



WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

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**NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE AND FILING WITH THE LEGISLATIVE RULE-
MAKING REVIEW COMMITTEE**

AGENCY: Health TITLE-SERIES: 64-107
RULE TYPE: Legislative Amendment to Existing Rule: No Repeal of existing rule: No
RULE NAME: 64-107 Designation of Comprehensive, Primary and Acute Stroke-Ready Hospitals

PRIMARY CONTACT

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CITE STATUTORY AUTHORITY: 16-1-4(b)(6); 16-5b-18

EXPLANATION OF THE STATUTORY AUTHORITY FOR THE LEGISLATIVE RULE, INCLUDING A DETAILED SUMMARY OF THE EFFECT OF EACH PROVISION OF THE LEGISLATIVE RULE WITH CITATION TO THE SPECIFIC STATUTORY PROVISION WHICH EMPOWERS THE AGENCY TO ENACT SUCH RULE PROVISION:

STATUTORY AUTHORITY

The Secretary of the Department of Health and Human Resources shall propose rules for legislative approval in accordance with W. Va. Code §29A-3-1 et seq. to implement the all of the provisions of W. Va. Code §16-1-4(b) (6), 16-5b-18. The Department of Health and Human Resources is empowered to enact each provision of W. Va. Code of State Rules 64-107 by the authority specifically found in W. Va. Code §.16-1-4(b)(6), 16-5b-18.

DATE eFiled FOR NOTICE OF HEARING OR PUBLIC COMMENT PERIOD: 6/27/2017

DATE OF PUBLIC HEARING(S) OR PUBLIC COMMENT PERIOD ENDED: 7/27/2017

COMMENTS RECEIVED: Yes

(IF YES, PLEASE UPLOAD IN THE COMMENTS RECEIVED FIELD COMMENTS RECEIVED AND RESPONSES TO COMMENTS)

PUBLIC HEARING: No

(IF YES, PLEASE UPLOAD IN THE PUBLIC HEARING FIELD PERSONS WHO APPEARED AT THE HEARING(S) AND TRANSCRIPTS)

RELEVANT FEDERAL STATUTES OR REGULATIONS: No

WHAT OTHER NOTICE, INCLUDING ADVERTISING, DID YOU GIVE OF THE HEARING?

SUMMARY OF THE CONTENT OF THE LEGISLATIVE RULE, AND A DETAILED DESCRIPTION OF THE RULE'S PURPOSE AND ALL PROPOSED CHANGES TO THE RULE:

Brief Summary of Rule: This legislative rule establishes the standards, criteria, and methods for designating various health care facilities in the State of West Virginia as meeting specific levels of care capability as stroke centers or facilities in order to identify those facilities best equipped and staffed to care for patients experiencing a stroke. This rule series applies to hospitals in the state that desire a designation as a Comprehensive Stroke Center, Primary Stroke Center or Acute Stroke-Ready Hospital.

STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE RULE:

Statement of Circumstances: This rule series is intended to implement the provisions of H.B. 4388, enacted during the 2016 regular legislative session. H.B. 4388 authorized the Department of Health and Human Resources (DHHR) to recognize and certify hospitals as a comprehensive stroke center, a primary stroke center or an acute stroke-ready hospital. W.Va. Code § 16-5B-18. The appropriate designation is to be based upon criteria recognized by the American Heart Association, the Joint Commission or other nationally recognized organization as set out in legislative rules. The DHHR is to provide an annual a list of all designated hospitals to the medical director of each licensed emergency medical service agency in this state. This list is to be maintained by the DHHR and will be updated annually on its website. The bill requires that the Secretary of the DHHR establish by legislative rule prehospital care protocols related to assessment, treatment and transport of patients identified as stroke patients. Protocols must include development and implementation of plans for the triage and transport within specified timeframes of onset of symptoms of acute stroke patients to the nearest comprehensive, primary or acute stroke ready hospital. The proposed rules are being proposed after consultation with an advisory committee selected by the Secretary. The advisory committee consists of representatives of the DHHR, an association with the primary purpose of promoting better heart health, a registered emergency medical technician, hospitals located in rural areas of the state and hospitals located in urban areas of this state.

