DEPARTMENT OF HEALTH AND SOCIAL SERVICES
DIVISION OF PUBLIC HEALTH
Emergency Medical Services

4306 Stroke System Regulation

1.0 Purpose

The purpose of this regulation is to establish and define the conditions under which the Delaware Statewide Stroke System functions. The goal of this Stroke System is to ensure that every person who may be experiencing a stroke in Delaware receives the same high-quality care, thus decreasing morbidity and mortality from strokes.

2.0 Authority

This regulation is promulgated pursuant to the authority of 16 **Del.C.** Ch. 97, Emergency Medical Services Systems and 16 **Del.C.** Ch.10, Hospitals.

3.0 Organization

3.1 16 **Del.C.** Ch. 97 legislated the creation of a state-wide stroke system of care (SSoC) in 2016 (80 Del. Laws, c. 404). The statute placed the responsibility for the system's development, implementation, and maintenance to the Office of Emergency Medical Services. The legislation authorized the Director of Public Health (DPH) to establish a standing Stroke System Committee comprised of a network of stakeholders from the stroke spectrum of care, including prevention, prehospital care, acute care, and post-acute care. Committee leadership, along with subcommittee organization and leadership, is delineated in the Stroke System of Care Policies and Procedures which are established and approved by the committee, with final approval by the Director of DPH.

3.2 Committees

3.2.1 The Stroke System of Care Coordinator serves as administrator for the Stroke System and all related committees:

3.2.2 The Stroke System of Care Committee serves as the committee providing coordination, oversight, and guidance for all components of the Stroke System in Delaware.

3.2.3 The Quality Evaluation Subcommittee serves as the subcommittee that provides recommendations, advice, and assistance to DPH in its ongoing evaluation of the Delaware Stroke System. The Committee evaluates data related to system metrics of success and quality of patient care and outcomes.

3.2.4 Ad hoc subcommittees may be assigned as needed.

4.0 Definitions

The following words and terms, when used in this regulation, have the following meaning:

"**Acute Stroke Ready Hospital**" or "**ASRH**" means a hospital or emergency center with a dedicated program for stroke care. It is the least comprehensive of the 4 stroke program certifications by The Joint Commission (TJC).

"**Advanced Life Support**" or "**ALS**" means a course of the AHA. Advanced Life Support refers to more advanced emergency medical response than Basic Life Support (BLS).

"**American Heart Association**" or "**AHA**" means a non-profit organization dedicated to fighting heart disease and stroke, including a division specifically for stroke prevention, education, and care. The American Heart Association maintains the Get With The Guidelines (GWTG) Stroke Registry.

"**Basic Life Support**" or "**BLS**" means entry-level emergency medical response as part of the prehospital triage scheme.

"**Certification**" means the process by which a healthcare facility petitions an organization to certify that their facility meets and maintains specified standards. For example, TJC certifies hospitals as stroke centers.

"**Comprehensive Stroke Center**" or "**CSC**" means the most extensive of TJC stroke program certifications. These centers maintain specific capabilities to be able to receive and care for the most complex stroke cases.

"**Dedicated**" means a resource used solely for a specific program.

"**Department of Health and Social Services**" or "**DHSS**" means a cabinet-level department that is comprised of several divisions that promote health and well-being for the citizens of Delaware.

"**Designation**" means a classification by which a hospital is identified by DHSS to have the appropriate resources to manage stroke patients with varying degrees of severity and is granted the authorization to function as a Delaware Stroke Center.

"**Division of Public Health**" or "**DPH**" means an agency under DHSS predominantly focused on physical health and well-being and emergency response and services.

"**Emergency Medical Services**" or "**EMS**" means the coordination of prehospital personnel, facilities, equipment, transportation, and communication to provide for the effective and coordinated delivery of medical care in emergencies resulting from accidents, illnesses, or natural disasters.

"**Facility**" means any location where healthcare is provided. May include stand-alone emergency departments, hospitals, skilled nursing, or rehabilitation.

"**Get With the Guidelines Stroke Registry**" or "**GWTG**" means an AHA created stroke patient registry and tool to evaluate performance indicators set by TJC.

"**Hospital**" means a licensed institution that provides diagnostic and therapeutic medical care. In Delaware, all stroke centers are in hospitals.

"**Interfacility transfer**" means the transfer of a patient from one healthcare facility to another healthcare facility.

"**Large vessel occlusion**" or "**LVO**" means the specific type of ischemic stroke where significant blockage of a major cerebral artery is present. LVOs often result in significant loss of blood flow, impact on higher level brain function, and less favorable outcomes.

