



DNV Healthcare Inc.
Primary Stroke Center Certification Program - Requirements
PSC 1.0

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Use of DNV Healthcare Primary Stroke Center Certification Requirements

Effective Date

These DNV Healthcare Primary Stroke Center Certification Requirements, PSC 1.0 (Revision 3), Effective Date: [December 1, 2009](#)

Federal Laws, Rules and Regulations

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 Primary Stroke Center Certification requirements.

The Primary Stroke Center Certification requirements are based in whole or in part on the Center for Medicare and Medicaid (CMS) Conditions of Participation, NIAHOSM Accreditation requirements, and ISO 9001 quality management system requirements. Primary Stroke Centers, through their association with 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 Healthcare.

Professional References

- ◆ Brain Attack Coalition
American Stroke Association – a Division of the American Heart Association
- Schwamm, L., et al; *Guidelines for Prevention of Stroke in Patients With Ischemic Stroke for Recommendations From the American Stroke Association's Task Force on the Development of Stroke Systems; Stroke, Journal of the American Heart Association, 2005*
- Schwamm, L. et al; *Recommendations for the Establishment of Stroke Systems of Care: Recommendations From the American Stroke Association's Task Force on the Development of Stroke System;, Stroke, Journal of the American Heart Association, 2005*
- Goldstein, L. et al; *Primary Prevention of Ischemic Stroke: A Guideline From the American Heart Association/American Stroke Association Stroke Council: Cosponsored by the Atherosclerotic Peripheral Vascular Disease Interdisciplinary Working Group; Cardiovascular Nursing Council; Clinical Cardiology Council; Nutrition, Physical Activity, and Metabolism Council; and the Quality of Care and Outcomes Research Interdisciplinary Working Group: The American Academy of Neurology affirms the value of this guideline; Stroke, Journal of the American Heart Association, 2006.*
- Alberts, M. et al; *Recommendations for Comprehensive Stroke Centers: A Consensus Statement From Brain Attack Coalition – Special Report - Stroke, Journal of the American Heart Association*

DNV HEALTHCARE PRIMARY STROKE CENTER CERTIFICATION ADMINISTRATION OF CERTIFICATION

INTRODUCTION

The Primary Stroke Center Certification (PSC) Program is offered by DNV Healthcare Inc. (DNVHC) and integrates requirements related to the NIAHOSM Accreditation Program, CMS Conditions of Participation for hospitals (CoPs), ISO 9001:2008 Quality Management System Requirements, the Guidelines of the Brain Attack Coalition and Recommendations of the American Stroke Association

Hospitals seeking and maintaining a Primary Stroke Center 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 DNVHC or another approved accreditation organization approved by CMS to deem healthcare organizations in compliance with the CoPs

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

REGULATORY AND POLICY REFERENCE

- The Medicare Conditions of Participation for hospitals are in 42 CFR Part 482.
- Survey authority and compliance regulations can be found at 42 CFR Part 488 Subpart A.
- Should an individual or entity (hospital) refuse to allow immediate access upon reasonable request to a State Agency, CMS surveyor, or DNV Healthcare Inc, (DNVHC) staff, the Office of the Inspector General (OIG) may exclude the hospital from participation in all Federal healthcare programs in accordance with 42 CFR §1001.1301 that impact the PSC
- The regulatory authority for the photocopying of records and information during the survey is found at 42 CFR §489.53(a)(13).
- The DNVHC Certification Process, Certification Requirements, and CMS State Operations Manual (SOM) provide the policies and procedures regarding certification activities.
- The ISO 9001 (Quality Management System [QMS]) and ISO 19011 (Guidelines for Quality and/or Environmental Management Systems Auditing) as well as related provide the basis for the certification assessment activities
- American Stroke Association / American Heart Association - Guidelines for Stroke Patients and Establishment of Stroke Systems of Care
- Brain Attack Coalition – Pathways and Guidelines

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

If the Certification Assessment is completed in conjunction with a DNVHC 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 DNVHC Accreditation Survey, the PSC will only be provided advance notice of the upcoming survey not to exceed one week prior to the assessment of the PSC.