SUMMARIZE IN A CLEAR AND CONCISE MANNER THE OVERALL ECONOMIC IMPACT OF THE PROPOSED LEGISLATIVE RULE:

A. ECONOMIC IMPACT ON REVENUES OF STATE GOVERNMENT:

This legislative rule establishes the standards, criteria, and methods for designating various health care facilities in the State of West Virginia as meeting specific levels of care capability as stroke centers or facilities in order to identify those facilities best equipped and staffed to care for patients experiencing a stroke. The rule series is intended to implement the provisions of W.Va. Code § 16-5B-18 by designating hospitals in the state as Comprehensive Stroke Centers, Primary Stroke Centers or Acute Stroke-Ready Hospitals.

B. ECONOMIC IMPACT OF THE LEGISLATIVE RULE ON THE STATE OR ITS RESIDENTS:

This legislative rule establishes the standards, criteria, and methods for designating various health care facilities in the State of West Virginia as meeting specific levels of care capability as stroke centers or facilities in order to identify those facilities best equipped and staffed to care for patients experiencing a stroke. The rule series is intended to implement the provisions of W.Va. Code § 16-5B-18 by designating hospitals in the state as Comprehensive Stroke Centers, Primary Stroke Centers or Acute Stroke-Ready Hospitals.

C. FISCAL NOTE DETAIL:

Effect of Proposal	Fiscal Year		
	2017 Increase/Decrease (use "-")	2018 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost			
Personal Services	136,772.00	136,772.00	136,772.00
Current Expenses			
Repairs and Alterations			
Assets			
Other			
2. Estimated Total Revenues	12,000.00	8,000.00	35,000.00

D. EXPLANATION OF ABOVE ESTIMATES (INCLUDING LONG-RANGE EFFECT):

This rule will have no fiscal impact on the state. Staff currently working in the Trauma Designation and Categorization Unit will be responsible for the addition of the Stroke Designation activities as outlined in this Rule. Half of those salaries have been designated in this fiscal note. Revenues from the facilities seeking stroke designation will be used to support the travel of these staff to conduct the onsite visits that will be conducted for purposes of this Rule. There are currently six WV facilities with stroke designation from national entities. It is anticipated that an additional four facilities (for a total of 10 stroke designated facilities) would seek designation after the first year. As the program evolves and grows, more facilities are expected to participate. However, this number will fluctuate from year to year with the addition/removal of facilities seeking designation at any given time depending on their own economic situations, patient needs, etc.

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENTS ARE TRUE AND CORRECT.

TITLE 64
LEGISLATIVE RULE
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR PUBLIC HEALTH

SERIES 107
DESIGNATION OF COMPREHENSIVE, PRIMARY AND ACUTE STROKE-READY HOSPITALS.

§64-107-1. General.

1.1. Scope. -- This legislative rule establishes the standards, criteria, and methods for designating various health care facilities in the State of West Virginia as meeting specific levels of care capability as stroke centers or facilities in order to identify those facilities best equipped and staffed to care for patients experiencing a stroke.

1.2. Authority. -- . Va. Code §§ 16-1-4(b)(6) and 16-5B-18.

1.3. Filing Date. --

1.4. Effective Date. --

1.5 Sunset Provision: This rule shall terminate and have no further force or effect upon the expiration of 5 years from its effective date.

1.6. Applicability. – This rule series applies to hospitals in the state that desire a designation as a Comprehensive Stroke Center, Primary Stroke Center or Acute Stroke-Ready Hospital.

1.7. Purpose -- This rule series is intended to implement the provisions of *W. Va. Code § 16-5B-18* by designating hospitals in the state as Comprehensive Stroke Centers, Primary Stroke Centers or Acute Stroke-Ready Hospitals.

§64-107-2. Definitions.

For the purposes of this rule series:

2.1. "ASRH" means an Acute Stroke-Ready Hospital.

2.2. "Certification" or "certified" means certification of a Comprehensive Stroke Center (CSC), Primary Stroke Center (PSC) or Acute Stroke-Ready Hospital (ASRH) using evidence-based standards, from a nationally recognized certifying body approved by the Office.

2.3. "MRC" or "Committee" means the Medical Review Committee.

2.4. "CSC" means a Comprehensive Stroke Center.