"**Performance improvement**" means the continuous study and adaptation of the functions and processes of a healthcare organization to increase the probability of achieving desired outcomes and to better meet the needs of patients.

"**Prevention**" means the efforts to decrease the numbers and severity of strokes.

"**Primary Stroke Centers**" or "**PSC**" are the succeeding certification of stroke programs by TJC following ASRH. They provide critical elements such as additional diagnostics and designated bed space for stroke patients.

"**Protocols**" means written standards for clinical practice in a variety of situations within the Stroke System.

"**Quality Evaluation Committee**" or "**QE Committee**" means the subcommittee of the Stroke System Committee that provides recommendations, advice, and assistance to DPH in its ongoing evaluation of the Delaware Stroke System of Care. It evaluates data related to system metrics of success and quality of patient care and outcomes.

"**Stroke**" means a cerebrovascular accident caused by a change in blood flow that damages brain tissue. Typically caused by blood clots blocking perfusion in the brain (ischemic strokes and transient ischemic attacks) but can also be caused by non-traumatic subarachnoid or intracerebral bleeding (hemorrhagic strokes).

"**Stroke System Committee**" or "**SSC**" means the committee providing coordination, oversight, and guidance for all components of the Stroke System of Care in Delaware as established in Delaware code.

"**The Joint Commission**" or "**TJC**" means the national body that certifies or accredits various healthcare settings. The Joint Commission provides certification for stroke care centers.

"**Thrombectomy-Capable Stroke Centers**" or "**TSC**" means the third tier of TJC-certified stroke programs. In addition to the features and capabilities of ASRH and PSC, a TSC can provide endovascular procedures.

"**Transfer agreement**" means a formal written agreement between facilities that provides for the acceptance of patients in transfer.

"**Triage**" means the sorting of patients in terms of priority need for care so that appropriate treatment, transportation, and destination decisions can be made according to predetermined protocols.

"**Vision, aphasia, neglect**" or "**VAN**" means a prehospital stroke assessment tool focused on identifying LVOs. It considers motor function, visual disturbances, aphasia, and neglect (neglect evaluates senses and gaze). The assessment results in a VAN positive or VAN negative score. VAN positive indicates a high probability of an LVO.

"**Verified**" means successful completion of the process in which the stroke care capability and performance of an institution are evaluated by experienced on-site reviewers on behalf of TJC or other accrediting body.

5.0 Stroke System of Care Committees and Leadership

5.1 Stroke System of Care Committee and Committee Leadership Overview

5.1.1 Committees and their minimum memberships are defined within 16 **Del.C.** Ch. 97 Emergency Medical Services Systems and this regulation.

5.1.2 Committee leaders maintain a system-wide perspective and communicate with other committees to encourage open dialogue and system-wide problem solving.

5.1.3 Committee leaders model a collaborative approach toward Committee members and DPH/Office of Emergency Medical Services (EMS) personnel.

5.2 Leadership:

5.2.1 Presides at respective committee meetings and performs related administrative duties according to Roberts' Rules of Order;

5.2.2 Appointed by the Director of Public Health for a 3-year term and may serve subsequent terms; and

5.2.3 May serve as immediate past committee chairperson following completion of term or terms of service.

5.3 Stroke System of Care Medical Advisor:

5.3.1 Serves as an advisor on both specific and general stroke clinical and patient care issues which are brought to the Stroke System Committee or its subcommittees;

5.3.2 Assists the Stroke System Committee and its subcommittees in developing clinical-oriented system policies and protocols;

5.3.3 Serves as a leader in stroke prevention and public education activities;

5.3.4 Serves as liaison to the Stroke System Quality Evaluation Committee for medical issues requiring physician input; and

5.3.5 Is experienced in medical leadership through a previous role such as physician chairman or medical director.

5.4 Standing Committees and Subcommittees

5.4.1 The committee and subcommittees of the Stroke System of Care are as follows:

5.4.1.1 Stroke System Committee (SSC);

5.4.1.2 Stroke System Quality Evaluation Committee (QE Committee);

5.4.1.3 Stroke System Education and Prevention Subcommittee (Education Committee); and

5.4.1.4 Ad hoc subcommittees and workgroups.

5.4.2 SSC - Scope

5.4.2.1 The SSC is the overarching standing committee providing coordination, oversight, and guidance for all components of the Stroke System of Care in Delaware and is supported by the Stroke System Coordinator.

5.4.2.2 The SSC serves as an advisory committee only, providing recommendations to the DPH Director. The SSC has no regulatory, or other, authority.