SURVEYOR INFORMATION GATHERING AND INVESTIGATION

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 patient care settings, including inpatient units, outpatient settings, emergency departments, imaging, rehabilitation, remote locations, satellites, etc. associated with the PSC.
- The surveyors will review clinical records, staff records, and other documentation necessary to validate information gained from observations and interviews.

DEFINITIONS

AMA	American Medical Association
APIC	Association for Professionals in Infection Control and Epidemiology
CDC	Centers for Disease Control and Prevention
CEO	Chief Executive Officer
CFR	Code of Federal Regulations
CMS	Centers for Medicare and Medicaid Services
CR	Certification Requirement. Additional explanatory information under each major accreditation requirement in this Guide.
DEA	Drug Enforcement Administration
FDA	Food and Drug Administration
HHA	Home Health Agency
ISMP	Institute for Safe Medication Practices
ISO	International Organization for Standardization
Life Safety Code	Life Safety Code® of the National Fire Protection Association
NFPA	National Fire Protection Association
OIG	Office of Inspector General, Department of Health and Human Services
PRN (prn)	Pro re nata, as the occasion arises, when necessary
PSC	Primary Stroke Center
QIO	Quality Improvement Organization
QMS	Quality Management System
SMDA	Safe Medical Devices Act of 1990
SNF	Skilled Nursing Facility

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 TOP MANAGEMENT

CR.1 Top 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 include aspects of individual character, competence, training, experience and judgment are 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 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 shall be a Neurologist, Neurosurgeon, or other medical professional with qualifications as defined for diagnosis and treatment of cerebrovascular disease

PM.2 MANAGEMENT COMMITMENT

Top 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 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 SYSTEM (QM)

QM.1 QUALITY MANAGEMENT SYSTEM

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. This quality management system shall ensure that corrective and preventive actions taken by the PSC are implemented, measured and monitored.

In addition to any other Quality Management System standard, the PSC is required to comply with QM.1 at all times as a part of its Quality Management System.

- CR.1 The PSC shall develop, implement and maintain an ongoing system for managing quality and patient safety.
- CR.2 The PSC shall implement quality assessment and performance improvement efforts to address priorities for improved quality of care and patient safety and ensure that corrective and preventive actions are implemented and evaluated for effectiveness.
- CR.3 The PSC shall assure that adequate resources are allocated for measuring, assessing, improving, and sustaining the PSC's performance and reducing risk to patients.
- CR.4 Control of Documents: the PSC's documents (i.e. policies, procedures, forms) are structured in a manner to ensure that only the proper revisions are available for use;
- CR.5 Control of Records: the PSC ensures that suitable records are maintained
- CR.6 Internal Reviews (Internal Audits) – the PSC conducts internal reviews of its processes and ensures that resultant corrective/preventive action measures have been implemented and verified to be effective;
- CR.7 The PSC has established measurable quality objectives and the results are analyzed, addressed, and;
- CR.8 Appropriate information has been submitted to the oversight group for quality management as well as top management for review and analysis during a management review process.

QM.2 QUALITY OUTLINE

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

Top 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 PSC Certification Program.

QM.4 MANAGEMENT REPRESENTATIVE

A management representative shall be designated and shall have the responsibility and authority for ensuring that the requirements of the Quality Management System are implemented and maintained for the PSC.

QM.5 DOCUMENTATION AND MANAGEMENT REVIEWS

Any variation, deficiency or non-conformity identified by the PSC shall be addressed by the PSC. Appropriate corrective or preventive action shall be determined, applied, and documented. 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. This documentation shall become a part of the Management Review performed at regular intervals, at a minimum of once annually.

