**Section 1110.225 Cardiac Catheterization**

This Section contains Review Criteria that pertain to the Cardiac Catheterization category of service.

a) Peer Review

Any applicant proposing the establishment or modernization of a cardiac catheterization unit shall detail in its application for permit the mechanism for adequate peer review of the program. Peer review teams will evaluate the quality of studies and related morbidity and mortality of patients and also the technical aspects of providing the services such as film processing, equipment maintenance, etc.

b) Establishment or Expansion of Cardiac Catheterization Service

There shall be not additional adult or pediatric catheterization categories of service started in a health planning area unless:

1) the standards as outlined in 77 Ill. Adm. Code 1100.620 are met; unless

2) in the circumstances where area programs have failed to meet those targets, the applicant can document historical referral volume in each of the prior 3 years for cardiac catheterization in excess of 400 annual procedures (e.g., certification of the number of patients transferred to other service providers in each of the last 3 years).

c) Unnecessary Duplication of Services

1) Any application proposing to establish cardiac catheterization services must indicate if it will reduce the volume of existing facilities below 200 catheterizations.

2) Any applicant proposing the establishment of cardiac catheterization services must contact all facilities currently providing the service within the planning area in which the applicant facility is located, to determine the impact the project will have on the patient volume at existing services.

d) Modernization of Existing Cardiac Catheterization Equipment

An applicant with a proposed project for the modernization of existing equipment that provides cardiac catheterization services shall document that the minimum utilization standards (as outlined in 77 Ill. Adm. Code 1100.620) are met.

e) Support Services

1) Any applicant proposing the establishment of a dedicated cardiac catheterization laboratory must document the availability of the following support services;

A) Nuclear medicine laboratory.

B) Echocardiography service.

C) Electrocardiography laboratory and services, including stress testing and continuous cardiogram monitoring.

D) Pulmonary Function unit.

E) Blood bank.

F) Hematology laboratory-coagulation laboratory.

G) Microbiology laboratory.

H) Blood Gas laboratory.

I) Clinical pathology laboratory with facilities for blood chemistry.

2) These support services need not be in operation on a 24-hour basis but must be available when needed.

f) Laboratory Location

Due to safety considerations in the event of technical breakdown it is preferable to group laboratory facilities. Thus in projects proposing to establish additional catheterization laboratories such units must be located in close proximity to existing laboratories unless such location is architecturally infeasible.

g) Staffing

It is the policy of the State Board that if cardiac catheterization services are to be offered that a cardiac catheterization laboratory team be established. Any applicant proposing to establish such a laboratory must document that the following personnel will be available:

1) Lab director board-certified in internal medicine, pediatrics or radiology with subspecialty training in cardiology or cardiovascular radiology.

2) A physician with training in cardiology and/or radiology present during examination with extra physician backup personnel available.

3) Nurse specially trained in critical care of cardiac patients, knowledge of cardiovascular medication, and understanding of catheterization equipment.

4) Radiologic technologist highly skilled in conventional radiographic techniques and angiographic principles, knowledgeable in every aspect of catheterization instrumentation, and with thorough knowledge of the anatomy and physiology of the cardiovascular system.

5) Cardiopulmonary technician for patient observation, handling blood samples and performing blood gas evaluation calculations.

6) Monitoring and recording technician for monitoring physiologic data and alerting physician to any changes.

7) Electronic radiologic repair technician to perform systematic tests and routine maintenance; must be immediately available in the event of equipment failure during a procedure.

8) Darkroom technician well trained in photographic processing and in the operation of automatic processors used for both sheet and cine film.

h) Continuity of Care

Any applicant proposing the establishment, expansion or modernization of a cardiac catheterization service must document that written transfer agreements have been established with facilities with open-heart surgery capabilities for the transfer of seriously ill patients for continuity of care.

i) Multi-Institutional Variance

1) A variance to the establishment requirements of subsection (b), Establishment or Expansion of Cardiac Catheterization Service shall be granted if the applicant can demonstrate that the proposed new program is necessary to alleviate excessively high demands on an existing operating program's capacity.

2) Each of the following must be documented:

A) That the proposed unit will be affiliated with the existing operating program. This must be documented by written referral agreements between the facilities, and documentation of shared medical staff;

B) That the existing operating program provides open heart surgery;

C) That initiation of a new program at the proposed site is more cost effective, based upon a comparison of charges, than expansion of the existing operating program;

D) That the existing operating program currently operates at a level of more than 750 procedures annually per laboratory; and

E) That the proposed unit will operate at the minimum utilization target occupancy and that such unit will not reduce utilization in existing programs below target occupancy (e.g., certification of the number of patients transferred to other service providers in each of the last 3 years and market studies developed by the applicant indicating the number of potential catheterization patients in the area served by the applicant).

3) The existing operating program cannot utilize its volume of patient procedures to justify a second affiliation agreement until such time as the operating program is again operating at 750 procedures annually per laboratory and the affiliate is operating at 400 procedures per laboratory.