



DNV GL - HEALTHCARE

PRIMARY STROKE CENTER CERTIFICATION PROGRAM - REQUIREMENTS PSC 2.0

Contents

INTRODUCTION.....	5
REGULATORY AND POLICY REFERENCE	5
ABBREVIATIONS AND DEFINITIONS	7
PROGRAM MANAGEMENT (PM)	9
PM.1 SENIOR MANAGEMENT.....	9
PM.2 MANAGEMENT COMMITMENT	10
QUALITY MANAGEMENT (QM).....	11
QM.1 MANAGEMENT.....	11
QM.2 QUALITY OUTLINE/PLAN.....	11
QM.3 QUALITY OBJECTIVES	11
QM.4 QUALITY REPRESENTATIVE.....	11
QM.5 DOCUMENTATION AND PROGRAM REVIEW	11
QM.6 SYSTEM REQUIREMENTS	12
QM.7 MEASUREMENT, MONITORING, ANALYSIS	12
QM.8 PATIENT SAFETY SYSTEM.....	14
PATIENT CARE SERVICES (PC)	15
PC.1 PLANNING FOR SERVICE DELIVERY	15
PC.2 REVIEW OF REQUIREMENTS RELATED TO PSC SERVICE DELIVERY	15
PC.3 CONTROL OF SERVICE DELIVERY	15
PC.4 EMERGENCY DEPARTMENT (ED)	16
PC.5 EMERGENCY MEDICAL SERVICES	18
PC.6 TELEMEDICINE/TELESTROKE	19
PC.7 ACUTE STROKE TEAM (AST)	19
PC.8 PROTOCOLS.....	20
PC.9 TRANSFER AGREEMENT.....	22
PC.10 PLAN OF CARE	22
PC.11 MEDICATION MANAGEMENT	23
PC.12 DIAGNOSTIC TESTS	24
PC.13 REHABILITATION SERVICES	25
PC.14 PATIENT/FAMILY/COMMUNITY EDUCATION.....	26
MEDICAL STAFF (MS)	27
MS.1 ADMISSION REQUIREMENTS	27
MS.2 CONSULTATION	27
MS.3 NEUROSURGICAL COVERAGE.....	27

NURSING SERVICES (NS)	29
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STAFFING MANAGEMENT (SM) 30

- SM.1 PERSONNEL 30
- SM.2 COMPETENCE, TRAINING AND AWARENESS..... 30
- SM.3 DETERMINING AND MODIFYING STAFFING 31

PATIENT RIGHTS (PR) 33

- PR.1 SPECIFIC RIGHTS..... 33
- PR.2 ADVANCE DIRECTIVE..... 33
- PR.3 LANGUAGE AND COMMUNICATION 34
- PR.4 INFORMED CONSENT 34
- PR.5 GRIEVANCE PROCEDURE..... 35

MEDICAL RECORDS (MR)..... 36

- MR.1 ORGANIZATION 36
- MR.2 CONFIDENTIALITY 36
- MR.3 RECORD CONTENT 36
- MR.4 REQUIRED DOCUMENTATION..... 37

PHYSICAL ENVIRONMENT (PE) 38

DNV GL - HEALTHCARE PRIMARY STROKE CENTER CERTIFICATION

Effective Date

These DNV GL - Healthcare Primary Stroke Center Certification Requirements, PSC 2.0 Effective Date: [July 1, 2015](#).

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.

DNV GL - HEALTHCARE PRIMARY STROKE CENTER CERTIFICATION

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 admit the patient to a dedicated stroke unit or designated stroke beds. 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," or alteplase).

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.

REGULATORY AND POLICY REFERENCE

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

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 GLHC or another accreditation organization, approved by CMS to deem healthcare organizations in compliance with the CoPs.

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

healthcare organization is currently certified by DNV GL - HC, it is referred to as a "Certified Organization."

