July 24, 2017

West Virginia Bureau of Public Health
Brian Skinner, General Counsel
350 Capitol Street, Room 702
Charleston, WV 25301

RECEIVED
JUL 25 2017
COMMISSIONER'S OFFICE
BUREAU FOR PUBLIC HEALTH

Re: Comments for Proposed Rule 64-107, HB4388

Dear Mr. Skinner, ESQ.

On behalf of the American Heart Association (AHA), including its American Stroke Association (ASA) division, and more than 35 million volunteers and supporters, we appreciate this opportunity to voice our concerns for Proposed Rule 64-107. Please consider this communication our official public comment on this matter. The AHA/ASA has long advocated for accessible, quality patient care for stroke victims. Time lost is brain lost, making appropriate response time vital for survival and a decreased chance of living with a disability as a result of suffering a stroke.

Although the rule related to this bill was to be written last year, ***after*** the first meeting of the advisory committee, the DHHR/Bureau for Public Health has only recently released a draft rule, apparently without the required review by the committee, and filed it with the Secretary of State's office to be put forth for public comment.

The content of the rule, as written is problematic:

1. The "Sunset" provision, which terminates the rule after five years threatens the sustainability of the improvements in stroke patient care afforded by HB 4388.
   Recommendation: *Our request is that a provision is put forth in year 4 so that this rule will get renewed to assure stroke patient care is not compromised.*
2. One of the main purposes of the regulation was to establish EMS transport protocols, a critical component of the bill. As written, the rule fails in that regard as it only discusses the composition and role of the committee. There is no mention of transport protocols.
   Recommendation: *This is a vital part of the legislation. We implore you to include EMS transport protocols in this rule. It is our understanding the EMS transport protocols are already established. However, it is essential that they be referenced in this rule as well to ensure proper stroke patient care.*

3. By establishing their own criteria for "Acute Stroke Ready Hospitals Without Certification", the DHHR/BPH has violated the scope of the legislation. HB4388 clearly specified the criteria for designation (Joint Commission or other nationally recognized accrediting body), therefore, the DHHR/BPH is not adhering to the legislation since the department is not a nationally recognized accrediting body. Nor does the Department have the capacity or ability to review, inspect and evaluate facilities for this high-level of stroke patient care.
   Recommendation: *The American Heart & Stroke Association and our national certifying partners do not support the establishment of a state's own certification system. The section of Proposed Rule 64-107 that outlines a path for Acute Stroke Ready Hospitals to be certified*

July 25, 2017,

Brian Skinner, General Counsel

Bureau of Public Health

350 Capital Street, Room 702

Charleston, WV 25301

Dear Sir,

This letter serves as a response proposed by the Department of Health on June 27th, 2017 regarding Designation of Comprehensive, Primary and Acute Stroke-Ready Hospitals.

Comments for **Proposed Rule 64-107, HB4388** include:

We did not receive notification of the proposal until Thursday July 20th and all public comments are due on July 27th. The notice was sent to us from the Chair of the Appalachian Stroke Network, when it was made available to her. Have all facilities received notification and adequate time to review and respond?

1.5 Sunset Provision: Is this needed and if so, please clarify the meaning and definition.

2.2 Certifying bodies: There are additional certifying bodies such as American Heart Association and American Stroke Association, The Joint Commission, DNV-GL which should be added to the list.

2.4 "CSC": There is a new certification in development, " Thrombectomy Capable" which should be added to this making it "CSC and/or Thrombectomy Capable Center." This additional certification will require the facility to provide 24/7 endovascular treatment. Currently WVU is the only hospital in the state to potentially meet CSC status. This will create additional financial burden to families living in the southern part of the state that will require transfer to the Northern part of the state bypassing facilities with the capabilities to perform endovascular treatment closer to home. Our facility serves a large part of Southern WV as well as parts of KY, OH and even into VA, patients will be transferred further distances from home requiring lodging, food, additional transportation cost for family members.

3.1 Two tiered terms should suffice.

9.6 Biennial fee: proposal states this is used for "On-site visits." If required Certification is from a governing board, who conducts On-site visits, please clarify the need for additional On-site visits?