2.5. "Department" means the Department of Health and Human Resources.

2.6. "Designation" or "designated" means the Department's recognition of a hospital as a Comprehensive Stroke Center, Primary Stroke Center or Acute Stroke-Ready Hospital.

2.7. "Director" means the Director of the Office of Emergency Medical Services within the Bureau for Public Health.

2.8. "Emergency Medical Services Advisory Council" or "EMSAC" means the Emergency Medical Services Advisory Council created by W.Va. Code § 16-4C-5.

2.9. "Office" means the Office of Emergency Medical Services within the Bureau for Public Health, authorized by W.Va. Code § 16-4C-4. The Office of Emergency Medical Services is the office within the Department charged with the administration of this rule series.

2.10. "PSC" means a Primary Stroke Center.

2.11 "SSAC" means the State Stroke Advisory Committee

§64-107-3. State Stroke Advisory Committee

3.1 Of the members first appointed, one-third shall be appointed for a term of one year, one-third shall be appointed for a term of 2 years, and the remaining members shall be appointed for a term of 3 years. The terms of subsequent appointees shall be 3 years. Members may be reappointed for additional terms.

3.2 The State Stroke Advisory Committee shall function as an advisory body to the Secretary of the Department and report biannually at regularly scheduled meetings.

3.3. The State Stroke Advisory Committee shall make recommendations to the Office of Emergency Medical Services related to the establishment and revision of evidence based protocols for the triage, treatment and transport of possible acute stroke patients to the appropriate CSC, Primary Stroke Center or Acute Stroke-Ready Hospital.

3.4. The State Stroke Advisory Committee shall advise the OEMS on the development of stroke networks.

3.5. The State Stroke Advisory Committee shall collect and evaluate de-identified stroke care data from stroke network hospitals and EMS Systems to evaluate and make recommendations to the Office of Emergency Medical Services for improvement in stroke systems of care.

3.6. Annually, the State Stroke Advisory Committee and the Office will consider adopting new nationally recognized recommendations.

3.7. The State Stroke Advisory Committee shall forward recommendations of certifying bodies to the Office at least annually.

3.8. The Office will consult the State Stroke Advisory Committee when reviewing and approving certifying bodies.

3.9. The Office will maintain and post on the Office's website a current list of the names, phone numbers and website information, if available, of the approved certifying bodies. The list will be reviewed at least annually.

§64-107-4. Stroke Care – Restricted Practices.

The provisions of this rule series related to Comprehensive Stroke Centers, Primary Stroke Centers or Acute Stroke-Ready Hospitals are not medical practice guidelines and may not be used to restrict the authority of a hospital to provide services for which it has received a license under State law.

§64-107-5 Comprehensive Stroke Center (CSC) Designation.

5.1. Subject to Section 7, Comprehensive Stroke Center is valid for a period of two years and shall expire at the end of the specified day in the month and year stated therein.

5.2. Each designated CSC shall have its designation renewed upon the Office's receipt of a copy of the certifying body's certification renewal and an application form available through the Office.

5.3. A hospital shall submit a copy of its certification report from the certifying body as soon as practical, but no later than 30 business days after the hospital receives the certification.

§64-107-6. Request for Comprehensive Stroke Center Designation.

6.1. A hospital that is already certified as a CSC by a nationally recognized certifying body approved by the Office shall send a copy of the certificate and the appropriate fee to the Office along with an application available through the Office.

6.2. Within 30 business days after the Office receives the hospital's certificate indicating that the hospital is a certified CSC in good standing with the certifying body and the application available through the Office, the hospital shall be deemed to be a State-designated Comprehensive Stroke Center.

6.3. The Office will send designation notices to hospitals that it designates as Comprehensive Stroke Centers. A list of designated Comprehensive Stroke Centers will be maintained on the Office's website at <http://www.wvoems.org/>. Names of designated Comprehensive Stroke Centers will be added upon designation.

6.4. The application available through the Office will include a statement that the hospital meets the requirements for CSC designation. The applicant hospital shall a letter of commitment that includes a contact list of stroke personnel with email addresses and phone numbers.

6.5. The application available through the Office will instruct the hospital to provide proof of current CSC certification from a nationally recognized certifying body approved by the Office.