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

Goal 2015:

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

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

AND

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

ABBREVIATIONS AND DEFINITIONS

AANN	American Association of Neuroscience Nurses
Acute care phase	includes critical care units, intermediate care units, stroke units, and general medical units
ASR/Acute Stroke Ready	Organization that can provide timely access to stroke care but not able to meet all of the criteria for PSCs or CSCs
AIS	Acute Ischemic Stroke
AMA	American Medical Association
ABNN	American Board of Neuroscience Nursing
BAC	Brain Attack Coalition
CDC	Centers for Disease Control and Prevention
CEO	Chief Executive Officer
CFR	Code of Federal Regulations
CMS	Centers for Medicare Medicaid Services
CR	Certification Requirement
CSC	Comprehensive Stroke Center
CSRN	Certified Stroke Registered Nurse
DEA	Drug Enforcement Administration
EMS	Emergency Medical Services
FDA	Food and Drug Administration
GCS	Glasgow Coma Scale score
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
Life Safety Code	Life Safety Code® of the National Fire Protection Association
NIHSS	National Institutes of Health Stroke Scale
NFPA	National Fire Protection Association
PRN (prn)	Pro re nata, as the occasion arises, when necessary
Primary Stroke Center/PSC	Primary Stroke Center
QMS	Quality Management System
Tele-stroke/Tele-medicine	an approach to treating vascular disease that allows a neurologist to provide remote treatment for a stroke victim. Electronic communications may include telephone, internet or video conferencing, providing consultation and diagnostic services.
TIA	Transient Ischemic Attack
tPA	tissue plasminogen activator (thrombolytic medication)
Troponin	complex of three regulatory proteins (troponin C , troponin I , and troponin T) that is integral to muscle contraction in skeletal muscle and cardiac muscle. Often elevated after stroke.

PROGRAM MANAGEMENT (PM)

The 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 Criteria that 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 and,

CR.1d The personnel working in the PSC are properly licensed 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 and qualifications of the medical director for the PSC.

CR.1f(1) The medical director for the PSC must have sufficient knowledge of the diagnosis and treatment of cerebrovascular disease.

Note: Primary Stroke Centers, a designated director 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.

Examples of such knowledge might include 2 or more of the following:

- Completion of a vascular neurology fellowship or board certification in vascular neurology;
- Participation (as an attendee or faculty) in at least 2 regional, national, or international stroke courses or conferences in the past 2 years;
- 5 or more peer-reviewed publications in the area of clinical cerebrovascular disease;
- 8 or more continuing medical education credits (or equivalent educational exposure) each year in the area of cerebrovascular disease; and
- Other criteria agreed on by local physicians and hospital administrators.

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 the PSC Program and ensuring that objectives are established,
- CR.3 Conducting Program reviews and ensuring the availability of resources.

PM.3 PROGRAM MANAGEMENT

The PSC leadership shall:

- CR.1 Determine the processes needed for the PSC Program and their application throughout the PSC,
- 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

Senior 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.

QM.5 DOCUMENTATION AND PROGRAM REVIEW

- CR.1 Variations, deficiencies or non-conformities identified by the PSC shall be addressed by the stroke committee. Appropriate actions will be determined, applied, and documented.

CR.2 A review shall 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 (or nurse practitioner or physician's assistant) and a quality facilitator. Other discipline representatives and practitioners members are at the discretion of the ASR. This interdisciplinary group shall conduct quality and programmatic reviews.

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

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.

Note: This interdisciplinary group may be considered as the "core" members of the Acute Stroke Team (AST) as opposed to the "response" members. Some members may be in both roles.

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 (both process and outcomes 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 require established measures that 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 must define the frequency and detail of the measurement.

Furthermore, the PCS shall develop performance measures and strategies for measuring, refining and reassessing, 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/MRI initiation ≤ 25 minutes (Target Stroke: ≤ 20 minutes)

CR.2d Door to CT interpretation ≤ 45 minutes (Target Stroke: ≤ 35 minutes)

CR.2e Order to lab results ≤ 45 minutes, if ordered (Target Stroke: ≤ 30 minutes)

CR.2f Computer link from when determined medically necessary by ED physician ≤ 20 minutes

CR.2g Door to IV tPA bolus ($\geq 75\%$ compliance) ≤ 60 minutes

AND

Door to IV tPA bolus ($\geq 50\%$ compliance) ≤ 45 minutes (Target Stroke)

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

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

Note: Target stroke time goals are noted on each appropriate parameter above.

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

Note: This will include current Core Measures as required per CMS (only applicable for patients who are admitted).

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.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.

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.

PATIENT CARE SERVICES (PC)

PC.1 PLANNING FOR SERVICE DELIVERY

The PSC 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.1 quality objectives and requirements for the PSC;
- CR.2 the need to establish processes, documents and resources specific to the PSC;
- CR.3 required verification, validation, monitoring, and measurement, specific to the PSC;
- CR.4 records needed to provide evidence that the processes meet requirements. The output of this planning shall be in a form suitable for the PSC's method of operations.

