DNV·GL

NATIONAL INTEGRATED ACCREDITATION FOR HEALTHCARE ORGANIZATIONS

LEVEL 3 - Acute Stroke Ready Certification
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DNV GL - HEALTHCARE ACUTE STROKE READY CERTIFICATION REQUIREMENTS

Effective Date

This DNV GL - Healthcare Acute Stroke Ready Certification Requirements, ASR 1.0 Effective Date: January 1, 2015.

Federal Laws, Rules and Regulations

The Acute Stroke Ready (ASR) Certification requirements are based in whole or in part of the most current recommendations from the Brain Attack Coalition (BAC), American Heart Association and the American Stroke Association. (AHA/ASA) and the Center for Medicare and Medicaid (CMS) Conditions of Participation

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, in part, Acute Stroke Ready Certification requirements.

ASRs, through their association to the Hospitals participating in the Medicare and Medicaid program, are expected to comply with current Conditions of Participation. When new or revised requirements are published, ASRs are expected to demonstrate compliance in a time frame consistent with the effective date as published by CMS in the Federal Register and/or as required by DNVGL Healthcare.

DNV GL - HEALTHCARE ACUTE STROKE READY CERTIFICATION

INTRODUCTION

The Acute Stroke Ready (ASR) Certification Program is offered by DNV GL - Healthcare (DNV GL- HC) and integrates requirements related to the Guidelines of the Brain Attack Coalition, the recommendations of the American Heart Association, the American Stroke Association and to the CMS Conditions of Participation for hospitals (CoPs)

ASRs are designed to be a part of a larger stroke system of care which will include all levels of stroke care.The stroke-ready certification will mean that a hospital is equipped to evaluate, stabilize and provide emergency care to patients with acute stroke symptoms. The intent of the ASR is to provide initial diagnostic services, stabilization, emergent care and therapies to patients with an acute stroke who are seen in the emergency department. In most cases, the ASR would be in a remote location and not in a densely populated urban or suburban area where there might be a nearby PSC or CSC.

An ASR hospital has the infrastructure and capability to care for acute stroke, including administration of intravenous thrombolytic therapy (also known as tissue plasminogen activator "tPA," or alteplase).

An ASR has fewer overall capabilities than a Primary Stroke Center, but has staff and resources able to diagnose, stabilize, treat, and transfer most patients with stroke. Most acute stroke patients may be transferred to a Primary Stroke Center or a Comprehensive Stroke Center that would provide ongoing care and/or endovascular procedures, as indicated, after initial treatment and stabilization.

If an ASR intends to admit many or most patients with an acute stroke, it is a recommendation that the facility develop a stroke unit with elements and procedures similar to those of a stroke unit at a PSC.

REGULATORY AND POLICY REFERENCE

- The Medicare Conditions of Participation for hospitals are in 42 CFR Part 482.
- The DNVGL HC Certification Process, Certification Requirements, and applicable CMS State Operations Manual (SOM) provide the policies and procedures regarding certification activities.
- American Stroke Association / American Heart Association - Guidelines for Stroke Patients and Establishment of Stroke Systems of Care
- Brain Attack Coalition – Pathways and Guidelines

Surveyors assess the ASR's compliance with the ASR Certification Requirements for services and locations in which the ASR operates for patient care services.

Organizations seeking and maintaining Acute Stroke Ready certification 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 DNVGL- HC or another accreditation organization, approved by CMS to deem healthcare organizations in compliance with the CoPs.

This Certification Program addresses healthcare organizations that are either applying for DNV GL - Healthcare for certification in the Acute Stroke Ready Certification (ASR) Program or are currently certified by DNV GL - HC. When a healthcare organization has applied for but not received DNV GL - HC certification, it is referred to as an “Applicant Organization.” When a healthcare organization is currently certified by DNV GL - HC, it is referred to as a “Certified Organization.

If the Certification Assessment is completed in conjunction with a DNVGL- HC Accreditation Survey for the hospital, the assessment will not be announced to the ASR. If the Certification Assessment is conducted separate and apart to a DNV GL Accreditation Survey, the ASR will be provided advance notice of the upcoming survey not to exceed one month prior to the assessment of the ASR.

Surveyor Information Gathering and Investigation

The objective of assessment activities is to determine the ASR’s compliance with the requirements through observations, interviews, and document review.

- The surveyors will focus attention on actual and potential patient outcomes, as well as required processes.
- The surveyors will assess the care and services provided, including the appropriateness of the care and services within the context of the certification requirements.
- The surveyors will visit the emergency room, imaging locations and other patient care settings as appropriate to the level of services provided by the ASR.
- The surveyors will review clinical records, staff records, and other documentation necessary to validate information gained from observations and interviews.
- The surveyors will review transfer agreements, telemedicine/tele-stroke capabilities and equipment.