64.107.11 This section should be removed: ASRH should require national certification. This insures all facilities are currently providing consistent Evidence based practice for our patients. Only Hospitals that meet certification criteria and earn National certification should be recognized.

64.107.18 Data collection and Submission: All CSC and PSC currently enter data into a National database. This needs clarification. If additional database is required, consideration must be made regarding additional resources and financial burden on facilities. Are the current databases capturing the information needed or required?

Thank you for your consideration. Our goal is to assure quality patient care for stroke victims and in doing such, prevent decreased chance of living with disability following a stroke. I respectfully request these considerations be reviewed and revised.

Respectfully,

Mitzi Beckett, BSN, RN, SCRN

Stroke Program Coordinator

Cabell Huntington Hospital

July 26, 2017

Brian Skinner, General Council
Bureau of Public Health
350 Capitol Street, Room 702
Charleston, WV 25301

Dear Mr. Skinner, ESQ,

This letter is to serve as a follow-up, with clarification and comments, to my facsimile sent on 7/24/2017 at 10:29:43AM in response to the public comment period on the proposed rule: Designation of Comprehensive, Primary and Acute Stroke Ready hospitals.

I have been a neuroscience nurse for thirty years, the last ten of which involved care of the stroke patient population specifically. I have been involved with the effort in advocating accessible, quality patient care for stroke victims in our region for over a decade. Countless hours of discussions, meetings, conference calls, draft proposals have occurred since as early as 2006 but nothing was ever finalized at the state level, even after input from stroke experts across the state. While I do believe an official stroke advisory committee is a step in the right direction, I do consider the content of the rule, as written, problematic.

1. The "sunset" provision threatens the sustainability of the improvements finally made for our stroke population.
2. All sections concerning Comprehensive Stroke Center (CSC) should include "Thrombectomy Capable" as CSC equivalent certification. This is a new certification in development for hospitals providing endovascular treatment 24/7 and will be available within the next one to two years. It is neither medically or financially in the best interest of residents in southern West Virginia to transport to Morgantown, or out of the state when thrombectomy is needed and is available nearby (i.e. Huntington).
3. **Remove "ASRH without national certification".** It is important to the integrity and sustainability of the program for all stroke centers to be reviewed by a national certifying body which lends credibility and validity to a program. The state does not have the qualifications or resources to fully inspect, assess, and evaluate facilities for such a high-level of stroke patient care and this is beyond the scope of the legislation.
4. It would be beneficial to add a section to give the State Stroke Advisory Committee direction to develop and submit evidence based statewide stroke EMS transport protocol as indicated in the legislation.
5. The fee for Stroke Center designation warrants an itemization of costs and how the funds will be utilized. Specifically, hospitals need to understand the benefit of paying a separate state fee in addition to the cost of nationally-recognized certification. No site visits or other review is required as this is being monitored by the certifying body. Any fee, if required, should be minimal.
6. Hospitals utilizing an existing data collection system will not have resources to duplicate data collection or submission. The current stroke certified hospitals in the state utilize the same data collection system. During the past decade of working towards improving stroke care in our state, it was determined that it is possible to develop a specific process using this particular data collection system to look at state-specific data. Since most stroke centers in the state are already using this system, it would be beneficial to incorporate its use in moving forward with the desire to maintain statewide stroke data.
7. As mentioned above, site visits are not warranted which would alleviate travel costs. Any fee that is required for state certification could be used to cover any cost associated with the development of statewide data in said data system alluded to in #6 above.

Thank you for your consideration.

Sincerely,

Jenny Lobo Edwards, MSN, RN, CNRN, SCRN
St. Mary's Medical Center
Neuroscience Nurse Specialist / Stroke Program Coordinator
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PRIVILEGED COMMUNICATION
TELECOPY TRANSMITAL SHEET

*** PLEASE CONFIRM TRANSMISSION ***

To:	Brian Skinner, General Counsel	From:	Jenny Edwards, MSN, CNRN, SCRN
Company:	Bureau of Public Health	Dept:	SMMC Neuroscience
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E-mail:		E-mail:	jenny.edwards@st-marys.org
Date:	July 24, 2017		
Pages:	14	(Including this page)	

Re: **Title 64 Series107 – Designation of Comprehensive, Primary, and Acute Stroke-Ready Hospitals**

This information is intended only for the use of the individual or entity to which it is addressed and may contain information that is strictly confidential, privileged and exempt from disclosure under applicable law. It is intended for the sole use of the individual of entity named above. If the reader of this message is not the intended recipient of agent responsible for delivering the message to the intended recipient, you are herby notified that any use, dissemination, duplication or publication of this communication by a person or entity other than as named above is strictly prohibited. If you received this communication by mistake please notify the sender immediately by telephone and return it to the sender at St. Mary's Medical Center, Huntington, WV 25702, at our expense.

