



DNV GL - HEALTHCARE VAD FACILITY CREDENTIALING PROGRAM REQUIREMENTS

Revision 17.0

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Use of DNV GL VAD Facility Credentialing Program Requirements

Effective date

DNV GL Healthcare (DNV GL) VAD Facility Credentialing Program document.
Requirements 17.0
Effective Date: 21 July 2017

National Professional Organizations - Standards of Practice

The 2013 International Society for Heart and Lung Transplantation Guidelines for
Mechanical Circulatory Support: Executive Summary

http://www.ishlt.org/ContentDocuments/JHLT_Feb13_MCS_Guidelines.pdf and

the HFSA 2010 Comprehensive Heart Failure Practice Guidelines

<http://www.hfsa.org/heart-failure-guidelines-2/>

referenced in these VAD Credentialing Program Requirements are consultative and
considered in the credentialing decision.

Federal Laws, Rules, and Regulations

The most current version of Federal law and the Code of Federal Regulations
referenced in this DNV GL VAD Facility Credentialing Program document are
incorporated herein by reference and constitute Ventricular Assist Device for
Destination Therapy Facility Credentialing Requirements set out under Medicare
Decision Memo for Ventricular Assist Devices for Bridge-to-Transplant and Destination
Therapy (CAG-00432R).

Glossary

CFR	Code of Federal Regulations
CMS	Centers for Medicare Medicaid Services
CoPs	Conditions of Participation
ED	Emergency Department
EMS	Emergency Medical Systems
FMEA	Failure Mode Effect Analysis
HFSA	Heart Failure Society of America
ISHLT	International Society for Heart and Lung Transplantation
PI	Performance Improvement
QA	Quality Assessment
QI	Quality Improvement
QMS	Quality Management System
RCA	Root Cause Analysis
VAD	Ventricular Assist Device

QUALITY MANAGEMENT SYSTEM (QM)

QM.1 QUALITY MANAGEMENT SYSTEM

The governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the VAD Program, medical staff, and administrative officials) is responsible and accountable for ensuring that the VAD Program implements and maintains an effective quality management system (QMS). This QMS shall ensure that corrective and preventive actions taken by the VAD Program are implemented, measured, and monitored.

In addition to any other QMS standard, the VAD Program is required to comply with QM.1 at all times as part of its QMS.

- CR.1 The VAD Program must develop, implement, and maintain an ongoing system for measuring, monitoring, and managing quality and patient safety.
- CR.2 The VAD Program must implement quality assessment (QA) and performance improvement (PI) efforts to address priorities for improved quality of care and patient safety and those corrective and preventive actions are implemented and evaluated for effectiveness.
- CR.3 The standards for QA and PI will focus on using information derived from measurement data to improve or validate clinical practice.
- CR.4 The VAD Program must have a formal documentation process for all policies, procedures, protocols, and forms.
 - CR.4a All policies, procedures, protocols and forms are reviewed at least annually with date of the review/revision documented.
 - CR.4b All previous policies, procedures, protocols, and forms are removed from any manuals, references or patient care areas to ensure that only the most current versions are available for use.
- CR.5 Control of records: the VAD Program ensures that suitable records are maintained.
- CR.6 The VAD Program conducts internal reviews of its processes and resultant corrective/preventive action measures are implemented and verified to be effective.
 - CR.6a At the time of the credentialing survey, the established VAD Program must provide at least 6 months of collected data on each performance measure and 12 months of data annually thereafter. At the time of the six-month follow-up survey for initial VAD Programs, the Program must provide cumulative collected data on each performance measure and 12 months of data annually thereafter.
 - CR.6b The VAD Program is accountable for ensuring the accuracy and completeness of the performance measure data.
 - CR.6c Feedback shall be given to clinicians who fail to meet VAD Program goals.
- CR.7 The VAD Program has established measurable quality objectives and the results are analyzed.

- CR.8 Appropriate information has been submitted to the host hospital's oversight group for quality management as well as top management for review and analysis during a management review process.

