Proposed Requirements for Advanced Certification in Ventricular Assist Device Destination Therapy (VAD) Disease-Specific Care (DSC) Certification Program

Program Management (DSPR)

**DSPR.1**

1. The program defines its leadership roles.

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<th>Elements of Performance for DSPR.1</th>
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<td>2. The program identifies members of its leadership team.</td>
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<td>3. The program defines the accountability of its leader(s).</td>
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<td>4. The program leader(s) guides the program in meeting the mission, goals, and objectives.</td>
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<tr>
<td>5. The program leader(s) identifies, in writing, the composition of the interdisciplinary team.</td>
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**Requirement Specific to Ventricular Assist Device Destination Therapy**

a. The interdisciplinary VAD team includes:

- One or more board-certified cardiologists, one of whom must practice as an advanced heart failure specialist
- One or more board-certified cardiac surgeons
- A VAD coordinator
- Designated VAD registered nurse

Note: The VAD coordinator role can be fulfilled by the registered nurse.

- A social worker
- A palliative care provider

5. The program leader(s) participate in designing, implementing, and evaluating care, treatment, and services.

6. The program leader(s) provides for the uniform performance of care, treatment, and services.

7. The program leader(s) makes certain that practitioners practice within the scope of their licensure, certification, training, and current competency.

8. The program leader(s) monitors the performance of the program’s interdisciplinary team as it relates to achievement of the program’s mission, goals, and objectives.

**DSPR.2**

22. The program is collaboratively designed, implemented, and evaluated.

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<th>Elements of Performance for DSPR.2</th>
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<tr>
<td>23. The interdisciplinary team designs the program.</td>
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<td>24. The interdisciplinary team implements the program.</td>
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<td>25. The interdisciplinary team evaluates the program.</td>
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<td>26. The interdisciplinary team uses the results of the program evaluation to improve performance.</td>
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</table>
**Advanced DSC Certification for VAD**

**DSPR.3**
27 The program meets the needs of the target population.

*Elements of Performance for DSPR.3*

28 1. The leader(s) define, in writing, the program’s mission and scope of service.
29 2. The leader(s) approve the program’s mission and scope of service.
30 3. The program identifies its target population.

*Requirement Specific to Ventricular Assist Device Destination Therapy*

31 a. The program has a process to determine eligibility for VAD placement that at a minimum includes:
32 b. The use of specific criteria for determining the inclusion or exclusion of patients
33 c. An interdisciplinary approach to determining which patients are eligible for VAD placements

34 4. The services provided by the program are relevant to the target population.

**DSPR.4**
41 The program follows a code of ethics.

*Elements of Performance for DSPR.4*

42 1. The program protects the integrity of clinical decision making.
43 2. The program respects the patient’s right to decline participation in the program.
44 3. The program has a process for receiving and resolving complaints and grievances in a timely manner.

**DSPR.5**
45 The program determines the care, treatment, and services it provides.

*Elements of Performance for DSPR.5*

46 1. The program defines in writing the care, treatment, and services it provides.
47 2. The program communicates to the patient the care, treatment, and services it provides.
48 3. The program provides care, treatment, and services to patients in a planned and timely manner.
49 4. The program complies with applicable law and regulation.
50 5. The program informs the patient and family about how to access care, treatment, and services, including after hours (if applicable).
51 6. The program has a process to provide emergency/urgent care.

*Requirements Specific to Ventricular Assist Device Destination Therapy*

52 a. The program provides 24 hours a day, 7 days a week support for the patient and family regarding how to handle emergency and urgent care following discharge from the hospital.
53 b. The VAD program designates practitioners to be on-call to assist discharged patients and families after hours.
The program provides the number and types of practitioners needed to deliver or facilitate the delivery of care, treatment, and services.

The program evaluates services provided through contractual arrangement to make certain the care, treatment, and services are consistently provided in a safe, quality manner. This evaluation is documented.

