Open Heart Surgery, Transplant Surgery Committee, & Cardiac Catheterization Committee (OHTCCOM)

Perimeter Center

9960 Mayland Drive, Board Room 1;

Henrico, Virginia 23233

February 20, 2026, at 11:30 a.m.

Agenda

1. Call to Order and Welcome – Dr. Baker
2. Roll Call - Ms. Miller
3. Review of Agenda
4. Public Comment Period
5. Approval of Meeting Minutes of February 11, 2026
6. Review of Criteria and Standard for Cardiac Catheterization Services
7. Wrap-Up
8. Meeting Adjournment

Meeting Minutes

**SHSP TF – OHTC Committee**

(Open Heart Surgery, Transplant Surgery, & Catheterization Committee)

February 10, 2026

Time 6 p.m.

Virtual Connect

**Task Force Members in Attendance (alphabetical by last name):** Dr. Kathy Baker (chair), Mr. Michael Desjadon, Mr. Paul Dreyer, Ms. Amanda Dulin, Dr. Thomas Eppes

**Staff in Attendance (alphabetical by last name): –**Mr. Geoff Garner, Senior Policy Analyst, VDH OLC; VDH OLC; Mr. Antwon Jacobs COPN Supervisor; Ms. Casey Miller, Policy Analyst

Dr. Baker called the meeting to order at 6:04 p.m.

Ms. Miller took roll. The full committee is in attendance and a quorum is established.

The meeting minutes from November 11, 2026, were reviewed. Dr Eppes made a motion to approve the minutes; Dr. Baker seconded the motion. The meeting minutes were approved by everyone except Mr. Desjadon who was not present at the November 11th meeting.

There was no public comment.

Dr. Baker advised the goal for this meeting is to review the standard and definitions.

The subcommittee engaged in a conversation about the 12VAC5-230-700 travel time standard.

Dr. Eppes made a motion to remove the travel time standard; Ms. Dulin seconded the motion.

Ms. Miller took a roll call vote:

Dr. Baker - agree

Mr. Desjadon - disagree

Mr. Dreyer - agree

Ms. Dulin - agree

Dr. Eppes - agree

Dr. Baker reiterated the committee's recommendation to remove travel time from the organ transplant standards, because the committee does not think that it is relevant in this unique situation to access quality.

Mr. Garner confirmed that as the policy team is writing the new standard, the existing travel times standard regulation will be replaced with new regulation which will most likely be titled, "Pre and Post Transplant Services". It will be written as what is currently 700B.

Dr. Baker agreed.

The committee engaged in a conversation about 12VAC5-230-710, the need for new service and 12VAC5-230-720, transplant volumes, survival rates, service proficiency, and systems operations.

Mr. Desjadon recommended new language under 12VAC5-230-720, “A. Proposals to establish organ transplantation services should demonstrate that the minimum number of transplants would be performed annually when the program reaches maturity. The minimum number of transplants required by organ system is:”.

Dr. Eppes moved to accept the new language under 12VAC5-230-720, as suggested by Mr. Desjadon; Dr. Baker seconded the motion.

Ms. Miller took a roll call vote:

Dr. Baker - accept

Mr. Desjadon - accept

Mr. Dreyer - accept

Ms. Dulin - accept

Dr. Eppes – accept

The committee discussed the current table of transplant procedures and recommended new numbers.

| Minimum organ transplants | Current | Recommended change |
|---|---|---|
| Kidney | 30 | none |
| Pancreas or kidney/pancreas | 12 | 6 |
| Heart | 17 | none |
| Heart/Lung | 12 | 6 |
| Lung | 12 | 12 |
| Live | 21 | none |
| Intestine | 2 | none |

Mr. Dreyer moved to approve the changes in the table; Mr. Desjadon seconded the motion.

Ms. Miller took a roll call vote:

Dr. Baker - accept

Mr. Desjadon - accept

Mr. Dreyer - accept

Ms. Dulin -oppose

Dr. Eppes – accept

The committee discussed survivability and reviewed the chart of one-year survival rates by organ (below).

Dr. Eppes suggested that the committee should include language that the survivability rates will be reviewed annually by the one-year survival rate table.

| | |
|---|---|
| Kidney | 95% |
| Pancreas or kidney/pancreas | 90% |
| Heart | 85% |
| Heart/Lung | 70% |
| Lung | 77% |
| Liver | 86% |
| Intestine | 77% |

Mr. Dreyer referred to the scientific registry in comparison to Virginia.