QM.2 QUALITY OUTLINE

The VAD Program shall clearly outline its methodology, practice, and related policies for addressing how quality and performance are measured, monitored, analyzed, and continually improved to promote favorable health outcomes and reduce risks for patients.

QM.3 QUALITY OBJECTIVES

The governing body shall ensure that VAD Program quality objectives, including those needed to meet requirements for the VAD Program, are established. The quality objectives shall be measurable and consistent with the DNV GL VAD Facility Credentialing Program.

QM.4 VAD PROGRAM MANAGEMENT REPRESENTATIVE

A VAD Program representative shall be designated and shall have the responsibility and authority for ensuring requirements of the QMS are implemented and maintained for the VAD Program.

QM.5 DOCUMENTATION AND MANAGEMENT REVIEWS

Any variation, deficiency, or non-conformity identified by the VAD Program shall be addressed by the VAD Program. Appropriate corrective or preventive action will be determined, applied, and documented. Documentation of activities may take the form of a Failure, Mode and Effect Analysis (FMEA), Root Cause Analysis (RCA), Performance Report, non-Conformity Report, specific Improvement Project analysis, etc. This documentation shall become a part of the host hospital's Management Review performed at regular intervals, at a minimum of once annually. Feedback to clinicians who fail to meet the Program's goals shall be included as part of the Management Review.

QM.6 SYSTEM REQUIREMENTS

In establishing the VAD Program QMS, the VAD Program shall be required to have the following as a part of this system:

- CR.1 A multidisciplinary group to oversee the QMS that includes at least a senior management representative, VAD Program representative (QM.4), VAD Program Coordinator, cardiovascular surgeon, and practitioners who must be doctors of medicine or osteopathy. The VAD Program should also include consideration of registered nurses, social workers, palliative care specialists, dieticians, and perfusionists as representatives.
- CR.2 Written document defining the VAD Program QMS, to include all clinical and nonclinical services;
- CR.3 Measurable Quality Objectives; and,
- CR.4 Goal Measurement/ prioritization of activities based in some manner on:

- CR.4a Problem-prone areas, processes, or functions;
- CR.4b A consideration of the incidence, prevalence and severity of problems in these areas, processes or functions, and;
- CR.4c A consideration of efforts to affect health outcomes, improve patient safety and quality of care.

QM.7 MEASUREMENT, MONITORING, ANALYSIS

The VAD Program shall strive to optimize its overall effectiveness of processes and systems of the service. This goal shall be accomplished by identifying primary performance measures for each component and for the Program function as a whole (both process and outcomes measures) and by employing the methodologies for collaboration with key stakeholders.

Evaluations of the VAD Program should encompass overall patient outcomes, linkages among key components of the VAD Program and potential problems that impede the care provided under the VAD Program.

- CR.1 The VAD Program must collect and analyze data on at least four performance measures related to or identified in clinical practice guidelines:
 - CR.1a Two of the measures must be clinical process or outcomes measures.
 - CR.1b The two remaining measures may also be clinical or related to health status, functional status, administrative or financial areas, or patient perception of care.

Measures chosen should be evidenced-based, relevant, valid, and reliable. Emphasis will be on the use of performance measures for improving care. Furthermore, the VAD Program shall develop performance measures and strategies for measuring, refining, and reassessing the following key program components:

- CR.2 Performance Measurement and Improvement:
 - CR.2a Comprehensive and organized approach to performance improvement
 - CR.2b Variances tracked at the individual patient level;
 - CR.2c Data tracking to evaluate process measures and participant outcomes;
 - CR.2d Evaluation of the patient/family perception of quality care survey;
 - CR.2e Quality and integrity of the data collected is maintained; and,
 - CR.2f Effectiveness of the interventions implemented in response to improvement opportunities identified by the measurement activity.
- CR.3 Sub-acute care and secondary prevention including measures of patient outcomes and avoidance of complications post-VAD placement.
- CR.4 Rehabilitation with performance measures to evaluate patient outcomes (mortality, functional status, and community discharge) and the percentage of VAD patients who require transfer to a sub-acute or acute rehabilitation facility post discharge.