6.6. A hospital designated as a CSC shall pay a biennial fee of \$3,200.00.

§64-107-7. Suspension and Revocation of Comprehensive Stoke Center Designation.

7.1. A hospital that no longer meets nationally recognized, evidence-based standards for CSCs, or loses its CSC certification, shall notify the Office, in writing, within 5 business days, upon notification from the certifying body with a list of deficiencies, if applicable.

7.2. Suspension of Designation

7.2.a. The Office shall have the authority and responsibility to suspend or revoke the hospital's CSC designation upon receiving notice that the hospital's CSC certification has lapsed or been revoked by the State recognized certifying body.

7.2.b. The Office shall have the authority and responsibility to suspend the hospital's CSC designation, in extreme circumstances in which patients may be at risk for immediate harm or death, until such time as the certifying body investigates and makes a final determination regarding certification. The Office will notify the hospital's certifying body and provide the hospital with written notice of the Office's decision to suspend designation.

7.2.c. Upon receipt of the Office's written notice to suspend designation, the hospital shall have 15 business days in which to make a written request for an administrative hearing to contest the Office's decision. Administrative hearings will be conducted in accordance with *W.Va. Code R. §§ 64-1-1 et seq. (Rules of Procedure for Contested Case Hearings and Declaratory Rulings)*. The Office will notify the hospital and the hospital's certifying body of the Office's final administrative decision to revoke designation.

7.2.d. The Office will suspend the hospital's CSC designation at the request of a hospital seeking to suspend its own Office designation.

7.2.e. The Office shall have the authority to conduct investigations. All applicants for designation and designees shall fully cooperate with any Office investigation, including providing patient medical records as requested by the Office. The failure to fully cooperate shall be grounds for denying, suspending or revoking a designation.

7.3. The Office will restore any previously suspended or revoked Office designation upon notice to the Office that the certifying body has confirmed or restored the CSC certification of that previously designated hospital.

§64-107-8. Primary Stroke Center (PSC) Designation.

8.1. Subject to Section 10, Primary Stroke Center designation is valid for a period of two years and shall expire at the end of the specified day in the month and year stated therein.

8.2. Each designated PSC shall have its designation renewed upon the Office's receipt of a copy of the certifying body's certification renewal, an application available through the Office along with the fee provided in subsection 9.6.

8.3. The Office shall consult with the State Stroke Advisory Committee in developing designation, re-designation, and de-designation processes for PSCs.

8.4. A hospital shall submit a copy of its certification report from the certifying body as soon as practical, but no later than 30 business days after the hospital receives the certification. Upon receipt of the certification renewal, the Office will begin the re-designation process.

§64-107-9. Request for Primary Stroke Center Designation.

9.1. A hospital that is already certified as a Primary Stroke Center by a nationally recognized certifying body approved by the Office shall send a copy of the certificate and the appropriate fee to the Office, along with an application available through the Office.

9.2. Within 30 business days after the Office receives the hospital's certificate indicating that the hospital is a certified PSC in good standing with the certifying body, and the completed application available through the Office, the hospital shall be deemed to be a State-designated PSC.

9.3. The Office will send designation notices to hospitals that it designates and will add the names of designated PSCs to the website listing immediately upon designation. Subject to section 10, the Office will remove the name of a hospital from the website listing when a hospital loses its designation after notice and, if requested by the hospital, a hearing.

9.4. The application available through the Office shall include a statement that the hospital meets the requirements for PSC designation. The applicant hospital shall provide a letter of commitment along with a contact list of stroke personnel including email addresses and phone numbers.

9.5. The application available through the Office will instruct the hospital to provide proof of current PSC certification from a nationally recognized certifying body approved by the Office.

9.6 A hospital designated as a PSC shall pay a biennial fee of \$3,200.00.

§64-107-10. Suspension and Revocation of Primary Stroke Center Designation.

10.1. A hospital that no longer meets nationally recognized, evidence-based standards for Primary Stroke Centers, or loses its PSC certification, shall notify the Office and the Regional Emergency Medical Services Board of Directors, in writing, within 5 business days, upon notification from the certifying body.

