DNV HEALTHCARE INC

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January 16, 2013

Louis B. Jacques, M.D.
Director, Coverage and Analysis Group, CMS
7500 Security Blvd. Mailstop S3-02-01
Baltimore, MD 21244-1850

Via: Electronic mail c/o Roya Lofti (Roya.Lotfi@cms.hhs.gov)

Re: Formal Request for Reconsideration- Facilities Criteria- National Coverage Determination (NCD) for Artificial Hearts and Related Devices- Update

Dear Dr. Jacques:

This updated letter along with the updated enclosed supporting documentation both originally submitted on November 28, 2011 is a continuation of our formal request for reconsideration of the National Coverage Determination (NCD) for Artificial Heart and Related Devices. Specifically, DNV Healthcare Inc. (DNV) requests that the Facility Criteria for this NCD be amended to include the DNV Mechanical Circulatory Support Certification Program as an acceptable credential as one of the criteria for facilities qualifying under this NCD. The intended benefit categories are inpatient hospital services and prosthetic devices.

This letter also identifies the current status of DNV's CMS deeming authority and the current number of accredited and disease-specific certified hospitals from that originally specified in the November 28, 2011 letter.

Background

Medicare covers ventricular assist devices (VAD) and artificial hearts when implanted under the coverage criteria stated in §20.9 of NCD Manual 100.03. Facility criteria for this coverage are specified in relevant part as follows:

> (third bullet. Page 38)
>
> "Effective March 27, 2009, all facilities must have met the above facility criteria and have been credential by the Joint Commission under the Disease Specific Certification Program for Ventricular Assist Devices (standards dated February 2007)."

At this time, the Joint Commission's VAD program (above) is the only certification program for facilities to qualify under this NCD. The DNV MCS Program Certification Requirements, MCS 1.0 is now offered as an alternative to the TJC VAD certification program. The DNV MCS Program is enclosed and made a part of this formal request.

In August, 2009, TJC published a change in eligibility requirements for programs seeking disease-specific care certification that required the program's parent organization to be Joint Commission accredited, if the organization is eligible for accreditation. A February, 2010 clarification by TJC stated that for VAD, a program does not have to be TJC accredited. While hospitals may now switch hospital accreditation

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organizations, this TJC eligibility requirement places hospitals that have VAD programs and want to switch accreditation organizations from TJC to DNV to retain TJC as the (currently) only VAD certification program to qualify under this NCD.

DNV Healthcare Inc. History

DNV Healthcare Inc. is an operating company of Det Norske Veritas. DNV has corporate offices in Houston, Texas and Cincinnati (Milford), Ohio. Det Norske Veritas is an international, independent, self-supported, tax-paying foundation that has more than 300 offices in over 100 countries and more than 9,000 employees. Established in 1864 in Oslo, Norway, Det Norske Veritas operates 15 offices in the United States and has been in this country since 1898. The corporate purpose of DNV is safeguarding life, property, and the environment. Det Norske Veritas has a worldwide reputation for quality and integrity in certification, standards development and risk management in a wide range of industries, including extensive international healthcare experience.

The DNV Healthcare Inc. application for hospital deeming authority was approved by CMS effective September 26, 2008. On August 24, 2012 CMS granted DNV Healthcare Inc. continued deeming authority for hospitals through September 26, 2018. This six-year approval is the maximum time allowed by law. The initial hospital deeming authority was the first such application to be approved by CMS in over 40 years. CMS has also granted DNV Healthcare Inc. deeming authority for critical access hospitals through December 23, 2014. Since September 26, 2008, 266 hospitals and critical access hospitals throughout the United States have been accredited by DNV. An additional 75 hospitals have signed contracts and are in the process of being surveyed and accredited. This total of 266 accredited hospitals and 75 hospitals in the DNV queue represents a steady growth after DNV received its initial deeming authority. As hospitals continue to become familiar with DNV, the current growth curve is trending upward with an average of approximately 2 new hospitals per week seeking DNV accreditation.

DNV's Integrated Accreditation™ approach enhances DNV's mission to maintain and improve hospital quality and patient safety. The Integrated Accreditation™ model combines standards that meet the Medicare Conditions of Participation for Hospitals with the ISO 9001 Quality Management System. This Integrated Accreditation™ model is unique in hospital accreditation and is receiving rave reviews all across the spectrum. DNV also believes in a collaborative survey style in which the accreditation function is viewed both by DNV and the hospital as a business asset and not merely an inspection. DNV receives accolades all across the spectrum from newly accredited hospitals to hospitals that have been accredited by DNV for 3 or more years.