- CR.5 The VAD Program will establish specific guidelines related to the post-discharge education of patient, family and / or primary caregivers, and EMS / ED teams local to the patient's residence post-discharge including:
 - CR.5a Patient/family care training with each patient and primary caregiver to ensure that patients and their caregivers have proper post-hospitalization education prior to discharge;
 - CR.5b Emergency notification system: the VAD patient and primary caregivers must demonstrate proficiency in the ability to notify the appropriate resources in case of an emergency; and,
 - CR.5c EMS training: EMS and ED teams local to the patient's residence must be informed of the ensuing patient discharge. The VAD Program Team will provide education to the appropriate personnel (establish and maintain open communication with the local EMS and ED Teams).
- CR.6 The VAD Program shall evaluate all organized services and processes, both direct and supportive, including services provided by any contracted service. The monitoring shall include the use of internal reviews of the VAD Program Measurement, monitoring and analysis of processes of the VAD Program have the ability to detect variation, identify problem processes, identify both positive and negative outcomes, and effectiveness of actions taken to improve performance and/or reduce risks.
- CR.7 The VAD program shall take measures to ensure the highest return percentage of "patient perception of quality of care surveys" completed by each patient enrolled in the VAD Program.
- CR.8 The organization shall determine and select opportunities for VAD Program future needs and expectations.

NOTE: Examples can include breakthrough change, innovation and re-organization.

QM.8 PATIENT SAFETY SYSTEM

- CR.1 The host hospital shall have a means for establishing clear expectations for identifying and detecting the prevalence and severity of incidents that impact or threaten patient safety. This shall include medical errors and adverse patient events.
- CR.2 The host hospital's Patient Safety System shall be documented and shall address the following:
 - CR.2a Detection;
 - CR.2b Preventative and corrective action;
 - CR.2c Defined processes to reduce risk;
 - CR.2d Implementation of action plans;
 - CR.2e On-going measurement to ensure action effectiveness;
 - CR.2f Management review of response and resource allocation to the results of the patient adverse event and other analyses; and,
 - CR.2g Policy and practice of informing patients and/or families about unexpected adverse events.

PROGRAM MANAGEMENT (PM)

The VAD Program shall establish, document, implement and maintain the VAD Facility Credentialing Program criteria and continually improve VAD Program effectiveness in accordance with the requirements of this DNV GL VAD Facility Credentialing Program.

PM.1 TOP MANAGEMENT

- CR.1 The host hospital top management is responsible and accountable for ensuring the following:
 - CR.1a The host hospital must be accredited by an organization approved by CMS or certified by the state agency acting on behalf of CMS;
 - CR.1b The VAD Program is in compliance with all applicable Federal and State laws regarding the health and safety of its patients;
 - CR.1c The VAD Program is licensed by the appropriate State, if applicable;
 - CR.1d Criteria that include aspects of individual character, competence, training, experience and judgment is established for the selection of individuals working for the VAD Program, directly or under contract;
 - CR.1e The personnel working in the VAD Program are properly licensed or otherwise meet all applicable Federal, State, and local laws;
 - CR.1f Responsibilities and authorities are defined and communicated within the VAD Program; and,
 - CR.1g Appointment and qualifications of the Medical Director for the VAD Program.
 - CR.1g(i) The Medical Director for the VAD Program will be a Cardiologist, Cardiothoracic Surgeon, or other medical professional with qualifications as defined for diagnosis and treatment of cardiovascular disease.

PM.2 MANAGEMENT COMMITMENT

Host hospital top management shall provide evidence of its commitment to the development and implementation of the VAD Program and continually improving its effectiveness by:

- CR.1 Communicating to the VAD Program the importance of meeting customer as well as statutory and regulatory requirements;
- CR.2 Establishing the VAD Program, ensuring that objectives are established; and,
- CR.3 Conducting VAD Program reviews and ensuring the availability of resources.

NURSING SERVICES (NS)

NS.1 NURSING SERVICES

- CR.1 The host hospital must have a well-organized nursing service with a plan of administrative authority and delineation of responsibilities for the delivery of patient care under the VAD Program.
- CR.2 There shall be 24-hour nursing services and a VAD coordinator must coordinate with nurse managers, the supervision, and evaluation of the nursing care for each patient of the VAD Program.
- CR.3 Inpatient units providing care to a VAD patient must have documentation that all nurses caring for the VAD patient population have passed initial and annual competency tests.