Variables such as staffing, setting, or payment source do not affect outcomes of care, treatment, and services.

The program has current reference and resource materials.

**Elements of Performance for DSPR.6**

1. Practitioners have access to reference materials, including clinical practice guidelines, in either hard copy or electronic format.
2. Reference materials and resources are current and evidence-based.

The program's facilities are safe and accessible.

Note: The program may use the organization’s plan and processes for safety and accessibility if they address the program’s unique needs and target population.

**Elements of Performance for DSPR.7**

1. The program identifies its security risks.
2. The program implements strategies to minimize security risks.
3. The unique needs of the program’s patients and/or the program’s setting are included in the organization’s emergency management plan.
4. The program implements strategies to minimize the risk of disruption of care due to an emergency.
5. The program evaluates its fire risk.
6. The program implements strategies to minimize the risk of fire and address fire safety-related issues.
7. The program develops a medical equipment management plan.
8. The program has a process for maintaining the most up-to-date device information, including manufacturer recalls and warnings.

The program implements its medical equipment management plan.

The program evaluates risks to its power, gas, and communication services.

The program implements strategies to minimize risks to its power, gas, and communication services.

The program educates staff on environment of care risk-reduction strategies.

The program tracks incidents related to the environment of care and makes changes accordingly.

Requirement Specific to Ventricular Assist Device Destination Therapy

1. The program has a process for maintaining the most up-to-date device information, including manufacturer recalls and warnings.

8. The program implements its medical equipment management plan.
9. The program evaluates risks to its power, gas, and communication services.
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Delivering or Facilitating Clinical Care (DSDF)

**DSDF.1**

Practitioners are qualified and competent.

**Elements of Performance for DSDF.1**

1. Practitioners have education, experience, training, and/or certification consistent with the program’s scope of services, goals and objectives, and the care provided.

**Requirements Specific to Ventricular Assist Device Destination Therapy**

a. The interdisciplinary team has at least the following experience and expertise:

   - One or more board-certified cardiologists, each of whom:
     i. Is trained and experienced in advanced heart failure therapies
     ii. Has had recent experience managing patients who have had ventricular assist devices placed or heart transplants
     iii. Has sufficient competency in evaluating patients for transplant as evidenced by having worked in or trained in a transplant center
     - One cardiologist who must be board certified or board eligible in advanced heart failure.
     - One or more board-certified cardiac surgeons, each of whom has successfully placed 10 ventricular assist devices in the last 36 months with current activity occurring in the last year.
     Note: Acceptable ventricular assist device procedures include placement of long-term devices and devices that are part of studies for U.S. Food and Drug Administration approval.
     - A registered nurse who has experience and expertise in providing care for a VAD patient
     - A VAD coordinator who has experience and expertise in the complete course of treatment of a VAD patient
     Note: The VAD coordinator role can be fulfilled by the registered nurse.
     - A social worker who has experience and expertise in the assessment and evaluation of a VAD patient and his or her family
     - A palliative care provider who has experience and expertise working with a VAD patient and his or her family

2. The program verifies each practitioner’s licensure using a primary source verification process upon hire and at licensure expiration.

3. The program assesses practitioner competency at time of hire. This assessment is documented.

**Requirement Specific to Ventricular Assist Device Destination Therapy**

a. The cardiac surgeon is privileged by the organization for VAD implantation.

b. One or more cardiologists, including the heart failure specialist, are privileged by the organization to care for the VAD patient population.

4. Orientation provides information and necessary training pertinent to the practitioner’s responsibilities. Completion of the orientation is documented.

5. The program assesses practitioner competence on an ongoing basis. This assessment is documented.

6. The program identifies and responds to each practitioner’s program-specific learning needs.

7. Ongoing in-service and other education and training activities are relevant to the program’s scope of services.

**DSDF.2**

The program develops a standardized process originating in clinical practice guidelines (CPGs) or evidence-based practice to deliver or facilitate the delivery of clinical care.