MESSAGE: Copy of 64 CSR 107 draft with my comments in red ink are included in this transmission.
Thank you!

FORM: Fax92502
Adopted Date:
Revised Date:
Reviewed Date

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

Field Code Changed

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.* -- *W. 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. "CSC" means a Comprehensive Stroke Center, including Thrombectomy-Capable Stroke Center.

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

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

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

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

2.8. "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.

2.9. "PSC" means a Primary Stroke Center.

§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.

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 assist with 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 10, Comprehensive Stroke Center designation shall remain valid at all times while the hospital maintains its certification as a CSC, in good standing, with the certifying body.

5.2. The duration of a CSC designation shall coincide with the duration of its CSC certification.

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

5.4. A hospital shall submit a copy of its certification renewal 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 annual 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. __________ 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 provide the following:

6.4.1. Hospital name and address;

6.4.2. Hospital chief executive officer/administrator typed name and signature;

6.4.3. Hospital stroke medical director typed name and signature; and

6.4.4. Contact person typed name, e-mail address and phone number.

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 an annual fee of $500.

§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.

7.2. Suspension of Designation

7.2.1. 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.

7.2.2. 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.

7.2.3. 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.

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

7.2.5. 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 shall remain valid at all times while the hospital maintains its certification as a PSC in good standing with the Office-approved certifying body.

8.2. The duration of a PSC designation shall coincide with the duration of its PSC certification.

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

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

8.5. A hospital shall submit a copy of its certification renewal 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 annual 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 the following:

9.4.1. Hospital name and address;

9.4.2. Hospital chief executive officer/administrator typed name and signature;

9.4.3. Hospital stroke medical director typed name and signature; and

9.4.4. Contact person typed name, email address and phone number.

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 an annual fee of $350.

§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.*

10.2.1. 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.

10.2.2. 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.

10.2.3. 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.

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

10.2.5. 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.~~

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~~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 an annual 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 annual 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 annual written attestation, on a Office 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, 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 policies and procedures that are consistent with nationally recognized, evidence-based protocols for the provision of emergent stroke care.

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12.2. Hospital policies, procedures or protocols relating to emergent stroke care and stroke patient outcome shall be reviewed at least annually, 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 be limited to the ability of the hospital to:

12.3.1. Create written acute care policies, procedures, or protocols related to emergent stroke care, including transfer criteria;

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12.3.2. Participate in the data collection system, if available;

12.3.3. Maintain a written transfer agreement with one or more hospitals that have neurosurgical expertise;

12.3.4. Designate a Clinical Director of Stroke Care who shall be a clinical member of the hospital staff with training or experience, as defined by the facility, in the care of patients with cerebrovascular disease. This training or experience may include, but is not limited to, completion of a fellowship or other specialized training in the area of cerebrovascular disease, attendance at national courses, or prior experience in neuroscience intensive care units. The Clinical Director of Stroke Care may be a neurologist, neurosurgeon, emergency medicine physician, internist, radiologist, advanced practice nurse, or physician assistant;

12.3.5. Provide rapid access to an acute stroke team, as defined by the facility, that considers and reflects nationally recognized, evidenced-based protocols or guidelines;

12.3.6. Administer thrombolytic therapy, or subsequently developed medical therapies that meet nationally recognized, evidence-based stroke protocols or guidelines;

12.3.7. Conduct brain image tests at all times, which shall consider and reflect current nationally recognized evidence-based protocols or guidelines;

12.3.8. Conduct blood coagulation studies at all times, which shall consider and reflect current nationally recognized evidence-based protocols or guidelines;