CASE MANAGEMENT (CM)

CM. 1 CASE MANAGEMENT

- CR.1 A registered nurse, social worker, or other appropriately qualified personnel must develop, or supervise, the management of the patient through discharge.
 - CR.1a The responsible personnel should have experience in case management, discharge planning, knowledge of social and physical factors that affect functional status at discharge, and knowledge of community resources to meet post-discharge needs.
- CR.2 The discharge planning evaluation shall include:
 - CR.2a An evaluation of the likelihood of a patient needing post-hospital services and of the availability of the services;
 - CR.2b An evaluation of the likelihood of a patient's capacity for self-care or of the possibility of the patient being cared for in the environment from which he or she entered the organization; and,
 - CR.2c A means to inform the patient or the patient's family of their freedom to choose among participating Medicare providers of post-hospital care services, and must, when possible, respect patient and family preferences when they are expressed.
- CR.3 The discharge planning evaluation shall be completed on a timely basis so that appropriate arrangements are made before discharge, and unnecessary delays in discharge are avoided.
- CR.4 The discharge planning evaluation shall be a part of the patient's medical record and be used when forming the discharge plan with the patient or individual acting on his or her behalf; and,
- CR.5 If the results of the discharge evaluation so indicate, or at the request of the patient's physician, a registered nurse, social worker, or other appropriately qualified personnel shall develop, or supervise the development of, a discharge plan and associated educational materials.

- CR.5a The results of the discharge planning evaluations must be discussed with the patient or individual acting on their behalf.

STAFFING MANAGEMENT(SM)

SM.1 PERSONNEL (GENERAL)

Personnel performing work affecting conformity to the VAD Program requirements shall be competent on the basis of appropriate education, training, skills, and experience.

- CR.1 The host hospital shall have a policy and practice outlining and verifying that each staff member possesses a valid and current license or certification as required by the VAD Program and Federal and State laws. This written policy shall be strictly enforced and compliance data reported to top management.

SM.2 COMPETENCE, TRAINING, AND AWARENESS

The VAD Program shall:

- CR.1 Determine the necessary competence for personnel performing work affecting conformity to the VAD Program requirements;
- CR.2 Have evidence to demonstrate initial and ongoing training in the care of VAD patients;
- CR.3 Where applicable, provide training or take other actions to achieve the necessary competence;
- CR.4 Evaluate the effectiveness of the actions taken;
- CR.5 Provide continuing education or other equivalent educational activity no less than annually to staff members assigned to care for VAD patients, as determined appropriate by the VAD Program Director and as appropriate to the care practitioners' level of responsibility related specifically to VAD Program;
- CR.6 Ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives; and,
- CR.7 Maintain appropriate records of education, training skills and experience.

SM.3 DETERMINING AND MODIFYING STAFFING

- CR.1 The method for determining and modifying staffing shall be validated through periodic reporting of variance from core staffing, outlining justification and linking that justification with patient and process outcomes, including any untoward patient events or process failures.
- CR.2 This validation shall be completed and reported to quality management oversight, when indicated.

SM.4 JOB DESCRIPTION

- CR.1 All VAD Program personnel, whether clinical or supportive, including contract staff, shall have available a current job description that contains the experience, educational and physical requirements, and performance expectations for that position.

SM.5 ORIENTATION

- CR.1 All VAD Program personnel, whether clinical or supportive, including contract staff, shall receive an orientation to specific job duties and responsibilities, and their work environment, as required by Federal and State law and regulation and the VAD Program. The orientation shall take place prior to the individual functioning independently in their job.