Dr. Baker agreed that the committee should include a caveat that the survival rate at one year should be reviewed every two years to ensure quality is met.

Mr. Garner advised the task force is statutorily charged with the responsibility of review of all the standards at least every two years.

The committee discussed removing the table of one year survival rates by organ and adding a link to www.srtr.org.

Mr. Dreyer suggested adding language to include, “Applicants shall demonstrate that they will achieve and maintain one-year survival rates equal to or higher to the latest Tier III performance of the Scientific Registry of Transplant Recipients”.

The committee discussed implementation of the new language, removal of the current table, and replacement with the link to Tier III of the Scientific Registry of Transplant Recipients. Dr. Eppes made a motion to that effect; Amanda Dulin seconded the motion.

Ms. Miller took a roll call vote:

Dr. Baker - accept

Mr. Desjadon - accept

Mr. Dreyer - accept

Ms. Dulin - accept

Dr. Eppes – accept

Motion carried.

The committee agreed that under 12VAC5-230-730, Expansion of Transplant, there are no recommended changes.

The committee agreed that under 12VAC5-230-740, Staffing, there are no recommended changes.

Dr. Baker stated the committee has data for cardiac catheterization and asked Ms. Dulin if she had looked at this data.

Ms. Dulin advised that this area will be more competitive and that the committee can look at the data by the planning area that COPN had previously provided, additionally, the ALSD 2024 data is accessible.

The committee will meet to discuss Cardiac Catheterization Services in person at the Perimeter Center on February 20, 2026, at 11:30 a.m. Dr. Baker, Mr. Desjadon, Mr. Dreyer, and Ms. Dulin will be in attendance. Dr. Eppes will not be present.

Meeting adjourned at 7:41 p.m.

## Open Heart Surgery, Transplant Surgery Committee, & Cardiac Catheterization Committee (OHTC)

State Health Services Plan Task Force

**Updating Definitions  in the VAC regarding Open Heart Surgery, Transplant Surgery Committee, & Cardiac Catheterization**
https://law.lis.virginia.gov/admincode/title12/agency5/chapter230/section10/
Redlined Document

**Participants:**

**VDH Policy Staff:**

**Goal**: Determine which definitions in the Open Heart Surgery, Transplant Surgery Committee, & Cardiac Catheterization in the Virginia Code need the following:

- Added
- Brought up-to-date

- Deleted

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## Recommended Revisions

1. **Wait Time** –

2. **Travel Time -**

3. **SHSP** –

4. **SMFP -**

12VAC5-230-10. Definitions.

The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

**"Acute psychiatric services"** means hospital-based inpatient psychiatric services provided in distinct inpatient units in general hospitals or freestanding psychiatric hospitals.

**"Acute substance abuse disorder treatment services"** means short-term hospital-based inpatient treatment services with access to the resources of (i) a general hospital, (ii) a psychiatric unit in a general hospital, (iii) an acute care addiction treatment unit in a general hospital licensed by the Department of Health, or (iv) a chemical dependency specialty hospital with acute care medical and nursing staff and life support equipment licensed by the Department of Behavioral Health and Developmental Services.

**"Bassinet"** means an infant care station, including warming stations and isolettes.

**"Bed"** means that unit, within the complement of a medical care facility, subject to COPN review as required by Article 1.1 (§ 32.1-102.1 et seq.) of the Code of Virginia and designated for use by patients of the facility or service. For the purposes of this chapter, bed does include cribs and bassinets used for pediatric patients but does not include cribs and bassinets in the newborn nursery or neonatal special care setting.

**"Cardiac catheterization"** means an invasive procedure where a flexible tube is inserted into the patient through an extremity blood vessel and advanced under fluoroscopic guidance into the heart

chambers or coronary arteries. A cardiac catheterization may be conducted for diagnostic or therapeutic purposes but does not include a simple right heart catheterization for monitoring purposes as might be performed in an electrophysiology laboratory, pulmonary angiography as an isolated procedure, or cardiac pacing through a right electrode catheter.

