DNV GL HEALTHCARE

PRIMARY STROKE CENTER CERTIFICATION REQUIREMENTS

Revision 19-1

DNV GL Healthcare USA, Inc.
400 Techne Center Drive, Suite 100
Milford, OH 45150
Phone 866-523-6842 • Fax 513-947-1250
Table of Contents

DNV GL Healthcare Primary Stroke Center Certification Requirements (PSC) .................................. 5
EFFECTIVE DATE .......................................................................................................................... 5
FEDERAL LAWS, RULES AND REGULATIONS ......................................................................... 5
INTRODUCTION .......................................................................................................................... 6
REGULATORY AND POLICY REFERENCE ........................................................................... 6
SURVEYOR INFORMATION GATHERING AND INVESTIGATION ........................................ 7
ELIGIBILITY ................................................................................................................................. 8
SURVEY PROCESS ...................................................................................................................... 9
ABBREVIATIONS AND DEFINITIONS .................................................................................... 11
PROGRAM MANAGEMENT (PM) .......................................................................................... 13
PM.1 SENIOR MANAGEMENT .................................................................................................. 13
PM.2 MANAGEMENT COMMITMENT ...................................................................................... 14
PM.3 PROGRAM LEADERSHIP .................................................................................................. 14
QUALITY MANAGEMENT (QM) ............................................................................................. 15
QM.1 MANAGEMENT .............................................................................................................. 15
QM.2 QUALITY OUTLINE/PLAN .............................................................................................. 15
QM.3 QUALITY OBJECTIVES ................................................................................................. 15
QM.4 QUALITY REPRESENTATIVE .......................................................................................... 15
QM.5 DOCUMENTATION AND PROGRAM REVIEW ............................................................ 15
QM.6 SYSTEM REQUIREMENTS ............................................................................................. 16
QM.7 MEASUREMENT, MONITORING, ANALYSIS ................................................................. 16
QM.8 PATIENT SAFETY SYSTEM ............................................................................................ 18
QM.9 DNV GL HEALTHCARE STROKE CENTER METRICS FOR MEASURING PROCESSES & QUALITY ..................................................................................... 18
PATIENT CARE SERVICES (PC) ............................................................................................ 19
PC.1 PLANNING FOR SERVICE DELIVERY ............................................................................ 19
PC.2 REVIEW OF ELIGIBILITY & ONGOING REQUIREMENTS RELATED TO PSC SERVICE DELIVERY ............................................................................................................ 19
PC.3 CONTROL OF SERVICE DELIVERY .............................................................................. 20
PC.4 EMERGENCY DEPARTMENT (ED) .................................................................................. 20
PC.5 EMERGENCY MEDICAL SERVICES .............................................................................. 22
PC.6 TELEMEDICINE/TELESTROKE ......................................................................................... 23
PC.7 ACUTE STROKE TEAM (AST) .......................................................................................... 23
PC.8 PROTOCOLS ..................................................................................................................... 25
PC.9 TRANSFER AGREEMENT ................................................................................................. 26
PC.10 PLAN OF CARE .............................................................................................................. 27
PC.11 MEDICATION MANAGEMENT ...................................................................................... 28
PC.12 DIAGNOSTIC TESTS ...................................................................................................... 30
PC.13 REHABILITATION SERVICES ........................................................................................ 30
PC.14 PATIENT/FAMILY/COMMUNITY EDUCATION ............................................................. 31
MEDICAL STAFF (MS) ............................................................................................................ 33
MS.1 CREDENTIALING AND PRIVILEGES ............................................................................ 33
MS.2 PROGRAM MEDICAL DIRECTOR .................................................................................... 33
MS.3 ADMISSION REQUIREMENTS .......................................................................................... 33
Please Note:

With the release of PSC, Revision 19-0, there were some small corrections and clarifications that needed to be added. There were no new requirements added in Revision 19-1, therefore the changes made in Revision 19-0 remain highlighted in blue. The corrections and clarifications for 19-1 will be in green.

Please Note:

New metrics will be expected to be measured beginning on October 1, 2019 but will not be surveyed until January 1, 2020. (This is required only for those organizations who are performing thrombectomies, clippings, coiling’s etc.).

Physician education requirements that have been added in the Revisions 19-0 and 19-1 will be expected to be actively put into place during the calendar year 2020. This requirement will be expected to be in full compliance and will be surveyed beginning January 1, 2021.

Previous physician education requirements for the stroke medical director shall still be surveyed and scored to the same standards as before. Individual physician roles and education requirements are now defined in the SM.2 CR.4 table.

New Non-physician education requirements are expected to be in full compliance by January 1, 2020.

FEDERAL LAWS, RULES AND REGULATIONS

The Primary Stroke Center 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, Primary Stroke Center Certification requirements.

Primary Stroke Centers 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, PSCs 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 DNV GL Healthcare.

For hospitals, outside of the United States, the Medicare participation requirement is not applied. If the country where the hospital stroke center is located has relevant rules, regulations, protocols or laws that affect the qualifications or requirements, those laws will be incorporated and adhered to.

Please Note: American Heart Association/American Stroke Association will, on occasion, review the Guidelines for stroke care to provide an up to date comprehensive set of recommendations for clinicians. DNV GL Primary Stroke standards are reviewed and revised on a continual basis, and especially when a study becomes a new recommendation or when there has been a correction. It should be noted however,
if new recommendations are not entered in to this document, the PSC is still expected to follow any new recommendations within published guidelines from the AHA/ASA, much like that as required by CMS.

INTRODUCTION

The Primary Stroke Certification (PSC) Program is offered by DNV GL Healthcare USA, Inc. (DNV GL HC) and integrates requirements related to the CMS Conditions of Participation for hospitals (CoPs), the Guidelines of the Brain Attack Coalition and Recommendations of the American Heart Association and the American Stroke Association.

PSCs are designed to be a part of a larger stroke system of care which will include all levels of stroke care. The PSC certification will mean that a hospital is equipped to evaluate, stabilize and to provide emergency care to most patients with acute stroke symptoms and either admit the patient to a designated unit or designated stroke beds, or to stabilize, treat and facilitate transfer to the next higher level of care. The intent of the PSC is to be fully capable to provide initial diagnostic services, stabilization, emergent care and therapies to patients with an acute stroke who are seen in the emergency department.

A PSC hospital has the infrastructure and capability to care for acute stroke, including administration of intravenous thrombolytic therapy (also known as tissue plasminogen activator “tPA,” Alteplase or Tenecteplase).

A PSC has fewer overall capabilities than a Comprehensive Stroke Center, but has staff and resources able to diagnose, stabilize and treat most patients with stroke. Stroke patients may be transferred to a Comprehensive Stroke Center that would provide a higher level of care and/or endovascular procedures and neurosurgical interventions, as indicated by the individual, after initial treatment and stabilization.

Some PSC hospitals will have the capability to perform some selected invasive treatments or procedures. If a PSC hospital does perform any endovascular procedures, DNV GL will include the review of these procedures during the survey process. These procedures can range from surgical procedures to interventional procedures, including but not limited, to coiling’s, thrombectomies and other endovascular procedures. If a program offers and performs any of these procedures, they will also be expected to gather data on the appropriate metrics for those selected procedures such as door to puncture, recanalization, complications etc.

REGULATORY AND POLICY REFERENCE

- The DNV GL HC Certification Process, Certification Requirements, and applicable CMS State Operations Manual (SOM) provide the policies and procedures regarding certification activities.

- The Medicare Conditions of Participation for hospitals are in 42 CFR Part 482. *(For American Hospitals only)*


- Brain Attack Coalition – Pathways and Guidelines.

Organizations seeking and maintaining a PSC 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 DNV GL or another accreditation organization, approved by CMS to deem healthcare organizations in compliance with the CoPs. *(For American Hospitals only)*

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

The Certification Assessment is conducted separate and apart from a DNV GL Hospital Accreditation Survey or any other certification surveys. The PSC will be provided with advance notice of the upcoming survey at least one month prior to the on-site assessment of the PSC.