Two key indicators from the 2011 DNV Hospital Satisfaction Survey illustrate acceptance of the DNV model. When asked if the DNV accreditation program is better that their previous accreditation program, 92.8% of the respondents gave DNV a score of 4 or 5 (on a 1 (low)-5 (high) scale). When asked if the hospital would recommend DNV to others based on the work carried out for their organization, 97.7% of the respondents gave DNV a score or 4 or 5.

Development of DNV Healthcare Inc. Mechanical Circulatory Support Certification Program

The DNV MCS Program was developed in response to the demand from VAD hospitals that want to change to DNV for hospital accreditation and not rely solely on TJC for VAD certification. The DNV MCS

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program is the second of three -disease-specific certification programs developed by DNV. DNV has developed and made available to hospitals throughout the United States Primary Stroke Center Certification (PSCC) and Comprehensive Stroke Center Certification (CSCC). There are currently 57 hospitals throughout the country that are PSCC-certified by DNV and one hospital CSCC-certified by DNV. Several hospitals have applied to DNV for PSCC and CSCC certification.

DNV Healthcare Inc. engaged the services of Sharon H. Allan, RN, MSN, CCRC, Clinical Nurse Specialist-QI Team Leader, Cardiac Surgery / Heart and Lung Transplant Department of Cardiac Surgery / CTC / QI, The Johns Hopkins Hospital to design the program. It has been peer reviewed by Robin J. Trupp RN, PhD, ACNP-BC, CCRN, FAHA and Jim Levett, M.D., a cardiothoracic surgeon who chairs our Standards and Appeals Board. Dr. Trupp is an expert in heart failure presented to us by the Society of Chest Pain Centers, Inc. Finally, the program was submitted to two CMS-approved VAD facilities for review and comment.

Based upon the information presented above, DNV formally requests a reconsideration of the Facilities Criteria- National Coverage Determination (NCD) for Artificial Hearts and Related Devices to include the DNV MCS Program Certification Requirements as an acceptable credential as one of the criteria for facilities qualifying under this NCD. DNV believes it is important for hospitals to have a choice in determining the VAD certification program it wishes to pursue.

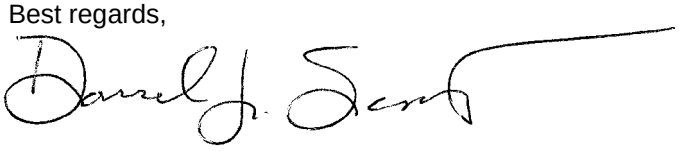
DNV is willing to submit this request in any other form reasonably requested by CMS in order for CMS to comply with Section 508 of the Rehabilitation Act of 1973.

DNV looks forward to working closely with CMS throughout the NCD Reconsideration Process and to providing any additional information that CMS may require.

For further assistance, please contact me at your convenience.

An electronic version of the DNV MCS Program Certification Requirements is enclosed.

Best regards,



Darrel J. Scott, FACHE
Senior Vice President,
Regulatory & Legal Affairs

Enclosure

c: Dr. Kimberly Smith- electronic mail (Kimberly.Smith@cms.hhs.gov) w/ enclosure

DNV Healthcare Inc.

Mechanical Circulatory Support

Certification Program – Requirements

MCS 1.0

DNV Healthcare Inc.

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TABLE OF CONTENTS

DEFINITIONS

CFR	Code of Federal Regulations
CMS	Centers for Medicare Medicaid Services
CoPs	Conditions of Participation
DSC	Disease Specific Care
ED	Emergency Department
EMS	Emergency Medical Systems
EPP	Emergency Power Pack
FMEA	Failure Mode Effect Analysis
HHA	Home Health Agency
MCS	Mechanical Circulatory Support
MCSD	Mechanical Circulatory Support Device
PI	Performance Improvement
QA	Quality Assessment
QI	Quality Improvement
QMS	Quality Management System
PBU	Power Base Unit
RCA	Root Cause Analysis
SNF	Skilled Nursing Facility
VAD	Ventricular Assist Device

Use of DNV MCS Program Certification Requirements

Effective date

These DNV Healthcare MCS Program Certification Requirements, MCS 1.0 are effective (upon CMS approval).

Federal Laws, Rules and Regulations

The most current version of Federal law and the Code of Federal Regulations referenced in this Certification Program document are incorporated herein by reference and constitute Ventricular Assist Device for Destination Therapy Certification Requirements set out under Medicare Decision Summary CAG-00119R.

INTRODUCTION

The Mechanical Circulatory Support (MCS) Program (formerly known as Ventricular Assist Device (VAD) Program) is offered by DNV Healthcare Inc. (DNV) for patients who require Mechanical Circulatory Support Devices (MCSD) and integrates requirements related to CMS Conditions of Participation for Hospitals (CoPs) and Medicare Decision Summary CAG-00119R – Ventricular Assist Devices as Destination Therapy.