QM.6 SYSTEM REQUIREMENTS

In establishing the Quality Management System, the PSC shall be required to have the following as a part of this system:

- CR.1 Interdisciplinary group to oversee the Quality Management System that includes at least top management, Quality Facilitator/Management Representative, and practitioner(s) who shall be doctors of medicine or osteopathy. This interdisciplinary group shall conduct Management Reviews;
- CR.2 Written document defining the Quality Management System, to include all 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 Focus on problem-prone areas, processes or functions,
 - CR.4b Consider the incidence, prevalence and severity of problems in these areas, processes or functions,
 - CR.4c Affect health outcomes, improve patient safety and quality of care.

QM.7 MEASUREMENT, MONITORING, ANALYSIS

The PSC shall strive to optimize the overall effectiveness of processes and systems of the service. This goal shall be accomplished by identifying primary performance measures for each component and for the system function as a whole (both process and outcomes measures) and by employing the methodologies for collaboration with key stakeholders.

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

- CR.1 Community education; 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.
- CR.2 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.

This data shall capture stroke team response time to acute stroke patients, treatments used and patient disposition. It is 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.3 Hyperacute stroke treatment with performance measures involving the timeliness and effectiveness of the acute treatment of both ischemic and hemorrhagic stroke and the prevention of complications.
- CR.4 Sub-acute care and secondary prevention including measures of patient outcomes and avoidance of complications and recurrent strokes.

CR.5 Rehabilitation with performance measures to evaluate patient outcomes (mortality, functional status, and community discharge) and the percentage of stroke patients who receive the appropriate level of rehabilitation services in the system.

Specific indicators for consideration to address the performance measures described above may include (or be related to):

- tPA considered / thrombolytic therapy administered
- Screening of patients for dysphasia
- Deep Vein thrombosis prophylaxis
- Lipid profile during hospitalization (discharged on cholesterol reducing medications if needed)
- Offering of Patient Education about stroke
- Smoking cessation / advice / counseling
- Plan / assessed for rehabilitation considered
- Antithrombotic medications started within 48 hours
- Antithrombotic medications prescribed at discharge
- Anticoagulants prescribed for patients with atrial fibrillation

The PSC shall also evaluate all organized services and processes, both direct and supportive, including services provided by any contracted service. The monitoring shall include the use of internal reviews (audits) of the PSC at scheduled intervals, not to exceed one year and data related to these processes. 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 effectiveness of actions taken to improve performance and/or reduce risks. The PSC shall define the frequency and detail of the measurement. Those functions to be measured at a minimum shall include the following:

- Threats to patient safety;
- Medication therapy/medication use;
- Effectiveness of pain management system;
- Infection control system, including nosocomial infections;
- Utilization Management System;
- Customer satisfaction;
- Unanticipated deaths,
- Adverse event/near miss and other medical errors;
- Critical and/or pertinent processes, both clinical and supportive;
- Physical Environment Management Systems

QM.8 PATIENT SAFETY SYSTEM

CR.1 The PSC shall have a means for establishing clear expectations for identifying and detecting the prevalence and severity of incidents that impact or threaten patient safety. This shall include medical errors and adverse patient events.

CR.2 The PSC's Patient Safety System shall be documented and shall address the following:

- CR.2a detection;
- CR.2b preventive and corrective action;
- CR.2c defined processes to reduce risk;
- CR.2d implementation of action plans;
- CR.2e on-going measurement to ensure action effectiveness;
- CR.2f management review of response and resource allocation to the results of patient adverse event and other analysis; and,
- CR.2g policy and practice of informing patients and/or their families about unexpected adverse events.

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:

NOTE: There is no specific requirement as to the design and location of the Stroke Unit(s). The PSC can define the designation of the unit(s) and/or beds for treatment of acute stroke patients. The PSC shall identify a specified unit to which most stroke patients are admitted and criteria when this may vary. The staff and services provided for these acute stroke patients shall meet the specified requirements as defined under the PSC.

