HEALTH FACILITIES PLANNING BOARD

NOTICE OF PROPOSED AMENDMENTS

1) Heading of the Part : Processing, Classification Policies and Review Criteria

2) Code Citation: 77 Ill. Adm. Code 1110

3)

Section Numbers:	Proposed Action:
1110.210	Amend
1110.220	Repeal
1110.230	Amend
1110.234	New
1110.310	Repeal
1110.320	Repeal
1110.410	Repeal
1110.420	Repeal
1110.510	Repeal
1110.520	Repeal
1110.530	Amend
1110.610	Repeal
1110.620	Repeal
1110.630	Amend
1110.1410	Repeal
1110.1420	Repeal
1110.1430	Amend
1110.2310	Repeal
1110.2320	Repeal
1110.2330	Amend
1110.2410	Repeal
1110.2420	Repeal
1110.2430	Amend
1110.3030	New

4) Statutory Authority:
Illinois Health Facilities Planning Act [20 ILCS 3960]

5) A Complete Description of the Subjects and Issues Involved:

Definitions:

Proposed amendments would consolidate all definitions in Part 1100 and Part 1110 to Section 1100.220 – General Definitions. The proposed relocation and consolidation of definitions provides a central source for all review-based

definitions. This will simplify the process of searching for definitions related to project review subjects and criteria.

Sections 1110.220; 1110.520; 1110.620; 1110.1420; 1110.2320; and 1110.2420 will be repealed.

General Requirements:

Proposed Sections 1110.210 and 1110.230 change "Review Criteria" to "Information Requirements". The proposed "Information Requirements" will present an overview of the applicant, the proposed project, and all options considered and rejected, in favor of the proposed project. The three "Information Requirements" to be addressed are: Background of Applicant; Purpose of Project; and Alternatives to the Proposed Project.

Two of the redundant existing review criteria are incorporated into "Category of Service" review criteria in Sections F through AE of Part 1110. Existing criterion "Project Scope and Size" has been relocated to proposed Section 1110.232.

"Project Scope and Size, Utilization and Unfinished/Shell Space"

In the proposed new Section 1110.232, review criteria for both "Size of Project" and "Project Services Utilization" are relocated to a new Section (1110.234), which incorporates criteria concerning the physical aspects of a project, as well as "utilization" for projects that involve services, functions or equipment for which HFPB has not established utilization or occupancy standards in Part 1100.

In addition, this rule includes a new criterion for the review of "Unfinished/Shell Space". HFPB is required to consider shell space or unfinished space proposed in a project, per a mandate of the Health Facilities Planning Act.

"Category of Service" Rules:

A new format has been developed for all "Category of Service" review criteria. The new format reflects the intent and purposes of the Health Facilities Planning Act, and since the format will be applied to all "Category of Service" review criteria, it provides a uniform approach to the review and assessment of proposed projects.

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The proposed new format retains most of the existing requirements, and also incorporates "Need" and "Location" requirements from the existing "General Review Criteria" in Section 1110.230. Subparts D and E will be repealed, since the requirements have been incorporated into the "Category of Service" review criteria.

"Clinical Service Areas Other Than Categories of Service" – Review Criteria

The proposed new rule contains review criteria that are applicable only to those CON projects or components of projects concerning Clinical Service Areas that are not "Categories of Service", but for which utilization standards are listed in Part 1110- Attachment B.

6) Published studies or reports, and sources of underlying data, used to compose this rulemaking: None

7) Will this rulemaking replace any emergency rulemaking currently in effect? No.

8) Does this rulemaking contain an automatic repeal date? No.

9) Does this rulemaking contain incorporations by reference? No.

10) Are there any other proposed rulemakings pending on this Part? No.

11) Statement of Statewide Policy Objectives:
This rulemaking does not create or expand a State Mandate.

12) Time, Place and Manner in which interested persons may comment on this proposed rulemaking:

Public comment may be submitted at the Health Facilities Planning Board meeting, which starts at 9:00 AM on Wednesday, May 2, 2007.

The meeting will be conducted at:

Inn at 835
835 S. Second Street
Springfield, Illinois

HEALTH FACILITIES PLANNING BOARD

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Interested persons may present their comments concerning this rulemaking within 45 days after the publication of this issue of the *Illinois Register* to:

Claire Burman
Coordinator, Rules Development
Illinois Health Facilities Planning Board
100 W. Randolph Street, 6th Floor
Chicago, Illinois 60601
(312)814-2565
e-mail: CLAIRE.BURMAN@illinois.gov

13) Initial Regulatory Flexibility Analysis:

A) Types of small businesses, small municipalities and not for profit corporations affected: Hospitals, long term care facilities, ESRD facilities, Ambulatory Surgical Treatment Centers, Comprehensive Physical Rehabilitation Centers

B) Reporting, bookkeeping or other procedures required for compliance: None

C) Types of professional skills necessary for compliance: None

14) Regulatory Agenda on which this rulemaking was summarized:
January 2006

The full text of the Proposed Amendments begins on the next page:

HEALTH FACILITIES PLANNING BOARD

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~~TITLE 77: PUBLIC HEALTH~~
~~CHAPTER II: HEALTH FACILITIES PLANNING BOARD~~
~~SUBCHAPTER a: ILLINOIS HEALTH CARE FACILITIES PLAN~~

TITLE 77: PUBLIC HEALTH
CHAPTER II: HEALTH FACILITIES PLANNING BOARD
SUBCHAPTER a: ILLINOIS HEALTH CARE FACILITIES PLAN

PART 1110
PROCESSING, CLASSIFICATION POLICIES AND REVIEW CRITERIA

SUBPART A: GENERAL APPLICABILITY AND PROJECT CLASSIFICATION

Section
1110.10 Introduction to Part 1110
1110.20 Projects Required to Obtain a Permit (Repealed)
1110.30 Processing and Reviewing Applications
1110.40 Classification of Projects
1110.50 Recognition of Services Which Existed Prior to Permit Requirements
1110.55 Recognition of Non-hospital Based Ambulatory Surgery Category of Service
1110.60 Master Design Projects
1110.65 Master Plan or Capital Budget Projects

SUBPART B: REVIEW CRITERIA – DISCONTINUATION

Section
1110.110 Introduction
1110.120 Discontinuation – Definition
1110.130 Discontinuation – Review Criteria

SUBPART C: GENERAL PURPOSE, MASTER DESIGN, AND FACILITY CONVERSION ~~CHANGES OF OWNERSHIP~~ INFORMATION REQUIREMENTS AND REVIEW CRITERIA

Section
1110.210 Introduction
1110.220 Definitions – General Review Criteria (Repealed)

HEALTH FACILITIES PLANNING BOARD

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NON-HOSPITAL BASED AMBULATORY SURGERY

Section
1110.1510 Introduction
1110.1520 Non-Hospital Based Ambulatory Surgery – Definitions
1110.1530 Non-Hospital Based Ambulatory Surgery – Projects Not Subject to This Part
1110.1540 Non-Hospital Based Ambulatory Surgery – Review Criteria

SUBPART Q: CATEGORY OF SERVICE REVIEW CRITERIA – COMPUTER SYSTEMS

Section
1110.1610 Introduction (Repealed)
1110.1620 Computer Systems – Definitions (Repealed)
1110.1630 Computer Systems – Review Criteria (Repealed)

SUBPART R: CATEGORY OF SERVICE REVIEW CRITERIA – GENERAL LONG-TERM CARE

Section
1110.1710 Introduction
1110.1720 General Long-Term Care – Definitions
1110.1730 General Long-Term Care – Review Criteria

SUBPART S: CATEGORY OF SERVICE REVIEW CRITERIA – SPECIALIZED LONG-TERM CARE

Section
1110.1810 Introduction
1110.1820 Specialized Long-Term Care – Definitions
1110.1830 Specialized Long-Term Care – Review Criteria

SUBPART T: CATEGORY OF SERVICE REVIEW CRITERIA – INTRAOPERATIVE MAGNETIC RESONANCE IMAGING

Section

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SUBPART Y: CATEGORY OF SERVICE REVIEW CRITERIA – KIDNEY TRANSPLANTATION

Section
1110.2410 Introduction- (Repealed)
1110.2420 Kidney Transplantation – Definitions (Repealed)
1110.2430 Kidney Transplantation – Review Criteria

SUBPART Z: CATEGORY OF SERVICE REVIEW CRITERIA – SUBACUTE CARE HOSPITAL MODEL

Section
1110.2510 Introduction
1110.2520 Subacute Care Hospital Model – Definitions
1110.2530 Subacute Care Hospital Model – Review Criteria
1110.2540 Subacute Care Hospital Model – State Board Review
1110.2550 Subacute Care Hospital Model – Project Completion

SUBPART AA: CATEGORY OF SERVICE REVIEW CRITERIA – POSTSURGICAL RECOVERY CARE CENTER ALTERNATIVE HEALTH CARE MODEL

Section
1110.2610 Introduction
1110.2620 Postsurgical Recovery Care Center Alternative Health Care Model – Definitions
1110.2630 Postsurgical Recovery Care Center Alternative Health Care Model – Review Criteria
1110.2640 Postsurgical Recovery Care Center Alternative Health Care Model – State Board Review
1110.2650 Postsurgical Recovery Care Center Alternative Health Care Model – Project Completion

SUBPART AB: CATEGORY OF SERVICE REVIEW CRITERIA – CHILDREN'S RESPITE CARE ALTERNATIVE HEALTH CARE MODEL

1110.2710 Introduction
1110.2720 Children's Respite Care Center Alternative Health Care Model – Definitions

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SUBPART AC: CATEGORY OF SERVICE REVIEW CRITERIA – COMMUNITY-BASED RESIDENTIAL REHABILITATION CENTER ALTERNATIVE HEALTH CARE MODEL

SUBPART AE: ~~————~~CLINICAL SERVICE AREAS OTHER THAN CATEGORY OF ~~————————~~SERVICE – REVIEW CRITERIA

AUTHORITY: Implementing and authorized by the Illinois Health Facilities Planning Act [20 ILCS 3960].

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SOURCE: Fourth Edition adopted at 3 Ill. Reg. 30, p. 194, effective July 28, 1979; amended at 4 Ill. Reg. 4, p. 129, effective January 11, 1980; amended at 5 Ill. Reg. 4895, effective April 22, 1981; amended at 5 Ill. Reg. 10297, effective September 30, 1981; amended at 6 Ill. Reg. 3079, effective March 8, 1982; emergency amendments at 6 Ill. Reg. 6895, effective May 20, 1982, for a maximum of 150 days; amended at 6 Ill. Reg. 11574, effective September 9, 1982; Fifth Edition adopted at 7 Ill. Reg. 5441, effective April 15, 1983; amended at 8 Ill. Reg. 1633, effective January 31, 1984; codified at 8 Ill. Reg. 18498; amended at 9 Ill. Reg. 3734, effective March 6, 1985; amended at 11 Ill. Reg. 7333, effective April 1, 1987; amended at 12 Ill. Reg. 16099, effective September 21, 1988; amended at 13 Ill. Reg. 16078, effective September 29, 1989; emergency amendments at 16 Ill. Reg. 13159, effective August 4, 1992, for a maximum of 150 days; emergency expired January 1, 1993; amended at 16 Ill. Reg. 16108, effective October 2, 1992; amended at 17 Ill. Reg. 4453, effective March 24, 1993; amended at 18 Ill. Reg. 2993, effective February 10, 1994; amended at 18 Ill. Reg. 8455, effective July 1, 1994; amended at 19 Ill. Reg. 2991, effective March 1, 1995; emergency amendment at 19 Ill. Reg. 7981, effective May 31, 1995, for a maximum of 150 days; emergency expired October 27, 1995; emergency amendment at 19 Ill. Reg. 15273, effective October 20, 1995, for a maximum of 150 days; recodified from the Department of Public Health to the Health Facilities Planning Board at 20 Ill. Reg. 2600; amended at 20 Ill. Reg. 4734, effective March 22, 1996; amended at 20 Ill. Reg. 14785, effective November 15, 1996; amended at 23 Ill. Reg. 2987, effective March 15, 1999; amended at 24 Ill. Reg. 6075, effective April 7, 2000; amended at 25 Ill. Reg. 10806, effective August 24, 2001; amended at 27 Ill. Reg. 2916, effective February 21, 2003; amended at 31 Ill. Reg. ____, effective _____.~~.~~

SUBPART C: GENERAL PURPOSE, MASTER DESIGN, AND FACILITY CONVERSION ~~CHANGES OF OWNERSHIP~~ – INFORMATION REQUIREMENTS AND REVIEW CRITERIA

Section 1110.210 Introduction

a) This Subpart contains all General Purpose and Scope, Master Design, and Facility Conversion Information Requirements and Review Criteria that apply in total or in part to all projects, with the exception of projects solely involving "Discontinuation."~~.~~

b) Each required point of information is intended to provide the Health Facilities Planning Board with an overview of the need for a proposed project. HFPB 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 below, to determine whether sufficient project need has been documented ~~,~~ to issue a Certificate of ~~O~~Need (CON) permit.