5.4.2.3 The SSC and Stroke System Coordinator are responsible for the development and maintenance of the Stroke System Plan.

5.4.3 Stroke System Quality Evaluation Committee - Scope

5.4.3.1 Acts as the standing committee of the SSC that focuses on system performance improvement;

5.4.3.2 Provides recommendations, advice, and assistance to DPH in its ongoing evaluation of the Delaware Stroke System;

5.4.3.3 Evaluate statewide and hospital specific stroke data and outcomes with bench-marking against state and national performance measures.

5.4.3.4 Evaluates trend analysis of system components;

5.4.3.5 Makes recommendations for improvement actions;

5.4.3.6 Evaluates the effectiveness of actions taken and methodologies for follow-up;

5.4.3.7 Supports stroke prevention, research, and system activities by publishing or assisting others with publishing reports;

5.4.3.8 Assists with supervision of the State Stroke Registry; and

5.4.3.9 Provides administration through the State Stroke System Coordinator, in conjunction with the Stroke System QE Committee Chairperson.

5.4.4 Stroke System Education and Prevention Subcommittee (Education Committee)

5.4.4.1 Scope:

5.4.4.1.1 Acts as the standing committee of the SSC that focuses on state-wide public education, awareness, and prevention;

5.4.4.1.2 Serves as the injury-prevention component of the Delaware State Stroke System Plan;

5.4.4.1.3 Decreases death and disability from stroke through public education; and

5.4.4.1.4 Supports statewide public education and community outreach efforts.

5.4.4.2 Membership:

5.4.4.2.1 Is comprised of volunteers from agencies involved with stroke education and prevention; and

5.4.4.2.2 Unlike other stroke committees and subcommittees, leadership length of term is not defined.

5.4.5 Ad-hoc Subcommittees:

5.4.5.1 Are established as needed by the SSC Chair or Stroke System Coordinator and with approval by the SSC;

5.4.5.2 Will be comprised of volunteer membership from the SSC and defined by the ad-hoc committee's need; and

5.4.5.3 Will be led by a volunteer from the ad-hoc subcommittee with an undefined length of term.

6.0 Delaware Stroke Center Requirements

6.1 To be considered a participant in Delaware's Prehospital Stroke Triage Scheme and receive potential stroke patients from EMS and patient transport agencies, a facility must be recognized as a Delaware Stroke System of Care participating stroke center. To be recognized as an Stroke System of Care participating stroke center, the following is required:

6.1.1 Stroke certification from TJC, or equivalent nationally verified guidelines-based accrediting organization per 16 **Del.C.** Ch. 10.

6.1.2 Participation in 75% (3) of the quarterly SSC and Quality Evaluation Committee meetings, verified by attendance logs.

6.1.3 Submit stroke patient data to the AHA Get With The Guidelines (GWTG) Stroke Registry, no later than 90 days after the end of the quarter.

6.1.4 Agree to the sharing of performance indicator data and the use of the State of Delaware's GWTG Super User account to evaluate and improve the performance of the SSoC. The facility must maintain an acceptable standard of care for Delaware stroke patients as determined by the QE Committee and evidenced by review of GWTG stroke data.

6.1.5 Agree to provide timely patient care feedback to EMS and patient transporting agencies for the purpose of loop closure and performance improvement.

6.1.6 Enter into a Memorandum of Understanding (MOU) with the State of Delaware agreeing to these terms and requirements.

6.1.7 Be in compliance with this regulation and 16 **Del.C.** Ch. 97.

6.2 To be considered a participant in Delaware's Prehospital Stroke Triage Scheme and receive potential stroke patients from EMS and patient transport agencies, an out-of-state facility will receive Delaware reciprocity as a Delaware Stroke System of Care participating stroke center if the following requirements are met:

6.2.1 Stroke certification from TJC, or equivalent nationally verified guidelines-based accrediting organization.

6.2.2 Submit stroke patient data to the AHA GWTG Stroke Registry, or other similar registry/database from which data can be reported.

6.2.3 Agree to sharing of performance indicator data required by Stroke System of Care participating stroke centers, as requested by the Stroke System of Care/QE Committee.

6.3 The QE Committee chairperson may appoint a Facility Review Subcommittee to review a stroke facility's compliance with these requirements. Failure to adhere to the above requirements may result in a facility being removed from Delaware's Prehospital Stroke Triage Scheme and lose the ability to receive potential stroke patients from EMS and patient transport agencies.