ABBREVIATIONS AND DEFINITIONS

AANN	American Association of Neuroscience Nurses
ASR/Acute Stroke Ready	Organization that can provide timely access to stroke care but not able to meet all of the criteria for PSCs or CSCs
AIS	Acute Ischemic Stroke
AMA	American Medical Association
ABNN	American Board of Neuroscience Nursing
BAC	Brain Attack Coalition
CDC	Centers for Disease Control and Prevention
CEO	Chief Executive Officer
CFR	Code of Federal Regulations
CMS	Centers for Medicare Medicaid Services
CR	Certification Requirement
CSC	Comprehensive Stroke Center
CSRN	Certified Stroke Registered Nurse
DEA	Drug Enforcement Administration
EMS	Emergency Medical Services
FDA	Food and Drug Administration
GCS	Glasgow Coma Scale score
IAT	Rapid local delivery of thrombolytic agent through a micro catheter placed near the site of occlusion
ICH	Intracerebral hemorrhage
ISMP	Institute for Safe Medication Practices
ISO	International Organization of Standardization
Life Safety Code	Life Safety Code® of the National Fire Protection Association
NIHSS	National Institutes of Health Stroke Scale

NFPA	National Fire Protection Association
PRN (prn)	Pro re nata, as the occasion arises, when necessary
Primary Stroke Center/PSC	Primary Stroke Center
acute care phase	includes critical care units, intermediate care units, stroke units, and general medical units.
Hyper acute phase	includes the pre-hospital setting and the emergency department (ED)
QMS	Quality Management System
Tele-stroke/Tele-medicine	an approach to treating vascular disease that allows a neurologist to provide remote treatment for a stroke victim. Electronic communications may include telephone, internet or video conferencing, providing consultation and diagnostic services.
TIA	Transient Ischemic Attack
tPA	tissue plasminogen activator (thrombolytic medication)
Troponin	complex of three regulatory proteins (**troponin** C, **troponin** I, and **troponin** T) that is integral to muscle contraction in skeletal muscle and cardiac muscle. Often elevated after stroke.

PROGRAM MANAGEMENT (PM)

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

PM.1 SENIOR MANAGEMENT

CR.1 Senior Management is responsible and accountable for ensuring that the following:

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

CR.1b the ASR is licensed by the appropriate State or local authority responsible for licensing of ASR (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 ASR, directly or under contract and,

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

CR.1e responsibilities and authorities are defined and communicated to the ASR.

CR.1f appointment and qualifications of the medical director for the ASR

CR.1f(i) The medical director for the ASR must have sufficient knowledge of the diagnosis and treatment of cerebrovascular disease
Note: The ASR medical director does not need to be board certified in neurology. The medical director can be an emergency room physician.

PM.2 MANAGEMENT COMMITMENT

Senior management shall provide evidence of its commitment to the development and implementation of the ASR Program and continually improving its effectiveness by:

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

CR.2 establishing and assisting in meeting the ASR Programs mission, goals and objectives,

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

PM.3 PROGRAM LEADERSHIP

The ASR program leadership shall:

CR.1 define in writing the programs mission and scope of service which describes the design, implementation and evaluation of the processes needed for the ASR Program service delivery.

CR.2 determine criteria and methods needed to ensure consistent, effective care and treatment

CR.3 conduct program reviews to determine achievement towards goals, objectives and outcomes

CR.4 monitor, measure, and analyze program processes, and

CR.5 implement actions necessary to achieve planned results and continual improvement of these processes

QUALITY MANAGEMENT (QM)

QM.1 QUALITY MANAGEMENT

The governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the Acute Stroke Ready(ASR)), medical staff, and administrative officials are responsible and accountable for ensuring that the ASR implements and is included in the host hospital quality management system. The host hospital will assure that adequate resources are allocated for measuring, assessing, improving, and sustaining the ASRs performance and reducing risk to patients.

CR.1 The ASR must be involved in and implement the host hospitals method for maintaining an ongoing system for managing quality and patient safety.

CR.2 The ASR must implement quality assessment and performance improvement efforts to address priorities for improved quality of care and patient safety and that corrective and preventive actions are implemented and evaluated for effectiveness.

CR.3 The ASR has established programmatic measurable quality objectives and the results are analyzed addressed; and

CR.4 Appropriate information from the ASR has been submitted to the host hospital oversight group for quality management.

QM.2 QUALITY OUTLINE/PLAN

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

QM.3 QUALITY OBJECTIVES

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

QM.4 QUALITY REPRESENTATIVE

A quality representative shall be designated and shall have the responsibility and authority for ensuring that the requirements of the ASR program are implemented and maintained.

QM.5 DOCUMENTATION AND PROGRAM REVIEW

CR.1 Any variation, deficiency or non-conformity identified by the ASR shall be addressed by the stroke committee. Appropriate actions will be determined, applied, and documented.

CR.2 Review performed at regular intervals, at a minimum of once a quarter, with an annual evaluation of the effectiveness of the ASR program components and metrics.

Note: Documentation of activities may take the form of a Failure, Mode and Effect Analysis, Root Cause Analysis, Performance Report, Non-Conformity Report, specific Improvement Project analysis, etc.

QM.6 SYSTEM REQUIREMENTS

The ASR will participate and follow the system requirements of the host hospital in establishing a quality system, the ASR shall be required to have the following as a part of this system:

CR.1 An Interdisciplinary group to oversee the ASR specific quality data that includes the medical director of the ASR, the nurse stroke coordinator (or nurse practitioner or physician's assistant) and a quality facilitator. Other discipline representatives and practitioners members are at the discretion of the ASR. This interdisciplinary group shall conduct quality and programmatic reviews;

CR.2 A written document defining the quality oversight process, to include components of the ASR 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 the incidence, prevalence and severity of problems in these areas, processes or functions,

CR.4c and effect on health outcomes, improve patient safety and quality of care.