12.3.9. Maintain a log 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 log 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 log or nationally recognized stroke data registry to the Office upon request. The hospital may share unidentified patient data with its Regional Emergency Medical Services Board of Directors, EMSAC, the Office or other stroke network partners for quality improvement purposes. Hospitals shall review and analyze the following data elements quarterly, at a minimum, and submit a summary to the Office with the annual written attestation. The stroke patient log shall contain, at a minimum:

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

12.3.9.a. Date of emergency visit;

12.3.9.b. Mode of patient arrival;

12.3.9.c. Time presented in the emergency department;

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

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

12.3.9.f. Time of blood coagulation results available;

12.3.9.g. Time of brain imaging;

12.3.9.h. Time of brain imaging results available;

12.3.9.i. Time and type of thrombolytic therapy or nationally recognized evidence-based exclusion criteria;

12.3.9.j. Time of transfer from the emergency department;

12.3.9.k. Time of transfer if from another location in the hospital; and

12.3.9.l. Transfer/discharge diagnosis and destination;

12.3.10. Admit stroke patients to a unit that can provide appropriate care that considers and reflects nationally recognized, evidence-based protocols or guidelines or transfer stroke patients to an ASRH, PSC, or CSC, or another facility that can provide the appropriate care that considers and reflects nationally recognized, evidence-based protocols or guidelines;

12.3.11. At a minimum, demonstrate compliance with nationally recognized quality indicators; and

12.3.12. Comply with nationally accepted guidelines regarding stoke awareness community education, hospital education and EMS education provided by the hospital regarding stroke treatment.

§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

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~~to meet, the criteria for ASRH designation (See Section 12) and pays an annual fee. 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 the following:~~

~~13.2.1. Hospital name and address;~~

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~~13.2.2. Hospital chief executive officer/administrator typed name and signature;~~

~~13.2.3. Chief medical officer (or designee) typed name and signature;~~

~~13.2.4. Hospital stroke director typed name, clinical credentials and signature; and~~

~~13.2.5. Contact person typed name, e-mail address and phone number.~~

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

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~~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, as follows:~~

~~13.4.1. A copy of the hospital's stroke policies, procedures or protocols related to the provision of emergent stroke care;~~

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~~13.4.2. A copy of the hospital's transfer agreement with one or more hospitals that have board certified or board eligible neurosurgical expertise, and policies, procedures or protocols related to the transfer;~~

~~13.4.3. The hospital stroke director's name, contact information and curriculum vitae or resume to demonstrate that the director is a clinical member of the hospital staff or a clinical designee of the hospital administrator;~~

~~13.4.4. A copy of the hospital's policies, procedures or protocols related to the administration of thrombolytic therapy, or subsequently developed medical therapies that meet nationally recognized evidence-based stroke protocols or guidelines;~~

~~13.4.5. A letter from the stroke director or hospital administrator indicating how the hospital conducts and interprets brain image tests at all times that consider and reflect nationally recognized evidence-based stroke protocols or guidelines;~~

~~13.4.6. Documentation of laboratory accreditation by a nationally recognized accrediting body;~~

~~13.4.7. A sample stroke log or verification of use of a nationally recognized stroke data registry that meets the minimum requirements (See Section 18);~~

~~13.4.8. Each ASRH shall submit a description of its comprehensive ongoing quality improvement plan, including, but not limited to, all of the quality measurements in subsection 13.5. The description shall include the steps an ASRH would use to implement performance improvement processes.~~

~~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 three years.~~

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

~~13.6.1. Results time for door-to-blood coagulation study;~~

~~13.6.2. Completed time for door-to-brain imaging;~~

~~13.6.3. Results time for door-to-brain imaging;~~

~~13.6.4. Time for door-to-thrombolytic therapy, if applicable;~~

~~13.6.5. Time for door-to-transfer from emergency department, if applicable; and~~

~~13.6.6. 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 hospital designated as an ASRH shall pay an annual fee of $250.~~

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

~~14.1. *Emergency Suspension.*~~

~~14.1.1. 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.~~

~~14.1.2. 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.*~~

~~14.2.1. 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.~~

~~14.2.2. 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~~

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Office finds that the hospital is not in substantial compliance with current ASRH criteria as set forth in this rule series.

14.2.3. 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 shall remain valid at all times while the hospital maintains its certification as an ASRH, in good standing, with the certifying body.

