Open Meeting on Rules Redevelopment
Illinois Health Facilities Planning Board
April 12, 2006

“Open Heart Surgery”
“Cardiac Catheterization”
Follow-up Meeting - Panel Discussion

Harold Washington College
Community Room #203
30 E. Lake Street
Chicago, IL

Teleconference:
Illinois Department of Public Health
2nd Floor Conference Room
525 West. Jefferson Street
Springfield, IL
Rules Process

- Open Meetings/Public Participation-Input
- Draft Rules Reviewed and Approved by Board
- Submission to JCAR
- Publication in the Illinois Register
- Formal Public Hearings and Comment Period
- Reconsideration by the Board
- Consideration and approval by JCAR
Meeting Protocols

- Comments/Discussion Limited to Current Topic
- All Interested Parties Invited to Participate
- Written Comments Requested
- Time Limitations - As Required
- Check with website
  [http://www.idph.state.il.us/about/hfph/hfpbrules.htm](http://www.idph.state.il.us/about/hfph/hfpbrules.htm)
Meeting Objectives

- **Review main issues regarding “Open Heart Surgery” and “Cardiac Catheterization”**.
  - Discussion will relate to issues raised at the 4/18/05 meeting, and other current issues, as presented.
  - Detailed discussion of policy viability will also be addressed.
  - Said discussion will provide practical direction for the preparation of draft rules for the subject services.

- **Identify opportunities for improvement**.
  - Satisfy statutory requirements, while meeting the needs of the stakeholders: applicants, staff, Board Members and public.
  - Identify experts in subject fields to assist IHFPB in updating policies.
Health Facilities Planning Act – 2004:

- **Purpose of the Act**
  - Establish a procedure designed to reverse the trends of increasing costs of health care resulting from unnecessary construction or modification of health care facilities.
  - Improve the financial ability of the public to obtain necessary health services.
  - Establish an orderly and comprehensive health care delivery system which will guarantee the availability of quality health care to the general public.

- **The Procedure**
  - Requires a person establishing, constructing, or modifying a health care facility to have the qualifications, background, character and financial resources to adequately provide a proper service for the community.
  - Promotes orderly and economic development of health care facilities that avoids unnecessary duplication of such services.
  - Promotes planning for and the development of health care facilities needed for comprehensive health care, especially in areas where the health planning process has identified needs.
  - Carries out these purposes in coordination with the Agency and the comprehensive State health plan developed by that Agency.
Issues Raised at 4/18/05 Meeting

1. Determine different requirements, as appropriate, for Diagnostic, Interventional, and Freestanding Cardiac Catheterization
2. Consider designated requirements for: Pediatrics, Adults, Freestanding Facilities.
3. Should cardiac services be clustered?
4. Examine the impact of “quantity” as related to “quality” and “cost-effectiveness”.
5. Determine appropriate volume thresholds for facility and/or “teams”.
6. Address different time periods for utilization thresholds.
7. Develop a database or use existing ACC database for cardiac service outcomes to compare “like” facilities with “like” facilities.
8. Clarify definitions for: “procedures”, “case” and “patients”. 
Other Issues to Consider

1. Is an on-site surgical component necessary for facilities that provide diagnostic cardiac cath services? For those that provide both diagnostic and interventional cardiac cath?

2. If the surgical component would be provided at another facility (through a formal agreement), could any “prep work” be done prior to transporting the patient or during the transport?

3. What follow-up procedure would be instituted to determine a facility’s compliance with utilization requirements, and whether facilities would actually discontinue services if the utilization standard is not met? Examine outcomes when utilization is not met after a permit is granted?

4. Examine problems other than mortality, such as infection, post-op bleeding...
Part 1100 – Narrative and Planning Policies

SUBPART D
Section 1100. 610

“Open Heart Surgery”
Section 1100.610 – Bed Need & Utilization: “Open Heart Surgery”

- Planning Areas: Health Service Areas
  - Issues related to Planning Areas

Utilization Standards:

- **Adult** - There should be a minimum of 200 open heart operations performed annually by each facility within 3 years after initiation, in any institution in which open heart surgery is performed for adults. Higher case loads, over 200 per annum, are encouraged.
  - Issues:

- **Pediatric** – There should be a minimum of 75 pediatric open heart operations performed annually by each facility within 3 years after initiation of the service.
  - Issues:

programs doing both adult and pediatric open heart surgery.
  - Issues:
Section 1100.610 - Bed Need & Utilization: “Open Heart Surgery” (continued…)

- Open Heart Surgery Programs:
  - The need for an open heart surgery category of service shall be institution specific and determined by:
    - the volume of at least 200 patients referred to other institutions for surgery following a cardiac catheterization procedure at the applicant facility;
    - OR-
    - a minimum of 750 cardiac catheterizations were performed annually at the applicant facility.
Part 1110 – Category of Service Review Criteria

SUBPART M
Section 1110.1210 - 1110.1230

“Open Heart Surgery”
SUBPART - “Open Heart Surgery”

Section 1110.1210 - Introduction

a) “Subpart M contains Review Criteria which pertain to the Open Heart Surgery category of service. These Review Criteria are utilized in addition to the “General Review Criteria” outlined in Subpart C and any other applicable Review Criteria outlined in Subparts D and E.”

b) “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 category of service when reported to the agency within 30 days of occurrence.”
SUBPART - “Open Heart Surgery”

Section 1110.1220 – Definitions

- **Cardiac Surgeon** – a physician eligible or Board certified by the American Board of Thoracic Surgery.
- **Cardiac Surgery Room** – a physically identifiable room(s) adequately staffed and equipped for the performance of open and closed heart surgery, and extracorporeal bypass.
- **Cardiological Team** – the designated specialists and support personnel who consistently work together in the performance of open heart surgery.
- **Cardiovascular Surgical Procedures** – any surgical procedures dealing with the heart, coronary arteries, and surgery of the great vessels.
- **Cardiovascular Surgical Procedures** – the programs, equipment and staff dealing with the surgery of the heart, coronary arteries and great vessels.
SUBPART - “Open Heart Surgery”

Section 1110.1220 – Definitions (continued…)

- **Closed Heart Surgery** – any cardiovascular surgical procedures which do not include the use of a heart/lung pump.
- **Extracorporeal Circulation (Bypass)** – the circulation of blood outside the body, as through a heart/lung apparatus for carbon dioxide-oxygen exchange.
- **Open Heart Surgery** – a category of service which utilizes any form of cardiac surgery which requires the use of extracorporeal circulation and oxygenation. The use of a pump during the procedure distinguishes “open heart” from “closed heart” surgery.
- **Pump Procedures** - the utilization of a heart/lung pump in surgery to perform the work of the heart and lungs. Included in these procedures are Myocardial Revascularization, Aortic and Mitral Valve Replacement, Ventricular Aneurysm Repairs, Pulmonary Valvuoplasty, and all other procedures utilizing a cardiac pump.
SUBPART - “Open Heart Surgery” (continued…)

Section 1110.1230 - Review Criteria

- **Peer Review:**
  
  The applicant must document the mechanism for peer review of an open heart surgery program.

- **Establishment of Open Heart Surgery:**
  
  - The applicant must 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 must 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.
SUBPART - “Open Heart Surgery”
(continued…)

Section 1110.1230 - Review Criteria

- Unnecessary Duplication of Services
  - The applicant must document that the volume of any existing service within 90 minutes travel time 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 90 minutes travel time currently providing open heart surgery to determine the projected impact the project will have on exiting open heart surgery volume.
SUBPART - “Open Heart Surgery”
(continued…)

Section 1110.1230 - Review Criteria

Support Services

The applicant must document that the following support services and facilities are immediately available on a 24-hour basis and how such services will be mobilized in the case of emergencies:

- Surgical and cardiological team appropriate for age group served.
- Cardiac surgical intensive care unit.
- 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.
- Catheterization-angiographics laboratory services.
SUBPART - “Open Heart Surgery” (continued…)

- Section 1110.1230 - Review Criteria
  - Support Services
    - Nuclear medicine laboratory
    - Cardiographics laboratory, electrocardiography including exercise stress testing, continuous electrocardiography including exercise stress testing, continuous electrocardiograph (ECG) monitoring and phonocardiography.
    - Echocardiography service – This may or may not be a part of the cardiographics laboratory.
    - Hemotology laboratory.
    - Microbiology laboratory.
    - Blood gas and electrolyte laboratory with microtechniques for pediatric patients.
SUBPART - “Open Heart Surgery”
(continued…)

