**Section 205.130 Approval of Surgical Procedures**

a) The list of surgical procedures performed by a center shall be included in the application as provided in Section 205.120 and in the renewal application as provided in Section 205.125. All surgical procedures to be performed in a facility must be approved by the facility's Consulting Committee prior to their performance, and annually reviewed and reapproved. Documentation of the approval must be submitted with the initial and renewal applications.

b) If, after reviewing the quarterly data submission required by Section 205.620 of this Part, the Department questions the safety of a procedure being performed because of the complications or postoperative hospitalizations reported as being associated with the procedure, the Department shall request that the facility's Consulting Committee review the reported cases and submit the findings of that review within 30 days after the request.

c) The Department may disapprove a procedure based upon the following:

1) The Department's review of the statistical information submitted in accordance with Section 205.620 of this Part and the Consulting Committee's review required in subsection (b) above indicate that the procedure cannot be safely performed in the surgery center as indicated by life threatening or repeated complications, or repeated postoperative hospitalizations; or

2) The results of a complaint investigation indicate that the procedure is potentially life threatening or results in repeated complications or postoperative hospitalizations; or

3) Evidence becomes available from other sources, such as a national study or a warning from the Food and Drug Administration or other regulatory body, that the procedure cannot be safely performed in an ambulatory setting.

d) The Director shall issue a Notice of Disapproval, which shall be effective immediately, and which shall provide the facility with fifteen days in which to request a hearing to contest the Notice of Disapproval. Such hearing will be conducted by the Department in accordance with the Department's administrative hearing rules (77 Ill. Adm. Code 100) and the Illinois Administrative Procedure Act (Ill. Rev. Stat. 1991, ch. 127, par. 1001-1 et seq.) [5 ILCS 100].

(Source: Amended at 18 Ill. Reg. 17250, effective December 1, 1994)