PC.2 REVIEW OF REQUIREMENTS RELATED TO PSC SERVICE DELIVERY

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

- 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.

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 tPA
 - 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 60 minutes of the arrival to the emergency department, (Target Stroke within 45 min)
- CR.4b Times of all assessments,
- CR.4c The patient has been screened for dysphagia before receiving any oral medications, food or fluids,
- CR.4d The patient has been tested for blood glucose levels before tPA eligibility is determined,
- CR.4e The emergent ischemic patient has been assessed with the NIHSS by a qualified member of the AST,
- CR.4f Intravenous tPA 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.

tPA Monitoring Requirements	Pre Bolus	During Infusion	Post Infusion
Neurological assessment	No more than 15 minutes before bolus	every 15 minutes during the one hour infusion	Every 15 minutes for the first hour after infusion
			Every 30 minutes for next 6 hours
			Hourly from eighth post infusion hour until 24 hours after infusion
Blood Pressure	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) and a documented 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 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.

[\(See OM.7 CR.2\)](#)

CR.6 Maintain a current and complete call schedule with contact information of the physicians on staff and/or available for the PSC.

CR.7 The Emergency department will maintain a log that includes:

CR.7a A log documenting call times, response times, patient diagnoses, treatments, outcomes and dispositions will be kept and used for quality data review.

CR.7b 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 (Target: ≤45 minutes). Documentation of these results shall be maintained in a log, database or registry and reviewed by the stroke team regularly.

CR.7c PCS 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.7d PCS must keep a log of times that it is notified that referral 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 Pre-hospital Stroke Screen or other 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 at least two hours of annual training in stroke diagnosis and treatment. This EMS training may be co-sponsored with other healthcare facilities in the community.

Training could address:

- Reliable identification of stroke patients using a standardized assessment tool
- Conditions that mimic acute stroke symptoms, such as patients presenting with:
 - a) Hypoglycemia
 - b) Alcohol and drug intoxication
 - c) Postictal hemiparesis
 - d) 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 of telemedicine technologies available on site at the PSC.

Note: This may be a range of technologies from a phone call to live interactive physical exam with real time viewing of the patient and/or their neuroimaging studies.

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

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

CR.4 The telestroke link should be fully established within 20 minutes of when it is considered necessary by the PSC physician, in order to meet the less than or equal to 60 minute door to needle time. (Target Stroke: equal to or less than 45 minutes)

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

PC.7 ACUTE STROKE TEAM (AST)

CR.1 The organization must have a designated interdisciplinary Core Stroke team with trained personnel. 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 and/or in program specific competencies.

CR.1a 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.1b 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; or
- Other qualified professional with expertise defined by the medical staff and PSC
- 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
- Other disciplines as determined by the program (i.e. dietician)

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

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

Note: AST may be a separate 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 and ongoing education and training with focus on cerebrovascular disease and treatment of acute stroke patients to ensure competence of personnel.

CR.3a The PSC will require 8 hours of education and training to the members of the Stroke Team personnel, initially and 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 CR.7](#) 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:

CR.1a TIA

CR.1b Ischemic stroke

CR.1c Hemorrhagic stroke

CR.1d Telemedicine/Telestroke consultation

CR.1e tPA therapy administration and post monitoring

CR.1f Dysphagia screening (evidence based tool)

CR.1g Blood pressure and oxygenation management

CR.1h Transfer (both receiving to the PSC and out to a CSC)

CR.1i In house stroke alert

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

CR.2 The response process shall include an early implementation of stroke pathway (protocol) and one call notification to the Stroke Team upon entry to the ED or prior upon notification from EMS personnel.

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

CR.3b Blood pressure management parameters

CR.3c Blood glucose control

CR.3d Parameters to treat fever

CR.3e Oxygenation management parameters

CR.3f Laboratory 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 fibrinolytic therapy with intravenous tPA. Once intravenous tPA 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 has a written transfer agreement (or understanding) with at least one comprehensive stroke center.