**SURVEYOR INFORMATION GATHERING AND INVESTIGATION**

Surveyors assess the PSC’s compliance with the PSC Certification Requirements for services and locations in which the PSC operates for patient care services. The objective of assessment activities is to determine the PSC’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, ICU, designated inpatient units, rehabilitation areas and other patient care settings as appropriate to the level of services provided by the PSC.
- 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.
ELIGIBILITY

Before the survey is scheduled, an organization must be able to demonstrate that they are eligible to become an applicant candidate.

PSC applicant organizations must be able to demonstrate that they:

- Meet the requirements of a Primary Stroke Center
- Are in current compliance with all Medicare Conditions of Participation at the time of application and at the time of the survey.
- Have administered IV Alteplase to 10 eligible patients for the initial application.
- Have administered IV Alteplase to an average of 20 eligible patients over 24 months or two-year time frame.

Note: IV Alteplase that was given at another hospital based on tele-stroke recommendation by the PSC and transferred to the PSC may be counted in the eligibility numbers.

If the patient is not transferred to the PSC, but there is evidence of follow up monitoring, that patient may also be counted in the eligibility number.

(These cases must be added to the programs indicator tracking to be included in the eligibility numbers.)

Have advanced imaging capabilities:

- CT scanning capability 24/7/365
- CT angiography available on site 24/7/365
- CT Perfusion (CTP) (strongly encouraged, but not required, yet)
- Magnetic resonance imaging (MRI) including diffusion weighted

In addition, the applicant organization will:

- Have a designated unit, ICU or designated beds for stroke patients that include staff and licensed independent practitioners with the expertise and experience to provide neuro care.
- Participate in a stroke registry such as INSTOR, Coverdell, GWTG or State required program etc. (For non-American hospitals, an equivalent data capture process will be identified)
SURVEY PROCESS

Before the Survey

Organizations that are in the process of becoming an applicant organization will receive support from the DNV GL stroke program staff. The sales team acts as an account manager right in the beginning of the process, giving information about DNV GL, the stroke program, and assisting through the application and contract development. A member of the team will build a quote for your organization, based on general rates and how many facilities may be involved in the application.

As an organization works its way through a review of the standards, there is a clinical team that is available to answer implementation, compliance and interpretive guideline questions. The DNV GL stroke program staff know that your success in meeting the guidelines will mean better outcomes and success for your patients. The stroke program was developed to partner with healthcare organizations to improve the delivery of stroke care to the patients, their families and the communities that are served.

The organization will complete an application that will be reviewed for eligibility by the DNV GL stroke program director. Once eligibility had been determined, the application will be processed, a contract will be developed and sent to the applicant organization.

The scheduling department will then contact the identified person listed on the application. They will work with the applicant organization to select dates that are available for survey.

The stroke surveys occur every year and they are announced. This allows the applicant organization to arrange schedules and to send notices to everyone that would need to be at the facility during the survey to represent their specific departments, processes and responsibilities.

The assigned lead surveyor for the survey will contact the stroke coordinator or other assigned person at the organization to introduce themselves, obtain any needed logistical information, answer any last-minute questions and review the proposed agenda.

During the Survey

Once on site, surveyors assess compliance with the certification requirements for services and locations in which the PSC operates for patient care services. The objective of assessment activities is to determine compliance with the requirements through observations, interviews and document review.

The surveyors will focus attention on:
- actual and potential patient outcomes
- required processes
- the care and services provided, including the appropriateness of the care and services within the context of the certification requirements and identified best practices.
- leadership involvement, commitment and oversight of program

The surveyors will visit:
- the emergency department
- imaging locations
- interventional/surgical suites (if applicable)
- ICU/ designated inpatient units
- rehabilitation areas and
- other patient care settings, as appropriate to the level of services provided.

The surveyors will review:
- policies
- protocols/order sets
• transfer agreements
• telemedicine capability and documentation
• clinical records
• personnel files and training records,
• credentialing files and
• other documentation necessary to validate information gained from observations and interviews.

After the Survey

Once the survey has been completed, you will receive your report within ten business days. You will be expected to write a corrective action plan for each finding and submit to DNV GL within ten calendar days. The corrective action plan (CAP) will be reviewed to determine if the CAP addresses each finding until the full report is complete and accepted. If there are questions or clarifications needed during the review process, a technical review team member will contact your organization for clarification.

(For non-American hospitals, there may be some changes in the time allotted as to when reports and corrective actions will be due.)

For level 2 non-conformities (NC-2), once the corrective action plans have been accepted, there are no requirements to send further data or other information. Those findings and the accepted corrective action plan will be reviewed on site during the following year’s survey for validation of implementation.

For level 1 non-conformities (NC-1), you will need to send specific requested data within 90 days to validate that the corrective action is in place and that it was effective in addressing the non-conformities.

For initial surveys, DNV GL awards the PSC certificate on the acceptance of the corrective action plan that has been submitted, however there are some rare occasions where there is a valid concern about the organizations ability to address the non-conformities or if a serious patient issue is identified.

If that happens, the certificate will be delayed pending submission of corrective action data that is obtained to support that the issue is resolved or mitigated. At that time, further information and submitted data will be reviewed and a determination by the certification committee will be made.

One recommendation may be to accept the submitted information and issue the certificate. One other recommendation may be that a surveyor needs to revisit on site for a day, to survey only those components that would need in person validation. Both processes as described, happen rarely, but they do happen. This is a risk-based approach to our process, and we need to have a high confidence level at the initial survey.

Some circumstances that could trigger a delay on awarding of certification could include but not be limited to issues such as:

• Significant inadequate monitoring of patient’s condition post administration of Alteplase, Tenecteplase, post endovascular procedures or other surgical interventions
• Lack of 24/7 coverage for neurology
• Lack of designated medical director or nurse stroke coordinator
• Loss or lack of medical staff to perform neuro interventions (if applicable)
• Lack of privileging for medical staff for performed procedures
ABBREVIATIONS AND DEFINITIONS

AANN  American Association of Neuroscience Nurses

ABEM  American Board of Emergency Medicine

ABNN  American Board of Neuroscience Nursing

ACEP  American College of Emergency Physicians

Acute care phase includes critical care units, intermediate care units, stroke units, and general medical units

AF or A fib  an irregular heartbeat that puts the patient at a 5x greater risk for stroke. A fib may be detected by monitoring the heart's rhythm over time

AHA  American Heart Association

AIS  Acute Ischemic Stroke

ASR/Acute Stroke Ready Organization that can provide timely access to stroke care but not able to meet all the criteria for PSCs or CSCs

Alteplase  tissue plasminogen activator tPA (thrombolytic medication)

AMA  American Medical Association

AOBEM  American Osteopathic Board of Emergency Medicine

AVM  Arteriovenous malformation

BAC  Brain Attack Coalition

CDC  Centers for Disease Control and Prevention

CEA  Carotid Endarterectomy

CFR  Code of Federal Regulations

CMS  Centers for Medicare Medicaid Services

CNRN  Certified Neuroscience Registered Nurse

CR  Certification Requirement

CSC  Comprehensive Stroke Center

CSRN  Certified Stroke Registered Nurse

EMS  Emergency Medical Services

FDA  Food and Drug Administration

GCS  Glasgow Coma Scale score
Hyper acute phase includes the pre-hospital setting and the emergency department (ED)

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


MRA Magnetic Resonance Angiography

mRs Modified Rankin Scale

NIHSS National Institutes of Health Stroke Scale

NFPA National Fire Protection Association

PSC Primary Stroke Center

PWI Perfusion weighted imaging

QMS Quality Management System

SAH Subarachnoid hemorrhage

SCRN Stroke Certified Registered Nurse

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.

