HEALTH FACILITIES AND SERVICES REVIEW BOARD

NOTICE OF ADOPTED AMENDMENTS

TITLE 77: PUBLIC HEALTH
CHAPTER II: HEALTH FACILITIES AND SERVICES REVIEW BOARD
SUBCHAPTER a: ILLINOIS HEALTH CARE FACILITIES PLAN

PART 1110
PROCESSING, CLASSIFICATION POLICIES AND REVIEW CRITERIA

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AUTHORITY: Authorized by Section 12 of, and implementing, the Illinois Health Facilities Planning Act [20 ILCS 3960] and the Alternative Health Care Delivery Act [210 ILCS 3].

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SUBPART A: APPLICABILITY; PROJECT CLASSIFICATION; DISCONTINUATION OF CATEGORY OF SERVICE

Section 1110.10 Introduction; Definition of Terms; Referenced Statutes

a) Introduction
An application for permit *shall be made to the* Health Facilities and Services Review Board (HFSRB) and shall *contain such information as* HFSRB *deems necessary* [20 ILCS 3960/6]. The applicant is responsible for addressing all pertinent review criteria that relate to the scope of a construction or modification project or to a project for the acquisition of major medical equipment. Applicable review criteria may include, but are not limited to, general review criteria, discontinuation, category of service criteria, and financial and economic feasibility criteria. Applications for permits shall be processed, classified and reviewed in accordance with all applicable HFSRB rules. HFSRB shall consider a project's conformance with all applicable review criteria in evaluating applications and in determining whether a permit should be issued.

b) Definition of Terms
Definitions pertaining to this Part are contained in the Act, 77 Ill. Adm. Code 1100 and 1130, and various Sections of this Part. HFSRB's operational rules relating to the processing and review of applications for permit are contained in 77 Ill. Adm. Code 1130.

c) Referenced Statutes

1) Illinois Statutes

Alternative Health Care Delivery Act [210 ILCS 3]

Ambulatory Surgical Treatment Center Act [210 ILCS 5]

Clinical Social Work and Social Work Practice Act [225 ILCS 20]

Community Benefits Act [210 ILCS 76]

Dietitian Nutritionist Practice Act [225 ILCS 30]

Emergency Medical Services (EMS) Systems Act [210 ILCS 50]

End Stage Renal Disease Facility Act [210 ILCS 62]

Hospital Licensing Act [210 ILCS 85]

Illinois Administrative Procedure Act [5 ILCS 100]

Illinois Health Facilities Planning Act [20 ILCS 3960]

Nursing Home Care Act [210 ILCS 45]

2) Federal Statutes

Public Health Service Act (42 USC 254E)

Social Security Act – Title XVIII (42 USC 1395)

Social Security Act – Title XIX (42 USC 1396)

Social Security Act Amendments of 1982 (PL 92-603) (42 USC 1329)

Section 1110.20 Classification of Projects

When an application for permit has been received by HFSRB, the Administrator shall classify the project into one of the following classifications:

a) Emergency Review Classification

1) An emergency review classification applies only to those construction or modification projects that affect the inpatient or outpatient operation of a health care facility and are necessary because one or more of the following conditions exist:

A) An imminent threat to the structural integrity of the building;

B) An imminent threat to the safe operation and functioning of the mechanical, electrical or comparable systems of the building; or

C) Other *hazardous conditions that may harm or injure persons using the facility*. [20 ILCS 3960/12(9)]

2) Applications classified as emergency will be reviewed for conformance with the following review criteria:

A) Documentation has been provided that verifies the existence of at least one of the conditions specified in subsection (a)(1);

B) Failure to proceed immediately with the project would result in closure or impairment of the inpatient operation of the facility; and

C) The emergency conditions did not exist longer than 30 days prior to the receipt of the application for permit.

3) Further details concerning the process for emergency applications are provided in 77 Ill. Adm. Code 1130.610.

b) Non-Substantive Review Classification
Non-substantive projects are those construction or modification projects that are not classified as substantive or emergency. Applications classified as non-substantive will be reviewed for conformance with the applicable review criteria in this Part.

c) Substantive Review Classification

1) *Substantive projects shall include no more than the following:*

A) *Projects to construct:*

i) *A new or replacement facility located on a new site; or*

ii) *A replacement facility located on the same site as the original facility and the cost of the replacement facility exceeds the capital expenditure minimum, which shall be reviewed by the Board within 120 days;*

B) Projects proposing:

i) Establishment of a category of *service within an existing health care facility; or*

ii) *Discontinuation of a* category of *service within an existing healthcare facility* or discontinuation of a health care facility.

C) Projects that involve *more than 20 beds, or more than 10% of total bed capacity, as defined by* HFSRB*, whichever is less, over a 2-year period,* and propose a change in the bed capacity of a health care facility by:

i) *An increase in the total number of beds;*

ii) *A redistribution of beds among various categories of service; or*

iii) *A relocation of beds from one physical facility or site to another.* [20 ILCS 3960/12(8)]

2) Applications classified as substantive will be reviewed for conformance with all applicable review criteria contained in this Part.

d) Classification Appeal
Appeal of any classification may be made to HFSRB at the next scheduled meeting following the date of the Administrator's determination.

SUBPART B: INTRODUCTION; GENERAL INFORMATION; GENERAL REVIEW CRITERIA

Section 1110.100 Introduction

a) This Subpart contains the Information Requirements and Review Criteria that apply in total or in part to all projects that require a permit, (with the exception of projects solely involving discontinuation and long term care), including:

1) Purpose of Project, Safety Net Impact Statement and Alternatives − Information Requirements;

2) Project Scope and Size, Utilization and Unfinished/Shell Space Review Criteria.

b) Each required point of information is intended to provide HFSRB with an overview of the need for a proposed project. HFSRB shall consider a project's conformance with the applicable information requirements contained in this Subpart, as well as a project's conformance with all applicable review criteria indicated in subsection (c), to determine whether sufficient project need has been documented to issue a Certificate of Need (CON) permit.

c) The review criteria to be addressed (as required) are contained in the following Parts and Subparts:

1) Section 1110.120 contains review criteria concerning Project Scope and Size, Utilization and Unfinished Shell Space, and Section 1110.270 contains review criteria concerning Clinical Service Areas Other Than Categories of Service;

2) Subpart C contains service specific review criteria that shall be addressed, as applicable, to the category of service included in a proposed project;

3) 77 Ill. Adm. Code 1120 contains review criteria pertaining to financial and economic feasibility;

4) 77 Ill. Adm. Code 1130 contains the CON operational requirements that may be applicable to a proposed project; and

5) *An application for a permit or exemption shall be made to* HFSRB *upon forms provided by* HFSRB. *This application shall contain such information as* HFSRB *deems necessary*. [20 ILCS 3960/6]

d) Definitions for Subparts B and C are contained in the Act, in 77 Ill. Adm. Code 1100.220 and throughout this Part.

Section 1110.110 Background of the Applicant, Purpose of Project, Safety Net Impact Statement, and Alternatives − Information Requirements

The information requirements contained in this Section are applicable to all projects except projects that are solely for discontinuation. An applicant shall document the *qualifications, background, character and financial resources to adequately provide a proper service for the community* and also demonstrate that the project promotes the *orderly and economic development of health care facilities in the State of Illinois that avoids unnecessary duplication of facilities* or service. [20 ILCS 3960/2]

a) Background of Applicant – Review Criteria

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 health care facility, or against any health care facility owned or operated by the applicant, directly or indirectly, within 3 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 77 Ill. Adm. Code 1100 and 1130 for definitions of terms such as "adverse action", "ownership interest" and "principal shareholder").

EXAMPLES:

Examples of facilities owned or operated by an applicant include:

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.

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.

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.

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.

2) 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 3 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:

i) cited, arrested, taken into custody, charged with, indicted, convicted or tried for, or pled guilty to the commission of any felony or misdemeanor or violation of the law, except for minor parking violations; or

ii) 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.

3) 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 (a). 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.

4) 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.

b) Purpose of the Project – Information Requirements
The applicant shall document that the project will provide health services that improve the health care or well-being of the market area population to be served. The applicant shall define the planning area or market area, or other, per the applicant's definition.

1) The applicant shall address the purpose of the project, i.e., identify the issues or problems that the project is proposing to address or solve. Information to be provided shall include, but is not limited to, identification of existing problems or issues that need to be addressed, as applicable and appropriate for the project. Examples of such information include:

A) The area's demographics or characteristics (e.g., rapid area growth rate, increased aging population, higher or lower fertility rates) that may affect the need for services in the future;

B) The population's morbidity or mortality rates;

C) The incidence of various diseases in the area;

D) The population's financial ability to access health care (e.g., financial hardship, increased number of charity care patients, changes in the area population's insurance or managed care status);

E) The physical accessibility to necessary health care (e.g., new highways, other changes in roadways, changes in bus/train routes or changes in housing developments).

2) The applicant shall cite the source of the information (e.g., local health department Illinois Project for Local Assessment of Need (IPLAN) documents, Public Health Futures, local mental health plans, or other health assessment studies from governmental or academic and/or other independent sources).

3) The applicant shall detail how the project will address or improve the previously referenced issues, as well as the population's health status and well-being. Further, the applicant shall provide goals with quantified and measurable objectives with specific time frames that relate to achieving the stated goals.

4) For projects involving modernization, the applicant shall describe the conditions being upgraded. For facility projects, the applicant shall include statements of age and condition and any regulatory citations. For equipment being replaced, the applicant shall also include repair and maintenance records.

c) Safety Net Impact Statement – Information Requirements
All health care facilities, with the exception of skilled and intermediate long term care facilities licensed under the Nursing Home Care Act, shall provide a safety net impact statement, which shall be filed with an application for a substantive project (see Section 1110.40). *Safety net services are the services provided by health care providers or organizations that deliver health care services to persons with barriers to mainstream health care due to lack of insurance, inability to pay, special needs, ethnic or cultural characteristics, or geographic isolation*. [20 ILCS 3960/5.4]

1) A safety net impact statement shall describe, if reasonably known by the applicant, all of the following information:

A) *The project's material impact, if any, on essential safety net services in the community;*

B) *The project's impact on the ability of another provider or health care system to cross-subsidize safety net services;* and

C) *How the discontinuation of a facility or service might impact the remaining safety net providers in a given community.*

2) A safety net impact statement shall also include all of the following:

A) Certification describing the amount of charity care provided by the applicant for the 3 fiscal years prior to submission of the application. *The amount calculated by hospital applicants shall be in accordance with the reporting requirements in the Illinois*

Community Benefits Act. Non-hospital applicants shall report charity care, at cost, in accordance with an appropriate methodology specified by the Board. (See 77 Ill. Adm. Code 1120.20(c).)

B) Certification describing the amount of care provided to Medicaid patients for the 3 fiscal years prior to submission of the application. Hospital and non-hospital applicants shall provide Medicaid information consistent with data reported in IDPH's Inpatients and Outpatients Served by Payor Source and Inpatient and Outpatient Revenue by Payor Source.

C) *Any information the applicant believes is directly relevant to safety net services, including information regarding teaching, research, and any other service.* [20 ILCS 3960/5.4(d)(3)]

3) Safety Net Impact Statement Response

A) *Any person, community organization, provider or health system or other entity wishing to comment upon or oppose the application may file a safety net impact statement response with the Board, which shall provide additional information concerning a project's impact on the safety net services in the community.* [20 ILCS 3960/5.4(f)]

B) *Applicants shall be provided an opportunity to submit a reply to any safety net impact statement response.* [20 ILCS 3960/5.4(g)]

4) HFSRB State Board Staff Report
The HFSRB State Board Staff Report shall indicate:

A) Whether a safety net impact statement was filed by the applicant;

B) Whether the safety net impact statement included information on *charity care, the amount of care provided to Medicaid patients, and information on teaching research, or any other service provided by the applicant that is directly relevant to safety net services* [20 ILCS 3960/5.4(h)]; and

C) *Names of the parties submitting responses and the number of responses and replies, if any, that were filed* [20 ILCS 3960/5.4(h)].

d) Alternatives to the Proposed Project – Information Requirements
The applicant shall document that the proposed project is the most effective or least costly alternative for meeting the health care needs of the population to be served by the project.

1) Alternative options shall be addressed. Examples of alternative options include:

A) Proposing a project of greater or lesser scope and cost;

B) Pursuing a joint venture or similar arrangement with one or more providers or entities to meet all or a portion of the project's intended purposes; developing alternative settings to meet all or a portion of the project's intended purposes;

C) Utilizing other health care resources that are available to serve all or a portion of the population proposed to be served by the project; and

D) Other considerations.

2) Documentation shall consist of a comparison of the project to alternative options. The comparison shall address issues of cost, patient access, quality and financial benefits in both the short term (within one to 3 years after project completion) and long term. This may vary by project or situation.

3) The applicant shall provide empirical evidence, including quantified outcome data, that verifies improved quality of care, as available.

Section 1110.120 Project Scope and Size, Utilization and Unfinished/Shell Space − Review Criteria

a) Size of Project – Review Criteria

1) The applicant shall document that the physical space proposed for the project is necessary and appropriate. The proposed square footage cannot deviate from the square footage range indicated in Appendix B, or exceed the square footage standard in Appendix B if the standard is a single number, unless square footage can be justified by documenting, as described in subsection (a)(2).

2) If the project square footage is outside the standards in Appendix B, the applicant shall submit architectural floor plans (see HFSRB NOTE) of the project identifying all clinical service areas and those clinical service areas or components of those areas that do not conform to the standards. The applicant shall submit documentation of one or more of the following:

   A) The proposed space is appropriate and neither excessive nor deficient in relation to the scope of services provided, as justified by clinical or operational needs; supported by published data or studies, as available; and certified by the facility's Medical Director; or

   B) The existing facility's physical configuration has constraints that require an architectural design that exceeds the standards of Appendix B, as documented by architectural drawings delineating the constraints or impediments, in accordance with this subsection (a); or

   C) Additional space is mandated by governmental or certification agency requirements that were not in existence when the Appendix B standards were adopted; or

   D) The project involves the conversion of existing space that results in excess square footage.

   HFSRB NOTE: Architectural floor plans submitted shall identify clinical service areas or components and shall designate the areas in square footage. Architectural floor plans must be of sufficient accuracy and format to allow measurement. Format may be either a digital drawing format (.dwg file or equivalent) or a measurable paper copy 1/16 scale or larger.

b) Project Services Utilization − Review Criterion

The applicant shall document that, by the end of the second year of operation, the annual utilization of the clinical service areas or equipment shall meet or exceed the utilization standards specified in Appendix B. The number of years projected shall not exceed the number of historical years documented. If the applicant does not meet the utilization standards in Appendix B, or if service areas do not have utilization standards in 77 Ill. Adm. Code 1100, the applicant shall justify its own utilization standard by providing published data or studies, as applicable and available from a recognized source, that minimally include the following:

1) Clinical encounter times for anticipated procedures in key rooms (for example, procedure room, examination room, imaging room);

2) Preparation and clean-up times, as appropriate;

3) Operational availability (days/year and hours/day, for example 250 days/year and 8 hours/day); and

4) Other operational factors.

c) Size of the Project and Utilization:
For clinical service areas for which norms are not listed in Appendix B (for example, central sterile supply, laboratory, occupational therapy, pharmacy, physical therapy, respiratory therapy, cardiac rehabilitation, speech pathology and audiology), the applicant shall document that the proposed departmental gross square footage is necessary and appropriate. The documentation shall consist of:

1) Basis for the determination of the space (for example, key rooms, equipment, personnel, utilization, etc.); and

2) Methodology applied.

d) Unfinished or Shell Space − Review Criterion
If the project includes unfinished space (i.e., shell space) that is to meet an anticipated future demand for service, the applicant shall document that the amount of shell space proposed for each department or clinical service area is justified, and that the space will be consistent with the standards of Appendix B as stated in subsections (a) and (b). The applicant shall provide the following information:

1) The total gross square footage of the proposed shell space;

2) The anticipated use of the shell space, specifying the proposed SF to be allocated to each department, area or function;

3) Evidence that the shell space is being constructed due to:

A) Requirements of governmental or certification agencies; or

B) Experienced increases in the historical occupancy or utilization of those departments, areas or functions proposed to occupy the shell space. The applicant shall provide the historical utilization for the department, area or function for the latest 5-year period for which data are available, and, based upon the average annual percentage increase for that period, project the future utilization of the department, area or function through the anticipated date when the shell space will be placed into operation.

e) Assurances
The applicant shall submit the following:

1) The applicant representative who signs the CON application shall submit a signed and dated statement attesting to the applicant's understanding that, by the end of the second year of operation after project completion, the applicant will meet or exceed the utilization standards specified in Appendix B.

2) For shell space, the applicant shall submit the following:

A) Verification that the applicant will submit to HFSRB a CON application to develop and utilize the shell space, regardless of the capital thresholds in effect at that time or the categories of service involved;

B) The anticipated date by which the subsequent CON application (to develop and utilize the subject shell space) will be submitted; and

C) The estimated date when the shell space will be completed and placed into operation.

