**Section 1110.230 In-Center Hemodialysis Projects**

a) Introduction

1) This Section applies to projects involving the In-Center Hemodialysis category of service. Applicants proposing to establish, expand or modernize this category of service shall comply with the applicable subsections of this Section as follows:

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| PROJECT TYPE | REQUIRED REVIEW CRITERIA | | |
| Establishment of Services or Facility | (b)(1) | − | Planning Area Need – 77 Ill. Adm. Code 1100 (formula calculation) |
|  | (b)(2) | − | Planning Area Need – Service to Planning Area Residents |
|  | (b)(3) | − | Planning Area Need – Service Demand − Establishment of In-Center Hemodialysis |
|  | (b)(5) | − | Planning Area Need − Service Accessibility |
|  | (c)(1) | − | Unnecessary Duplication of Services |
|  | (c)(2) | − | Maldistribution |
|  | (c)(3) | − | Impact of Project on Other Area Providers |
|  | (e) | − | Staffing |
|  | (f) | − | Support Services |
|  | (g) | − | Minimum Number of Stations |
|  | (h) | − | Continuity of Care |
|  | (i) | − | Relocation (if applicable) |
|  | (j) | − | Assurances |
| Expansion of Existing Services | (b)(2) | − | Planning Area Need – Service to Planning Area Residents |
|  | (b)(4) | − | Planning Area Need – Service Demand – Expansion of In-Center Hemodialysis |
|  | (e) | − | Staffing − Availability |
|  | (f) | − | Support Services |
|  | (j) | − | Assurances |
| In-Center Hemodialysis Modernization | (d)(1) | − | Deteriorated Facilities |
| (d)(2) & (3) | − | Documentation |
| (f) | − | Support Services |

2) If the proposed project involves the relocation of an existing facility or service, the applicant shall comply with the requirements listed in subsection (a)(1) (Establishment of Services or Facility), as well as requirements in Section 1110.290 (Discontinuation) and subsection (i) of this Section (Relocation of Facilities).

3) If the proposed project involves the replacement of a facility or service (onsite or new site), the number of stations being replaced shall not exceed the number justified by historical utilization rates for each of the latest 2 years, unless additional stations can be justified per the criteria for Expansion of Existing Services.

b) Planning Area Need − Review Criterion

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

1) 77 Ill. Adm. Code 1100

A) The number of stations to be established for in-center hemodialysis 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 standard 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), for each category of service included in the project.

B) Applicants proposing to add stations to an existing in-center hemodialysis 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) Applicants proposing to expand an existing in-center hemodialysis service shall submit patient origin information by zip code, based upon the patient's legal residence (other than a health care facility).

3) Service Demand – Establishment of In-Center Hemodialysis Service

The number of stations proposed to establish a new in-center hemodialysis service is necessary to accommodate the service demand experienced annually by the existing applicant facility over the latest 2-year period, as evidenced by historical and projected referrals, or, if the applicant proposes to establish a new facility, the applicant shall submit projected referrals. The applicant shall document subsection (b)(3)(A) and either subsection (b)(3)(B) or (C).

A) Historical Referrals

i) If the applicant is an existing facility, the applicant shall document the number of referrals to other facilities, for each proposed category of service, for each of the latest 2 years.

ii) Documentation of the referrals shall include: patient origin by zip code; name and specialty of referring physician; name and location of the recipient facility.

B) Projected Referrals

The applicant shall provide physician referral letters that attest to:

i) The physician's total number of patients (by facility and zip code of residence) who have received care at existing facilities located in the area, as reported to The Renal Network at the end of the year for the most recent 3 years and the end of the most recent quarter;

ii) The number of new patients (by facility and zip code of residence) located in the area, as reported to The Renal Network, that the physician referred for in-center hemodialysis for the most recent year;

iii) An estimated number of patients (transfers from existing facilities and pre-ESRD, as well as respective zip codes of residence) that the physician will refer annually to the applicant's facility within a 24-month period after project completion, based upon the physician's practice experience. The anticipated number of referrals cannot exceed the physician's documented historical caseload;

iv) An estimated number of existing patients who are not expected to continue requiring in-center hemodialysis services due to a change in health status (e.g., the patients received kidney transplants or expired);

v) The physician's notarized signature, the typed or printed name of the physician, the physician's office address and the physician's specialty;

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; and

vii) Each referral letter shall contain a statement attesting that the information submitted is true and correct, to the best of the physician's belief.

C) Projected Service Demand − Based on 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 10 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 for the applicant's market area, as defined by HFSRB, for each category of service in the application; and

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

4) Service Demand – Expansion of In-Center Hemodialysis Service

The number of stations to be added for each category of service is necessary to reduce the facility's experienced high utilization and to meet a projected demand for service. The applicant shall document subsection (b)(4)(A) and either (b)(4)(B) or (C):

A) Historical Service Demand

i) An average annual utilization rate that has equaled or exceeded utilization standards for in-center hemodialysis service, as specified in 77 Ill. Adm. Code 1100, for each of the latest 2 years.