Hospitals seeking and maintaining a MCS Program must participate in the Medicare program and be in compliance with the CoPs by the Centers for Medicare and Medicaid Services (CMS). Compliance with the CMS CoPs may be demonstrated by maintaining accreditation with DNV or another approved accreditation organization approved by CMS.

This Certification Program addresses healthcare organizations that are either applying to DNV Healthcare Inc. for certification of its MCS Program or are currently MCS Program certified by DNV. When a healthcare organization has applied for but not yet received DNV certification, it is referred to as an “Applicant Organization” When a healthcare organization is currently MCS Program-certified by DNV it is referred to as a “Certified Organization”.

GENERAL INFORMATION

A. Background: A mechanical circulatory support device (MCSD) is an implantable device used to assist a damaged or weakened heart in pumping blood. These devices are used for support of blood circulation post-cardiotomy, as a bridge to a heart transplant, or in those patients with end-stage heart failure. Destination therapy is an indication for patients who are not heart transplant eligible and therefore expect to require use of the MCSD through the end of life.

B. Policy: Through a National Coverage Determination (NCD Manual 100-03 §20.9, “Artificial Hearts and Related Devices”) issued on October 2003, Medicare began coverage of the destination therapy indication. The 2003 decision established hospital criteria and an application process through which hospitals were required to submit information to CMS and if approved, would then be listed on the CMS Web site as an approved VAD (MCSD) hospital. At that time contractors were instructed to use that Web site to determine which hospitals in their area were Medicare approved for VADs (MCSs) as destination therapy (Change Request 2958, Issued

October 14, 2003). Effective March 27, 2007, new facility criteria were established and hospitals must now receive certification from an accreditation organization approved by CMS.

For MCSs (effective for services performed on or after October 1, 2003, facility criteria updated March 27, 2007, patient selection criteria updated November 9, 2010), CMS has determined that the evidence is adequate to conclude that MCSD implantation improves health outcomes and is reasonable and necessary when the device has received FDA approval for a destination therapy indication and only for patients with NYHA Class IV end-stage ventricular heart failure who are not candidates for heart transplantation and who now must meet all of the following conditions:

- *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; and,*
- *Have a left ventricular ejection fraction (LVEF) < 25%, and,*
- *Have 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.*

Implementation date for this Summary of Changes 7220 is January 6, 2011.

Any patient eligible for a heart transplant is eligible for a MCSD as a bridge to transplant.

REGULATORY AND POLICY REFERENCE

- The Medicare Conditions or Participation for hospitals are in 42 CFR Part 482.
- Survey authority and compliance regulations can be found at 42 CFR Part 488 Subpart A.
- Should an individual or entity (hospital) refuse to allow immediate access upon reasonable request to a State Agency, CMS surveyor, or DNV Healthcare Inc. (DNV) staff, the Office of the Inspector General (OIG) may exclude the hospital from participation in all Federal healthcare programs in accordance with 42 CFR §1001.1301 and 1861(b)(2) that impacts MCSDs within the Inpatient Hospital Services benefit category of the Social Security Act.
- The regulatory authority for the photocopying of records and information during the survey is found at 42 CFR §489.53(a)(13).
- The DNV Certification Process, Certification Requirements, and CMS State Operations Manual (SOM) provide the policies and procedures regarding certification activities.
- The ISO 9001 (Quality Management Systems [QMS] and ISO 19011 (Guidelines for Quality and/or Environmental Management Systems Auditing) as well as related guidelines provide the basis for the certification assessment activities
- National Coverage Determination (NCD). NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, qualified independent contractors, the Medicare Appeals Council, and administrative law judges (ALJs) (see 42 CFR section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare

Advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

PROGRAM MANAGEMENT (PM)

The MCS Program shall establish, document, implement and maintain the MCS Program and continually improve its effectiveness in accordance with the requirements of this Certification Program.

PM.1 TOP MANAGEMENT

CR.1 Top management is responsible and accountable for ensuring the following:

CR.1a the MCS Program is in compliance with all applicable Federal and State laws regarding the health and safety of its patients;

CR.1b the MCS Program is licensed by the appropriate State, if applicable;

CR.1c Criteria that includes aspects of individual character, competence, training, experience and judgment is established for the selection of individuals working for the MCS Program, directly or under contract;

CR.1d the personnel working in the MCS program are properly licensed or otherwise meet all applicable Federal, State and local laws.

CR.1e responsibilities and authorities are defined and communicated within the MCS Program; and,

CR.1f appointment and qualifications of the Medical Director for the MCS Program.