Section 1110.130 Additional General Review Criteria for Master Design and Related

Projects Only

a) System Impact of Master Plan. The applicant must document that the proposed master plan or future construction or modification projects will have a positive impact on the health care delivery system of the planning area in terms of improved access, long term institutional viability, and availability of services. Documentation shall address:

1) the availability of alternative health care facilities within the planning area and the impact the applicant's proposed future projects will have on the utilization of those facilities;

2) how the services proposed in the applicant's future projects will improve access to area residents;

3) what the potential impact on area residents would be if the proposed services were not to be replaced or developed; and

4) the anticipated role of the facility in the delivery system, including anticipated patterns of patient referral and any contractual or referral agreement between the applicant and other providers that will result in the transfer of patients to the applicant's facility.

b) Master Plan or Related Future Projects – Review Criterion
The applicant must document that all beds and services to be developed pursuant to the master design project must be needed and that access to each service will be improved as a result of the proposed master plan or the construction or modification projects. The applicant must indicate anticipated completion dates for the future construction or modification projects, and document:

1) that:

A) the proposed number of beds and services to be developed pursuant to the master design project must be consistent with the bed or service need determination of 77 Ill. Adm. Code 1100; or

B) if bed or service need determinations do not support the proposed number of beds and services, there are existing factors that support the need for that development at the time of project completion. These factors include, but are not limited to:

i) limitations on governmental funded or charity patients that are expected to continue;

ii) restrictive admission policies of existing planning area health care facilities that are expected to continue;

iii) the planning area population is projected to exhibit indicators of medical care problems, such as average family income below poverty levels or projected high infant mortality; and

2) utilization of the proposed beds and services will meet or exceed the utilization targets established in 77 Ill. Adm. Code 1100 within 2 years after completion of the future construction or modification projects. Documentation shall include:

A) historical service/bed utilization levels;

B) projected trends in utilization, including the rationale and projection assumptions used in those projections;

C) anticipated market factors such as referral patterns or changes in population characteristics (age, density, wellness) that would support utilization projections; and

D) anticipated changes in the delivery of the service due to changes in technology, care delivery techniques or physician availability that would support the projected utilization levels.

c) Relationship to Previously Approved Master Design Projects – Review Criterion

1) The applicant must document that any construction or modification project submitted pursuant to an approved master design project is consistent with the approved design permit. When the construction or modification represents a single phase of a multiple phase master plan, the applicant must document that the proposed phase is consistent with the approved master plan, and that any elements that will be utilized to support additional phases are justified under the approved master design permit. Documentation shall consist of:

A) schematic architectural plans for all construction or modification approved in the master design permit;

B) the estimated project cost for the proposed project and also for the total construction/modification project approved in the master design permit;

C) an item by item comparison of the construction elements (i.e., site, number of buildings, number of floors, etc.) in the proposed project to the approved master design permit; and

D) a comparison of proposed beds and services to those approved under the master design permit.

2) Approval of a proposed construction or modification project that is but one phase in a multiple phase project does not obligate approval or positive findings on construction or modification projects in future phases. Future applications, including those involving the replacement or addition of beds, are subject to the review criteria and bed need in effect at the time of State Board review.

SUBPART C: CATEGORY OF SERVICE REVIEW CRITERIA

Section 1110.200 Medical/Surgical, Obstetric, Pediatric and Intensive Care

a) Introduction

1) This Section applies to projects involving the following categories of hospital bed services: Medical/Surgical; Obstetrics; Pediatrics; and Intensive Care. Applicants proposing to establish, expand or modernize a category of hospital bed service shall comply with the applicable subsections of this Section, as follows:

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)(5)	−	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)	−	Performance Requirements
	(g)	−	Assurances
Expansion of Existing Services	(b)(2)	−	Planning Area Need – Service to Planning Area Residents
	(b)(4)	−	Planning Area Need – Service Demand – Expansion of Existing Category of Service
	(e)	−	Staffing Availability
	(f)	−	Performance Requirements
	(g)	−	Assurances
Category of Service Modernization	(d)(1) & (2) & (3)	−	Deteriorated Facilities
	(d)(4)	−	Occupancy
	(f)	−	Performance Requirements

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

3) If the proposed project involves the replacement of a hospital or service on a new site, the applicant shall comply with the requirements of subsection (a)(1) (Establishment of Services or Facility).

4) If the proposed project involves the replacement of a hospital or service (onsite or new site), the number of beds being replaced shall not exceed the number justified by historical occupancy rates for each of the latest 2 years, unless additional beds can be justified per the criteria for Expansion of Existing Services.

b) Planning Area Need − Review Criterion
The applicant shall document that the number of beds to be established or added is necessary to serve the planning area's population, based on the following:

1) 77 Ill. Adm. Code 1100 (formula calculation)

A) The number of beds to be established for each category of service is in conformance with the projected bed deficit specified in 77 Ill. Adm. Code 1100, as reflected in the latest updates to the Inventory.

B) The number of beds proposed shall not exceed the number of the projected deficit, to meet the health care needs of the population served, in compliance with the occupancy standard specified in 77 Ill. Adm. Code 1100.

2) Service to Planning Area Residents

A) Applicants proposing to establish or add beds 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.

B) Applicants proposing to add beds to an existing category of service shall provide patient origin information for all admissions for the last 12-month period, verifying that at least 50% of admissions were residents of the area. For all other projects, applicants shall document that at least 50% of the projected patient volume will be from residents of the area.

C) Applicants proposing to expand an existing category of service shall submit patient origin information by zip code, based upon the patient's legal residence (other than a health care facility).

3) Service Demand – Establishment of Bed Category of Service
The number of beds proposed to establish a new 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. The applicant shall document subsection (b)(3)(A) and either subsection (b)(3)(B) or (C):

A) Historical Referrals
If the applicant is an existing facility, the applicant shall document the number of referrals to other facilities, for each proposed 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 a category of service or establish a new hospital 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) 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.

C) Project Service Demand − Based on Rapid Population Growth
If a projected demand for service is based upon rapid population growth in the applicant facility's existing market area (as

experienced annually within the latest 24-month period), the projected service demand shall be determined as follows:

i) The applicant shall define the facility's market area based upon historical patient origin data by zip code or census tract;

ii) Population projections shall be produced, using, as a base, the population census or estimate for the most recent year, for county, incorporated place, township or community area, by the U.S. Census Bureau or IDPH;

iii) Projections shall be for a maximum period of 10 years from the date the application is submitted;

iv) Historical data used to calculate projections shall be for a number of years no less than the number of years projected;

v) Projections shall contain documentation of population changes in terms of births, deaths, and net migration for a period of time equal to, or in excess of, the projection horizon;

vi) Projections shall be for total population and specified age groups for the applicant's market area, as defined by HFSRB, for each category of service in the application; and

vii) Documentation on projection methodology, data sources, assumptions and special adjustments shall be submitted to HFSRB.

4) Service Demand – Expansion of Existing Category of Service
The number of beds to be added for each category of service is necessary to reduce the facility's experienced high occupancy and to meet a projected demand for service. The applicant shall document subsection (b)(4)(A) and either subsection (b)(4)(B) or (C):

A) Historical Service Demand

i) An average annual occupancy rate that has equaled or exceeded occupancy standards for the category of service, as specified in 77 Ill. Adm. Code 1100, for each of the latest 2 years;

ii) If patients have been referred to other facilities in order to receive the subject services, the applicant shall provide documentation of the referrals, including: patient origin by zip code; name and specialty of referring physician; and name and location of the recipient hospital, for each of the latest 2 years.

B) Projected Referrals
The applicant shall provide 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. The percentage of project referrals used to justify the proposed expansion cannot exceed the historical percentage of applicant market share within a 24-month period after project completion;

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.

C) Projected Service Demand – Based on Rapid Population Growth:
If a projected demand for service is based upon rapid population growth in the applicant facility's existing market area (as

experienced annually within the latest 24-month period), the projected service demand shall be determined as follows:

i) The applicant shall define the facility's market area based upon historical patient origin data by zip code or census tract;

ii) Population projections shall be produced, using, as a base, the population census or estimate for the most recent year, for county, incorporated place, township or community area, by the U.S. Census Bureau or IDPH;

iii) Projections shall be for a maximum period of 10 years from the date the application is submitted;

iv) Historical data used to calculate projections shall be for a number of years no less than the number of years projected;

v) Projections shall contain documentation of population changes in terms of births, deaths and net migration for a period of time equal to or in excess of the projection horizon;

vi) Projections shall be for total population and specified age groups for the applicant's market area, as defined by HFSRB, for each category of service in the application; and

vii) Documentation on projection methodology, data sources, assumptions and special adjustments shall be submitted to HFSRB.

5) Service Accessibility
The number of beds being established or added for each 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 (b)(5) only, all services within the established radii outlined in 77 Ill. Adm. Code 1100.510(d) 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, 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; and

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 the established radii outlined in 77 Ill. Adm. Code 1100.510(d) 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 the established radii outlined in 77 Ill. Adm. Code 1100.510(d) of the project site that provide the categories of bed service that are proposed by the project.

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) A ratio of beds to population that exceeds one and one-half times the State average;

B) 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

C) 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 a category of hospital bed service, the applicant shall document that the inpatient bed 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 bedrooms); or

D) Additional space for diagnostic or therapeutic purposes.

2) Documentation shall include the most recent:

A) IDPH Centers for Medicare and Medicaid Services (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 a narrative explanation of how the proposed staffing will be achieved.

f) Performance Requirements − Bed Capacity Minimum

1) Medical-Surgical
The minimum bed capacity for a new medical-surgical category of service within a Metropolitan Statistical Area (MSA), as defined by the U.S. Census Bureau, is 100 beds.

2) Obstetrics

A) The minimum unit size for a new obstetric unit within an MSA is 20 beds.

B) The minimum unit size for a new obstetric unit outside an MSA is 4 beds.

3) Intensive Care
The minimum unit size for an intensive care unit is 4 beds.

4) Pediatrics
The minimum size for a pediatric unit within an MSA is 4 beds.

g) 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 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.

Section 1110.205 Comprehensive Physical Rehabilitation Beds

a) Introduction

1) This Section applies to projects involving the Comprehensive Physical Rehabilitation (CPR) category of service. Applicants proposing to establish, expand or modernize CPR shall comply with the applicable subsections of this Section, as follows:

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 CPR
	(b)(5)	−	Planning Area Need − Service Accessibility
	(c)(1)	−	Unnecessary Duplication of Services
	(c)(2)	−	Maldistribution
	(c)(3)	−	Impact of Project on Other Area Providers
	(e)(1)	−	Staffing Availability
	(f)	−	Performance Requirements
	(g)	−	Assurances
Expansion of Existing Services	(b)(2)	−	Planning Area Need – Service to Planning Area Residents
	(b)(4)	−	Planning Area Need – Service Demand – Expansion of CPR
	(e)(1)	−	Staffing − Availability
	(f)	−	Performance Requirements
	(g)	−	Assurances
Comprehensive Physical	(d)(1)	−	Deteriorated Facilities
	(d)(2) & (3)	−	Documentation
	(d)(4)	−	Occupancy

Rehabilitation Modernization	(f) − Performance Requirements

2) If the proposed project involves the replacement of a hospital or service on-site, the applicant shall comply with the requirements listed in subsection (a)(1) (Comprehensive Physical Rehabilitation Modernization) plus subsection (g) (Assurances).

3) If the proposed project involves the replacement of a hospital or service on a new site, the applicant shall comply with the requirements of subsection (a)(1) (Establishment of Services or Facility).

4) If the proposed project involves the replacement of a hospital or service (on-site or new site), the number of beds being replaced shall not exceed the number justified by historical occupancy rates for each of the latest 2 years, unless additional beds can be justified per the criteria for Expansion of Existing Services.

b) Planning Area Need − Review Criterion
The applicant shall document that the number of beds to be established or added is necessary to serve the planning area's population, based on the following:

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

A) The number of beds to be established for each category of service is in conformance with the projected bed deficit specified in 77 Ill. Adm. Code 1100, as reflected in the latest updates to the Inventory.

B) The number of beds proposed shall not exceed the number of the projected deficit, to meet the health care needs of the population served, in compliance with the occupancy standard specified in 77 Ill. Adm. Code 1100.

2) Service to Planning Area Residents

A) Applicants proposing to establish or add beds 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.

B) Applicants proposing to add beds to an existing CPR service shall provide patient origin information for all admissions for the last 12-month period, verifying that at least 50% of admissions were residents of the area. For all other projects, applicants shall document that at least 50% of the projected patient volume will be from residents of the area.

C) Applicants proposing to expand an existing CPR service shall submit patient origin information by zip code, based upon the patient's legal residence (other than a health care facility).

3) Service Demand – Establishment of Comprehensive Physical Rehabilitation
The number of beds proposed to establish CPR 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. The applicant shall document subsection (b)(3)(A) and either subsection (b)(3)(B) or (C).

A) Historical Referrals
If the applicant is an existing facility, the applicant shall document the number of referrals to other facilities, for each proposed category of hospital bed 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 CPR or to establish a new hospital 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 whom 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) 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.

C) Projected Service Demand − Based on Rapid Population Growth
If a projected demand for services is based upon rapid population growth in the applicant facility's existing market area (as experienced annually within the latest 24-month period), the projected service demand shall be determined as follows:

i) The applicant shall define the facility's market area based upon historical patient origin data by zip code or census tract;

ii) Population projections shall be produced, using, as a base, the population census or estimate for the most recent year, for county, incorporated place, township or community area, by the U.S. Census Bureau or IDPH;

iii) Projections shall be for a maximum period of 10 years from the date the application is submitted;

iv) Historical data used to calculate projections shall be for a number of years no less than the number of years projected;

v) Projections shall contain documentation of population changes in terms of births, deaths and net migration for a period of time equal to, or in excess of, the projection horizon;

vi) Projections shall be for total population and specified age groups for the applicant's market area, as defined by HFSRB, for each category of service in the application; and

vii) Documentation on projection methodology, data sources, assumptions and special adjustments shall be submitted to HFSRB.

4) Service Demand – Expansion of Comprehensive Physical Rehabilitation
The number of beds to be added for each category of service is necessary to reduce the facility's experienced high occupancy and to meet a projected demand for service. The applicant shall document subsection (b)(4)(A) and either subsection (b)(4)(B) or (C):

A) Historical Service Demand

i) An average annual occupancy rate that has equaled or exceeded occupancy standards for the category of service, as specified in 77 Ill. Adm. Code 1100, for each of the latest 2 years.

ii) If patients have been referred to other facilities in order to receive the subject services, the applicant shall provide documentation of the referrals, including: patient origin by zip code; name and specialty of referring physician; and name and location of the recipient hospital, for each of the latest 2 years.

B) Projected Referrals
The applicant shall provide 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. The percentage of project referrals used to justify the proposed expansion cannot exceed the historical percentage of applicant market share, within a 24-month period after project completion;

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.

C) Projected Service Demand – Based on Rapid Population Growth
If a projected demand for service is based upon rapid population growth in the applicant facility's existing market area (as experienced annually within the latest 24-month period), the projected service demand shall be determined as follows:

i) The applicant shall define the facility's market area based upon historical patient origin data by zip code or census tract;

ii) Population projections shall be produced, using, as a base, the population census or estimate for the most recent year, for county, incorporated place, township or community area, by the U.S. Census Bureau or IDPH;

iii) Projections shall be for a maximum period of 10 years from the date the application is submitted;

iv) Historical data used to calculate projections shall be for a number of years no less than the number of years projected;

v) Projections shall contain documentation of population changes in terms of births, deaths and net migration for a period of time equal to or in excess of the projection horizon;

vi) Projections shall be for total population and specified age groups for the applicant's market area, as defined by HFSRB, for each category of service in the application; and

vii) Documentation on projection methodology, data sources, assumptions and special adjustments shall be submitted to HFSRB.

5) Service Accessibility
The number of beds being established or added for each 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 (b)(5) only, all services within the established radii outlined in 77 Ill. Adm. Code 1100.510(d) 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, 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; and

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 the established radii outlined in 77 Ill. Adm. Code 1100.510(d) 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 the established radii outlined in 77 Ill. Adm. Code 1100.510(d) from the project site that provide the categories of bed service that are proposed by the project.

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) A ratio of beds to population that exceeds one and one-half times the State average;

B) 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

C) 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) Comprehensive Physical Rehabilitation Modernization

1) If the project involves modernization of a CPR service, the applicant shall document that the inpatient bed 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

1) 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 a narrative explanation of how the proposed staffing will be achieved.

f) Performance Requirements − Bed Capacity Minimums

1) The minimum freestanding facility size for comprehensive physical rehabilitation is a minimum facility capacity of 100 beds.

2) The minimum hospital unit size for comprehensive physical rehabilitation is 16 beds.

g) 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.

Section 1110.210 Acute Mental Illness and Chronic Mental Illness

a) Introduction

1) This Section applies to projects involving Acute Mental Illness (AMI) and Chronic Mental Illness (CMI). Applicants proposing to establish, expand or modernize AMI and CMI categories of service shall comply with the applicable subsections of this Section, as follows:

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 AMI and/or CMI
	(b)(5)	−	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)	−	Performance Requirements
	(g)	−	Assurances
Expansion of Existing Services	(b)(2)	−	Planning Area Need – Service to Planning Area Residents
	(b)(4)	−	Planning Area Need – Service Demand – Expansion of AMI and/or CMI

	(e)	−	Staffing Availability
	(f)	−	Performance Requirements
	(g)	−	Assurances
Category of Service Modernization	(d)(1)	−	Deteriorated Facilities
	(d)(2) & (3)	−	Documentation
	(d)(4)	−	Occupancy
	(f)	−	Performance Requirements

2) If the proposed project involves the replacement of a hospital or service onsite, the applicant shall comply with the requirements listed in subsection (a)(1) (AMI and/or CMI Modernization) plus subsection (g) (Assurances).

3) If the proposed project involves the replacement of a hospital or service offsite, the applicant shall comply with the requirements of subsection (a)(1) (Establishment of Services or Facility).

4) If the proposed project involves the replacement of a hospital or service (onsite or new site), the number of beds being replaced shall not exceed the number justified by historical occupancy rates for each of the latest 2 years, unless additional beds can be justified per the criteria for Expansion of Existing Services.

b) Planning Area Need − Review Criterion
The applicant shall document that the number of beds to be established or added is necessary to serve the planning area's population, based on the following:

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

A) The number of beds to be established for each category of service is in conformance with the projected bed deficit specified in 77 Ill. Adm. Code 1100, as reflected in the latest updates to the Inventory.

B) The number of beds proposed shall not exceed the number of the projected deficit, to meet the health care needs of the population served, in compliance with the occupancy standard specified in 77 Ill. Adm. Code 1100.

2) Service to Planning Area Residents

A) Applicants proposing to establish or add beds 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.

B) Applicants proposing to add beds to an existing AMI and/or CMI service shall provide patient origin information for all admissions for the last 12-month period, verifying that at least 50% of admissions were residents of the area. For all other projects, applicants shall document that at least 50% of the projected patient volume will be from residents of the area.

C) Applicants proposing to expand an existing AMI and/or CMI service shall submit patient origin information by zip code, based upon the patient's legal residence (other than a health care facility).

3) Service Demand – Establishment of AMI and/or CMI
The number of beds proposed to establish a new AMI and/or CMI service is necessary to accommodate the service demand experienced 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. The applicant shall document subsection (b)(3)(A) and subsection (b)(3)(B) or (C).