QM.7 MEASUREMENT, MONITORING, ANALYSIS

The ASR 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 ASR should encompass overall patient outcomes, linkages among key components of the ASR, potential problems that impede the care provided under the ASR. Furthermore, the ASR should develop performance measures and strategies for measuring, refining and reassessing the following key system components:

CR.1 Notification and EMS; including data exchange between EMS, ED and the Stroke Team so that relevant pre-hospital data can be incorporated into the evaluation of effectiveness of the ASR.

NOTE: This data will capture stroke team response time to acute stroke patients, treatments used and patient disposition. It is the discretion of the ASR to determine the collection of this data as to whether this is through written or electronic means and/or may be done retrospectively through chart reviews.

CR.2 Hyper acute stroke treatment with specific performance measures involving the timeliness and effectiveness of the acute treatment of both ischemic and hemorrhagic stroke and the prevention of complications.

CR.2a Door to physician ≤10 minutes

CR.2b Door to stroke team ≤15 minutes

CR.2c Door to CT/MRI initiation ≤25 minutes

CR.2d Door to CT/MRI interpretation ≤45 minutes

CR.2e Order to lab results ≤45 minutes, if ordered

CR.2f Computer link from determined medically necessary by ED physician ≤20 minutes (if applicable)

CR.2g Door to IV tPA bolus (≥50% compliance) ≤60 minutes

CR.2h Transfer of patients to PSC/CSC ≤2 hours of ED arrival (or when medically stable)

OR

CR.2i Door to monitored bed admission ≤3 hours (if admitted)

CR.3 Sub-acute care and secondary prevention including specific measures of patient outcomes and avoidance of complications and recurrent strokes.
(Core measures, applicable only if patients are admitted)

CR.4 Rehabilitation with performance measures to evaluate patient outcomes (mortality, functional status, and community discharge) and the percentage of stroke patient who receive the appropriate level of rehabilitation services in the system
(applicable only if patients are admitted).

QM.8 PATIENT SAFETY SYSTEM

CR.1 The ASR shall follow and participate in the host hospitals program for establishing clear expectations for identifying and detecting the prevalence and severity of incidents that impact or threaten patient safety.

PATIENT CARE SERVICES (PC)

PC.1 PLANNING FOR SERVICE DELIVERY

The ASR shall have a plan and develop the processes needed for ASR service delivery. Planning of the ASR service delivery shall be consistent with the certification requirements of the processes of the ASR Program. In planning service delivery, the ASR shall determine the following, as appropriate, a written plan or description of:

CR.1 quality objectives and requirements for the ASR;

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

CR.3 required verification, monitoring, and measurement, specific to the ASR

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 ASR's method of operations.

NOTE: While ASRs do not usually admit patients, there may be times when it is determined that a certain patient can have their care treated in the host hospital. There is no specific requirement as to the design and location of a unit that would be considered a stroke unit(s). The ASR can define the designation of a unit(s) and/or beds for treatment of acute stroke patients. The ASR will identify a specified unit to which most stroke patients are admitted and criteria when this may vary. The staff and services provided for these acute stroke patients will meet the specified requirements as defined under the ASR.

PC.2 REVIEW OF REQUIREMENTS RELATED TO ASR SERVICE DELIVERY

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

CR.1 ASR Program requirements are defined,

CR.2 the ASR has the ability to meet the defined requirements.

CR.3 Records of the results of reviews and actions shall be maintained.

CR.4 When the ASR Program requirements are changed, the ASR shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

PC.3 CONTROL OF SERVICE DELIVERY

The ASR 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 ASR Program,

CR.2 the availability of policies, procedures, protocols, as necessary,

CR.3 the availability, use and monitoring of suitable equipment,

PC.4 EMERGENCY DEPARTMENT (ED)

CR.1 The ASR is responsible for developing and maintaining pathways, protocols and processes to rapidly identify, evaluate and treat potential stroke patients.

CR. 2 Emergency Department practitioners and staff demonstrate knowledge and understanding of the stroke protocol in place, including effective communication with EMS personnel, notification of the stroke team and initiation of the stroke protocol concurrent with the ED evaluation and management.

CR.3 The emergency department practitioners and staff demonstrate knowledge in the delivery of acute therapies that can improve a patient's outcome with a variety of strokes, when indicated, including, but not limited to:

- Intravenous tPA
- Reversal of coagulopathies
- Control and reduction of elevated intracranial pressure
- Control of seizures
- Blood pressure management

CR.3 Documentation supports (that):

CR.3a The patient has been assessed and treatment decisions made within 60 minutes of the arrival to the emergency department.

CR.3b Times of all assessments

CR.3c The patient has been screened for dysphagia before receiving any oral medications, food or fluids.

CR.3d The patient has been tested for blood glucose levels before tPA eligibility is determined.

