

DNV HEALTHCARE INC

1400 Ravello Drive
Katy, Texas 77449
(281) 396-1000

400 Techne Center Drive,
Suite 100,
Milford, Ohio 45150
(513) 947-8343



October 12, 2012

Medicare Evidence Development and Coverage
Advisory Committee (MEDCAC)
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

Via: Electronic mail (MedCACpresentations@cms.hhs.gov)

Re: MEDCAC Meeting- November 14, 2012-
Management of Heart Failure with the
Use of Ventricular Assist Devices

Dear Committee Members:

These written comments are submitted pursuant to CMS-3274-N regarding written comments for the above-referenced meeting.

On November 28, 2011, DNV Healthcare Inc. (DNV) submitted a formal request for reconsideration of the National Coverage Determination (NCD) for Artificial Heart and Related Devices. DNV Healthcare Inc. (DNV) requested 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. This request remains under review by the Coverage and Analysis Group of CMS.

DNV believes its formal request for reconsideration of the NCD regarding facility criteria has a direct impact on Question 2(b) to be addressed by the Committee: "Please discuss the role, if any, of facility VAD specific certification to assure attainment and maintenance of any characteristics identified in question 2(a)."

DNV believes the approval of a second VAD facility certification program will broaden the base of objective criteria regarding facility evaluation and provide CMS and the MEDCAC a valuable tool for evaluating patient outcomes in facilities certified by different programs. In addition, several large hospitals with VAD programs have switched their accreditation to DNV and want to retain their VAD certification with the same accreditation organization. It should also be noted that as a condition of retaining DNV accreditation, DNV-accredited hospitals seeking DNV VAD facility certification are or will become compliant with the ISO 9001 Quality Management System. This quality management system is unique for U.S. hospital accreditation and will allow for an additional objective criterion to compare VAD facilities certified by different programs.

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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 is 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 (TJC) VAD program (above) is the only certification program for facilities to qualify under this NCD. The DNV MCS Program Certification Requirements, Upon CMS approval of DNV’s formal request for reconsideration of the National Coverage Determination (NCD) for Artificial Heart and Related Devices regarding Facility Criteria, MCS 1.0 will be offered as an alternative to the TJC VAD certification program. The DNV MCS Program is enclosed and made a part of this formal request.

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 initial DNV Healthcare Inc. application for hospital deeming authority was approved by CMS effective September 26, 2008 and renewed for six (6) years-the maximum time allowed by law-on August 24, 2012. The initial hospital deeming authority was the first such application to be approved by CMS in over 40 years. Since that date more than 250 hospitals and critical access hospitals throughout the United States have been accredited by DNV. An additional 70+ hospitals have signed contracts and are in the process of being surveyed and accredited. This total represents a steady growth after DNV received its initial deeming authoring. 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 than 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 of 4 or 5.

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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 have changed or want to change to DNV for hospital accreditation and not rely solely on TJC for VAD facility certification. The DNV MCS program is the third disease-specific certification program developed by DNV. DNV has developed and made available to hospitals throughout the United States a Primary Stroke Center Certification (PSCC) and Comprehensive Stroke Center Certification (CSCC). There are currently 32 hospitals throughout the country that are PSCC-certified by DNV and several hospitals have applied to DNV for CSCC certification.

For Further Information, contact:

Darrel J. Scott, FACHE
Senior Vice President, Regulatory & Legal Affairs
DNV Healthcare Inc.
400 Techne Center Drive, Suite 100
Milford, OH 45150
Ph: 513-388-4862
Email: Darrel.Scott@dnv.com

Enclosure: DNV Healthcare Inc. Mechanical Circulatory Support Certification Program –
Requirements, MCS 1.0