Ohio Administrative Code

Rule 3701-22-38 General adult cardiac catheterization service standards.

Effective: August 31, 2025

(A) The provisions of rules 3701-22-38 to 3701-22-42.1 of the Administrative Code are applicable to each provider of cardiac catheterization services performing procedures on adult patients greater than or equal to eighteen years of age. An adult cardiac catheterization service may serve a patient less than eighteen years of age if the patient's attending physician and the adult service's medical director determine that the adult service best serves the needs of the patient.

(B) Each provider of cardiac catheterization services will:

(1) Designate in writing to the director the service level classification, as defined in this chapter, it provides or intends to provide;

(2) Designate in writing to the director the scope of services, including the number of procedure and control rooms, provided within the service level classification;

(3) Meet the requirements of this chapter for the service level classification designated; and

(4) Not hold itself out to any person or government entity by means of signage, advertising, or other promotional efforts as having a service level classification for which it is not designated.

(C) Each provider of cardiac catheterization services will have an established written protocol for the emergency transfer and care of patients who require emergency medical/surgical management during or immediately after cardiac catheterization.

(D) Each provider of cardiac catheterization services will have immediate access to services for hematology and coagulation disorders, electrocardiography, and diagnostic radiology. Access to clinical pathology, nuclear medicine and nuclear cardiology, doppler-echocardiography, pulmonary function testing, and microbiology will be available within a reasonable amount of time to meet the needs of the service.

(E) Each provider of cardiac catheterization services will establish and maintain a quality assessment review process, including methodology, for reviewing the quality of cardiac catheterization procedures performed by each physician credentialed to perform such procedures. The review methodology will, at a minimum, assess the following:

(1) Appropriateness of cardiac catheterization studies and interventions;

(2) Technical quality of cardiac catheterization studies;

(3) Procedure result;

(4) Rate of therapeutic success; and

(5) Rate of procedural complications.

(F) Each provider of cardiac catheterization services will have explicit criteria based upon current recommendations of recognized professional societies and accrediting bodies, specifying the number of times a year an appropriately privileged physician will perform each catheterization procedure in order to retain privileges to perform that procedure.

(G) Each provider of cardiac catheterization services will conduct an ongoing review of all cases with mortality or significant morbidity within sixty days of the procedure.

(H) Each provider of cardiac catheterization services will establish and maintain a database to support the review process detailed in paragraph (E) of this rule. The results of analysis and review will be documented and used to guide periodic random and selected peer reviews of individual physicians with respect to maintaining their credentials to perform specific cardiac catheterization procedures.

(I) Adult cardiac catheterization service will only be provided in a fully permanent setting within the permanent frame of the building of a licensed hospital that is classified as a general hospital or a special hospital-cardiac that primarily furnishes limited services to patients with cardiac conditions.

The hospital will:

(1) Operate inpatient medical and surgical services in the same building and accessible by gurney from the cardiac catheterization laboratory;

(2) Operate an intensive/critical care unit with licensed special care beds, that is:

(a) Reviewed and accredited or certified as such as part of the hospital's accreditation or certification program in the same building;

(b) Accessible by gurney from the cardiac catheterization laboratory; and

(c) The unit will provide appropriate equipment and staff to care for coronary patients and have twenty-four hour monitoring capability.

(3) Provide a setting in the same building as the adult cardiac catheterization laboratory in which ambulatory cardiac catheterization patients can be observed for at least two to six hours after the procedure depending on the access site and the nursing assessment of the patient; and

(4) Provide adequate physician coverage to manage post-procedure complications.

(J) For the purpose of rules 3701-22-38 to 3701-22-42.1 of the Administrative Code the following references are defined and all documents are available at www.acc.org:

(1) "2012 expert consensus document" means 2012 American college of cardiology foundation/society for cardiovascular angiography and interventions expert consensus document on cardiac catheterization laboratory standards update (June 12, 2012);

(2) "2014 expert consensus document" means the 2014 society for cardiovascular angiography and interventions/American college of cardiology/American heart association expert consensus document update on percutaneous coronary intervention without on-site surgical backup (June 17, 2014);

(3) "Table 2: support services" means 2012 American college of cardiology foundation/society for cardiovascular angiography and interventions expert consensus document on cardiac catheterization laboratory standards update, table 2: optimal (recommended) on-site support services for invasive cardiac procedures (June 12, 2012).

(4) "Table 3: facility requirements" means 2014 Society for cardiovascular angiography and interventions/American college of cardiology/American heart association expert consensus document update on percutaneous coronary intervention without on-site surgical backup, table 3: facility requirements for percutaneous coronary intervention programs without on-site surgery (June 17, 2014);

(5) "Table 4: personnel recommendations" means 2014 society for cardiovascular angiography and interventions/American college of cardiology/American heart association expert consensus document update on percutaneous coronary intervention without on-site surgical backup, table 4: personnel recommendations (June 17, 2014);

(6) "Table 5: general exclusion criteria" means the 2012 American college of cardiology foundation/society for cardiovascular angiography and interventions expert consensus document on cardiac catheterization laboratory standards update, table 5: general exclusion criteria for invasive cardiac procedures in a setting without cardiothoracic surgery (June 12, 2012);

(7) "Table 5: recommendations for off-site surgical backup and case selection" means the 2014 Society for cardiovascular angiography and interventions/American college of cardiology/American heart association expert consensus document update on percutaneous coronary intervention without on-site surgical backup, table 5: recommendations for off-site surgical backup and case selection (June 17, 2014); and

(8) "Table 6: patient and lesion characteristics" means the 2014 Society for cardiovascular angiography and interventions/American college of cardiology/American heart association expert consensus document update on percutaneous coronary intervention without on-site surgical backup, table 6: patient and lesion characteristics that could be unsuitable for nonemergency procedures at facilities without an on-site cardiac surgery (June 17, 2014);

(K) For the purpose of rules 3701-22-38 to 3701-22-42.1 of the Administrative Code, major bleeding is defined as:

(1) Bleeding event within seventy two hours;

(2) Hemorrhagic stroke;

(3) Tamponade;

(4) Post-PCI transfusion for patients with a pre-procedure hemoglobin >8 g/dL; or

(5) Absolute hemoglobin decrease from pre-PCI to post-PCI of >= 3 g/dl and pre- procedure hemoglobin=<16 g/dL.