CR1f(i). The Medical Director for the MCS 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

Management shall provide evidence of its commitment to the development and implementation of the MCS Program and continually improving its effectiveness by:

CR.1 communicating to the MCS Program the importance of meeting customer as well as statutory and regulatory requirements;

CR.2 establishing the MCS Program and ensuring that objectives are established; and,

CR.3 conducting MCS Program reviews and ensuring the availability of resources.

PM.3 PROGRAM MANAGEMENT

The MCS Program shall:

CR.1 determine the processes needed for the MCS Program and their application throughout the MCS Program;

CR.2 determine criteria and methods needed to ensure that both the operation and control of these processes is effective;

CR.3 ensure the availability of resources and information necessary to support the operation and monitoring of these processes;

CR.4 monitor, measure where applicable, and analyze these processes;

CR.5 implements actions necessary to achieve planned results and continual improvement of these processes; and,

CR.6 take measures to ensure the highest return percentage of "patient perception of quality of care surveys" completed by each patient enrolled in the MCS Program.

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 MCS Program, medical staff, and administrative officials) is responsible and accountable for ensuring that the MCS Program implements and maintains an effective quality management system (QMS). This QMS shall ensure that corrective and preventive actions taken by the MCS Program are implemented, measured and monitored.

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

CR.1 The MCS Program must develop, implement and maintain an ongoing system for measuring, monitoring, and managing quality and patient safety.

CR.2 The MCS 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 MCS Program must collect and analyze data on at least four performance measures related to or identified in clinical practice guidelines for each program

- CR.4a Two of the measures must be clinical process or outcomes process measures.
- CR.4b The remaining two measures may be clinical or related to health status, functional status, financial or administrative areas, or the participant's perception of care.
- CR.4c The performance measures must directly relate to the disease-specific MCS Program.

CR.4d The performance measures must be consistent with current evidence-based clinical practice rationale. Literature references and/or expert consensus must be available to support those performance measures chosen by the MCS Program

CR.5 The MCS Program must have a formal documentation process for all policies, procedures, protocols and forms.

CR 5a. All policies, procedures, protocols and forms are reviewed at least annually with date of the review/revision denoted..

CR 5b. 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.6 Control of records: the MCS Program ensures that suitable records are maintained.

CR.7 The MCS Program conducts internal reviews of its processes and resultant corrective/preventive action measures have been implemented and verified to be effective.

CR.7a At the time of the initial certification visit, the MCS Program must provide at least 6 months of collected data on each performance measure and 12 months of data annually thereafter.

CR.7b The MCS Program is accountable for ensuring the accuracy and completeness of the performance measure data.

CR.7c The MCS Program must establish a data history that supports quality improvement objectives.

CR.7d Feedback should be given to clinicians who fail to meet MCS Program goals.

CR.8 The MCS Program has established measurable quality objectives and the results are analyzed.

CR.9 Appropriate information has been submitted to the oversight group for quality management as well as top management for review and analysis during a management review process.

QM.2 QUALITY OUTLINE

The MCS 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

Management shall ensure that the MCS Program quality objectives, including those needed to meet requirements for the MCS Program, are established. The quality objectives shall be measurable and consistent with the MCS Certification Program.

QM.4 MANAGEMENT REPRESENTATIVE

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

QM.5 DOCUMENTATION AND MANAGEMENT REVIEWS

Any variation, deficiency or non-conformity identified by the MCS Program shall be addressed by the MCS 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 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 REQUIREMENT

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

CR.1 Interdisciplinary group to oversee the QMS that includes at least senior management representative, Quality Facilitator/Management representative, cardiovascular surgeon, and practitioners who must be doctors of medicine or osteopathy. MCS coordinators, registered nurses and perfusionists should also be considered as representatives. This interdisciplinary group shall conduct Management Reviews;

CR.2 Written document defining the QMS, to include all clinical and non-clinical 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 consider the incidence, prevalence and severity of problems in these areas, processes or functions; and,
- CR4.c affect health outcomes, improve patient safety and quality of care.

QM.7 MEASUREMENT, MONITORING, ANALYSIS

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

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

The MCS Program should collect and analyze data on at least four performance measures related to or identified in clinical practice guidelines. Two of the measures must be clinical

process or outcomes measures. 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 MCS Program should develop performance measures and strategies for measuring, refining and reassessing the following key system components:

CR.1 Performance Measurement and Improvement:

- CR.1a Comprehensive and organized approach to performance improvement;
- CR.1b Variances tracked at the individual patient level;
- CR.1c Data tracking to evaluate process measures and participant outcomes;
- CR.1d Evaluation of the patient/family perception of quality care survey;
- CR.1e Quality and integrity of the data collected is maintained; and,
- CR.1f Effectiveness of the interventions implemented in response to improvement opportunities identified by the measurement activity.