A) Historical Referrals
If the applicant is an existing facility, the applicant shall document the number of referrals to other facilities, for each proposed category of hospital bed 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 a new AMI and/or CMI service or establish a new hospital shall submit the following:

i) Physician referral and/or DHS-funded mental health provider (59 Ill. Adm. Code 132) letters that attest to the 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 and/or DHS-funded mental health provider 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 and/or mental health provider's documented historical 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.

C) Projected Service Demand − Based on Rapid Population Growth
If a projected demand for service is based upon rapid population growth in the applicant facility's existing market area (as experienced within the latest 24-month period), the projected service demand shall be determined as follows:

i) The applicant shall define the facility's market area based upon historical patient origin data by zip code or census tract. Applicants proposing to use zip code data to define the project market area shall indicate the sources of that information;

ii) Population projections shall be produced, using, as a base, the population census or estimate for the most recent year, for county, incorporated place, township or community area, by the U.S. Census Bureau or IDPH;

iii) Projection shall be for a maximum period of 10 years from the date the application is submitted;

iv) Historical data used to calculate projections shall be for a number of years no less than the number of years projected;

v) Projections shall contain documentation of population changes in terms of births, deaths and net migration for a period of time equal to, or in excess of, the projection horizon;

vi) Projections shall be for total population and specified age groups for the applicant's market area, as defined by HFSRB, for each category of service in the application; and

vii) Documentation on projection methodology, data sources, assumptions and special adjustments shall be submitted to HFSRB.

D) Patient Type
The applicant shall identify the type of patients that will be served by the project by providing the clinical conditions anticipated (e.g., eating disorder, borderline personality disorder, dementia) and age groups (e.g., childhood, adolescent, geriatric) targeted.

4) Service Demand – Expansion of AMI and/or CMI Service
The number of beds to be added for each category of service is necessary to reduce the facility's experienced high occupancy and to meet a projected demand for service. The applicant shall document subsection (b)(4)(A) and either subsection (b)(4)(B) or (C):

A) Historical Service Demand

i) An average annual occupancy rate that has equaled or exceeded occupancy standards for the category of service, as specified in 77 Ill. Adm. Code 1100, for each of the latest 2 years.

ii) If patients have been referred to other facilities in order to receive the subject services, the applicant shall provide

documentation of the referrals, including: patient origin by zip code; name and specialty of referring physician; and name and location of the recipient hospital, for each of the latest 2 years.

B) Projected Referrals
The applicant shall provide 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 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. The percentage of project referrals used to justify the proposed expansion cannot exceed the historical percentage of applicant market share, within a 24-month period after project completion;

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.

C) Projected Service Demand – Based on Rapid Population Growth
If a projected demand for service is based upon rapid population growth in the applicant facility's existing market area (as experienced within the latest 24-month period), the projected service demand shall be determined as follows:

i) The applicant shall define the facility's market area based upon historical patient origin data by zip code or census tract;

ii) Population projections shall be produced, using, as a base, the population census or estimate for the most recent year, for county, incorporated place, township or community area, by the U.S. Census Bureau or IDPH;

iii) Projections shall be for a maximum period of 10 years from the date the application is submitted;

iv) Historical data used to calculate projections shall be for a number of years no less than the number of years projected;

v) Projections shall contain documentation of population changes in terms of births, deaths and net migration for a period of time equal to or in excess of the projection horizon;

vi) Projections shall be for total population and specified age groups for the applicant's market area, as defined by HFSRB, for each category of service in the application; and

vii) Documentation on projection methodology, data sources, assumptions and special adjustments shall be submitted to HFSRB.

5) Service Accessibility
The number of beds being established or added for each 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 (b)(5) only, all services within the established radii outlined in 77 Ill. Adm. Code 1100.510(d) 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, 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) Distance to other planning area providers, according to 77 Ill. Adm. Code 1100.510(d);

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 Criteria

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 the established radii outlined in 77 Ill. Adm. Code 1100.510(d) 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 the established radii outlined in 77 Ill. Adm. Code 1100.510(d) from the project site that provide the categories of bed service that are proposed by the project.

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, bed and services characterized by such factors as, but not limited to:

   A) A ratio of beds to population that exceeds one and one-half times the State average;

   B) 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

   C) 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) AMI and/or CMI Modernization

1) If the project involves modernization of an AMI and/or CMI service, the applicant shall document that the inpatient bed 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 a narrative explanation of how the proposed staffing will be achieved.

f) Performance Requirements − Bed Capacity Minimums

1) The minimum unit size for a new AMI unit within an MSA is 20 beds.

2) The minimum unit size for a new AMI unit outside an MSA is 10 beds.

g) 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.

Section 1110.215 Neonatal Intensive Care

This Section contains Review Criteria that pertain to the Neonatal Intensive Care category of service.

a) Staffing

1) The applicant must document that the personnel possessing proper credentials in the following categories are available to staff the service:

A) Full-time Neonatal Director – a neonatologist.

B) Full-time Subspecialty Obstetrical Director – an obstetrician certified by the American Board of Obstetrics and Gynecology in the subspecialty of Maternal and Fetal Medicine or a licensed osteopathic physician with equivalent training and experience and certified by the American Osteopathic Board of Obstetrics and Gynecology.

C) Other neonatologists and obstetricians sufficient in number to serve the projected number of maternal and neonatal patients to be

served by the facility and to ensure adequate back-up to the neonatal and obstetrical directors so that there will be continuity of patient care and consultation. Backup neonatologists and obstetricians shall have credentials equivalent to those of Neonatal and Obstetrical Directors.

D) Full-time Nurse-Director of the obstetric-newborn nursing service who is experienced in perinatal nursing, with a master's degree.

E) Other nurses adequate in number to serve the projected number of maternal and neonatal patients to be served by the facility.

F) Obstetric anesthesia services under the direct supervision of a board-certified anesthesiologist with training in maternal, fetal and neonatal anesthesia shall be available 24 hours a day. The directors of obstetric anesthesia services shall ensure the backup supervision of their services when they are unavailable.

G) One or more licensed social workers with perinatal/neonatal experience.

H) Respiratory therapists with experience in neonatal care and adequate in number to ensure availability of a minimum of one respiratory therapist for every 4 patients on mechanical ventilators.

I) Registered dietician with experience in perinatal nutrition.

2) Documentation shall include a narrative explanation of how positions will be filled.

b) Need for Additional Beds. The applicant must document that the proposed neonatal intensive care beds are needed. Bed need may be documented by any of the following:

1) no neonatal intensive care services exist within the planning area;

2) that for each of the last 2 years for which data is available, the yearly occupancy rate for the service at the affiliated perinatal center has exceeded the target occupancy rate;

3) existing providers of the service within the planning area cannot provide care to a patient caseload due to a limitation on funding for care providing; or

4) that for each of the last 2 years for which data is available, the yearly occupancy rate for the service at the applicant facility has exceeded the target occupancy rate.

c) Obstetric Service. The applicant must document the availability within the facility of an obstetric service capable of providing care to high-risk mothers. Documentation must include a detailed assessment of obstetric service capability. This requirement does not apply to a facility dedicated to the care of children.

Section 1110.220 Open Heart Surgery

a) Introduction
This Section contains Review Criteria that pertain to the Open Heart Surgery category of service. Open heart surgical procedures performed on an emergency basis due to a complication occurring during a cardiac catheterization procedure shall not constitute establishment of the open heart surgery category of service when reported to the agency within 30 days of occurrence.

b) Review Criteria

1) Peer Review. The applicant must document the mechanism for peer review of an open heart surgery program.

2) Establishment of Open Heart Surgery. The applicant must document that a minimum of 200 open heart surgical procedures will be performed during the second year of operation or that 750 cardiac catheterizations were performed in the latest 12-month period for which data is available. Anticipated open heart surgical volume must be documented by historical referral volume of at least 200 patients directly referred following catheterization at the applicant facility to other institutions for open heart surgery for each of the last 2 years.

3) Unnecessary Duplication of Services. The applicant must document that the volume of any existing service within 90 minutes travel time from the applicant will not be reduced below 350 procedures annually for adults and 75 procedures annually for pediatrics. Documentation shall consist of

proof of contact of all facilities within 90 minutes travel time currently providing open heart surgery to determine the projected impact the project will have on existing open heart surgery volume.

4) Support Services. The applicant must document that the following support services and facilities are immediately available on a 24-hour basis and how those services will be mobilized in the case of emergencies.

A) Surgical and cardiological team appropriate for age group served.

B) Cardiac surgical intensive care unit.

C) Emergency room with full-time director, staffed 24 hours for cardiac emergencies with acute coronary suspect surveillance area and voice communication linkage to the ambulance service and the coronary care unit.

D) Catheterization-angiographics laboratory services.

E) Nuclear medicine laboratory.

F) Cardiographics laboratory, electrocardiography, including exercise stress testing, continuous electrocardiograph (ECG) monitoring and phonocardiography.

G) Echocardiography service. This may or may not be a part of the cardiographics laboratory.

H) Hematology laboratory.

I) Microbiology laboratory.

J) Blood gas and electrolyte laboratory with microtechniques for pediatric patients.

K) Electrocardiographic laboratory.

L) Blood bank and coagulation laboratory.

M) Pulmonary function unit.

N) Installation of pacemakers.

O) Organized cardiopulmonary resuscitation team or capability.

P) Preventive maintenance program for all biomedical devices, electrical installations, and environmental controls.

Q) Renal dialysis.

5) Staffing

A) The applicant must document that a cardiac surgical team will be established. The team shall be composed of at least the following:

i) Two cardiac surgeons (at a minimum, one of which must be certified and the other qualified by the American Board of Thoracic Surgery) with special competence in cardiology, including cardiopulmonary anatomy, physiology, pathology and pharmacology; extracorporeal perfusion technique; and interpretation of catheterization angiographic data.

ii) Operating room nurse personnel (registered nurse (RN), licensed practical nurse (LPN), surgical technician). The nurse to patient ratio for the ICU module of open heart surgery patient care should be no less than one nurse per one patient in the immediate recovery phase and one nurse per 2 patients thereafter.

iii) Anesthesiologists (board certified by the American Board of Anesthesiology).

iv) Adult cardiologists (board certified by the American Board of Internal Medicine with subspecialty certification in cardiology).

v) Physician who is board certified in anatomic and clinical pathology, with special expertise in microbiology, bloodbanking, lab aspects of blood coagulation, blood

gases and electrolytes.

vi) Pump technician, or operator of the extracorporeal pump oxygenator, who should have in-depth experience on the active cardiac surgical service that includes perfusion physiology, mechanics of pump operation, sterile technique, and use of monitoring equipment, whether he/she be a physician, nurse or technician.

vii) Radiologic technologist experienced in angiographic principles and catheterization procedure techniques who is experienced in the usage, operation and care of all catheterization equipment.

B) Documentation shall include a narrative explanation of how positions will be filled.

Section 1110.225 Cardiac Catheterization

This Section contains Review Criteria that pertain to the Cardiac Catheterization category of service.

a) Peer Review
Any applicant proposing the establishment or modernization of a cardiac catheterization unit shall detail in its application for permit the mechanism for adequate peer review of the program. Peer review teams will evaluate the quality of studies and related morbidity and mortality of patients and also the technical aspects of providing the services such as film processing, equipment maintenance, etc.

b) Establishment or Expansion of Cardiac Catheterization Service
There shall be not additional adult or pediatric catheterization categories of service started in a health planning area unless:

1) the standards as outlined in 77 Ill. Adm. Code 1100.620 are met; unless

2) in the circumstances where area programs have failed to meet those targets, the applicant can document historical referral volume in each of the prior 3 years for cardiac catheterization in excess of 400 annual procedures (e.g., certification of the number of patients transferred to other

service providers in each of the last 3 years).

c) Unnecessary Duplication of Services

1) Any application proposing to establish cardiac catheterization services must indicate if it will reduce the volume of existing facilities below 200 catheterizations.

2) Any applicant proposing the establishment of cardiac catheterization services must contact all facilities currently providing the service within the planning area in which the applicant facility is located, to determine the impact the project will have on the patient volume at existing services.

d) Modernization of Existing Cardiac Catheterization Equipment
An applicant with a proposed project for the modernization of existing equipment that provides cardiac catheterization services shall document that the minimum utilization standards (as outlined in 77 Ill. Adm. Code 1100.620) are met.

e) Support Services

1) Any applicant proposing the establishment of a dedicated cardiac catheterization laboratory must document the availability of the following support services;

A) Nuclear medicine laboratory.

B) Echocardiography service.

C) Electrocardiography laboratory and services, including stress testing and continuous cardiogram monitoring.

D) Pulmonary Function unit.

E) Blood bank.

F) Hematology laboratory-coagulation laboratory.

G) Microbiology laboratory.

H) Blood Gas laboratory.

I) Clinical pathology laboratory with facilities for blood chemistry.

2) These support services need not be in operation on a 24-hour basis but must be available when needed.

f) Laboratory Location
Due to safety considerations in the event of technical breakdown it is preferable to group laboratory facilities. Thus in projects proposing to establish additional catheterization laboratories such units must be located in close proximity to existing laboratories unless such location is architecturally infeasible.

g) Staffing
It is the policy of the State Board that if cardiac catheterization services are to be offered that a cardiac catheterization laboratory team be established. Any applicant proposing to establish such a laboratory must document that the following personnel will be available:

1) Lab director board-certified in internal medicine, pediatrics or radiology with subspecialty training in cardiology or cardiovascular radiology.

2) A physician with training in cardiology and/or radiology present during examination with extra physician backup personnel available.

3) Nurse specially trained in critical care of cardiac patients, knowledge of cardiovascular medication, and understanding of catheterization equipment.

4) Radiologic technologist highly skilled in conventional radiographic techniques and angiographic principles, knowledgeable in every aspect of catheterization instrumentation, and with thorough knowledge of the anatomy and physiology of the cardiovascular system.

5) Cardiopulmonary technician for patient observation, handling blood samples and performing blood gas evaluation calculations.

6) Monitoring and recording technician for monitoring physiologic data and alerting physician to any changes.

7) Electronic radiologic repair technician to perform systematic tests and

routine maintenance; must be immediately available in the event of equipment failure during a procedure.

8) Darkroom technician well trained in photographic processing and in the operation of automatic processors used for both sheet and cine film.

h) Continuity of Care
Any applicant proposing the establishment, expansion or modernization of a cardiac catheterization service must document that written transfer agreements have been established with facilities with open-heart surgery capabilities for the transfer of seriously ill patients for continuity of care.

i) Multi-Institutional Variance

1) A variance to the establishment requirements of subsection (b), Establishment or Expansion of Cardiac Catheterization Service shall be granted if the applicant can demonstrate that the proposed new program is necessary to alleviate excessively high demands on an existing operating program's capacity.

2) Each of the following must be documented:

A) That the proposed unit will be affiliated with the existing operating program. This must be documented by written referral agreements between the facilities, and documentation of shared medical staff;

B) That the existing operating program provides open heart surgery;

C) That initiation of a new program at the proposed site is more cost effective, based upon a comparison of charges, than expansion of the existing operating program;

D) That the existing operating program currently operates at a level of more than 750 procedures annually per laboratory; and

E) That the proposed unit will operate at the minimum utilization target occupancy and that such unit will not reduce utilization in existing programs below target occupancy (e.g., certification of the number of patients transferred to other service providers in each of the last 3 years and market studies developed by the applicant

indicating the number of potential catheterization patients in the area served by the applicant).

3) The existing operating program cannot utilize its volume of patient procedures to justify a second affiliation agreement until such time as the operating program is again operating at 750 procedures annually per laboratory and the affiliate is operating at 400 procedures per laboratory.

Section 1110.230 In-Center Hemodialysis Projects

a) Introduction

1) This Section applies to projects involving the In-Center Hemodialysis category of service. Applicants proposing to establish, expand or modernize this category of service shall comply with the applicable subsections of this Section as follows:

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 In-Center Hemodialysis
	(b)(5)	−	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
	(f)	−	Support Services
	(g)	−	Minimum Number of Stations
	(h)	−	Continuity of Care
	(i)	−	Relocation (if applicable)
	(j)	−	Assurances
Expansion of Existing Services	(b)(2)	−	Planning Area Need – Service to Planning Area Residents

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	(b)(4)	−	Planning Area Need – Service Demand – Expansion of In-Center Hemodialysis
	(e)	−	Staffing − Availability
	(f)	−	Support Services
	(j)	−	Assurances
In-Center Hemodialysis Modernization	(d)(1)	−	Deteriorated Facilities
	(d)(2) & (3)	−	Documentation
	(f)	−	Support Services

2) If the proposed project involves the relocation of an existing facility or service, the applicant shall comply with the requirements listed in subsection (a)(1) (Establishment of Services or Facility), as well as requirements in Section 1110.290 (Discontinuation) and subsection (i) of this Section (Relocation of Facilities).

3) If the proposed project involves the replacement of a facility or service (onsite or new site), the number of stations being replaced shall not exceed the number justified by historical utilization rates for each of the latest 2 years, unless additional stations can be justified per the criteria for Expansion of Existing Services.

b) Planning Area Need − Review Criterion
The applicant shall document that the number of stations to be established or added is necessary to serve the planning area's population, based on the following:

1) 77 Ill. Adm. Code 1100

A) The number of stations to be established for in-center hemodialysis is in conformance with the projected station deficit specified in 77 Ill. Adm. Code 1100, as reflected in the latest updates to the Inventory.

B) The number of stations proposed shall not exceed the number of the projected deficit, to meet the health care needs of the population served, in compliance with the utilization standard specified in 77 Ill. Adm. Code 1100.

2) Service to Planning Area Residents

A) Applicants proposing to establish or add stations 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.

B) Applicants proposing to add stations to an existing in-center hemodialysis service shall provide patient origin information for all admissions for the last 12-month period, verifying that at least 50% of admissions were residents of the area. For all other projects, applicants shall document that at least 50% of the projected patient volume will be from residents of the area.

C) Applicants proposing to expand an existing in-center hemodialysis service shall submit patient origin information by zip code, based upon the patient's legal residence (other than a health care facility).

3) Service Demand – Establishment of In-Center Hemodialysis Service
The number of stations proposed to establish a new in-center hemodialysis 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 facility, the applicant shall submit projected referrals. The applicant shall document subsection (b)(3)(A) and either subsection (b)(3)(B) or (C).