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

1) Subpart C, Section 1110.232 contains review criteria concerning "Project Scope and Size,"~~,~~ "Utilization" and "Unfinished Shell Space"; and Section 1110.3030 contains review criteria concerning "Clinical Service Areas Other Than Categories of Service";

2) Subparts F through AE of this Part~~,~~ contain service specific review criteria that shall be addressed, as applicable to the Category~~(ies)~~ of Service included in a proposed project;

3) Subpart AF contains review criteria pertaining to financial and economic feasibility;

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

5) An application for a permit or exemption shall be made to the State Board upon forms provided by the State Board. This application shall contain such information as the State Board deems necessary. Such application shall include affirmative evidence on which the Director may make the findings required under this Section and upon which the State Board may make its decision on the approval or denial of the permit or exemption.~~(~~ [20 ILCS 3960/6]~~)~~

d) Definitions for Subpart C and Subparts F through AE (service specific) are contained in the Act and in 77 Ill. Adm. Code 1100.220.

~~This Subpart C contains all General, Master Design, and Changes of Ownership Review Criteria that apply in total or in part to all projects except discontinuation and certain non-substantive projects.~~

(Source: Amended at 31 Ill. Reg._____, effective_____)

Section 1110.220 Definitions – General Review Criteria (Repealed)

~~a) "Board Certified or Board Eligible Physician" means a physician who has satisfactorily completed an examination (or is "eligible" to take such examination) in a medical specialty and has taken all of the specific training requirements for certification by a specialty board. For purposes of this definition, "medical specialty" shall mean a specific area of medical practice by health care professionals. A listing of specialty boards may be found in Appendix A of this Part.~~

~~b) "Health Services" means diagnostic, treatment or rehabilitative services which are grouped, for purposes of review, into clinically related Categories of Service based upon level or type of support functions, equipment or treatment provided to patients/residents. Categories of Service, when established or discontinued, are subject to review regardless of cost.~~

~~c) "Level of Care" means a specific degree of, type of, or approach to patient/resident care within a defined category of service.~~

~~d) "Surgery" means a category of service pertaining to the performance of any type of surgical operation(s). Surgical areas include but are not limited to:~~

~~1) Operating Rooms;~~

~~2) Nurses Station;~~

3) Nurses' Lockers and Lounge;

4) Doctor's Lockers and Lounge;

5) Scrub Areas;

6) General Storage Space;

7) Linen Storage Area;

8) Circulation Space;

9) Patient Holding Area; and

10) Recovery.

e) "Distinct Unit" means a physically distinct area comprising all beds served by a nursing station in which a particular category of service is provided and which utilizes a nursing staff assigned exclusively to the distinct area.

f) "DRG" means diagnostic related groups utilized in the Medicare program for health care reimbursement.

(Source: RepealedAmended at 31 Ill. Reg. _____, effective _____)

Section 1110.230 Project Purpose, Background and Alternatives – Information Requirements General Review Criteria

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 – Information Requirements

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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 fitness of the applicant, HFPB shall consider whether adverse action has been taken against the applicant, or against any health care facility owned or operated by the applicant, directly or indirectly, within three years preceding the filing of the application. A health care facility is considered "owned or operated" by every person or entity that,

within the three years preceding the filing of the application, 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 such person or entity (refer to 77 Ill. Adm. Code 1100 and 1130 for definitions such as “adverse action,” “ownership interest,” and “principal shareholder”).

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

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

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

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

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

The applicant, Healthfair, Inc., owns and operates XYZ Nursing Home, Inc.

3) The applicant shall submit the following information:

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

B) A certified listing from the applicant~~,~~ ~~listing~~of any adverse action taken against any facility owned and/or operated by the applicant during

the three years prior to the filing of the application;

C) Authorization permitting HFPB and Illinois Department of Public Health (IDPH)~~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 (where 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 HFPB.

4) If, during a given calendar year, an applicant submits more than one application for permit, the documentation provided with the prior application(s) may be utilized to fulfill the information requirements of this criterion. In such 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~~ The applicant is able to submit amendments to previously submitted information, as needed to update and/or clarify data.

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 should include, but is not limited to, existing identification of problems or issues that need to be addressed, including:

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 morality 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 ~~A~~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) 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 that shall be addressed include, but are not limited to:

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. Such a comparison shall address issues of cost, patient access, quality, and financial benefits in both the short term (within one to three 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.

~~a)~~ ~~Location – Review Criterion~~

~~An applicant who proposes to establish a new health care facility or a new category of service or who proposes to acquire major medical equipment that is not located in a health care facility and that is not being acquired by or on behalf of a health care facility must document the following:~~

~~1)~~ ~~that the primary purpose of the proposed project will be to provide care to the residents of the planning area in which the proposed project will be physically located. Documentation for existing facilities shall include patient origin information for all admissions for the last 12 months. Patient origin information must be presented by zip code and be based upon the patient's legal residence other than a health care facility for the last six months immediately prior to admission. For all other projects for which referrals are required to support the project, patient origin information for the referrals is required. Each referral letter must contain a certification by the health care worker physician that the representations contained therein are true and correct. A complete set of the referral letters with original notarized signatures must accompany the application for permit.~~

~~2)~~ ~~that the location selected for a proposed project will not create a maldistribution of beds and services. Maldistribution is typified by such factors as: a ratio of beds to population (population will be based upon the most recent census data by zip code), within 30 minutes travel time under normal driving conditions of the proposed facility, which exceeds one and one half times the State average; an average utilization rate for the last 12 months for the facilities providing the proposed services within 30 minutes travel time under normal driving conditions of the proposed project which is below the Board's target occupancy rate; or the lack of a sufficient population concentration in an area to support the proposed project.~~

~~b)~~ ~~Background of Applicant – Review Criterion~~

~~1)~~ ~~The applicant shall 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 fitness of the applicant, the State Board shall consider whether adverse action has been taken against the applicant, or against any health care facility owned or operated by the applicant, directly or indirectly, within three years preceding the filing of the application.~~

~~2)~~ ~~For purposes of this subsection:~~

~~A)~~ ~~"Adverse action" means conviction of any felony or any misdemeanor involving fraud or dishonesty; any supervision, probation, suspension, revocation, termination, or denial of a license or certificate or registration; imposition of a conditional license; termination or suspension from participation in any program involving payment authorized under Title XVIII (Medicare) or Title XIX (Medicaid) of the Social Security Act, as amended; or denial, suspension, revocation or termination of accreditation by an nationally recognized organization.~~

~~B)~~ ~~A health care facility is considered "owned or operated" by every person or entity which, within the three years preceding the filing of the application, owns, directly or indirectly, an ownership interest as specified in this subsection (b)(2).~~

~~C)~~ ~~"Ownership interest" means any legal or equitable interest, including any interest arising from a lease or management agreement, which gives rise to participation in profits or losses, or which gives rise to the exercise or implementation of any decision-making authority respecting the operations or finances of the health care facility.~~

~~i) In the case of an individual, "ownership interest" includes any interest owned or exercised, directly or indirectly, by or for the individual's spouse or children.~~

~~ii) In the case of a partnership, "ownership interest" includes any interest owned or exercised, directly or indirectly, by or for any general partner, and the partnership is considered to be owned by all of its general partners.~~

~~iii) In the case of a limited liability company, "ownership interest" includes any interest owned, directly or indirectly, by or for any member or partner, and the limited liability company is considered to be owned by all of its members or partners.~~

~~iv) In the case of an estate, "ownership interest" includes any interest owned or exercised, directly or indirectly, by any beneficiary, and the estate is considered to be owned by all of its beneficiaries.~~

~~v) In the case of a trust, "ownership interest" includes any interest owned or exercised, directly or indirectly, by any beneficiary, and the trust is considered to be owned by all of its beneficiaries.~~

~~vi) In the case of a corporation, "ownership interest" includes any interest owned, directly or indirectly, by or for any principal shareholder, member, director or officer, and the corporation is considered to be owned by its principal shareholders, members, directors and officers.~~

~~D) "Principal shareholder" means:~~

~~i) In the case of a corporation having 30 or more shareholders, a person who, directly or indirectly, beneficially owns, holds or has the power to vote 5% or more of any class of securities issued by the corporation.~~

ii) ~~In the case of a corporation having fewer than 30 shareholders, a person who, directly or indirectly, beneficially owns, holds or has the power to vote 50% or more of any class of securities issued by the corporation, or any member of any group of five or fewer shareholders which, directly or indirectly, beneficially own, hold or have the power to vote 80% or more of any class of securities issued by the corporation.~~

~~E) If any person or entity owns any option to acquire stock, the stock shall be considered to be owned by such person or entity.~~

~~3) Examples of facilities owned or operated by the applicant:~~

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

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

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

~~D) Drs. Faith, Hope and Charity own 40%, 35%, and 10%, respectively, of the shares of Healthfair, Inc., a corporation, which 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.~~

~~4) Documentation to be submitted shall include:~~

~~A) A listing of all health care facilities owned or operated by the applicant, including licensing, certification and accreditation identification numbers, if applicable;~~

~~B) proof of current licensure and, if applicable, certification and accreditation of all health care facilities owned or operated by the applicant;~~

~~C) a certification from the applicant listing any adverse action taken against any facility owned or operated by the applicant during the three years prior to the filing of the application;~~

~~D) authorizations permitting the State Board and Agency access to information in order to verify any documentation or information submitted in response to the requirements of this subsection (b)(4) or to obtain any additional documentation or information which the State Board or IDPH finds pertinent to this subsection (b)(4). Failure to provide the authorization shall constitute an abandonment or withdrawal of the application without any further action by the State Board.~~

~~5) If during a given calendar year, an applicant submits more than one application for permit, the documentation provided with the prior application may be utilized to fulfill the data requirements of this Part. In these cases, applicant must state that the information has been previously provided to IDPH, cite the project for the prior application, and certify that no changes have occurred regarding the information which has been previously provided.~~

~~6) In addition to documentation submitted by the applicant, the State Board and IDPH shall review the official records of IDPH, other State agencies, and, where applicable, those of other states, respecting licensure and certification, and shall review the records of nationally recognized~~

~~accreditation organizations to determine compliance with the requirements of this subsection (b).~~

~~c)~~ ~~Alternatives to the Proposed Project – Review Criterion. The applicant must document that the proposed project is the most effective or least costly alternative. Documentation shall consist of a comparison of the proposed project to~~