CR.2 Community education: evaluating community outreach initiatives by measuring the knowledge in the community about the causes, signs, symptoms and treatment of heart failure and the established guidelines for MCS patient selection.

CR.3 Collaboration with EMS including data exchange between EMS, ED and the MCS Team so that relevant pre-hospital data can be incorporated into the evaluation of effectiveness of the MCS Program.

CR.4 Sub-acute care and secondary prevention including measures of patient outcomes and avoidance of complications post-MCSD placement.

CR.5 Rehabilitation with performance measures to evaluate patient outcomes (mortality, functional status, and community discharge) and the percentage of MCSD patients who require transfer to a sub acute or acute rehabilitation facility post discharge.

CR.6 The MCS 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:

- Patient/family care training with each patient and primary caregiver to ensure the patient and their caregiver have proper post-hospitalization education prior to discharge.
- Emergency notification system: MCS patient and primary caregivers must demonstrate proficiency in the ability to notify the appropriate resources in case of an emergency.
- EMS training: EMS and ED teams local to the patient's residence must be informed of the ensuing patient discharge. MCS Team will provide education to the appropriate personnel (establish and maintain open communication with the local EMS and ED Teams).

CR.7 The MCS team 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 MCS Program.

- Measurement, monitoring and analysis of processes of the MCS 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.
- The frequency and detail of these measurements must be defined by the MCS Program
- Functions to be measured at a minimum must include the following:
    - Threats to patient safety;
    - Medication therapy/medication use;
    - Medication reconciliation;
    - Effectiveness of pain management;
    - Infection control system. Including nosocomial infections;
    - Utilization Management System;
    - Customer satisfaction;
    - Unanticipated deaths;
    - Adverse event/near miss and other medical errors;
    - Critical and/or pertinent processes, both clinical and supportive; and,
    - Physical Environment Management Systems.

QM.8 PATIENT SAFETY SYSTEM

CR.1 The MCS Program 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 MCS Program'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.

PATIENT CARE SERVICES (PC)

PC.1 PLANNING FOR SERVICE DELIVERY

The MCS Program shall plan and develop the processes needed for MCS service delivery. Planning of the MCS Program service delivery shall be consistent with the certification requirements of the processes of the MCS Program. In planning MCS services delivery, the MCS Program shall determine the following, as appropriate:

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

CR.1 quality objectives and requirements for the MCS Program

CR.2 the need to establish processes and documents, and to provide resources specific to the MCS Program;

CR.3 required verification, validation, monitoring, and measurement, specific to the MCS 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 MCS Program's method of operations.

PC.2 REVIEW OF REQUIREMENTS RELATED TO THE DELIVERY OF MCS SERVICES

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

CR.1 MCS Program requirements are clearly defined;

CR.2 the MCS 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 that if any MCS Program requirements are changed, the MCS Program shall ensure that all relevant documents are amended; and,

CR.5 communication to all relevant personnel are 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 MCS Program.

PC.3 CONTROL OF SERVICE DELIVERY

The MCS 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 MCS 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.

PC.4 EMERGENCY DEPARTMENT (ED) AND CORONARY CARE UNIT (CCU)

CR.1 The MCS Program is responsible for developing and maintaining efficient pathways, protocols and processes to rapidly identify, evaluate and treat potential MCS patients. Destination therapy is for patients with advanced end-stage heart failure, who require permanent mechanical cardiac support and are not eligible for heart transplantation. The MCSs 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.

CR.2 The MCSDs are covered by Medicare for 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.2a 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.2b The patient has a left ventricular ejection fraction (LVEF) < 25%; and,

CR.2c The patient has demonstrated functional limitation with a peak oxygen consumption of $\leq$ 14 ml/kg/min unless balloon pump or inotrope dependent or physically unable to perform the test.

CR.3 The organization must have a designated MCS Team with trained personnel.

CR.3a All members of the MCS team should have current job descriptions available that contains the experience, educational and physical requirements, and performance expectations for that role on the MCS team.

CR.4 The MCS Team must collaborate with personnel in the ED and ICU's where cardiac patients are cared for, to organize and coordinate the identification of patients who meet the appropriateness criteria for consideration of a MCSD.

CR.5 The MCS Team must maintain a current and complete call schedule with contact information of the physicians and/or MCS Coordinators available for the MCS Team.

PC.5 MCS TEAM AND PROTOCOL

CR.1 The MCS 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 MCS team.

CR.1a The MCS Program Director must be certified in Advanced Heart Failure.