A) Historical Referrals

i) If the applicant is an existing facility, the applicant shall document the number of referrals to other facilities, for each proposed category of service, for each of the latest 2 years.

ii) Documentation of the referrals shall include: patient origin by zip code; name and specialty of referring physician; name and location of the recipient facility.

B) Projected Referrals
The applicant shall provide physician referral letters that attest to:

i) The physician's total number of patients (by facility and zip code of residence) who have received care at existing facilities located in the area, as reported to The Renal Network at the end of the year for the most recent 3 years and the end of the most recent quarter;

ii) The number of new patients (by facility and zip code of residence) located in the area, as reported to The Renal Network, that the physician referred for in-center hemodialysis for the most recent year;

iii) An estimated number of patients (transfers from existing facilities and pre-ESRD, as well as respective zip codes of residence) that the physician will refer annually to the applicant's facility within a 24-month period after project completion, based upon the physician's practice experience. The anticipated number of referrals cannot exceed the physician's documented historical caseload;

iv) An estimated number of existing patients who are not expected to continue requiring in-center hemodialysis services due to a change in health status (e.g., the patients received kidney transplants or expired);

v) The physician's notarized signature, the typed or printed name of the physician, the physician's office address and the physician's specialty;

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

vii) Each referral letter shall contain a statement attesting that the information submitted is true and correct, to the best of the physician's belief.

C) Projected Service Demand − Based on Rapid Population Growth
If a projected demand for service is based upon rapid population growth in the applicant facility's existing market area (as

experienced annually within the latest 24-month period), the projected service demand shall be determined as follows:

i) The applicant shall define the facility's market area based upon historical patient origin data by zip code or census tract;

ii) Population projections shall be produced, using, as a base, the population census or estimate for the most recent year, for county, incorporated place, township or community area, by the U.S. Census Bureau or IDPH;

iii) Projections shall be for a maximum period of 10 years from the date the application is submitted;

iv) Historical data used to calculate projections shall be for a number of years no less than the number of years projected;

v) Projections shall contain documentation of population changes in terms of births, deaths and net migration for a period of time equal to or in excess of the projection horizon;

vi) Projections shall be for total population and specified age groups for the applicant's market area, as defined by HFSRB, for each category of service in the application; and

vii) Documentation on projection methodology, data sources, assumptions and special adjustments shall be submitted to HFSRB.

4) Service Demand – Expansion of In-Center Hemodialysis Service
The number of stations to be added for each category of service is necessary to reduce the facility's experienced high utilization and to meet a projected demand for service. The applicant shall document subsection (b)(4)(A) and either (b)(4)(B) or (C):

A) Historical Service Demand

i) An average annual utilization rate that has equaled or exceeded utilization standards for in-center hemodialysis service, as specified in 77 Ill. Adm. Code 1100, for each of the latest 2 years.

ii) If patients have been referred to other facilities in order to receive the subject service, the applicant shall provide documentation of the referrals, including: patient origin by zip code; name and specialty of referring physician; and name and location of the recipient facility, for each of the latest 2 years.

B) Projected Referrals

i) The applicant shall provide physician letters that attest to:

- the physician's total number of patients (by facility and zip code of residence) who have received care at existing facilities located in the area, as reported to The Renal Network at the end of the year for the most recent 3 years and the end of the most recent quarter;

- the number of new patients (by facility and zip code of residence) located in the area, as reported to The Renal Network, that the physician referred for in-center hemodialysis for the most recent year;

- an estimated number of patients (transfers from existing facilities and pre-ESRD, as well as respective zip codes of residence) that the physician will refer annually to the applicant's facility within a 24-month period after project completion, based upon the physician's practice experience. The anticipated number of referrals cannot exceed the physician's documented historical caseload. The percentage of project referrals used to justify the proposed expansion cannot exceed the historical percentage of applicant market share, within a 24-month period after project completion;

ii) 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;

iii) The physician shall verify that the patient referrals have not been used to support another pending or approved CON application for the subject services; and

iv) Each referral letter shall contain a statement attesting that the information submitted is true and correct, to the best of the physician's belief.

C) Projected Service Demand – Based on Rapid Population Growth
If a projected demand for service is based upon rapid population growth in the applicant facility's existing market area (as experienced annually within the latest 24-month period), the projected service demand shall be determined as follows:

i) The applicant shall define the facility's market area based upon historical patient origin data by zip code or census tract;

ii) Population projections shall be produced, using, as a base, the population census or estimate for the most recent year, for county, incorporated place, township or community area, by the U.S. Census Bureau or IDPH;

iii) Projections shall be for a maximum period of 10 years from the date the application is submitted;

iv) Historical data used to calculate projections shall be for a number of years no less than the number of years projected;

v) Projections shall contain documentation of population changes in terms of births, deaths and net migration for a period of time equal to or in excess of the projection horizon;

vi) Projections shall be for total population and specified age groups for the applicant's market area, as defined by HFSRB, for each category of service in the application; and

vii) Documentation on projection methodology, data sources, assumptions and special adjustments shall be submitted to HFSRB.

5) Service Accessibility
The number of stations being established or added for the subject 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 (b)(5) only, all services within the established radii outlined in subsection (b)(5)(C) 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) The travel radius for purposes of subsection (b)(5)(A)(v) is:

i) For applicant facilities located in the counties of Cook and DuPage, the radius shall be 5 miles.

ii) For applicant facilities located in the counties of Lake, Kane and Will, the radius shall be 10 miles.

iii) For applicant facilities located in the counties of Kankakee, Grundy, Kendall, DeKalb, McHenry, Winnebago, Champaign, Sangamon, Peoria, Tazewell, Rock Island, Monroe, Madison and St. Clair, the radius shall be 15 miles.

iv) For applicant facilities located in any other area of the State, the radius shall be 19 miles.

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 the established radii outlined in subsection (c)(4) 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 the established radii outlined in subsection (c)(4) of the project site that provides the categories of station service that are proposed by the project.

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, stations and services characterized by such factors as, but not limited to:

   A) A ratio of stations to population that exceeds one and one-half times the State average;

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

   C) Insufficient population to provide the volume or caseload necessary to utilize the services proposed by the project at or above utilization 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.

4) The travel radius for purposes of subsection (c)(1) is:

A) For applicant facilities located in the counties of Cook and DuPage, the radius shall be 5 miles.

B) For applicant facilities located in the counties of Lake, Kane and Will, the radius shall be 10 miles.

C) For applicant facilities located in the counties of Kankakee, Grundy, Kendall, DeKalb, McHenry, Winnebago, Champaign, Sangamon, Peoria, Tazewell, Rock Island, Monroe, Madison and St. Clair, the radius shall be 15 miles.

D) For applicant facilities located in any other area of the State, the radius shall be 19 miles.

d) Category of Service Modernization

1) If the project involves modernization of an in-center hemodialysis 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 relocation or modernization of in-center hemodialysis or a facility shall meet or exceed the utilization standards for the categories of service, as specified in 77 Ill. Adm. Code 1100.

e) Staffing
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.

1) Qualifications

A) Medical Director – Medical direction of the facility shall be vested in a physician who has completed a board-approved training program in nephrology and has at least 12-months experience providing care to patients receiving dialysis.

B) Registered Nurse – The nurse responsible for nursing services in the unit shall be a registered nurse (RN) who meets the practice requirements of the State of Illinois and has at least 12-months experience in providing nursing care to patients on maintenance dialysis.

C) Dialysis Technician – This individual shall meet all applicable State of Illinois requirements (see the End Stage Renal Disease Facility Act). In addition, the applicant shall document its requirements for training and continuing education.

D) Dietitian – This individual shall be a registered dietitian with the Commission on Dietetic Registration, meet the practice requirements of the State of Illinois (see the Dietitian Nutritionist Practice Act) and have a minimum of one year of professional work experience in clinical nutrition as a registered dietitian.

E) Social Worker – The individual responsible for social services shall have a Master's of Social Work and meet the State of Illinois requirements (see the Clinical Social Work and Social Work Practice Act).

2) Documentation shall consist of:

A) Medical Director
Curriculum vitae of Medical Director, including a list of all in-center hemodialysis facilities where the position of Medical Director is held.

B) All Other Personnel
A narrative explanation of how positions will be filled.

3) Training
The applicant proposing to establish an in-center hemodialysis category of service shall document that an ongoing program of training in dialysis techniques for nurses and technicians will be provided at the facility.

4) Staffing Plan
The applicant proposing to establish an in-center hemodialysis category of service shall document that at least one RN will be on duty when the unit is in operation and will maintain a ratio of at least one direct patient care provider to every 4 patients.

5) Medical Staff
The applicant shall provide a letter certifying whether the facility will or will not maintain an open medical staff.

f) Support Services – Review Criterion

An applicant proposing to establish an in-center hemodialysis category of service must submit a certification from an authorized representative that attests to each of the following:

1) Participation in a dialysis data system;

2) Availability of support services consisting of clinical laboratory service, blood bank, nutrition, rehabilitation, psychiatric and social services; and

3) Provision of training for self-care dialysis, self-care instruction, home and home-assisted dialysis, and home training provided at the proposed facility, or the existence of a signed, written agreement for provision of these services with another facility.

g) Minimum Number of Stations
The minimum number of in-center hemodialysis stations for an End Stage Renal Disease (ESRD) facility is:

1) Four dialysis stations for facilities outside an MSA;

2) Eight dialysis stations for a facility within an MSA.

h) Continuity of Care
An applicant proposing to establish an in-center hemodialysis category of service shall document that a signed, written affiliation agreement or arrangement is in effect for the provision of inpatient care and other hospital services. Documentation shall consist of copies of all such agreements.

i) Relocation of Facilities – Review Criterion
This criterion may only be used to justify the relocation of a facility from one location in the planning area to another in the same planning area and may not be used to justify any additional stations. A request for relocation of a facility requires the discontinuation of the current category of service at the existing site and the establishment of a new category of service at the proposed location. The applicant shall document the following:

1) That the existing facility has met the utilization targets detailed in 77 Ill. Adm. Code 1100.630 for the latest 12-month period for which data is available; and

2) That the proposed facility will improve access for care to the existing patient population.

j) Assurances
The applicant representative who signs the CON application shall submit a signed and dated statement attesting to the applicant's understanding that:

1) By the second year of operation after the project completion, the applicant will achieve and maintain the utilization standards specified in 77 Ill. Adm. Code 1100 for each category of service involved in the proposal; and

2) An applicant proposing to expand or relocate in-center hemodialysis stations will achieve and maintain compliance with the following adequacy of hemodialysis outcome measures for the latest 12-month period for which data are available:

≥ 85% of hemodialysis patient population achieves urea reduction ratio (URR) ≥ 65% and ≥ 85% of hemodialysis patient population achieves Kt/V Daugirdas II 1.2.

Section 1110.235 Non-Hospital Based Ambulatory Surgical Treatment Center Services

a) Projects Not Subject to this Section
The specific criteria of this Subpart will not apply to hospital projects that will provide ambulatory surgical service and that will be operated in accordance with the provisions of the Hospital Licensing Act.

b) Recognition

1) Due to revisions in this Section, HFSRB shall recognize the existence of the non-hospital based ASTC services for licensed facilities that are able to verify the existence of these ASTC services prior to January 1, 2014. The following documentation shall be submitted to HFSRB to substantiate the claim that the ASTC services existed prior to that date:

A) verification that identified outpatient surgical procedures were performed at the facility prior to January 1, 2014; and

B) verification that the facility obtained a license as an ASTC prior to January 1, 2014;

2) Documentation shall be in the form of a letter from IDPH's licensure program confirming that an ASTC license was obtained and a copy of the most recent HFSRB Ambulatory Surgical Treatment Center Data Profile for the subject facility. Documentation for an ASTC service that has not been performed during the most recent year shall include:

A) a letter from IDPH's licensure program confirming that an ASTC license was obtained prior to January 1, 2014; and

B) either:

i) a copy of the Annual Ambulatory Surgical Treatment Center Data Profile showing when the procedure in question was performed; or

ii) a copy of the CON permit letter that identifies the services included in the permit approval.

3) Recognition by HFSRB of the non-hospital based ASTC services exempts the facility from the requirement of obtaining a permit for establishment of a health care facility and establishment of the identified and verified ASTC services. The exemption shall be valid and remain in effect provided that the following requirements are met:

A) the procedures and scope of services provided at the facility remain restricted to the ASTC services (e.g., podiatry, ophthalmology, plastic surgery) in operation on or before January 1, 2014;

B) the facility has obtained a license from IDPH on or before January 1, 2014; and

C) the facility has petitioned HFSRB for recognition of the service no more than 90 days after April 15, 2014.

4) The ASTC shall be subject to the provisions of 77 Ill. Adm. Code 1100.640 and subsections (a) and (c) of this Section regarding subsequent transactions that require a permit. Failure to comply with any of the

requirements of this Part or subsequent discontinuation of the facility shall:

A) void the recognition of the verified ASTC services and their subsequent exemption;

B) subject the facility to the sanctions and penalties provided by Section 14.1 of the Act and 77 Ill. Adm. Code 1130.790; and

C) require a permit or exemption to:

i) establish an ASTC or ASTC service;

ii) change ownership;

iii) expand an existing ASTC;

iv) modernize an existing ASTC when the estimated total project cost exceeds the capital expenditure minimum. The current threshold is determined under 77 Ill. Adm. Code 1130.Appendix A and posted on HFSRB's website (www.hfsrb.illinois.gov); or

v) discontinue an ASTC.

c) Review Criteria

1) Introduction

A) Ambulatory Surgical Treatment Centers required to be licensed pursuant to the Ambulatory Surgical Treatment Center Act are defined as health care facilities subject to the requirements of the Illinois Health Facilities Planning Act and HFSRB rules (77 Ill. Adm. Code 1100, 1110, 1120 and 1130). Facilities devoted to abortion and related care, including those licensed as PSTCs under the ASTC Act are not subject to HFSRB rules related to Non-Hospital Based ASTCs. The addition of any other ASTC services (other than abortion-related services) will require a CON permit.

B) A permit is required for:

i) the establishment of a new non-hospital based ambulatory surgical treatment center (ASTC);

ii) the addition or establishment of a new ASTC service to an existing non-hospital based ASTC;

iii) the increase or expansion of the number of surgical/treatment rooms for an existing ASTC service in a non-hospital based ASTC, if the total estimated project cost exceeds the capital expenditures minimum. The current threshold is posted on HFSRB's website (www.hfsrb.illinois.gov); or

iv) any action with a total estimated project cost that exceeds the capital expenditures minimum. The current threshold is determined under 77 Ill. Adm. Code 1130.Appendix A and posted on HFSRB's website (www.hfsrb.illinois.gov).

C) Applicants proposing to establish an ASTC or add or expand an ASTC service in an existing ASTC facility shall describe how the proposed project will address the following indicators of need, as presented in the following table:

PROJECT TYPE	**REQUIRED REVIEW CRITERIA**		
Establishment of ASTC Facility or Additional ASTC Service	(c)(2)(B)(i) & (ii)	−	Service to GSA Residents
	(c)(3)(A) & (B) or (C)	−	Service Demand − Establishment
	(c)(5)(A) & (B)	−	Treatment Room Need Assessment
	(c)(6)	−	Service Accessibility
	(c)(7)(A) through (C)	−	Unnecessary Duplication/ Maldistribution
	(c)(8)(A) & (B)	−	Staffing
	(c)(9)	−	Charge Commitment
	(c)(10)(A) & (B)	−	Assurances

Expansion of Existing ASTC Service	(c)(2)(B)(i) & (ii)	−	Service to GSA Residents
	(c)(4)(A) through (C)	−	Service Demand – Expansion
	(c)(5)(A) & (B)	−	Treatment Room Need Assessment
	(c)(8)(A) & (B)	−	Staffing
	(c)(9)	−	Charge Commitment
	(c)(10)(A) & (B)	−	Assurances

D) In addition to addressing the applicable criteria listed in the chart in subsection (c)(1)(C), the applicant shall indicate:

i) The existing and the proposed ASTC services as specified in Appendix A;

ii) The existing and the proposed number of surgical/treatment rooms for each ASTC service as specified in Appendix A;

iii) If an ASTC service is not specified in Appendix A, the applicant shall indicate the existing and proposed ASTC services, the existing and proposed number of surgical/treatment rooms, and the professional standards applicable to the proposed ASTC services.

E) Transition Period for Meeting this Section's Requirements

i) Multi-specialty ASTCs that provided at least 3 of the ASTC services listed in Appendix A prior to April 15, 2014, except those ASTCs described in subsection (c)(1)(E)(iii), shall be exempt from this Section's CON application requirements for adding additional ASTC services until January 1, 2018.

ii) Effective April 15, 2014, multi-specialty ASTCs adding new services shall notify HFSRB of what services are being added and the effective date of those services. The notification of each new service added shall be submitted to HFSRB within 30 days after the service addition. Beginning January 1, 2018, multi-specialty ASTCs seeking

to add additional ASTC services shall apply for a CON permit pursuant to the provisions of this Section.

iii) Multi-specialty ASTCs that, as a condition of CON permit issuance, agreed to apply for CON permits when adding services shall continue to apply for CON permits when adding new services.

F) Sanctions and Penalties
Noncompliance with the requirements of subsection (b) and this subsection (c) shall be considered a violation and shall be subject to the sanctions and penalties in the Act (see 20 ILCS 3960/14.1) and in 77 Ill. Adm. Code 1130.790.

2) Geographic Service Area Need
The applicant shall document that the ASTC services and the number of surgical/treatment rooms to be established, added or expanded are necessary to serve the planning area's population, based on the following:

A) 77 Ill. Adm. Code 1100 (Formula Calculation)
As stated in 77 Ill. Adm. Code 1100, no formula need determination for the number of ASTCs and the number of surgical/treatment rooms in a geographic service area has been established. Need shall be established pursuant to the applicable review criteria of this Part.

