

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

- (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) Level I services 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 shall implement patient exclusion criteria consistent with the 2012 table 5: general exclusion criteria.
- (D) Each level I service shall comply with the personnel and staffing requirements set forth in rule 3701-84-31 of the Administrative Code.
- (E) Each level I service shall comply with the facilities, equipment, and supplies requirements set forth in rule 3701-84-32 of the Administrative Code.
- (F) Each level I service shall 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 a 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 ninety days by the quality assessment review process required in paragraph (E) of rule 3701-84-30 of the Administrative Code.
- (I) Beginning January 1, 2017, each provider of level I services shall submit to the department an annual report for the prior year that meets the following criteria:
- (1) Maintains patient confidentiality;
  - (2) Shall be filed with the department within forty-five days after the close of the calendar year (February fourteenth); and
  - (3) Include, at a minimum, the following information:
    - (a) All emergent patient transfers that become necessary during or immediately after cardiac catheterization to the receiving service for interventional medical management;
    - (b) The number and type of procedures performed;
    - (c) Post-procedure in-hospital mortality rate;
    - (d) Vascular access injury requiring surgery or other intervention;
    - (e) Major bleeding; and
    - (f) Emergency PCI procedures performed when clinically indicated.
- (J) Each level I service shall obtain a signed informed consent form from each patient prior to performance of the diagnostic procedure. The informed consent shall include 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 notify 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. 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.

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CERTIFIED ELECTRONICALLY

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Certification

03/18/2016

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Date

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