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

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

3) Section Numbers: Proposed Actions:

1110.220 Amendment

1110.280 Amendment

4) Statutory Authority: Illinois Health Facilities Planning Act [20 ILCS 3960/12]

5) A Complete Description of the Subjects and Issues Involved: The Board has recently adopted new rules that changed one of its metrics for determining planning area need to "distance" from "normal travel time." Because of an oversight, the Board did not make this change for the Open Heart Surgery category of service (77 Ill. Adm. Code 1110.220) and the Freestanding Emergency Center Medical Services category of service (77 Ill Adm. Code 1110.280). These changes are now being made. The requirement that hospitals that do not have the Open Heart Surgery category of service report emergency open heart surgery following a cardiac catheterization complication is being eliminated. In addition, since these rules became effective, the Emergency Medical Services (EMS) Systems Act has been amended and changes are being made to reflect the changes in this Act.

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

7) Will this rulemaking replace any emergency rule 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 rulemakings pending on this Part: No

11) Statement of Statewide Policy Objective: This rulemaking may affect units of local government that own or operate hospitals.

12) Time, Place and Manner in which interested persons may comment on this proposed rulemaking: Interested persons may present their comments concerning this rulemaking within 45 days after the publication of this issue of the *Illinois Register* to:

Ann Guild

Compliance Analyst

Health Facilities and Services Review Board

69 West Washington Street, Suite 3501

Chicago IL 60602

312/814-6226

Ann.Guild@illinois.gov

13) Initial Regulatory Flexibility Analysis:

A) Types of small businesses, small municipalities and not-for-profit corporations affected: This rulemaking may affect units of small businesses, small municipalities and not-for-profit corporations that own or operate hospitals.

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 2017

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

TITLE 77: PUBLIC HEALTH

CHAPTER II: HEALTH FACILITIES AND SERVICES REVIEW BOARD

SUBCHAPTER a: ILLINOIS HEALTH CARE FACILITIES PLAN

PART 1110

PROCESSING, CLASSIFICATION POLICIES AND REVIEW CRITERIA

SUBPART A: APPLICABILITY; PROJECT CLASSIFICATION

Section

1110.10 Introduction; Definition of Terms; Referenced Statutes

1110.20 Classification of Projects

SUBPART B: INTRODUCTION; GENERAL INFORMATION;

GENERAL REVIEW CRITERIA

Section

1110.100 Introduction

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

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

1110.130 Additional General Review Criteria for Master Design and Related Projects Only

SUBPART C: CATEGORY OF SERVICE REVIEW CRITERIA

Section

1110.200 Medical/Surgical, Obstetric, Pediatric and Intensive Care

1110.205 Comprehensive Physical Rehabilitation Beds

1110.210 Acute Mental Illness and Chronic Mental Illness

1110.215 Neonatal Intensive Care

1110.220 Open Heart Surgery

1110.225 Cardiac Catheterization

1110.230 In-Center Hemodialysis Projects

1110.235 Non-Hospital Based Ambulatory Surgical Treatment Center Services

1110.240 Selected Organ Transplantation

1110.245 Kidney Transplantation

1110.250 Subacute Care Hospital Model

1110.255 Postsurgical Recovery Care Center Alternative Health Care Model

1110.260 Community-Based Residential Rehabilitation Center Alternative Health Care Model

1110.265 Long Term Acute Care Hospital Bed Projects

1110.270 Clinical Service Areas Other Than Categories of Service

1110.275 Birth Center − Alternative Health Care Model

1110.280 Freestanding Emergency Center Medical Services

1110.290 Discontinuation – Review Criteria

1110.APPENDIX A ASTC Services

1110.APPENDIX B State Guidelines − Square Footage and Utilization

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

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 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. 13659, effective October 2, 2015; former Part repealed at 42 Ill. Reg. 5444, and new Part adopted at 42 Ill. Reg. 5447, effective March 7, 2018; amended at 42 Ill. Reg. \_\_\_\_\_\_\_, effective \_\_\_\_\_\_\_.

SUBPART C: CATEGORY OF SERVICE REVIEW CRITERIA

**Section 1110.220 Open Heart Surgery**

a) Introduction

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

b) Review Criteria

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

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

3) Unnecessary Duplication of Services. The applicant shall document that the volume of any existing service within the relevant travel radius from the applicant will not be reduced below 350 procedures annually for adults and 75 procedures annually for pediatrics. Documentation shall consist of proof of contact of all facilities within the travel radius currently providing open heart surgery to determine the projected impact the project will have on existing open heart surgery volume. For purposes of subsection (b)(3), the following travel radii apply:

A) Category 1: For applicant facilities located in the counties of Cook, DuPage, Lake, Will and Kane, the radius shall be 20 miles.

B) Category 2: For applicant facilities in McHenry, Kankakee, Rock Island, St. Clair, Winnebago, Peoria, Sangamon and Champaign, the radius shall be 34 miles.