~~alternative options. Such a comparison must address issues of cost, patient access, quality, and financial benefits in both the short and long term. If the alternative selected is based solely or in part on improved quality of care, the applicant shall provide empirical evidence including quantifiable outcome data that verifies improved quality of care. Alternatives must include, but are not limited to: purchase of equipment, leasing or utilization (by contract or agreement) of other facilities, development of freestanding settings for service and alternate settings within the facility.~~

~~d)~~ ~~Need For the Project – Review Criterion. The project must be needed.~~

~~1)~~ ~~If the State Board has determined need pursuant to Part 1100, the proposed project shall not exceed additional need determined unless the applicant meets the criterion for a variance.~~

~~2)~~ ~~If the State Board has not determined need pursuant to Part 1100, the applicant must document that it will serve a population group in need of the services proposed and that insufficient service exists to meet the need. Documentation shall include but not be limited to:~~

~~A)~~ ~~area studies (which evaluate population trends and service use factors);~~

~~B)~~ ~~calculation of need based upon models of estimating need for the service (all assumptions of the model and mathematical calculations must be included);~~

~~C)~~ ~~historical high utilization of other area providers; and~~

~~D) identification of individuals likely to use the project.~~

~~3) If the project is for the acquisition of major medical equipment that does not result in the establishment of a category of service, the applicant must document that the equipment will achieve or exceed any applicable target utilization levels specified in Appendix B within 12 months after acquisition.~~

~~e) Size of Project – Review Criterion. The applicant must document that the size of a proposed project is appropriate.~~

~~1) The proposed project cannot exceed the norms for project size found in Appendix B of this Part unless the additional square footage beyond the norm can be justified by one of the following:~~

~~A) the proposed project requires additional space due to the scope of services provided;~~

~~B) the proposed project involves an existing facility where the facility design places impediments on the architectural design of the proposed project;~~

~~C) the proposed project involves the conversion of existing bed space and the excess square footage results from that conversion; or~~

~~D) the proposed project includes the addition of beds and the historical demand over the last five year period for private rooms has generated a need for conversion of multiple bed rooms to private usage.~~

~~2) When the State Board has established utilization targets for the beds or services proposed, the applicant must document that in the second year of operation the annual utilization of the beds or service will meet or exceed the target utilization. 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 which would increase utilization.~~

(Source: Amended at 31 Ill. Reg. _____, effective _____)

Section 1110.234 Project Scope and Size, Utilization, and Unfinished/Shell Space - Review Criteria

a) Size of Project – Review Criterion

The applicant shall document that the amount of physical space proposed for the project is necessary and not excessive. The proposed gross square

footage (GSF) cannot exceed the GSF standards of Appendix B, unless the additional GSF can be justified by documenting one of the following:

1) Additional space is needed due to the scope of services provided, justified by clinical or operational needs, as supported by published data or studies;

2) The existing facility's physical configuration has constraints or impediments and requires an architectural design that results in a size exceeding the standards of Appendix B;

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

b) Project Services Utilization - Review Criterion

This criterion is applicable only to projects or portions of projects that involve services, functions, or equipment for which the State Board has not established utilization standards or occupancy targets in 77 Ill. Adm. Code 1100. The applicant shall document that in the second year of operation the annual utilization of the service or equipment shall meet or exceed the utilization standards specified in Appendix B.

c) 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 must document that the

amount of shell space proposed for each department or area is justified, and that such space will not exceed the ~~gross square footage (~~GSF~~)~~ standards of Appendix B unless the amount of space is mandated by a governmental or certification agency. 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 GSF 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 five-~~-~~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.

d) Assurances

The applicant shall submit the following:

1) Verification that the applicant will submit to HFPB~~,~~ 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; ~~and~~

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

3) The anticipated date when the shell space will be completed and placed into operation.

(Source: Added at 31 Ill. Reg. _____, effective _____)

SUBPART D: REVIEW CRITERIA RELATING TO ALL PROJECTS INVOLVING ESTABLISHMENT OF ADDITIONAL BEDS OR SUBSTANTIAL CHANGE IN BED CAPACITY

Section 1110.310 Introduction~~-~~ (Repealed)

~~Subpart D contains all Bed Related Review Criteria. These criteria apply only to projects proposing the addition of inpatient beds to a Category of Service and are utilized in addition to the General Review Criteria outlined in Subpart C.~~

(Source: Repealed ~~Added~~ at 31 Ill. Reg. _____, effective _____)

Section 1110.320 Bed Related Review Criteria (Repealed)

~~a) Establishment of Additional Hospitals – Review Criterion. A proposed general hospital to be located within a Metropolitan Statistical Area (M.S.A.*) must contain a minimum of 100 MS beds.~~

~~AGENCY NOTE: *M.S.A.'s are defined and named in the U.S. Bureau of the Census publication, Metropolitan Statistical Areas: 1984, available from the U.S. Government Printing Office, Washington, D.C. 20402.~~

~~b) Allocation of Additional Beds – Review Criterion. The applicant proposing to establish a category of service must document that access to the service will be improved. Documentation shall consist of at least one of the following:~~

~~1) the proposed service is not available within the planning area;~~

~~2) existing facilities have restricted admission policies resulting in access limitations;~~

~~3) existing service providers are experiencing occupancy levels in excess of the category of service target levels;~~

~~4) the travel time to existing service providers is excessive (exceeds 45 minutes) for area residents to be served by the project.~~

~~c) Addition of Beds to Existing Facilities – Review Criterion~~

~~1) The applicant must document that the addition of beds is necessary. Documentation shall consist of evidence that:~~

~~A) existing inpatient bed services over the latest 12 month period have averaged at or above the target occupancy; or~~

~~B) when occupancy levels over that period fall below the target occupancy the services affected cannot be converted to provide the needed bed space due to architectural or programmatic considerations.~~

~~2) An applicant proposing to add beds while operating an acute care service (for purposes of this subsection, acute care services means: M-S, OB, Pediatrics, ICU, Acute Mental Illness, and Burn services) must document the appropriateness of the length of stay in existing services. Documentation shall consist of a comparison of patient length of stay with other providers within the planning area. An applicant whose existing services have a length of stay longer than that of other area providers must document that the severity or type of illness treated at the applicant facility is greater.~~

(Source: Repealed at 31 Ill. Reg._____, effective_____)

SUBPART E: MODERNIZATION REVIEW CRITERIA

Section 1110.410 Introduction (Repealed)

~~Subpart E contains all Modernization Review Criteria. These criteria apply only to modernization projects and are utilized in addition to the General Review Criteria outlined in Subpart C.~~

(Source: Repealed at 31 Ill. Reg._____, effective _____)

Section 1110.420 Modernization Review Criteria (Repealed)

~~(Source: Added at 31 Ill. Reg. _____, effective _____)~~

~~a) Modernization of Beds – Review Criterion. The applicant must document that the number of beds proposed in each category of service affected does not exceed the number of beds needed to support the facility's utilization in each service proposed at the appropriate modernization target as found in Part 1100. (Utilization shall be based upon the latest 12 month period for which data are available.)~~

~~b) Modern Facilities – Review Criterion. The applicant must document that the proposed project meets one of the following:~~

~~1) The proposed project will result in the replacement of equipment or facilities which 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) The proposed project is necessary to provide expansion for diagnostic treatment, ancillary training, or other support services to meet the requirements of existing services or services previously approved to be added or expanded. 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.~~

~~c) Major Medical Equipment – Review Criterion~~

~~Proposed projects for the acquisition of major medical equipment must document that the equipment will achieve or exceed any applicable target utilization levels specified in Appendix B within 12 months after acquisition.~~

(Source: Repealed at 31 Ill. Reg. ____, effective _____)

SUBPART F: CATEGORY OF SERVICE REVIEW CRITERIA~~-~~ – MEDICAL/SURGICAL, OBSTETRIC, PEDIATRIC AND INTENSIVE CARE

Section 1110.510 Introduction (Repealed)

~~Subpart F contains Review Criteria which pertain to the Medical/Surgical, Obstetric, Pediatric and Intensive Care categories of service. These Review Criteria are utilized in addition to the "General Review Criteria" outlined in Subpart C and any other applicable Review Criteria outlined in Subparts D and E.~~

(Source: Repealed at 31 Ill.Reg. _____, effective _____)

Section 1110.520 Medical/Surgical, Obstetric, Pediatric and Intensive Care – Definitions (Repealed)

~~a) Medical/Surgical~~

~~1) "Medical-Surgical Service" means a category of service pertaining to the medical-surgical care performed at the direction of a physician in behalf of patients by physicians, dentists, nurses and other professional and technical personnel. For purposes of this Subchapter, the medical-surgical category of service includes such subcategories of service as medical, surgical, ophthalmology, intermediate intensive care, tuberculosis, gynecology (outside obstetric (OB) department), research, eyes-ears-nose and throat, orthopedic, neurology, cardio-thoracic-vascular, trauma, inpatient renal dialysis, special care units, substance abuse/addiction treatment, dental and urology. The medical-surgical category of service does not include the following categories of service and their subcategories:~~

~~A) Obstetric Service;~~

~~B) Pediatric Service;~~

~~C)~~ ~~Intensive Care Service;~~

~~D)~~ ~~Rehabilitation Service;~~

~~E)~~ ~~Acute Mental Illness Treatment Service;~~

~~F)~~ ~~Neonatal Intensive Care Service;~~

~~G)~~ ~~Burn Treatment Service;~~

~~H)~~ ~~General Long-Term Care Categories of Service; and~~

~~I)~~ ~~Specialized Long-Term Care Categories of Service.~~

~~2)~~ ~~"Medical-Surgical Unit" means an assemblage of inpatient beds and related facilities in which medical-surgical services are provided to a defined and limited class of patients according to their particular medical care needs.~~

~~b)~~ ~~Obstetrics~~

~~1)~~ ~~"Combined Maternity and Gynecological Unit" means an entire facility or a distinct part of a facility which provides both a program of maternity care (as defined in subsection (b)(3) below) and a program of obstetric gynecological care (as defined in subsection (b)(5) below) and which is designed, equipped, organized and operated in accordance with the requirements of the Hospital Licensing Act [210 ILCS 85].~~

~~2)~~ ~~"Fertility Rate" means projections of population fertility based upon resident birth occurrence as provided by IDPH.~~

~~3)~~ ~~"Maternity Care" means a subcategory of obstetric service related to the medical care of the patient prior to and during the act of giving birth either to a living child or to a dead fetus and to the continuing medical care of~~

~~both patient and newborn infant under the direction of a physician in behalf of the patient by physicians, nurses, and other professional and technical personnel.~~

~~4) "Maternity Facility or Unit" means an entire facility or a distinct part of a facility which provides a program of maternity and newborn care and which is designed, equipped, organized, and operated in accordance with the requirements of the Hospital Licensing Act.~~

~~5) "Obstetric Gynecological Care" means a subcategory of obstetric service where medical care is provided to clean gynecological, surgical, or medical cases which are admitted to a postpartum section of an obstetric unit in accordance with the requirements of the Hospital Licensing Act.~~

~~6) "Obstetric Service" means a category of service pertaining to the medical or surgical care of maternity and newborn patients or medical or surgical cases which may be admitted to a postpartum unit.~~

~~c) Pediatrics~~

~~1) "Designated Pediatric Beds" means beds within the facility which are primarily used for pediatric patients and are not a component part of a distinct pediatric unit as defined in subsection (c)(2) below.~~

~~2) "Pediatric Facility or Distinct Pediatric Unit" means an entire facility or a distinct unit of a facility, where the nurses' station services only that unit, which provides a program of pediatric service and is designed, equipped, organized and operated to render medical-surgical care to the 0-14 age population.~~

~~3) "Pediatric Service" means a category of service for the delivery of treatment pertaining to the non-intensive medical-surgical care of a pediatric patient (0-14 years in age) performed at the direction of a physician in behalf of the patient by physicians, dentists, nurses, and other professional and technical personnel.~~

