

CARDIAC SERVICES

12 VAC 5-260-30. Accessibility; financial considerations.

A. Adult cardiac catheterization services should be accessible within a one hour driving time, under normal conditions, for 90% of Virginia's population.

B. Cardiac catheterization services should be accessible to all patients in need of services without regard to their ability to pay or the payment source.

C. Providers of cardiac catheterization services serving rural areas should facilitate the transport of patients residing in rural areas to needed cardiac catheterization services, directly or through coordinated efforts with other organizations. Preference will be given in the review of competing applications to applicants who can demonstrate a history of commitment to the development of transportation resources for rural populations.

12 VAC 5-260-40. Availability; need for new services; alternatives.

A. Need for new service. No new cardiac catheterization service should be approved unless (i) all existing cardiac catheterization laboratories located in the planning district in which the proposed new service will be located where used for at least 960 diagnostic-equivalent cardiac catheterization

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procedures for the relevant reporting period; and (ii) it can be reasonably projected that the proposed new service will perform at least 200 diagnostic equivalent procedures in the first year of operation, 500 diagnostic equivalent procedures in the second year of operation, and 800 diagnostic equivalent procedures in the third year of operation without reducing the utilization of existing laboratories in the planning district such that less than 960 diagnostic equivalent procedures are performed at any of those existing laboratories.

B. Mobile cardiac catheterization service. Proposals for the use of freestanding or mobile cardiac catheterization services should only be approved if such services will be provided at a site located on the campus of a general/community hospital and complies with all applicable sections of the state medical facilities plan as determined by the department.

C. Alternative need for new services in ~~remote~~ rural areas. Notwithstanding the standards for approval of new cardiac catheterization services outlined above, consideration will be given to the approval of new cardiac catheterization services which will be located at a general hospital located 60 minutes or more driving time, under normal conditions, from any site at which cardiac catheterization services are available if it can be reasonably projected that the proposed new services will perform at least 200 diagnostic-equivalent procedures in the first year of operation, 400 diagnostic-equivalent procedures in the second year of operation, and 600 diagnostic-equivalent procedures in the third year of operation without reducing the utilization of existing laboratories located within 60 to 70 minutes

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driving time, under normal conditions, from the proposed new service location.

D. Need for expanded service. Proposals for the expansion of cardiac catheterization services should not be approved unless all existing cardiac catheterization laboratories operated by the applicant have performed at least 1,200 diagnostic-equivalent cardiac catheterization procedures for the relevant reporting period, and it can be reasonably demonstrated that the expanded cardiac catheterization service will achieve a minimum of 200 diagnostic equivalent procedures per laboratory to be added in the first 12 months of operation, 400 diagnostic equivalent procedures in the second 12 months of operation, and 600 procedures per laboratory in the third year of operation, without reducing the utilization of existing cardiac catheterization laboratories in the planning district below 960 diagnostic equivalent procedures.

E. Replacement.

1. Proposals for the replacement of existing cardiac catheterization services should not be approved unless the equipment to be replaced has been in service for at least five years and; (i) in the case of providers located within 60 minutes driving time, under normal conditions, of alternative cardiac catheterization services, the equipment to be replaced has been used in the performance of at least 960 diagnostic-equivalent cardiac catheterization procedures in the relevant reporting period; or (ii) in the case of providers located beyond 60 minutes driving time, under normal conditions, of alternative

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cardiac catheterization services, the equipment to be replaced has been used in the performance of at least 600 diagnostic-equivalent cardiac catheterization procedures in the relevant reporting period.

2. Additionally, all proposals for replacement of cardiac catheterization services should comply with all applicable sections of this state medical facilities plan component, as determined by the department.

F. Emergency availability. Cardiac catheterization services should be available for emergency cardiac catheterization within 30 minutes or less at all times.

G. Pediatric services. No new or expanded pediatric cardiac catheterization services should be approved unless the proposed new or expanded service will be provided at: (i) a hospital that also provides open heart surgery services, provides pediatric tertiary care services, has a pediatric intensive care unit and provides neonatal special care; or (ii) a hospital that is a regional perinatal center, has a cardiac intensive care unit and provides open heart surgery services; and it can be reasonably demonstrated that each proposed laboratory will perform at least 100 pediatric cardiac catheterization procedures in the first year of operation, 200 pediatric cardiac catheterization procedures in the second year of operation and 400 pediatric cardiac catheterization procedures in the third year of operation.