SM.6 STAFF EVALUATIONS

- CR.1 The performance/competency evaluation shall contain indicators that will objectively measure the ability of VAD Program staff to perform all job duties as outlined in the job description. Relevant indicators shall then be selected from this complete list of indicators for measurement as outline below.
- CR.2 The staff shall be evaluated initially and on an on-going basis against indicators that measure issues and opportunities for improvement that are identified through the following:
 - CR.2a Variations and problem processes identified through the analysis of outcomes measurement as required by the VAD Program;
 - CR.2b New technology/equipment/processes;
 - CR.2c Customer satisfaction feedback;
 - CR.2d Scheduled training session outcomes;
 - CR.2e Staff learning needs assessments that include variations identified through prior staff performance measurement;
 - CR.2f Staff feedback;
 - CR.2g Medical staff feedback; and,
 - CR.2h Requirements of Federal and State law (as applicable).
- CR.3 Indicator measurement for contract staff may be modified based on VAD outcomes and frequency of service of the individual. Modification of this measurement must take place no less than annually and shall be justified by data analysis.
- CR.4 The VAD Program shall aggregate the objective performance data for the individual staff and within each job classification to identify variations for further training, coaching and mentoring:
 - CR.4a Re-measurement shall follow any intervention.

- CR.4b The outcomes of this measurement shall be reported in the aggregate to top management.
- CR.5 The host hospital shall define a timeframe, not less than annually, and a policy and practice for sharing the indicators measurement of individual staff member with those staff members that allows for staff feedback.
- CR.6 The host hospital shall require each staff member, including contract staff, to participate in continuing education as required by individual licensure/certification, professional association, law or regulation, or VAD policy. Compliance with this standard shall be reported to Quality Management Oversight.

PATIENT RIGHTS (PR)

PR.1 PATIENT RIGHTS

The host hospital shall protect and promote each patient's rights. The host hospital shall inform, whenever possible, each patient and/or legal representative (as allowed under State law) of the patient's rights in advance of providing or discontinuing care and allow the patient to exercise his or her rights accordingly.

- CR.1 The host hospital shall comply with 42 CFR 484.13 - Condition of participation: Patient Rights.
- CR.2 Collectively, the VAD Program team must ensure that patients and caregivers have the knowledge and support necessary to participate in shared decision making and to provide appropriate informed consent.

PR.2 LANGUAGE AND COMMUNICATION

The host hospital shall communicate with the patient and/or legal representative in language and format that the patient and/or legal representative understand.

- CR.1 The host hospital's policy and practice provides for competent individuals to interpret the patient's language for individuals who do not speak English or provide alternative communication aids for those who are deaf, blind, or otherwise impaired.

INFECTION PREVENTION AND CONTROL (IC)

IC.1 INFECTION PREVENTION AND CONTROL SYSTEM

- CR.1 The VAD Program shall participate in the host hospital's infection control and prevention program to maintain a sanitary environment for VAD patients, staff, and others.

MEDICAL RECORDS SERVICE (MR)

MR.1 MEDICAL RECORD SERVICE

- CR.1 The host hospital shall maintain a medical record service in compliance with 42 CFR §482.24- Condition of participation: Medical Record Services.

PHYSICAL ENVIRONMENT (PE)

The host hospital will abide by the management systems for maintaining the physical environment in place under the operation of the hospital and applicable CMS Conditions of Participation (CoPs) and accreditation organization requirements.

PE.1 INFRASTRUCTURE

The host hospital shall determine, provide, and maintain the infrastructure needed to achieve conformity to the VAD Program requirements. Infrastructure includes, as applicable:

- CR.1 Buildings, workspace and associated utilities;
- CR.2 Process equipment (both hardware and software); and,
- CR.3 Supporting services (such as transport, communication, or information systems).

PE.2 WORK ENVIRONMENT

The host hospital shall determine and manage the work environment needed to facilitate patient care.

- CR.1 The facilities for the VAD Program shall be maintained to ensure the safety of patients, visitors, and staff.
- CR.2 The VAD Program must maintain adequate and safe facilities for its services.

PE.3 SAFETY MANAGEMENT SYSTEM

- CR.1 The host hospital shall provide and maintain safe and adequate diagnostic and therapeutic facilities.
- CR.2 The host hospital shall require that facilities, supplies, and equipment be properly maintained and ensure an acceptable level of safety and quality. The extent and complexity of facilities shall be determined by the services offered under the VAD Program.
- CR.3 The host hospital shall require that the VAD Program maintain an environment free of hazards and manages staff activities to reduce the risk of occupational related illnesses or injuries.
- CR.4 The host hospital shall address safety recalls and alerts involving the VAD Program.