~~d) Intensive Care~~

~~1) "Intensive Care Service" means a category of service providing the coordinated delivery of treatment to the critically ill patient or to patients requiring continuous care due to special diagnostic considerations requiring extensive monitoring of vital signs through mechanical means and through direct nursing supervision. This service is given at the direction of a physician in behalf of patients by physicians, dentists, nurses, and other professional and technical personnel. The intensive care category of service includes the following subcategories; medical Intensive Care Unit (ICU), surgical ICU, coronary care, pediatric ICU, and combinations of such ICU. This category of service does not include intermediate intensive or coronary care and special care units which are included in the medical-surgical category of service.~~

~~2) "Intensive Care Unit" means a distinct part of a facility which provides a program of intensive care service and which is designed, equipped, organized and operated to deliver optimal medical care for the critically ill or for patients with special diagnostic conditions requiring specialized equipment, procedures and staff, and which is under the direct visual supervision of a qualified professional nurses' staff. Effective February 15, 2003, the repeal of 77 Ill. Adm. Code 1110.1010, 1110.1020 and 1110.1030, the beds and corresponding utilization for the Burn Treatment category of service will be included in the Intensive Care category of service.~~

(Source: Repealed at 31 Ill. Reg. ____, effective _____)

Section 1110.530 Medical/Surgical, Obstetric, Pediatric and Intensive Care –

Review Criteria

Applicants proposing to establish, expand or modernize Medical/Surgical, Obstetric, Pediatric or Intensive Care beds shall describe how the proposed project will address all of the following indicators of need:

a) Planning Area Need - Review Criterion

The applicant shall document that the number of beds to be established, added or modernized is necessary to serve the planning area's population, based on the following:

1) ~~Part~~77 Ill. Adm. Code 1100 Formula Calculation

A) The number of beds to be established or added 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 bed 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) Patient origin information shall be presented by zip code and be based upon the patient's legal residence (other than a health care facility) for the last six months immediately prior to admission.

3) Service Demand – Establishment of Beds

The number of beds proposed to establish a new category of service, or to expand an existing category of service, is necessary to accommodate the service demand experienced by the applicant facility over the latest two-year period. The applicant shall document:

A) Historical Referrals

~~t~~The number of referrals to other facilities, for each proposed category of service, for each of the latest two years. Documentation of the referrals shall include: patient origin by zip code; name and specialty of referring physician; ~~the~~ name and location of the recipient hospital.

B) Projected Service Demand

The applicant shall provide 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, and an estimate as to the number of patients the physician will refer to the applicant's facility. 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. The anticipated number of referrals cannot exceed the physician's experienced caseload.

4) Service Demand – Expansion of Bed Capacity

The number of beds to be added (at an existing facility) 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 the following:

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 two years.

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

B) Projected Service Demand – Based on Rapid Population Growth:

A projected demand for service, based upon rapid population growth in the applicant facility's existing market area (as experienced within the latest 12-month period), 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 five years from the date the application is submitted; ~~and~~

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~~(s)~~, 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.

C) Projected Referrals:

The applicant shall provide physician referral letters that attest to the physician's total number of patients (by zip code of residence) who~~that~~ have received care at existing facilities located in the area during the 12-month period prior to submission of the application, and an estimate as to the number of patients whom the physician will refer to the applicant's facility. 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. The anticipated number of referrals cannot exceed the physician's experienced caseload.

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) The project will provide service for at least 50% of the population who must currently travel over 30 minutes to receive service;~~.~~

vi) For purposes of this Section only, all services within the 30-minute 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;

viii) –Complete 12-month utilization record for which IDPH ~~—~~ -annual facility data are available.

6) Category of Service Modernization

A) If the project involves modernization of beds, 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:

i) High cost of maintenance;

ii)~~)~~ Non-compliance with licensing or life safety codes;

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

iv) Additional space for diagnostic or therapeutic purposes.

B) Documentation shall include the following, as applicable to the factors cited in the application:

i) Copies of maintenance reports;

ii) Copies of citations for l~~L~~ife s~~S~~afety code violations;

iii) -IDPH licensing reports; -and~~? or?;~~

iv) -Joint Commission on Accreditation of Healthcare - Organizations (JCAHO) reports.

b) 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 30 minutes travel time (under normal driving conditions) of the project's site;

B) The total population of the identified zip code areas (based upon the most recent census data available); and

C) The names and locations of all existing or approved health care facilities located within 30 minutes travel time from the project site~~,~~ that provide the categories of 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 minimum 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 minimum utilization standards.

3) The applicant shall document that the proposed project will not lower the utilization of other area providers below the minimum occupancy standard specified in 77 Ill. Adm. Code 1100.

c) Staffing - Review Criterion

1) An applicant proposing to establish a new hospital or to add beds to an existing hospital shall document that a sufficient supply of personnel will be available to staff the total number of beds proposed. Sufficient staff availability shall be based upon evidence that for the latest 12-month period prior to submission of the application, those hospitals located in zip code areas that are (in total or in part) within one hour travel time (under normal driving conditions) 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 from 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 non-rebuttable assumption that

the existing facility has not experienced staffing vacancy rates in excess of 10%. Copies of any correspondence received from the facilities must 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.

d) Assurances

The applicant shall document that in the second year of operation after the project completion date, the annual utilization of the beds for each category of service will meet or exceed the minimum 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.

~~a) Unit Size - Review Criterion~~

~~1) Obstetrics~~

~~A) The minimum unit size for a new obstetric unit within a Metropolitan Statistical Area is 20 beds.~~

~~B) The minimum unit size for a new obstetric unit outside a Metropolitan Statistical Area is 7 beds.~~

~~2) Intensive Care. The minimum unit size for an intensive care unit is 4 beds.~~

~~3) Pediatrics. The minimum size for a pediatric unit within a Metropolitan Statistical Area is 16 beds.~~

~~b) Variances to Bed Need -- Review Criterion. The applicant must document one or more of the following.~~

~~1) High Occupancy Variance~~

~~A) The applicant must document that the applicant facility has experienced high occupancy. Documentation shall consist of evidence that the historical average annual occupancy rate has equaled or exceeded the target occupancy for the prior 24-month period.~~

~~B) The applicant must also document that the number of beds proposed will not exceed the number needed to reduce the facility's high occupancy to the target occupancy, or if the number of beds proposed exceeds the number of beds justified by the applicant's historical workload, then projections may be used. Utilization projections must be based upon the following:~~

~~i) projections shall be based upon population projections from the U.S. Bureau of the Census;~~

~~ii) projections shall be for a maximum period of 5 years from the date the application is submitted;~~

~~iii) projections shall be zip code and age-specific; and~~

~~iv) projections shall be based upon the applicant's service area as defined by historical patient origin, and shall not include projected changes in market share.~~

~~The projections provided must also demonstrate that the proposed number of beds will not exceed the number of beds needed to meet the target occupancy rate over the next 5 years.~~

~~2) Medically Underserved Variance~~

~~A) The applicant must document that access to the proposed service is restricted in the planning area as documented by:~~

~~i) the absence of the service within the planning area;~~

~~ii) limitations on governmentally funded or charity patients;~~

~~iii) restrictive admission policies of existing providers;~~

~~iv) the area population and existing care system exhibit indicators of median care problems such as an average family income level below the State average poverty level, high infant mortality or designation as a Health Manpower Shortage Area; or~~

~~v) the project will provide service for a portion of the population who must currently travel over 45 minutes to receive service.~~

~~B) Documentation shall consist of location and utilization of other planning area service providers; patient location information and all applicable time-travel studies; a certification of waiting times and scheduling or admission restrictions that exist in area providers; and an assessment of area population characteristics which would indicate an access problem.~~

C) The applicant must also document that the number of beds proposed will not exceed the number needed at the target

occupancy rate to meet the health care needs of the population identified as having restricted access.

(Source: Amended at 31 Ill. Reg , effective)

SUBPART G: CATEGORY OF SERVICE REVIEW CRITERIA - COMPREHENSIVE PHYSICAL REHABILITATION

Section 1110.610 Introduction (Repealed)

Subpart G contains Review Criteria which pertain to the Comprehensive Physical Rehabilitation category of service. These Review Criteria are utilized in addition to the "General Review Criteria" outlined in Subpart C and any other applicable Review Criteria outlined in Subparts D and E.

(Source: RepealedAmended at 931 Ill. Reg. , 3734, effective March 6, 1985)

Section 1110.620 Comprehensive Physical Rehabilitation—Definitions (Repealed)

a) "Comprehensive Physical Rehabilitation" means a category of service provided in a comprehensive physical rehabilitation facility providing the coordinated interdisciplinary team approach to physical disability under a physician licensed to practice medicine in all its branches, who directs a plan of management of one or more of the classes of chronic disabling disease or injury. Comprehensive physical rehabilitation must include but is not limited to the services of: elements as specified in the federal regulations defining "a rehabilitation unit - distinct part" (42 CFR 405.471(i) (1986)). Comprehensive physical rehabilitation services can only be provided by a comprehensive physical rehabilitation facility.

~~b)~~ ~~"Comprehensive Physical Rehabilitation Facility" means a distinct bed unit of a hospital or a special referral hospital which provides a program of comprehensive physical rehabilitation and which is designed, equipped, organized and operated to deliver inpatient rehabilitation services; and which is licensed by the Department of Public Health under the "Hospital Licensing Act" or is a facility operated or maintained by the State or a state agency.~~

~~c)~~ ~~There are two types of comprehensive physical rehabilitation facilities:~~

~~1)~~ ~~Freestanding comprehensive physical rehabilitation facility means a specialty hospital dedicated to the provision of comprehensive rehabilitation; and~~

~~2)~~ ~~Hospital/based comprehensive physical rehabilitation facility means a distinct unit, located in a hospital, dedicated to the provision of comprehensive physical rehabilitation.~~

(Source: Repealed at 31 Ill. Reg. _____, effective _____)

Section 1110.630 Comprehensive Physical Rehabilitation --Review Criteria

Applicants proposing to establish, expand or modernize Comprehensive Physical Rehabilitation beds shall describe how the proposed project will address all of the following indicators of need:

a) Planning Area Need - Review Criterion~~n~~

The applicant shall document that the number of beds to be established, added or modernized is necessary to serve the planning area's population, based on the following:

1) ~~Part~~77 Ill. Adm. Code 1100 Formula Calculation

A) The number of beds to be established or added 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 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 bed 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) Patient origin information must be presented by zip code and be based upon the patient's legal residence (other than a health care facility) for the last six months immediately prior to admission.

3) Service Demand – Establishment of Beds

The number of beds proposed to establish a new category of service, or to expand an existing category of service, is necessary to accommodate the service demand experienced by the applicant facility over the latest two-

year period. The applicant shall document:

A) Historical Referrals

~~t~~The number of referrals to other facilities, for each proposed category of service, for each of the latest two years. Documentation of the referrals shall include: patient origin by zip code; name and specialty of referring physician; and the name and location of the recipient hospital.

B) Projected Service Demand

The applicant shall provide physician referral letters that attest to the physician's total number of patients (by zip code of residence) ~~that~~ who have received care at existing facilities located in the area during the 12-month period prior to submission of the application, and an estimate as to the number of patients whom the physician will refer to the applicant's facility. 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. The anticipated number of referrals cannot exceed the physician's experienced caseload.

4) Service Demand – Expansion of Bed Capacity

The number of beds to be added (at an existing facility) 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 the following:

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 two years.

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

B) Projected Service Demand – Based on Rapid Population Growth:

A projected demand for service, based upon rapid population growth in the applicant facility's existing market area (as experienced within the latest 12-month period), 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 five years from the date the application is submitted; ~~and~~

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~~(s)~~, 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.

