DNV GL - Healthcare	Advisory Notice	Notice No: 2015-06

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SUBJECT: New Version Comprehensive Stroke Center Standards 2.0

DISTRIBUTION: All DNV GL - Healthcare Customers, Employees and Sub-contractors

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DNVGL is proud to announce an updated version of the Comprehensive Stroke Center Requirements 2.0 is now complete and ready for distribution. This advisory notice will give some basic information and highlight some additions to this new version. A fully detailed crosswalk will be sent out very soon and posted on the website.

These requirements are marked as effective September 1, 2015; however, you will have until October 1, 2015 to study them before the standards become applicable. While there have not been many changes or additions, there are some additions that may take organizations time to comply with.

If an organization does not have a new requirement in place at the time of a CSC survey after October 1, 2015, the surveyor will categorize that finding as an NC-2. This will give your organizations an opportunity to develop a corrective action plan and a year to comply with that particular standard. The compliance of that requirement, and any others that were cited, will be validated during the next annual survey per DNV GL survey policy.

Below you will see a general description of changes and additions in this new version. We are always striving to improve patient care alongside our partner hospitals. These new guidelines are based on updated current national guidelines combined with lessons learned since the introduction of the previous version of the comprehensive stroke program.

1. **Target Stroke: New Addition**

   DNV GL is committed to being a partner with organizations who are striving to improve their Door to Needle times. Therefore we are encouraging our partner organizations to adopt the Target Stroke Phase II challenge of:

   - Achieving Door to Needle times (time of bolus administration) within 60 minutes in 75% or more of acute ischemic stroke patients treated with IV tPA

     AND

- Achieving Door to Needle times (time of bolus administration) within 45 minutes in 50% or more of acute ischemic stroke patients treated with IV tPA

Starting January 1, 2016, we will begin to report nonconformance in organizations if their tPA door to needle times do not show improvement or have continued to not meet the 75% of tPA given within 60 minutes or less. We will not report nonconformance for the new target of 50% of tPA given within 45 minutes or less, as this will take almost all organizations some time to get to that goal. There will be discussion about the plans and processes that your organization is working on to move closer to that goal during the survey.

2. Notes: New Addition

You will see that we have added clarifying notes at the end of some requirement sections. These were developed in part by using the questions and clarifications that many of you had. The reaction in the field to this new addition had been very positive. We will continue to add to those notes as issues need more clarification.

3. Education requirements: Clarification

There were many issues about who needed stroke/neuro specific education and the appropriate numbers of hours for stroke team and other department personnel. Education requirements are now addressed under Acute Stroke Team, ICU/Critical care management and further delineated under the competence section.

4. Emergency Medical Services: Addition

A new section for EMS was added to highlight and acknowledge the key role with the timely recognition, treatment, transfer, and outcomes of patients with acute stroke. The pre hospital assessment and early notification had been identified in recent AHA recommendations and this delineation of expectations and process was added to reflect those recommendations. While some of the requirements in this section will look new, the requirements were in the processes of most of the CSCs already. New requirements include:

- Having a document of cooperation in place between the CSC and the EMS,
- The program and EMS determining circumstances and alternate protocols in which the CSC would be on diversion and not able to accept patients
- The program having access to treatment protocols utilized by EMS providers and pre-hospital personnel in response to patients reporting symptoms of stroke
- The program having stroke patient priority destination protocols utilized by EMS providers that address transport of stroke patients, in accordance with law and regulation

5. Expanded Telestroke Section: Clarification / Addition

The organization must now have a written description of the type of telemedicine technologies available on site at the CSC which may include the description of the technical requirements of the equipment (such as speed and resolution), depending on the system used. The medical professionals providing remote medical guidance will now have evidence of training and expertise that is required. There is also a new addition concerning the timeliness of the link to the neuro consultant that, if used, should be fully established within 20 minutes of when it is considered necessary by contracting emergency room, ASR or PSC physicians. That applies to phone as well as computer linkage.