**"Commissioner"** means the State Health Commissioner.

**"Competing applications"** means applications for the same or similar services and facilities that are proposed for the same health planning district, or same health planning region for projects reviewed on a regional basis, and are in the same batch review cycle.

**"Complex therapeutic cardiac catheterization"** means the performance of cardiac catheterization for the purpose of correcting or improving certain conditions that have been determined to exist in the heart or great arteries or veins of the heart, specifically catheter-based procedures for structural treatment to correct congenital or acquired structural or valvular abnormalities.

**"Computed tomography" or "CT"** means a noninvasive diagnostic technology that uses computer analysis of a series of cross-sectional scans made along a single axis of a bodily structure or tissue to construct an image of that structure.

**"Continuing care retirement community" or "CCRC"** means a retirement community consistent with the requirements of Chapter 49 (§ 38.2-4900 et seq.) of Title 38.2 of the Code of Virginia.

**"COPN"** means a Medical Care Facilities Certificate of Public Need for a project as required in Article 1.1 (§ 32.1-102.1 et seq.) of Chapter 4 of Title 32.1 of the Code of Virginia.

**"COPN program"** means the Medical Care Facilities Certificate of Public Need Program implementing Article 1.1 (§ 32.1-102.1 et seq.) of Chapter 4 of Title 32.1 of the Code of Virginia.

**"DEP"** means diagnostic equivalent procedure, a method for weighing the relative value of various cardiac catheterization procedures as follows: a diagnostic cardiac catheterization equals 1 DEP, a simple therapeutic cardiac catheterization equals 2 DEPs, a same session procedure (diagnostic and simple therapeutic) equals 3 DEPs, and a complex therapeutic cardiac catheterization equals 5 DEPs. A multiplier of 2 will be applied for a pediatric procedure (i.e., a pediatric diagnostic cardiac catheterization equals 2 DEPs, a pediatric simple therapeutic cardiac catheterization equals 4 DEPs, and a pediatric complex therapeutic cardiac catheterization equals 10 DEPs.)

**"Diagnostic cardiac catheterization**" means the performance of cardiac catheterization for the purpose of detecting and identifying defects in the great arteries or veins of the heart or abnormalities in the heart structure, whether congenital or acquired.

**"Direction"** means guidance, supervision, or management of a function or activity.

**"Gamma knife®"** means the name of a specific instrument used in stereotactic radiosurgery.

**"Health planning district"** or "Planning district" means means the same contiguous areas designated as planning districts by the Virginia Department of Housing and Community Development or its successor.

**"Health planning region"** or "Planning region" means a contiguous geographic area of the Commonwealth as designated by the State Board of Health with a population base of at least 500,000 persons, characterized by the availability of multiple levels of medical care services, reasonable travel time for tertiary care, and congruence with planning districts.

**"Health system"** means an organization of two or more medical care facilities, including hospitals, that are under common ownership or control and are located within the same health planning district, or health planning region for projects reviewed on a regional basis.

**"Hospital"** means a medical care facility licensed as an inpatient hospital or outpatient surgical center by the Department of Health or as a psychiatric hospital by the Department of Behavioral Health, and Developmental Services.

**"ICF/MR"** means an intermediate care facility for the mentally retarded.

**"Indigent"** means any person whose gross family income is equal to or less than 200% of the federal Nonfarm Poverty Level or income levels A through E of 12VAC5-200-10 and who is uninsured.

**"Inpatient"** means a patient who is hospitalized longer than 24 hours for health or health related services.

**"Intensive care beds" or "ICU"** means inpatient beds located in the following units or categories:

1. General intensive care units are those units where patients are concentrated by reason of serious illness or injury regardless of diagnosis. Special lifesaving techniques and equipment are immediately available and patients are under continuous observation by nursing staff;

2. Cardiac care units, also known as Coronary Care Units or CCUs, are units staffed and equipped solely for the intensive care of cardiac patients; and

3. Specialized intensive care units are any units with specialized staff and equipment for the purpose of providing care to seriously ill or injured patients based on age selected categories of diagnoses, including units established for burn care, trauma care, neurological care, pediatric care, and cardiac surgery recovery but does not include bassinets in neonatal special care units.

**"Lithotripsy"** means a noninvasive therapeutic procedure to (i) crush renal and biliary stones using shock waves (i.e., renal lithotripsy) or (ii) treat certain musculoskeletal conditions and relieve the pain associated with tendonitis (i.e., orthopedic lithotripsy).