CR.3e The emergent ischemic patient has been assessed with the NIHSS by a qualified practitioner.

CR.3f Intravenous tPA administered for eligible patients within 3-4.5 hours of onset of ischemic stroke

CR.3g The assessment and treatment of signs and symptoms of neurological deterioration post IV thrombolytic therapy per AHA/ASA guidelines

tPA Monitoring Requirements	*During Infusion*	*Post Infusion*
Neurological assessment	*every 15 minutes during the one hour infusion*	*Every 15 minutes for the first hour after infusion*
		Every 30 minutes for next 6 hours
		Hourly from eighth post-infusion hour until 24 hours after infusion
Blood Pressure	*every 15 minutes during the one hour infusion*	*every 15 minutes for the first 1 hour after infusion*
		Every 30 minutes for the next 6 hours
		Hourly from eighth post - infusion hour until 24 hours after infusion

CR.3h Recognition, assessment, and management of complications of acute stroke (vital signs, neuro status) and the process for notification of deterioration to medical staff and others.

CR.3i In the event an eligible patient with ischemic stroke does not receive IV thrombolytic therapy, documentation will support the rationale.

CR.4 There are specified timeframes related to the assessment and initial treatment that have been addressed with the stroke protocol as applicable to the emergency department. (See QM.7 CR.2)

CR.5 Maintain a current and complete call schedule with contact information of the physicians on staff and/or available for the ASR.

CR.6 The Emergency department will maintain a log that includes:

CR.6a A log documenting call times, response times, patient diagnoses, treatments, outcomes and dispositions will be kept and used for quality data review.

CR.6b Door to needle-time for administration of intravenous tissue plasminogen activator (tPA) to eligible ischemic stroke patients shall have as its goal a time of less than or equal to 60 minutes. Documentation of these results shall be maintained in a log, database or registry and reviewed by the stroke team regularly.

CR.6c ASR must keep a log of times it notifies EMS that it is unable to provide services for stroke patients in accordance with local policies and procedures.

CR.6d ASR must keep a log of times that it is notified that referral PSCs/CSCs were not able to provide Neurosurgical and/or Endovascular services.

PC.5 EMERGENCY MEDICAL SERVICES

The Emergency Medical Service plays a key role with the timely recognition, treatment, transfer, and outcomes of patients with acute stroke. The ASR has established a strong relationship with the community Emergency Medical Services (EMS). Interagency collaboration with development and review of policies/procedures and education is strongly encouraged.

CR.1 A document of cooperation between the ASR and the EMS is in place. This document is a written plan for transporting and receiving patients with stroke symptoms via the EMS system

CR.2 The hospital collaborates with emergency medical services (EMS) providers to make certain of the following:

CR.2a The program has a relationship with EMS providers that include notification when a patient with suspected stroke is being transported to the hospital in order to activate the stroke alert (refer to applicable state limitations on notification in transit).

CR.2b The program has access to treatment protocols utilized by EMS providers and prehospital personnel in response to patients reporting symptoms of stroke.

CR.2c The program has stroke patient priority destination protocols utilized by EMS providers that address transport of stroke patients, in accordance with law and regulation.

CR.2d The program works collaboratively with EMS to establish that personnel have specific training in the use of at least one accepted field assessment tool such as the Cincinnati Prehospital Stroke Scale or the Los Angeles Prehospital Stroke Screen.

CR.2e The program and EMS determine circumstances and alternate protocols in which the ASR would be on diversion and not able to accept patients.

CR.2f The program works collaboratively with EMS to establish that personnel have at least two hours of annual training in stroke diagnosis and treatment. This EMS training may be cosponsored with other healthcare facilities in the community.

Training could address:

- Reliable identification of stroke patients using a standardized assessment tool.
- Conditions that mimic acute stroke symptoms, such as patients presenting with:
  a) Hypoglycemia,
  b) Alcohol and drug intoxication,
  c) Postictal hemiparesis, and
  d) Other non-stroke causes of acute neurological deficits

PC.6 TELEMEDICINE/TELESTROKE

CR.1 The organization must have a written description of the type of telemedicine technologies available on site at the ASR.
Note: This may be a range of technologies from a phone call to live interactive physical exam with real time viewing of the patient and/or their neuroimaging studies.

CR.2 There will be a description of the technical requirements (such as speed and resolution) of equipment both at the sending and receiving site.

CR.3 The medical professionals providing remote medical guidance will have evidence of training and expertise that is required.

CR.4 The telestroke link should be fully established within 20 minutes of when it is considered necessary by the ASR physician, in order to meet the 60 minute door to needle time.
Note: In other less urgent cases, the time frame may be longer.

PC.7 ACUTE STROKE TEAM (AST)

CR.1 The organization must have a designated acute stroke team (AST) with trained personnel. All members of the stroke team should have current job description available that contains the experience, educational and physical requirements, and performance expectations for their role on the stroke team.
Note: This may be an addendum to a job description or in program specific competencies.

CR.1a The ASR shall define the criteria, qualifications, roles and responsibilities (through plan, policy or procedure) required for designation of qualified practitioners, professionals and other personnel assigned to the AST.

