

CERTIFICATE OF NEED REVIEW STANDARDS FOR CARDIAC
CATHETERIZATION (CC) SERVICES
SUMMARY OF PROPOSED CHANGES

Highlights of Proposed Changes

Section 1- Applicability

- Section 1 modified only for consistency with other CON review standards.

Section 2- Definitions

- The definitions that pertain only to a certain section have been moved to that section to make it easier for the reader to identify the defined terms.
- Eliminated definitions that are no longer needed.
- Clarified definitions.
- Modified definition for cardiac catheterization procedure to exclude the implantation of cardiac permanent pacemakers and implantable cardioverter defibrillators (ICD) devices that are performed in an interventional radiology laboratory or operating room.
- Added new definition for elective PCI.
- Modified definition for therapeutic cardiac catheterization service to include transcatheter valves, other structural heart disease procedures, and left sided arrhythmia procedures.

Section 3- Initiation of Cardiac Catheterization Service

- Sections 3, 4, 5, 6, and 7 were combined as these sections related to the initiation of a CC service.
- Section modified for consistency within review standards for initiation of CC services.
- Subsection 4 was modified to reflect the SACs recommendation of the minimum 500 procedure equivalents to initiate, in which 400 must be within the category of CC procedures. Projection procedures for initiation of primary PCI decreased from 48 to 36.
- Added subsection 5 outlining requirements to initiate elective PCI without on-site open heart surgery services.
- Annual maintenance volume requirements have been moved to the project delivery requirements.

Section 4- Replace Existing Cardiac Catheterization Service or Laboratory

- The replacement section will cover both the replacement of the laboratory and equipment as well as replacing the existing service to a new geographical site as part of replacing the entire hospital.
- Replacement of a laboratory or equipment will no longer require the applicant to meet set volume requirements. Upgrades to existing CC services, without replacement of the laboratory or equipment will not require CON review/approval.
- Further clarification of replacement definition as it applies to CC laboratories and relocation of CC service to a new site.

Section 5- Expand a Cardiac Catheterization Service

- The Department eliminated the requirement to project procedure equivalents.
- The Department modified the volume requirement for existing and approved laboratories to include the SAC's recommendation of 1,400 procedure equivalents, and minimum threshold must be met in each applicable service category.

Section 6- Acquire a Cardiac Catheterization Service

- Added language for acquisition consistent with other CON review standards which includes the following:
 - Acquisition of CC services as part of the overall acquisition of a hospital.
 - Renewal of lease for angiography x-ray equipment without volume requirements.

Section 7- Medicaid Participation

- No changes proposed. Modification to section is to standardize language similar to other standards on Medicaid participation requirement.

Section 8- Project Delivery Requirements

- Divided requirements into distinct groups: quality assurance, access to care, monitoring and reporting, and specialized services.
- Annual volume requirements have been moved to the applicable project delivery requirements subsection.
- Added project delivery requirements for elective PCI without on-site open heart surgery services.

Section 9- Methodology for Computing Cardiac Catheterization Equivalents

- The Department deleted language under the previous Section 11(2) to allow for the counting of peripheral catheterizations under expansion. Further, due to elimination of volume requirements for replacement, this language is no longer necessary.
- The Department modified the procedures and weight equivalents to reflect the SAC's recommendations.

Section 10- Documentation of Projections

- The Department modified the language to reflect the minimum projected volume requirement from 48 to 36 ST segment elevation AMI cases for primary PCI services.
- The Department modified the language to reflect the addition of elective PCI services.

Section 11- Comparative Reviews and Planning Policies

- No changes proposed, except updated effective dates.

Addition of Health Services Areas - Appendix A

- Added to facilitate modifications within PCI requirements.

Current Appendix B

- Moved from previous Appendix A (identification of rural, micropolitan, and metropolitan statistical area counties).