**"Long-term acute care hospital" or "LTACH"** means an inpatient hospital that provides care for patients who require a length of stay greater than 25 days and is, or proposes to be, certified by the Centers for Medicare and Medicaid Services as a long-term care inpatient hospital pursuant to 42

CFR Part 412. An LTACH may be either a freestanding facility or located within an existing or host hospital.

**"Magnetic resonance imaging" or "MRI"** means a noninvasive diagnostic technology using a nuclear spectrometer to produce electronic images of specific atoms and molecular structures in solids, especially human cells, tissues and organs.

**"Medical rehabilitation"** means those services provided consistent with 42 CFR 412.23 nd 412.24.

**"Medical/surgical"** means those services available for the care and treatment of patients not requiring specialized services.

**"Minimum survival rates"** means the base percentage of transplant recipients who survive at least one year or for such other period of time as specified by the United Network for Organ Sharing (UNOS).

**"Neonatal special care"** means care for infants in one or more of the higher service levels designated in 12VAC5-410-443 .

**"Nursing facility"** means those facilities or components thereof licensed to provide long-term nursing care.

**"Obstetrical services"** means the distinct organized program, equipment and care related to pregnancy and the delivery of newborns in inpatient facilities.

**"Off-site replacement"** means the relocation of existing beds or services from an existing medical care facility site to another location within the same health planning district.

**"Open heart surgery"** means a surgical procedure requiring the use or immediate availability of a heart-lung bypass machine or "pump." The use of the pump during the procedure distinguishes "open heart" from "closed heart" surgery.

**"Operating room"** means a room used solely or principally for the provision of surgical procedures involving the administration of anesthesia, multiple personnel, recovery room access, and a fully controlled environment.

**"Operating room use"** means the amount of time a patient occupies an operating room and includes room preparation and cleanup time.

**"Operating room visit"** means one session in one operating room in an inpatient hospital or outpatient surgical center, which may involve several procedures. Operating room visit may be used interchangeably with "operation" or "case."

**"Outpatient"** means a patient who visits a hospital, clinic, or associated medical care facility for diagnosis or treatment, but is not hospitalized 24 hours or longer.

**"Pediatric"** means patients younger than 18 years of age. Newborns in nurseries are excluded from this definition.

**"Perinatal services"** means those resources and capabilities that all hospitals offering general level newborn services as described in 12VAC5-410-443 must provide routinely to newborns.

**"PET/CT scanner"** means a single machine capable of producing a PET image with a concurrently produced CT image overlay to provide anatomic definition to the PET image. For the purpose of granting a COPN, the State Board of Health pursuant to § 32.1-102.2 A 6 of the Code of Virginia has designated PET/CT as a specialty clinical service. A PET/CT scanner shall be reviewed under the PET criteria as an enhanced PET scanner unless the CT unit will be used independently. In such cases, a PET/CT scanner that will be used to take independent PET and CT images will be reviewed under the applicable PET and CT services criteria.

**"Planning horizon year"** means the particular year for which bed or service needs are projected.

**"Population"** means the census figures shown in the most current series of projections published by a demographic entity as determined by the commissioner.

**"Positron emission tomography" or "PET"** means a noninvasive diagnostic or imaging modality using the computer-generated image of local metabolic and physiological functions in tissues produced through the detection of gamma rays emitted when introduced radionuclides decay and release positrons. A PET device or scanner may include an integrated CT to provide anatomic structure definition.

**"Primary service area"** means the geographic territory from which 75% of the patients of an existing medical care facility originate with respect to a particular service being sought in an application.

**"Procedure"** means a study or treatment or a combination of studies and treatments identified by a distinct ICD-10 or CPT code performed in a single session on a single patient.

**"Qualified"** means meeting current legal requirements of licensure, registration, or certification in Virginia or having appropriate training, including competency testing, and experience commensurate with assigned responsibilities.

**"Radiation therapy"** means treatment using ionizing radiation to destroy diseased cells and for the relief of symptoms. Radiation therapy may be used alone or in combination with surgery or chemotherapy.

**"Relevant reporting period"** means the most recent 12-month period, prior to the beginning of the applicable batch review cycle, for which data is available from VHI or a demographic entity as determined by the commissioner.

