

ILLINOIS REGISTER

HEALTH FACILITIES AND SERVICES REVIEW BOARD

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TITLE 77: PUBLIC HEALTH
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SUBCHAPTER a: ILLINOIS HEALTH CARE FACILITIES PLAN

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

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

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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 32 Ill. Reg. 12332, effective July 18, 2008; amended at 33 Ill. Reg. 3312, effective February 6, 2009; amended at 34 Ill. Reg. 6121, effective April 13, 2010; amended at 35 Ill. Reg. 16989, effective October 7, 2011; amended at 36 Ill. Reg. 2569, effective January 31, 2012; amended at 38 Ill. Reg. 8861, effective April 15, 2014; amended at 39 Ill. Reg. _____, effective _____.

SUBPART P: CATEGORY OF SERVICE REVIEW CRITERIA –
NON-HOSPITAL BASED AMBULATORY SURGICAL TREATMENT CENTER SERVICES

**Section 1110.1540 Non-Hospital Based Ambulatory Surgical Treatment Center Services –
Review Criteria**

- a) Introduction
 - 1) *Ambulatory Surgical Treatment Centers required to be licensed pursuant to the Ambulatory Surgical Treatment Center Act [210 ILCS 5] are defined as healthcare facilities subject to the requirements of the Health Facilities Planning Act [20 ILCS 3960/3] and HFSRB rules (77 Ill. Adm. Code 1100, 1110, 1120 and 1130). Facilities devoted to abortion and related care, including those licensed as PSTCs under the ASTC Act are not subject to HFSRB rules related to Non-Hospital Based ASTCs. The addition of any other ASTC services (other than abortion-related services) will require a CON permit.*
 - 2) A permit is required for:
 - A) the establishment of a new non-hospital based ambulatory surgical treatment center (ASTC); or
 - B) the addition or establishment of a new ASTC service to an existing non-hospital based ASTC; or
 - C) the increase or expansion of the number of surgical/treatment rooms for an existing ASTC service in a non-hospital based ASTC, if the total estimated project cost exceeds the capital expenditures

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minimum. The current threshold is posted on HFSRB's website (www.hfsrb.illinois.gov); or

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

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

PROJECT TYPE	REQUIRED REVIEW CRITERIA		
Establishment of ASTC Facility or Additional ASTC Service	(a)(5)(A) & (B)	–	Introduction – Identification of ASTC Service and # of Surgical/Treatment Rooms
	(b)(1) through (4)	–	Background of the Applicant
	(c)(2)(A) & (B)	–	Service to GSA Residents
	(d)(1) & (2) or (3)	–	Service Demand – Establishment
	(f) (1) & (2)	–	Treatment Room Need Assessment
	(g)	–	Service Accessibility
	(h)(1) through (3)	–	Unnecessary Duplication/Maldistribution
	(i)(1) & (2)	–	Staffing
	(j)	–	Charge Commitment
	(k)(1) & (2)	–	Assurances
Expansion of Existing ASTC Service	(a)(5)(A) & (B)	–	Introduction – Identification of ASTC Service and # of Surgical/Treatment Rooms
	(b)(1) through (4)	–	Background of the Applicant

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(c)(2)(A) & (B)	–	Service to GSA Residents
(e)(1) through (3)	–	Service Demand – Expansion
(f) (1) & (2)	–	Treatment Room Need Assessment
(i)(1) & (2)	–	Staffing
(j)	–	Charge Commitment
(k)(1) & (2)	–	Assurances

- 4) In addition to addressing the applicable criteria listed in the chart in subsection (a)(4), the applicant shall indicate:
- A) The existing and the proposed ASTC services as specified in Appendix A;
 - B) The existing and the proposed number of surgical/treatment rooms for each ASTC service as specified in Appendix A;
 - C) If an ASTC service is not specified in Appendix A, the applicant shall indicate the existing and proposed ASTC services, the existing and proposed number of surgical/treatment rooms, and the professional standards applicable to the proposed ASTC services.
- 5) Transition Period for Meeting Section 1110.1540 Requirements
- A) Multi-specialty ASTCs that provided at least three of the ASTC services listed in Appendix A prior to April 15, 2014, except those ASTCs described in subsection (a)(5)(C), shall be exempt from this Section's CON application requirements for adding additional ASTC services until January 1, 2018.
 - B) Effective April 15, 2014, multi-specialty ASTCs adding new services shall notify HFSRB of what services are being added and the effective date of those services. The notification of each new service added shall be submitted to HFSRB within 30 days after the service addition. Beginning January 1, 2018, multi-specialty ASTCs seeking to add additional ASTC services shall apply for a CON permit pursuant to the provisions of this Section.