CR.1b The AST will be comprised of personnel that may be employed, contracted or otherwise available in some manner to the ASR to encompass the following: Physicians, nurses or nurse practitioners and physician assistants.

CR.2 The acute stroke team is available and on call 24/7.
Note: AST may be a separate team or the rapid response team in the hospital

CR.2a The AST should respond to suspected patients with an acute stroke who are in the ED or an inpatient unit in the host hospital.

Note: Although their presence in the hospital is preferred, members of the AST may reside outside of the hospital as long as they can be at the bedside within 15 minutes of being called.

CR.3 Members of the Stroke Team will receive initial and ongoing education and training with focus on cerebrovascular disease with an emphasis on acute care, diagnosis and treatment.

CR.3a The ASR will require no less than 4 hours of education and training to members of the stroke team annually.

PC.8 PROTOCOLS

CR.1 The ASR shall develop a stroke pathway (protocol) for the work up, diagnosis and treatment of acute stroke patients, including time parameters. This will be shared with emergency department practitioners, EMS providers and if admitted, to ICU and/or designated unit for the care of acute stroke patients.

There shall be written protocols for:

CR.1a TIA

CR.1b Ischemic stroke

CR.1c Hemorrhagic stroke

CR.1d Telemedicine/Telestroke consultation

CR.1e tPA therapy administration and post monitoring

CR.1f Dysphagia screening (evidence based tool)

CR.1g Blood pressure and oxygenation management

CR.1h Transfer

Note: Protocols and or pathways used to rapidly identify and evaluate potential stroke patients shall be available in the ED, acute care areas and stroke designated beds/units (as applicable) and updated at least annually.

CR.2 Early implementation of stroke pathway (protocol) and one call notification to the Stroke Team upon entry to the ED or prior upon notification from EMS personnel.

CR.3 The stroke protocols (pathways) will include:

CR.3a standardized order sets for the diagnosis, evaluation and management of the acute stroke patient following current AHA guidelines

CR.3b vital signs and neurological function checks

CR.3c blood pressure management parameters

CR.3d blood glucose control

CR.3e parameters to treat fever

CR.3f oxygenation management parameters

CR.3g blood tests (including point of care)

CR.3h brain imaging

CR.3i inclusion and exclusion criteria

CR.3 If the ASR does not transfer patients for neurosurgical emergencies, the ASR shall have a fully functioning operating room 24/7 and appropriate qualified neurosurgical staff within a maximum of two hours when determined to be immediately needed by the patient.

CR.4 If the ASR does transfer patients for neurosurgical emergencies, there is a written protocol for rapid transfer.

CR.4a There is documentation for any event in which neurosurgical services were not available within 3 hours of identified need from the collaborating PSC/CSC stroke center.

PC.9 TRANSFER AFREEMENT

The ASR has evidence to support that coverage for neurosurgical services is in place or arrangements (transfer agreements) have been made with another facility to provide these services.

CR.1 The ASR has a written transfer agreement (or understanding) with at least one primary stroke center and one comprehensive stroke center.

Note: one CSC alone is sufficient

The transfer agreement will include:

CR.1a Contact names and phone numbers

CR.1b hours of operation

CR.1c transportation options (ground, air)

CR.1d address 24/7 basis

CR.1e bypass or diversion plan for additional receiving hospital

CR.1f monitoring personnel required during transfer, dependent on patient's condition and related to the therapy used.

CR.2 There is a written document/ transfer agreement with a transportation vendor that cover both ground ambulance and air ambulance transfer options.

PC.10 PLAN OF CARE

CR.1 ASR staff shall develop and maintain a plan of care prepared by qualified individuals for each patient within 24 hours of admission that reflects the input of other disciplines, as appropriate. Documentation of these interdisciplinary findings, including pain assessment and interventions shall be included in the plan of care, as appropriate.

CR.2 ASR staff shall develop a standardized plan of care for the emergent stroke patient which will include identified individual needs for the patient based on their condition and the family's needs. Documentation of interdisciplinary findings and plans, including but not limited to:

CR.2a pain assessment and interventions

CR.2b vital signs and neurological time frames and parameters for management

CR.2c Positioning of head of bed

CR.2d oxygenation

CR.2e Fluid intake

CR.2f Cardiac monitoring

CR.2g Patient/family education

CR.3 The plan of care will include relevant co-morbidities, as indicated.

CR.4 the plan of care will include initial discharge planning for continuing care and treatment based on needs, condition and prognosis of the patient.

Note: The plan of care may be in many forms such as included in the protocols, a separate document or standardized format within nursing/admission notes.

PC.11 MEDICATION MANAGEMENT

CR.1 The ASR shall have a pharmacy service that meets the needs of the patients. Medications will be administered in accordance with accepted professional principles. The pharmacy service must have an adequate number of qualified personnel to ensure effective medication management services, including emergency services.

CR.2 All medications shall be administered by or under the supervision of nursing or other qualified personnel in accordance with applicable Federal and State laws. All drugs and biologicals shall be administered only upon the orders of the practitioner responsible for the care of the 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.

CR.4 The ASR (through the medical staff or pharmaceutical oversight group) shall select a list of medications to be available for the ASR. The list shall be available to all appropriate staff at all times.