C) Projected Referrals:

The applicant shall provide physician referral letters that attest to the physician's total number of patients (by zip code of residence) ~~that~~ who have received care at existing facilities located in the area during the 12-month period prior to submission of the application, and an estimate as to the number of patients ~~that~~who will be referred by the physician to the applicant's facility. 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. The anticipated number of referrals cannot exceed the physician's experienced caseload.

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~~must~~ 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) The project will provide service for at least 50% of the population who must currently travel over 45 minutes to receive service;~~.~~

vi) For purposes of this ~~s~~Section only~~.~~, ~~A~~all services within 45-minutes 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 Questonnaire;

viii) Complete 12-month utilization record for which IDPH annual facility data are available.

6) Category of Service Modernization

A) If the project involves modernization of beds, 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:

i) High cost of maintenance;

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

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

iv) – Additional space for diagnostic or therapeutic purposes.

B) Documentation shall include the following, as applicable to the factors cited in the application:

i) Copies of maintenance reports;

ii) Copies of citations for life safety code violations;

iii) IDPH licensing reports; and

~~-~~iv) ~~Joint Commission on Accreditation of Healthcare Organizations (~~JCAHO~~)~~ reports.~~;~~

b) Unnecessary Duplication/Maldistribution - Review Criterion

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

A) A list of all zip code areas (in total or in part) that are located within 45 minutes travel time (under normal driving conditions) of the project's site;

B) The total population of the identified zip code areas (based upon the most recent census data available); and

C) The names and locations of all existing or approved health care facilities located within 45 minutes travel time from the project site, that provide the categories of service that are proposed by the project.

2) The applicant shall document that the project will not result in ~~an~~ a maldistribution of services. Maldistribution exists when the identified 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 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 established pursuant to 77 Ill. Adm. Code 1100.

3) The applicant shall document that the proposed project will not lower the utilization of other area providers below the occupancy standard specified in 77 Ill. Adm. Code 1100.

c) Staffing - Review Criterion

1) Availability

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

B) 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 ~~that~~who are subject to licensing by the Department of Financial and Professional Regulation.

C) 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 from 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 non-rebuttable assumption that the existing facility has not experienced staffing vacancy rates in

excess of 10%. Copies of any correspondence received from the facilities must be included in the application.

D) 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.

2) Personnel Qualifications

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

A) Medical Director – Medical direction of the facility shall be vested in a physician who is a doctor of medicine licensed to practice in all of its branches and who has had three years of post-graduate specialty training in the medical management of inpatients requiring rehabilitation services.

B) Rehabilitation Nursing – Supervisors, for all nurses participating as part of the rehabilitation team, must be available on staff and shall

have documented education in rehabilitation nursing and at least one year of rehabilitation nursing experience.

C) Allied Health – The following allied health specialists shall be available on staff:

i) Physical Therapist – Graduate of a program in physical therapy approved by the American Physical Therapy Association; is licensed to practice in the State of Illinois.

ii) Occupational Therapist – Registered by the American

Occupational Therapy Association or graduate of an approved educational program, with the experience needed for registration. Educational programs are approved by the American Medical Association's council on Medical Education in collaboration with the American Occupational Therapy Association; is licensed to practice in the State of Illinois.

iii) Social Worker

D) Other Specialties – The following personnel shall be available on staff or on a consulting basis:

i) Speech Pathologist;

ii) Psychologist;

iii) Vocational Counselor or Specialist;

iv) Dietietian;

v) Pharmacist;

vi) Audiologist; and

vii) Prosthetist and Orthotist;

3) Documentation shall consist of:

A) Medical Director

Curriculum Vitae of Medical Director

B) Other Personnel

i) ~~I~~Letters of interest from potential employees;

ii) ~~a~~Applications filed with the applicant for a position;

iii) ~~s~~Signed contracts with required staff; or

iv) ~~n~~Narrative explanation of how other positions will be filled.

d) Facility Size – Review Criterion

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.

e) Assurances

The applicant shall document that in the second year of operation, the annual utilization of the beds for each category of service 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.

~~a) Facility Size – Review Criterion~~

~~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 15 beds.~~

~~b) Access Variance to Bed Need – Review Criterion~~

~~1) The applicant must document that access to the proposed service is restricted in the planning area as documented by:~~

~~A) the absence of the service within the planning area;~~

~~B) limitations on governmentally funded or charity patients;~~

~~C) restrictive admission policies of existing providers; or~~

~~D) the project will provide service for a portion of the population who must currently travel over 45 minutes to receive service.~~

~~2) The applicant must also document that the number of beds proposed will not exceed the number needed to meet the health care needs of the~~

~~population identified as having restricted access at the target occupancy rate.~~

~~c) Staffing Requirements – Review Criterion~~

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

~~A) Medical Director – Medical direction of the facility shall be vested in a physician who is a doctor of medicine licensed to practice in all of its branches and who has had three year of post-graduate specialty training in the medical management of inpatients requiring rehabilitation services.~~

~~B) Rehabilitation Nursing – Supervisors, for all nurses participating as part of the rehabilitation team, must be available on staff and shall have documented education in rehabilitation nursing and at least one year of rehabilitation nursing experience.~~

~~C)~~ ~~Allied Health – The following allied health specialists must be available on staff:~~

~~i)~~ ~~Physical Therapist – Graduate of a program in physical therapy approved by the American Physical Therapy Association.~~

~~ii)~~ ~~Occupational Therapist – Registered by the American Occupational Therapy Association or graduate of an approved educational program, with the experience needed for registration. Educational programs are approved by the American Medical Association's council on Medical Education in collaboration with the American Occupational Therapy Association.~~

~~iii)~~ ~~Social Worker~~

~~D)~~ ~~Other Specialties – The following personnel must be available on staff or on a consulting basis:~~

~~i)~~ ~~Speech Pathologist;~~

~~ii)~~ ~~Psychologist;~~

~~iii)~~ ~~Vocational Counselor or Specialist;~~

~~iv)~~ ~~Dietician;~~

~~v)~~ ~~Pharmacist;~~

~~vi)~~ ~~Audiologist;~~

~~vii)~~ ~~Prosthetist and Orthotist; and~~

~~viii)~~ ~~Dentist.~~

~~2) Documentation shall consist of:~~

~~A) letters of interest from potential employees;~~

~~B) applications filed with the applicant for a position;~~

~~C) signed contracts with required staff; or~~

~~D) a narrative explanation of how other positions will be filled.~~

(Source: Amended at 31 Ill. Reg. ____, effective _____)

SUBPART O: CATEGORY OF SERVICE REVIEW CRITERIA– IN-CENTER HEMODIALYSIS ~~CHRONIC RENAL DIALYSIS~~

Section 1110.1410 Introduction (Repealed)

~~Subpart O contains Review Criteria which pertain to the Chronic Renal Dialysis category of service. These Review Criteria are utilized in addition to the "General Review Criteria" outlined in Subpart C and any other applicable Review Criteria outlined in Subparts D and E.~~

(Source: Repealed at 31 Ill. Reg. _____, effective _____)

Section 1110.1420 Chronic Renal Dialysis Service – Definitions (Repealed)

~~"Acute Dialysis" is dialysis given on an intensive care, inpatient basis to patients suffering from (presumably reversible) acute renal failure, or to patients with chronic renal failure with serious complications.~~

~~"Chronic Renal Dialysis" is a category of service in which dialysis is performed on a regular long-term basis in patients with chronic irreversible renal failure. The maintenance and preparation of patients for kidney transplantation (including the immediate post-operative period and in case of organ rejection) or other acute~~

~~conditions within a hospital does not constitute a chronic renal dialysis category of service.~~

~~"Dialysis" is a process by which dissolved substances are removed from a patient's body by diffusion from one fluid compartment to another across a semipermeable membrane. The two types of dialysis which are recognized in classical practice are hemodialysis and peritoneal dialysis.~~

~~"Hematocrit" means a measure of the packed cell volume of red blood cells expressed as a percentage of total blood volume.~~

~~"Hemodialysis" is a type of dialysis that involves the use of artificial kidney through which blood is circulated on one side of a semipermeable membrane while the other side is bathed by a salt dialysis solution. The accumulated toxic products diffuse out of the blood into the dialysate bath solution. The concentration and total amount of water and salt in the body fluid is adjusted by appropriate alternations in composition of the dialysate fluid.~~

~~"Peritoneal Dialysis" is a type of dialysis in which the dialysate fluid is injected slowly into the peritoneum, causing dialysis of water and waste products to occur through the peritoneal sac which acts as a semipermeable membrane. The fluid and waste, after accumulating for a period of time (1 hour), is drained from the abdomen and the process is repeated. This procedure is much slower than hemodialysis, requiring the patient to be immobilized for a long period of time.~~

~~"Renal Dialysis Facility" means a freestanding facility or a unit within an existing health care facility that furnishes routine chronic dialysis service(s) to chronic renal disease patients. Such types of services are: self-dialysis, training in self-dialysis, dialysis performed by trained professional staff and chronic maintenance dialysis including peritoneal dialysis.~~

~~"Self-Care Dialysis Training" is a program which trains Chronic Renal Disease patients or their helpers, or both, to perform self-care dialysis.~~

~~"Self-Dialysis" or "Self-Care Dialysis" is maintenance dialysis performed by a trained patient at home or in a special facility with or without the assistance of a family member or other helper.~~

~~"Urea" means the chief product of urine and the final product of protein metabolism in the body.~~

~~"Urea Reduction Ratio (URR)" means the amount of blood cleared of urea during dialysis. It is reflected by the ratio of the measured level of urea before dialysis and urea remaining after dialysis. The larger the URR, the greater the amount of urea removed during the dialysis treatment.~~

(Source: Repealed at 31 Ill. Reg. _____, effective _____)

Section 1110.1430 Review Criteria for In-Center Hemodialysis Projects ~~Chronic Renal Dialysis – Review Criteria~~

Applicants proposing to establish, expand or modernize ~~i~~I~~n-c~~C~~enter ~~h~~H~~emodialysis stations shall describe how the proposed project will address all of the following indicators of need:

a) Planning Area Need - Review Criterion

The applicant shall document that the number of stations to be established, added or modernized is necessary to serve the planning area's population, based on the following:

1) ~~Part~~77 Ill. Adm. Code 1100 Formula Calculation

A) The number of stations to be established or added 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 target 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).

B) Applicants proposing to add stations to an existing 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) Patient origin information shall~~must~~ be presented by zip code and be based upon the patient's legal residence as reported in the patient's records immediately prior to admission.

3) Service Demand – Establishment of Beds

The number of stations proposed to establish a new category of service, or to expand an existing category of service, is necessary to accommodate the service demand experienced by the applicant facility over the latest 12-month period prior to submission of the application. The applicant shall document:

A) Historical Referrals

The applicant shall provide physician referral letters that attest to the physician's total number of patients ~~that~~who have received i~~I~~in-~~c~~c~~C~~enter ~~h~~h~~H~~emodialysis at existing facilities during the 12-month period prior to submission of the application.

B) Projected Service Demand

The physician referral letters shall provide an estimate as to the number of patients who ~~that~~ will be referred by the physician to the applicant's facility. Documentation of patients shall include: patient origin by zip code; type of patient (current in-center hemodialysis or pre-dialysis), patient initials and current treatment facility for existing dialysis patients. Each referral letter must contain the physician's notarized signature, the typed or printed name of the physician, the physician's office address, the physician's specialty, and verification by the physician that the patient referrals have not been used to support another CON application for in-center hemodialysis services. The anticipated number of referrals cannot exceed the physician's experienced caseload.

4) Service Demand – Expansion of Bed Capacity

The number of stations to be added (at an existing facility) is necessary to reduce the facility's experienced high occupancy, and to meet a projected demand for service. The applicant shall document the following:

A) Historical Service Demand

i) An average annual utilization rate that meets the utilization target for the category of service, as specified in 77 Ill. Adm. Code 1100, for each of the latest two years.