10.2. Suspension of Designation.

10.2.a. The Office shall have the authority and responsibility to suspend a hospital's PSC designation upon receiving notice from the hospital's certifying body that the hospital's PSC certification has lapsed, or been revoked, suspended or cancelled.

10.2.b. In extreme circumstances where patients may be at risk for immediate harm or death, as determined by the Director, the Office shall have the authority and responsibility to suspend a hospital's PSC designation, until such time as the certifying body investigates and makes a final determination regarding certification. The Office will notify the hospital's certifying body and provide the hospital with written notice of its decision to suspend designation.

10.2.c. Upon receipt of the Office's written notice to suspend designation, the hospital shall have 15 business days in which to make a written request for an administrative hearing to contest the Office's decision. Administrative hearings will be conducted in accordance with *W. Va. Code R. §§ 64-1-1 et seq. (Rules of Procedure for Contested Case Hearings and Declaratory Rulings)*. The Office will notify the hospital and the hospital's certifying body of the Office's final administrative decision to revoke designation.

10.2.d. The Office will suspend a hospital's PSC designation at the request of a hospital seeking to suspend its own Office designation.

10.2.e. The Office shall have the authority to conduct investigations. All applicants for designation and designees shall fully cooperate with any Office investigation, including providing patient medical records as requested by the Office. The failure to fully cooperate shall be grounds for denying, suspending or revoking a designation.

10.3. Revocation of Designation. The Office shall have the authority and responsibility to revoke a hospital's designation if the hospital's certification has been revoked by the State-recognized certifying body.

10.4. The Office will restore any previously suspended or revoked Office designation upon notice to the Office that the certifying body has confirmed or restored the PSC certification of that previously designated hospital.

10.5. The Office shall consult with the State Stroke Advisory Committee in developing designation and de-designation processes for PSCs.

§64-107-11. Acute Stroke-Ready Hospital (ASRH) Designation without National Certification.

11.1. The Office recognizes that diagnostic capabilities and treatment modalities for the care of stroke patients will change because of rapid advances in science and medicine. Nothing in this rule series prohibits a hospital, without designation, from providing emergency stroke care. Requirements pertaining to Acute Stroke-Ready Hospitals may not be used to restrict the authority of a hospital to provide services for which it has received a license under State law.

11.2. The Office will attempt to designate hospitals as ASRHs in all areas of the State as long as they meet the criteria in this Section.

11.3. Any hospital seeking designation as an ASRH shall apply for and receive ASRH designation from the Office, provided that the hospital attests, on an application available through the Office (See Section 12), that it meets, and will continue to meet, the criteria for ASRH designation and pays appropriate fee. The Office will post and maintain ASRH designation instructions, including the request form, on its website.

11.4. Upon receipt of a completed application available through the Office attesting that the hospital meets the criteria set forth in this rule series, signed by a hospital administrator or designee, the Office will designate a hospital as an ASRH no more than 30 business days after receipt of an attestation that meets the requirements for attestation in Section 13.1, unless the Office, within 30 days after receipt of the attestation, chooses to conduct an onsite survey prior to designation. If the Office chooses to conduct an onsite survey prior to designation, then the onsite survey shall be conducted within 90 days after receipt of the attestation. The Office will notify the hospital of the designation in writing. The Office has the authority to conduct on-site visits to assess compliance with this rule series.

11.5. The Office will add the names of designated ASRHs to the website listing immediately upon designation and shall immediately remove the name of a hospital from the website listing when a hospital loses its designation after notice and, if requested by the hospital, a hearing.

11.6. The Office will require biannual written attestation by ASRHs to indicate compliance with ASRH criteria, as described in this rules series, and will automatically renew ASRH designation of the hospital. The hospital shall provide the attestation, along with any necessary supporting documentation. Supporting documentation shall include any documents supporting the attestation that have changed significantly since the previous annual attestation. If the Office chooses to conduct an onsite survey prior to designation, then the onsite survey shall be conducted within 90 days after receipt of the attestation. The Office will notify the hospital of the designation in writing. The Office has the authority to conduct on-site visits to assess compliance with this rule series.

11.7. ASRH designation requires biannual written attestation, on an Office approved form, by an ASRH to indicate compliance with ASRH criteria, as described in this rule series. The Office, after determining that the ASRH meets the requirements for attestation and upon receipt of the appropriate fee, will

automatically renew the ASRH designation of the hospital. Within 30 business days, the Office will provide written acknowledgment of the hospital's designation renewal.