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

B) Projected Referrals

i) The applicant shall provide physician letters that attest to:

• the physician's total number of patients (by facility and zip code of residence) who have received care at existing facilities located in the area, as reported to The Renal Network at the end of the year for the most recent 3 years and the end of the most recent quarter;

• the number of new patients (by facility and zip code of residence) located in the area, as reported to The Renal Network, that the physician referred for in-center hemodialysis for the most recent year;

• an estimated number of patients (transfers from existing facilities and pre-ESRD, as well as respective zip codes of residence) that the physician will refer annually to the applicant's facility within a 24-month period after project completion, based upon the physician's practice experience. The anticipated number of referrals cannot exceed the physician's documented historical caseload. The percentage of project referrals used to justify the proposed expansion cannot exceed the historical percentage of applicant market share, within a 24-month period after project completion;

ii) 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;

iii) The physician shall verify that the patient referrals have not been used to support another pending or approved CON application for the subject services; and

iv) Each referral letter shall contain a statement attesting that the information submitted is true and correct, to the best of the physician's belief.

C) Projected Service Demand – Based on 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 10 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 for the applicant's market area, as defined by HFSRB, for each category of service in the application; and

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

5) Service Accessibility

The number of stations being established or added for the subject 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) For purposes of this subsection (b)(5) only, all services within the established radii outlined in subsection (b)(5)(C) 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.

C) The travel radius for purposes of subsection (b)(5)(A)(v) is:

i) For applicant facilities located in the counties of Cook and DuPage, the radius shall be 5 miles.

ii) For applicant facilities located in the counties of Lake, Kane and Will, the radius shall be 10 miles.

iii) For applicant facilities located in the counties of Kankakee, Grundy, Kendall, DeKalb, McHenry, Winnebago, Champaign, Sangamon, Peoria, Tazewell, Rock Island, Monroe, Madison and St. Clair, the radius shall be 15 miles.

iv) For applicant facilities located in any other area of the State, the radius shall be 19 miles.

c) 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 that are located, in total or in part, within the established radii outlined in subsection (c)(4) 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 subsection (c)(4) of the project site that provides the categories of station 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, stations and services characterized by such factors as, but not limited to:

A) A ratio of stations 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.

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 occupancy standards specified in 77 Ill. Adm. Code 1100; and

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

4) The travel radius for purposes of subsection (c)(1) is:

A) For applicant facilities located in the counties of Cook and DuPage, the radius shall be 5 miles.

B) For applicant facilities located in the counties of Lake, Kane and Will, the radius shall be 10 miles.

C) For applicant facilities located in the counties of Kankakee, Grundy, Kendall, DeKalb, McHenry, Winnebago, Champaign, Sangamon, Peoria, Tazewell, Rock Island, Monroe, Madison and St. Clair, the radius shall be 15 miles.

D) For applicant facilities located in any other area of the State, the radius shall be 19 miles.

d) Category of Service Modernization

1) If the project involves modernization of an in-center hemodialysis 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:

A) High cost of maintenance;

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

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

D) Additional space for diagnostic or therapeutic purposes.

2) Documentation shall include the most recent:

A) IDPH CMMS 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.

4) Projects involving the relocation or modernization of in-center hemodialysis or a facility shall meet or exceed the utilization standards for the categories of service, as specified in 77 Ill. Adm. Code 1100.

e) Staffing

The applicant shall document that relevant clinical and professional staffing needs for the proposed project were considered and that licensure and The Joint Commission staffing requirements 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.

1) Qualifications

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) 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 (see the End Stage Renal Disease Facility Act). In addition, the applicant shall document its requirements for training and continuing education.

D) Dietitian – This individual shall be a registered dietitian with the Commission on Dietetic Registration, meet the practice requirements of the State of Illinois (see the Dietitian Nutritionist Practice Act) and have 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 Master's of Social Work and meet the State of Illinois requirements (see the Clinical Social Work and Social Work Practice Act).

2) Documentation shall consist of:

A) Medical Director

Curriculum vitae of Medical Director, including a list of all in-center hemodialysis facilities where the position of Medical Director is held.

B) All Other Personnel

A narrative explanation of how positions will be filled.

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) Staffing Plan

The applicant proposing to establish an in-center hemodialysis category of service shall document that at least one RN will be on duty when the unit is in operation and will maintain a ratio of at least one direct patient care provider to every 4 patients.

5) Medical Staff

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

f) Support Services – Review Criterion

An applicant proposing to establish an in-center hemodialysis category of service must submit a certification from an authorized representative that attests to each of the following:

1) Participation in a dialysis data system;

2) Availability of support services consisting of clinical laboratory service, blood bank, nutrition, rehabilitation, psychiatric and social services; and

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

g) Minimum Number of Stations

The minimum number of in-center hemodialysis stations for an End Stage Renal Disease (ESRD) facility is:

1) Four dialysis stations for facilities outside an MSA;

2) Eight dialysis stations for a facility within an MSA.

h) Continuity of Care

An applicant proposing to establish an in-center hemodialysis 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.

i) 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) 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) That the proposed facility will improve access for care to the existing patient population.

j) Assurances

The applicant representative who signs the CON application shall submit a signed and dated statement attesting to the applicant's understanding that:

1) By the second year of operation after the project completion, the applicant will achieve and maintain the utilization standards specified in 77 Ill. Adm. Code 1100 for each category of service involved in the proposal; and

2) An applicant proposing to expand or relocate in-center hemodialysis stations will achieve and maintain compliance with the following adequacy of hemodialysis outcome measures for the latest 12-month period for which data are available:

≥ 85% of hemodialysis patient population achieves urea reduction ratio (URR) ≥ 65% and ≥ 85% of hemodialysis patient population achieves Kt/V Daugirdas II 1.2.