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

B) Projected Service Demand – Based on Rapid Population Growth:

A projected demand for service, based upon rapid population growth in the applicant facility's existing market area (as experienced within the latest 12-month period), determined as follows:

i) The applicant shall define the facility's market area based upon historical patient origin data by 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 five years from the date the application is submitted; ~~and~~

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's horizon;

v) Projections shall be for total population and specified age groups for the applicant's market area~~(s)~~, 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.

C) Projected Referrals:

The applicant shall provide physician referral letters that attest to the physician's total number of patients (by zip code of residence) ~~that~~who have received care at existing facilities located in the area during the 12-month period prior to submission of the application, and an estimate as to the number of patients ~~that~~who will be referred by the physician to the applicant's facility. Documentation of patients shall include: patient origin by zip code, type of patient

(current in-center hemodialysis or pre-dialysis), patient initials and current treatment facility for existing dialysis patients. Each referral letter shall contain the physician's notarized signature, the typed or printed name of the physician, the physician's office address, the physician's specialty~~,~~ and verification by the physician that the patient referrals have not been used to support another pending or approved CON application for in-center hemodialysis services. The anticipated number of referrals cannot exceed the physician's experienced caseload.

5) Service Accessibility

The number of stations being established or added 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) ~~t~~The absence of the proposed service within the planning area;

ii) A~~a~~ccess 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) ~~r~~Restrictive admission policies of existing providers;

iv) ~~t~~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) ~~t~~The project will provide service for at least 50% of the population who must currently travel over 30 minutes to receive service;~~.~~

vi) For purposes of this ~~s~~Section only. All services within 30-minutes 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) ~~t~~The location and utilization of other planning area service providers;

ii) ~~p~~Patient location information by zip code;

iii) ~~i~~Independent time-travel studies;

iv) ~~a~~A certification of waiting times;

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

v) ~~a~~An assessment of area population characteristics that document that access problems exist;

vi) ~~m~~Most recently published IDPH Hospital Questonnaire;

vii) ~~c~~Complete 12-month utilization record for which IDPH annual facility data is~~are~~ available.

6) Category of Service Modernization

A) If the project involves modernization of stations, the applicant shall document that station 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:

i) ~~h~~High cost of maintenance;

ii) ~~n~~Non-compliance with licensing or life safety codes;

iii) ~~c~~Changes in standards of care; or

iv) A~~a~~dditional space for diagnostic or therapeutic purposes.

B) Documentation shall include the following, as applicable to the factors cited in the application:

i) Copies of maintenance reports;

ii) Copies of citations for l~~L~~ife s~~S~~afety code violations;

iii) IDPH Licensing reports; and

iv) ~~Joint Commission on Accreditation of Healthcare Organizations (~~JCAHO ~~)~~ reports.

b) Unnecessary Duplication/Maldistribution - Review Criterion

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

A) ~~a~~A list of all zip code areas (in total or in part) that are located within 30 minutes travel time (under normal driving conditions) of the project's site;

B) ~~t~~The total population of the identified zip code areas (based upon the most recent census data available); and

C) ~~t~~The names and locations of all existing or approved health care facilities located within 30 minutes travel time from the project site~~,~~ that provide the categories of service that are proposed by the project.

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

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

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

C) ~~i~~Insufficient population to provide the volume or caseload necessary to utilize the services proposed by the project at the utilization target established pursuant to 77 Ill. Adm. Code 1100.

3) The applicant shall document that the proposed project will not lower the utilization of other area providers below the utilization target specified in 77 Ill. Adm. Code 1100.

c) Staffing - Review Criterion

1) Availability

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

B) 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 ~~that~~who are subject to licensing by the Department of Financial and Professional Regulation.

C) 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 from 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 non-rebuttable assumption that the existing facility has not experienced staffing vacancy rates in excess of 10%. Copies of any correspondence received from the facilities must be included in the application.

D) 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.

2) Qualifications

The applicant shall document the availability of qualified staff and other health manpower and management for the provision of quality ESRD services.

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)~~registered nurse~~ 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.

D) Dietitian – This individual shall be a registered dietitian with the Commission on Dietetic Registration, meet the practice requirements of the State of Illinois and haves ~~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 Masters of Social Work.

3) Documentation shall consist of:

A) Medical Director

Curriculum Vitae of Medical Director

B) All Other Personnel

i~~.~~) ~~l~~Letters of interest from potential employees;

ii~~.~~) ~~a~~Applications filed with the applicant for a position;

iii~~).~~ ~~s~~Signed contracts with required staff; or

iv~~).~~ ~~a~~A narrative explanation of how other positions will be filled.

~~4~~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~~5) Staffing Plan

The applicant proposing to establish an ~~I~~in-~~C~~center ~~H~~hemodialysis category of service shall document that at least one RN will be on duty when unit is in

operation and will maintain a ratio of at least one direct patient care provider to every four patients.

~~5~~6) Medical Staff

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

d) Minimum Size - Review Criterion

The minimum number of in-center hemodialysis stations for an ESRD facility is:

1) ~~f~~Four dialysis stations for facilities outside a Metropolitan Statistical Area ;

2) E~~e~~ight dialysis stations for a facility within a Metropolitan Statistical Area.

e) Support Services – Review Criterion

An applicant proposing to establish an i~~I~~n-c~~C~~enter h~~H~~emodialysis category of service must submit a certification from an authorized representative that attests to each of the following:

1) ~~p~~Participation in a dialysis data system;

2) A~~a~~vailability of support services consisting of clinical laboratory service, blood bank, nutrition, rehabilitation, psychiatric, and social services; and

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

f) Continuity of Care – Review Criterion

An applicant proposing to establish an i~~I~~n-c~~C~~enter h~~H~~emodialysis 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.

g) 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) ~~t~~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) ~~T~~that the proposed facility will improve access for care to the existing patient population.

h) Assurances

1) The applicant shall document that in the second year of operation after the project completion date, the annual utilization of the stations will meet the utilization target 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.

2) An applicant proposing to expand or relocate in-incenter hemodialysis stations shall demonstrate compliance with the following outcome measures for the latest recent 12-month period for which data is available:

A) Adequacy of Hemodialysis

>85% of hemodialysis patient population achieve urea reduction ratio (URR) > 65% and/or >85% of hemodialysis patient population achieve Kt/V Daugirdas II > 1.2

B) Anemia Management

> 85% of the hemodialysis patient population achieve hemoglobin > 11 gm/dL

~~a) Data System – Review Criterion. An applicant proposing to establish a renal dialysis facility must document that a chronic renal dialysis data system exists or will be established. This criterion shall not be applicable to existing renal dialysis facilities that are relocating or adding stations.~~

~~b) Minimum Size of Renal Dialysis Center or Renal Dialysis Facilities – Review Criterion. The minimum facility size for establishment of a renal dialysis facility is:~~

~~1) three dialysis stations within the facility in areas not included in an MSA or in an MSA of less than 500,000 people;~~

~~2) six dialysis stations in MSA's of over 500,000 population.~~

~~c) Variance to Station Need – Review Criterion~~
~~An applicant proposing to establish a renal dialysis facility or to add stations when no need for additional stations exists in the planning area must document one of the following:~~

~~1) a new facility will improve access in a geographic area that is within 30 minutes travel time of the proposed facility site as evidenced by documentation that verifies:~~

~~A) all existing renal dialysis facilities in the area are operating at or in excess of the target utilization level for the latest 12 month period for which data is available; and~~

~~B)~~ ~~a sufficient number of patients is experiencing an access problem to justify the proposed number of stations at the minimum utilization level detailed in 77 Ill. Adm. Code 1100; and~~

~~C)~~ ~~the caseload at all existing renal dialysis facilities in the area will not be adversely affected; or~~

~~2)~~ ~~additional stations are needed to reduce high utilization of an existing facility as evidenced by documentation that verifies that the number of proposed stations will reduce the facility's experienced utilization level for the latest 12 month period for which data is available to the minimum utilization level detailed in 77 Ill. Adm. Code 1100.~~

~~d) Support Services – Review Criterion. The applicant proposing to establish a renal dialysis facility must document that clinical and pathological laboratory services, blood bank, nutrition, rehabilitation, psychiatric and social services, and self-care dialysis support services, will be available. Documentation shall consist of a narrative as to how such services will be provided. This criterion shall not be applicable to existing renal dialysis facilities that are relocating or adding stations.~~

~~e) Affiliation Agreements – Review Criterion. The applicant proposing to establish a renal dialysis facility must document that a 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. This criterion shall not be applicable to existing renal dialysis facilities that are relocating or adding stations.~~

~~f) Self-Care and Home Dialysis Training – Review Criterion. The applicant proposing to establish a renal dialysis facility must document that self-care dialysis, self-care instruction, home dialysis and home training will be provided at the applicant facility or that a written agreement with another facility for the provision of these services exists. Documentation shall consist of a certification that services are provided by the applicant or copies of all agreements for provision of such services. This criterion shall not be applicable to existing renal dialysis facilities that are relocating or adding stations.~~

~~g) 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. The applicant must document the following:~~

~~1) that the existing facility has met the occupancy targets detailed in 77 Ill. Adm. Code 1100.630 for the latest 12 month period for which data is available;~~

~~2) that the proposed facility will improve access for care to the existing patient population; and~~

~~3) that the existing facility needs to be replaced in order to comply with Section 1110.420(b).~~

~~h) Addition of Stations – Review Criterion. This criterion applies to an existing facility which proposes the addition of stations at the existing site. The applicant must document the following:~~

~~1) that the existing facility has met the occupancy targets set forth in 77 Ill. Adm. Code 1100.630 for the latest 12 month period for which data is available;~~

~~2) that the proposed project will not adversely impact the workload at any other existing facility within 30 minutes travel time of the applicant facility; and~~

~~3) that a need for additional stations exists in the planning area based upon the update to the Inventory of Health Care Facilities in effect at the time of State Board consideration; or that the proposed project is in conformance with the variance set forth in subsection (c) of this Section.~~

~~i) Quality of Care – Review Criterion. The applicant must demonstrate the following:~~

~~1) that greater than 65% of its patients achieve a urea reduction ratio (URR) of 0.65 or better; and~~

~~2) that greater than 65% of its patients achieve a hematocrit level of 31% or better.~~

(Source: Amended at 31 Ill. Reg. _____, effective _____)

SUBPART X: CATEGORY OF SERVICE REVIEW CRITERIA – SELECTED ORGAN TRANSPLANTATION

Section 1110.2310 Introduction (Repealed)

~~Subpart X contains review criteria which pertain to the selected organ transplantation category of service. These review criteria are utilized in addition to the "General Review Criteria" outlined in Subpart C and any other applicable Review Criteria outlined in Subparts D and E.~~

(Source: Repealed at 31 Ill. Reg. _____, effective _____)

Section 1110.2320 Selected Organ Transplantation – Definitions (Repealed)

~~a) The selected organ transplantation service means a category of service relating to the surgical transplantation of any of the following human organs: heart, lung, heart-lung, liver, pancreas, or intestine and small bowel. It does not include bone marrow or cornea transplants.~~

~~b) A selected organ transplantation center means a hospital which provides staffing and other adult or pediatric medical and surgical specialty services required for the care of a transplant patient.~~

~~c) "Teaching Institution" for the purpose of this Subpart means a hospital having a major relationship with a medical school as defined and listed in the current~~

~~"Directory of Residency Training Programs" developed by the American Medical Association, 535 Dearborn, Chicago, Illinois 60610 and the National Organ Procurement and Transplantation Network.~~

(Source: Repealed at 31 Ill. Reg. _____, effective _____)

Section 1110.2330 Selected Organ Transplantation – Review Criteria

Applicants proposing to establish, expand or modernize a Selected Organ Transplantation category of service shall describe how the proposed project will address all of the following indicators of need:

a) Planning Area Need - Review Criterion

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

1) ~~Part~~77 Ill.Adm.Code 1100 Formula Calculation

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

2) Service to Planning Area Residents

A) 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).