Tenecteplase tissue plasminogen activator Tnkase (thrombolytic medication)

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 PSC shall establish, document, implement and maintain the PSC 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:

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

CR.1b The PSC is licensed by the appropriate State or local authority responsible for licensing of PSC (if applicable);

CR.1c Hiring, appointments and privileging criteria includes aspects of individual character, competence, training, experience and judgment is established for the selection of individuals working for the PSC, directly or under contract.

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

CR.1e Responsibilities and authorities are defined and communicated within the PSC,

CR.1f Appointment, privileging and re-privileging of an identified medical director who is charged with the overall management of the stroke care provided by the PSC.

CR.1g Appointment, privileging and re-privileging of all practitioners who are performing procedures or involved in stroke program activities that may require specific skills, training or education.

CR.2 The medical director for the PSC should have training and expertise in cerebrovascular disease. The director does not have to be a neurologist or neurosurgeon but should have sufficient knowledge of cerebrovascular disease to provide administrative leadership and clinical guidance. Qualifications for the PSC Director shall include greater than or equal to 2 of the following:

CR.2a Board-certified neurologist, neurosurgeon or Interventional Neuro-radiologist that has completed a stroke fellowship, Interventional Neuroradiology fellowship or vascular neurosurgery fellowship or has equivalent experience

CR.2b Completion of a vascular neurology fellowship or board certification in vascular neurology;

CR.2c Participation (as an attendee or faculty) in at least 2 regional, national, or international stroke courses or conferences in the past 2 years;

CR.2d 5 or more peer-reviewed publications in the area of clinical cerebrovascular disease;

CR.2e 8 or more continuing medical education credits (or equivalent educational experience) each year in the area of cerebrovascular disease; and

CR.2f Other criteria agreed on by the medical staff and the host hospital governing body or other criteria as determined by the local health care system.
CR.3  The medical director or designee shall be currently credentialed and privileged to provide stroke care and is available 24 hours per day, 7 days per week (24/7) to provide leadership on medical, logistical, and administrative issues.

CR.4  The director shall be involved in the assessment of patients and provide consultative advice to other treating physicians.

CR.5  There shall be a written delineation of scope, coverage, authority and responsibilities of the stroke medical director.

   CR.5a  If there is a co-program medical director identified, there shall be a written delineation of scope, coverage, authority and responsibilities of each co-director.

**PM.2 MANAGEMENT COMMITMENT**

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

CR.1  Communicating to the PSC the importance of meeting customer as well as statutory and regulatory requirements,

CR.2  Establishing and assisting in meeting the PSC Programs mission, goals and objectives,

CR.3  Conducting Program reviews and ensuring the availability of resources.

**PM.3 PROGRAM LEADERSHIP**

The PSC 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 PSC Program service delivery.

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

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

CR.4  Monitor, measure where applicable, and analyze these processes, and

CR.5  Implement actions necessary to achieve planned results and continual improvement of these processes.
QUALITY MANAGEMENT (QM)

QM.1 MANAGEMENT

The governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the Primary Stroke Center (PSC)), medical staff, and administrative officials are responsible and accountable for ensuring that the PSC implements and maintains an effective quality management system. The host hospital will assure that adequate resources are allocated for measuring, assessing, improving, and sustaining the PSCs performance and reducing risk to patients.

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

CR.2 The PSC 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 PSC has established programmatic measurable quality objectives and the results are analyzed addressed; and

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

QM.2 QUALITY OUTLINE/PLAN

The PSC 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

Program management shall ensure that PSC Program quality objectives, including those needed to meet requirements for the PSC Program are established. The quality objectives shall be measurable and consistent with the requirements of the PSC 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 PSC program are implemented and maintained. (This may be the stroke coordinator in some facilities.)

QM.5 DOCUMENTATION AND PROGRAM REVIEW

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

CR.2 Program processes and data review will be performed at regular intervals, at a minimum of once a quarter, with an annual evaluation of the effectiveness of the PSC 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 PSC will participate in and follow the system requirements of the host hospital in establishing a quality system, the PSC will be required to have the following as a part of this system.

CR.1 An Interdisciplinary group to oversee the PSC specific quality data that includes the medical director of the PSC, the nurse stroke coordinator (may be a registered nurse or an advanced nurse practitioner) and a quality representative. This will be considered the Core Stroke Team. Other discipline representatives and practitioner members that are included, are at the discretion of the PSC. This interdisciplinary group shall conduct quality and programmatic reviews.

CR.2 There shall be a written document defining the quality oversight process, to include all components of the PSC clinical and non-clinical services.

CR.3 Measurable Quality Objectives; and,

CR.4 Goal Measurement / Prioritization of activities based in some manner to:
   CR.4a Identify problem-prone areas, processes or functions,
   CR.4b Consider the incidence, prevalence and severity of problems in these areas, processes or functions,
   CR.4c And their effect on health outcomes to improve patient safety and quality of care.

QM.7 MEASUREMENT, MONITORING, ANALYSIS

The PSC 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 including: structure, process and outcome measures.

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

Measurement, monitoring and analysis of processes of the PSC requires that established measures have the ability to detect variation, identify problem processes, identify both positive and negative outcomes, and the effectiveness of actions taken to improve performance and/or reduce risks.

The PSC leadership shall be responsible for the development of performance measures and strategies for measuring, refining and reassessing. PSC leadership shall define the frequency and detail of the measurement for, at a minimum, 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 PSC.

Note: This data will capture stroke team response time to acute stroke patients, treatments used and patient disposition. It is at the discretion of the PSC 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 shall have 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 initiation ≤20 minutes

CR.2d Door to CT interpretation ≤45 minutes

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

CR.2f Connected contact (computer linkage, phone, or whatever form the organization utilizes) to telemedicine consultant from the time when determined medically necessary by ED physician ≤20 minutes

CR.2g Door to IV Alteplase bolus (≥75% compliance) ≤60 minutes AND Door to IV Alteplase bolus (≥50% compliance) ≤45 minutes

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

CR.2i Door to monitored bed admission ≤3 hours

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

Monitored bed has the capability to have continuous monitoring of vital signs, pulse oximetry and other requirements, as needed.

If the organization is keeping the patient in the emergency room as the monitored bed requirement prior to transfer or admission, adequate staffing with demonstrated competence to physiologically monitor the patient must also be provided.

CR.3 There shall be secondary prevention measures of patient outcomes and avoidance of complications and recurrent strokes.

<table>
<thead>
<tr>
<th>#</th>
<th>SM</th>
<th>Stroke Measurements</th>
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<td>Assessed for Rehabilitation</td>
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</table>

CR.4 There shall be rehabilitation performance measures to evaluate patient outcomes (mortality, functional status, community discharge) and the percentage of stroke patients who receive the
appropriate level of rehabilitation services in the system. (Only applicable for patients who are admitted).

**CR.4a** Pre-Morbid Modified Rankin Score by or at discharge *(all)*

**CR.4b** Modified Rankin Score at time of discharge *(all)*

**CR.4c** Modified Rankin Score 90 days after discharge
(Only for patients treated with thrombolysis and/or mechanical intervention)

**CR.5** There shall be community education performance measures, evaluating 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. **The PSC shall offer at least 2 programs a year to educate the public about stroke prevention, diagnosis, and/or the availability of acute therapies.**

**CR.6** The PSC shall monitor all perioperative and other complication rates and overall outcomes.

**CR.6a** The perioperative mortality rate for aneurysm clipping, coiling and other surgical or interventional procedures *(including thrombolytic administration)* should be documented and reviewed. *(as applicable)*

**CR.6b** A formal M&M process shall review all cases that meet defined quality indicators. Records of the results of the M&M review and actions arising from the review shall be documented and maintained.