PE.4 SECURITY MANAGEMENT SYSTEM

- CR.1 The host hospital shall develop a system that provides for a secure environment.
- CR.2 The host hospital shall provide for identification of patients, employees, and others.
- CR.3 The host hospital shall require a process for reporting and investigating security related issues.

PE.5 MEDICAL EQUIPMENT MANAGEMENT SYSTEM

- CR.1 The host hospital shall ensure that effective processes are in place for the acquisition, safe use, and the appropriate selection of equipment used within the VAD Program.
- CR.2 The host hospital shall address issues related to the VAD Program’s initial service inspection, the orientation, and the demonstration of use of rental or physician owned equipment.

PE.6 UTILITY MANAGEMENT SYSTEM

- CR.1 The host hospital shall ensure maintenance, testing, and inspection processes for critical utilities used in the operation of the VAD Program.
- CR.2 The host hospital shall ensure emergency processes for utility system failures or disruptions.
- CR.3 The host hospital will ensure that all relevant utility systems shall be maintained, inspected and tested.

VAD PROGRAM SERVICE DELIVERY (SD)

SD.1 PLANNING FOR SERVICE DELIVERY

The VAD Program shall plan and develop the processes needed for VAD service delivery. Planning of the VAD Program service delivery shall be consistent with the requirements of the processes of the DNV GL VAD Facility Credentialing Program.

NOTE: There is no specific requirement as to the design and location of the VAD Unit(s). The VAD Team can define the designation of the unit(s) and/or beds for treatment and care of the post-VAD patient. The VAD Program Team will identify a specified ICU for the placement of the majority of VAD patients post-operatively and specified units for the admission of the majority of VAD patient readmissions. It is acknowledged these criteria may vary from institution to institution. The staff and services provided for these VAD patients will meet the specified requirements as defined under the CMS guidelines for the care of a VAD patient.

In planning VAD services delivery, the VAD Program shall determine the following, as appropriate:

- CR.1 Quality objectives and requirements for the VAD Program;
- CR.2 The need to establish processes and documents, and to provide resources specific to the VAD Program;

- CR.3 Required verification, validation, monitoring, and measurement, specific to the VAD Program; and,
- CR.4 Records needed to provide evidence that the processes meet requirements. The output of this planning shall be in a form suitable for the VAD Program's method of operations.

SD.2 REVIEW OF REQUIREMENTS RELATED TO THE DELIVERY OF VAD SERVICES

The VAD Program shall review requirements related to the VAD Program. This review shall be conducted prior to the VAD Program's commitment to provide services to patients and shall ensure:

- CR.1 VAD Program requirements are clearly defined;
- CR.2 The VAD Program has the ability to meet the defined requirements;
- CR.3 Records of the results of the review and actions arising from the review shall be maintained;
- CR.4 If any VAD Program requirements are changed, the VAD Program shall ensure that all relevant documents are amended; and,
- CR.5 Communication to all relevant personnel is made about any changes and the competence of all practitioners is reassessed when new techniques or responsibilities are introduced and periodically within the timeframes defined by the VAD Program.

SD.3 CONTROL OF SERVICE DELIVERY

The VAD Program shall plan and carry out services under controlled conditions. Controlled conditions shall include, as applicable:

- CR.1 The availability of information that describes the characteristics of the VAD Program;
- CR.2 The availability of work instructions, as necessary;
- CR.3 The use of suitable equipment;
- CR.4 The availability and use of monitoring and measuring equipment; and,
- CR.5 The implementation of monitoring and measurement.

SD.4 CORONARY CARE UNIT (CCU), INTENSIVE CARE UNIT (ICU) AND OTHER UNITS CARING FOR VAD PATIENTS

- CR.1 The VAD Program is responsible for developing and maintaining efficient pathways, protocols and processes to rapidly identify, evaluate, and treat VAD program patients.
- CR.2 The VAD Program Team must collaborate with personnel in the CCU, ICU, and other units (e.g., ED, GI Lab, Cardiac Catheterization Lab) where cardiac patients are cared for, to organize and coordinate the patients care.