CR.4a Medications available to the ASR (identified within the formulary) will include IV thrombolytic therapy medications for treatment of ischemic stroke.

CR.4b The ASR (through the pharmacy oversight) has protocols in place to ensure that IV thrombolytic therapy for treatment of stroke is being using in accordance with established guidelines for administration.

CR.5 Emergency department practitioners will have access to appropriately qualified personnel for consultation regarding the use of IV thrombolytic therapy, when obtained from a physician competent and privileged in the diagnosis and treatment of ischemic stroke.

CR.6 Emergency department practitioners can demonstrate safe use of tPA:

CR.6a safe time frames for administration of tPA

CR.6b indications for use

CR.6c exclusion /contraindication criteria

CR.6d dosage and mixing instructions

CR.6e monitoring protocols for identification of post tPA neurological deterioration

Note: A useful strategy is to mix drug and set up the bolus drip and one hour infusion as soon as a patient is recognized as a possible tPA candidate. Some drug manufacturers will replace, free of charge, medications that are mixed but not used.

Note: Dosing charts and standardized order sets can facilitate timely administration and minimize dosing errors.

PC.12 DIAGNOSTIC TESTS

CR.1 Laboratory services must be in house and available 24/7 to complete and interpret initial tests within 45 minutes of being ordered.

CR.1a Documentation should include completed diagnostic studies including complete blood count, chemistries, coagulation studies, troponin and, when indicated, an ECG, chest x-ray, pregnancy test, etc. as ordered.

Note: If laboratory turnaround times cannot meet this target, point-of-care testing may be performed in the emergency department , according to ASR policy.

Note: Glucose testing performed by EMS prior to arrival may be accepted, according with the policy of the ASR and EMS services.

CR.2 Basic Magnetic Resonance Imaging (MRI) and non- contrast computed tomography (CT) must be available for the ASR. A MRI technologist and radiology technologist trained in CT techniques must be available for the ASR.

CR.2a Documentation should include completed and interpreted CT/MRI exams for patients who are candidates for the treatment of tPA within 45 minutes.

CR.2b The brain imaging study should be interpreted by a physician with expertise in reading CT or MRI Studies

CR.3 The physician's evaluation, diagnostic testing including neuroimaging and contact with a physician with stroke expertise should be performed concurrently.

CR.3a Concurrent conditions shall be communicated to the consulting physician as well as the stroke assessment findings.

PC.13 REHABILITATION SERVICES

(*applicable only if ASR admits patients other than for palliative, hospice or end of life care*)

CR.1 The ASR provides rehabilitation, physical therapy, and audiology or speech pathology services. The service(s) shall be provided in a manner that ensures the patient's health and safety.

CR.2 Rehabilitation Services as defined by the medical staff and PSC, and consistent with State and Federal law, shall be performed by competent physical therapists, physical therapy assistants, occupational therapists, occupational therapy assistants, speech-language pathologists, or audiologists. Staff shall have experience in the treatment of stroke patients.

CR.3 The ASR shall require physical, occupational and speech therapists to be readily available by consultation for patient assessment and therapy during the patient hospitalization. Consults and assessments will be completed, when possible, within 24 hours of admission or when feasible once the patient is medically stable.

CR.3a If the ASR does not have inpatient rehabilitation services on site, there shall be a documented referral protocol in place and knowledge of nearby facilities offering this service.

CR.4 The organization shall have a written treatment plan that is in accordance with orders from practitioner's, who are authorized by the medical staff, to order rehabilitation services. The orders, treatment plan, results, notes and other related documentation shall be maintained in the patient's medical record.

CR.5 The treatment plan and the personnel qualifications must be in accordance with national acceptable standards of practice.

PC.14 PATIENT/FAMILY/COMMUNITY EDUCATION

CR.1 The ASR Program will ensure that it provides for the involvement of patients and/or family members in:

CR.1a making decisions about the plan of care goals during hospitalization

CR.1b discussing and planning for lifestyle changes to manage disease/condition

CR.1c discussing and planning for post hospital needs, including possible placement

CR.2 Community education shall be offered at least once per year and should stress knowledge in the community about the causes, signs and symptoms of stroke as well as emerging stroke prevention strategies.

MEDICAL STAFF (MS)

MS.1 ADMISSION REQUIREMENTS (if admitted)

Patients are admitted to the Stroke Unit/designated stroke beds only on the recommendation of a licensed practitioner permitted by the State to admit patients to the ASR.

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

CR.1a doctor of medicine or osteopathy who may delegate such care to other qualified health care professionals to the extent allowed by State law and qualified as;

CR.1a(1) a Neurologist or Neurosurgeon, board certified or eligible; or

CR.1a(2) Physician with expertise in cerebrovascular disease; or

CR.1a(3) other qualified professional with expertise defined by the medical staff and ASR.

CR.2 The medical staff shall ensure that:

CR.2a a doctor of medicine or osteopathy with expertise in cerebrovascular disease is on duty to supervise patient care, order medications and to manage emergency situations.

CR.2b the hospital has designated a doctor of medicine or osteopathy to be responsible for the care of each patient presenting to the ASR with a confirmed diagnosis or signs of acute stroke at the time of admission or that develops during hospitalization 24/7.