B) Applicants shall document that at least 50% of the projected patient volume will be from residents of the area. Patient origin information must be presented by zip code and be based upon the patient's legal residence (other than a health care facility) for the last six months immediately prior to admission.

3) Service Demand

The project to establish a new category of service, or to expand an existing category of service, is necessary to accommodate the service demand experienced by the applicant facility over the latest two-year period. The applicant shall document:

A) Historical Referrals

The number of referrals to other facilities, for the proposed category of service, for each of the latest two years. Documentation of the referrals shall include: patient origin by zip code; name and specialty of referring physician; type of transplant; ~~the~~ name and location of the recipient hospital.

B) Projected Service Demand

The applicant shall provide physician referral letters that attest to the physician's total number of patients (by zip code of residence) ~~that~~who have received care at existing facilities located in the area during the 12-month period prior to submission of the application, and an estimate as to the number of patients who~~that~~ will be referred by the physician to the applicant's facility. Each referral letter

must contain the physician's notarized signature, the typed or printed name of the physician, the physician's office address, and the physician's specialty. The anticipated number of referrals cannot exceed the physician's experienced caseload.

4) Service Accessibility

The category of service is necessary to improve access for planning area residents. The applicant shall~~must~~ document the following:

A) Service Restrictions

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

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

ii) A~~a~~ccess 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) ~~r~~Restrictive admission policies of existing providers;

~~t~~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;

iv)

v) The project will provide service for at least 50% of the population who must travel over 30 minutes to receive service; or

~~Tthree;~~

vi) For purposes of this ~~s~~Section only, all services within the one~~-~~-hour 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) T~~t~~he location and utilization of other planning area service providers;

ii) P~~p~~atient location information by zip code;

iii) ~~i~~Independent time-travel studies;

iv) A ~~a~~ certification of waiting times;

v) S~~s~~cheduling or admission restrictions that exist in area providers;

vi) A~~a~~n assessment of area population characteristics that document that access problems exist;

vii) ~~m~~Most recently published IDPH Hospital Questonnaire;

viii) ~~c~~Complete 12-month utilization record for which IDPH annual facility data is~~are~~ available.

5) Category of Service Modernization

A) If the project involves modernization of a 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:

i) ~~h~~High cost of maintenance;

ii) ~~n~~Non-compliance with licensing or life safety codes;

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

iv) ~~a~~Additional space for diagnostic or therapeutic purposes.

B) Documentation shall include the following, as applicable to the factors cited in the application:

i) Copies of maintenance reports;

ii) Copies of citations for l~~L~~ife s~~S~~afety code violations;

iii) IDPH Licensing reports; and

iv) ~~Joint Committee on Accreditation of Healthcare Organizations (~~JCAHO~~)~~ reports.

b) Unnecessary Duplication/Maldistribution - Review Criterion

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

A) ~~a~~A list of all zip code areas (in total or in part) that are located within three~~3~~ hours travel time (under normal driving conditions) of the project's site;

B) ~~t~~The total population of the identified zip code areas (based upon the most recent census data available); and

C) ~~t~~The names and locations of all existing or approved health care facilities located within three~~3~~ hours~~,~~ travel time that provide the category of service that is 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 has an excess supply of facilities, beds, and services characterized by such factors as, but not limited to:

A) ~~h~~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

B) ~~i~~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 the proposed project will not lower the utilization of other area providers below the occupancy standard specified in 77 Ill. Adm. Code 1100.

c) Staffing - Review Criterion

1) An applicant proposing to establish a new category of service shall document that a sufficient supply of personnel will be available to staff the proposed project. Sufficient staff availability shall be based upon evidence that for the latest 12-month period prior to submission of the application, those hospitals located in zip code areas that are (in total or in part) within one hour travel time (under normal driving conditions) 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~~that~~ are subject to licensing by the Department of Financial and Professional Regulation.

3) An applicant shall~~must~~ 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 from 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 non-rebuttable assumption that the existing facility has not experienced staffing vacancy rates in excess of 10%. Copies of any correspondence received from the facilities shall~~must~~ 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 must provide documentation as to how sufficient staff shall be obtained to operate the proposed project, in accordance with licensing requirements.

d) Surgical Staff – Review Criterion~~.~~

The applicant shall document that the facility has on staff transplant surgeon~~(~~s~~)~~ certified in the applicable specialty 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.

e) 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.

f) Support – Review Criterion~~.~~

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

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

immunosuppressive drugs;

2) ~~a~~Access to tissue typing services; and

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

g) Assurances – Review Criterion

1) The applicant shall document that in the second year of operation after the project completion date, the annual utilization for the category of service 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.

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

3) The applicant shall document that the transplant program will be performed in conjunction with graduate medical education.

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

5) The applicant shall document that information on finances (cost and charges) and patient outcomes will be provided to the Department of Public Health.

~~a) Establishment of a Program – Review Criterion~~

~~1) The applicant must document the following:~~

~~A) the applicant is a teaching institution; and~~

~~B) the transplantation program will be performed in conjunction with graduate medical education.~~

~~2) Documentation shall consist of a written agreement between the applicant and the medical school detailing the relationship of the transplantation program to graduate medical education.~~

~~b) Physical Facilities – Review Criterion. The applicant must document sufficient operating and recovery room resources, intensive care resources and personnel to operate the transplant program as reflected in the norms found in Appendix B of this Part.~~

~~c) Access to Donor Organs – Review Criterion. The applicant must document access to donor organs. This must be accomplished by membership in the National Organ Procurement and Transplantation Network and in a Regional Organ Procurement Agency.~~

~~d) Recipient Selection – Review Criterion. The applicant must provide a copy of its procedures for selecting transplant candidates and distribution of organs.~~

~~e) Surgical Staff – Review Criterion. The applicant must document that the facility has on staff transplant surgeon(s) certified in the applicable specialty 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 certification by the hospital administrator that the personnel with the appropriate certification and experience are on the hospital staff.~~

~~f) Collaborative Support – Review Criterion. The applicant must 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.~~

~~g) Ancillary Services – Review Criterion. The applicant must document on site access to microbiology, clinical chemistry, radiology, blood bank and resources required to monitor use of immunosuppressive drugs. The applicant must also have access to tissue typing services and be able to provide psychiatric and social counseling for the transplant recipient and for their families.~~

~~h) Data – Review Criterion. The applicant must document that information on finances (cost and charges) and patient outcomes will be provided to the Department of Public Health.~~

(Source: Amended at 31 Ill. Reg._____, effective _____)

SUBPART Y: CATEGORY OF SERVICE REVIEW CRITERIA – KIDNEY TRANSPLANTATION

Section 1110.2410 Introduction (Repealed)

~~Subpart Y contains Review Criteria which pertain to the Kidney Transplantation category of service. These review criteria are utilized in addition to the "General Review Criteria" outlined in Subpart C and any other applicable Review Criteria outlined in Subparts D and E.~~

(Source: Repealed at 31 Ill. Reg._____, effective_____)

Section 1110.2420 Kidney Transplantation – Definitions (Repealed)

~~a) Kidney Transplantation is a category of service which involves the surgical replacement of a nonfunctioning human kidney with a donor kidney in order to restore renal function to the patient.~~

~~b) Kidney Transplantation Center means a hospital which directly furnishes transplantation and other medical and surgical specialty services required for the care of the kidney transplant patient, including inpatient dialysis furnished directly or under arrangement.~~

(Source: Repealed at 31 Ill. Reg. _____, effective _____)

Section 1110.2430 Kidney Transplantation – Review Criteria

Applicants proposing to establish, expand or modernize a Kidney Transplantation category of service shall describe how the proposed project will address all of the following indicators of need:

a) Planning Area Need - Review Criterion

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

1) ~~Part~~77 Ill.Adm.Code 1100 Formula Calculation

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

2) Service to Planning Area Residents

A) 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).

B) Applicants shall document that at least 50% of the projected patient volume will be from residents of the area. Patient origin information must be presented by zip code and be based upon the patient's legal residence (other than a health care facility) for the last six months immediately prior to admission

3) Service Demand

The project to establish a new category of service is necessary to accommodate the service demand experienced by the applicant facility over the latest two-year period. The applicant shall document:

A~~).~~ Historical Referrals

The number of referrals to other facilities, for the proposed category of service, for each of the latest two years. Documentation of the referrals shall include: patient origin by zip code; name and specialty of referring physician; ~~the~~ name and location of the recipient hospital.

B~~).~~ Projected Service Demand

The applicant shall provide physician referral letters that attest to the physician's total number of patients (by zip code of residence)

~~that~~who have received care at existing facilities located in the area during the 12-month period prior to submission of the application, and an estimate as to the number of patients ~~that~~who will be referred by the physician to the applicant's facility. 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. The anticipated number of referrals cannot exceed the physician's experienced caseload.

4) Service Accessibility

The 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) ~~t~~The absence of the proposed service within the planning area;

ii) ~~a~~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) ~~r~~Restrictive admission policies of existing providers;

iv) ~~t~~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) T~~t~~he project will provide service for at least 50%of the population who must currently travel over three~~3~~ hours to receive service.

vi) For purposes of this Section only, all services within the 30-minute 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) ~~t~~The location and utilization of other planning area service providers;

ii) P~~p~~atient location information by zip code;

iii) I~~in~~ndependent time-travel studies;

iv) ~~a~~A certification of waiting times;

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

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

vii) ~~m~~Most recently published IDPH Hospital Questonnaire;

viii) ~~c~~Complete 12-month utilization record for which IDPH annual facility data are available.

5) Category of Service Modernization

A) If the project involves modernization of a 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:

i) ~~h~~High cost of maintenance;

ii) ~~n~~Non-compliance with licensing or life safety codes;

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

iv) ~~a~~Additional space for diagnostic or therapeutic purposes.

B) Documentation shall include the following, as applicable to the factors cited in the application:

i) Copies of maintenance reports;

ii) Copies of citations for l~~L~~ife s~~S~~afety code violations;

iii) IDPH Licensing reports;

iv) ~~Joint Commission on Accreditation of Healthcare Organizations~~ JCAHO reports.

b) Unnecessary Duplication/Maldistribution - Review Criterion

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

A) ~~a~~A list of all zip code areas (in total or in part) that are located within ~~3~~three hours travel time (under normal driving conditions) of the project's site;

B) ~~t~~The total population of the identified zip code areas (based upon the most recent census data available); and

C) ~~t~~The names and locations of all existing or approved health care facilities located within ~~3~~three hours travel time~~,~~ that provide the category of service that is proposed by the project.

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

A) ~~h~~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

B) ~~i~~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 the proposed project will not lower the utilization of other area providers below the occupancy standard specified in 77 Ill. Adm. Code 1100.

c) Staffing - Review Criterion

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

B) 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~~that~~ are subject to licensing by the Department of Financial and Professional Regulation.

C) 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 from 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 non-rebuttable assumption that the existing facility has not experienced staffing vacancy rates in excess of 10%. Copies of any correspondence received from the facilities ~~must~~shall be included in the application.

D) 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.

c) Surgical Staff – Review Criterion~~.~~

The applicant shall document that the facility has on staff transplant surgeon~~(s)~~ certified in the applicable specialty 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.

d) Support Services – Review Criterion

The applicant shall document that the following are available on premises: laboratory services, social services, dietetic services and self-care dialysis support services, inpatient dialysis services, pharmacy, specialized blood facilities (including tissue typing). The applicant shall 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.

e) Assurances – Review Criterion~~.~~

1) The applicant shall document that in the second year of operation after the project completion date, the annual utilization for the category of service 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.