The transfer agreement will include:

CR.1a Contact names and phone numbers

CR.1b Hours of operation

CR.1c Transportation options (ground, air)

CR.1d Address 24/7 basis

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

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

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

PC.10 PLAN OF CARE

- CR.1 Nursing staff shall develop a standardized plan of care for the emergent stroke patient which will include identified individual needs for the patient based on their condition and the family's needs. Documentation of interdisciplinary findings and plans, including but not limited to:

CR.1a Pain assessment and interventions

CR.1b Vital signs and neurological time frames and parameters for management

CR.1c Positioning of head of bed

CR.1d Oxygenation

CR.1e Fluid intake

CR.1f Cardiac monitoring

CR.1g Patient/family education

CR.1h Potential complications specific to treatment (i.e. bleeding with tPA)

CR.2 Nursing staff shall develop and maintain a plan of care prepared by qualified individuals for each patient within 24 hours of admission that reflects the input of other disciplines, as appropriate. Documentation of these interdisciplinary findings and interventions shall be included in the plan of care, as appropriate.

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

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

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

PC.11 MEDICATION MANAGEMENT

CR.1 The 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 be available to all appropriate staff at all times.

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.

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.

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

CR.6a Safe time frames for administration of tPA

CR.6b Indications for use

CR.6c Exclusion /contraindication criteria

CR.6d Dosage and mixing instructions

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

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

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

Note: A total dose of 0.9 mg/kg of tPA is given, not to exceed a maximum dose of 90 mg. The first 10% of the dose is given as an IV bolus over 1 minute, and the remaining dose (90%) is given as an IV drip over the following hour. tPA should be diluted 1:1 in sterile water or normal saline, and the mixture should be gently swirled.

If the patient's weight is not known and cannot be quickly ascertained from self-report or by other means such as prior records, two healthcare workers should independently estimate the patient's weight and the resulting average estimate should be used as the approximate weight for drug administration.

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. (Target Stroke: ≤ 30 minutes)

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

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

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 Basic Magnetic Resonance Imaging (MRI) and non-contrast computed tomography (CT) must be available 24/7. An MRI technologist and radiology technologist trained in CT techniques must be available for the PSC.

CR.2a Documentation should include completed and interpreted CT/MRI exams for patients who are candidates for the treatment of tPA within 45 minutes.
(Target Stroke: \leq 35 minutes)

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

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

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

PC.13 REHABILITATION SERVICES

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

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

CR.3a 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.3b 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.

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

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

PC.14 PATIENT/FAMILY/COMMUNITY EDUCATION

CR.1 The 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 annual programs 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 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;

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

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

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

CR.2 The PSC shall ensure that:

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

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

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.2 CONSULTATION

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

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

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

Note: May be in person or by telemedicine/telestroke.

MS.3 NEUROSURGICAL COVERAGE

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

- CR.2 A 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.

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 or licensed practical 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, program narrative or in program specific competencies.

CR.2b Nursing staff not assigned to the PSC, shall receive initial and annual education, training and direction for 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 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 lesser number should apply in ICU.

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

CR.5 Non-employee licensed nurses who are working 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.

STAFFING MANAGEMENT (SM)

SM.1 PERSONNEL

Personnel performing work affecting conformity to the PSC Program requirements shall be competent on the basis of 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 evidence to demonstrate initial 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.

CR.5 Evaluate the effectiveness of the actions taken,

CR.6 Ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and

CR.7 Maintain appropriate records of education, training, skills and experience.

CR.7a Requirement of eight (8) hours of initial and annual education for the Stroke Coordinator and Medical Director.

CR.7b Requirement of eight (8) hours of initial and (4) hours annual education for the ICU and ER Nurse Manager.

CR.7c Requirement of eight (8) hours of initial and (4) hours annual education for members of a dedicated stroke unit /ICU.

CR.7d Requirement of two (2) hours of initial and (1) hour of annual education for nursing staff not assigned to the PSC and areas where in-house strokes may need to be identified.

CR.7e Requirement of four (4) hours of initial and (2) annual education for nurses in the ED.

CR.7f Other staff members (contracted or employed) receive two (2) hours of initial education and one (1) hour of annual education specifically related (Radiology technicians, Pharmacology, Rehabilitation, other).

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).

SM.3 DETERMINING AND MODIFYING STAFFING

CR.1 The method for determining and modifying staffing shall be validated through periodic reporting of variance from core staffing, outlining justification and linking that justification with patient and process outcomes, including any untoward patient events or process failures.

SM.4 JOB DESCRIPTION

All personnel, whether clinical or supportive, including contract staff, shall have available a current job description that contains the experience, educational and physical requirements, and performance expectations for that position.