7.0 State of Delaware Triage, Transport, and Transfer Protocols

7.1 Due to the dynamic nature of identification and evolution of best practices in prehospital care, the prehospital stroke triage guidance will be found solely in the current "State of Delaware, Department of Health and Social Services, DPH, Office of Emergency Medical Services, Statewide Standard Treatment Protocols, Guidelines,

Policies, and Paramedic Standing Orders" and "Statewide Standard Treatment Protocols and Basic Life Support Standing Orders". The Stroke System Committee will provide input for the EMS Medical Director during the revision process of the standing orders.

7.2 For PSCs that have neurointerventional capabilities, direct routing of prehospital patients for mechanical thrombectomy evaluation may be considered by the SSoC in collaboration with the Delaware Emergency Medical Services Oversight Council (DEMSOC)/state EMS medical director, after initial and ongoing review of data, metrics, and outcomes of neurointerventional cases performed at the PSC by the QE committee to ensure that all Delaware patients are receiving the same standard of care.

7.3 Interfacility Transfer Protocol

7.3.1 Refer to the current *Delaware Stroke System Guideline Interfacility Transfer Protocol*, available online at https://dhss.delaware.gov/dhss/dph/ems/ems.html.

7.3.2 Rationale. The optimal outcome for the stroke patient is time dependent. It is to the patient's advantage to receive a level of medical intervention capable of providing comprehensive services for a patient's condition as promptly as possible. To perform appropriate and timely hospital-based triage, candidates for interfacility transfer must be identified quickly and the transfer process carried out promptly.

7.3.3 Formal written transfer agreements and procedures must be established and made readily available to staff before the need for their implementation.

7.3.4 As soon as the need for interfacility transfer is identified, the referring physician should initiate the transfer process by contacting the receiving facility following established transfer agreements and procedures. Care of the patient while awaiting transfer will be discussed by the referring and receiving physicians; the referring physician will continue to be responsible for treatment decisions and care of the patient until:

7.3.4.1 The patient transfer is completed by a non-hospital-based transport service; or

7.3.4.2 Care is assumed by the receiving hospital's transport team.

7.3.5 The most appropriate, available mode of interfacility transportation is determined by the referring physician, with consideration of operational factors as well as clinical needs arriving at the best decision at the time of transfer request.

7.3.6 Stroke patients who are to be transferred to another facility must be transported to a Delaware-recognized stroke center or a stroke center verified by TJC (or other nationally verified guidelines-based accrediting body such as Det Norske Veritas (DNV), according to the guidelines in subsections 7.3.6.1 through 7.3.6.4. These guidelines are adapted from the following American Heart Association (AHA) guidelines with additional review and recommendations of the Stroke System Committee:

7.3.6.1 Guidelines for the Early Management of Patients With Acute Ischemic Stroke (2019).

7.3.6.2 Recommendations for the Establishment of Stroke Systems of Care (2019).

7.3.6.3 Guidelines for Management of Patients With Spontaneous Intracerebral Hemorrhage (2022).

7.3.6.4 Guidelines for Management of Patients With Aneurysmal Subarachnoid Hemorrhage (2023).

7.3.7 Acute ischemic stroke patients requiring inter-facility transfer for neurointerventional evaluation for mechanical thrombectomy will go to the closest nationally certified and Delaware-recognized TSC or CSC.

7.3.7.1 If the closest TSC or CSC is located outside the state of Delaware, the receiving facility will be determined by the transferring facility based upon availability of transport teams, differences in transport times, and patient/family requests, with preference given to treating Delaware stroke patients within the state of Delaware if feasible without significant delays in care.

7.3.7.2 Out of state facilities treating Delaware stroke patients will be required to submit their endovascular data, metrics, and outcomes as requested by the QE Committee, and as is required of facilities performing mechanical thrombectomy within the state of Delaware. If this condition is not met, the SSoC may consider removal of that facility as a Delaware-recognized stroke center.

7.3.7.3 If a stroke patient needing evaluation for mechanical thrombectomy arrives at a facility that does not have neurointerventional capabilities, and another hospital within the same health system does have neurointerventional capabilities but is not TSC or CSC certified, transfer to that hospital may be considered based upon availability of resources, transport times, and patient/family requests. These hospitals will be held to the conditions stated in subsection 7.3.7.2 of this regulation to ensure that all Delaware patients are receiving the same standard of care.

7.3.7.4 Acute ischemic stroke patients without suspected LVO requiring inter-facility transfer for additional stroke evaluation or care, or post-thrombolytic care, due to unavailable resources at their current facility, will go to a nationally certified and Delaware-recognized PSC, TSC, or CSC.