**"Rural"** means territory, population, and housing units that are classified as "rural" by the Bureau of the Census of the U.S. Department of Commerce, Economic and Statistics Administration.

**"Simple therapeutic cardiac catheterization"** means the performance of cardiac catheterization for the purpose of correcting or improving certain conditions that have been determined to exist in the heart, specifically catheter-based treatment procedures for relieving coronary artery narrowing.

**"SMFP"** means the state medical facilities plan as contained in Article 1.1 (§ 32.1-102.1 et seq.) of Chapter 4 of Title 32.1 of the Code of Virginia used to make medical care facilities and services needs decisions.

**"Stereotactic radiosurgery" or "SRS"** means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a therapeutic dose to a tissue volume. SRS may be delivered in a single session or in a fractionated course of treatment up to five sessions.

**"Stereotactic radiotherapy" or "SRT"** means more than one session of stereotactic radiosurgery.

**"Substance abuse disorder treatment services"** means services provided to individuals for the prevention, diagnosis, treatment, or palliation of chemical dependency, which may include attendant medical and psychiatric complications of chemical dependency. Substance abuse disorder treatment services are licensed by the Department of Behavioral Health, and Developmental Services.

**"Supervision"** means to direct and watch over the work and performance of others.

**"Use rate"** means the rate at which an age cohort or the population uses medical facilities and services. The rates are determined from periodic patient origin surveys conducted for the department by the regional health planning agencies or other health statistical reports authorized by Chapter 7.2 (§ 32.1-276.2 et seq.) of Title 32.1 of the Code of Virginia.

**"VHI"** means Virginia Health Information, the health data organization defined in § 32.1-276.4 of the Code of Virginia and under contract with the Virginia Department of Health.

**Statutory Authority**

§§ 32.1-12 and 32.1-102.2 of the Code of Virginia.

## Criteria and Standards for Open Heart Surgery

### 12VAC5-230-440. Travel time.

A. Open heart surgery services should be within 60 minutes driving time one way under normal conditions of 95% of the population of the health planning district using mapping software as determined by the commissioner.

B. Such services shall be available 24 hours a day, seven days a week.

### 12VAC5-230-450. Need for new service.

A. No new open heart services should be approved unless:

1. The service will be available in an inpatient hospital with an established cardiac catheterization service that has performed an average of 1,200 DEPs for the relevant reporting period and has been in operation for at least 30 months;

2. Open heart surgery services located in the health planning district performed an average of 400 open heart and closed heart surgical procedures for the relevant reporting period; and

3. The proposed new service will perform at least 150 procedures per room in the first year of operation and 250 procedures per room in the second year of operation without significantly reducing the utilization of existing open heart surgery services in the health planning district.

B. Preference may be given to a project that locates new open heart surgery services at an inpatient hospital more than 60 minutes driving time one way under normal condition from any site in which open heart surgery services are currently available and:

1. The proposed new service will perform an average of 150 open heart procedures in the first year of operation and 200 procedures in the second year of operation without significantly reducing the utilization of existing open heart surgery rooms within two hours driving time one way under normal conditions from the proposed new service location below 400 procedures per room; and

2. The hospital provided an average of 1,200 cardiac catheterization DEPs during the relevant reporting period in a service that has been in operation at least 30 months.

**12VAC5-230-460. Expansion of service.**

Proposals to expand open heart surgery services shall demonstrate that existing open heart surgery rooms operated by the applicant have performed an average of:

1. 400 adult equivalent open heart surgery procedures in the relevant reporting period if the proposed increase is within one hour driving time one way under normal conditions of an existing open heart surgery service; or

2. 300 adult equivalent open heart surgery procedures in the relevant reporting period if the proposed service is in excess of one hour driving time one way under normal conditions of an existing open heart surgery service in the health planning district.

**12VAC5-230-470. Pediatric open heart surgery services.**

No new pediatric open heart surgery service should be approved unless the proposed new service is provided at an inpatient hospital that:

1. Has pediatric cardiac catheterization services that have been in operation for 30 months and have performed an average of 200 pediatric cardiac catheterization procedures for the relevant reporting period; and

2. Has pediatric intensive care services and provides specialty or subspecialty neonatal special care.

**12VAC5-230-480. Staffing.**

A. Open heart surgery services should have a medical director who is board certified in cardiovascular or cardiothoracic surgery by the appropriate board of the American Board of Medical Specialists.