§64-107-12. Acute Stroke-Ready Hospital Designation Criteria without National Certification.

12.1 Hospitals seeking Acute Stroke-Ready Hospital designation that do not have national certification shall develop and utilize policies and procedures that are consistent with nationally recognized, evidence-based protocols for the provision of emergent stroke care.

12.2. Hospital policies, procedures or protocols relating to emergent stroke care and stroke patient outcome shall be reviewed at least quarterly, or more often as needed, by a hospital committee that oversees quality improvement. Adjustments shall be made as necessary to advance the quality of stroke care delivered.

12.3. Criteria for ASRH designation of hospitals shall meet current Joint Commission accreditation standards/guidelines.

12.4. Hospitals seeking Acute Stroke-Ready Hospital designation must maintain a registry of stroke patients, which shall be available for review upon request by the Office or any hospital that has a written transfer agreement with the ASRH. The stroke patient registry shall be available to be used for internal hospital quality improvement purposes. Hospitals may alternatively participate in a nationally recognized stroke data registry. Hospitals shall submit data from their stroke patient registry or nationally recognized stroke data registry to the Office upon request. The hospital shall share patient data with its Regional Medical Review Committee and the State Medical Review Committee. The patient registry shall contain at a minimum:

12.4.a. The patient's medical record number;

12.4.b. Date of emergency visit

12.4.c. Mode of patient arrival

12.4.d. Time presented in the emergency department

12.4.e. Last time patient was observed to be free of current symptoms (i.e., time of last known well), if known

12.4.f. Baseline initial stroke severity score upon arrival at the hospital (i.e., National Institutes of Health (NIH) Stroke Scale)

12.4.g. Time of blood coagulation results available

12.4.h. Time of brain imaging

12.4.i. Time of brain imaging results available

12.4.j. Time and type of thrombolytic therapy or nationally recognized evidence-based exclusion criteria

12.4.k. Time of transfer from the emergency department

12.4.l. Time of transfer if from another location in the hospital; and

12.4.m. Transfer/discharge diagnosis and destination.

§64-107-13. Request for Acute Stroke-Ready Hospital Designation without National Certification.

13.1 Any hospital seeking designation as an Acute Stroke-Ready Hospital shall apply for and receive ASRH designation from the Office, provided that the hospital attests, on a form developed by the Office in consultation with the State Stroke Advisory Subcommittee, that the hospital meets, and will continue to meet, the criteria for ASRH designation (See Section 12) and pays the appropriate fee as provided in subsection 13.8. The Office will post and maintain ASRH designation instructions, including an application available on the Office website.

13.2 The application available through the Office shall include a statement that the hospital meets the designation criteria in Section 12 of this rule series. The hospital shall provide a letter of commitment that includes a contact list of stroke personnel including email addresses and telephone numbers.

13.3. The hospital shall indicate on the application whether it is applying for an initial ASRH designation or a renewal.

13.4. The hospital shall provide the Office with supporting documentation indicating compliance with each designation criterion in Section 12 of this rule series with the initial ASRH application, that meets current Joint Commission accreditation standards/guidelines.

13.5. For re-designation, the hospital shall provide the Office with updated supporting documentation, including quality outcomes, indicating compliance with ASRH criteria in Section 12. Hospitals shall submit a full application every two years.

13.6. Quality outcomes data shall include a summary of the following quality outcomes, as indicated by the stroke registry:

13.6.a. Results time for door-to-blood coagulation study;

13.6.b. Completed time for door-to-brain imaging;

13.6.c. Results time for door-to-brain imaging;

13.6.d. Time for door-to-thrombolytic therapy, if applicable;

13.6.e. Time for door-to-transfer from emergency department, if applicable; and

13.6.f. Non-emergency department patients transferred out of the hospital for stroke diagnosis.

13.7. Each ASRH shall submit a copy of its comprehensive quality assessment, including, but not limited to, all of the quality measurements in subsection (e) that do not meet nationally recognized evidenced-based stroke guidelines. For each outcome not meeting national guidelines, the ASRH shall implement a written quality improvement plan.

