**Section 1110.2330 Selected Organ Transplantation – Review Criteria**

a) Introduction

1) This Section applies to projects involving the following category of service: Selected Organ 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) through (4) | − | Background of the Applicant |
|  | (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)  | − | Collaborative Support |
|  | (h)  | − | Support Services |
|  | (i)  | − | Performance Requirements |
|  | (j)  | − | Assurances |
| Category of Service Modernization | (b)(1) through (4) | − | Background of the Applicant |
|  | (d)(1)  | − | Deteriorated Facilities |
|  | (d)(2) & 3  | − | Documentation |
|  | (d)(4)  | − | Utilization |
|  | (i)  | − | Performance Requirements |
|  | (j)  | − | Assurances |

2) If the proposed project involves the replacement of a facility or service on site, the applicant shall comply with the requirements listed in subsection (a)(1) for "Category of Service Modernization" plus subsection (j) (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) for "Establishment of Services or Facility", as well as requirements in Section 1110.130 (Discontinuation) and Section 1110.1430(i) (Relocation of Facilities).

4) If the proposed project involves the replacement of a hospital or service (onsite or new site), the number of key rooms being replaced shall not exceed the number justified by historical occupancy rates for each of the latest two years.

b) Background of Applicant – Review Criterion

1) An applicant must demonstrate that it is fit, willing and able, and *has the qualifications, background and character to adequately provide a proper standard of health care service for the community.* [20 ILCS 3960/6] In evaluating the qualifications, background and character of the applicant, HFSRB shall consider whether adverse action has been taken against the applicant, including corporate officers or directors, LLC members, partners, and owners of at least 5% of the proposed healthcare facility, or against any health care facility owned or operated by the applicant, directly or indirectly, within three years preceding the filing of the application. A health care facility is considered "owned or operated" by every person or entity that owns, directly or indirectly, an ownership interest. If any person or entity owns any option to acquire stock, the stock shall be considered to be owned by that person or entity (see to 77 Ill. Adm. Code 1100 and 1130 for definitions of terms such as "adverse action", "ownership interest" and "principal shareholder").

2) Examples of facilities owned or operated by an applicant include:

A) The applicant, Partnership ABC, owns 60% of the shares of Corporation XYZ, which manages the Good Care Nursing Home under a management agreement. The applicant, Partnership ABC, owns or operates Good Care Nursing Home.

B) The applicant, Healthy Hospital, a corporation, is a subsidiary of Universal Health, the parent corporation of Healthcenter Ambulatory Surgical Treatment Center (ASTC), its wholly-owned subsidiary. The applicant, Healthy Hospital, owns and operates Healthcenter ASTC.

C) Dr. Wellcare is the applicant. His wife is the director of a corporation that owns a hospital. The applicant, Dr. Wellcare, owns or operates the hospital.

D) Drs. Faith, Hope and Charity own 40%, 35% and 10%, respectively, of the shares of Healthfair, Inc., a corporation, that is the applicant. Dr. Charity owns 45% and Drs. Well and Care each own 25% of the shares of XYZ Nursing Home, Inc. The applicant, Healthfair, Inc., owns and operates XYZ Nursing Home, Inc.

3) The applicant shall submit the following information:

A) A listing of all health care facilities currently owned and/or operated by the applicant in Illinois or elsewhere, including licensing, certification and accreditation identification numbers, as applicable;

B) A listing of all health care facilities currently owned and/or operated in Illinois, by any corporate officers or directors, LLC members, partners, or owners of at least 5% of the proposed health care facility;

C) A certified listing from the applicant of any adverse action taken against any facility owned and/or operated by the applicant during the three years prior to the filing of the application;

D) A certified listing of each applicant, corporate officer or director, LLC member, partner and owner of at least 5% of the proposed facility, identifying those individuals that have been cited, arrested, taken into custody, charged with, indicted, convicted or tried for, or pled guilty to:

i) the commission of any felony or misdemeanor or violation of the law, except for minor parking violations; or

ii) has been the subject of any juvenile delinquency or youthful offender proceeding;

E) Unless convictions have been expunged, all convictions shall be detailed in writing and any police or court records regarding any matters disclosed shall be submitted for HFSRB's consideration;

F) A certified listing of each applicant, corporate officer or director, LLC member, partner and owner of at least 5% of the proposed facility who has been charged with fraudulent conduct or any act involving moral turpitude. Any such matter shall be disclosed in detail;

G) A certified listing of each applicant, corporate officer or director, LLC member, partner and owner of at least 5% of the proposed facility who has any unsatisfied judgments against him or her;

H) A certified listing of each applicant, corporate officer or director, LLC member, partner and owner of at least 5% of the proposed facility. Any matter shall be discussed in detail;

I) A certified listing of each applicant, corporate officer or director, LLC member, partner and owner of at least 5% of the proposed facility who is in default in the performance or discharge of any duty or obligation imposed by a judgment, decree, order, or directive of any court or governmental agency. Any matter shall be discussed in detail;

J) Authorization permitting HFSRB and IDPH access to any documents necessary to verify the information submitted, including, but not limited to: official records of IDPH or other State agencies; the licensing or certification records of other states, when applicable; and the records of nationally recognized accreditation organizations. Failure to provide the authorization shall constitute an abandonment or withdrawal of the application without any further action by HFSRB. Any fees paid will be forfeited.

4) If, during a given calendar year, an applicant submits more than one application for permit, the documentation provided with the prior applications may be utilized to fulfill the requirements of this subsection (b). In these instances, the applicant shall attest that the information has been previously provided, cite the project number of the prior application, and certify that no changes have occurred regarding the information that has been previously provided. The applicant is able to submit amendments to previously submitted information, as needed to update and/or clarify data.

5) The documentation for the "Background of the Applicant" is required one time per application, regardless of the number of categories of service involved in a proposed project.

c) 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 two-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 two 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 experienced caseload;

iii) 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 the following:

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 (c)(4) only, all services within the three-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, as applicable to cited restrictions, 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.

d) 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 three 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 population); and

C) The names and locations of all existing or approved health care facilities located within three 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.

e) Category of Service Modernization

1) If the project involves modernization of this category of service, the applicant shall document that the inpatient 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) 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 utilization standards for the category of service, as specified in 77 Ill. Adm. Code 1100.

f) 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 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.

g) Surgical Staff – Review Criterion

The applicant shall document that the facility has at least one 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.

h) Collaborative Support – Review Criterion

The applicant shall document collaboration with experts in the fields of hepatology, cardiology, pediatrics, infectious disease, nephrology with dialysis capability, pulmonary medicine with respiratory therapy support, pathology, immunology, anesthesiology, physical therapy and rehabilitation medicine. Documentation of collaborate involvement shall include, but not be limited to, a plan of operation detailing the interaction of the transplant program and the stated specialty areas.

i) Support Services – Review Criterion

An applicant shall submit a certification from an authorized representative that attests to each of the following:

1) Availability of on-site access to microbiology, clinical chemistry, radiology, blood bank and resources required to monitor use of immunosuppressive drugs;

2) Access to tissue typing services; and

3) Ability to provide psychiatric and social counseling for the transplant recipients and for their families.

j) Performance Requirements

1) The applicant shall document that the proposed category of service will be provided at a teaching institution.

2) The applicant shall document that the proposed category of service will be performed in conjunction with graduate medical education.

3) The applicant shall provide proof of membership in the Organ Procurement and Transplantation Network (OPTN) and a federally designated organ procurement organization (OPO).

k) 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.

(Source: Amended at 38 Ill. Reg. 8861, effective April 15, 2014)