Section 1110.1230 - Review Criteria

Support Services
- Electrocardiographic laboratory.
- Blood bank and coagulation laboratory.
- Pulmonary function unit.
- Installation of pacemakers.
- Organized cardiopulmonary resuscitation team or capability.
- Preventative maintenance program for all biomedical devices, electrical installations, and environmental controls.
- Renal Dialysis.
SUBPART - “Open Heart Surgery”

Section 1110.1230 - Review Criteria

◆ Staffing

The applicant must document that a cardiac surgical team will be established. Such a team must be composed of at least the following:

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

B. Operating Room nurse personnel (Registered Nurse, Licensed Practical Nurse, and Surgical Technician). The nurse to patient ratio for the ICU module of open heart surgery patient care should be no less than one nurse per one patient in the immediate recovery phase and one nurse per two patients thereafter.
SUBPART - “Open Heart Surgery”

Section 1110.1230 - Review Criteria

- **Staffing (continued...)**
  - C. *Anesthesiologists* (Bd. Certified by the American Bd. of Anesthesiology).
  - D. *Adult cardiologists* (Bd. Certified by the American Bd. Of Internal Medicine with subspecialty certification in cardiology).
  - E. *Physician who is Bd. Certified in anatomic and clinical pathology*, with special expertise in microbiology, bloodbanking, lab aspects of blood coagulation, blood gases, and electrolytes.
  - F. *Pump technician or operator of the extracorporeal pump oxygenator*, who should 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/she be a physician, nurse or technician.
  - G. *Radiologic Technologist* experienced in angiographic principles and catheterization procedure techniques who is experienced in the usage, operation and care of all catheterization equipment.
SUBPART - “Open Heart Surgery”

Section 1110.1230 - Review Criteria

- **Staffing (continued...)**
  - Documentation shall consist of:
  - Letters of interest from potential employees;
  - Applications filed with the applicant for a position;
  - Signed contracts with the required staff; or
  - A narrative explanation of how other positions will be filled.
Part 1100 – Narrative and Planning Policies

SUBPART D
Section 1100.620

“Cardiac Catheterization”
Section 1100.620 – Bed Need & Utilization: “Cardiac Catheterization”

- **Planning Areas:** Health Service Areas

- **Utilization Standards:** 200 Cardiac Catheterization procedures annually w/in 2 years after initiation

- **Need Determination:** No additional cardiac catheterization service shall be started unless each facility in the planning area offering cardiac catheterization services operates at a level of 400 procedures annually.
Part 1110 – Category of Service Review Criteria

SUBPART N
Section 1110.1310 - 1110.1330

“Cardiac Catheterization”
SUBPART - “Cardiac Catheterization”

Section 1110.1310 – Introduction

Subpart N contains Review Criteria which pertain to the Cardiac Catheterization category of service. These Review Criteria are utilized in addition to the “General Review Criteria” outlined in Subpart C and any other applicable Review Criteria outlined in Subparts D and E.
SUBPART - “Cardiac Catheterization”

Section 1110.1320 – Definitions

- **Adult Catheterization** – the cardiac catheterization of patients 15 years of age and older.

- **Cardiac Catheterization Category of Service** – for the purposes of this subpart, the performance of catheterization procedures which due to safety and quality considerations are preferably performed within a cardiac catheterization laboratory or special procedure room. Procedures which do not require the use of such specialized settings such as listed below, are not recognized as procedures which under this Subchapter would in and of themselves qualify a facility as having a cardiac catheterization category of service.
SUBPART - “Cardiac Catheterization”

Section 1110.1320 – Definitions

- Cardiac Catheterization Category of Service
  (continued…)

These special settings include:
- Pericardiocentesis
- Myocardial biopsy
- Cardiac pacemaker insertion or replacement
- Right heart catheterization w/a flow-directed catheter (e.g. Swan-Ganz)
- Intra-aortic balloon pump assistance w/intra-aortic balloon catheter placement
- Certain types of electrophysiology
- Aterial pressure or blood gas monitoring
- Fluoroscopy
- Cardiac ultrasound
SUBPART - “Cardiac Catheterization”

Section 1110.1320 – Definitions

- **Dedicated Cardiac Catheterization Laboratory** – a distinct laboratory which is staffed, equipped and operated solely for the provision of cardiac catheterization.