**Elements of Performance for DSDF.2**

1. The selected clinical practice guidelines are evaluated for their relevance to the target population.
The selected clinical practice guidelines are based on evidence that is determined to be current by the clinical leaders. Program leader(s) and practitioners review and approve clinical practice guidelines prior to implementation. Practitioners are educated about clinical practice guidelines and their use. The program demonstrates evidence that it is following the clinical practice guidelines when providing care, treatment, and services.

**Requirement Specific to Ventricular Assist Device Destination Therapy**
- Inclusion criteria for VAD implant are as follows:
  - Patients who have an anticipated survival benefit
  - Patients with New York Heart Association Functional Classification Class IV heart failure symptoms who have failed to respond to optimal medical management
  - Patients with a demonstrated functional limitation with a peak oxygen consumption of less than or equal to 14 ml/kg/min
  - Patients with a continued need for intravenous inotropic therapy
  - Patients who have been evaluated for heart transplant and were not selected as candidates
  
  Note: To receive CMS reimbursement, patients must meet current CMS patient selection and coverage criteria.

The program implements modifications to clinical practice guidelines based on current evidence-based practice.

**DSDF.3**
The program is implemented through the use of clinical practice guidelines selected to meet the patient's needs.

**Elements of Performance for DSDF.3**

1. The program establishes an interdisciplinary team based on the patient's assessed needs and direction from clinical practice guidelines.

2. The assessment(s) and reassessment(s) are completed according to the patient's needs and clinical practice guidelines.

**Requirement Specific to Ventricular Assist Device Destination Therapy**
- The VAD patient is evaluated for post-implant clinical improvement to determine further treatment options.

3. The program implements care, treatment, and services based on the patient's assessed needs.

**Requirement Specific to Ventricular Assist Device Destination Therapy**
- The program has the ability to perform diagnostic tests to assess the VAD patient. These may include electrocardiography, echocardiography with device implant, exercise testing, nuclear cardiology, electrophysiology, cardiovascular MRI, pacing, diagnostic catheterization of right- and left-sided heart, and interventional catheterization.

**DSDF.4**
The program develops a plan of care that is based on the patient's assessed needs.

**Elements of Performance for DSDF.4**

1. The plan of care is developed using an interdisciplinary approach and patient participation.

**Requirement Specific to Ventricular Assist Device Destination Therapy**
- The program demonstrates an interdisciplinary approach for the outpatient management of the VAD patient.
2. The program individualizes the plan of care for each patient.

3. The individualized plan of care is based on the patient’s goals and the time frames to meet those goals.

4. The individualized plan of care reflects coordination of care with other programs, as determined by patient co-morbidities.

**Requirements Specific to Ventricular Assist Device Destination Therapy**

- a. Patients are identified for palliative care, when indicated.
- b. Patients are referred to palliative care, when indicated.
- c. Patients receive palliative care services, when indicated.

5. The program explains the plan of care to the patient in a manner he or she can understand.

6. The program informs patients of all potential consequences of not complying with recommended care, treatment, and services.

7. The program informs patients of their responsibility to provide information to facilitate treatment and cooperate with practitioners.

8. The program continually evaluates, revises, and implements revisions to the plan of care to meet the patient's ongoing needs.

**DSDF.5**

The program manages co-morbidities and concurrently occurring conditions and/or communicates the necessary information to manage these conditions to other practitioners.

**Elements of Performance for DSDF.5**

1. The program coordinates care for patients with multiple health needs.

**Requirement Specific to Ventricular Assist Device Destination Therapy**

- a. The interdisciplinary team conducts regularly scheduled VAD meetings to discuss coordination of care for VAD patients in the program.

2. Patients with co-morbidities and co-occurring conditions needing clinical and/or psychosocial care, treatment, and services are managed by the program’s practitioners or referred to other practitioners for care.