MS.2 CONSULTATION

CR.1 Medical professionals providing remote consultations have training and expertise to meet the host hospital requirements for telemedicine consultations.

CR.2 The medical staff shall define in its bylaws the circumstances and criteria under which consultation or management by a physician or other qualified licensed independent practitioner is required to address any co-morbidities of the patients under the care of the ASR as required.

CR.3 Emergency room physicians have 24 hour access to a consultation about use of tPA from a physician privileged in the diagnosis and treatment of ischemic stroke.

Note: May be in person or by telestroke.

MS.3 NEUROSURGICAL COVERAGE

CR.1 Neurosurgical coverage is described in a written plan.

CR.2 Neurosurgical services are available within three hours of it being determined as necessary.

CR.3 Written protocols for transfer include communication to and from receiving facility.

CR.4 If the ASR does not transfer patients for neurosurgical emergencies, the ASR shall have a fully functioning operating room 24/7 and appropriate qualified neurosurgical staff within a maximum of two hours when determined to be immediately needed by the patient.

NURSING SERVICES (NS)

NS.1 NURSING SERVICE

CR.1 The ASR must have a well-organized nursing service with a plan of administrative authority and delineation of responsibilities for delivery of patient care for patients under the ASR.

CR.2 There shall be 24-hour nursing services and a registered nurse must supervise and evaluate the nursing care for each ASR patient.

CR.2a Nursing staff assigned to the response stroke team should have current job description available that contains the experience, educational and physical requirements, and performance expectations, including continuing education regarding the care of acute stroke patients

Note: May be in form of addendum to job description or in program specific competencies.

CR.2a(1) Nursing staff assigned to the ASR will require 4 hours of education and training regarding the care of acute stroke patients annually.

CR.2b Nursing staff not directly assigned to the ASR shall receive education, training and direction for accessing the stroke team as well as basic identification and emergency care of acute stroke patients.

CR.3 There shall be adequate numbers of licensed registered nurses, licensed practical nurses, supervisory, and other staff to provide nursing care to all patients of the ASR as needed. A registered nurse must be immediately available for the bedside care of every patient, as required by State law.

CR.3a In areas where patients may be admitted, the nursing: patient ratio in the stroke unit/dedicated beds or ICU for care of stroke patients should be 1:3 or 1:4. This may be modified accordingly based on both volume and acuity of patients.

CR.4 A registered nurse shall make any decisions regarding delegation of nursing care to other nursing staff, based on individual patient need and staff qualifications.

CR.5 Non-employee licensed nurses who are working with ASR patients, must adhere to the policies and procedures of the ASR. The director of the ASR must provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel that occur within the responsibility of the nursing service.

STAFFING MANAGEMENT (SM)

SM.1 PERSONNEL (GENERAL)

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

CR.1 The ASR shall have a policy and practice for outlining and verifying that each staff member possesses a valid and current license or certification as required by the ASR and Federal and State law.

SM.2 COMPENTENCE, TRAINING AND AWARENESS

The ASR shall:

CR.1 determine the necessary competencies for personnel performing work affecting conformity and competency of ASR program requirements,

CR.2 have evidence to demonstrate initial and ongoing training in the care of acute stroke patients for individuals assigned to ASR patients

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

CR.4 at least annually, provide continuing education or other equivalent educational activity to staff members assigned to the ASR, as determined appropriate by the ASR director and as appropriate to the care practitioners' level of responsibility related specifically to ASR services.

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 in cerebrovascular disease

CR.7a Requirement of four (4) hours of initial and annual education for the Stroke Coordinators

CR.7b Requirement of four (4) hours of initial and annual education for nurses in the ED.

CR.7c Requirement of four (4) hours of initial and annual education for ASR medical director

Note: This annual requirement may be met in a variety of ways, including online continuing medical credits, attendance at grand rounds, regional and national meetings and various educational courses.

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.

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. ASR specific requirements may be in an addendum to the job description or in program specific competencies

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, the host hospital, regulation and the ASR. The ASR shall determine orientation content that must 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 and additional program specific competencies.

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 by variations and problem processes identified through the analysis of structures processes and outcomes measurement as required by the ASR;

CR.3 The ASR shall follow the host hospitals definition for a timeframe, not to exceed one calendar year, and a policy and practice for sharing the indicators measurement of individual staff members with those staff members that allows for staff feedback.

SR.4 The ASR shall follow the host hospital requirement that each staff member, including contract staff, to participate in continuing education as required by individual licensure/certification, professional association, law or regulation.

PATIENT RIGHTS (PR)

PR.1 SPECIFIC RIGHTS

The ASR shall protect and promote each patient's rights as required by the host hospital policies. The ASR 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 and/or family participation and means for making informed decisions regarding his/her plan of care;

CR.2 Information to the patient and/or family of patient care and to involve the patient and family to make informed decisions regarding their planning for care 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;

CR.6 Procedure for submission of a written or verbal grievance.
(See PR.5 Grievance Procedure)

CR.7 Pain Management

PR.2 ADVANCE DIRECTIVE

The ASR must allow the patient to formulate advance directives and to have ASR staff and practitioners comply with the advance directives in accordance and in participation with the host hospital policies as well as Federal and State laws, rules and regulations.