**QM.8 PATIENT SAFETY SYSTEM**

**CR.1** The PSC 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.

**Note:** This may include data such as falls, medication errors, safety initiatives etc. The host hospital will determine data designation for inclusion in program as well as any indicators specific to the safety of the stroke programs population as determined by the stroke committee.

**QM.9 DNV GL HEALTHCARE STROKE CENTER METRICS FOR MEASURING PROCESSES & QUALITY**

**See Addendum A and B**

**PLEASE NOTE:** This is ONLY applicable for PSCs who perform invasive procedures such as thrombectomies, clippings, coiling’s, etc.
PATIENT CARE SERVICES (PC)

PC.1 PLANNING FOR SERVICE DELIVERY

CR.1 The PSC team, with other disciplines, shall plan and develop the processes needed for PSC service delivery. Planning of the PSC service delivery shall be consistent with the certification requirements of the processes of the PSC Program. In planning PSC services delivery, the PSC shall determine the following, as appropriate:

CR.1a quality objectives and requirements for the PSC;
CR.1b the need to establish processes, documents and resources specific to the PSC;
CR.1c required verification, validation, monitoring, and measurement, specific to the PSC;
CR.1d records needed to provide evidence that the processes meet requirements. The output of this planning shall be in a form suitable for the PSC's method of operations.

PC.2 REVIEW OF ELIGIBILITY & ONGOING REQUIREMENTS RELATED TO PSC SERVICE DELIVERY

CR.1 PSC Program requirements are defined.
CR.2 The PSC has the ability to meet the defined requirements.
CR.3 Records of the results of review and actions shall be maintained.
CR.4 When the PSC Program requirements are changed, the PSC shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

CR.5 Acute Stroke team available 24/7
CR.6 Written protocol for Acute Stroke triage and diagnosis
CR.7 Written agreement/plan with primary EMS agency

CR.8 The PSC shall have administered IV Alteplase to 10 patients for initial eligibility. The PSC shall subsequently administer IV Alteplase to an average of 20 eligible patients over 24 months or two years.

Note: The following two conditions may be applied to the eligible patient numbers in addition to the administration of Alteplase at the PSC site.

IV Alteplase that was given at another hospital based on tele-stroke recommendation by the PSC and transferred to the PSC when the patient is stable for continued care may be counted in the eligibility number of Alteplase administrations.

OR

If the patient is not transferred to the PSC, but there is evidence of follow up monitoring, can be counted in the eligibility number (These cases must be added to the programs indicators tracking to be included in the eligibility numbers.)

CR.9 The PSC shall provide at least neuro-diagnostics, medical stabilization, IV thrombolytics, follow-up treatment, and any other interventions that the center is capable and equipped to provide.
CR.10 Written emergency stroke treatment protocol

CR.11 Neurosurgical coverage plan

CR.12 Transfer agreement and protocol with PSC/PSC+/CSC facility (at least 1 transfer agreement required for higher level of care--CSC preferred, if available)

CR.13 Designated stroke program medical director

CR.14 Designated nurse stroke coordinator

PC.3 CONTROL OF SERVICE DELIVERY

The PSC 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 PSC Program,

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

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

PC.4 EMERGENCY DEPARTMENT (ED)

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

CR.2 Emergency department practitioners and staff can 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 Alteplase
- Tenecteplase, if administered
- Reversal of coagulopathies
- Control and reduction of elevated intracranial pressure
- Control of seizures
- Blood pressure management

CR.4 Documentation supports (that):

CR.4a The patient has been assessed and treatment decisions have been made within 45 minutes of the arrival to the emergency department.
CR.4b  Times of all assessments.

CR.4c  The patient has had a dysphagia screen before receiving any oral medications, food or fluids.

CR.4d  The patient has been tested for blood glucose levels before Alteplase eligibility is determined.

CR.4e  The emergent stroke patient has been assessed with the NIHSS by a certified/qualified nurse or physician member of the Acute Stroke Team.

CR.4f  Intravenous Alteplase was administered for eligible patients within 3-4.5 hours of onset of ischemic stroke.

CR.4g  The assessment and treatment of signs and symptoms of blood pressure and neurological deterioration during and post IV thrombolytic therapy per current AHA/ASA guidelines are as follows:

<table>
<thead>
<tr>
<th>Alteplase Monitoring Requirements</th>
<th>Pre-Bolus</th>
<th>During Infusion</th>
<th>Post Infusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neurological assessment</td>
<td>No more than 15 minutes before bolus</td>
<td>every 15 minutes during the one-hour infusion</td>
<td>Every 15 minutes for the first hour after infusion</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Every 30 minutes for next 6 hours</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Hourly from eighth post infusion hour until 24 hours after infusion</td>
</tr>
</tbody>
</table>

| Vital Signs                      | No more than 15 minutes before bolus | 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.4h  There is recognition, assessment, and management of complications of acute stroke (vital signs, neuro status, angioedema etc.) and a process for notification of deterioration to medical staff and others.

CR.4i  In the event an eligible patient with ischemic stroke does not receive IV thrombolytic therapy, documentation will support the rationale.

CR.5  All patients are assessed for endovascular treatment options whether receiving Alteplase or if they are not a candidate for Alteplase. Documentation must be present as to the decision by the treating physician.
CR.6 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.7 Maintain a current and complete call schedule with contact information of the physicians on staff and/or available for the PSC.

CR.8 The Emergency department will maintain a log that includes:

CR.8a Documentation of call times, response times, patient diagnoses, treatments, outcomes and dispositions will be kept and used for quality data review.

CR.8b 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 ≤60 minutes in 75% of the cases AND ≤45 minutes in 50% of the cases. Documentation of these results shall be maintained in a log, database or registry and reviewed by the stroke team regularly.

CR.8c PSC 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.8d PSC must keep a log of times that it is notified that referral/receiving PSC+/ 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 Primary Stroke Center 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 PSC 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 a 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 pre-hospital 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 Pre-hospital Stroke Scale, Los Angeles Motor Scale (LAMS) or another accepted tool.

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

CR.2f The program works collaboratively with EMS to establish that personnel have annual training in stroke diagnosis and treatment. This EMS training may be co-sponsored with other healthcare facilities in the community.
Note: Training could address:

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

Note: EMS providers should be able to provide early pre-notification to receiving hospitals when a stroke is recognized in the field. This action may reduce door to needle time and increase the numbers of eligible patients to be treated.

PC.6 TELEMEDICINE/TELESTROKE

CR.1 The organization must have a written description of the type and usage of telemedicine technologies available on site at the PSC, if utilized.

Note: This may be a range of technologies from a phone call consultation 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 the training and expertise that is required.

CR.4 The telemedicine link or neuro consultant should be available within 20 minutes of when it is considered necessary by the emergency physician, in order to meet the less than or equal to 60-minute door to needle time.

Note: In other less urgent cases, the time frame may be defined to a longer time.

PC.7 ACUTE STROKE TEAM (AST)

CR.1 The organization must have a designated Interdisciplinary Stroke Team. This team may be divided into two main parts.

Part one is the code team members who respond to a stroke code, either through the emergency room and/or in-house stroke alerts.

The other part of the stroke team organization is the “task force” that works together daily to facilitate the adherence to stroke protocols and access to care for patients.

All members of the stroke team should have current job descriptions available that contain 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, program narrative, and/or in program specific competencies.
CR.1a Annual performance evaluations shall include performance of stroke related duties, activities and fulfillment of education requirements.

CR.1b The PSC shall define the criteria and qualifications (through plan, policy or procedure) required for designation of qualified practitioners, professionals and other personnel assigned to the Acute Stroke Team (AST).