**Requirement Specific to Ventricular Assist Device Destination Therapy**

- a. Psychological support is available for patients and their families to help them meet the unique challenges associated with VAD implantation.

3. The program communicates to other practitioner(s) important information regarding co-occurring conditions and co-morbidities that are needed to manage the patient’s conditions.
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**DSDF.6**

The program initiates discharge planning and facilitates arrangements for subsequent care, treatment, and services to achieve mutually agreed upon patient goals.

**Elements of Performance for DSDF.6**

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<tr>
<td>187</td>
<td>In preparation for discharge, the program discusses and plans with the patient and family the care, treatment, and services that are needed in order to achieve the mutually agreed upon self-management plan and goals.</td>
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**Requirements Specific to Ventricular Assist Device Destination Therapy**

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<td>190</td>
<td>Coordination of care for the VAD patient is conducted prior to discharge and includes at least the following:</td>
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<td>191</td>
<td>Contact information for a practitioner in the community is given to the patient to facilitate ongoing care</td>
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<td>192</td>
<td>Contact information for the VAD center practitioner is given to the patient to facilitate ongoing care</td>
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<td>193</td>
<td>The program has an outpatient management plan that includes:</td>
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<td>194</td>
<td>A schedule for follow-up appointments</td>
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<tr>
<td>195</td>
<td>A schedule for device checks</td>
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<tr>
<td>196</td>
<td>On-going patient and family education</td>
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<td>199</td>
<td>In preparation for discharge, the program considers the patient's anticipated needs and goals when identifying the setting and practitioners for continuing care, treatment, and services.</td>
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**Requirement Specific to Ventricular Assist Device Destination Therapy**

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<td>201</td>
<td>When the patient will not reside within a reasonable commuting distance from the facility following discharge, the program shall, at the time of discharge, arrange appropriate follow-up care with a facility and physician near the patient's residence.</td>
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<tr>
<td>204</td>
<td>In preparation for discharge, the program communicates the patient's needs and goals to other practitioners who will continue to support the patient in achieving the desired outcomes.</td>
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<tr>
<td>206</td>
<td>The program provides education and serves as a resource, as needed, to practitioners who are assuming responsibility for the patient's continued care, treatment, and services.</td>
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**Requirements Specific to Ventricular Assist Device Destination Therapy**

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<tbody>
<tr>
<td>208</td>
<td>Members of the interdisciplinary team are available to other practitioners managing the patient, as needed after discharge from the program.</td>
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<tr>
<td>209</td>
<td>The program provides ongoing education to first responders within the vicinity of the patient's residence.</td>
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Supporting Self-Management (DSSE)

DSSE.1

The program involves patients in making decisions about managing their disease or condition.

Elements of Performance for DSSE.1

1. The program involves patients in decisions about their care, treatment, and services.

Requirements Specific to Ventricular Assist Device Destination Therapy

a. Informed consent reflects the patient’s understanding of the following:
   - Preoperative, intraoperative, and postoperative plan of care, treatment, and services
   - Current survival and functional expectations after VAD implant
   - Alternative courses of treatment
   - Anticipated outpatient management plan
   - Quality of life factors such as physical function, psychosocial effect, symptoms, costs, caregiver burden
   - Patient expectations
   - Rehabilitation plan
b. The informed consent is provided by the surgeon.
c. The informed consent is documented.

2. The program assesses the patient’s readiness, willingness, and ability to engage in self-management activities.

3. The program assesses the family and/or caregiver’s readiness, willingness, and ability to provide or support self-management activities when needed.

4. The program utilizes the assessment of the patient and family and/or caregiver to guide the development of a self-management plan.

5. Patients and practitioners mutually agree upon goals.

DSSE.2

The program addresses the patient's self-management plan.

Elements of Performance for DSSE.2

1. The program promotes lifestyle changes that support self-management activities.

2. The program evaluates barriers to lifestyle changes.

Requirements Specific to Ventricular Assist Device Destination Therapy

a. The program facilitates a home assessment to evaluate whether the environment can support safe and reliable functioning of a VAD device.
b. The program evaluates the home assessment as part of its decision-making process for implantation of a VAD device.