7.3.7.5 Hemorrhagic stroke patients (non-traumatic intracerebral hemorrhage or subarachnoid hemorrhage) requiring interfacility transfer for neurosurgical, neuro critical care, neurointerventional evaluation due to unavailable resources at their current facility, will go to a Delaware-recognized or nationally certified CSC.

7.3.8 Documentation. Full documentation of the patient's course, including initial and subsequent assessment findings, treatment, and results of diagnostic studies including copies of CT scans, MRI (if available), and x-rays whenever possible should be uploaded or forwarded to the receiving hospital with or before the arrival of the patient.

7.3.9 Quality Management. All transfers to or from Delaware recognized stroke centers will be reviewed for both the stroke center and Stroke System quality management processes.

7.4 Follow-up and closed-loop closure. It is the responsibility of the receiving hospital to provide timely feedback to EMS and the transferring facility (as applicable) on the status and outcome of each patient received.

7.5 The Delaware Stroke System of Care QE Committee chairperson may appoint a Facility Review Subcommittee to review a stroke facility's compliance with these requirements. Failure to adhere to the above requirements may result in a facility being removed from Delaware's Prehospital Stroke Triage Scheme and lose the ability to receive potential stroke patients from EMS and patient transport agencies.

8.0 State of Delaware Stroke System Performance Improvement Plan

8.1 Purpose. The State of Delaware Stroke System is committed to the provision of optimal care for all injured persons. To attain this goal, DPH coordinates all medical services provided to stroke patients based on national standards for stroke care as set forth by TJC, Disease-Specific Care Certification Review Process Guide, 2022, and subsequent revisions and the American Heart Association's Get With The Guidelines Stroke Registry. This Performance Improvement Plan seeks to "improv[e] stroke care by promoting consistent adherence to the latest scientific treatment guidelines, [as evidenced by] numerous published studies demonstrating the program's success in achieving measurable patient outcome improvements." (https://www.heart.org/en/professional/quality-improvement/get-with-the-guidelines/get-with-the-guidelines-stroke)

8.2 Objectives

8.2.1 Based on national standards for stroke care quality improvement outlined in TJC's Disease-Specific Care Certification Review Process Guide, 2022, and subsequent revisions, the Stroke System's Performance Improvement Plan describes the framework for use in designing, measuring, assessing, and improving the Delaware Stroke System's organization, functions, and services.

8.2.2 The plan promotes performance improvement through education, facilitation of inter-hospital and intra-hospital communication, and systems coordination. It integrates all prehospital, medical staff, nursing, ancillary services, and operational performance improvement activities through systematic monitoring and evaluation of the appropriateness of patient care, the measurement of outcomes, and the identification of opportunities for improvement.

8.2.3 Improvement is accomplished by a collaborative approach with the appropriate facilities, services, and disciplines involved, utilizing the following objectives:

8.2.3.1 Continual systematic measurement to understand and maintain the stability of systems and processes;

8.2.3.2 Measurement of patient and systems outcomes to help determine priorities for improving systems and processes; and

8.2.3.3 Assessment of system competence and performance.

8.3 Authority

8.3.1 The care of the stroke patient is monitored and evaluated at both the facility and System levels. DPH has the authority for system data collection, review, and most importantly the authority to recommend corrective action in all aspects of stroke care throughout the continuum from onset to rehabilitation. DPH will guide, as needed, individual stroke centers in the development and implementation of their Stroke Performance Improvement Programs.

8.3.2 Maintenance of patient confidentiality is the joint responsibility of evaluators at the State and facility levels.

8.4 Prehospital Evaluation

8.4.1 Objective

8.4.1.1 DPH shall work with the Fire Prevention Commission to address improvements regarding prehospital care of the stroke patient. The AHA's GWTG and the current "State of Delaware, Department of Health and Social Services, DPH, Office of Emergency Medical Services, Statewide Standard Treatment Protocols, Guidelines, Policies, and Paramedic Standing Orders" and "Statewide Standard Treatment Protocols and Basic Life Support Standing Orders" will provide a basis for prehospital stroke care evaluation.

8.4.1.2 Evaluation

8.4.1.2.1 There will be an ongoing evaluation of all aspects of stroke care from the receipt of the call at central dispatch through the patient's care at the stroke center.