- CR.1 quality objectives and requirements for the PSC;
- CR.2 the need to establish processes and documents, and to provide 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 the review and actions arising from the review shall be maintained.
- CR.4 Where 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 work instructions, as necessary,
- CR.3 the use of suitable equipment,
- CR.4 the availability and use of monitoring and measuring equipment,
- CR.5 the implementation of monitoring and measurement

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 shall 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 Emergency Department documentation shall demonstrate that:
 - CR.3a patients are assessed and treatment decisions made within 60 minutes of arrival to the emergency department;
 - CR.3b intravenous tPA for selected patients is administered within 3 hours of onset of ischemic stroke;
 - CR.3b(1) Written consent is not necessary before administration of tPA for treatment of stroke, however a full discussion of the potential risks and benefits shall be provided;
 - CR.3c assessment and treatment of signs and symptoms of neurological deterioration post IV thrombolytic therapy;
 - CR.3d recognition, assessment, and management of complications of acute stroke.
- CR.4 There are specified timeframes related to the assessment and initial treatment that have been addressed with the stroke protocol as applicable to the emergency department.
- CR.5 Collaborate with ED personnel, emergency physicians and nurses, and stroke professionals to identify PSC capabilities to improve facilitation with EMS responders for triage and transport of acute stroke patients by;
 - CR.5a Working collaboratively with EMS personnel where possible to ensure patients symptomatic of acute stroke are rapidly assessed, treated, and transported;
 - CR.5b Offering EMS providers to participate with the PSC in education and training programs regarding stroke assessment and care;
- CR.6 Maintain a current and complete call schedule with contact information of the physicians on staff and/or available for the PSC.

PC.5 STROKE TEAM AND PROTOCOL

- CR.1 The organization shall have a designated stroke team with trained personnel. 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 Stroke Team.

The Stroke Team shall 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:

 - CR.1a doctor of medicine or osteopathy, qualified as;
 - CR.1a(1) neurologist or neurosurgeon, board certified or eligible; or
 - CR.1a(2) physician with expertise in cerebrovascular disease; or
 - CR.1a(3) other qualified professional with expertise defined by the medical staff and PSC
 - CR.1b emergency department personnel and emergency medical services
 - CR.1c nursing staff trained in the care of acute stroke patients
 - CR.1d radiologic technologists (including MRI and CT technologists)

CR.1e rehabilitation therapists with expertise in treatment of acute stroke patients

CR.1f case manager or social worker

CR.2 Members of the Stroke Team shall receive initial and ongoing education and training with focus on cerebrovascular disease and treatment of acute stroke patients to ensure competence of personnel.

CR.2a The PSC shall require no less than 8 hours of education and training for personnel

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

CR.3 All members of the stroke team shall have a current job description that contains the experience, educational and physical requirements, and performance expectations for their role on the stroke team.

CR.4 The PSC shall develop a stroke pathway (protocol) for the treatment of acute stroke patients. This shall be shared with emergency department practitioners, EMS providers and ICU and/or Stroke Unit for the care of acute stroke patients.

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 units and updated at least annually.

CR.5 Early implementation of stroke pathway (protocol) and notification to the Stroke Team upon entry to the ED or prior upon notification from EMS personnel. The stroke pathway (protocol) shall address:

CR.5a Evaluation and management of the acute stroke patient;

CR.5b Physician members of the stroke team shall have a current description of responsibilities available that contains the experience, educational and physical requirements, and performance expectations for their role on the stroke team, including diagnosis and treatment of cerebrovascular disease;

CR.5c 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.5d All hospital systems shall ensure access to neurological expertise when required.

CR.6 If the PSC does not transfer patients for neurosurgical emergencies, the PSC shall have the facilities and appropriate qualified neurosurgical staff within a minimum of two hours when determined to be immediately needed by the patient.

PC.6 PLAN OF CARE

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

PC.7 MEDICATION MANAGEMENT

CR.1 The PSC shall have a pharmacy service that meets the needs of the patients. Medications shall be administered in accordance with accepted professional principles. The pharmacy service shall be directed by a full time, part time, or consulting registered pharmacist responsible for developing, supervising, and coordinating all the activities of the pharmacy services. The pharmacy service shall 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) shall 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 using in accordance with established guidelines for administration.
- CR.5 Emergency department practitioners shall have access to appropriately qualified personnel for consultation regarding the use of IV thrombolytic therapy, when obtained from a physician competent and privileged in the diagnosis and treatment of ischemic stroke.
- CR.6 In the event an eligible patient with ischemic stroke does not receive IV thrombolytic therapy, documentation shall support the rationale when this is not received.

