



Ohio Administrative Code

Rule 3701-84-30.3 Level III adult cardiac catheterization service standards.

Effective: May 15, 2023

(A) Level III cardiac catheterization service or "level III service" means an adult cardiac catheterization service located in a hospital with an on-site open heart surgery service that provides all levels of diagnostic and therapeutic cardiac catheterization procedures.

(B) Each level III service shall operate on an organized, regular, twenty-four hour a day, seven days a week basis to perform primary PCI.

(C) Each level III service shall have provided at least one year of service performing diagnostic cardiac catheterizations prior to providing notice to the director of their intent to provide level III services. Accelerated designation may be granted to a service on a case-by-case basis by the director and not be construed as constituting precedent for the granting of an accelerated designation for any other service.

(D) Each level III service shall have the following:

(1) An on-site adult open heart surgery service available within the same hospital as the cardiac catheterization laboratory and is immediately accessible from the cardiac catheterization laboratory by gurney;

(2) An experienced cardiovascular surgical team that is readily available in less than sixty minutes on a twenty-four hour a day basis in the event that emergency open heart surgery is required; and

(3) Support services consistent with the 2012 expert consensus document, table 2: support services.

(E) Each level III service will comply with the personnel and staffing requirements set forth in rule 3701-84-31 of the Administrative Code.

(F) In addition to the general facilities, equipment, and supplies requirements set forth in rule 3701-



84-32 of the Administrative Code, each level III service, will have:

(1) One or more surgical suites that are equipped to accommodate thoracic and cardiac surgical procedures requiring cardiopulmonary bypass, with appropriate staff available in less than sixty minutes; and

(2) At a minimum, equipment consistent with the 2014 expert consensus document, table: 3 facility requirements.

(G) Each level III service will comply with the safety standards set forth in rule 3701-84-33 of the Administrative Code.

(H) Major complications and emergency transfers should be reviewed at least once every sixty days by the quality assessment review process required in paragraph (E) of rule 3701-84-30 of the Administrative Code and rule 3701-84-12 of the Administrative Code.

(I) Each level III service will obtain enrollment and maintain participation in a data registry to monitor operator and institutional volumes, outcomes, and procedural appropriateness.

(J) Reporting:

(1) Beginning January 1, 2023, and ending on December 31, 2024, each level III services will submit an annual report to the department by March first of each year that:

(a) Maintains patient confidentiality;

(b) Includes the numbers for the following:

(i) Cardiac catheterization procedures and electrophysiology studies or procedures conducted in a cardiac catheterization procedure room;

(ii) Electrophysiology studies or procedures conducted in an electrophysiology procedure room;



- (iii) Elective PCI;
 - (iv) Primary PCI;
 - (v) Post-procedure in-hospital mortality number;
 - (vi) Vascular access injury requiring surgery or other intervention; and
 - (vii) Major bleeding as defined in paragraph (K) of rule 3701-84-30 of the Administrative Code.
- (2) Beginning January 1, 2025, each level III service will submit the following information to the department by March first of each year as part of the hospital's annual report that:
- (a) Maintains patient confidentiality;
 - (b) Includes the number of procedures performed in the following categories:
 - (i) Cardiac catheterization procedures and electrophysiology studies or procedures conducted in a cardiac catheterization procedure room;
 - (ii) Electrophysiology studies or procedures conducted in an electrophysiology procedure room;
 - (iii) Elective PCI;
 - (iv) Primary PCI;
 - (v) Post-procedure in-hospital mortality number;
 - (vi) Vascular access injury requiring surgery or other intervention; and
 - (vii) Major bleeding as defined in paragraph (K) of rule 3701-84-30 of the Administrative Code.
- (K) Each level III service shall obtain a signed informed consent from each patient prior to the



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performance of any procedure.