CR.1b All cardio-thoracic Surgeons must be board certified and trained on all devices implanted.

CR.1c Physicians must have expertise in heart failure, cardiomyopathy and recent experience managing MCS 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.1c MCS coordinators (nurses, perfusionists, nurse practitioners) must be trained and demonstrate proficiency with all devices implanted at the facility.

CR.1e Practitioners meet educational requirement to manage the MCS patient population. Practitioners have experience, training and/or certification consistent with the mission, goals and objectives of the MCS program.

CR.1f The MCS Program shall maintain a multi-disciplinary approach to proper medical care of the MCS patient, including nurses, respiratory therapists, occupational therapists, physical therapists, dieticians, social workers, or pastoral care.

CR.1g Documentation of regularly scheduled MCS team meetings to organize and coordinate the plan of care for each MCS patient and to integrate the various MCS team members into that plan.

CR.1h 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 surgeon who has had the lead in implanting at least 10 MCSDs (as bridge-to-transplant or destination therapy) or total artificial hearts.

CR.3 Utilizing the most recent 36-month time period is appropriate for counting MCSD implantations towards the volume requirement.

CR.4 Artificial heart procedures are reflected in the volume requirement for a surgeon if that surgeon was the primary surgeon on the procedure.

CR.5 Facilities must be a member of the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS).

CR.6 MCSD implementation is reasonable and necessary when the procedure is performed in a Medicare-approved heart transplant facility that implanted at least 15 MCSDs as a bridge-to-transplant or as destination therapy or have been implanted as part of an FDA investigational device exemption (IDE) trial for one of these two indications in order to obtain initial certification. In addition, the facility must implant at least 10 MCSDs over the most recent three (3) year period. Each surgeon must perform at least ten (10) MCSD implants over the most recent three (3) year period in order for that surgeon to maintain certification The facility must have at least one (1) surgeon who performs at least ten (10) MCSD implants over the most recent three (3) year period to obtain and maintain certification.

Oversight will be provided for facilities that are certified to place an MCSD for either DT or BTT even though that facility may not be a Medicare-approved transplant center provided that facility works closely with a Medicare-approved transplant center for BTT patient referral for transplant evaluation and listing.

CR.7 Facility shall be an active, continuous member of a national, audited registry that requires submission of health data on all MCS destination therapy patients from the date of implantation throughout the remainder of their lives.

CR.8 This registry must have the ability to accommodate data related to any device approved by the FDA for destination therapy regardless of manufacturer.

CR.9 The registry must provide such routine reports as may be specified by CMS, and must have standards for quality and timeliness of data.

CR.9a Facilities failing to meet this requirement will be removed from INTERMACS membership.

CR.9b INTERMACS Registry, funded by the National Heart Lung and Blood Institute of the National Institutes of Health and sponsored by the International Society for Heart and Lung transplantation is an example of a registry that meets these characteristics.

CR.9c Facility shall have in place staff and procedures that ensure that prospective MCS recipients receive all information necessary to assist them in giving appropriate informed consent for the procedure so that they and their families are fully aware of the aftercare requirements and potential limitations, as well as benefits, following MCS implantation.

PC.6 PLAN OF CARE

CR.1 The MCS Team 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 MCSD implantation and interventions shall be included in the plan of care, as appropriate.

PC.7 MEDICATION MANAGEMENT

CR.1 The MCS Team 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 biological shall be administered only upon the orders of the practitioner responsible for the care of the 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.

PC.8 DEVICE MANAGEMENT

CR.1 All MCS coordinators and nursing staff caring for a MCS patient shall have documentation of proficiency in the use of the stated equipment.

CR.2 There shall be evidence of MCS training program for all personnel caring for MCS patients with regularly scheduled training updates and annual competencies.

CR.3 Hospitals also must have in place staff and procedures that ensure that prospective MCS recipients receive all information necessary to assist them in giving appropriate informed consent for the procedure so that they and their families are fully aware of the aftercare requirements and potential limitations, as well as benefits, following MCS implantation.

CR.4 Program addresses MCS patient's education needs. Patient / family training sessions will include but not be limited to:

CR.3a MCSD equipment review;

CR.3b review of all patient education handouts specific to their MCSD type;

CR.3c documentation of "hands on training" with return demonstration of independence with MCSD use;

CR.3d review of emergency call system and emergency procedures;

CR.3e written Patient Knowledge Assessment Tool;

CR.3f completion of a MCS Patient/caregiver education checklist;

CR.3g one successful supervised excursion and demonstration of the patient/caregiver's ability to be safely discharged to the community.

PC.9 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 MCSD will be ordered and completed according to the protocol for that study.

