the applicant shall submit projected referrals.

A) Historical Referrals

If the applicant is an existing facility, the applicant shall document the number of referrals to other facilities, for this category of service, for each of the latest 2 years. Documentation of the referrals shall include: patient origin by zip code; name and specialty of referring physician; name and location of the recipient hospital.

B) Projected Referrals

An applicant proposing to establish this category of service shall submit the following:

i) Physician referral letters that attest to the physician's total number of patients (by zip code of residence) who have received care at existing facilities located in the area during the 12-month period prior to submission of the application;

ii) An estimated number of patients the physician will refer annually to the applicant's facility within a 24-month period after project completion. The anticipated number of referrals cannot exceed the physician's documented historical caseload;

iii) Each referral letter shall contain the physician's notarized signature, the typed or printed name of the physician, the physician's office address and the physician's specialty; and

iv) Verification by the physician that the patient referrals have not been used to support another pending or approved CON application for the subject services.

4) Service Accessibility

The establishment of this category of service is necessary to improve access for planning area residents. The applicant shall document subsection (b)(4)(A) and either subsection (b)(4)(B) or (C):

A) Service Restrictions

The applicant shall document that at least one of the following factors exists in the planning area:

i) The absence of the proposed service within the planning area;

ii) Access limitations due to payor status of patients, including, but not limited to, individuals with health care coverage through Medicare, Medicaid, managed care or charity care;

iii) Restrictive admission policies of existing providers;

iv) The area population and existing care system exhibit indicators of medical care problems, such as an average family income level below the State average poverty level, high infant mortality, or designation by the Secretary of Health and Human Services as a Health Professional Shortage Area, a Medically Underserved Area, or a Medically Underserved Population;

v) For purposes of this subsection (b)(4) only, all services within the 3-hour normal travel time meet or exceed the utilization standard specified in 77 Ill. Adm. Code 1100.

B) Supporting Documentation

The applicant shall provide the following documentation concerning existing restrictions to service access:

i) The location and utilization of other planning area service providers;

ii) Patient location information by zip code;

iii) Independent time-travel studies;

iv) A certification of waiting times;

v) Scheduling or admission restrictions that exist in area providers;

vi) An assessment of area population characteristics that document that access problems exist;

vii) Most recently published IDPH Hospital Questionnaire.

c) Unnecessary Duplication/Maldistribution − Review Criterion

1) The applicant shall document that the project will not result in an unnecessary duplication. The applicant shall provide the following information:

A) A list of all zip code areas that are located, in total or in part, within 3 hours normal travel time of the project's site;

B) The total population of the identified zip code areas (based upon the most recent population numbers available for the State of Illinois); and

C) The names and locations of all existing or approved health care facilities located within 3 hours normal travel time from the project site that provide this category of service.

2) The applicant shall document that the project will not result in maldistribution of services. Maldistribution exists when the identified area (within the planning area) has an excess supply of facilities, beds and services characterized by such factors as, but not limited to:

A) Historical utilization (for the latest 12-month period prior to submission of the application) for existing facilities and services that is below the occupancy standard established pursuant to 77 Ill. Adm. Code 1100; or

B) Insufficient population to provide the volume or caseload necessary to utilize the services proposed by the project at or above occupancy standards.

3) The applicant shall document that, within 24 months after project completion, the proposed project:

A) Will not lower the utilization of other area providers below the occupancy standards specified in 77 Ill. Adm. Code 1100; and

B) Will not lower, to a further extent, the utilization of other area hospitals that are currently (during the latest 12-month period) operating below the occupancy standards.

d) Category of Service Modernization

1) If the project involves modernization of this category of service, the applicant shall document that the areas to be modernized are deteriorated or functionally obsolete and need to be replaced or modernized, due to such factors as, but not limited to:

A) High cost of maintenance;

B) Non-compliance with licensing or life safety codes;

C) Changes in standards of care (e.g., private versus multiple bed rooms); or

D) Additional space for diagnostic or therapeutic purposes.

2) Documentation shall include the most recent:

A) IDPH CMMS inspection reports; and

B) The Joint Commission reports.

3) Other documentation shall include the following, as applicable to the factors cited in the application:

A) Copies of maintenance reports;

B) Copies of citations for life safety code violations; and

C) Other pertinent reports and data.

4) Projects involving the replacement or modernization of a category of service or hospital shall meet or exceed the occupancy standards for the categories of service, as specified in 77 Ill. Adm. Code 1100.

e) Staffing Availability − Review Criterion

The applicant shall document that relevant clinical and professional staffing needs for the proposed project were considered and that licensure and The Joint Commission staffing requirements can be met. In addition, the applicant shall document that necessary staffing is available by providing letters of interest from prospective staff members, completed applications for employment, or a narrative explanation of how the proposed staffing will be achieved.

f) Surgical Staff – Review Criterion

The applicant shall document that the facility has at least one kidney transplant surgeon certified in the applicable specialty on staff and that each has had a minimum of one year of training and experience in transplant surgery, post-operative care, long-term management of organ recipients and the immunosuppressive management of transplant patients. Documentation shall consist of curricula vitae of transplant surgeons on staff and certification by an authorized representative that the personnel with the appropriate certification and experience are on the hospital staff.

g) Support Services – Review Criterion

The applicant must document that the following are available on premises: laboratory services, social services, dietetic services, self-care dialysis support services, inpatient dialysis services, pharmacy and specialized blood facilities (including tissue typing). The applicant must also document participation of the center in a recipient registry. Documentation shall consist of a certification as to the availability of such services and participation in a recipient registry.

h) Performance Requirements

The applicant shall document that:

1) The proposed category of service will be provided at a teaching institution;

2) The proposed category of service will be performed in conjunction with graduate medical education;

3) The applicant renal transplantation center has membership in the Organ Procurement and Transplantation Network (OPTN) and a federally designated organ procurement organization (OPO); and

4) The subject renal transplantation center is performing 25 or more transplants per year.

i) Assurances

The applicant representative who signs the CON application shall submit a signed and dated statement attesting to the applicant's understanding that, by the second year of operation after the project completion, the applicant will achieve and maintain the occupancy standards specified in 77 Ill. Adm. Code 1100 for each category of service involved in the proposal.