Ohio Administrative Code

Rule 3701-84-30.1 Level I cardiac catheterization service standards.

Effective: May 15, 2023

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

(B) Each level I service shall perform only diagnostic cardiac catheterization procedures to diagnose anatomical and/or physiological problems in the heart. Diagnostic cardiac catheterization procedures include:

(1) Intracoronary administration of drugs;

(2) Left heart catheterization;

(3) Right heart catheterization;

(4) Coronary angiography;

(5) Basic diagnostic electrophysiology studies not involving transseptal puncture;

(6) Intra-aortic balloon pump or, if required for patient stabilization for transfer, placement of percutaneous left ventricular assist device; and

(7) Device implantation, including, but not limited to defibrillators.

(C) Each level I service will implement patient exclusion criteria consistent with the 2012 table 5: general exclusion criteria.

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

(E) Each level I service will comply with the facilities, equipment, and supplies requirements set forth in rule 3701-84-32 of the Administrative Code.

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

(G) Each level I 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 I 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 collaborative training programs among staff of the services party to the agreement, including the cardiologists from the level I 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.

(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) Reporting:

(1) Beginning January 1, 2023, and ending on December 31, 2024, each level I services will submit the following information to the department by March first of each year that;

(a) Maintains patient confidentiality;

(b) Includes the numbers for the following:

(i) Diagnostic cardiac catheterization and electrophysiology studies as provided in paragraphs (B)(1) to (B)(7) conducted in a cardiac catheterization procedure room;

(ii) Diagnostic electrophysiology studies conducted in an electrophysiology procedure room;

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

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

(v) Major bleeding as defined in paragraph (K) of rule 3701-84-30 of the Administrative Code;

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

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

(2) Beginning January 1, 2025, each level I 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 numbers for the following;

(i) Diagnostic catheterization and electrophysiology studies as provided in paragraphs (B)(1) to (B)(7) conducted in a cardiac catheterization procedure room;

(ii) Diagnostic electrophysiology studies conducted in an electrophysiology procedure room;

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

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

(v) Major bleeding as defined in paragraph (K) of rule 3701-84-30 of the Administrative Code;

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

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

(J) Prior to performance of a diagnostic procedure, each level I service shall obtain a signed informed consent form that includes an acknowledgment by the patient that the diagnostic 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.

(K) Nothing in this rule shall prohibit the provision of emergency care, including emergent PCI, when clinically indicated. The service shall 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 I 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.