**Section 1110.235 Non-Hospital Based Ambulatory Surgical Treatment Center Services**

a) Projects Not Subject to this Section

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

b) Recognition

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

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

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

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

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

B) either:

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

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

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

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

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

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

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

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

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

C) require a permit or exemption to:

i) establish an ASTC or ASTC service;

ii) change ownership;

iii) expand an existing ASTC;

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

v) discontinue an ASTC.

c) Review Criteria

1) Introduction

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

B) A permit is required for:

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

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

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

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

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

|  |  |
| --- | --- |
| **PROJECT TYPE** | **REQUIRED REVIEW CRITERIA** |
| Establishment of ASTC Facility or Additional ASTC Service | (c)(2)(B)(i) & (ii) | − | Service to GSA Residents |
| (c)(3)(A) & (B) or (C) | − | Service Demand − Establishment  |
| (c)(5)(A) & (B) | − | Treatment Room Need Assessment |
| (c)(6) | − | Service Accessibility |
| (c)(7)(A) through (C) | − | Unnecessary Duplication/Maldistribution |
| (c)(8)(A) & (B) | − | Staffing  |
| (c)(9) | − | Charge Commitment |
| (c)(10)(A) & (B)  | − | Assurances |
| Expansion of Existing ASTC Service | (c)(2)(B)(i) & (ii) | − | Service to GSA Residents |
| (c)(4)(A) through (C) | − | Service Demand – Expansion |
| (c)(5)(A) & (B) | − | Treatment Room Need Assessment |
| (c)(8)(A) & (B) | − | Staffing  |
| (c)(9) | − | Charge Commitment |
| (c)(10)(A) & (B)  | − | Assurances |

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

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

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

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

E) Transition Period for Meeting this Section's Requirements

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

ii) Effective April 15, 2014, multi-specialty ASTCs adding new services shall notify HFSRB of what services are being added and the effective date of those services. The notification of each new service added shall be submitted to HFSRB within 30 days after the service addition. Beginning January 1, 2018, multi-specialty ASTCs seeking to add additional ASTC services shall apply for a CON permit pursuant to the provisions of this Section.

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

F) Sanctions and Penalties

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

2) Geographic Service Area Need

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

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

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

B) Service to Geographic Service Area Residents

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

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

ii) The applicant shall provide patient origin information by zip code for all admissions for the last 12-month period, verifying that at least 50% of admissions were residents of the GSA. Patient origin information shall be based upon the patient's legal residence (other than a health care facility) for the last 6 months immediately prior to admission.

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

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

A) Historical Referrals

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

i) patient origin by zip code of residence;

ii) name and specialty of referring physician;

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

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

B) Projected Service Demand

The applicant shall provide the following documentation:

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

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

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

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

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

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

C) Projected Service Demand − Rapid Population Growth

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

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

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

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

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

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

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

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

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

4) Service Demand − Expansion of Existing ASTC Service

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

A) Historical Service Demand

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

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

B) Projected Service Demand − Projected Referrals

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

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

C) Projected Service Demand − Rapid Population Growth

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

5) Treatment Room Need Assessment – Review Criterion

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

B) For each ASTC service, the applicant shall provide the number of patient treatments/sessions, the average time (including setup and cleanup time) per patient treatment/session, and the methodology used to establish the average time per patient treatment/session (e.g., experienced historical caseload data, industry norms or special studies).

6) Service Accessibility

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

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

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

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

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

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

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

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

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

7) Unnecessary Duplication/Maldistribution − Review Criterion

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

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

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

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

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

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

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

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

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

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

8) Staffing

A) Staffing Availability

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

B) Medical Director

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

9) Charge Commitment

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

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

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

10) Assurances

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

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