**Section 1110.270 Clinical Service Areas Other Than Categories of Service**

a) Introduction

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

A) Surgery

B) Emergency Services and/or Trauma

C) Ambulatory Care Services (organized as a service)

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

E) Therapeutic Radiology

F) Laboratory

G) Pharmacy

H) Occupational Therapy/Physical Therapy

I) Major Medical Equipment

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

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

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

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

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

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

b) Need Determination − Establishment

The applicant shall describe how the need for the proposed establishment was determined by documenting the following:

1) Service to the Planning Area Residents

A) Either:

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

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

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

2) Service Demand

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

A) Referrals from Inpatient Base

For CSAs that will serve as a support or adjunct service to existing inpatient services, the applicant shall document a minimum 2-year historical and 2-year projected number of inpatients requiring the subject CSA.

B) Physician Referrals

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

C) Historical Referrals to Other Providers

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

D) Population Incidence

The applicant shall submit documentation of incidence of service based upon IDPH statistics or category of service statistics.

3) Impact of the Proposed Project on Other Area Providers

The applicant shall document that, within 24 months after project completion, the proposed project will not:

A) Lower the utilization of other area providers below the utilization

standards specified in Appendix B.

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

4) Utilization

Projects involving the establishment of CSAs shall meet or exceed the utilization standards for the services, as specified in Appendix B. If no utilization standards exist in Appendix B, the applicant shall document its anticipated utilization in terms of incidence of disease or conditions, or historical population use rates.

c) Service Modernization

The applicant shall document that the proposed project meets one of the following:

1) Deteriorated Equipment or Facilities

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

2) Necessary Expansion

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

3) Utilization

A) Major Medical Equipment

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

B) Service or Facility

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

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