13.8. After receipt of a completed application that meets the requirements of this Section, the Office will designate a hospital as an ASRH no more than 30 business days after receipt of the form. The Office will notify the hospital, in writing, of the designation.

13.9. A designation issued pursuant to these rules shall be for a period of two years and shall expire at the end of the specified day in the month and year stated therein.

13.10. A hospital designated as an ASRH shall pay a biennial fee of \$1,600.00.

§64-107-14. Suspension and Revocation of Acute Stroke-Ready Hospital Designation without National Certification.

14.1. Emergency Suspension.

14.1.a. When the Director or his or her designee has determined that the hospital no longer meets the Acute Stroke-Ready Hospital criteria set forth in this rule series, and the potential of an immediate and serious danger to public health, safety, and welfare exists, the Office will issue an emergency written order of suspension of ASRH designation.

14.1.b. If the ASRH fails to eliminate the violation immediately or within a fixed period of time, not exceeding 10 business days, as determined by the Director, the Director may immediately revoke by written order, the ASRH designation.

14.2. Suspension and Revocation.

14.2.a. If the ASRH fails to eliminate the violation immediately or within a fixed period time, not exceeding 10 business days, as determined by the Director, the Director may immediately revoke the ASRH designation by written order. The ASRH may appeal the revocation, by delivering to the Office a written request for an administrative hearing within 15 days after receipt of the written order of revocation.

14.2.b. The Director shall have the authority and responsibility to suspend, revoke, or refuse to issue or renew an ASRH designation, after notice and an opportunity for an administrative hearing, when the Office finds that the hospital is not in substantial compliance with current ASRH criteria as set forth in this rule series.

14.2.c. The Office shall consult with the State Stroke Advisory Committee in developing the designation, re-designation, and de-designation processes for ASRHs.

§64-107-15. Acute Stroke-Ready Hospital Designation with National Certification.

15.1. Subject to Section 17, Acute Stroke-Ready Hospital designation is valid for a period of two years and shall expire at the end of the specified day in the month and year stated therein.

15.2. Each designated ASRH shall have its designation renewed upon the Office's receipt of a copy of the certifying body's certification, an application available through the Office along with the fee as provided in subsection 16.7.

15.3. The Office shall consult with the State Stroke Advisory Committee in developing designation, re-designation and de-designation processes for ASRHs.

15.4. A hospital must submit a copy of its certification renewal from the certifying body as soon as practical, but no later than 30 business days after that certification is received by the hospital. Upon the Office's receipt of the renewal certification, the Office shall renew the hospital's ASRH designation.

§64-107-16. Request for Acute Stroke-Ready Hospital Designation with National Certification.

16.1. The Office shall require a hospital that is already certified as an Acute Stroke-Ready Hospital, through an Office-approved certifying body, to send a copy of the report to the Office.

16.2. Within 30 business days after the Office's receipt of a hospital's ASRH report and an application available through the Office that indicates the hospital is a certified ASRH, in good standing, the hospital shall be deemed a State-designated ASRH.

16.3. The Office shall add the names of designated ASRHs to the website listing immediately upon designation and shall immediately remove the name of a hospital from the website listing when a hospital loses its designation after notice and, if requested by the hospital, a hearing.

16.4. The application shall include a statement that the hospital meets the requirements for ASRH designation. The applicant hospital shall a letter of commitment that includes a contact list of stroke personnel with email addresses and telephone numbers

16.5. Hospitals applying for ASRH designation via national ASRH certification shall provide to the Office proof of current ASRH certification, in good standing, by a nationally recognized certifying body.

16.6. A designation issued pursuant to these rules shall be for a period of two years active and shall expire at the end of the specified day in the month and year stated therein.

16.7. A hospital designated as an ASRH shall pay a biennial fee of \$1,600.00.

§64-107-17. Suspension and Revocation of Acute Stroke-Ready Hospital Designation with National Certification.

17.1. The Office will immediately remove the name of a hospital from the website listing when a hospital loses its designation after notice and, if requested by the hospital, a hearing.

17.2. The Office will issue an emergency suspension of ASRH designation when the Director has determined that the hospital no longer meets the ASRH criteria and an immediate and serious danger to the public health, safety and welfare exists.