PC.8 DIAGNOSTIC TESTS

- CR.1 Documentation shall include completed diagnostic studies (Laboratory, Imaging, ECG, chest x-ray) within 60 minutes of the patients arrival in the Emergency Department (door-to-interpretation). These services shall be made available 24/7.
- CR.2 Basic Magnetic Resonance Imaging (MRI) and computed tomography (CT) shall be available for the PSC. A MR technologist and radiology technologist trained in CT techniques shall be available for the PSC.
 - CR.2a Documentation shall include completed CT exams for patients who are candidates for the treatment with tPA within 45 minutes (door-to-interpretation). These services shall be made available 24/7.
 - CR.2b The brain imaging study shall be interpreted by a physician with expertise in reading CT or MRI Studies
 - CR.2c If the PSC does not have MRI and CT on site, there shall be a documented referral protocol in place and knowledge of nearby facilities offering this service
- CR.3 The physician's evaluation, diagnostic testing including neuroimaging and contact with a physician with stroke expertise shall be performed concurrently.

PC.9 REHABILITATION SERVICES

- CR.1 The PSC shall provide 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 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 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 shall be completed when possible within 24 hours of admission or when feasible once the patient is medically stable.
- CR.3a 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 in accordance with the orders of a practitioner authorized by the medical staff to order the 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 shall be in accordance with national acceptable standards of practice.

PC.10 PATIENT MANAGEMENT

The PSC Program shall ensure that it provides:

- CR.1 for the involvement of patients in making their own decisions about managing their disease or condition including changes in their lifestyle
- CR.2 Community education programs that may be delivered through various means to address:
- CR.2a Risk factors, signs, symptoms for stroke or other cardiovascular diseases
- CR.2b General prevention efforts that target smoking cessation, obesity, and diabetes
- CR.2c Management of hypertension, lipid levels, atrial fibrillation, and medication adherence

MEDICAL STAFF (MS)

MS.1 ADMISSION REQUIREMENTS

Patients shall be admitted to the Stroke Unit 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 and PSC
- 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

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.

NURSING SERVICES (NS)

NS.1 NURSING SERVICE

- CR.1 The PSC shall 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 shall supervise and evaluate the nursing care for each patient of the PSC. A registered nurse or licensed practical nurse shall be on duty at all times.
- CR.2a Nursing staff assigned to the stroke team shall have current job description that contains the experience, educational and physical requirements, and performance expectations, including continuing education regarding the care of acute stroke patients.
- CR.2a(1) Nursing staff assigned to the PSC shall require no less than 8 hours of education and training regarding the care of acute stroke patients
- CR.2b Nursing staff not directly assigned to the PSC shall receive 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 shall 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 or ICU for care of stroke patients should be 1:3 or 1:4. This shall be modified accordingly based on both volume and acuity of patients.
- CR.4 A registered nurse shall make any decisions regarding delegation of nursing care to other nursing staff, based on individual patient need and staff qualifications.
- CR.5 Non-employee nurses who are working in the PSC shall adhere to the policies and procedures of the PSC. The director of the PSC shall provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel that occur within the responsibility of the nursing service.

STAFFING MANAGEMENT (SM)

SM.1 PERSONNEL (GENERAL)

Personnel performing work affecting conformity to the 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. This written policy shall be strictly enforced and compliance data reported to top management.

SM.2 COMPETENCE, TRAINING AND AWARENESS

The PSC shall:

- CR.1 determine the necessary competence 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;
- 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 director 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.

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.
- CR.2 This validation shall be done at least monthly and reported to top management.

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.