PC.10 PATIENT MANAGEMENT

The MCS 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 MCS team members on a 24/7 basis for managing urgent health issues, even after discharge.

MEDICAL STAFF

MS.1 ADMISSION REQUIREMENTS

Patients are consulted by the MCS Team for appropriateness of implantation of a MCSD. 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 MCS Team as required.

CR.1 The MCS Team shall ensure that every patient is under the care of a:

- CR.1a Cardiothoracic surgeon, board certified, trained on all devices implanted;
- CR.1b Physician with expertise in heart failure and cardiomyopathy;
- CR.1c MCS team coordinators (nurse, perfusionist, nurse practitioner) proficient with all devices implanted at the facility; and,
- CR.1d other qualified professional with expertise defined by the medical staff and the MCS Team.

NURSING SERVICES (NS)

NS.1 NURSING SERVICE

CR.1 The MCS Program 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 MCS Program.

CR.2 There shall be 24-hour nursing services and an MCS coordinator must coordinate with nurse managers, the supervision and evaluation of the nursing care for each patient of the MCS Program.

CR.3 Inpatient units providing care to an MCS patient must have documentation that all nurses caring for the MCS patient population have passed initial and annual competency tests.

STAFFING MANAGEMENT (SM)

SM.1 PERSONNEL (GENERAL)

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

CR.1 The MCS Program 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 MCS 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 MCS Program shall:

CR.1 determine the necessary competence for personnel performing work affecting conformity to the MCS Program requirements;

CR.2 have evidence to demonstrate initial and ongoing training in the care of MCS patients;

CR.3 where applicable, provide training or take other actions to achieve the necessary competence;

CR.4 at least every 6 months, provide continuing education or other equivalent educational activity to staff members assigned to care for MCS patients, as determined appropriate by the MCS Program Director and as appropriate to the care practitioners' level of responsibility related specifically to MCS Program;

CR.5 evaluate the effectiveness of the actions taken;

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 done at least every 6 months and reported to top management.

SM.4 JOB DESCRIPTION

All 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

All 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 MCS 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 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 MCS 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 MCS outcomes and frequency of service of the individual. Modification of this measurement must take place no less than every calendar year and shall be justified by data analysis.

CR.4 The MCS Team 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 MCS Team shall define a timeframe, not to exceed one calendar year, 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 MCS Program 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 MCS policy. Compliance with this standard shall be reported to Quality Management Oversight.

PATIENT RIGHTS (PR)

PR.1 SPECIFIC RIGHTS

The MCS Program shall protect and promote each patient's rights. The MCS Program 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. The written listing of these rights shall be provided to the patient and / or family and shall include policies and procedures that address the following:

CR.1 Patient participation and means for making informed decisions regarding his/her plan of care;

CR.2 Information to the patient and family of patient care and to involve the patient and family to make informed decisions regarding their care planning and treatment, including the requesting and/or refusing treatment, their health status, not to be construed as a demand for the provision of treatment or services deemed medically unnecessary or inappropriate;

CR.3 Personal privacy;

CR.4 Provision of care in a safe setting;

CR.5 Confidentiality of clinical records; and,

CR.6 Pain management.

PR.2 ADVANCE DIRECTIVES

The MCS Team must allow the patient to formulate advance directives and to have MCS staff and practitioners comply with the advance directives in accordance with Federal and State law, rules and regulations.

CR.1 The MCS Program shall document in the patient's medical record whether or not the patient has executed advance directive.

CR.2 The MCS Program shall not condition the provision of care or otherwise discriminate based on the execution of the advance directive.

CR.3 The MCS Program shall ensure compliance with State law regarding the provision of an advance directive

CR.4 The MCS Program shall provide education for staff regarding the advance directive.

CR.5 When the advance directive exists and is not in the patient's medical record, a written policy for follow-up and compliance shall exist.

PR.3 LANGUAGE AND COMMUNICATION

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

CR.1 MCS Program 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.

PR.4 INFORMED CONSENT

CR.1 Hospitals also must have in place staff and procedures that ensure that prospective MCSD recipients receive all information necessary to assist them in giving appropriate informed consent for the procedure so that they and their families are fully aware of the aftercare requirements and potential limitations, as well as benefits, following MCSD implantation.

CR.2 The MCS Team shall obtain an informed written consent from each patient or authorized representative for the provision of surgical implantation of the MCS.

CR.3 The consent shall include an explanation of risks, benefits, and alternatives for surgery, procedures, diagnostic tests and participation in activities related to the MCS Program as defined by the Medical Staff.

MEDICAL RECORDS SERVICE (MR)

MR.1 COMPLETE MEDICAL RECORD

CR.1 The MCS Program shall maintain an accurately written, promptly completed medical record for each inpatient and outpatient.