- CR.3 The VAD Program Team must maintain a current and complete call schedule with contact information for the appropriate physicians and VAD Program Coordinator available for the VAD Program Team.

SD.5 VAD PROGRAM TEAM AND PROTOCOL

- CR.1 The VAD Program Team shall define the criteria and qualifications (through plan, policy, or procedure) required for designation of qualified practitioners, professional and other personnel assigned to the VAD Program Team. Beneficiaries receiving VADs for DT must be managed by an explicitly identified cohesive, team of medical professionals with the appropriate qualifications, training, and experience. The team embodies collaboration and dedication across medical specialties to offer optimal patient-centered care. VAD Program Team members must be based at the VAD Credentialed Facility. The VAD Program Team must include, at a minimum, all of the following individuals with experience working with patients before and after the placement of a VAD:
- CR.1a The VAD Program Medical Director must be trained in advanced Heart Failure with clinical competence in medical and device-based management including VADs, and clinical competence in the management of patients before and after heart transplant;
 - CR.1b All cardio-thoracic surgeons must be trained on all devices implanted and at least one cardiologist trained in advanced heart failure with clinical competence in medical and device- based management including VADs, and the management of patients before and after heart transplant;
 - CR.1c Physicians must have expertise in heart failure, cardiomyopathy and recent experience (within the past 24 months) managing VAD patients or heart transplants, and have sufficient competency in evaluating patients for transplant as evidenced by having worked in or been trained in a heart failure/transplant center;
 - CR.1d VAD program coordinators (nurses, perfusionists, nurse practitioners) must be trained and demonstrate proficiency with all devices implanted at the facility;
 - CR.1e Social worker;
 - CR.1f Palliative Care Specialist;
 - CR.1g Practitioners meet the educational requirements to manage the VAD patient population. Practitioners must have experience, training, and/or certification consistent with the mission, goals and objectives of the VAD Program;
 - CR.1h The VAD Program shall maintain a multi-disciplinary approach to proper medical care of the VAD patient, including the participation of nurses, occupational therapists, physical therapists, dieticians, respiratory therapists, pastoral care, psychologists, and pharmacists, as appropriate;
 - CR.1i Documentation of regularly scheduled VAD Program Team meetings to organize and coordinate the plan of care for each VAD patient and to integrate the various VAD Program Team members into that plan; and,
 - CR.1j Documentation of quality improvement initiatives, performance measures and/or clinical indicators are presented and discussed at least on a quarterly basis.

- CR.2 Facility shall have at least one physician with cardiothoracic surgery privileges and individual experience implanting at least 10 durable, intracorporeal, left ventricular VADs as BTT or DT over the course of the previous 36 months with activity in the last year.
- CR.3 Utilizing the most recent 36-month time period, with activity in the past year is appropriate for counting VAD implantations towards the volume requirement.
- CR.4 The medical staff bylaws shall include criteria for determining the privileges to be granted to VAD Program practitioners and a procedure for applying the criteria to those individuals that request privileges.

SD.6 VAD CANDIDATES

Destination therapy is for patients with advanced end-stage heart failure, who require permanent mechanical cardiac support and are not eligible for heart transplantation at the time of VAD implant. The VADs used for destination therapy are covered by Medicare only if they have received approval from the FDA for that purpose, and the device is used according to the FDA-approved labeling instructions. VAD placement candidates are patients who have chronic end-stage heart failure (New York Heart Association Class IV end-stage left ventricular failure), who are not candidates for heart transplantation, and meet all of the following conditions:

- CR.1 The patient's Class IV end-stage ventricular heart failure symptoms have failed to respond to optimal medical management, including beta-blockers, and ACE inhibitors (if tolerated) for at least 45 of the last 60 days or have been balloon pump dependent for 7 days, or IV inotrope dependent for 14 days;
- CR.2 The patient has a left ventricular ejection fraction (LVEF) < 25%; and,
- CR.3 The patient has demonstrated functional limitation with a peak oxygen consumption of < 14 ml/kg/min unless balloon pump or inotrope dependent or physically unable to perform the test.