Note: PSC specific requirements may be in an addendum to the job description or in program specific competencies.

SM.5 ORIENTATION

All personnel, whether clinical or supportive, including contract staff, shall receive an orientation to specific job duties and responsibilities, and their work environment, as required by Federal and State law, the host hospital, regulation and the 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 hospitals definition for a timeframe and a policy and practice for sharing the indicators measurement of individual staff members with those staff members that allows for staff feedback.
- SR.4 The 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.

- CR.1 The PSC shall document in the patient's medical record whether or not the patient has executed an advance directive.
- CR.2 The PSC shall not condition the provision of care or otherwise discriminate based on the execution of the advance directive.
- CR.3 The PSC, through the host hospital, shall ensure compliance with State law regarding the provision of an advance directive.
- CR.4 The PSC, through the host hospital, shall provide education for staff regarding the advance directive.

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

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 tPA is recognized as the standard of care and is approved by the FDA for qualified individuals who present within 3 hours of ischemic stroke onset. If the patient has decision-making capacity or a proxy decision maker is present, a documented discussion regarding risks, benefits, and alternatives to IV tPA should take place prior to the administration of the medication. Unless required by local practices, a signed informed consent document is not a prerequisite to the administration of IV tPA in these circumstances.
- CR.2 If the patient lacks capacity and no proxy decision maker can be found after a reasonable effort, then the physician may administer the medication based on the principle of implied consent for emergency treatment. The physician and other members of the health care team should document the patient's absence of decision-making capacity, that attempts to contact a proxy decision maker were unsuccessful, and that there is an urgent medical need to proceed with treatment in the absence of consent.
- CR.3 When the duration of stroke symptoms exceeds the duration indicated by standard of care for IV tPA administration, the principle of implied consent for emergency treatment is not applicable, and physicians should obtain informed consent. Local practices will determine whether a signed informed consent document is necessary in these cases. Regardless of whether written or verbal consent is required, physicians should document the informed consent discussion in the medical record.

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

PR.5 GRIEVANCE PROCEDURE

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

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

- A list of who to contact
- Review and resolution of grievances
- Specification of reasonable timeframes for review and response to grievances
- PSC contact person
- Steps taken to investigate
- Results of the grievance process; and
- Date of completion

MEDICAL RECORDS (MR)

MR.1 ORGANIZATION

- CR.1 Administrative responsibility for medical records shall rest with the medical record service of the host hospital.
- CR.2 The PSC shall maintain the host hospitals policies on an accurately written, promptly completed medical record for each inpatient and outpatient.
- CR.3 The host hospital organization shall have a process for providing services for the completion, filing, and retrieval of the medical record. The process for completion of the medical record must address timeframes.
- CR.4 Authenticity and security of all record entries shall be safeguarded.
- CR.5 Medical records (original or legally reproduced form) shall be retained for a period of at least five (5) years or as required by host hospital, state and local laws.
- CR.6 The coding and indexing system shall be designed in such a way that allows for timely retrieval by diagnosis and procedure, in order to support medical care evaluation studies.
- CR.7 Original medical records shall be released by the organization only in accordance with Federal or State laws, court orders, or subpoenas.

MR.2 CONFIDENTIALITY

- CR.1 Confidentiality of patient records shall be assured.
- CR.2 Individuals who are authorized by the patient to receive information from or copies of records shall follow processes designed to protect improper or inadvertent release of private information to unauthorized individuals.
- CR.3 The organization shall also ensure that the medical record cannot be altered or accessed by unauthorized individuals.

MR.3 RECORD CONTENT

- CR.1 The medical record shall contain information to:
 - CR.1a Justify treatment, 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 within time frame required by the host hospital and/or State law.

CR.5a Telephone or verbal orders are to be used infrequently and when used must be accepted only by personnel authorized by the medical staff and in accordance with Federal and State law.

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

MR.4 REQUIRED DOCUMENTATION

All records must document the following, as appropriate:

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

CR.2 Admitting diagnosis,
(if admitted)

CR.3 Results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient,

CR.4 Documentation of complications, organization acquired infections, and unfavorable reactions to drugs and anesthesia,

CR.5 Properly executed informed written consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, signed by the patient or his/her authorized representative ([See PR.4 for tPA consent policy](#)),

CR.6 All practitioners' orders, nursing notes, reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient's condition,

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

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

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

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

PHYSICAL ENVIRONMENT (PE)

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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