B) Service to Geographic Service Area Residents
The applicant shall document that the primary purpose of the project will be to provide necessary health care to the residents of the geographic service area (GSA) in which the proposed project will be physically located.

i) The applicant shall provide a list of zip code areas (in total or in part) that comprise the GSA. The GSA is the area consisting of all zip code areas that are located within the established radii outlined in 77 Ill. Adm. Code 1100.510(d) of the project's site.

ii) The applicant shall provide patient origin information by zip code for all admissions for the last 12-month period,

verifying that at least 50% of admissions were residents of the GSA. Patient origin information shall be based upon the patient's legal residence (other than a health care facility) for the last 6 months immediately prior to admission.

3) Service Demand – Establishment of an ASTC Facility or Additional ASTC Service
The applicant shall document that the proposed project is necessary to accommodate the service demand experienced annually by the applicant, over the latest 2-year period, as evidenced by historical and projected referrals. The applicant shall document the information required by subsection (c)(3) and either subsection (c)(3)(B) or (C):

A) Historical Referrals
The applicant shall provide physician referral letters that attest to the physician's total number of treatments for each ASTC service that has been referred to existing IDPH-licensed ASTCs or hospitals located in the GSA during the 12-month period prior to submission of the application. The documentation of physician referrals shall include the following information:

i) patient origin by zip code of residence;

ii) name and specialty of referring physician;

iii) name and location of the recipient hospital or ASTC; and

iv) number of referrals to other facilities for each proposed ASTC service for each of the latest 2 years.

B) Projected Service Demand
The applicant shall provide the following documentation:

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 IDPH-licensed ASTCs or hospitals located in the GSA during the 12-month period prior to submission of the application;

ii) Documentation demonstrating that the projected patient volume, as evidenced by the physician referral letters, is from within the GSA defined under subsection (c)(2)(B);

iii) An estimated number of treatments the physician will refer annually to the applicant facility within a 24-month period after project completion. The anticipated number of referrals cannot exceed the physician's experienced caseload. The percentage of projected referrals used to justify the proposed establishment cannot exceed the historical percentage of applicant market share within a 24-month period after project completion;

iv) Referrals to health care providers other than IDPH-licensed ASTCs or hospitals will not be included in determining projected patient volume;

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

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

C) Projected Service Demand − Rapid Population Growth
If a projected demand for service is based upon rapid population growth in the applicant facility's existing market area (as experienced annually within the latest 24-month period), the projected service demand shall be determined as follows:

i) The applicant shall define the facility's market area based upon historical patient origin data by zip code or census tract;

ii) Population projections shall be produced, using, as a base, the population census or estimate for the most recent year, for county, incorporated place, township or community area, by the U.S. Census Bureau or IDPH;

iii) Projections shall be for a maximum period of 5 years from the date the application is submitted;

iv) Historical data used to calculate projections shall be for a number of years no less than the number of years projected;

v) Projections shall contain documentation of population changes in terms of births, deaths and net migration for a period of time equal to, or in excess of, the projection horizon;

vi) Projections shall be for total population and specified age groups or the applicant's market area, as defined by HFSRB, for each specialty in the application;

vii) Documentation on projection methodology, data sources, assumptions and special adjustments shall be submitted; and

viii) The applicant shall estimate the future demand for the number of treatments or procedures based upon population growth and no change in the facility's market share.

4) Service Demand − Expansion of Existing ASTC Service
The number of surgical/treatment rooms to be added at an existing facility is necessary to reduce the facility's experienced high utilization and to meet a projected demand for service. The applicant shall document the information required by subsections (c)(4)(A)(i) and (ii) and either subsections (c)(4)(B)(i) and (ii) or subsection (c)(4)(C):

A) Historical Service Demand

i) The applicant shall document an average utilization rate that has equaled or exceeded the standards specified in 77 Ill. Adm. Code 1100 for existing surgical/treatment rooms for each of the latest 2 years.

ii) If patients have been referred to other IDPH-licensed facilities in order to receive the subject services, the

applicant shall provide documentation of the referrals, including: patient origin by zip code of residence; name and specialty of referring physician; and the name and location of the recipient hospital or ASTC, for each of the latest 2 years.

B) Projected Service Demand − Projected Referrals

i) The applicant shall provide physician referral letters that attest to the physician's total number of patients (by zip code of residence) that have received treatments at existing IDPH-licensed facilities located in the GSA during the 12-month period prior to submission of the application, and an estimate of the number of patients that will be referred by the physician to the applicant's facility.

ii) Each physician referral letter shall contain the notarized signature, the typed or printed name, the office address and the specialty of the physician. The anticipated number of referrals cannot exceed the physician's experienced caseload.

C) Projected Service Demand − Rapid Population Growth
If a projected demand for service is based upon rapid population growth in the applicant facility's existing market area (as experienced annually within the latest 24-month period), the projected service demand shall be determined as described in subsection (c)(3)(C).

5) Treatment Room Need Assessment – Review Criterion

A) The applicant shall document that the proposed number of surgical/treatment rooms for each ASTC service is necessary to service the projected patient volume. The number of rooms shall be justified based upon an annual minimum utilization of 1,500 hours of use per room, as established in 77 Ill. Adm. Code 1100.

B) For each ASTC service, the applicant shall provide the number of patient treatments/sessions, the average time (including setup and cleanup time) per patient treatment/session, and the methodology

used to establish the average time per patient treatment/session (e.g., experienced historical caseload data, industry norms or special studies).

6) Service Accessibility
The proposed ASTC services being established or added are necessary to improve access for residents of the GSA. The applicant shall document that at least one of the following conditions exists in the GSA:

A) There are no other IDPH-licensed ASTCs within the identified GSA of the proposed project;

B) The other IDPH-licensed ASTC and hospital surgical/treatment rooms used for those ASTC services proposed by the project within the identified GSA are utilized at or above the utilization level specified in 77 Ill. Adm. Code 1100;

C) The ASTC services or specific types of procedures or operations that are components of an ASTC service are not currently available in the GSA or that existing underutilized services in the GSA have restrictive admission policies;

D) The proposed project is a cooperative venture sponsored by 2 or more persons, at least one of which operates an existing hospital. Documentation shall provide evidence that:

i) The existing hospital is currently providing outpatient services to the population of the subject GSA;

ii) The existing hospital has sufficient historical workload to justify the number of surgical/treatment rooms at the existing hospital and at the proposed ASTC, based upon the treatment room utilization standard specified in 77 Ill. Adm. Code 1100;

iii) The existing hospital agrees not to increase its surgical/treatment room capacity until the proposed project's surgical/treatment rooms are operating at or above the utilization rate specified in 77 Ill. Adm. Code 1100 for a period of at least 12 consecutive months; and

iv) The proposed charges for comparable procedures at the ASTC will be lower than those of the existing hospital.

7) Unnecessary Duplication/Maldistribution − Review Criterion

A) The applicant shall document that the project will not result in an unnecessary duplication. The applicant shall provide the following information for the proposed GSA zip code areas identified in subsection (c)(2)(B)(i):

i) the total population of the GSA (based upon the most recent population numbers available for the State of Illinois); and

ii) the names and locations of all existing or approved health care facilities located within the GSA that provide the ASTC services that are proposed by the project.

B) The applicant shall document that the project will not result in maldistribution of services. Maldistribution exists when the GSA has an excess supply of facilities and ASTC services characterized by such factors as, but not limited to:

i) a ratio of surgical/treatment rooms to population that exceeds one and one-half times the State average;

ii) historical utilization (for the latest 12-month period prior to submission of the application) for existing surgical/treatment rooms for the ASTC services proposed by the project that are below the utilization standard specified in 77 Ill. Adm. Code 1100; or

iii) insufficient population to provide the volume or caseload necessary to utilize the surgical/treatment rooms proposed by the project at or above utilization standards specified in 77 Ill. Adm. Code 1100.

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

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

ii) will not lower, to a further extent, the utilization of other GSA facilities that are currently (during the latest 12-month period) operating below the utilization standards.

8) Staffing

A) Staffing Availability
The applicant shall document that relevant clinical and professional staffing needs for the proposed project were considered and that the staffing requirements of licensure and The Joint Commission or other nationally recognized accrediting bodies 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.

B) Medical Director
It is recommended that the procedures to be performed for each ASTC service are under the direction of a physician who is board certified or board eligible by the appropriate professional standards organization or entity that credentials or certifies the health care worker for competency in that category of service.

9) Charge Commitment
In order to meet the objectives of the Act, which are *to improve the financial ability of the public to obtain necessary health services; and to establish an orderly and comprehensive health care delivery system that will guarantee the availability of quality health care to the general public; and cost containment and support for safety net services must continue to be central tenets of the Certificate of Need process* [20 ILCS 3960/2], the applicant shall submit the following:

A) a statement of all charges, except for any professional fee (physician charge); and

B) a commitment that these charges will not increase, at a minimum, for the first 2 years of operation unless a permit is first obtained pursuant to 77 Ill. Adm. Code 1130.310(a).

10) Assurances

A) The applicant shall attest that a peer review program exists or will be implemented that evaluates whether patient outcomes are consistent with quality standards established by professional organizations for the ASTC services, and if outcomes do not meet or exceed those standards, that a quality improvement plan will be initiated.

B) The applicant shall document that, in the second year of operation after the project completion date, the annual utilization of the surgical/treatment rooms will meet or exceed the utilization standard specified in 77 Ill. Adm. Code 1100. Documentation shall include, but not be limited to, historical utilization trends, population growth, expansion of professional staff or programs (demonstrated by signed contracts with additional physicians) and the provision of new procedures that would increase utilization.

Section 1110.240 Selected Organ Transplantation

a) Introduction

1) This subsection (a) 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:

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

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NOTICE OF ADOPTED AMENDMENTS

	(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	(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) (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) (Establishment of Services or Facility), as well as requirements in Section 1110.290 (Discontinuation) and Section 1110.230(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 2 years.

b) Planning Area Need − Review Criteria
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 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 (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, 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.

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 population); 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 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) 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 utilization standards for the category 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 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) 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.

h) 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.

i) 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).

j) 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.

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:

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.

Section 1110.250 Subacute Care Hospital Model

a) Introduction

1) This Section contains review criteria that pertain to the subacute care hospital model category of service. Definitions pertaining to this Subpart are contained in the Act, in 77 Ill. Adm. Code 1100 and 1130, and in the Alternative Health Care Delivery Act. The subacute care hospital model category of service is a demonstration program that is authorized by the Alternative Health Care Delivery Act. These subacute care hospital model review criteria are utilized in addition to the applicable review criteria of this Subpart C and 77 Ill. Adm. Code 1120. This Subpart also contains the methodology the State Board will utilize in evaluating competing applications, if any, for the establishment of any subacute care hospital models.

2) A facility at any time may be caring for subacute patients. A permit must be obtained to establish a subacute care hospital model. Existing hospitals and long term care facilities providing subacute care are not required to obtain a permit, *provided, however, that the facilities shall not hold themselves out to the public as subacute care hospitals* (Section 15 of the Alternative Health Care Delivery Act). Establishment of a subacute care hospital model category of service occurs when a facility holds itself out to the general public as a subacute care hospital. In these instances, failure to obtain a permit will result in the application of sanctions as provided for in the Illinois Health Facilities Planning Act.

3) As the purpose of the demonstration project is to evaluate the subacute care hospital model for quality factors, access and the impact on health care costs, each applicant approved for the category of service will be required to periodically submit data necessary for evaluating the model's effectiveness.

4) Applications received for the subacute care hospital model shall be deemed complete upon receipt by HFSRB. Due to the comparative nature of the subacute care hospital model review, applicants will not be allowed to amend the application or provide additional supporting documentation during the review process. The application as submitted to HFSRB shall serve as the basis for all standard and prioritization evaluation.

b) Review Criteria

1) Distinct Unit
The applicant must document that the proposed unit or health care facility will be primarily self-contained and physically distinct and will have nursing staff dedicated to service within only that unit. Auxiliary personnel and contracted professional personnel must be available for care of unit patients but need not be dedicated to providing service to only the subacute care hospital model. Documentation shall include a physical layout of the unit detailing travel patterns to ancillary and support services and to patient and visitor access and a detailed summary of all shared services and how costs for those services will be allocated between the model and the hospital or long term care facility. Also, the applicant must provide a detailed staffing plan that includes staff qualifications, staffing patterns for the proposed subacute care hospital and the manner in which non-dedicated staff services will be provided.

2) Contractual Relationship
The applicant must document the capability to handle cases of complications, emergencies or exigent circumstances.

A) An applicant must document, for a model to be located in a currently licensed long term care facility, the capability through the existence of a contractual relationship (which includes a transfer agreement) with a general acute care hospital.

B) An applicant must document, for a model to be located on a designated site previously licensed as a hospital (see 77 Ill. Adm. Code 740(c)), capability through the existence of a contractual arrangement (transfer agreement) with a general acute care hospital.

C) An applicant must document, for a model to be located in a licensed hospital, that the emergency capability continues to exist in accordance with the requirements of hospital licensure.

3) Unit Size
The applicant must document that the number of subacute care beds proposed will equal or exceed the minimum number established for the planning area. The minimum subacute care hospital unit size is 10 beds in rural planning areas (as defined in 77 Ill. Adm. Code 1100.720(a)) and 30 beds in all other planning areas.

c) HFSRB Evaluation. HFSRB shall evaluate each application for the subacute care hospital model category of service based upon compliance with the conditions set forth in subsections (c)(1), (2) and (3).

1) HFSRB Prioritization of Hospital Applications

A) All hospital applications for each planning area shall be rank ordered based on points awarded as follows:

i) Compliance with all applicable review criteria of Subpart B – 10 Points.

ii) Compliance with all review criteria of subsection (b) – 10 Points.

iii) Compliance with all applicable review criteria of 77 Ill. Adm. Code 1120 – 10 Points.

iv) In rural areas an applicant shall be awarded 25 Points if documentation is provided that the subacute care hospital model will provide the necessary financial support for the facility to provide continued acute care services. The documentation shall consist of:

- Factors within the facility or area that will prevent the facility from complying with the minimum financial ratios established in 77 Ill. Adm. Code 1120 within the next 2 years;

- Historical documentation that the facility has failed to comply with the minimum financial ratios in each of the last 3 calendar years; and

- Projected revenue from the subacute hospital care model and the positive impact of that revenue on the financial position of the applicant facility. The applicant must explain how the revenue will impact the facility's financial position, causing the facility to comply with the financial viability ratios of 77 Ill. Adm. Code 1120. Alternatively, documentation can be provided showing that projected revenue from the subacute hospital model will be sufficient to operate the subacute care hospital care model in compliance with the financial viability ratios of 77 Ill. Adm. Code 1120, or that the applicant facility has entered into a binding agreement with another institution that guarantees the financial viability of the subacute hospital care model in accordance with the ratios established in 77 Ill. Adm. Code 1120 for a period of at least 5 years, regardless of the financial ratios of the applicant facility.

v) Location in a medically underserved area (as defined by the Department of Health and Human Services (section 332 of the Public Health Service Act (42 USC 254E)) as a health professional shortage area) – 3 Points.

vi) A multi-institutional system arrangement exists for the referral of subacute patients under which the applicant facility serves as the receiving facility for the system. A multi-institutional system consists of a network of licensed hospitals and long term care facilities located within the planning area and within 60 minutes travel time of the

applicant that are interrelated by contractual agreement that provides for an exclusive best effort arrangement concerning the transfer of patients between facilities. Best effort arrangement means that the referring facility will encourage and recommend to its medical staff that patients requiring subacute care will be transferred only to the applicant facility – 1 Point per each additional facility in the multi-institutional system, to a maximum of 10 Points.

vii) The existence of Medicare and Medicaid certification at the applicant facility and historic volume at the applicant facility. The following point allocation will be applied:

- In the last calendar or fiscal year, Medicare/ Medicaid patient days were between 10% and 25% of total facility patient days – 2 Points.

- In the last calendar or fiscal year, Medicare/ Medicaid patient days were between 26% and 50% of total facility patient days – 4 Points.

- In the last calendar or fiscal year, Medicare/ Medicaid patient days exceeded 50% of total facility patient days – 6 Points.

viii) For each of the last 5 calendar years, the applicant facility documents a case mix consisting of ventilator cases, head trauma cases, rehabilitation patients including spinal cord injuries, amputees and patients with orthopaedic problems requiring subacute care, or patients with multiple complex diagnoses that included physiological monitoring on a continual basis, of such magnitude that, if placed in the proposed subacute facility, these patients would have constituted an annual occupancy exceeding 75%. If a multi-institutional system, as defined in subsection (c)(1)(A)(vi), has an exclusive best efforts agreement, then each of the cases listed in this subsection (c)(1)(A)(viii) from such signatory facilities may be counted in computing the 75% annual occupancy threshold – 5 Points.

ix) The applicant institution has documented that, during the last calendar year, at least 25% of all patient days of the applicant facility were reimbursed through contractual relationships with PPOs or HMOs – 3 Points.

x) If the applicant institution, over the last 5 calendar year period, has been issued a notice of revocation of license from IDPH or has been decertified from the federal Title XVIII or XIX programs – Loss of 25 Points.

xi) The applicant institution is accredited by The Joint Commission – 3 Points and 1 additional Point if accreditation is "with commendation".

xii) Staff support for the subacute care hospital model:

- Full time Medical Director exclusively for the model – 1 Point.

- Physical therapist, 2 full-time equivalents (FTEs) or more – 1 Point.

- Occupational therapist, 1 FTE or more – 1 Point.

- Speech therapist, 1 FTE or more – 1 Point.

xiii) In areas where competing applications have been filed, 3 Points will be allocated to the applicant with the lowest positive mean net margin over the last 3 fiscal years. Each applicant must submit copies of the audited financial reports of the applicant facility for the latest 3 fiscal years.

B) Required Point Totals – Hospital Applications
A hospital application for the development of a subacute care hospital model must obtain a minimum of 50 Points for approval. The applicant within the planning area receiving the most points shall be granted the permit for the category of service if the minimum point total has been exceeded. In the case of tie scores, HFSRB shall base its decision on considerations relating to location, scope of service and access.