SD.7 ADMISSION REQUIREMENTS

Patients are consulted by the VAD Program Team for appropriateness of implantation of a VAD. The medical staff shall define the circumstances and criteria under which consultation or management by a physician or other qualified licensed practitioner is required to address any co-morbidities of the patients under the care of the VAD Program Team as required.

- CR.1 The VAD Program Team shall ensure that every patient is under the care of a:
 - CR.1a Cardiothoracic surgeon, trained on all devices implanted;
 - CR.1b Physician with expertise in heart failure and cardiomyopathy;
 - CR.1c VAD Program Team member (nurse, perfusionist, nurse practitioner) proficient with all devices implanted at the facility; and,
 - CR.1d A social worker, a palliative care specialist, and other qualified professionals with expertise defined by the medical staff and the VAD Program Team.

SD.8 PLAN OF CARE

- CR.1 The host hospital shall develop and maintain a plan of care prepared by qualified individuals for each patient that reflects the input of other disciplines, as appropriate. Documentation of these interdisciplinary findings, including patient appropriateness for VAD implantation and interventions shall be included in the plan of care, as appropriate.

SD.9 MEDICATION MANAGEMENT

- CR.1 The host hospital shall provide pharmacy services to meet the needs of the patients. Medications will be administered in accordance with accepted professional principles. The pharmacy service will be directed by a full-time, part-time, or consulting registered pharmacist responsible for developing, supervising, and coordinating all the activities of the pharmacy services. The pharmacy service must have an adequate number of qualified personnel to ensure medication management services, including emergency services.
- CR.2 All medications shall be administered by or under the supervision of nursing or other qualified personnel in accordance with applicable Federal and State laws. All drugs and biologicals shall be administered only upon the orders of the practitioner responsible for the care of the VAD patient in accordance with approved medical staff policies and procedures, and accepted standards of practice.
- CR.3 All compounding, packaging, and dispensing of medication shall be under the supervision of a pharmacist.

SD.10 DEVICE MANAGEMENT

- CR.1 All VAD Coordinators and nursing staff caring for a VAD patient shall have documentation of proficiency in the use of the stated equipment.
- CR.2 There shall be evidence of a VAD training program for all personnel caring for VAD patients with regularly scheduled training updates and annual competencies.
- CR.3 The VAD Program addresses VAD patient's education needs. Patient / family training sessions will include but not be limited to:
 - CR.3a VAD equipment review;
 - CR.3b Review of all patient education handouts specific to their VAD type;
 - CR.3c Documentation of "hands on training" with return demonstration of independence with VAD use;
 - CR.3d Review of emergency call system and emergency procedures;
 - CR.3e Written Patient Knowledge Assessment Tool; and,
 - CR.3f Patient/caregiver successful demonstration of independence in the care of their VAD and ability to be safely discharged back into the community.

SD.11 DIAGNOSTIC TESTS

- CR.1 Documentation should include completed diagnostic studies (laboratory, imaging, echocardiogram, chest x-ray, anticoagulation management).
- CR.2 Diagnostic testing will be obtained on an inpatient and outpatient basis as appropriate to identify trends, assess device function, monitor anticoagulation therapies when indicated and to monitor health management issues.
- CR.3 Diagnostic studies associated with an investigational VAD will be ordered and completed according to the protocol for that study.

SD.12 PATIENT MANAGEMENT

The VAD Program will ensure that it provides:

- CR.1 Involvement of patients in making their own decisions about managing their disease or condition including changes in their lifestyle;
- CR.2 Treatment of the patient when a new or recurring condition needs medical intervention. The patient may be either treated by the practitioners in the program or referred to an appropriate practitioner;
- CR.3 Community education programs to referring physician base as well as EMS and ED personnel in the vicinity of the patient's home; and,
- CR.4 Availability of VAD Program Team members on a 24/7 basis for managing urgent health issues, even after discharge.