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- C) Multi-specialty ASTCs that, as a condition of CON permit issuance, agreed to apply for CON permits when adding services shall continue to apply for CON permits when adding new services.
- 6) **Sanctions and Penalties**
Noncompliance with the requirements of Sections 1110.1535 through 1110.1540 shall be considered a violation and shall be subject to the sanctions and penalties in the Act (see 20 ILCS 3960/14.1) and in 77 Ill. Adm. Code 1130.790.
- b) **Background of the Applicant – Review Criterion**
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]
- 1) An 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 with particular regard to the qualification, background and character of the applicant* [20 ILCS 3960/6(d)]. In evaluating the qualifications, background and character of the applicant, HFSRB shall consider whether adverse action has been taken against the applicant, including corporate officers or directors, LLC members, partners, and owners of at least 5% of the proposed healthcare facility, or against any health care facility owned or operated by the applicant, directly or indirectly, within three years preceding the filing of the application. A health care facility is considered "owned or operated" by every person or entity that owns, directly or indirectly, an ownership interest. If any person or entity owns any option to acquire stock, the stock shall be considered to be owned by that person or entity (see 77 Ill. Adm. Code 1100 and 1130 for definitions of terms such as "adverse action", "ownership interest" and "principal shareholder").
- 2) Examples of facilities owned or operated by an applicant include:

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- A) The applicant, Partnership ABC, owns 60% of the shares of Corporation XYZ, which manages the Good Care Nursing Home under a management agreement. The applicant, Partnership ABC, owns or operates Good Care Nursing Home.
 - B) The applicant, Healthy Hospital, a corporation, is a subsidiary of Universal Health, the parent corporation of Healthcenter Ambulatory Surgical Treatment Center (ASTC), its wholly-owned subsidiary. The applicant, Healthy Hospital, owns and operates Healthcenter ASTC.
 - C) Dr. Wellcare is the applicant. His wife is the director of a corporation that owns a hospital. The applicant, Dr. Wellcare, owns or operates the hospital.
 - D) Drs. Faith, Hope and Charity own 40%, 35% and 10%, respectively, of the shares of Healthfair, Inc., a corporation, that is the applicant. Dr. Charity owns 45% and Drs. Well and Care each own 25% of the shares of XYZ Nursing Home, Inc. The applicant, Healthfair, Inc., owns and operates XYZ Nursing Home, Inc.
- 3) The applicant shall submit the following information:
- A) A listing of all health care facilities currently owned and/or operated by the applicant in Illinois or elsewhere, including licensing, certification and accreditation identification numbers, as applicable;
 - B) A listing of all health care facilities currently owned and/or operated in Illinois, by any corporate officers or directors, LLC members, partners, or owners of at least 5% of the proposed health care facility;
 - C) A certified listing from the applicant of any adverse action taken against any facility owned and/or operated by the applicant during the three years prior to the filing of the application;
 - D) A certified listing of each applicant, corporate officer or director, LLC member, partner and owner of at least 5% of the proposed facility, identifying those individuals that have been cited, arrested,

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taken into custody, charged with, indicted, convicted or tried for, or pled guilty to:

- i) the commission of any felony or misdemeanor or violation of the law, except for minor parking violations; or
 - ii) has been the subject of any juvenile delinquency or youthful offender proceeding;
- E) Unless convictions have been expunged, all convictions shall be detailed in writing and any police or court records regarding any matters disclosed shall be submitted for HFSRB's consideration;
- F) A certified listing of each applicant, corporate officer or director, LLC member, partner and owner of at least 5% of the proposed facility who has been charged with fraudulent conduct or any act involving moral turpitude. Any such matter shall be disclosed in detail;
- G) A certified listing of each applicant, corporate officer or director, LLC member, partner and owner of at least 5% of the proposed facility who has any unsatisfied judgments against him or her;
- H) A certified listing of each applicant, corporate officer or director, LLC member, partner and owner of at least 5% of the proposed facility. Any matter shall be discussed in detail;
- I) A certified listing of each applicant, corporate officer or director, LLC member, partner and owner of at least 5% of the proposed facility who is in default in the performance or discharge of any duty or obligation imposed by a judgment, decree, order, or directive of any court or governmental agency. Any matter shall be discussed in detail;
- J) Authorization permitting HFSRB and IDPH-access to any documents necessary to verify the information submitted, including, but not limited to: official records of IDPH or other State agencies; the licensing or certification records of other states, when applicable; and the records of nationally recognized accreditation organizations. Failure to provide the authorization

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shall constitute an abandonment or withdrawal of the application without any further action by HFSRB.