2) State Board Prioritization – Long Term Care Facilities

A) All long term care applications for each planning area shall be rank ordered based on points awarded as follows:

i) Compliance with all applicable review criteria of Subpart B – 10 Points.

ii) Compliance with all review criteria of subsection (b) – 10 Points.

iii) Compliance with all applicable review criteria of 77 Ill. Adm. Code 1120 – 10 Points.

iv) The applicant has had an Exceptional Care Contract with the Illinois Department of Healthcare and Family Services for at least 2 years in the past 4 years – 3 Points.

v) Location in a medically underserved area (as defined by the federal Department of Health and Human Services (section 332 of the Public Health Service Act (42 USC 254E)) as a health professional shortage area) – 3 Points.

vi) The existence of Medicare and Medicaid certification at the applicant facility and historic volume at the facility. The following point allocation will be applied:

- In the last calendar year or fiscal year, Medicare/ Medicaid patient days were between 10% and 25% of total facility patient days – 3 Points.

- In the last calendar or fiscal year, Medicare/ Medicaid patient days were between 26% and 50% of total facility patient days – 6 Points.

- In the last calendar or fiscal year, Medicare/ Medicaid patient days exceeded 50% of total facility patient days – 9 Points.

vii) For each of the last 2 calendar years, the applicant institution documents a casemix consisting of ventilator cases, head trauma cases, rehabilitation patients including stroke cases, spinal cord injury, amputees and patients with orthopaedic problems requiring subacute care, or patients with multiple complex diagnoses that included physiological monitoring on a continual basis, of such magnitude that, if placed in the proposed subacute facility, these patients would have constituted an annual occupancy exceeding 50%. If a multi-institutional system, as defined in subsection (c)(2)(A)(xiii), has an exclusive best efforts agreement, then each of the cases listed in this subsection (c)(2)(A)(vii) from the signatory facilities may be counted in computing the 50% annual occupancy threshold – 5 Points.

viii) The applicant has documented that, during the last calendar year, at least 20% of all patient days of the applicant facility were reimbursed through contractual relationships with PPOs or HMOs – 3 Points.

ix) If the applicant, over the last 5 year period, has been issued a notice of revocation of license from IDPH or decertified from the federal Title XVIII or XIX programs – Loss of 25 Points.

x) Staff support for the subacute care hospital model:

- Full time Medical Director exclusively for the model – 1 Point.
- Physical therapist, 2 FTEs or more – 1 Point.
- Occupational therapist, 1 FTE or more – 1 Point.
- Speech therapist, 1 FTE or more – 1 Point.

xi) In areas where competing applications have been filed, 3 Points will be allocated to the application with the lowest positive mean net margin over the last 3 fiscal years. Each

applicant must submit copies of the audited financial reports of the applicant facility for the latest 3 fiscal years.

xii) The applicant institution is accredited by the Joint Commission – 3 Points and 1 additional Point if accreditation is "with commendation".

xiii) A multi-institutional system arrangement exists for the referral of subacute patients under which the applicant facility serves as the receiving facility for the system. A multi-institutional system consists of a network of licensed hospitals and long term care facilities located within the planning area and within 60 minutes travel time of the applicant that are interrelated by contractual agreement that provides for an exclusive best effort arrangement concerning the transfer of patients between facilities. Best effort arrangement means the referring facility will encourage and recommend to its medical staff that patients requiring subacute care will only be transferred to the applicant facility – 1 Point per each additional facility in the multi-institutional system to a maximum of 10 Points.

B) A long term care facility's application for the development of a subacute care hospital model must obtain a minimum of 50 Points for approval. The applicant within the planning area receiving the most points shall be granted the permit for the category of service if the minimum point total has been exceeded. In the case of tie scores, HFSRB shall base its selection on considerations relating to location, scope of service and access.

3) HFSRB Prioritization of Previously Licensed Hospital Applications in Chicago

A) All applications for sites previously licensed as hospitals in Chicago shall be rank ordered based upon points awarded as follows:

i) Compliance with all applicable review criteria of Subpart C – 10 Points.

ii) Compliance with all review criteria of subsection (b) – 10 Points.

iii) Compliance with all applicable review criteria of 77 Ill. Adm. Code 1120 – 10 Points.

iv) Documentation that the proposed number of beds will be utilized at an occupancy rate of 75% or more within 2 years after permit approval. Documentation shall consist of historical subacute caseload from one or more referral facilities whose subacute caseload, in the future, would be transferred to the subacute model for care, anticipated caseload from physician referrals to the unit, and demographic studies projecting the need for subacute service within the primary market of the proposed subacute hospital care model – 10 Points.

B) Required Point Totals – Previously Licensed Hospitals
The applicant within the planning area receiving the most points shall be granted the permit for the category of service. In the case of tie scores, HFSRB shall base its selection on considerations relating to location, scope of service and access.

d) Project Completion

1) Since the purpose for establishment of this category of service is to evaluate the alternative delivery model for effectiveness, these projects are not complete until the model is evaluated and the decision made to adopt or not adopt the model as an ongoing licensed level of service separate from an alternative delivery model. A discontinuation permit will not be required of a facility holding a subacute care hospital model permit if the facility elects to discontinue the model but retain licensed subacute care beds. The subacute care hospital model project shall be considered complete as of the date IDPH is notified of the discontinuation. If, during the course of the model evaluation period, an approved provider of the subacute hospital care model elects to discontinue the category of service, a replacement provider of the same type may be approved by the State Board. If a need for an additional subacute care hospital model exists, applications shall be approved in accordance with subsection (c). Any alteration to the subacute care hospital model during the life of the permit

is subject to State Board review.

2) All assurances and charges for service presented in the application shall be in effect for the life of the permit unless altered with the approval of the State Board.

3) A subacute care hospital model shall have 24 months from the date of permit issuance to become operational. Failure to begin operation in this time period shall result in the permit becoming null and void.

Section 1110.255 Postsurgical Recovery Care Center Alternative Health Care Model

a) Introduction

1) This Section contains review criteria that pertain to the postsurgical recovery care center alternative health care model category of service. Definitions pertaining to this Section are contained in the Act, 77 Ill. Adm. Code 1100 and 1130, and the Alternative Health Care Delivery Act. The postsurgical recovery care center alternative health care model category of service is a demonstration program that is authorized by the Alternative Health Care Delivery Act. These postsurgical recovery care center alternative health care model review criteria are utilized in addition to the applicable review criteria of Subpart B and 77 Ill. Adm. Code 1120. This Section also contains the methodology HFSRB will utilize in evaluating competing applications, if any, for the establishment of any postsurgical recovery care center alternative health care models.

2) A postsurgical recovery care center alternative health care model must obtain a CON permit to establish the category of service prior to receiving a license for the service. Failure to obtain a permit will result in the application of sanctions as provided for in the Illinois Health Facilities Planning Act.

3) As the purpose of the demonstration project is to evaluate the model for quality factors, access and the impact on health care cost, each applicant approved for the category of service will be required to periodically submit data necessary for evaluating the model's effectiveness. All data requests of this type shall be a component of the semiannual progress reports required of all permit holders. Data collected shall be provided to

IDPH and the Illinois State Board of Health for use in their evaluation of the model.

4) Applications received for the postsurgical recovery care center alternative health care model shall be deemed complete upon receipt by HFSRB. All postsurgical recovery care center alternative health care models, for the purposes of review, shall be considered the establishment of a category of service rather than an addition of beds. Due to the comparative nature of the postsurgical recovery care center alternative health care model review, applicants will not be allowed to amend the application or provide additional supporting documentation during the review process prior to the initial HFSRB decision. The application, as submitted to HFSRB, shall serve as the basis for all standard and prioritization evaluations.

b) Review Criteria

1) Needs/Unit Size
The applicant must specify the number of beds to be in the proposed postsurgical recovery care center. The applicant must also document that the proposed number of beds is justified (utilizing the 80% occupancy target) based upon the anticipated number of patients who will utilize the service. Documentation shall consist of: patient identification numbers, ICD 10 Code or procedure type, patient length of stay and surgical referral site for each inpatient surgical case that occurred in surgical referral sites over the last 12 month period that could have received surgical recovery services within the model if it had been available.

2) Staffing
The applicant must document that the postsurgical recovery care center will be a separate and distinct (physically separate and identifiable) facility and have a dedicated nursing staff (i.e., that staff members working a shift are assigned only to cover the model), a medical director and 24 hours/day, 7 days/week on call physician coverage by a physician licensed to practice medicine in all of it branches. The on-call physician must be able to be physically present at the model within 15 minutes upon request. Documentation shall consist of: physical layout of the center (i.e., design drawings); identification of the number and type of staff positions dedicated to the model; identification of the facility medical director, including a signed commitment to the facility by that person stating a willingness to hold that position; and evidence that the required physician

coverage will be accomplished.

3) Patient Mix
The applicant must document that the postsurgical recovery care center is capable of providing recovery care to patients receiving a wide variety of surgical procedures. For the purposes of this subsection (b)(3), the following specialties (listing not inclusive of all surgical procedures that can recover in the model) shall be recognized: general surgery; eyes-ears-nose-throat; orthopaedic; plastic surgery; ophthalmology; urology; obstetrics-gynecology; and gastroenterology. The applicant must document that anticipated referrals would result in admissions coming from at least 3 of these surgical specialties and that each of the 3 specialty groups represents a minimum of 10% of facility admissions totaling at least 30%. Documentation shall consist of a detailed listing of the types of surgical procedures that will be performed for which recovery care will be provided and the protocols as to how recovery care will be given to each type of surgical patient, with details concerning how patient safety will be assured.

4) Travel Time/Patient Transfer
The applicant must document that the model will be located no farther than 30 minutes travel time by medical transport from all surgical referral sites. Documentation shall consist of identification of all surgical referral sites and the travel time/travel distance to the recovery care center. The applicant must also document who will have the responsibility for the transfer of patients from the surgical site to the postsurgical recovery care center and provide all transfer protocols, which must demonstrate the safe transfer of the surgical patients to the postsurgical recovery care center from each surgical referral site.

5) On Site Emergency Care
The applicant must document that the postsurgical recovery care center will have the capability to provide on-site emergency services sufficient to stabilize a patient for transfer to an acute care facility. Documentation shall consist of all protocols established for the treatment of emergency patients and the requirements established by the model for the education of staff in emergency procedures. Each postsurgical recovery care center must document that a crash cart is available on site and that staff trained in cardiac defibrillation are available at all times.

c) HFSRB Evaluation

1) HFSRB shall evaluate each application for the postsurgical recovery care center alternative health care model category of service (refer to 77 Ill. Adm. Code 1100.750(c) for development restrictions) based upon compliance with the conditions set forth in subsection (c)(2).

2) HFSRB Prioritization

A) An application for the category of service must meet the development restrictions specified in 77 Ill. Adm. Code 1100.750(c).

B) All applications for each planning area shall be rank ordered based on points awarded as follows:

i) Compliance with all applicable review criteria of Subpart B – 10 Points.

ii) Compliance with all review criteria of subsection (b) – 10 Points.

iii) Compliance with all applicable review criteria of 77 Ill. Adm. Code 1120 – 10 Points.

iv) Location in a medically underserved area (as defined by the federal Department of Health and Human Services (section 332 of the Public Health Service Act) as a health professional shortage area) – 3 Points.

v) To ensure that the model evaluates a wide range of surgical cases, an applicant shall be awarded an additional point for each designated surgical specialty area beyond the required 3 areas from which patients are referred to the postsurgical recovery care center.

vi) Historical Medicare and Medicaid surgical revenue at the surgical referral sites: 10% to 25% – 3 Points, 26% to 50% – 6 Points and over 50% – 9 Points.

vii) Accreditation of the applicant facility or facilities by The Joint Commission or the Accreditation Association for Ambulatory Healthcare (AAAHC) – 3 Points.

C) A postsurgical recovery care center alternative health care model must obtain a minimum of 30 Points to be considered for approval. Competing applications within a planning area that have obtained the points necessary for permit consideration shall be evaluated by the HFSRB to determine which application best implements the goals of the Health Facilities Planning Act and the Alternative Health Care Delivery Act.

d) Project Completion

1) Since the purpose of establishment of this category of service is to evaluate the alternative delivery model for effectiveness, these projects are not complete until the model is evaluated and the decision made to adopt or not adopt the model as an ongoing licensed level of service separate from an alternative delivery model. A discontinuation permit will not be required of a facility holding a postsurgical recovery care center alternative health care model permit if the facility elects to discontinue the model. The postsurgical recovery care center alternative health care model project shall be considered complete as of the date the Agency receives notice of the discontinuation. If a need for an additional model exists, applications shall be approved in accordance with this Section. Any alteration, discontinuation or abandonment of the approved category of service during the life of the permit is subject to State Board review.

2) All assurances and charges for service presented in the application shall be in effect for the life of the permit unless altered with approval of the State Board. Charges may be annually adjusted for inflation, not to exceed the growth in the health care component of the Consumer Price Index.

3) A postsurgical recovery care center alternative health care model shall have a period of 18 months from the date of permit issuance to become operational. Failure to begin operation in this time period shall result in the permit becoming null and void.

Section 1110.260 Community-Based Residential Rehabilitation Center Alternative Health Care Model

a) Introduction

1) This Section contains review criteria that pertain to the community-based residential rehabilitation center category of service. Definitions pertaining to this Section are contained in the Act, 77 Ill. Adm. Code 1100 and 1130, and the Alternative Health Care Delivery Act. The community-based residential rehabilitation category of service is a demonstration program authorized by the Alternative Health Care Delivery Act.

2) As the purpose of the demonstration project is to evaluate the community-based residential rehabilitation model for quality factors, access, and the impact on health care costs, the model approved for the category of service will be required to periodically submit data necessary for evaluating the model's effectiveness. Data collected shall be provided to IDPH and the Illinois State Board of Health for use in their evaluation of the model.

b) Review Criteria

1) Staffing
The applicant shall furnish a detailed staffing plan that provides: staff qualifications; identification of the number and type of staff positions dedicated to the model; how special staffing circumstances will be handled; staffing patterns for the proposed community-based residential rehabilitation center; and the manner in which non-dedicated staff services will be provided.

2) Mandated Services
The applicant shall document that the community-based residential rehabilitation center has the capability of providing the minimum range of services required under Section 35 of the Alternative Health Care Delivery Act. Documentation shall consist of a narrative of how services will be provided.

3) Unit Size
The applicant shall document the number and location of all beds in the model. The applicant shall also document that the number of community-based residential rehabilitation beds shall not exceed 12 beds in any one residence, as defined in Section 35 of the Alternative Health Care Delivery

Act. No community-based residential rehabilitation center alternative health care delivery model shall exceed 100 beds.

4) Utilization
The applicant shall document that the target utilization for this model (as defined at 77 Ill. Adm. Code 1100.770(c)) will be achieved by the second year of the model's operation. Documentation shall include, but not be limited to, historical utilization trends, population growth, expansion of professional staff or programs, and new procedures that increase utilization.

5) Background of Applicant
The applicant shall demonstrate experience in providing the services required by the model. Additionally, the applicant shall document that the programs provided in the model have been accredited by the Commission on Accreditation of Rehabilitation Facilities as a Brain Injury Community-Integrative Program for at least 3 of the last 5 years.

c) In order for an application for the community-based residential rehabilitation center alternative health care model to be approved, the applicant must comply with all criteria established in subsection (b). Competing applications within a planning area that comply with all criteria shall be evaluated by the State Board to determine which application best implements the goals of the Health Facilities Planning Act and the Alternative Health Care Delivery Act.

d) Project Completion

1) Since the purpose for the establishment of this category of service is to evaluate the alternative model for effectiveness, these projects are not complete until such time as the model is evaluated and the decision made to adopt or not adopt the model as an ongoing licensed level of service separate from an alternative delivery model. A permit will not be required of a community-based residential rehabilitation alternative health care model that proposes to cease participation in the demonstration program. If the facility proposes to discontinue the model, written notice containing the reasons for the discontinuation must be received by the State Board at least 90 days prior to the anticipated discontinuation. The project shall be considered abandoned as of the date IDPH receives notice of the actual discontinuation or the date the last client is discharged, whichever is later, and the facility should be removed from the inventory.

2) After obtaining its initial certificate of need, a community-based residential rehabilitation center alternative health care delivery model must obtain an additional certificate of need from the State Board before increasing the bed capacity of the center, as mandated by Section 35(b) of the Alternative Health Care Delivery Act.

3) All assurances for service presented in the application shall be in effect until the demonstration program has been completed, unless altered with approval of the State Board.

4) A community-based residential rehabilitation center alternative health care model shall have a period of 12 months from the date of permit issuance to become operational. Failure to begin operation in this time period shall result in the permit becoming null and void.

Section 1110.265 Long Term Acute Care Hospital Bed Projects

a) Introduction

1) This Section applies to projects involving Long Term Acute Care Hospital (LTACH) services. Applicants proposing to establish, expand or modernize an LTACH category of service shall comply with the applicable subsections of this Section, as follows:

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)(5)	−	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)	−	Performance Requirements
	(g)	−	Assurances
Expansion of Existing Services	(b)(2)	−	Planning Area Need – Service to Planning Area Residents
	(b)(4)	−	Planning Area Need – Service Demand – Expansion of Category of Service
	(e)	−	Staffing Availability
	(f)	−	Performance Requirements
	(g)	−	Assurances
Category of Service Modernization	(d)(1)	−	Deteriorated Facilities
	(d)(2) & (3)	−	Documentation
	(d)(4)	−	Occupancy
	(f)	−	Performance Requirements

2) If the proposed project involves the replacement of a hospital or service on-site, the applicant shall comply with the requirements listed in subsection (a)(1) (Category of Service Modernization) plus subsection (g) (Assurances).

3) If the proposed project involves the replacement of a hospital or service on a new site, the applicant shall comply with the requirements of subsection (a)(1) (Establishment of ASTC Facility or Additional ASTC Service).

4) If the proposed project involves the replacement of a hospital or service (onsite or new site), the number of beds being replaced shall not exceed the number justified by historical occupancy rates for each of the latest 2 years, unless additional beds can be justified per the criteria for Expansion of Existing Services.

5) If the proposed project involves the conversion of existing acute care beds to LTACH services, the applicant shall comply with the requirements of subsection (a)(1) (Establishment of ASTC Facility or Additional ASTC Service), as well as requirements in subsection (b)(6) (Conversion of Existing General Acute Care Beds).

b) Planning Area Need − Review Criteria
The applicant shall document that the number of LTACH beds to be established or added is necessary to serve the planning area's population, based on the following:

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

A) The number of LTACH beds to be established is in conformance with the projected bed deficit specified in 77 Ill. Adm. Code 1100, as reflected in the latest updates to the Inventory.