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 and regulation and the PSC. The orientation shall 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 objectively measure the ability of staff to perform all job duties as outlined in the job description. Relevant indicators shall then be selected from this complete list of indicators for measurement as outlined below.
- 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 through the following:
 - CR.2a variations and problem processes identified through the analysis of outcomes measurement as required by the PSC;
 - CR.2b new technology/equipment/processes;
 - CR.2c customer satisfaction feedback;

- CR.2d scheduled training session outcomes;
- CR.2e staff learning needs assessments that include variations identified through prior staff performance measurement;
- CR.2f staff feedback;
- CR.2g medical staff feedback; and,
- CR.2h requirements of Federal or State law (as applicable).

- CR.3 Indicator measurement for contract staff may be modified based on PSC outcomes and frequency of service of the individual. Modification of this measurement shall take place no less than every calendar year and shall be justified by data analysis.
- CR.4 The PSC shall aggregate the objective performance data for the individual staff and within each job classification to identify variations for further training, coaching, and mentoring.
 - CR.4a Re-measurement shall follow any intervention.
 - CR.4b The outcomes of this measurement shall be reported in the aggregate to top management.
- CR.5 The PSC shall define a timeframe, not to exceed one calendar year, and a policy and practice for sharing the indicators measurement of individual staff members with those staff members that allows for staff feedback.
- CR.6 The PSC shall require each staff member, including contract staff, to participate in continuing education as required by individual licensure/certification, professional association, law or regulation, or PSC policy. Compliance with this standard shall be reported to Quality Management Oversight.

PATIENT RIGHTS (PR)

PR.1 SPECIFIC RIGHTS

The PSC shall protect and promote each patient's rights. 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 participation and means for making informed decisions regarding his/her plan of care;
- CR.2 Information to assist the patient or family to make informed decisions regarding their care planning 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 shall allow the patient to formulate advance directives and to have PSC staff and practitioners comply with the advance directives in accordance with 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 shall ensure compliance with State law regarding the provision of an advance directive.
- CR.4 The PSC shall provide education for staff regarding the advance directive.
- CR.5 When the advance directive exists and is not in the patient's medical record, a written policy for follow-up and compliance shall exist.

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 PSC 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 written 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.

PR.5 GRIEVANCE PROCEDURE

The PSC shall develop and implement a formal grievance procedure, approved by the governing body, for submission of a patient's written or verbal grievance to the PSC, that provides for the following:

- CR.1 A list of whom to contact;
- CR.2 The governing body's responsibility for effective operation of the grievance process. The governing body shall review and resolve grievances or have written delegation of this function to an appropriate person or committee;
- CR.3 Specification of reasonable timeframes for review and response to grievances;
- CR.4 Grievance resolutions shall be in writing and directed to the patient. The grievance resolution shall include the following:
 - CR.4a PSC contact person;
 - CR.4b steps taken to investigate;
 - CR.4c results of the grievance process; and,
 - CR.4d date of completion.

MEDICAL RECORDS SERVICE (MR)

MR.1 COMPLETE MEDICAL RECORD

- CR.1 The PSC shall maintain an accurately written, promptly completed medical record for each inpatient and outpatient.
- CR.2 The 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 shall address timeframes.

CR.3 Authenticity and security of all record entries shall be safeguarded.

MR.2 RETENTION

CR.1 Medical records (original or legally reproduced form) shall be retained for a period of at least five (5) years.

CR.2 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.

MR.3 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.

CR.4 Original medical records shall be released by the organization only in accordance with Federal or State laws, court orders, or subpoenas.

MR.4 RECORD CONTENT

CR.1 The medical record shall contain information to:

CR.1a justify admission and 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 PSC policy.

CR.3 Authentication may include written signatures or initials. Electronic authentication is permissible.

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

CR.5 Verbal orders shall be in accordance with Federal and State law and authenticated within forty (48) hours or earlier if required by State law.

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

CR.5b Verbal orders shall be authenticated in accordance with Federal and State law by the ordering practitioner or a practitioner responsible for the care of the patient. If there is not State law that designates a specific timeframe for the authentication of verbal orders, the orders shall be authenticated within 48 hours.