8.4.1.2.2 Evaluation will document the quality of care provided and compliance with protocols. Areas in need of improvement will be identified. Major areas of review are as follows:

8.4.1.2.2.1 Completion of assessment with VAN/electrocardiogram/blood glucose/Last Known Well which is hours elapsed since a patient was known to be at their baseline, without signs and symptoms of their current stroke activity;

8.4.1.2.2.2 Scene time;

8.4.1.2.2.3 Transport decisions;

8.4.1.2.2.4 Transport to the appropriate facility;

8.4.1.2.2.5 Under/over triage with VAN;

8.4.1.2.2.6 Documentation; and

8.4.1.2.2.7 Data collection.

8.4.2 Delaware will follow national standards for prehospital data collection. DPH will collaborate with the State Fire Prevention Commission to determine the minimum data sets to be collected by BLS and ALS providers. Data used for the evaluation of prehospital care must be consistent with the design of the Delaware Stroke Registry, as collected by the medical facilities and analyzed by DPH.

8.4.3 Performance improvement indicators will be determined by the Stroke System QE Committee based on Delaware prehospital protocols and national and Delaware standards of care.

8.4.4 Performance Improvement

8.4.4.1 A completed prehospital patient care record must be provided to the receiving facility for inclusion in the patient's emergency room or hospital medical record. Facilities and prehospital providers are strongly encouraged to establish a mechanism for the exchange of information, including the provision of feedback to prehospital providers on triage decisions made. Additionally, the hospital's stroke registrar will include this record's data in the facility's stroke registry for outcome evaluation.

8.4.4.2 A performance improvement program model shall be developed by DPH or its designee for the use of BLS and ALS agencies. Recommendations for changes in educational curricula, patient care protocols, etc., shall be based on analysis of information obtained through the prehospital evaluation process. DPH shall also develop a mechanism for prehospital providers to have input into quality assurance issues, including the identification of educational needs and methods of addressing them.

8.5 Stroke Center Evaluation

8.5.1 All recognized stroke facilities will design a performance improvement plan that meets the standards and requirements established by TJC or other nationally recognized accreditation body. Hospital performance improvement plans will be verified during site surveys and quality improvement visits.

8.5.2 Design. When new processes or systems are developed within an institution, the design will be based on the following:

8.5.2.1 Up-to-date sources of information about designing processes and systems including practice guidelines, clinical pathways, professional standards, and regulatory standards;

8.5.2.2 The needs and expectations of internal and external consumers; and

8.5.2.3 The performance of the processes and systems and their outcomes including internal and external (benchmarking) comparison data.

8.5.3 Measure. Quality indicators (audit filters) will be based on nationally recognized guidelines set forth by TJC. They are established to evaluate the process or outcome of the care or services provided or to determine the level of performance of existing processes and the outcomes resulting from these processes. Data collection and measurement will be systematic, related to relevant standards of care, and

prioritized according to high volume, high risk, or problem-prone areas. In addition, the needs, expectations, and feedback from patients and their families, employees, results of ongoing monitoring activities (e.g., infection control), safety of the patient care environment, utilization, and risk management findings will be included.

8.5.4 Data collection will be designed to:

8.5.4.1 Assess new or existing processes;

8.5.4.2 Measure the level of performance and stability of important existing processes;

8.5.4.3 Set performance improvement priorities;

8.5.4.4 Establish benchmarks of performance to identify potential opportunities for improvement;

8.5.4.5 Identify patterns and trends that may require focused attention;

8.5.4.6 Provide comparative performance data to use for performance improvements; and

8.5.4.7 Evaluate whether changes have improved the processes.

8.5.5 Quality indicators (audit filters) may:

8.5.5.1 Measure events or phenomena that are expected to occur at some level of frequency:

8.5.5.2 Relate data about either a process or an outcome;

8.5.5.3 Relate data about occurrences that are either desirable or undesirable;

8.5.5.4 Relate data that guide the Stroke Program in improving norms of performance instead of focusing exclusively on censoring or eliminating individual outliers; and

8.5.5.5 Identify serious events that may trigger an opportunity for improvement and require further data collection.

8.5.6 Focused audits will be used to periodically examine the process of care as recommended by TJC and may include the following:

8.5.6.1 Noncompliance with hospital criteria for stroke center designation

8.5.6.2 The absence of documentation of required information/patient assessment findings on stroke care records

8.5.7 Assessment

8.5.7.1 After collection, the data will be analyzed to determine the following:

8.5.7.1.1 If the design specifications for new processes were met;

8.5.7.1.2 The level of performance and stability of existing processes;

8.5.7.1.3 Priorities for possible improvement of existing processes;

8.5.7.1.4 Actions and strategies to improve the performance of processes; and

8.5.7.1.5 Whether changes in the processes resulted in improvement.

8.5.7.2 This assessment will be accomplished using statistical quality control techniques and tools, comparative benchmarking data (TJC, GWTG, and others), a review of the stroke program's processes and outcomes over time, and other reference material as appropriate. Intensive assessment will be used when measurement indicates that potential performance or system-related opportunities for improvement exist, a single serious event occurs, the control limits are met, or when undesirable variation in performance has occurred or is occurring.