B) The number of LTACH beds proposed shall not exceed the number of the projected deficit, to meet the health care needs of the population served, in compliance with the occupancy standard specified in 77 Ill. Adm. Code 1100.

2) Service to Planning Area Residents

A) Applicants proposing to establish or add beds 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.

B) Applicants proposing to add beds to an existing LTACH service shall provide patient origin information for all admissions for the last 12-month period, verifying that at least 75% of admissions were residents of the area. For all other projects, applicants shall document that at least 75% of the projected patient volume will be from residents of the area.

C) Applicants proposing to expand an existing LTACH service shall submit patient origin information by zip code, based upon the patient's legal residence (other than a health care facility).

3) Service Demand – Establishment of LTACH Service
The number of beds proposed to establish a new category of hospital bed 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. The applicant shall document subsection (b)(3)(A) and either subsection (b)(3)(B) or (C).

A) Historical Referrals
If the applicant is an existing facility, the applicant shall document the number of referrals to other facilities, for each proposed category of hospital 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, and name and location of the recipient hospital.

B) Projected Referrals
An applicant proposing to establish a category of service or establish a new hospital 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 LTACH facilities located in the area or had a length of stay of over 25 days in a general acute care hospital and were considered to be LTACH candidates, annually over the latest 2-year period prior to submission of the application; and an estimate as to the number of patients that will be referred to the applicant's facility;

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.

C) Projected Service Demand − Based on Rapid Population Growth
If a projected demand for service is based upon rapid population growth in the applicant facility's existing market area (as experienced annually within the latest 24-month period), the projected service demand shall be determined as follows:

i) The applicant shall define the facility's market area based upon historical patient origin data by zip code or census tract;

ii) Population projections shall be produced, using, as a base, the population census or estimate for the most recent year, for county, incorporated place, township or community area, by the U.S. Census Bureau or IDPH;

iii) Projections shall be for a maximum period of 10 years from the date the application is submitted;

iv) Historical data used to calculate projections shall be for a number of years no less than the number of years projected;

v) Projections shall contain documentation of population changes in terms of births, deaths and net migration for a period of time equal to, or in excess of, the projection horizon;

vi) Projections shall be for total population and specified age groups for the applicant's market area, as defined by HFSRB, for each category of service in the application; and

vii) Documentation on projection methodology, data sources, assumptions and special adjustments shall be submitted to HFSRB.

D) Type of Patients

The applicant shall identify the type of patients that will be served by the project by providing the anticipated diagnosis (by DRG classification) for anticipated admissions to the facility. The applicant shall also indicate the types of service (e.g., ventilator care, etc.) to be provided by the project.

4) Service Demand – Expansion of Bed Category of Service
The number of beds to be added for each category of service is necessary to reduce the facility's experienced high occupancy and to meet a projected demand for service. The applicant shall document subsection (b)(4)(A) and either subsection (b)(4)(B) or (C):

A) Historical Service Demand

i) An average annual occupancy rate that has equaled or exceeded occupancy standards for the category of service, as specified in 77 Ill. Adm. Code 1100, for each of the latest 2 years.

ii) If patients have been referred to other facilities in order to receive the subject services, the applicant shall provide documentation of the referrals, including: patient origin by zip code; name and specialty of referring physician; and name and location of the recipient hospital, for each of the latest 2 years.

B) Projected Referrals
The applicant shall provide the following:

i) Physician referral letters that attest to the number of patients (by zip code of residence) that have received care at existing LTACH facilities located in the area or had a length of stay of over 25 days in a general acute care hospital and were considered to be LTACH candidates, 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. The percentage of project referrals used to justify the proposed expansion cannot exceed the historical percentage of applicant market share, within a 24-month period after project completion;

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.

C) Projected Service Demand – Based on Rapid Population Growth
If a projected demand for service is based upon rapid population growth in the applicant facility's existing market area (as experienced annually within the latest 24-month period), the projected service demand shall be determined as follows:

i) The applicant shall define the facility's market area based upon historical patient origin data by zip code or census tract;

ii) Population projections shall be produced, using, as a base, the population census or estimate for the most recent year, for county, incorporated place, township or community area, by the U.S. Census Bureau or IDPH;

iii) Projections shall be for a maximum period of 10 years from the date the application is submitted;

iv) Historical data used to calculate projections shall be for a number of years no less than the number of years projected;

v) Projections shall contain documentation of population changes in terms of births, deaths and net migration for a period of time equal to or in excess of the projection horizon;

vi) Projections shall be for total population and specified age groups for the applicant's market area, as defined by HFSRB, for each category of service in the application; and

vii) Documentation on projection methodology, data sources, assumptions and special adjustments shall be submitted to HFSRB.

5) Service Accessibility
The number of beds being established or added for each 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 (b)(5) only, all services within the established radii outlined in 77 Ill. Adm. Code 1100.510(d) 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, 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.

6) Conversion of Existing General Acute Care Beds – Review Criterion
An applicant proposing to establish a Long Term Acute Care Hospital category of service through the conversion of existing general acute care beds shall:

A) Address Section 1110.30 for discontinuation of categories of service;

B) Identify modifications in scope of services or elimination of clinical service areas, not covered in Section 1110.290 (e.g., Emergency Department Classification, Surgical Services, Outpatient Services, etc.);

C) Submit a statement as to whether the following clinical service areas are to be available to the general population (non-LTACH): operating rooms, surgical procedure rooms, diagnostic services, therapy services (physical, occupational, speech, respiratory) and other outpatient services; and

D) Document that changes in clinical service areas will not have an adverse impact upon the health care delivery system. An applicant shall document that a written request for information on any adverse impact was received by all hospitals within the established radii outlined in 77 Ill. Adm. Code 1100.510(d), and that the request included a statement that a written response be provided to the applicant no later than 15 days after receipt. Failure by an existing facility to respond to the applicant's request for information within the prescribed 15-day response period shall constitute a nonrebuttable assumption that the existing facility will not be adversely impacted.

c) Unnecessary Duplication/Maldistribution − Review Criteria

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 the established radii outlined in 77 Ill. Adm. Code 1100.510(d) 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 the established radii outlined in 77 Ill. Adm. Code 1100.510(d) of the project site that provide the categories of bed service that are proposed by the project.

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) A ratio of beds to population that exceeds one and one-half times the State average;

B) 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

C) 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) LTACH Modernization

1) If the project involves modernization of an LTACH category of service, the applicant shall document that the inpatient bed 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) Noncompliance 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) Performance Requirements

1) Bed Capacity Minimum
An applicant shall document that the project will result in a facility capacity of at least 50 LTACH beds located in an MSA and 25 LTACH beds in a non-MSA.

2) Length of Stay

A) An applicant proposing to add beds to an existing service shall document that the average length of stay (ALOS) for the subject service is consistent with the planning area's 3-year ALOS.

B) Documentation shall consist of the 3-year ALOS for all hospitals within the planning area (as reported in the Annual Hospital Questionnaire).

C) An applicant whose existing services have an ALOS exceeding 125% of the ALOS for area providers shall document that the severity or type of illness treated at the applicant facility is significantly higher than the planning area average. Documentation shall be provided from CMMS or other objective records.

D) An applicant whose existing services have an ALOS lower than the planning area ALOS shall submit an explanation as to the reasons for the divergence.

3) Be certified by Medicare as a Long Term Acute Care Hospital within 12 months after the date of project completion.

g) Assurances
The applicant representative who signs the CON application shall submit a signed and dated statement attesting to the applicant's understanding that, within 30 months 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.

Section 1110.270 Clinical Service Areas Other Than Categories of Service

a) Introduction

1) These criteria are applicable only to those projects or components of projects (including major medical equipment), concerning Clinical Service Areas (CSAs) that are not Categories of Service, but for which utilization standards are listed in Appendix B, including:

A) Surgery

B) Emergency Services and/or Trauma

C) Ambulatory Care Services (organized as a service)

D) Diagnostic and Interventional Radiology/Imaging (by modality)

E) Therapeutic Radiology

F) Laboratory

G) Pharmacy

H) Occupational Therapy/Physical Therapy

I) Major Medical Equipment

2) The applicant shall also comply with requirements of the review criterion in Section 1110.120(a) (Size of Project – Review Criteria), as well as all other applicable requirements in this Part and 77 Ill. Adm. Code 1100 and 1130. Applicants proposing to establish, expand or modernize CSAs shall comply with the applicable subsections of this Section, as follows:

PROJECT TYPE	REQUIRED REVIEW CRITERIA		
New Services or Facility or Equipment	(b)	−	Need Determination − Establishment
Service Modernization	(c)(1)	−	Deteriorated Facilities and/or
	(c)(2)	−	Necessary Expansion PLUS
	(c)(3)(A)	−	Utilization − Major Medical Equipment or
	(c)(3)(B)	−	Utilization − Service or Facility

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

4) If the proposed project involves the replacement of a facility or service on a new site, the applicant shall comply with the requirements of subsection (a)(2) (New Services or Facility or Equipment).

5) Projects involving the replacement of a service or facility shall meet or exceed the utilization standards for the service, as specified in Appendix B.

6) The number of key rooms proposed in a replacement or modernization project shall be justified by the historical utilization for each of the latest 2 years, per utilization standards cited in Appendix B.

b) Need Determination − Establishment
The applicant shall describe how the need for the proposed establishment was determined by documenting the following:

1) Service to the Planning Area Residents

A) Either:

i) The primary purpose of the proposed project is to provide care to the residents of the planning area in which the proposed service will be physically located; or

ii) If the applicant service area includes a primary and secondary service area that expands beyond the planning area boundaries, the applicant shall document that the primary purpose of the project is to provide care to residents of the service area; and

B) Documentation shall consist of strategic plans or market studies conducted, indicating the historical and projected incidence of disease or health conditions, or use rates of the population. The number of years projected shall not exceed the number of historical years documented. Any projections and/or trend analyses shall not exceed 10 years.

2) Service Demand
To demonstrate need for the proposed CSA services, the applicant shall document one or more of the indicators presented in subsections (b)(2)(A) through (D). For any projections, the number of years projected shall not exceed the number of historical years documented. Any projections and/or trend analyses shall not exceed 10 years.

A) Referrals from Inpatient Base
For CSAs that will serve as a support or adjunct service to existing inpatient services, the applicant shall document a minimum 2-year

historical and 2-year projected number of inpatients requiring the subject CSA.

B) Physician Referrals
For CSAs that require physician referrals to create and maintain a patient base volume, the applicant shall document patient origin information for the referrals. The applicant shall submit original signed and notarized referral letters, containing certification by the physicians that the representations contained in the letters are true and correct.

C) Historical Referrals to Other Providers
If, during the latest 12-month period, patients have been sent to other area providers for the proposed CSA services, due to the absence of those services at the applicant facility, the applicant shall submit verification of those referrals, specifying: the service needed; patient origin by zip code; recipient facility; date of referral; and physician certification that the representations contained in the verifications are true and correct.

D) Population Incidence
The applicant shall submit documentation of incidence of service based upon IDPH statistics or category of service statistics.

3) Impact of the Proposed Project on Other Area Providers
The applicant shall document that, within 24 months after project completion, the proposed project will not:

A) Lower the utilization of other area providers below the utilization standards specified in Appendix B.

B) Lower, to a further extent, the utilization of other area providers that are currently (during the latest 12-month period) operating below the utilization standards.

4) Utilization
Projects involving the establishment of CSAs shall meet or exceed the utilization standards for the services, as specified in Appendix B. If no utilization standards exist in Appendix B, the applicant shall document its

anticipated utilization in terms of incidence of disease or conditions, or historical population use rates.

c) Service Modernization
The applicant shall document that the proposed project meets one of the following:

1) Deteriorated Equipment or Facilities
The proposed project will result in the replacement of equipment or facilities that have deteriorated and need replacement. Documentation shall consist of, but is not limited to: historical utilization data, downtime or time spent out of service due to operational failures, upkeep and annual maintenance costs, and licensure or fire code deficiency citations involving the proposed project.

2) Necessary Expansion
The proposed project is necessary to provide expansion for diagnostic treatment, ancillary training or other support services to meet the requirements of patient service demand. Documentation shall consist of, but is not limited to: historical utilization data, evidence of changes in industry standards, changes in the scope of services offered, and licensure or fire code deficiency citations involving the proposed project.

3) Utilization

A) Major Medical Equipment
Proposed projects for the acquisition of major medical equipment shall document that the equipment will achieve or exceed any applicable target utilization levels specified in Appendix B within 12 months after acquisition.

B) Service or Facility
Projects involving the modernization of a service or facility shall meet or exceed the utilization standards for the service, as specified in Appendix B. The number of key rooms being modernized shall not exceed the number justified by historical utilization rates for each of the latest 2 years, unless additional key rooms can be justified per subsection (c)(2) (Necessary Expansion).

C) If no utilization standards exist, the applicant shall document in detail its anticipated utilization in terms of incidence of disease or conditions, or population use rates.

Section 1110.275 Birth Center – Alternative Health Care Model

a) Introduction

1) This Section contains review criteria that pertain to the birth center model category of service. The birth center model category of service is a demonstration program that is authorized by the Alternative Health Care Delivery Act. Definitions pertaining to this category of service are contained in 77 Ill. Adm. Code 1100 and 1130 and in the Alternative Health Care Delivery Act. These birth center model review criteria are utilized in addition to the applicable review criteria of Subpart B and 77 Ill. Adm. Code 1120.

2) A Certificate of Need (CON) permit shall be obtained to establish a birth center model. CON application forms are available from HFSRB's website (www.hfsrb.illinois.gov).

3) Failure to obtain a permit will result in the application of sanctions as provided for in the Illinois Health Facilities Planning Act.

4) CON applications for permits received for the birth center model shall be deemed complete upon receipt by HFSRB.

5) As the purpose of the demonstration project is to evaluate the birth center model for quality factors, access and the impact on health care costs, each applicant approved for the category of service will be required to periodically submit data necessary for evaluating the model's effectiveness.

b) Review Criteria

1) Location Requirements

A) *There shall be no more than 10 birth center alternative health care models in the demonstration program* including:

i) A total of 4 located in the combined Cook, DuPage, Kane, Lake, McHenry and Will counties;

ii) A total of 3 located in municipalities with a population of 50,000 or more not located in an area described in subsection (b)(1)(A)(i); and

iii) A total of 3 located in rural areas.

B) In each of the geographic groups identified in subsection (b)(1)(A), one birth center shall be owned or operated by a hospital and one birth center shall be owned and operated by a federally qualified health center.

C) Documentation

i) The applicant shall document that the proposed birth center will be located in one of the geographic areas stated in the Alternative Health Care Delivery Act and described in subsection (b)(1)(A); and

ii) The applicant shall document that the proposed birth center is owned or operated by a hospital or owned or operated by a federally qualified health center or owned and operated by a private person or entity.

D) As stated in Section 30 of the Alternative Health Care Delivery Act, *there shall be no more than 2 birth centers authorized to operate in any single health planning area for obstetric services as determined under the Illinois Health Facilities Planning Act* [20 ILCS 3960].

2) Service Provision to a Health Professional Shortage Area

A) *The first 3 birth centers authorized to be operated by* IDPH *shall be located in or predominantly serve the residents of a health professional shortage area, as determined by the U.S. Department of Health and Human Services.* [210 ILCS 3/30] The applicant shall document whether the proposed site is located in or will

predominantly serve the residents of a health professional shortage area.

B) *If a birth center is located outside of a health professional shortage area*:

i) *the birth center shall be located in a health planning area with a demonstrated need for obstetrical service beds, as determined by the Health Facilities and Services Review Board*; *or*

ii) *there* shall *be a reduction in the existing number of obstetrical service beds in the planning area so that the establishment of the birth center does not result in an increase in the total number of obstetrical service beds in the health planning area.* [210 ILCS 3/30]

3) Admission Policies
A birth center may not discriminate against any patient requiring treatment because of the source of payment for services, including Medicare and Medicaid recipients. [210 ILCS 3/35] Documentation shall consist of copies of all admission policies to be in effect at the facility and a signed statement that no restrictions on admissions due to these factors will occur.

4) Bed Capacity
The applicant shall document that the proposed birth center will have no more than 10 beds.

5) Staffing Availability
The applicant shall document that relevant clinical and professional staffing needs for the proposed project were considered and that licensure staffing requirements can be met. In addition, the applicant shall document that necessary staffing is available by providing a narrative explanation of how the proposed staffing will be achieved.

6) Emergency Surgical Backup
The applicant shall document that either:

A) The birth center will operate under a hospital license and will be *located within 30 minutes ground travel time from the hospital to allow for an emergency caesarian delivery to be started within 30 minutes* after *the decision that a caesarian delivery is necessary*; or

B) A contractual agreement has been signed with a licensed hospital for the referral and transfer of patients in need of an emergency caesarian delivery. *Birth centers shall be located within 30 minutes ground travel time from the licensed hospital to allow for an emergency caesarian delivery to be started within 30 minutes* after *the decision that a caesarian delivery is necessary.* [210 ILCS 3/35]

7) Education
A birth center shall offer prenatal care and community education services and shall coordinate these services with other health care services available in the community. [210 ILCS 3/35] Documentation shall consist of a written narrative on the prenatal care and community education services offered by the birth center and how these services are being coordinated with other health services in the community.

8) Inclusion in Perinatal System

A) Requirements

i) *At a minimum,* the birth center's *participation shall require a birth center to establish a letter of agreement with a hospital designated under the Perinatal System.*

ii) *A hospital that operated or has a letter of agreement with a birth center shall include the birth center under its maternity service plan under the Hospital Licensing Act and shall include the birth center in the hospital's letter of agreement with its perinatal center.* [210 ILCS 3/30]

B) Documentation

i) A hospital that operated or has a letter of agreement with a birth center shall provide a copy of the hospital's letter of

agreement with its perinatal center and of copy of the hospital's maternity service plan.

ii) An applicant that is not a hospital shall identify the regional perinatal center that will provide neonatal intensive care services, as needed, to the applicant birth center patients. A letter of intent, signed by both the administrator of the proposed birth center and the administrator of the regional perinatal center, shall be provided.