- 4) If, during a given calendar year, an applicant submits more than one application for permit, the documentation provided with the prior applications may be utilized to fulfill the information requirements of this subsection (b). In these instances, the applicant shall attest that the information has been previously provided, cite the project number of the prior application, and certify that no changes have occurred regarding the information that has been previously provided. The applicant is able to submit amendments to previously submitted information, as needed to update and/or clarify data.
 - 5) The documentation for the "Background of the Applicant" is required one time per application, regardless of the number of categories of service involved in a proposed project.
- c) Geographic Service Area Need – Review Criterion
The applicant shall document that the ASTC services and the number of surgical/treatment rooms to be established, added or expanded are necessary to serve the planning area's population, based on the following:
- 1) 77 Ill. Adm. Code 1100 (Formula Calculation)

As stated in 77 Ill. Adm. Code 1100, "No formula need determination for the number of ASTCs and the number of surgical/treatment rooms in a geographic service area has been established. Need shall be established pursuant to the applicable review criteria of 77 Ill. Adm. Code 1110."
 - 2) Service to Geographic Service Area Residents
The applicant shall document that the primary purpose of the project will be to provide necessary health care to the residents of the geographic service area (GSA) in which the proposed project will be physically located.
 - A) The applicant shall provide a list of zip code areas (in total or in part) that comprise the GSA. The GSA is the area consisting of all zip code areas that are located within 45 minutes multi-directional travel time (under normal driving conditions) of the project's site.

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- B) The applicant shall provide patient origin information by zip code for all admissions for the last 12-month period, verifying that at least 50% of admissions were residents of the GSA. Patient origin information shall be based upon the patient's legal residence (other than a health care facility) for the last six months immediately prior to admission.

d) Service Demand – Establishment of an ASTC Facility or Additional ASTC Service

The applicant shall document that the proposed project is necessary to accommodate the service demand experienced annually by the applicant, over the latest two-year period, as evidenced by historical and projected referrals. The applicant shall document the information required by subsection (d)(1) and either subsection (d)(2) or (3):

1) Historical Referrals

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

- A) patient origin by zip code of residence;
- B) name and specialty of referring physician;
- C) name and location of the recipient hospital or ASTC; and
- D) number of referrals to other facilities for each proposed ASTC service for each of the latest two years.

2) Projected Service Demand

The applicant shall provide the following documentation:

- A) Physician referral letters that attest to the physician's total number of patients (by zip code of residence) who have received care at existing IDPH-licensed ASTCs or hospitals located in the GSA during the 12-month period prior to submission of the application;

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- B) Documentation demonstrating that the projected patient volume, as evidenced by the physician referral letters, is from within the GSA defined under subsection (c)(2);
 - C) An estimated number of treatments the physician will refer annually to the applicant facility within a 24-month period after project completion. The anticipated number of referrals cannot exceed the physician's experienced caseload. The percentage of projected referrals used to justify the proposed establishment cannot exceed the historical percentage of applicant market share within a 24-month period after project completion;
 - D) Referrals to health care providers other than IDPH-licensed ASTCs or hospitals will not be included in determining projected patient volume;
 - E) Each physician referral letter shall contain the notarized signature, the typed or printed name, the office address, and the specialty of the physician; and
 - F) Verification by the physician that the patient referrals have not been used to support another pending or approved CON application for the subject services.
- 3) Projected Service Demand – Rapid Population Growth
If a projected demand for service is based upon rapid population growth in the applicant facility's existing market area (as experienced annually within the latest 24-month period), the projected service demand shall be determined as follows:
- A) The applicant shall define the facility's market area based upon historical patient origin data by zip code or census tract;
 - B) 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;
 - C) Projections shall be for a maximum period of five years from the date the application is submitted;

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- D) Historical data used to calculate projections shall be for a number of years no less than the number of years projected;
 - E) 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;
 - F) Projections shall be for total population and specified age groups or the applicant's market area, as defined by HFSRB, for each specialty in the application;
 - G) Documentation on projection methodology, data sources, assumptions and special adjustments shall be submitted; and
 - H) The applicant shall estimate the future demand for the number of treatments or procedures based upon population growth and no change in the facility's market share.
- e) Service Demand – Expansion of Existing ASTC Service
The number of surgical/treatment rooms to be added at an existing facility is necessary to reduce the facility's experienced high utilization and to meet a projected demand for service. The applicant shall document the information required by subsections (e)(1)(A) and (B) and either subsections (e)(2)(A) and (B) or (e)(3):
- 1) Historical Service Demand
 - A) The applicant shall document an average utilization rate that has equaled or exceeded the standards specified in 77 Ill. Adm. Code 1100 for existing surgical/treatment rooms for each of the latest two years.
 - B) If patients have been referred to other IDPH-licensed facilities in order to receive the subject services, the applicant shall provide documentation of the referrals, including: patient origin by zip code of residence; name and specialty of referring physician; and the name and location of the recipient hospital or ASTC, for each of the latest two years.