17.3. If the ASRH fails to eliminate the violation immediately or within a fixed period of time, not exceeding 10 days, as determined by the Director, the Director may immediately revoke the ASRH designation.

17.4. The ASRH may appeal the revocation, within 15 business days after receiving the Director's revocation order, by requesting an administrative hearing.

17.5. After notice and an opportunity for an administrative hearing, the Office will suspend, revoke or refuse to renew an ASRH designation when the Office finds that the hospital is not in substantial compliance with current ASRH criteria.

§64-107-18. Data Collection and Submission.

18.1. The Office will administer a data collection system to collect data that is already reported by designated Comprehensive Stroke Centers, Primary Stroke Centers, and Acute Stroke-Ready Hospitals to their certifying body, to fulfill certification requirements. CSCs, PSCs and ASRHs may provide data used in submission to their certifying body, to satisfy any Office reporting requirements. The Office may require submission of data elements in a format that is used statewide. If the Office establishes reporting requirements for designated CSCs, PSCs and ASRHs, the Office shall permit each designated CSC, PSC and ASRH to capture information using existing electronic reporting tools used for certification purposes

18.2. Stroke data collection systems and all stroke-related data collected from hospitals shall comply with the following requirements:

18.2.a. The confidentiality of patient records shall be maintained in accordance with State and federal laws.

18.2.b. Hospital proprietary information and the names of any hospital administrator, health care professional, or employee may not be subject to disclosure.

18.3.c. Information submitted to the Office shall be privileged and strictly confidential and shall be used only for the evaluation and improvement of hospital stroke care. Stroke data collected by the Office may not be directly available to the public and may not be subject to civil subpoena, nor discoverable or admissible in any civil, criminal, or administrative proceeding against a health care facility or health care professional.

§64-107-19. Statewide Stroke Assessment Tool.

19.1 The State Stroke Advisory Committee shall select or develop and submit an evidence-based statewide pre-hospital stroke assessment tool to clinically evaluate potential stroke patients to the Office for approval. The Committee shall select or develop, jointly with the EMSAC, the educational curriculum for instructing emergency medical service provider personnel on the use of the tool.

19.2. Upon approval of the pre-hospital stroke assessment tool, the Office will disseminate the tool to all EMS Systems for adoption. The Director shall post the Office-approved stroke assessment tool on the Office's website.

19.3. The State Stroke Advisory Committee shall review the Office-approved stroke assessment tool at least annually to ensure its clinical relevancy and to make changes when clinically warranted.

64-27-20 Stroke System Accountability.

20.1. Policies and procedures. To ensure system accountability, the Office will develop policies and procedures governing the components necessary to collect and analyze information within the stroke system of care including patient care information. These policies and procedures will include guidelines for medical review and audit to assure system quality as required by W.Va. Code § 55-7B-9c(k).

20.2. Medical Review and Quality Improvement. The medial review and quality improvement process for the stroke system of care shall consist of medical review committees at the local, regional, and state level. The Office will develop policies and procedures for the operation of these committees.

20.3. The MRC may make recommendations to the Office or to the state and regional Medical Policy and Care Committee concerning disciplinary actions or system policy issues as outlined in Medical Review Committee operation guidelines established by the Office.

20.4. The Chair of the MRC, with the approval of the committee, may temporarily appoint certain specialists to the committee as may be required to adequately and appropriately review specific cases. The temporary member shall follow all policies and procedures established by the committee and the Office.

20.5. If a designated facility fails to participate and abide by the policies and procedures governing the operation of the MRC, the Office may suspend or revoke the designation status of the facility.

64-27-21. Protocols for Assessment, Treatment and Transport of Stroke Patients.

21.1. The assessment, treatment, and transport of stroke patients by licensed emergency medical services agencies shall be in accordance with system-wide medical protocols and policies established by the State Medical Director in consultation with the state Emergency Medical Policy and Care Committee pursuant to *W.Va. Code R* § 64-48-9.1.a.2.

21.2. In addition to the list of designated CSCs, PSCs and ASRHs, to be maintained on the Office's website at <http://www.wvoems.org/>, the Office will provide licensed emergency medical services agencies an list of designated CSCs, PSCs and ASRHs annually.