CR.2 The organization shall have a process for providing services for the completion, filing and retrieval of the medical record. The process for completion of the medical record must address timeframes.

CR.3 Authenticity and security of all record entries shall be safeguarded.

MR.2 RETENTION

CR.1 Medical records (original or legally reproduced form) shall be retained for a period of at least five (5) years.

CR.2 The coding and indexing system shall be designed in such a way that allows for timely retrieval by diagnosis and procedure, in order to support medical care evaluation.

MR.3 CONFIDENTIALITY

CR.1 Confidentiality of patient records shall be assured.

CR.2 Individuals who are authorized by the patient to receive information from or copies of records shall follow processes designed to protect improper or inadvertent release of private information to unauthorized individuals.

CR.3 The organization shall also ensure that the medical record cannot be altered or accessed by unauthorized individuals.

CR.4 Original medical records shall be released by the organization only in accordance with Federal or State laws, court orders, or subpoenas.

MR.4 RECORD CONTENT

CR.1 The medical record shall contain information to:

CR.1a justify admission and continued hospitalization;

CR.1b support the diagnosis; and,

CR.1c describe the patient's progress and response to treatment, procedures and services.

CR.2 All entries shall be:

CR.2a legible, complete, dated and times; and,

CR.2b authenticated by the person responsible for providing or evaluating the services provided consistent with the MCS Program.

CR.3 Authentication may include written signatures or initials. Electronic authentication is permissible.

CR.4 All orders must be dated, timed and authenticated promptly by prescribing practitioner.

CR.5 Verbal orders must be in accordance with Federal and State laws and authenticated within forty eight (48) hours or earlier if required by law.

CR.5 (1) Telephone or verbal orders are to be used infrequently and when used must be accepted only by Personnel authorized by the medical staff and in accordance with Federal and State laws.

MR.5 REQUIRED DOCUMENTATION

All records must document the following, as appropriate:

CR.1 evidence of a physical examination, including a health history, must be performed no more than thirty (30) days prior to admission or within twenty-four (24) hours after admission or registration, but prior to surgery or procedures requiring anesthesia services;

CR.2 admitting diagnosis;

CR.3 results of all consultative evaluations of the patient and appropriate finding by clinical and other staff involved in the care of the patient;

CR.4 documentation of complications, organization acquired infections, and unfavorable reactions to drugs and anesthesia;

CR.5 properly executed informed written consent for procedures and treatments specified by the medical staff, or Federal or State law if applicable, signed by the patient or his/her authorized representative;

CR.6 all practitioners' orders, nursing notes, reports of treatment medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient's condition;

CR.7 discharge summary with outcome of hospitalization, disposition of care, and provisions for follow-up care; and,

CR.8 final diagnosis with completion of medical records within thirty (30) days of discharge.

PHYSICAL ENVIRONMENT (PE)

The MCS Program 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 MCS Program shall determine, provide and maintain the infrastructure needed to achieve conformity to the MCS 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 MCS Program shall determine and manage the work environment needed to facilitate patient care.

CR.1 The facilities for the MCS Program shall be maintained to ensure the safety of patients, visitors, and staff.

CR.2 The MCS Program must maintain adequate and safe facilities for its services.

CR.3 The MCS Program, through its senior leadership shall ensure that the physical environment and associated management systems adequately address issues identified throughout the MCS Program and there are prevention, correction, performance improvement and training programs to address these issues.

PE.3 SAFETY MANAGEMENT SYSTEM

CR.1 The MCS Program shall provide and maintain safe and adequate diagnostic and therapeutic facilities.

CR.2 The MCS Program 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 MCS Program.

CR.3 The MCS Program shall require that the MCS team maintain an environment free of hazards and manages staff activities to reduce the risk of occupational related illnesses or injuries.

PE.4 SECURITY MANAGEMENT SYSTEM

CR.1 The MCS Program shall develop a system that provides for a secure environment.

CR.2 The MCS Program shall provide for identification of patients, employees and others.

CR.3 The MCS Program shall require a process for reporting and investigating security related issues.

PE.5 MEDICAL EQUIPMENT MANAGEMENT SYSTEM

CR.1 The MCS Team shall ensure that effective processes are in place for the acquisition, safe use, and the appropriate selection of equipment used within the MCS Program.

CR.2 The MSC Program shall address issues related to the MCS 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 MCS Program shall ensure maintenance, testing, and inspection processes for critical utilities used in the operation of the MCS Program.

CR.2 The MCS Program shall ensure emergency processes for utility system failures or disruptions.

CR.3 The MCS Program will ensure that all relevant utility systems shall be maintained, inspected and tested.