In the case of pediatric cardiac surgery, the medical director should be board certified in cardiovascular or cardiothoracic surgery, with special qualifications and experience in pediatric cardiac surgery and congenital heart disease, by the appropriate board of the American Board of Medical Specialists.

B. Cardiac surgery should be under the direct supervision of one or more qualified physicians.

Pediatric cardiac surgery services should be under the direct supervision of one or more qualified physicians.

## Part IX. Organ Transplant

**12VAC5-230-700. Travel time.**

A. Organ transplantation services should be accessible within two hours driving time one way under normal conditions of 95% of Virginia's population using mapping software as determined by the commissioner.

B. Providers of organ transplantation services should facilitate access to pre and post transplantation services needed by patients residing in rural locations be establishing part-time satellite clinics.

**12VAC5-230-710. Need for new service.**

A. There should be no more than one program for each transplantable organ in a health planning region.

B. Performance of minimum transplantation volumes as cited in 12VAC5-230-720 does not indicate a need for additional transplantation capacity or programs.

Statutory Authority

**12VAC5-230-720. Transplant volumes; survival rates; service proficiency; systems operations.**

A. Proposals to establish organ transplantation services should demonstrate that the minimum number of transplants would be performed annually when the program reaches maturity. The minimum number transplants of required by organ system is:

| | |
|---|---|
| Kidney | 30 |
| Pancreas or kidney/pancreas | ~~12~~ 6 |
| Heart | 17 |
| Heart/Lung | ~~12~~ 6 |
| Lung | 12 |
| Liver | 21 |
| Intestine | 2 |

Note: Any proposed pancreas transplant program must be a part of a kidney transplant program that has achieved a minimum volume standard of 30 cases per year for kidney transplants as well as the minimum transplant survival rates stated in subsection B of this section.

B. ~~Applicants shall demonstrate that they will achieve and maintain at least the minimum transplant patient survival rates. Minimum one-year survival rates listed by organ system are:~~ Applicants shall demonstrate that they will achieve and maintain one-year survival rates equal to or higher to the latest Tier III performance of the Scientific Registry of Transplant Recipients <inbed link www.srtr.org >

| | |
|---|---|
| ~~Kidney~~ | ~~95%~~ |
| ~~Pancreas or kidney/pancreas~~ | ~~90%~~ |
| ~~Heart~~ | ~~85%~~ |

| | |
|---|---|
| ~~Heart/Lung~~ | ~~70%~~ |
| ~~Lung~~ | ~~77%~~ |
| ~~Liver~~ | ~~86%~~ |
| ~~Intestine~~ | ~~77%~~ |

**12VAC5-230-730. Expansion of transplant services.**

A. Proposals to expand organ transplantation services shall demonstrate at least two years successful experience with all existing organ transplantation systems at the hospital.

B. Preference may be given to a project expanding the number of organ systems being transplanted at a successful existing service rather than developing new programs that could reduce existing program volumes.

**12VAC5-230-740. Staffing.**

Organ transplant services should be under the direct supervision of one or more qualified physicians.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.



## Article 1. Criteria and Standards for Cardiac Catheterization Services

**12VAC5-230-380. Travel time.**

Article 1
Criteria and Standards for Cardiac Catheterization Services

Cardiac catheterization services should be within 60 minutes driving time one way under normal conditions of 95% of the population of the health planning district using mapping software as determined by the commissioner.

**Historical Notes**

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

**12VAC5-230-390. Need for new service.**

A. No new fixed site cardiac catheterization service should be approved for a health planning district unless:

1. Existing fixed site cardiac catheterization services located in the health planning district performed an average of 1,200 cardiac catheterization DEPs per existing and approved laboratory for the relevant reporting period;

2. The proposed new service will perform an average of 200 DEPs in the first year of operation and 500 DEPs in the second year of operation; and

3. The utilization of existing services in the health planning district will not be significantly reduced.

B. Proposals for mobile cardiac catheterization laboratories should be approved only if such laboratories will be provided at a site located on the campus of an inpatient hospital. Additionally, applicants for proposed mobile cardiac catheterization laboratories shall be able to project that they will perform an average of 200 DEPs in the first year of operation and 350 DEPs in the second year of operation without significantly reducing the utilization of existing laboratories in the health planning district below 1,200 procedures.