C) Category 3: For applicant facilities in all other counties, the radius shall be 42 miles.

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

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

B) Cardiac surgical intensive care unit.

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

D) Catheterization-angiographics laboratory services.

E) Nuclear medicine laboratory.

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

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

H) Hematology laboratory.

I) Microbiology laboratory.

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

K) Electrocardiographic laboratory.

L) Blood bank and coagulation laboratory.

M) Pulmonary function unit.

N) Pacemaker installation.

O) Organized cardiopulmonary resuscitation team or capability.

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

Q) Renal dialysis.

5) Staffing

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

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

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

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

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

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

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

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

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

(Source: Amended at 42 Ill. Reg. \_\_\_\_\_\_, effective \_\_\_\_\_\_\_\_\_\_\_\_)

**Section 1110.280 Freestanding Emergency Center Medical Services**

a) Introduction

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

b) Review Criteria

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

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

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

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

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

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

A) *in a municipality with a population of 50,000 or fewer inhabitants;*

B) *within 50 miles of the hospital that owns or controls the FEC; and*

C) *within 50 miles of the Resource Hospital affiliated with the FEC as part of the EMS system*. [210 ILCS 50/32.5(a)]

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

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

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

c) Area Need – Establishment or Expansion of Service

1) 77 Ill. Adm. Code 1100 Formula Calculation

No formula need calculation has been established for the FECMS category of service.

2) Service to Area Residents

Applicants proposing to establish or expand an FECMS category of service shall document that the primary purpose of the project will be to provide necessary health care to the residents of the geographic service area (GSA) (see 77 Ill. Adm. Code 1100.510(d).

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

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

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

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

3) Service Demand − Establishment of FECMS Category of Service

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

A) Historical Utilization

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

B) Projected Utilization

The applicant shall document:

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

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

C) Projected Service Demand – Documentation Parameters

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

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

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

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

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

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

4) Service Accessibility

The proposed project to establish or expand an FECMS category of service is necessary to improve access for GSA residents. The applicant shall document the following:

A) Service Restrictions

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

i) The absence of ED services within the GSA;

ii) The area population and existing care system exhibit indicators of medical care problems, such as high infant mortality, or designation by the Secretary of Health and Human Services as a Health Professional Shortage Area, a Medically Underserved Area, or a Medically Underserved Population;

iii) All existing emergency services within the established radii outlined in 77 Ill. Adm. Code 1100.510(d) meet or exceed the utilization standard specified in 77 Ill. Adm. Code 1100.

B) Supporting Documentation

The applicant shall provide the following documentation, as applicable, concerning existing restrictions to service access:

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

ii) Patient location information by zip code;

iii) Travel-time studies;

iv) A certification of waiting times;

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

vi) An assessment of GSA population characteristics that documents that access problems exist; and

vii) The most recently published IDPH Hospital Questionnaire.

d) Unnecessary Duplication/Maldistribution − Review Criterion

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

A) A list of all zip code areas (in total or in part) that are located within the established radii outlined in 77 Ill. Adm. Code 1100.510(d) of the project's site;

B) The total population of the identified zip code areas (based upon the most recent population numbers available for the State of Illinois population); and

C) The names and locations of all existing or approved health care facilities located within the established radii outlined in 77 Ill. Adm. Code 1100.510(d) from the project site that provide emergency medical services.

2) The applicant shall document that the project will not result in maldistribution of services. Maldistribution exists when the identified facilities within the relevant travel radius, as established by 77 Ill. Adm. Code 1100.510(d), have an excess supply of ED treatment stations characterized by such factors as, but not limited to:

A) Historical utilization (for the latest 12-month period prior to submission of the application) for existing ED within the established radii outlined in 77 Ill. Adm. Code 1100.510(d) of the applicant's site that is below the utilization standard established pursuant to 77 Ill. Adm. Code 1100; or

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

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

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

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

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

e) Category of Service Modernization

1) If the project involves modernization of an existing FECMS category of service, the applicant shall document that the existing treatment areas to be modernized are deteriorated or functionally obsolete and need to be replaced or modernized, due to such factors as, but not limited to:

A) High cost of maintenance;

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

C) Changes in standards of care; or

D) Need for additional space for diagnostic or therapeutic purposes.

2) Documentation shall include the most recent:

A) IDPH Inspection reports; and

B) The Joint Commission reports.

3) Other documentation shall include the following, as applicable

to the factors cited in the application:

A) Copies of maintenance reports;

B) Copies of citations for life safety code violations; and

C) Other pertinent reports and data.

f) Staffing Availability − Review Criterion

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

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

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

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

(Source: Amended at 42 Ill. Reg. \_\_\_\_\_\_, effective \_\_\_\_\_\_\_\_\_\_\_\_)