8.5.7.3 The assessment process will be interdisciplinary and interdepartmental depending upon the process or outcome under review.

8.5.8 Improvement. When an opportunity for improvement is identified or when the measurement of an existing process identifies the need to redesign a process, a systematic approach such as the Find, Organize, Clarify, Understand, Select and Plan, Do, Check, Act (FOCUS-PDCA) Six Sigma Model, will be implemented. This model is the ongoing process used to promote continuous improvement as described below:

8.5.8.1 Find (Identify) process to improve.

8.5.8.1.1 Develop an opportunity statement; and

8.5.8.1.2 Identify the process.

8.5.8.2 Organize a team that knows the process.

8.5.8.2.1 Identify employees who work closest with the process; and

8.5.8.2.2 Identify internal/external consumers and their expectations.

8.5.8.3 Clarify current knowledge of the process.
8.5.8.3.1 Identify sound areas of the process;
8.5.8.3.2 Determine if team members are appropriate to assess the process;
8.5.8.3.3 Identify the process flow; and
8.5.8.3.4 Identify problems/redundancies that can be eliminated to make the flow more efficient.
8.5.8.4 Understand the cause of process variation.
8.5.8.4.1 Identify variation in the process;
8.5.8.4.2 Identify measurable process characteristics;
8.5.8.4.3 Identify if the variation has a common or unique cause; and
8.5.8.4.4 Identify the effect the variation has on other hospital systems.
8.5.8.5 Select an improvement strategy.
8.5.8.5.1 Determine what changes can be made to improve the process; and
8.5.8.5.2 Start a description of the process to be improved.
8.5.8.6 Plan the improvement and data collection
8.5.8.6.1 Identify what improvements are to be made and in what order;
8.5.8.6.2 Assign responsibility for making the change;
8.5.8.6.3 Determine when the change will be effective; and
8.5.8.6.4 Determine what data will be collected to measure changes.
8.5.8.7 Do (put plan into action) the Improvement.
8.5.8.7.1 Initiate the change (pilot study period); and
8.5.8.7.2 Collect data.
8.5.8.8 Check the results.
8.5.8.8.1 Analyze the results of the data collection; and
8.5.8.8.2 Draw conclusions.
8.5.8.9 Act to sustain gains
8.5.8.9.1 Standardize the change;
8.5.8.9.2 Determine ongoing measurement of the process and reevaluation of implemented changes (effectiveness monitored for a minimum of 3 months following corrective action);
8.5.8.9.3 Policy and procedure development/revision; and
8.5.8.9.4 Education and communication of new process.
8.5.9 Following the identification and documentation of a specific problem in patient care or system performance by the peer-review process, corrective action is taken through 1 of the following mechanisms:
8.5.9.1 Change existing policies and procedures that govern or define the standard of care.
8.5.9.2 Provide professional education. Cases may be selected for discussion at the stroke service conferences; deficits in knowledge can be addressed through education of the whole group of providers or specific providers.
8.5.9.3 Provide counseling. Specific cases are reviewed by the Director of Stroke, chief of the service, or the supervisor, with the individual.
8.5.9.4 Provide credentials. Report information from quality improvement activities through the institution's performance improvement system for consideration at the time of credentialing, delineation of privileges, or evaluation.
8.6 Stroke System Evaluation
8.6.1 Stroke System evaluation encompasses the entire scope of care provided to stroke patients within the State of Delaware from stroke onset through rehabilitation.
8.6.2 DPH Responsibilities
8.6.2.1 Implement and monitor the State Stroke System Quality Improvement Program; and
8.6.2.2 Appoint a qualified Stroke System Medical Advisor and SSC Chairperson from candidates recommended by the SSC members. Terms of Service:
8.6.2.2.1 Terms of office are 3 years, and
8.6.2.2.2 Successive terms are permissible.

8.6.3 Stroke System Registry Coordinator Responsibilities

8.6.3.1 Review Stroke Registry data submitted for completeness.

8.6.3.2 Provide data for the QE Committee meetings, upon request.

8.6.3.3 Complete approved data requests from GWTG.

8.6.3.4 Function as staff for QE Committee.

8.6.4 Delaware State Stroke System QE Committee

8.6.4.1 The Stroke System QE Committee is a subcommittee of the Stroke System Committee.

8.6.4.2 Membership consists of representatives from each component of the statewide Stroke System.

8.6.4.3 Responsibilities of the QE Committee

8.6.4.3.1 The Delaware Stroke System QE Committee is charged with providing recommendations, guidance, and technical assistance to DPH in its ongoing evaluation of the Delaware Stroke System. Specific functions may include the following:

8.6.4.3.1.1 Assist the Stroke System Registry Coordinator in the supervision of the State Stroke Registry.

8.6.4.3.1.2 Assess stroke care standards and recommend actions for the development and implementation of statewide policies and procedures that guide and support the provision of stroke care or services.