CR.1c The Acute Stroke Team will be comprised of personnel that may be employed, contracted or otherwise available in some manner to the PSC to encompass the following areas of expertise:

- Neurologist or Neurosurgeon, board certified or eligible; or
- Physician with expertise in cerebrovascular disease;
- Diagnostic Radiologists
- Mobile Stroke Unit personnel, if applicable
- Surgeons with expertise performing carotid endarterectomies (CEA), if applicable
- Rapid Response Team designated members, if applicable
- Other qualified professional with expertise defined by the medical staff and PSC (as indicated)
- Emergency department personnel and emergency medical services
- Nursing staff trained in the care of acute stroke patients
- Radiology technologists (including MRI and CT technologists)
- Rehabilitation therapists with expertise in treatment of acute stroke patients
- Case manager or social worker (as indicated)
- Other qualified professionals with expertise defined by the medical staff and AST team, as indicated (i.e. dietician)

CR.2 The acute stroke team is available and on call 24/7.

CR.2a The AST should respond to suspected acute stroke patients who are in the Emergency department or on an inpatient unit in the hospital.

Note: AST may be a separate stroke team or the rapid response team in the 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 orientation and ongoing education and trainings that are related to or focused on cerebrovascular disease and treatment of acute stroke patients to ensure competence of personnel.

CR.3a The PSC Core Team members are required to have 8 hours of education initially in orientation and then annually.

Note: The PSC may determine the personnel assigned to the AST that could be required to receive less than the minimal required hours of education and training. This will be at the discretion of the PSC to exclude any personnel, with justification, when they are not specifically dedicated to the PSC. (See SM.2 for detailed requirements)
**PC.8 PROTOCOLS**

**CR.1** The PSC shall develop stroke protocols (pathways), based on current evidence-based practice for the treatment of emergent and ongoing care for acute stroke patients. This will be shared with emergency department practitioners, EMS providers and ICU and/or Stroke Unit for the care of acute stroke patients.

There shall be written protocols for **emergent and ongoing patient care including but not limited to:**

- **CR.1a** TIA
- **CR.1b** Ischemic stroke
- **CR.1c** Hemorrhagic stroke (ICH and SAH)
- **CR.1d** Telemedicine/Telestroke consultation
- **CR.1e** Alteplase and/or Tenecteplase therapy administration and post monitoring
- **CR.1f** Dysphagia screening (evidence-based tool)
- **CR.1g** Blood pressure and oxygenation management
- **CR.1h** Transfer (both receiving to the PSC and out to a CSC) *(See PC.9)*
- **CR.1i** In-house stroke alert
- **CR.1j** Post-operative/post procedure monitoring
- **CR.1k** 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 and reviewed and updated, if indicated, at least annually.

**CR.2** The response process shall include an early implementation of stroke pathway (protocol) and 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 standardized order sets for the diagnosis, evaluation and management of the acute stroke patient following current AHA guidelines that address:

- **CR.3a** Vital signs and neurological function check parameters
- **CR.3b** Blood pressure management parameters
- **CR.3c** Blood glucose control
- **CR.3d** Parameters to treat fever
- **CR.3e** Oxygenation management parameters
- **CR.3f** Blood tests (including point of care)
- **CR.3g** Brain imaging
- **CR.3h** Inclusion and exclusion criteria
**Note:** Recent AHA guidelines for emergency cardiovascular care for stroke patients recommend administration of oxygen to hypoxemic patients to maintain oxygen saturation >94%.

**Note:** Recent AHA guidelines for specific blood pressure management recommendations have been established for acute ischemic stroke patients being considered for fibrinolytic therapy.

These recommendations include bringing the blood pressure below 185/110 mm Hg to qualify for **thrombolytic** therapy with intravenous Alteplase. Once intravenous Alteplase is given, the blood pressure must be maintained below 180/105 mm Hg to limit the risk of ICH.

**Note:** Recent AHA guidelines for Hypoglycemia (blood glucose <60 mg/dL) should be treated in patients with acute ischemic stroke.

These recommendations indicate that persistent in-hospital hyperglycemia during the first 24 hours after stroke is associated with worse outcomes than normoglycemia, and thus, it is reasonable to treat hyperglycemia to achieve blood glucose levels in a range of 140 to 180 mg/dL and to closely monitor to prevent hypoglycemia in patients with acute ischemic stroke.

CR.4 If the PSC does not transfer patients for neurosurgical emergencies, the PSC 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.5 If the PSC does transfer patients for neurosurgical emergencies, there is a written protocol for rapid transfer.

CR.5a There is documentation for any event in which neurosurgical services were not available within 90 minutes of identified need from the collaborating CSC stroke center.

**PC.9 TRANSFER AGREEMENT**

The PSC 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 PSC shall have a written transfer protocol and transfer agreement with at least one facility capable of providing timely neurosurgical, cerebral endovascular and neuro ICU services 24 hours a day, seven days a week. The transfer agreement will include:

CR.1a 24/7 emergency contact information of acute stroke team and/or the receiving team at the receiving facility authorized to accept transfers

CR.1b The ability to transfer the patient 24/7, the ability of the receiving facility to accept the patient 24/7

CR.1c The ability to affect a transfer in a timely manner as appropriate for patient needs (target timeframe for transfer must be identified in the transfer agreement for both neurosurgical and endovascular services)

CR.1d Clinical criteria for transfer and processes for obtaining consultation for transfer decisions

CR.1e Patient 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 covers both ground ambulance and air ambulance transfer options.

CR.3 Develop a protocol for bypass or diversion plan for additional receiving hospitals.

**PC.10 PLAN OF CARE**

CR.1 Nursing staff shall develop a standardized plan of care for the emergent acute stroke patient which will include identified individual needs for the patient based on their condition and the family’s needs. Documentation of interdisciplinary findings shall be included in the plan of care, as appropriate. ([See PC.10 CR.2](#) for consideration of inclusion of appropriate items for acute stroke patients)

CR.2 Nursing staff will complete and maintain a plan of care prepared for each patient within 24 hours of admission that reflects the input of other disciplines, as appropriate. Documentation of these interdisciplinary findings, protocols and plans, may include but not limited to as indicated:

**CR.2a** Pain assessment and appropriate interventions, both medication and alternatives.

**CR.2b** Vital signs and neurological time frames and parameters for management:

- Temperature monitoring and management
- Blood pressure evaluation and management
- Neuros (defined as to what is being used) and NIHSS status
- Assess for any neurological deterioration, sudden marked changes in vital signs, changes in level of consciousness, nausea, vomiting, diaphoresis, new headache

**CR.2c** Cardiac monitoring, as indicated

**CR.2d** Positioning of head of bed as indicated/ordered

**CR.2e** Oxygenation

- O2 goal at or above 94%

**CR.2f** Aspiration/Swallowing/Dysphagia/Oral Hygiene Protocol

- Patients may not be able to clear secretions and could be at high risk for aspiration.

**CR.2g** Fluid intake/Fluid management

- Fluid management is crucial for the patient with acute stroke; both volume overload and depletion should be avoided

**CR.2h** Patient/family education individual risk factors as well as general risk factors

**CR.2i** Potential complications specific to treatment:

- Bleeding with Alteplase, Tenecteplase or invasive interventional procedures
- Angioedema
- Assess IV/arterial puncture sites, urine, gums, skin, emesis, etc. for bleeding
- Monitor extremities for color, temperature and sensation. (i.e. bleeding with Alteplase)

**CR.2j** Blood Glucose Monitoring

**CR.2k** Infection prevention
CR.2l Bowel/Bladder care, as indicated

CR.2m Mobility/Falls

CR.2n Pulmonary Embolism/DVT
- For immobile stroke patients without contraindications, intermittent pneumatic compression in addition to routine care (aspirin and hydration) is recommended over routine care to reduce the risk of DVT.