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

3) The applicant shall provide proof of membership in the Organ

Procurement and Transplantation Network (OPTN) and a federally designated organ procurement organization (OPO).

~~a) Establishment of Facilities – Review Criterion. The applicant must document that each existing renal transplantation center is serving a population base of more than two million people with the performance of 25 or more transplants per year and that an unserved population of at least two million people exists within three hours travel time. Documentation shall consist of travel time studies involving all existing service providers.~~

~~b) Kidney Transplantation Center – Review Criterion. The applicant must document that the following are available on premises: laboratory services, social services, dietetic services and self-care dialysis support services, inpatient dialysis services, pharmacy, 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.~~

~~c) Affiliation Agreements – Review Criterion. The applicant must document that the transplantation center is a teaching institution (see Section 1110.2320(c)).~~

(Source: Amended at 31 Ill. Reg. _____, effective _____)

SUBPART AE: ~~–~~CLINICAL SERVICE AREAS OTHER THAN CATEGORY OF SERVICE – REVIEW CRITERIA

Section 1110.3030 Review Criteria for Clinical Service Areas Other Than Categories of Service

These criteria are applicable only to those projects or components of projects concerning Clinical Service Areas that are not "Categories of Service,"~~,~~ but for which utilization standards are listed in Attachment B. In addition, all Clinical Service Areas shall address other applicable

requirements in this P~~p~~art~~Part 1110,~~ as well as those in 77 ~~.~~Ill. Adm. Code~~Parts~~ 1100 and 77 Ill. Adm. Code 1130. For those services which~~that~~ are not addressed in Attachment B or defined as a "Category of Service,"~~,~~ the applicant shall

comply
with requirements of the review criterion in S~~s~~ection 1110.232(a) ("Size of Project"), as well as all other
applicable requirements in this Part~~s~~ 1100 and 77 Ill. Adm. Code ~~,~~ 1110~~,~~ and 77 Ill. Adm. Code ~~and~~ 1130. ~~-~~Applicants proposing to establish,
expand

or modernize Clinical Service Areas, as defined above, shall describe how the proposed project will address all of the following indicators of need:

a) Planning Area Need - Review Criterion

The applicant shall document that the clinical service area~~(s)~~ to be established, expanded or modernized are necessary to serve the planning area's population, based on the following:

1) Service to Planning Area Residents

A) Applicants proposing to establish clinical service areas as a component of a proposed new facility 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).

B) Applicants proposing to add a new clinical service area or to expand an existing clinical service area at an existing facility shall provide patient origin information~~,~~ for the last 12-month period, verifying that at least 50% of the facility's inpatient admissions were residents of the area.

C) Patient origin information ~~must~~shall be presented by zip code and be based upon the patient's legal residence (other than a health care facility) for the last six months immediately prior to receipt of the application.

2) Service Demand - Establishment of Clinical Service Areas for a New Facility

The applicant shall document that each clinical service area (e.g., -emergency, surgery, imaging, laboratory, etc.) to be established at ~~a~~a proposed new facility is necessary to support the patient care functions of the facility and that the proposed GSF and anticipated utilization is consistent with the standards established in Appendix B.

3) Service Demand - Establishment of a New Clinical Service Area at -Existing Facility

The clinical service area to be established at an existing facility is -necessary to accommodate the demand experienced over the latest two-year period. The applicant shall document:

A) Historical Referrals

The number of referrals to other facilities, for each proposed new clinical service area, for each of the latest two years. Documentation of the referrals shall include: patient origin by zip code; name and specialty of referring physician; ~~the~~ name and location of the recipient hospital.

B) Projected Service Demand

The applicant shall provide physician referral letters that attest to the physician's total number of patients (by zip code of residence) ~~that~~who have received care at existing facilities located in the area during the 12-month period prior to submission of the application, and an estimate as to the number of patients who~~that~~ will be referred by the physician to the applicant's facility. 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. The anticipated number of referrals cannot exceed the physician's experienced caseload.

4) Expansion of Existing Clinical Service Area

The clinical service area expansion is necessary to accommodate an existing facility's experienced high utilization, and to meet a projected demand for service. The applicant shall document the following:

A) Historical Service Demand

i) An average annual utilization rate for the clinical service area~~(s)~~, for each of the latest three years that exceeds the utilization target specified in Appendix B; or

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

B) Projected Service Demand - Rapid Population Growth:

A projected demand for service, based upon rapid population growth in the applicant facility's existing market area (as experienced within the latest 12-month period), shall be determined as follows:

i) ~~t~~The applicant shall define the facility's market area based upon historical patient origin data by 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 five years from the date the application is submitted; ~~and~~

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~~(s)~~, 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.

5) Service Accessibility

The clinical service area to be established or expanded 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) ~~t~~The absence of the proposed clinical service area within the planning area;

ii) A~~a~~ccess 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) ~~r~~Restrictive admission policies of existing providers;

iv) ~~t~~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) ~~t~~The project will provide service for at least 50% of the population who must currently travel over 30 minutes to receive service;~~.~~

vi) ~~f~~For purposes of this ~~s~~Section only, all existing services within the 30-minute travel time~~,~~ meet or exceed the utilization standard~~,~~ specified in Appendix B.

B) Supporting Documentation

The applicant shall provide the following documentation, as applicable to the existing restrictions cited in the application:

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

ii) P~~p~~atient location information by zip code;

iii) ~~a~~All independent time-travel studies;

iv) ~~a~~A certification of waiting times;

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

vi) A~~a~~n assessment of area population characteristics that document that access problems exist;

vii) M~~m~~ost recently published IDPH Hospital Questionnaire;

viii) ~~c~~Complete 12-month utilization record for which IDPH annual facility data are available.

6) Category of Service Modernization

A) If the project involves modernization of clinical service areas other than categories of service, the applicant shall document that each clinical service area to be modernized is deteriorated or functionally obsolete~~,~~ and needs to be replaced or modernized, due to factors including, but not limited to:

i) ~~h~~High cost of maintenance;

ii) N~~n~~on-compliance with licensing or life safety codes;

iii) ~~c~~Changes in standards of care; or

iv) ~~a~~Additional space for diagnostic or therapeutic purposes.

B) Documentation shall include the following, as applicable to the factors cited in the application:

i) Copies of maintenance reports;

ii) Copies of citations for l~~L~~ife s~~S~~afety code violations;

iii) IDPH Licensing reports; and

iv~~ii~~) ~~Joint Commission on Accreditation of Healthcare Organizations (~~JCAHO~~)~~ reports.

b) 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~~A list of all zip code areas (in total or in part) that are located within 30 minutes travel time (under normal driving conditions) of the project's site;

B) ~~t~~The total population of the identified zip code areas (based upon the most recent census data available); and

C) ~~t~~The names and locations of all existing or approved health care facilities located within 30 minutes travel time from the project site ~~,~~that provide the clinical services that are proposed by the project.

2) The applicant shall document that the project will not result in maldistribution. Maldistribution is indicated by such factors as, but not limited to:

A) ~~h~~Historical utilization (for the latest 12-month period prior to submission of the application) at facilities located within 30 minutes travel time of the applicant's site below the minimum utilization standard specified in Appendix B; or

B) ~~i~~Insufficient population to provide the volume or caseload necessary to utilize the above clinical service areas proposed by the project at or above minimum utilization standards.

3) The applicant shall provide the following information:

A) ~~a~~A list of all zip code areas (in total or in part) that are located within 30 minutes travel time (under normal driving conditions) of the project's site;

B) ~~t~~The total population of the identified zip code areas (based upon the most recent census data available); and

C) ~~t~~The names and locations of all existing or approved health care facilities located within 30 minutes travel time from the project site~~,~~ that provide the clinical services that are proposed by the project.

3) The applicant shall document that the proposed project will not lower the utilization of other area providers below the minimum utilization standard specified in Appendix B.

c) Staffing - Review Criterion

1) An applicant proposing to establish or expand a clinical service area shall document that a sufficient supply of personnel will be available to staff the clinical service. Sufficient staff availability shall be based upon evidence that, for the latest 12-month period prior to submission of the application, those facilities located in zip code areas that are (in total or in part) within one hour travel time (under normal driving conditions) of the applicant facility's site have not experienced a staffing shortage with respect to the clinical service area 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 ~~that~~who are subject to licensing by the Department of 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 from 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 non-rebuttable assumption that the existing facility has not experienced staffing vacancy rates in excess of 10%. Copies of any correspondence received from the facilities must 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.

d) Assurances

The applicant shall document that in the second year of operation after the project completion date, the annual utilization of each clinical service area will meet or exceed the minimum utilization standard specified in Appendix B. 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.

(Source: Added at 31 Ill. Reg. _____, effective _____)

~~Section 1110.231 Introduction~~

~~This Subpart contains all General Purpose and Scope, Master Design, and Facility Conversion Information Requirements that apply in total or in part to all projects, with the exception of projects solely involving "Discontinuation".~~

~~Each required point of information is intended to provide HFPB with an overview of the need for a proposed project. HFPB 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 below, to determine whether sufficient project need has been documented, to issue a CON permit.~~

~~The review criteria to be addressed, (as required) are contained in the following Parts and~~

HEALTH FACILITIES PLANNING BOARD

NOTICE OF PROPOSED ~~RULES~~AMENDMENTS

~~Subparts:~~

~~a) Subpart C, Section 1110.232 contains review criteria concerning "Project Scope and Size", "Utilization" and "Unfinished Shell Space"; and Section 1110.2910 contains review criteria concerning "Clinical Service Areas Other Than Categories of Service";~~

~~b) Subparts F through AC of this Part, contain service specific review criteria that shall be addressed, as applicable to the Category(ies) of Service included in a proposed project;~~

~~c) Part 1120 contains review criteria pertaining to financial and economic feasibility;~~

~~d) Part 1130 contains the CON procedural requirements that may be applicable to a proposed project; and~~

~~e) *An application for a permit or exemption shall be made to the State Board upon forms provided by the State Board. This application shall contain such information as the State Board deems necessary. Such application shall include affirmative evidence on which the Director may make the findings required under this Section and upon which the State Board may make its decision on the approval or denial of the permit or exemption.* (20 ILCS 3960/6)~~

~~Definitions for Subpart C and Subparts F through AC (service specific) are contained in the Act and in 77 Ill. Adm. Code 1100.220~~

~~.~~

~~Section 1110.232 Project Purpose, Background 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 – Information Requirements~~

~~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 fitness of the applicant, HFPB shall consider whether adverse action has been taken against the applicant, or against any health care facility owned or operated by the applicant, directly or indirectly, within three years preceding the filing of the application. A health care facility is considered "owned or operated" by every person or entity that, within the three years preceding the filing of the application, 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 such person or entity (refer to 77 Ill. Adm. Code 1100 and 1130 for definitions such as "adverse action," "ownership interest," and "principal shareholder").~~

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

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

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

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

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

~~3) The applicant shall submit the following information:~~

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

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

~~C) authorization permitting HFPB 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 (where 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 HFPB.~~

~~4) If during a given calendar year, an applicant submits more than one application for permit, the documentation provided with the prior application(s) may be utilized to fulfill the information requirements of this criterion. In such 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.~~

~~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 should include, but is not limited to existing identification of problems or issues that need to be addressed, including~~

~~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 morality 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).~~

~~The applicant shall cite the source of the information (e.g., local health department *IPLAN* documents, *Public Health Futures*, local mental health plans, or other health assessment studies from governmental or academic and/or other independent sources).~~

~~2) 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.~~

~~3) 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) 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 that shall be addressed include, but are not limited to:~~

~~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. Such a comparison shall address issues of cost, patient access, quality, and financial benefits in both the short term (within one to three 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.~~

~~(Source: Added at _____, effective _____)~~