Ohio Administrative Code

Rule 3701-22-38.2 Level II cardiac catheterization service standards.

Effective: August 31, 2025

(A) Level II cardiac catheterization service or "level II service" means an adult cardiac catheterization service located in a hospital without an on-site open-heart surgery service that provides only diagnostic and authorized therapeutic cardiac catheterization procedures on an organized and regular basis.

(B) Level II services are prohibited from providing the following procedures:

(1) Transcatheter aortic valve replacement (TAVR);

(2) Revascularization of chronic total occlusion (CTO);

(3) Rotational coronary artherectomy;

(4) Alcohol septal ablation;

(5) Cardiac biopsy;

(6) Mitral valve clip;

(7) Transcatheter mitral valve (TMV) repair or replacement;

(8) Laser lead extraction;

(9) Atrial septal defect (ASD), patent foramen ovale (PFO), and ventricular septal defect (VSD) closure;

(10) Balloon aortic valvuloplasty;

(11) PCI of last remaining coronary artery;

(12) Left atrial appendage closure;

(13) Ventricular tachycardia ablation;

(14) Lead extractions; and

(15) Multivessel PCI in the setting of severe left ventricular dysfunction.

(C) Each level II service will 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 II 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 provider.

(D) Level II services will:

(1) Implement patient screening criteria consistent with the 2014 expert consensus document:

(a) Table 5: recommendations for off-site surgical backup and case selection; and

(b) Table 6: patient and lesion characteristics.

(2) Ensure that the medical director for the level II service monitors and ensures strict adherence to the patient selection criteria and treatment protocols.

(E) In addition to the general personnel and staffing requirements set forth in rule 3701-22-39 of the Administrative Code, each level II service will:

(1) Provide nursing and laboratory staff consistent with the 2014 expert consensus document, table 4: personnel recommendations; and

(2) Maintain personnel capable of endotracheal intubation and ventilator management within their scope of practice, both on-site and during transfer of the patient if necessary.

(F) In addition to the general facilities, equipment, and supplies requirements set forth in rule 3701-22-40 of the Administrative Code, each level II service will have, at a minimum, equipment consistent with the 2014 expert consensus document, table 3: facility requirements.

(G) Each level II service will comply with the safety standards set forth in rule 3701-22-41 of the Administrative Code.

(H) Each level II service will maintain a formal written transfer protocol for emergency medical/surgical management with a licensed hospital that provides open-heart surgery services, which can be reached expeditiously from the level II service by available emergency vehicle within a reasonable amount of time and that provides the greatest assurance for patient safety. The open-heart surgery service that is party to a transfer protocol is referred to as the receiving service. Each protocol will include:

(1) Provisions addressing indications, contraindications, and other criteria for the emergency transfer of patients in a timely manner;

(2) Assurance of the initiation of appropriate medical/surgical management in a timely manner;

(3) Assurance that surgical back-up is available for urgent cases during all hours of operation;

(4) Specification of mechanisms for continued substantive communication between the services party to the agreement and between their medical directors and physicians;

(5) Provisions for a collaborative training program among the staff of the services party to the agreement, including the cardiologists from the level II service and the cardiologist/cardiothoracic surgeon(s) from the receiving service;

(6) Provisions for the recommendation by the medical director of the receiving service, regarding the cardiac catheterization service's credentialing criteria; and

(7) Provisions for annual drilling activities to review and test the components of the written transfer protocol. An actual emergent patient transfer consistent with the written transfer protocol within the calendar year meets the requirement for an annual drill.

(I) Each level II service will maintain a formal written agreement with a ground and/or air ambulance service that can commit to on-site availability within thirty minutes of notification and is capable of advanced cardiac life support and intra-aortic balloon pump transfer of a patient to the hospital party per the written transfer protocol required by paragraph (H) of this rule. Ground and/or air ambulance service agreements should be consistent with the recommendations set forth in the 2014 expert consensus document, table 3: facility requirements.

(J) 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 3701-22-38 of the Administrative Code and rule 3701-22-11 of the Administrative Code.

(K) Each level II service will obtain enrollment and maintain participation in a data registry to monitor operator and institutional volumes and outcomes.

(L) Reporting: Each level II service will submit an annual report to the department by June first of each year that:

(1) Maintains patient confidentiality;

(2) Includes the numbers for the following:

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

(b) Electrophysiology studies or procedures conducted in an a cardiac catheterization laboratory or an electrophysiology procedure room;

(c) Elective PCI;

(d) Primary PCI;

(e) Post-procedure in-hospital mortality number;

(f) Vascular access injury requiring surgery or other intervention;

(g) Major bleeding as defined in paragraph (K) of rule 3701-22-38 of the Administrative Code;

(h) Emergent transfers to the receiving service for interventional medical management, that became necessary as a result of the cardiac catheterization procedure or electrophysiology study or procedure during or immediately after a cardiac catheterization procedure or an electrophysiology study or procedure; and

(i) Emergency PCI procedures performed when clinically indicated and reported to the department in accordance with paragraph (N) of this rule.

(M) Prior to the performance of any procedure, each level II service will obtain a signed informed consent form from each patient prior to performance of any procedure that includes an acknowledgment by the patient that the procedure is being performed in a cardiac catheterization service without an on-site open-heart surgery service and an acknowledgment that, if necessary as the result of an adverse event, the patient may be transferred to a receiving service for medical/surgical management.

(N) Nothing in this rule will prohibit the provision of emergency care, including emergent PCI, when clinically indicated. The service will provide notice to the department within forty-eight hours of any incident requiring action outside the scope of services authorized to be performed at the level II designation and ensure the notification:

(1) Maintains patient confidentiality;

(2) Indicates when the incident occurred;

(3) Describes the nature of the emergency and what actions were taken; and

(4) Includes the outcome.