**NOTE:** Recommend removal of compression stockings on order sets, if present.

CR.2o Skin Care
- minimize or eliminate skin friction, to minimize skin pressure, to provide appropriate support surfaces, to avoid excessive moisture, and to maintain adequate nutrition and hydration to prevent skin breakdown.
- Regular turning, good skin hygiene, and use of specialized mattresses, wheelchair (Braden Skin Assessment or other approved assessment)

CR.2p Nutrition
- Potential for dehydration due to reluctance to drink fluids/fear of choking
- Dehydration is a predictor of poor outcomes
- Dysphagia
- Appropriate food consistency for assessed condition
- Increased risk of respiratory complications and aspiration pneumonia

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

CR.4 The plan of care is updated at each phase of care and as patient’s conditions changes

CR.5 Patient and Family members (or identified significant others) are involved in the planning of care and in discharge planning.

CR.6 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 established interdisciplinary protocols, a separate document or standardized format within nursing/admission notes.

**PC.11 MEDICATION MANAGEMENT**

CR.1 The PSC 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 PSC (through the medical staff or pharmaceutical oversight group) shall select a list of medications to be available for the PSC. The list shall always be available to all appropriate staff.

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

CR.4b  The PSC (through the pharmacy oversight) has protocols in place to ensure that IV thrombolytic therapy for treatment of stroke is being used in accordance with established guidelines for administration. (See PC.11 CR.6c)

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

Note: If the emergency department’s licensed independent practitioners are privileged in the diagnosis and treatment of ischemic stroke, then access to bedside or telemedicine consultation is not necessary.

CR.6  Emergency department practitioners can demonstrate safe use of thrombolytics.

CR.6a  Safe time frames for administration of Alteplase. For the purpose of a definition as to safe and effective timeframe for the administration of Alteplase, the definition that will now be used, based on a review of the literature, is that the bolus will be given over one minute and the infusion is to start immediately, within, but not to exceed five minutes after the bolus administration is completed.

CR.6b  Exclusion/contraindication criteria

CR.6c  Dosage and mixing instructions
  - Follow manufacturer guidelines
  - Physician order for normal saline flush to be run at the same rate as Alteplase
  - Excess Alteplase discarded during preparation for patient safety
  - Program infusion pumps to flush the remainder of the dose still in the IV tubing to complete the full dose at 60 minutes
    (See PC.11 CR.4b)
  - Time of bolus, time of initiation of infusion and time of start of flush must be documented. (It is not necessary to document the end of the flush as that will vary depending on the amount of normal saline hung.)

CR.6d  Monitoring the protocols for identification of post Alteplase neurological deterioration
  - Monitor recognition and treatment of angioedema and other adverse conditions (See PC.4 CR.4g)

CR.6e  Transfer safety when Medication administration will continue during transport.
  - Sending hospital will verify with EMS that excess Alteplase has been withdrawn from the bottle.
  - Sending hospital should apply a label to the Alteplase bottle with the number of ml of fluid that are in the bottle.
  - Estimated time of completion should be verified with EMS.
  - EMS will be instructed that the infusion and flush must be completed at 60 minutes from start of infusion to complete the full dose (flush should be infused at the same rate as Alteplase) (See PC.11 CR.4b)
**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, and troponin levels as ordered and, when indicated, an ECG, chest x-ray, pregnancy test, etc.

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

**Note:** Baseline troponin assessment is recommended in patients presenting with AIS but, should not delay initiation of IV Alteplase.

**Note:** Blood draws and/or glucose testing performed by EMS prior to arrival may be accepted, according with the policies of the PSC and EMS services.

**CR.2** Non-contrast computed tomography (CT) must be available 24/7 and Basic Magnetic Resonance Imaging (MRI) must be available, when needed, 24/7. A radiology technologist trained in CT techniques must be available in house, 24/7.

**CR.2a** An MRI technologist may be on call and available (but not required in house) within these parameters:
- If using for critical decision rather than a CT, the same time frame as written for CT, so must be available in house.
- If using for acute treatment decision, then two hours from the order is the standard.
- For all other purposes, the hospital can make its own determination of time frame.

**CR.2b** Documentation should include completed and interpreted CT/(or MRI) exams for patients who are candidates for the treatment of Alteplase within 45 minutes.

**CR.2c** 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**

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.1** The PSC 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 Post Stroke rehabilitation shall focus on:

CR.2a Training for maximum recovery,
CR.2b Prevent and treat comorbid conditions,
CR.2c Enhance psychosocial coping
CR.2d Promote integration into the community
CR.2e Prevent recurrent strokes and other vascular events, and
CR.2f Enhance quality of life

CR.3 Rehabilitation services should be implemented as soon as possible. Mobilization of the stroke survivor and resumption of self-care activities should occur as soon as medically feasible. Both inpatient and outpatient rehabilitation programs can improve outcomes and prevent deterioration.

CR.4 The PSC shall require physical, occupational and speech therapists to be readily available 7 days per week by consultation for patient assessment and therapy during the patient hospitalization. Consults and assessments will be completed within 24 hours of admission or when feasible once the patient is medically stable.

CR.4a Documentation in the medical record of attempts to perform a patient assessment and reason why it was not able to be performed, is required.

CR.4b If the PSC 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. Documentation of referrals shall be in the medical record.

CR.5 Therapists, social workers, and nurse case managers must meet requirements for state licensure and preferably have at least one year of experience in the treatment of stroke survivors.

CR.6 The nurse care managers and social workers must have an adequate knowledge of inpatient rehabilitation facilities and community resources in their geographic regions.

CR.6a Nurse case managers and Social workers must have expertise regarding neurology/stroke care, care coordination, levels of rehabilitation and community resources in their geographic regions.

CR.7 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 and results, notes and other related documentation shall be maintained in the patient’s medical record.

PC.14 PATIENT/FAMILY/COMMUNITY EDUCATION

CR.1 The PSC 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 The PSC shall offer at least 2 programs a year to educate the public about stroke prevention, diagnosis, and/or the availability of acute therapies.

CR.3 Community outreach education programs are designed to be delivered through various means to address:

- Risk factors, signs, symptoms for stroke or other cardiovascular diseases
- General prevention efforts that target smoking cessation, obesity, and diabetes
- Management of hypertension, lipid levels, atrial fibrillation, and medication adherence
- Other issues as identified by the PSC

CR.4 The PSC 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. (See QM.7 CR.5)
MEDICAL STAFF (MS)

MS.1 CREDENTIALING AND PRIVILEGES

CR.1 The governing body shall appoint members of the medical staff and approve clinical privileges after considering the recommendations of the existing members of the medical staff and ensure that the medical staff is accountable to the governing body for the quality of care provided to patients.

CR.2 All individuals who are permitted by the organization and by state law to provide patient care services independently in the organization shall have delineated clinical privileges.

CR.3 There shall be a provision in the medical staff bylaws for a mechanism to ensure that all individuals with clinical privileges provide services only within the scope of privileges granted.

CR.4 If available and/or required by the medical staff to hold or maintain clinical privileges, include a review of individual performance data variation from criteria determined by the medical staff to identify need for training or proctoring that may be required.

MS.2 PROGRAM MEDICAL DIRECTOR

CR.1 The medical director for the PSC must have significant amount of training and expertise/knowledge as delineated in PM.1 CR.2.

CR.2 The director or designee shall be available 24 hours per day, 7 days per week (24/7) to provide leadership and deal with difficult medical, logistical, and administrative issues.

CR.3 The director shall be involved in the assessment of patients and provide consultative advice to other treating physicians.

CR.4 There shall be a written delineation of scope, coverage, authority and responsibilities of the stroke medical director.

CR.4a If there is a co-program director identified, there shall be a written delineation of scope, coverage, authority and responsibilities of each co-director.

MS.3 ADMISSION REQUIREMENTS

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 PSC.

