Ohio Administrative Code

Rule 3701-84-30.2 Level II cardiac catheterization service standards.

Effective: August 1, 2017

(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 regular basis.

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

(C) 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) Atrial fibrillation ablation;

(15) Lead extractions; and

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

(D) Each provider of a level II 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 II services. Accelerated designation may be granted to a service on a case-by-case basis by the director and shall not be construed as constituting precedent for the granting of an accelerated designation for any other service provider.

(E) Level II services shall:

(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.

(F) In addition to the general personnel and staffing requirements set forth in rule 3701-84-31 of the

Administrative Code, each level II service shall:

(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.

(G) In addition to the general facilities, equipment, and supplies requirements set forth in rule 3701-84-32 of the Administrative Code, each level II service shall have, at a minimum, equipment consistent with the 2014 expert consensus document, table 3: facility requirements.

(H) Each level II service shall comply with the safety standards set forth in rule 3701-84-33 of the Administrative Code.

(I) Each level II service shall maintain a formal written transfer protocol for emergency medical/surgical management with a registered 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 shall include, but not be limited to:

(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 at all hours;

(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 staff of the services party to the

agreement, including the cardiologists from the level II service and the cardiologist/cardiothoracic surgeon 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.

(J) Each level II service shall 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 to the written transfer protocol required by paragraph (I) 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.

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

(L) Each provider of a level II service shall obtain enrollment and maintain participation in the national cardiovascular data registry/CathPCI registry (NCDR).

(M) Beginning January 1, 2017, each provider of level II services shall submit an annual report to the department based upon the data submitted to the NCDR during the preceding year. At a minimum, the report shall;

(1) Maintain patient confidentiality;

(2) Be filed with the department within one hundred twenty days after the close of the calendar year (April thirtieth); and

(3) Include the following information:

(a) All emergent transfers that became necessary during or immediately after cardiac catheterization to the receiving service for interventional medical management;

(b) The number of procedures performed in the following categories:

(i) Diagnostic;

(ii) Elective PCI; and

(iii) Primary PCI.

(c) PCI in-hospital risk adjusted rate of bleeding (all patients);

(d) PCI in-hospital risk adjusted mortality rate (patients with ST segment elevation myocardial infarction);

(e) PCI in-hospital risk adjusted mortality (ST segment elevation myocardial infarction patients excluded):

(f) As appropriate, the proportion of PCI procedures with post procedure myocardial infarction:

(i) Among hospitals routinely collecting post-PCI biomarkers; or

(ii) Among hospitals who do not routinely collect post-PCI biomarkers;

(g) Composite proportion of PCI patients with death, emergency coronary artery bypass graft, stroke, or repeat target vessel revascularization; and

(h) Median time to immediate PCI for ST segment elevation myocardial infarction patients (in minutes).

(N) Each level II service shall provide notice to the department within thirty days of receipt of their service's NCDR report, for any quarter in which the service falls at or below the twenty-fifth percentile for the specific quality metrics designated in this paragraph. The report shall include a statement for each metric not met, an explanation as to why the service did not meet the metric, and how the service intends to meet the metric in the future. The report shall include the following metrics:

(1) PCI in-hospital risk adjusted rate of bleeding (all patients);

(2) PCI in-hospital risk adjusted mortality rate (patients with ST segment elevation myocardial infarction);

(3) PCI in-hospital risk adjusted mortality (ST segment elevation myocardial infarction patients excluded);

(4) As appropriate, the proportion of PCI procedures with post procedure myocardial infarction:

(a) Among hospitals routinely collecting post-PCI biomarkers; or

(b) Among hospitals who do not routinely collect post-PCI biomarkers;

(5) Composite proportion of PCI patients with death, emergency coronary artery bypass graft, stroke, or repeat target vessel revascularization; and

(6) Median time to immediate PCI for ST segment elevation myocardial infarction patients (in minutes).

(O) Each level II service shall obtain an signed informed consent form from each patient prior to performance of any procedure. The informed consent shall include 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.

(P) Nothing in this rule shall prohibit the provision of emergency care, including emergent PCI, when clinically indicated. The service shall notify 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. The notification shall:

(1) Maintain patient confidentiality;

(2) Indicate when the incident occurred;

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

(4) Include the outcome.