6. Expanded Protocol Section: Addition / Delineation

While the required protocols are not new, there were additions of the requirement for in house stroke alert protocol, Blood pressure and oxygenation management, and transfer (both receiving to the CSC and out to another CSC.) A new addition is a requirement for what should be included in a stroke protocol, following the current AHA guidelines for such issues as vital sign and neuro parameters, Blood pressure management parameters, Blood glucose control, Parameters to treat fever, Oxygenation management parameters and other items as included.

7. Transfer Agreements: Addition

New section that describes the content and circumstances of what a transfer agreement should include such as transportation options (ground, air), bypass or diversion plan for additional receiving hospital, if needed, Monitoring personnel required during transfer, dependent on patient's condition and related to the therapy used. The CSC must have a written transfer agreement (or understanding) with each PSC or ASR that the CSC provides services.

8. Plan of Care: Expanded

Plan of care section has been expanded to include those stroke specific standards of care as well as the requirement that the patient and the family be included in planning decisions on the care that the patient will receive.

9. Medication Management: Addition / Delineation

There is a new delineation that emergency department practitioners can demonstrate safe use of tPA in knowing safe time frames for administration of tPA, indications for use, exclusion and contraindication criteria, dosage and mixing instructions and monitoring protocols for identification of post tPA neurological deterioration.

10. Patient/Family/Community Education: Addition

While this is a new section, it pulled the family patient and community education together into one area. There is a new requirement that the CSC shall offer at least 2 annual programs to educate the public about stroke prevention, diagnosis, and/or the availability of acute therapies as well as the old requirement that the CSC shall evaluate the community outreach initiatives by measuring the knowledge in the community about the causes, signs and symptoms of stroke as well as emerging stroke prevention strategies.

11. Informed Consent: Delineation/Clarification

The concept of the informed consent is addressed here with an expanded discussion and direction if a patient cannot give consent as well as identification of tPA being a standard of care, determining if consent needs to be waited for when time is critical. New delineation was added that the requirement for all surgical interventions, the usual informed consent process of the host hospital be followed.

12. Medical Staff: Addition/Delineation

New sections under medical staff are:

Neuro surgical coverage

There was a new addition of the need for written protocols for transfer to include communication from other facilities that are transferring in as well as a transfer out to another CSC facility. And that each neurosurgeon should participate in greater than or equal to 10 surgical intervention cases per year. (Examples: clipping/coiling at least ten each, when possible. This can also include -CEA, craniotomies, EVD placement, etc.)

ICU / Critical Care Management and Coverage

This section delineates the medical staff responsibility/ability to set the criteria that the Intensivists must meet so that they can staff the ICU that contains the dedicated neuro beds under the condition that there is a neurologist on call for consultation 24/7 and can be in house within 45 minutes and that the criteria set by medical staff shall be in writing.

Endovascular Services

The CSC shall have the ability and equipment to perform revascularization procedures and microvascular surgery. The CSC will provide neurosurgical and endovascular Services for the treatment of cerebrovascular diseases including the following: IA infusions of vasodilators, was added. The expectation that the CSC shall have the ability and equipment to perform

revascularization procedures and microvascular surgery was added. Perioperative complications shall be tracked prospectively.

13.Medical Records : Addition

There is a new requirement that there be documentation indicating the reason if an eligible ischemic stroke patient does not receive IV thrombolytic therapy as well as an addition, specifically addressing documentation of post tPA monitoring per protocol and or hospital policy.

14.Rehabilitation: Addition

Expanded goals for post stroke rehabilitation. Also added the clarification that consults and assessments need to be performed and documented within 24 hours of admission or when feasible once the patient is medically stable. Documentation in the medical record of attempts to perform a patient assessment and reason why it was not able to be performed is required

15. Metrics: No new metrics/ Clarifications

Metric 12 added AVM back with ICH and SAH as it was left off last version

Metric 18 Complication rates for aneurysm coiling and clipping are now broken out to distinguish clipping and coiling each with and without rupture as well as combined number

Should you have any questions, do not hesitate to contact:

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