CR.1 The PSC 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:

- A Neurologist or Neurosurgeon, board certified or eligible; or
- Physician with expertise in cerebrovascular disease; or
- Other qualified professional with expertise defined by the medical staff.
CR.2 The medical staff shall ensure that:

CR.2a A doctor of medicine or osteopathy, with expertise in cerebrovascular disease, is on duty or on call at all times; and,

CR.2b A doctor of medicine or osteopathy is responsible for the care of each patient presenting to the PSC with a confirmed diagnosis or signs of acute stroke at the time of admission or that develops during hospitalization.

**MS.4 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 PSC as required.

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

**Note:** May be in person or by telemedicine.

CR.4 The PSC should have at least one or more physicians with expertise in cerebrovascular disease on call in order to ensure 24 hours per day, 7 days per week coverage.

CR.4a One or more neurologists (preferably) with fellowship training in vascular neurology;

CR.4b Neurologist should be available to answer emergency calls per telephone/tele-video within 20 minutes; and,

CR.4c Is available in-house within 45 minutes when needed.

**MS.5 NEUROSURGICAL SERVICES COVERAGE**

CR.1 Neurosurgical coverage is described in a written coverage plan that includes the types of practitioners and services provided by covering neurosurgeon and any involved facilities.

CR.2 If a hospital does not transfer patient for neurosurgical emergencies, a current Neurosurgical call schedule is available in the emergency room department.

CR.3 If the PSC needs to transfer patients for neurosurgical services, they are available within three hours of it being determined as necessary.

CR.4 Written protocols for transfer include communication from other facilities that are transferring in as well as a transfer out to a CSC facility.

CR.5 If the PSC does not transfer patients for neurosurgical emergencies, the PSC 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.6 If neurosurgery is provided, each neurosurgeon should participate in a case review of ten surgical intervention cases sampling of their neurosurgical cases.
Note: Cases reviewed could include but not be limited to CEAs, craniotomies, EVD placement, etc. Volume and frequency to be determined by medical staff.

**MS.6 ICU /CRITICAL CARE MANAGEMENT AND COVERAGE**

CR.1 The PSC should have physicians with training in critical care medicine or neurocritical care for managing patient care in the ICU or neuroscience ICU in order to care for ischemic stroke patients as well as for hemorrhagic stroke cases and others. These clinicians should have the following:

CR.1a Board-certified or board eligible neurologist, neurosurgeon, anesthesiologist or internist who has completed either a critical care fellowship or neuro critical care fellowship; or criteria set by medical staff and shall be in writing.

CR.1b Care for at least 10 patients with acute strokes per year; and,

CR.1c Attend greater than or equal to 8 hours per year of CME/CEU activities (or similar educational programs) related to or focused on cerebrovascular disease.

CR.2 Intensivists/Hospitalist/NP/PA that meet criteria set by the medical staff, may 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. (May use telemedicine)

CR.2a Criteria set by medical staff shall be in writing.

CR.2b There shall be documentation of review of individual intensivist meeting criteria and peer review of cases.

**MS.7 ENDOVASCULAR SERVICES (IF PROVIDED)**

CR.1 PSC shall have the ability and equipment to perform revascularization procedures and microvascular surgery. The PSC will provide neurosurgical and endovascular Services for the treatment of cerebrovascular diseases including the following:

CR.1a Neuro endovascular coilings

CR.1b Intracranial/extra cranial angioplasty (Stents, Balloons, Retrievers, liquid embolic agent)

CR.1c Thrombectomies

CR.2 PSC shall track perioperative complications of revascularization and microvascular procedures. Perioperative complications shall be tracked prospectively. (if applicable)
ANESTHESIA SERVICES (AS) (if provided for stroke)

AS.1 ORGANIZATION

Anesthesia services, including Deep and Moderate Sedation shall be provided in an organized manner, and function under the direction of a qualified Doctor of Medicine or Doctor of Osteopathy. The anesthesia service is responsible for all anesthesia services provided throughout the hospital. Areas where anesthesia services are furnished for stroke, may include (but are not limited to):

- Operating room suites
- Radiology department
- Emergency department
- Interventional Radiology (IR) (if provided for stroke)

CR.1 Anesthesia shall only be administered by the following:

CR.1a A qualified anesthesiologist, a Doctor of Medicine, doctor of osteopathy or nurse anesthetists.;

CR.1b The hospital’s medical staff will define (in writing) the criteria and qualifications for those physicians who have privileges for administering anesthesia/sedation in accordance with State laws and acceptable standards of practice.

CR.2 The Medical Staff, together with Anesthesia services will determine appropriate qualifications for a Licensed Practitioner, other than an Anesthesiologist, to provide Anesthesia services including Deep and Moderate Sedation.

CR.2a Non-Anesthesiologists providing Anesthesia services will demonstrate proficiency in anesthesia protocols and in the administration of anesthetic medications.

CR.2b Non-Anesthesiologists providing Anesthesia services will demonstrate proficiency in rescue capability.

Note: The host hospital may define what those criteria are, but these will include, at a minimum, current ACLS and any required certification and/or documented proficiency in airway management. (Board Certified Emergency Room physicians are exempted from ACLS requirement per ACEP, ABEM, AOBEM, unless the host hospital requires it)

CR.2c RNs will have documented, current ACLS unless host hospital has exempted them due to anesthesiology being present in these cases.; Technicians, such as CT techs, IR techs will have documented, current BLS.

Note: The hospital must ensure that procedures are in place to rescue patients whose level of sedation becomes deeper than initially intended, for example, patients who inadvertently enter a state of deep sedation/analgesia when moderate sedation intended was. All personnel assisting in a procedure carried out under moderate sedation or higher must have current documented proficiency commensurate with their role.

AS.2 ANESTHESIA SERVICES

CR.1 Anesthesia services shall be appropriate to the scope of the services offered.

CR.2 The PSC will follow the host hospital’s criteria as well as Federal and State Laws and requirements and acceptable standards of care with regards to pre-anesthesia screening, assessment and post anesthesia follow-up.
NURSING SERVICES (NS)

NS.1 NURSING SERVICE

CR.1 The PSC 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 PSC.

CR.2 There shall be 24-hour nursing services and a registered nurse must supervise and evaluate the nursing care for each PSC patient. A registered nurse shall be on duty at all times.

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.2b PSC nurses required training will include but not be limited to (when indicated):

- CR.2b (1) Nursing assessment and management of the function of ventriculostomy and external ventricular monitoring and drainage apparatus,
- CR.2b (2) Treatment of increased intracranial pressure,
- CR.2b (3) Nursing care of patients with ICH and SAH,
- CR.2b (4) Nursing care of patients receiving Alteplase and after thrombolytic therapy,
- CR.2b (5) Treatment of blood pressure abnormalities with parenteral vasoactive agents,
- CR.2b (6) Management of intubated/ventilated patients, and
- CR.2b (7) Detailed neurologic assessments and scales (i.e. NIHSS, Glasgow Coma Scale, etc.)
- CR.2b (8) Management of post thrombectomy and other invasive/surgical patients (If provided)

Note: Training can be documented by attendance at in-service sessions, participation in regional or national courses, and other modalities, as established by the PSC staff and the host hospital.

CR.2c Nurses (as defined by the organization) should:

- Be certified/qualified in NIHSS or equivalent standard neurologic assessments and scales,
- Have a working knowledge of the organizations stroke protocols, and/or care maps,
- Be knowledgeable of current stroke guidelines
- Be aware of new patient care techniques related to stroke.

CR.2d Nursing staff not assigned to the PSC, shall receive initial orientation and annual education, training and direction for identifying a stroke, accessing the stroke team as well as basic emergency care of acute stroke patients.
CR.3  There shall be adequate numbers of licensed registered nurses, licensed practical nurses, supervisory, and other support staff to provide nursing care to all patients of the PSC as needed. A registered nurse must be immediately available for the bedside care of every patient, as required by State law.

CR.3a  The nursing: patient ratio in the Stroke Unit/dedicated beds 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.

Note:  As staffing patterns are usually 1:2 in ICUs, the above number does not denote that a higher ratio should apply in ICU.