MR.5 IDENTIFICATION OF AUTHORS

The PSC shall have a system to identify the author of each entry into the medical record.

MR.6 REQUIRED DOCUMENTATION

All records shall document the following, as appropriate:

- CR.1 Evidence of a physical examination, including a health history, performed no more than thirty (30) days prior to admission or within twenty four (24) hours after admission or registration, but prior to surgery or procedure requiring anesthesia services:
- CR.2 Admitting diagnosis,
- CR.3 Results of all consultative evaluations of the patient and appropriate finding by clinical and other staff involved in the care of the patient,
- CR.4 Documentation of complications, organization acquired infections, and unfavorable reactions to drugs and anesthesia,
- CR.5 Properly executed informed written consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, signed by the patient or his/her authorized representative,
- 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.7 Discharge summary with outcome of hospitalization, disposition of case, and provisions for follow up care,
- CR.8 Final diagnosis with completion of medical records within thirty, (30) days following discharge

PHYSICAL ENVIRONMENT (PE)

The PSC shall abide by the management systems for maintaining the physical environment in place under the operation of the hospital, including applicable Life Safety Code (LSC) and National Fire Protection Association (NFPA) standards, as well as applicable CMS Conditions of Participation and accreditation organization requirements if the organization is currently accredited.

PE.1 INFRASTRUCTURE

The PSC shall determine, provide and maintain the infrastructure needed to achieve conformity to the PSC Program requirements. Infrastructure includes, as applicable;

- CR.1 buildings, workspace and associated utilities,
- CR.2 process equipment (both hardware and software), and
- CR.3 supporting services (such as transport, communication or information systems).

PE.2 WORK ENVIRONMENT

The PSC shall determine and manage the work environment needed to facilitate patient care

- CR.1 The facilities for the PSC shall be maintained to ensure the safety of patients, visitors, and staff.
- CR.2 The PSC shall maintain adequate and safe facilities for its services.

- CR.3 The PSC, through its senior leadership shall ensure that the physical environment and associated management systems adequately address issues identified throughout the PSC and there are prevention, correction, improvement and training programs to address these issues.

PE.3 SAFETY MANAGEMENT SYSTEM

- CR.1 The PSC shall provide and maintain safe and adequate facilities for its services. Diagnostic and therapeutic facilities shall be located for the safety of patients.
- CR.2 The PSC shall require that facilities, supplies, and equipment be maintained and ensure an acceptable level of safety and quality. The extent and complexity of facilities shall be determined by the services offered under the PSC.
- CR.3 The PSC shall require that the PSC maintain an environment free of hazards and manages staff activities to reduce the risk of occupational related illnesses or injuries.

PE.4 SECURITY MANAGEMENT SYSTEM

- CR.1 The PSC shall develop a system that provides for a secure environment.
- CR.2 The PSC shall provide for identification of patients, employees and others.
- CR.3 The PSC shall require a process for reporting and investigating security related issues.

PE.5 MEDICAL EQUIPMENT MANAGEMENT SYSTEM

- CR.1 The PSC shall ensure that effective processes are in place for the acquisition, safe use, and appropriate selection of equipment used within the PSC.
- CR.2 The PSC shall address issues related to the initial service inspection, orientation, and the use of physician-owned, rental, or demonstration equipment.

PE.6 UTILITY MANAGEMENT SYSTEM

- CR.1 The PSC shall ensure maintenance, testing, and inspection processes for critical utilities used in the operation of the PSC.
- CR.2 The PSC shall ensure that medical gas systems and HVAC systems are in place (e.g., includes areas for negative pressure).
- CR.3 The PSC shall ensure emergency processes for utility system failures or disruptions.
- CR.4 The PSC shall ensure that reliable emergency power, gas and water supply sources, with appropriate maintenance as required, are available to the PSC.
- CR.5 The PSC shall ensure that all relevant utility systems are maintained inspected, and, tested.