3. The program engages family and community support structures in the patient’s self-management plan, as directed by the patient.

Requirements Specific to Ventricular Assist Device Destination Therapy

a. The hospital ascertains, through the home assessment, that the patient’s home environment is satisfactory and that the patient has an adequate and reliable power supply and telephone service.
b. Communication is sent from the hospital to the power company informing it that a ventricular assist device patient lives in the vicinity.

4. The program assesses and documents the patient's response to recommended lifestyle changes.
Advanced DSC Certification for VAD

246 5. The program addresses the education needs of the patient regarding disease progression and health promotion.

248 6. The program revises the self-management plan according to the patient's assessed needs.

DSSE.3

249 The program addresses the patient's education needs.

Elements of Performance for DSSE.3

250 1. The program's education materials comply with recommended elements of care, treatment, and services, which are supported by literature and promoted through clinical practice guidelines and evidence-based practice.

253 2. The program presents content in an understandable manner according to the patient's level of literacy.

254 3. The program presents content in a manner that is culturally sensitive.

255 4. The program makes initial and ongoing assessments of the patient's comprehension of program-specific information.

Requirement Specific to Ventricular Assist Device Destination Therapy

258 a. The program educates the patient and family on troubleshooting the VAD and responding to alarms.

259 5. The program addresses the education needs of the patient regarding his or her disease or condition and care, treatment, and services.

Clinical Information Management (DSCT)

DSCT.1

261 Patient information is confidential and secure.

Elements of Performance for DSCT.1

262 1. Patients are made aware of how data and information related to them will be used by the program.

264 2. The program discloses health information only as authorized by the patient or as otherwise consistent with law and regulation.

266 3. Records and information are safeguarded against loss, destruction, tampering, and unauthorized access or use.

269 4. The program identifies, in writing, who is authorized to access, use, and disclose patient information.

269 5. The program defines a process for responding to a violation of confidentiality or security.

269 6. The program implements its process addressing a violation of confidentiality or security.

DSCT.2

270 Information management processes meet the program's internal and external information needs.

Elements of Performance for DSCT.2

271 1. Data are easily retrieved in a timely manner without compromising security and confidentiality.

273 3. The program uses aggregate data and information to support operations.

274 4. The program uses aggregate data and information to support performance improvement activities.
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The program uses aggregate data and information to support patient care.

**DSCT.3**

Patient information is gathered from a variety of sources.

**Elements of Performance for DSCT.3**

1. Information is gathered directly from the patient and family.
2. Information is gathered from relevant practitioners and/or health care organizations.

**Requirements Specific to Ventricular Assist Device Destination Therapy**

a. The program gathers information from all relevant practitioners or health care organizations prior to implantation of the ventricular assist device.
b. The program gathers information from all relevant practitioners or health care organizations at least annually after implantation of the ventricular assist device to ascertain any additional needs the patient may have related to the device.

**DSCT.4**

The program shares information with relevant practitioners and/or health care organizations about the patient’s disease or condition across the continuum of care.

**Elements of Performance for DSCT.4**

1. The program shares information directly with the patient.
2. The program shares information with relevant practitioners and/or health care organizations to facilitate continuation of patient care.

**DSCT.5**

The program initiates, maintains, and makes accessible a medical record for every patient.

**Elements of Performance for DSCT.5**

1. All relevant practitioners have access to patient information as needed.
2. The medical record contains sufficient information to identify the patient.
3. The medical record contains sufficient information to support the diagnosis.
4. The medical record contains sufficient information to justify the care, treatment, and services provided.
5. The medical record contains sufficient information to document the course and results of care, treatment, and services.
6. The medical record contains sufficient information to facilitate continuity of care.
7. The program reviews its medical records for completeness and accuracy.