C. Preference may be given to a project that locates new cardiac catheterization services at an inpatient hospital that is 60 minutes or more driving time one way under normal conditions from existing services if the applicant can demonstrate that the proposed new laboratory will perform an average of 200 DEPs in the first year of operation and 400 DEPs in the second year of operation without significantly reducing the utilization of existing laboratories in the health planning district.

**12VAC5-230-400. Expansion of services.**

Proposals to increase cardiac catheterization services should be approved only when:

1. All existing cardiac catheterization laboratories operated by the applicant's facilities where the proposed expansion is to occur have performed an average of 1,200 DEPs per existing and approved laboratory for the relevant reporting period; and

2. The applicant can demonstrate that the expanded service will achieve an average of 200 DEPs per laboratory in the first 12 months of operation and 400 DEPs in the second 12 months of operation without significantly reducing the utilization of existing cardiac catheterization laboratories in the health planning district.

**12VAC5-230-410. Pediatric cardiac catheterization.**

No new or expanded pediatric cardiac catheterization services should be approved unless:

1. The proposed service will be provided at an inpatient hospital with open heart surgery services, pediatric tertiary care services or specialty or subspecialty level neonatal special care;

2. The applicant can demonstrate that the proposed laboratory will perform at least 100 pediatric cardiac catheterization procedures in the first year of operation and 200 pediatric cardiac catheterization procedures in the second year of operation; and

3. The utilization of existing pediatric cardiac catheterization laboratories in the health planning district will not be reduced below 100 procedures per year.

**12VAC5-230-420. Nonemergent cardiac catheterization.**

A. Simple therapeutic cardiac catheterization. Proposals to provide simple therapeutic cardiac catheterization are not required to offer open heart surgery service available on-site in the same hospital in which the proposed simple therapeutic service will be located. However, these programs shall adhere to the requirements described in subdivisions 1 through 9 of this subsection.

The programs shall:

1. Participate in the Virginia Heart Attack Coalition, the Virginia Cardiac Services Quality Initiative, and the Action Registry-Get with the Guidelines or National Cardiovascular Data Registry to monitor quality and outcomes;

2. Adhere to strict patient-selection criteria;

3. Perform annual institutional volumes of 300 cardiac catheterization procedures, of which at least 75 should be percutaneous coronary intervention (PCI) or as dictated by American College of Cardiology (ACC)/American Heart Association (AHA) Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories effective 1991;

4. Use only AHA/ACC-qualified operators who meet the standards for training and competency;

5. Demonstrate appropriate planning for program development and complete both a primary PCI development program and an elective PCI development program that includes routine care process and case selection review;

6. Develop and maintain a quality and error management program;

7. Provide PCI 24 hours a day, seven days a week;

8. Develop and maintain necessary agreements with a tertiary facility that must agree to accept emergent and nonemergent transfers for additional medical care, cardiac surgery, or intervention; and

9. Develop and maintain agreements with an ambulance service capable of advanced life support and intra-aortic balloon pump transfer that guarantees a 30-minute or less response time.

B. Complex therapeutic cardiac catheterization. Proposals to provide complex therapeutic cardiac catheterization should be approved only when open heart surgery services are available on-site in the same hospital in which the proposed complex therapeutic service will be located. Additionally, these complex therapeutic cardiac catheterization programs will be required to participate in the Virginia Cardiac Services Quality Initiative and the Virginia Heart Attack Coalition.

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009; amended, Virginia Register Volume 37, Issue 14, eff. March 31, 2021.

**12VAC5-230-430. Staffing.**

A. Cardiac catheterization services should have a medical director who is board certified in cardiology and has clinical experience in performing physiologic and angiographic procedures.

In the case of pediatric cardiac catheterization services, the medical director should be board-certified in pediatric cardiology and have clinical experience in performing physiologic and angiographic procedures.

B. Cardiac catheterization services should be under the direct supervision or one or more qualified physicians. Such physicians should have clinical experience in performing physiological and angiographic procedures.

Pediatric catheterization services should be under the direct supervision of one or more qualified physicians. Such physicians should have clinical experience in performing pediatric physiologic and angiographic procedures.