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- 2) Projected Service Demand – Projected Referrals
 - A) The applicant shall provide physician referral letters that attest to the physician's total number of patients (by zip code of residence) that have received treatments at existing IDPH-licensed facilities located in the GSA during the 12-month period prior to submission of the application, and an estimate of the number of patients that will be referred by the physician to the applicant's facility.
 - B) Each physician referral letter shall contain the notarized signature, the typed or printed name, the office address and the specialty of the physician. The anticipated number of referrals cannot exceed the physician's experienced caseload.
- 3) Projected Service Demand – Rapid Population Growth

If a projected demand for service is based upon rapid population growth in the applicant facility's existing market area (as experienced annually within the latest 24-month period), the projected service demand shall be determined as described in subsection (d)(3).
- f) Treatment Room Need Assessment – Review Criterion
 - 1) The applicant shall document that the proposed number of surgical/treatment rooms for each ASTC service is necessary to service the projected patient volume. The number of rooms shall be justified based upon an annual minimum utilization of 1,500 hours of use per room, as established in 77 Ill. Adm. Code 1100.
 - 2) For each ASTC service, the applicant shall provide the number of patient treatments/sessions, the average time (including setup and cleanup time) per patient treatment/session, and the methodology used to establish the average time per patient treatment/session (e.g., experienced historical caseload data, industry norms or special studies).
- g) Service Accessibility

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

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- 1) There are no other IDPH-licensed ASTCs within the identified GSA of the proposed project;
 - 2) The other IDPH-licensed ASTC and hospital surgical/treatment rooms used for those ASTC services proposed by the project within the identified GSA are utilized at or above the utilization level specified in 77 Ill. Adm. Code 1100;
 - 3) The ASTC services or specific types of procedures or operations that are components of an ASTC service are not currently available in the GSA or that existing underutilized services in the GSA have restrictive admission policies;
 - 4) The proposed project is a cooperative venture sponsored by two or more persons, at least one of which operates an existing hospital. Documentation shall provide evidence that:
 - A) The existing hospital is currently providing outpatient services to the population of the subject GSA;
 - B) The existing hospital has sufficient historical workload to justify the number of surgical/treatment rooms at the existing hospital and at the proposed ASTC, based upon the treatment room utilization standard specified in 77 Ill. Adm. Code 1100;
 - C) The existing hospital agrees not to increase its surgical/treatment room capacity until the proposed project's surgical/treatment rooms are operating at or above the utilization rate specified in 77 Ill. Adm. Code 1100 for a period of at least 12 consecutive months; and
 - D) The proposed charges for comparable procedures at the ASTC will be lower than those of the existing hospital.
- h) 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 for the proposed GSA zip code areas identified in subsection (c)(2)(A):

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- A) the total population of the GSA (based upon the most recent population numbers available for the State of Illinois); and
 - B) the names and locations of all existing or approved health care facilities located within the GSA that provide the ASTC services that are proposed by the project.
- 2) The applicant shall document that the project will not result in maldistribution of services. Maldistribution exists when the GSA has an excess supply of facilities and ASTC services characterized by such factors as, but not limited to:
- A) a ratio of surgical/treatment rooms 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 surgical/treatment rooms for the ASTC services proposed by the project that are below the utilization standard specified in 77 Ill. Adm. Code 1100; or
 - C) insufficient population to provide the volume or caseload necessary to utilize the surgical/treatment rooms proposed by the project at or above utilization standards specified in 77 Ill. Adm. Code 1100.
- 3) The applicant shall document that, within 24 months after project completion, the proposed project:
- A) will not lower the utilization of other area providers below the utilization standards specified in 77 Ill. Adm. Code 1100; and
 - B) will not lower, to a further extent, the utilization of other GSA facilities that are currently (during the latest 12-month period) operating below the utilization standards.
- i) Staffing
- 1) Staffing Availability

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

2) Medical Director

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

j) Charge Commitment

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

- 1) a statement of all charges, except for any professional fee (physician charge); and
- 2) a commitment that these charges will not be increased, at a minimum, for the first two years of operation unless a permit is first obtained pursuant to 77 Ill. Adm. Code 1130.310(a).

k) Assurances

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

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

(Source: Amended at 39 Ill. Reg. _____, effective _____)