**Performance Measurement (DSPM)**

**DSPM.1**

The program has an organized, comprehensive approach to performance improvement.

**Elements of Performance for DSPM.1**

1. The program leader(s) identifies goals and sets priorities for improvement in a performance improvement plan.
The program leader(s) involves the interdisciplinary team and other practitioners across disciplines and/or settings in performance improvement planning and activities.

The program has a written performance improvement plan.

The program leader(s) shares the program performance improvement plan with organizational leadership.

The program collects data related to its target population to identify opportunities for performance improvement.

The program analyzes its performance measurement data to identify opportunities for performance improvement.

The program documents actions taken to achieve improvement.

The program determines if improvements have been achieved and are being sustained.

**DSPM.2**

The program maintains data quality and integrity.

### Elements of Performance for DSPM.2

1. The program uses standardized data, definitions, and measure specifications in a consistent manner.
2. Data collection is timely, accurate, complete, and relevant to the program.
3. The program minimizes data bias.

**Requirement Specific to Ventricular Assist Device Destination Therapy**

a. All patient data, from every FDA-approved device, are entered into the INTERMACS registry.

Note: INTERMACS is currently the only nationally audited registry for VAD.

4. The program monitors data reliability and validity.
5. The program uses sampling methodology based on measurement principles.
6. The program uses data analysis tools.

**DSPM.3**

The program collects measurement data to evaluate processes and outcomes.

Note: Measurement data must be internally trended over time and may be compared to an external data source for comparative purposes.

### Elements of Performance for DSPM.3

1. The program selects valid, reliable performance measures that are relevant to the target population and based on clinical practice guidelines or other evidence-based practice.

**Requirement Specific to Ventricular Assist Device Destination Therapy**

a. The program monitors the occurrence of the following adverse events throughout the episode of care:

- Bleeding
- Infection
- Stroke
- Readmission
- Device malfunction
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2. The program collects data related to processes and/or outcomes of care.

*Requirement Specific to Ventricular Assist Device Destination Therapy*

a. The program monitors at least the following data:

- Survival rate (all cause mortality)
- Functional capacity
- Any results provided by the national registry

3. The program collects patient satisfaction data relevant to its target population.

4. Data are aggregated at the program level.

5. The program reports aggregated data results to The Joint Commission at defined intervals.

6. The program communicates to staff and organizational leaders the identified improvement opportunities.

7. The program incorporates identified improvement opportunities into the performance improvement plan.

8. The program demonstrates improvement in processes and patient outcomes.

DSPM.4

The program collects and analyzes data to determine variance from the clinical practice guidelines.

**Elements of Performance for DSPM.4**

1. The program tracks data variances at the patient level.

2. The program evaluates variances that affect program performance and outcomes.

*Requirement Specific to Ventricular Assist Device Destination Therapy*

a. The program analyzes its VAD patient data in the INTERMACS registry to evaluate outcomes.

Note: INTERMACS is currently the only nationally audited registry for VAD.

3. The program uses data analysis to modify performance improvement activities in support of clinical practice guidelines.

DSPM.5

The program evaluates patient satisfaction with the quality of care.

**Elements of Performance for DSPM.5**

1. The program evaluates patient satisfaction with and perception of quality of care at the program level.

*Requirement Specific to Ventricular Assist Device Destination Therapy*

a. The program evaluates VAD patients’ perception of quality of life at the following intervals: pre-implant and post-implant at 3 months, 6 months, and every 6 months thereafter.

2. Patient satisfaction data are utilized for program-specific performance improvement activities.

DSPM.6

The program has a sentinel event process that includes identifying, reporting, managing, and tracking sentinel events.

**Elements of Performance for DSPM.6**

1. A process exists for identifying sentinel events related to the program.

2. A process exists for internally tracking sentinel events if and when they occur.

3. A process exists for analyzing sentinel events as they relate to program activity.
4. The program leader(s) implements changes to the program based on the analysis of sentinel events.