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H. Emergency availability of open heart surgery. No application for new, expanded, or replacement cardiac catheterization services which includes the provision or potential provision of PTCA, transseptal puncture, transthoracic left ventricular puncture, or myocardial biopsy services should be approved unless emergency open heart surgery services are, or will be available on-site at all times at the same hospital at which the proposed new, expanded, or replacement cardiac catheterization service will be located.

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2 VAC 5-260-80. Acceptability; consumer participation.

A. The waiting time for elective open heart surgery procedures should be less than one month.

B. Providers of open heart surgery should provide a program of patient and family education regarding the nature of the patient's heart disease, and which attempts to assure the family and the patient's joint compliance in the post-operative management of the patient.

The patient and his family should be fully informed and involved in the decision-making regarding the open heart surgery.

C. Providers of open heart surgery services should have in place a mechanism for identifying travel and housing problems for patients and their families, particularly in rural areas, and provide assistance in making arrangements for these services for those patients and their families who may need them during the period of surgery and post-operative management.

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12 VAC 5-260-100. Availability; need for the new service; alternatives.

A. Need for the new service. No new open heart services should be approved unless: (i) the service is to be made available in a general hospital which has established cardiac catheterization services that have been used for the performance of at least 960 diagnostic-equivalent procedures for the relevant reporting period and has been in operation for at least 30 months; (ii) all existing open heart surgery rooms located in the planning district in which the proposed new service will be located have been used for at least 400 adult-equivalent open heart surgical procedures for the relevant reporting period; and (iii) it can be reasonably projected that the proposed new service will perform at least 150 adult-equivalent procedures in the first year of operation, 250 adult-equivalent procedures in the second year of operation, and 400 adult-equivalent procedures in the third year of operation without reducing the utilization of existing open heart surgery programs in the planning district such that less than 400 adult-equivalent open heart procedures are performed at those existing laboratories.

B. Alternative need for new services in ~~remote~~ rural areas. Notwithstanding the standards for approval of new open heart services outlined above, consideration will be given to the approval of new open heart surgery services which will be located at a general hospital located more than two hours driving time, under normal conditions, from any site at which open heart surgery services are available if it can be reasonably projected that the proposed new service will perform at least 150 adult-equivalent

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open heart procedures in the first year of operation, 225 adult-equivalent procedures in the second year of operation, and 300 adult-equivalent procedures in the third year of operation without reducing the utilization of existing open heart surgery rooms within a 120-150 minute driving time, under normal conditions, from the proposed new service location below 400 adult-equivalent open heart surgical procedures per room. Such hospitals should also have provided at least 760 diagnostic-equivalent cardiac catheterization procedures during the relevant reporting period on equipment which has been in operation at least 30 months.

C. Need for expanded service. Proposals for the expansion of open heart surgery services should not be approved unless all existing open heart surgery rooms operated by the applicant have performed at least 400 adult-equivalent open heart surgery procedures in the relevant reporting period if the facility is within two hours driving time, under normal conditions, of an existing open heart surgery service, or at least 300 adult-equivalent open heart surgery procedures in the relevant reporting period if the facility that proposes expanded services is in excess of two hours driving time, under normal conditions, of an existing open heart surgery service.

Additionally, all proposals for the expansion of open heart surgery services should comply with all applicable sections of this State Medical Facilities Plan component, as determined by the department.

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D. Replacement. Proposals for the replacement of existing open heart surgery services should not be approved unless the equipment to be replaced has been in operation for at least 30 months; and (i) in case of providers located within two hour's driving time, under normal conditions, of alternative open heart surgery services, the open heart surgery equipment to be replaced has been used in the performance of at least 400 adult-equivalent procedures in the relevant reporting period; or (ii) in the case of providers located beyond two hour's driving time, under normal conditions, of alternative open heart surgery services, the open heart surgery room to be replaced has been used in the performance of at least 300 adult-equivalent procedures in the relevant reporting period.

Additionally, all proposals for the replacement of open heart surgery services should comply with all the applicable sections of the State Medical Facilities Plan component, as determined by the department.

E. Pediatric services. No new, expanded or replacement pediatric open heart surgery service should be approved unless the proposed new, expanded or replacement service is provided at a hospital that: (i) has cardiac catheterization services which have been in operation for 30 months and that have been used in the performance of at least 200 pediatric cardiac catheterization procedures for the relevant reporting period, provides pediatric tertiary care services, has pediatric intensive care

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services and provides neonatal special care; or (ii) is a regional perinatal center and has a cardiac intensive care unit.

I certify that this regulation is true, full, and correctly dated.

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Acting State Health Commissioner