- **Examination** – all cardiac diagnostic procedures (angiographic and physiologic studies) performed on a patient during one session in the laboratory.

- **Pediatric Catheterization** – the cardiac catheterization of patients below the age of 15 years.

- **Special Procedures Laboratory with a Cardiac Catheterization Service** – a laboratory which has the equipment, staff, and support services required to provide cardiac catheterization and in which catheterizations are routinely performed. The laboratory is also utilized for other procedures not directly related to cardiac catheterization.
SUBPART - “Cardiac Catheterization”

Section 1110.1330 – Review Criteria

- 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.

- Establishment or Expansion of Cardiac Catheterization Service

There shall not be additional adult or pediatric catheterization categories of service started in a health planning area unless:
- The standards as outlined in 77 Ill. Adm. Code 1100.620 are met; unless
- 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).
SUBPART - “Cardiac Catheterization”

Section 1110.1330 – Review Criteria

- 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 w/in 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.

- Modernization of Existing Cardiac Catheterization Equipment
  No proposed project for the modernization of existing equipment providing cardiac catheterization services will be approved unless the applicant documents that the minimum utilization standards (as outlined in 77Ill.Adm.Code 1100.620) are met.
SUBPART - “Cardiac Catheterization”

Section 1110.1330 – Review Criteria

Support Services
Any applicant proposing the establishment of a dedicated cardiac catheterization laboratory must document the availability of the following support services:

- Nuclear medicine
- Echocardiography
- Electrocardiography laboratory and services, including stress testing and continuous cardiogram monitoring
- Pulmonary Function unit
- Blood Bank
- Hematology laboratory – Coagulation laboratory
- Microbiology laboratory
- Blood Gas laboratory
- Clinical pathology laboratory w/facilities for blood chemistry.

These support services need not be in operation on a 24 hour basis, but must be available when needed.
SUBPART - “Cardiac Catheterization”

Section 1110.1330 – Review Criteria

- **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.

- **Staffing**
  It is the policy of the State Board that if cardiac catheterization services are to be offered, that a cardiac catheterization team be established. Any applicant proposing to establish such a laboratory must document that the following personnel will be available:
    - Lab director board-certified in Internal Medicine, Pediatrics or Radiology w/subspecialty training in Cardiology or cardiovascular Radiology.
SUBPART - “Cardiac Catheterization”

Section 1110.1330 – Review Criteria

- **Staffing** (continued...)
  - A **Physician** w/training in Cardiology and/or Radiology present during examination w/extra physician backup personnel available
  - Nurse specially trained in critical care of cardiac patients, knowledge of cardiovascular medicine, and understanding of catheterization equipment.
  - **Radiologic technician** highly skilled in conventional radiographic techniques and angiographic principles, knowledgeable in every aspect of catheterization instrumentation, and w/thorough knowledge of the anatomy and physiology of the cardiovascular system.
  - **Cardiopulmonary technician** for patient observation, handling blood samples and performing blood gas evaluation calculations.
SUBPART - “Cardiac Catheterization”

Section 1110.1330 – Review Criteria

◆ Staffing (continued...)
  • Monitoring and recording technician for monitoring physiologic data and alerting physician to any changes.
  • Electronic radiologic repair technician to perform systematic tests and routine maintenance; must be immediately available in the event of equipment failure during a procedure.
  • Darkroom technician, well-trained in photographic processing and in the operation of automatic processors used for both sheet and cine film.

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 w/facilities w/open heart surgery capabilities for the transfer of seriously ill patients for continuity of care.
SUBPART - “Cardiac Catheterization”

Section 1110.1330 – Review Criteria

- Multi-Institutional Variance

1) A variance to the establishment requirements of 1110.1330(b), “Establishment or Expansion of Cardiac Cath. 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 w/the existing operating program. This must be documented by written referral agreements between the facilities, and the documentation of shared medical staff;
   B) that the existing operating program provides open heart surgery;
SUBPART - “Cardiac Catheterization”

Section 1110.1330 – Review Criteria

- Multi-Institutional Variance

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 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.