8.6.4.3.1.3 Assess resources needed to support and sustain the Delaware State Stroke System.

8.6.4.3.1.4 Evaluate the coordination and integration of prehospital, inter-hospital, intra-hospital, and ancillary services.

8.6.4.3.1.5 Monitor the incidence of adverse outcomes regularly with comparison to regional and national norms.

8.6.4.3.1.6 Recommend action for identified problems or opportunities for improvement in patient care services.

8.6.4.3.1.7 Sponsor ongoing education regarding TJC and GWTG standards and provide a multidisciplinary educational forum for presentation and discussion of interesting, difficult, or controversial stroke patient management cases.

8.6.4.3.1.8 Evaluate the effectiveness of actions taken and determine follow-up.

8.6.4.3.1.9 Meet a minimum of 4 times per year, and as determined by the Committee or DPH.

8.6.4.3.1.10 Assess other sources of data to combine into a comprehensive database for evaluation of the continuum of stroke care in the State of Delaware.

8.6.4.3.1.11 Develop operational guidelines for the Committee's functioning.

8.6.4.3.1.12 Perform any other function deemed necessary by DPH.

8.6.4.3.2 Review of major areas within the Stroke System, including:

8.6.4.3.2.1 Triage;

8.6.4.3.2.2 Interfacility transfer;

8.6.4.3.2.3 Facility performance;

8.6.4.3.2.4 Impact of system;

8.6.4.3.2.5 Integrity of Stroke Registry data; and

8.6.4.3.2.6 Prevention trends.

8.7 Delaware State Stroke Registry

8.7.1 Patient Criteria. To generate consistent statewide data, all patients with an International Classification of Diseases (ICD) code included in TJC reporting requirements must be included in the stroke registry (GWTG).

8.7.2 Data Set

8.7.2.1 Facilities will abstract the required data as soon as possible, but no more than 90 days after the close of each quarter.

8.7.2.2 Data collected from contributing acute care facilities will form the State's stroke patient registry. System registry data will then be used in the process of formulating System reports, and for System quality improvement, data linkage, and research/prevention activities.

8.7.2.3 The Delaware State Stroke Registry data set is defined by GWTG.

8.7.3 Hospital Participation

8.7.3.1 All acute care facilities in Delaware that receive stroke patients will be required to contribute to the State stroke registry program by abstracting data into GWTG.

8.7.3.2 Each contributing facility will be responsible for the staff and resources to ensure timely and accurate stroke data abstraction.

8.7.3.3 Both the individual contributing facilities and the State will be responsible for data integrity and confidentiality.

8.8 Oversight. The Emergency Medical Services Office within DPH receives at least semi-annual reports of the Stroke System's Evaluation Committee activities. Minutes of each meeting will be forwarded to the System of Care Coordinator in a timely manner.

8.9 Confidentiality. As used in this section, "records" means the recordings of interviews and all oral or written reports, statements, minutes, memoranda, charts, data, statistics, and other documentation generated by the Evaluation Committee, its subcommittees, and the State Stroke Registry for the stated purpose of stroke system medical review or quality care review and audit.

8.9.1 All quality management proceedings shall be confidential. Records of the State Stroke Evaluation Committee, its subcommittees, the Delaware State Stroke Registry, and attendees at meetings held for stated purposes of stroke system medical review or quality care review and audit shall be confidential and privileged and shall be protected from direct or indirect means of discovery, subpoena, or admission into evidence in any judicial or administrative proceeding.

8.9.2 All studies, reports, and minutes will include only the patient stroke registry number with all other identifying information encoded or kept in locked files. Access to qualified researchers may be granted based on state, federal, and municipal statutes, bylaws, rules, regulations, and policies. All meeting attendees will be required to sign confidentiality statements. Any documented breach of confidentiality will be referred to DPH for appropriate action.

8.10 Biennial Review. This plan is reviewed at least biennially by DPH and the QE Committee.

9.0 Effective Date

This regulation shall become effective 90 days after the date of publication of the final implementing order in the *Delaware Register of Regulations*.

28 DE Reg. 390 (11/01/24)