CR.4  Reserved

CR.5  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.6  Non-employee licensed nurses who are working in the PSC must adhere to the policies and procedures of the PSC. The director of the PSC 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.

CR.7  Each PSC nurse stroke coordinator/manager should attend a national or regional meeting at least every other year that focuses on some aspect of cerebrovascular disease.
STAFFING MANAGEMENT (SM)

SM.1 PERSONNEL

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

CR.1 The PSC 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 PSC and Federal and State law.

SM.2 COMPETENCE, TRAINING AND AWARENESS

The PSC shall:

CR.1 Determine the necessary competencies for personnel performing work affecting conformity to PSC Program requirements,

CR.2 Have documented evidence to demonstrate initial orientation and ongoing training in the care of acute stroke patients for individuals assigned to the PSC 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 PSC, as determined appropriate by the PSC and as appropriate to the care practitioners’ level of responsibility related specifically to PSC services. 

See Education and Training Table below.

CR.5 Maintain appropriate records of education, training, skills and experience.

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. Education should be specifically related to diagnosis/assessment and management of acute stroke/cerebrovascular disease (may be policy/competency driven).

Note: The PSC may determine which personnel assigned to the Stroke Team are required to receive the minimum hours of education and training. It is at the discretion of the PSC to exclude any personnel, with justification, when they are not specifically dedicated to the PSC.
<table>
<thead>
<tr>
<th>Position</th>
<th>Annual Hours</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stroke Core Team</strong></td>
<td>8 education hours</td>
<td>Others as identified by PSC Leadership</td>
</tr>
<tr>
<td>Stroke Medical Director</td>
<td></td>
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<tr>
<td>Nurse Stroke Coordinator</td>
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<tr>
<td>Stroke Quality Representative</td>
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<tr>
<td>Stroke Advanced Practice Nurse</td>
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<tr>
<td>Or Physician’s Assistant</td>
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<tr>
<td><strong>Acute Stroke Team (AST)/Response Team</strong></td>
<td>8 education hours</td>
<td>If rapid response team answers in house strokes, at least one member of the rapid response team shall meet AST education criteria.</td>
</tr>
<tr>
<td>Emergency Department Medical Director</td>
<td></td>
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<tr>
<td>Interventional Radiologists</td>
<td></td>
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<tr>
<td>Neuro-Intensivists</td>
<td></td>
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<tr>
<td>Neurologists</td>
<td></td>
<td></td>
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<tr>
<td>Neuro-surgeons</td>
<td></td>
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<tr>
<td>Hospitalists</td>
<td>8 education hours</td>
<td>This depends on scope of service. Medical staff might require neuro specific training such as ENLS.</td>
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<tr>
<td>Intensivists</td>
<td></td>
<td></td>
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<tr>
<td><strong>ICU Nurse Manager</strong></td>
<td>8 education hours</td>
<td>If clinical supervision is assigned to nurse educator rather than nurse managers, then they must meet the educational requirement</td>
</tr>
<tr>
<td>Emergency Department Nurse Manager</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Emergency Department Physicians and RNs</strong></td>
<td>4 education hours</td>
<td></td>
</tr>
<tr>
<td>Pharmacists and Rehabilitation Therapists</td>
<td>4 education hours</td>
<td>For Pharmacy- All who are involved with the stroke program and/or prepare thrombolytics. For rehab- All who work with or assigned to stroke patients (OT, PT, Speech)</td>
</tr>
<tr>
<td>Neuro-Dedicated Unit-ICU RNs</td>
<td>8 education hours</td>
<td>All nurses that work in these settings with stroke patients</td>
</tr>
<tr>
<td>Interventionalist nurses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stroke Unit (Step Down) Mixed Population ICU RNs</td>
<td></td>
<td></td>
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<tr>
<td>Nurses not assigned to stroke units such as Med Surg, Obstetrics, etc.</td>
<td>One education hour</td>
<td>Should include but not be limited to: Recognition of stroke policy and process for in house stroke alert</td>
</tr>
<tr>
<td>All other staff</td>
<td>1 stroke awareness/recognition activity</td>
<td>FAST training could be an option and would be acceptable</td>
</tr>
</tbody>
</table>
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

CR.1 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.

Note: PSC specific requirements (including stroke specific educational requirements) may be in an addendum to the job description or in program specific competencies.

SM.5 ORIENTATION

CR.1 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 PSC. The PSC 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, the host hospital policies and any 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 PSC.

CR.3 The PSC shall follow the host hospital requirement that each staff member, including contract staff, participate in continuing education as required by individual licensure/certification, professional association, law or regulation.
PATIENT RIGHTS (PR)

PR.1 SPECIFIC RIGHTS

The PSC shall protect and promote each patient’s rights as required by the host hospital policies. The PSC 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 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 PSC must allow the patient to formulate advance directives and to have PSC staff and practitioners comply with the advance directives in accordance with the host hospital policies as well as Federal and State law, rules and regulations.

PR.3 LANGUAGE AND COMMUNICATION

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

CR.1 The PSC, 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 PSC shall obtain an informed consent from each patient or authorized representative for the provision of medical care under the PSC. The consent shall include an explanation of risks, benefits, and alternatives for procedures, diagnostic tests, and participation in activities related to the PSC, as defined by the medical staff and State law.
CR.1  **IV Alteplase** 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 physician shall document the discussion regarding risks, benefits, and alternatives to IV Alteplase which shall 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 Alteplase** 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 Alteplase** 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.

**Note:** 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 **Alteplase** in patients lacking capacity when an alternative form of consent cannot be obtained within the treatment window.

CR.4  Informed consent for IA/catheter therapy, CEA or any other surgical interventions shall follow the rules of the host hospital, state and other applicable local laws.

**PR.5  GRIEVANCE PROCEDURE**

The PSC shall participate in and follow the host hospital formal grievance process and procedure for submission of a patient's written or verbal grievance.
MEDICAL RECORDS (MR)

MR.1 ORGANIZATION

CR.1 Administrative responsibility for medical records shall rest with the medical record service of the host hospital. This includes paper records, electronic medical records and any reports from other sources such as patient transfer documents.

CR.2 The PSC shall maintain the host hospitals policies on an accurately written, promptly completed medical record for all patients in the organizations system.

CR.3 The host hospital organization shall have a process for providing services for the completion, filing, and retrieval of medical records. The process for completion of the medical record must address timeframes.

CR.4 Authenticity and security of all record entries shall be safeguarded.

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, admission and/or continued hospitalization;
   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 the host hospital and PSC policy.

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

CR.3 The PSC 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 by the practitioner, or a practitioner responsible for the care of the patient, 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.

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, except in emergencies,

CR.2 Admitting diagnosis,

CR.3 Documentation of all consultative evaluations, findings and recommendations 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 Alteplase consent policy),

CR.6 All practitioners’ orders, nursing notes, reports of treatments, medication administration records, radiology and laboratory reports, vital signs and other information necessary to diagnose, treat or monitor the patient’s condition,

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

CR.6b Documentation indicating the assessments of all stroke patients, whether they received Alteplase or not, to determine the eligibility/recommendation for endovascular intervention.

Note: Allowable reasons for not performing an endovascular procedure but still including the patient in the numerator may include:

- Diagnosis/documentation excludes eligibility
- Enrollment in a clinical trial
- Arrival time that is too late for treatment
- Deficits that are too severe or too mild
- Elevated creatinine
- Advance age
- Lack of major vessel occlusion
- Rapid improvement
- Refusal by patient/family
- Lack of appropriate surrogate to consent
- Insufficient evidence to support intervention per treating physician

CR.6c Assessments, re-assessments, interventions and monitoring (i.e. Post Alteplase) 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)

PE.1 The PSC 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, applicable CMS Conditions of Participation and any additional accreditation organization (AO) requirements.
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