



## Ohio Administrative Code

### Rule 3701-83-19.4 Cardiac catheterization procedures in an ambulatory surgical facility, reporting, review, quality assessment, and informed consent.

Effective: February 16, 2026

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(A) Each ASF providing cardiac catheterization procedures will report on the system prescribed by the director the ASF's volumes and outcomes.

(B) Each ASF that provides interventional services will obtain enrollment and maintain participation in a data registry to monitor volumes and outcomes.

(C) Reporting:

(1) Beginning January 1, 2026, and each calendar year thereafter, each ASF providing cardiac catheterization procedures will submit an annual report to the department for the year prior. The annual report will be due by June 1st of each year. The report will maintain patient confidentiality policy and include the following:

(a) Aggregate data for diagnostic services:

(i) The total number of diagnostic cardiac catheterization procedures;

(ii) The total number of post-procedure mortality;

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

(iv) Major bleeding as defined in paragraph (D) of this rule;

(v) Emergent transfers to the receiving service for interventional medical management, that becomes necessary as a result of the cardiac catheterization procedure; and

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



(b) Aggregate data for interventional services:

(i) The total number of cardiac catheterization procedures;

(ii) The total number of elective PCI;

(iii) The total number of primary PCI;

(iv) The total number of post-procedure mortality;

(v) The total number of vascular access injury needing surgery or other intervention;

(vi) The total number of major bleeding as defined in paragraph (D)(1) of this rule;

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

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

(D) For rules 3701-83-19.1 to 3701-83-19.5 of the Administrative Code, "major bleeding" is defined as:

(1) Bleeding event within seventy-two hours;

(2) Hemorrhagic stroke;

(3) Tamponade;

(4) Post-PCI transfusion for patients with a pre-procedure hemoglobin  $>8$  g/dL; or



(5) Absolute hemoglobin decreases from pre-PCI to post-PCI of  $\geq 3$  g/dl and pre- procedure hemoglobin  $\leq 16$  g/dL.

(E) Nothing in this rule will prevent the provision of emergency care, including emergent PCI, when clinically indicated. The ASF will provide notice to the department within forty-eight hours of any incident needing action outside the scope of services approved to be performed at the ASF 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.

(F) Major complications and emergency transfers will be reviewed at least once every sixty days by the quality assessment review process necessary in paragraph (G) of this rule.

(G) The quality assessment and performance improvement program will do all of the following:

(1) Monitor and evaluate all aspects of care including effectiveness, appropriateness, accessibility, continuity, efficiency, patient outcome, and patient satisfaction;

(2) Establish expectations, develop plans, and implement procedures to assess and improve quality of care and resolve identified problems;

(3) Establish expectations, develop plans, and implement procedures to assess and improve the health care facility's governance, management, clinical, and support processes;

(4) Establish information systems and appropriate data management processes to facilitate the collection, management, and analysis of data needed for quality assessment and performance improvement and to comply with the applicable data collection provisions of Chapter 3701-83 of the



Administrative Code;

(5) Document and report the status of the quality assessment and performance improvement program to the governing body every twelve months;

(6) Document and review all unexpected complications and adverse events, whether serious injury or death, that arise during an operation or procedure; and

(7) Hold regular meetings, chaired by the medical director of the ASF or designee, as necessary, but at least within sixty days after a serious injury or death, to review all deaths and serious injuries, and report findings. Any pattern that might indicate a problem will be investigated and remedied, if necessary.

(H) Each ASF will implement a program for proactive assessment of high-risk activities related to patient safety and to undertake appropriate improvements.

(I) Prior to performance of a diagnostic or interventional procedure, the ASF will obtain a signed informed consent form that includes an acknowledgment by the patient that the diagnostic procedure is being performed in an ASF 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 and/or surgical management.

(J) Each ASF will report to the director, in a manner and interval prescribed by the director, the data specified in the applicable rules of Chapter 3701-83 of the Administrative Code.