9) Medicare/Medicaid Certification
The applicant shall document that the proposed birth center will be certified to participate in the Medicare and Medicaid programs under titles XVIII and XIX, respectively, of the federal Social Security Act (42 USC 1395 and 1396).

10) Charity Care
All birth centers *shall provide charitable care consistent with that provided by comparable health care providers in the geographic area.* [210 ILCS 3/30] The applicant shall provide to HFSRB a copy of the charity care policy that will be adopted by the proposed birth center.

11) Quality Assurance
Each birth center *shall implement a quality assurance program with measurable benefits.* [210 ILCS 3/30] The applicant shall provide to HFSRB a copy of the quality assurance program to be adopted by the birth center.

Section 1110.280 Introduction Freestanding Emergency Center Medical Services

a) Introduction
No person shall construct, modify or establish a freestanding emergency center in Illinois, or acquire major medical equipment or make capital expenditures in relation to such a facility in excess of the capital expenditure minimum, as defined by the *Act, without first obtaining a permit from the State Board in accordance with* this Section. [20 ILCS 3960/5.1a]

b) Review Criteria

1) These criteria are applicable only to those projects or components of projects involving the freestanding emergency center (FEC) medical services (FECMS) category of service. In addition, the applicant shall address other applicable requirements in this Part, as well as those in 77 Ill. Adm. Code 1100 and 1130. Applicants proposing to establish, expand or modernize an FECMS category of service shall comply with the applicable subsections of this Section, as follows:

PROJECT TYPE	REQUIRED REVIEW CRITERIA		
Establishment of Service	(c)(1)	−	Planning Area Need – 77 Ill. Adm. Code 1100 Formula Calculation
	(c)(2)	−	Service to Area Residents
	(c)(3)	−	Service Demand for Establishment
	(c)(4)	−	Service Accessibility
	(d)(1)	−	Unnecessary Duplication of Services
	(d)(2)	−	Maldistribution
	(d)(3)	−	Impact on Other Providers
	(d)(4)	−	Request for Data from Other Providers
	(f)	−	Staffing Availability
Expansion of Existing Service	(c)(2)	−	Service to Area Residents
	(f)	−	Staffing Availability
Category of Service Modernization	(e)(1)	−	Deteriorated Facilities
	(e)(2)	−	Documentation
	(e)(3)	−	Additional Documentation

2) If the proposed project involves the replacement of an FEC facility on site, the applicant shall comply with the requirements listed in subsection (b)(1) for Category of Service Modernization.

3) If the proposed project involves the replacement of the FEC facility on a new site, the applicant shall comply with the requirements listed in subsection (b)(1) for Establishment of Service.

4) All projects shall meet or exceed the utilization standards for the service, as specified in 77 Ill. Adm. Code 1100.

5) All projects for an FEC must comply with the licensing requirements established in Section 32.5 of the Emergency Medical Services (EMS) Systems Act, including the requirements that the proposed FEC is located:

A) *in a municipality with a population of 75,000 or fewer inhabitants;*

B) *within 20 miles of the hospital that owns or controls the FEC; and*

C) *within 20 miles of the Resource Hospital affiliated with the FEC as part of the EMS system* (Section 32.5(a) of the Emergency Medical Services (EMS) Systems Act).

6) The applicant shall certify that it has reviewed, understands and plans to comply with all of the following requirements:

A) The requirements of becoming a Medicare provider of freestanding emergency services; and

B) The requirements of becoming licensed under the Emergency Medical Services (EMS) Systems Act.

c) Area Need – Establishment or Expansion of Service

1) 77 Ill. Adm. Code 1100 Formula Calculation
No formula need calculation has been established for the FECMS category of service.

2) Service to Area Residents
Applicants proposing to establish or expand an FECMS category of service shall document that the primary purpose of the project will be to provide necessary health care to the residents of the geographic service area (GSA), which is defined as 30 minutes travel time from the proposed FEC site.

A) For projects to establish an FECMS category of service, the applicant shall document that at least 50% of the projected patient volume will be residents of the GSA. Documentation shall consist of patient origin data, as follows:

i) Letters from authorized representatives of hospitals or other FEC facilities that are part of the Emergency Medical Services (EMS) System for the defined GSA, including patient origin data by zip code. If letters are submitted as documentation, a certification in each letter, by the authorized representative, that the representations contained in the letter are true and correct. A complete set of the letters with original notarized signatures shall accompany the application for permit; or

ii) Patient origin data by zip code from independent data sources (e.g., Illinois Hospital Association CompData or IDPH hospital discharge data), based upon the patient's legal residence, for patients receiving services at the existing GSA facilities' emergency departments (ED), verifying that at least 50% of the ED patients served during the last 12-month period were residents of the GSA.

B) An applicant proposing to expand an FECMS category of service shall provide patient origin information for all patients served at the existing FEC facility for the last 12-month period, verifying that at least 50% of patients served were residents of the GSA. The applicant shall submit patient origin information by zip code, based upon the patient's legal residence.

3) Service Demand − Establishment of FECMS Category of Service
The applicant shall document that establishment of an FECMS category of service is necessary to accommodate the service demand experienced annually by the existing GSA hospitals over the latest 2-year period.

A) Historical Utilization
The applicant shall document the annual number of ED patients that have received care at facilities that are located in the applicant's defined GSA for the latest 2-year period prior to submission of the application;

B) Projected Utilization
The applicant shall document:

i) the estimated number of patients anticipated to receive services at the proposed FEC. The anticipated number cannot exceed the documented historical caseload of all hospitals that are located in the applicant's defined GSA.

ii) if applicable, the estimated number of patients anticipated to receive services at the proposed FEC, based upon rapid population growth in the applicant facility's existing market area.

C) Projected Service Demand – Documentation Parameters

i) Population projections shall be produced, using, as a base, the population census or estimate for the most recent year for zip code, county, incorporated place, township, or community area by the U.S. Census Bureau or IDPH;

ii) Projections shall be for a maximum period of 10 years from the date the application is submitted;

iii) The number of years projected shall not exceed the number of historical years documented;

iv) Projections shall contain documentation of population changes in terms of births, deaths, and net migration for a period of time equal to or in excess of the projection horizon;

v) Projections shall be for total population and specified age groups for the applicant's market area, as defined by HFPB for each category of service in the application; and

vi) Documentation on projections methodology, data sources, assumptions and special adjustments shall be submitted to HFPB.

4) Service Accessibility
The proposed project to establish or expand an FECMS category of service is necessary to improve access for GSA 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 GSA:

i) The absence of ED services within the GSA;

ii) The area population and existing care system exhibit indicators of medical care problems, such as 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;

iii) All existing emergency services within the established radii outlined in 77 Ill. Adm. Code 1100.510(d) 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, concerning existing restrictions to service access:

i) The location and utilization of other GSA service providers;

ii) Patient location information by zip code;

iii) Travel-time studies;

iv) A certification of waiting times;

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

vi) An assessment of GSA population characteristics that documents 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 (in total or in part) that are located within the established radii outlined in 77 Ill. Adm. Code 1100.510(d) 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 the established radii outlined in 77 Ill. Adm. Code 1100.510(d) from the project site that provide emergency medical services.

2) The applicant shall document that the project will not result in maldistribution of services. Maldistribution exists when the identified facilities within the Normal Travel Time have an excess supply of ED treatment stations 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 ED within the established radii outlined in 77 Ill. Adm. Code 1100.510(d) of the applicant's site that is below the utilization standard established pursuant to 77 Ill. Adm. Code 1100; or

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

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

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

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

4) The applicant shall document that a written request was received by all existing facilities that provide ED service located within the established radii outlined in 77 Ill. Adm. Code 1100.510(d) of the project site asking the number of treatment stations at each facility, historical ED utilization, and the anticipated impact of the proposed project upon the facility's ED utilization. The request shall include a statement that a written response be provided to the applicant no later than 15 days after receipt. Failure by an existing facility to respond to the applicant's request for information within the prescribed 15-day response period shall constitute an assumption that the existing facility will not experience an adverse impact in utilization from the project. Copies of any correspondence received from the facilities shall be included in the application.

e) Category of Service Modernization

1) If the project involves modernization of an existing FECMS category of service, the applicant shall document that the existing treatment 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; or

D) Additional space for diagnostic or therapeutic purposes.

2) Documentation shall include the most recent:

A) IDPH 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.

f) Staffing Availability − Review Criterion

1) An applicant proposing to establish an FECMS category of service shall document that a sufficient supply of personnel will be available to staff the service. Sufficient staff availability shall be based upon evidence that for the latest 12-month period prior to submission of the application, those hospitals or FECs located in zip code areas that are (in total or in part) within one hour normal travel time of the applicant facility's site have not experienced a staffing shortage with respect to the categories of services proposed by the project.

2) A staffing shortage is indicated by an average annual vacancy rate of more than 10% for budgeted full-time equivalent staff positions for health care workers who are subject to licensing by the Department of Financial and Professional Regulation.

3) An applicant shall document that a written request for such information was received by all existing facilities within the zip code areas, and that the request included a statement that a written response be provided to the applicant no later than 15 days after receipt. Failure by an existing facility to respond to the applicant's request for information within the prescribed 15-day response period shall constitute an assumption that the existing facility has not experienced staffing vacancy rates in excess of 10%. Copies of any correspondence received from the facilities shall be included in the application.

4) If more than 25% of the facilities contacted indicated an experienced staffing vacancy rate of more than 10% percent, the applicant shall provide documentation as to how sufficient staff shall be obtained to operate the proposed project, in accordance with licensing requirements.

Section 1110.290 Discontinuation – Review Criteria

These criteria pertain to the discontinuation of categories of service and health care facilities.

a) Information Requirements − Review Criterion
The applicant shall provide at least the following information:

1) Identification of the categories of service and the number of beds, if any, that are to be discontinued;

2) Identification of all other clinical services that are to be discontinued;

3) The anticipated date of discontinuation for each identified service or for the entire facility;

4) The anticipated use of the physical plant and equipment after discontinuation occurs;

5) The anticipated disposition and location of all medical records pertaining to the services being discontinued and the length of time the records will be retained;

6) For applications involving discontinuation of an entire facility, certification by an authorized representative that all questionnaires and data required by HFSRB or the Illinois Department of Public Health (IDPH) (e.g., annual questionnaires, capital expenditures surveys, etc.) will be provided through the date of discontinuation and that the required information will be submitted no later than 60 days following the date of discontinuation.

b) Reasons for Discontinuation − Review Criterion
The applicant shall document that the discontinuation is justified by providing data that verifies that one or more of the following factors (and other factors, as applicable) exist with respect to each service being discontinued:

1) Insufficient volume or demand for the service;

2) Lack of sufficient staff to adequately provide the service;

3) The facility or the service is not economically feasible, and continuation impairs the facility's financial viability;

4) The facility or the service is not in compliance with licensing or certification standards.

c) Impact on Access − Review Criterion
The applicant shall document whether the discontinuation of each service or of the entire facility will have an adverse impact upon access to care for residents of the facility's market area. The facility's market area, for purposes of this Section, is the established radii outlined in 77 Ill. Adm. Code 1100.510(d). Factors that indicate an adverse impact upon access to service for the population of the facility's market area include, but are not limited to, the following:

1) The service will no longer exist within the established radii outlined in 77 Ill. Adm. Code 1100.510(d) of the applicant facility;

2) Discontinuation of the service will result in creating or increasing a shortage of beds or services, as calculated in the Inventory of Health Care Facilities, which is described in 77 Ill. Adm. Code 1100.70 and found on HFSRB's website;

3) Facilities or a shortage of other categories of service at determined by the provisions of 77 Ill. Adm. Code 1100 or other Sections of this Part.

d) The applicant shall provide copies of notification letters sent to other resources or health care facilities that provide the same services as those proposed for discontinuation and that are located within the established radii outlined in 77 Ill. Adm. Code 1100.510(d). The notification letter must include at least the anticipated date of discontinuation of the service and the total number of patients that received care or the number of treatments provided (as applicable) during the latest 24 month period.

Section 1110.APPENDIX A ASTC Services

The following is a list of ASTC services for Non-Hospital Based Ambulatory Surgical Treatment Centers (ASTC):

1. Cardiovascular
2. Colon and Rectal Surgery
3. Dermatology
4. General Dentistry
5. General Surgery
6. Gastroenterology
7. Neurological Surgery
8. Nuclear Medicine
9. Obstetrics/Gynecology
10. Ophthalmology
11. Oral/Maxillofacial Surgery
12. Orthopaedic Surgery
13. Otolaryngology
14. Pain Management
15. Physical Medicine and Rehabilitation
16. Plastic Surgery
17. Podiatric Surgery
18. Radiology

19. Thoracic Surgery

20. Urology

Other ASTC services will be considered on a case-by-case basis.

Section 1110.APPENDIX B State Guidelines − Square Footage and Utilization

The following area standards are established for departments, clinical service areas and facilities. All Diagnostic and Treatment utilization numbers are the minimums per unit for establishing more than one unit, except where noted in 77 Ill. Adm. Code 1100. HFSRB shall periodically evaluate the guidelines to determine if revisions should be made. Any revisions will be promulgated in accordance with the provisions of the Illinois Administrative Procedure Act.

Definitions pertaining to this Appendix are contained in 77 Ill. Adm. Code 1100.220.

HOSPITAL-BASED SERVICES

For hospitals, area determinations for departments and clinical service areas are to be made in departmental gross square feet (dgsf). Spaces to be included in the applicant's determination of square footage shall include all functional areas minimally required by the Hospital Licensing Act, applicable federal certification, and any additional spaces required by the applicant's operational program.

Service Areas	Square Feet/Unit or Key Room	Annual Utilization/Unit
ACUTE CARE		
Medical-Surgical, Pediatric, Obstetric & Long Term Acute Care Service	500-660 dgsf/Bed	See 77 Ill. Adm. Code 1100
Newborn Nursery (includes Level I, Level II, and Level II+ with extended neonatal capabilities)	160 dgsf/Obstetrics Bed & LDRP	
Labor Delivery Recovery (LDR)	1120-1600 dgsf/Room	400 Births/LDR Room
Labor Delivery Recovery Post-partum (LDRP)	1120-1600 dgsf/Bed	See 77 Ill. Adm. Code 1100
C-Section Suite	2075 dgsf/OR	800 Procedures/Room
Acute Mental Illness Service	440-560 dgsf/Bed	See 77 Ill. Adm. Code 1100
Comprehensive Physical Rehabilitation Service	525-660 dgsf/Bed	See 77 Ill. Adm. Code 1100

Hospital Based Long-Term Care	440-560 dgsf/Bed	See 77 Ill. Adm. Code 1100
CRITICAL CARE		
Intensive Care Service	600-685 dgsf/Bed	See 77 Ill. Adm. Code 1100
Neonatal Intensive Care (NICU) or Level III Nursery	434-568 dgsf/Bed or Bassinet	See 77 Ill. Adm. Code 1100
DIAGNOSTIC AND TREATMENT		
Diagnostic/Interventional Radiology (Excludes portables & mobile equipment/Utilization)		
• General Radiology	1300 dgsf/Unit	8000 procedures
• Fluoroscopy/Tomography/Other X-ray procedures	1300 dgsf/Unit	6500 procedures
• Dedicated Chest	900 dgsf/Unit	9000 procedures
• Mammography	900 dgsf/Unit	5000 visits
• Ultra-Sound	900 dgsf/Unit	3100 visits
• Angiography (Special Procedures)	1800 dgsf/Unit	1800 visits
• CT Scan	1800 dgsf/Unit	7000 visits
• PET	1800 dgsf/Unit	3600 visits
• MRI	1800 dgsf/Unit	2500 procedures
• Nuclear Medicine	1600 dgsf/Unit	2000 visits
Radiation Therapy		
• Accelerator	2400 dgsf/ Accelerator	7500 treatments
• Simulator	1800 dgsf/ Simulator	
Emergency Department	900 dgsf/ Treatment Station	2000 visits/station/year

Cardiac Catheterization	1800 dgsf	See 77 Ill. Adm. Code 1100 for establishment of service 1500 visits/year for additional units
Ambulatory Care	800 dgsf	2000 visits/year
Surgical Operating Suite (Class C)	2750 dgsf/ Operating Room	1500 hrs/Operating Room
Surgical Procedure Suite (Class B)	1100 dgsf/ Procedure Room	1500 hrs/Procedure Room
Post-Anesthesia Recovery Phase I	180 dgsf/Recovery Station	
Post-Anesthesia Recovery Phase II	400 dgsf/Recovery Station	
In-Center Hemodialysis	470 dgsf/Station	See 77 Ill. Adm. Code 1100

HFSRB NOTE: The standards for Post-Anesthesia Recovery Phase I and Post-Anesthesia Recovery Phase II shall be used as the standards for recovery stations associated with Surgical Operating Suite (Class C) and Surgical Procedure Suite (Class B).

OTHER FACILITIES

The following standards apply to new construction, the development of freestanding facilities, modernization, and the development of facilities in existing structures, including the use of leased space. For new construction, the standards are based upon the inclusion of all building components and are expressed in building gross square feet (bgsf). For modernization projects, the standards are based upon interior build-out only and are expressed in departmental gross square feet (dgsf). Spaces to be included in the applicant's determination of square footage shall include all functional areas minimally required for the applicable service areas by the appropriate rules required for IDPH licensure and/or federal certification and any additional spaces required by the applicant's operational program.

Service Areas	Square Feet/Unit	Annual Utilization/Unit
General Long Term Care	435-713 bgsf/Bed 350-570 dgsf/Bed	See 77 Ill. Adm. Code 1100

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NOTICE OF ADOPTED AMENDMENTS

ICF/DD Facilities	505-580 bgsf/Bed 404-464 dgsf/Bed	See 77 Ill. Adm. Code 1100
Ambulatory Surgical Treatment Center (ASTC) • Operating Room • Procedure Room • Recovery	2075-2750 bgsf/Treatment Room 1660-2200 dgsf/Treatment Room	Maximum of 4 recovery stations per operating room 1500 hrs of Surgery/OR or Procedure Room
In-Center Hemodialysis	450-650 bgsf/Room 360-520 dgsf/Room	See 77 Ill. Adm. Code 1100
Freestanding Emergency Center	840-1170 bgsf/Treatment Station 672-936 dgsf/Treatment Station	2000 visits/Treatment Room/year