

3701-84-30.3 Level III cardiac catheterization service standards.

- (A) Level III cardiac catheterization service or "level III service" means an adult cardiac catheterization service located in a hospital with an on-site open heart surgery service that provides all levels of diagnostic and therapeutic cardiac catheterization procedures.
- (B) Each level III service shall operate on an organized, regular, twenty-four hour a day, seven days a week basis to perform primary PCI.
- (C) Each provider of a level III service shall have provided at least one years of service performing diagnostic cardiac catheterizations prior to providing notice to the director of their intent to provide level III 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.
- (D) Each level III service shall have the following:
 - (1) An on-site adult open heart surgery service available within the same hospital as the cardiac catheterization laboratory and is immediately accessible from the cardiac catheterization laboratory by gurney;
 - (2) An experienced cardiovascular surgical team that is readily available in less than sixty minutes on a twenty-four hour a day basis in the event that emergency open heart surgery is required; and
 - (3) Support services consistent with the 2012 expert consensus document, table 2: support services.
- (E) Each level III service shall comply with the personnel and staffing requirements set forth in rule 3701-84-31 of the Administrative Code.
- (F) In addition to the general facilities, equipment, and supplies requirements set forth in rule 3701-84-32 of the Administrative Code, each level III service, shall have:
 - (1) One or more surgical suites that are equipped to accommodate thoracic and cardiac surgical procedures requiring cardiopulmonary bypass, with appropriate staff available in less than sixty minutes; and
 - (2) At a minimum, equipment consistent with the 2014 expert consensus document, table: 3 facility requirements.
- (G) Each level III service shall comply with the safety standards set forth in rule 3701-84-33 of the Administrative Code.
- (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) Each provider of a level III service shall obtain enrollment and maintain participation in the national cardiovascular data registry/CathPCI registry (NCDR). Level III services in operation as of the effective date of this rule shall obtain enrollment no

later than July 1, 2016.

- (J) Beginning January 1, 2017, each provider of level III 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 forty-five days after the close of the calendar year (February fourteenth); and
 - (3) include the following information:
 - (a) The number of procedures performed in the following categories:
 - (i) Diagnostic;
 - (ii) Elective PCI; and
 - (iii) Primary PCI.
 - (b) PCI in-hospital risk adjusted rate of bleeding (all patients);
 - (c) PCI in-hospital risk adjusted mortality rate (patients with ST segment elevation myocardial infarction);
 - (d) PCI in-hospital risk adjusted mortality (ST segment elevation myocardial infarction patients excluded);
 - (e) 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;
 - (f) Composite proportion of PCI patients with death, emergency coronary artery bypass graft, stroke, or repeat target vessel revascularization; and
 - (g) Median time to immediate PCI for ST segment elevation myocardial infarction patients (in minutes).
- (K) Each level III 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).
- (L) Each level III service provider shall obtain a signed informed consent from each patient prior to the performance of any procedure.

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CERTIFIED ELECTRONICALLY

Certification

03/18/2016

Date

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