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

CR.2 The ASR shall not condition the provision of care or otherwise discriminate based on the patient executing an advance directive.

CR.3 The ASR, through the host hospital, shall ensure compliance with Federal and State laws regarding the provision of an advance directive.

CR.4 The ASR, through the host hospital, shall provide education for staff regarding the advance directive.

CR.5 When it is determined that an advance directive exists and is not in the patient's medical record, the ASR will follow the host hospitals written policy for follow-up and compliance with the policy.

PR.3 LANGUAGE AND COMMUNICATION

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

CR.1 The ASR, through the host hospital 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

The ASR shall obtain an informed consent from each patient or authorized representative for the provision of medical care under the ASR. The consent shall include an explanation of risks, benefits, and alternatives for procedures, diagnostic tests, and participation in activities related to the ASR, as defined by the medical staff and State law.

CR.1 IV tPA is recognized as the standard of care - and is approved by the FDA - for qualified individuals who present within 3 hours of ischemic stroke onset. If the patient has decision-making capacity or a proxy decision maker is present, a documented discussion regarding risks, benefits, and alternatives to IV tPA should take place prior to the administration of the medication. Unless required by local practices, a signed informed consent document is not a prerequisite to the administration of IV tPA in these circumstances.

CR.2 If the patient lacks capacity and no proxy decision maker can be found after a reasonable effort, then the physician may administer the medication based on the principle of implied consent for emergency treatment. The physician and other members of the health care team should document the patient's absence of decision-making capacity, that attempts to contact a proxy decision maker were unsuccessful, and that there is an urgent medical need to proceed with treatment in the absence of consent.

CR.3 When the duration of stroke symptoms exceeds the duration indicated by standard of care for IV tPA administration, the principle of implied consent for emergency treatment is not applicable, and physicians should obtain informed consent. Local practices will determine whether a signed informed consent document is necessary in these cases. Regardless of whether written or verbal consent is required, physicians should document the informed consent discussion in the medical record.

Note: Regulatory precedents set by FDA and the Department of Health and Human Services in the United States and by the World Medical Association internationally support the use of intravenous tPA in patients lacking capacity when an alternative form of consent cannot be obtained within the treatment window.

PR.5 GRIEVANCE PROCEDURE

The ASR shall participate and follow the host hospital formal grievance procedure for submission of a patient's written or verbal grievance to the ASR that provides for the following:

CR.1 The ASR shall follow the host hospital policies on:

- A list of who to contact
- review and resolution of grievances
- Specification of reasonable timeframes for review and response to grievances
- ASR contact person
- steps taken to investigate
- results of the grievance process; and
- date of completion

MEDICAL RECORDS (MR)

MR.1 ORGANIZATION

CR.1 Administrative responsibility for medical records shall rest with the medical record service of the host hospital.

CR.2 The ASR shall maintain the host hospitals policies on an accurately written, promptly completed medical record for each inpatient and outpatient.

CR.3 The host hospital 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.4 Authenticity and security of all record entries shall be safeguarded.

CR.5 Medical records (original or legally reproduced form) shall be retained for a period of at least five (5) years or as required by host hospital, state and local laws.

CR.6 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 studies.

CR.7 Original medical records shall be released by the organization only in accordance with Federal or State laws, court orders, or subpoenas.

MR.2 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.

MR.3 RECORD CONTENT

CR.1 The medical record shall contain information to:

CR.1a justify treatment and admission (if applicable);

CR.1b support the diagnosis; and,

CR.1c describe the patient's progress and response to medications and services

CR.2 All entries shall be:

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

CR.2b authenticated by the person responsible for providing or evaluating the services provided consistent with host hospital and ASR policy.

Note: Authentication may include written signatures or initials. Electronic authentication is permissible.

CR.3 The ASR shall follow the host hospital system to identify the author of each entry into the medical record.

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

CR.5 Verbal orders must be in accordance with Federal and State law and authenticated within time frame required by the host hospital and/or State law.

CR.5a 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 law.

CR.5b Verbal orders must be authenticated in accordance with Federal and State law by the ordering practitioner or a practitioner responsible for the care of the patient.

MR.4 REQUIRED DOCUMENTATION

All records must document the following, as appropriate:

CR.1 Evidence of a physical examination, including a health history must be performed on all patients admitted for inpatient care and/or prior to surgery or procedure requiring anesthesia services:

CR.2 Admitting diagnosis,
(if admitted)

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 forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, signed by the patient or his/her authorized representative. (See PR.4 for tPA consent policy)

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.6a Documentation indicating reason if an eligible ischemic stroke patient does not receive IV thrombolytic therapy.

CR.6b Assessments, interventions and monitoring (i.e. Post tPA) including date and time, per protocol and/or hospital policy.

CR.7 Discharge summary with outcome of hospitalization, disposition of case, and provisions for follow up care,

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

PHYSICAL ENVIRONMENT (PE)

The ASR shall participate in the facility and safety management systems for maintaining the physical environment in place under the operation of the host hospital, including applicable National Fire Protection Association (NFPA) standards, CMS Conditions of Participation and any additional accreditation organization (AO) requirements.

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