15.2. The duration of an ASRH designation shall coincide with the duration of its ASRH certification.

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

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

15.5. 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 a Office-approved certifying body, to send a copy of the certificate to the Office.

16.2. Within 30 business days after the Office's receipt of a hospital's ASRH certificate 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 provide the following:

16.4.1. Hospital name and address;

16.4.2. Hospital chief executive officer/administrator typed name and signature;

16.4.3. Hospital stroke medical director typed name and signature; and

16.4.4. Contact person typed name, e-mail address and phone number.

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 hospital designated as an ASRH shall pay an annual fee of $250.

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

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17.1. The Office 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.

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 may 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. Nothing in this Section shall be construed to empower the Office to specify the form of internal recordkeeping.

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

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

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

18.3.3. 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 shall not be directly available to the public and shall 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 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 stroke assessment tool, the Office shall 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.

July 25, 2017

Brian Skinner, General Council
Bureau of Public Health
350 Capitol Street, Room 702
Charleston, WV 25301

Dear Mr. Skinner,

In response to the public comment period on proposed rule:
Designation of Comprehensive, Primary and Acute Stroke Ready hospitals

My comments to the proposed rule are as follows:

1. 1.5 Proposal to remove the sunset provision. Please define the purpose for sunsetting this rule.
2. 2.2 Add list of certifying bodies: the American Heart Association, The Joint Commission, DNV-GL and HFAP.
3. 2.4 and all sections concerning CSC or Comprehensive Stroke Center: Include "Thrombectomy Capable" as Comprehensive Stroke Center equivalent certification. This is a new certification in development for hospitals providing endovascular treatment 24/7 and will be available within the next one to two years. It is not medically nor financially in the best interest of residents in southern West Virginia to transport to Morgantown, or out of the state when thrombectomy is needed and is available nearby (ie. Huntington).
4. 3.1 Propose two groups, rotating at two years and second group after three years, then two years thereafter.
5. 64.107.11 **Remove this section, "ASRH without national certification".** It is important to the integrity and sustainability of the program for all stroke centers to be reviewed by a national certifying body. National certification gives credibility and validity to the program, which the state does not have qualifications nor resources to fully assess. This is beyond the scope of the legislation.
6. 64.107-20 – add section to give State Stroke Advisory Committee direction to develop and submit evidence based statewide stroke EMS transport protocol as indicated in the legislation.
7. Fee for Stroke Center designation: $3200 biennial fee for CSC and PSC, and $1600 for ASRH is excessive. Please define itemized costs and how the funds will be utilized. Define specifically to hospitals the benefit for paying this fee. Hospitals should request state designation in writing and by presenting certificate of National Certification. No site visits or other review is required as this is being monitored by the certifying body. If a fee is required, it should be minimal.
8. 64-107-18. Data collection and submission. Please define 'data collection system'. Hospitals utilizing an existing data collection system will not have resources to duplicate data collection nor submission. This would put additional burden on participating institutions.

Thank you for your consideration.

Sincerely,

Christy Franklin, RN, MS, CNRN
Director, St. Mary's Regional Neuroscience Center.
cfranklin@st-marys.org
(304)526-1184

From: Davis, Stephen [mailto:SMDavis@hsc.wvu.edu]
Sent: Thursday, July 13, 2017 9:24 AM
To: Raynes, Melissa J <Melissa.J.Raynes@wv.gov>
Subject: RE: Stroke Advisory Meeting

Dear Ms. Raynes:

Please again accept my apologies for not being able to attend tomorrow's important meeting. As requested, I am sending you some brief thoughts regarding the current proposed rule.

With regard to the rule,

1. It appears that this proposed rule is currently nonbinding, as section 1.6 indicates that the rule only applies to those hospitals "desiring" a designation. Is there any discussion of eventually making this role more binding? I believe we had originally discussed a system whereby all hospitals would be classified, and those hospitals not seeking designation would automatically be classified at the lowest level of care. I'm wondering if a similar approach is still being recommended, or if this is just a first step in a longer process.
2. With regard to section 3.5, does this refer to data in the PREMIS system, or will we need to create a new mechanism for capturing these data? Years ago, we had explored creating a mechanism whereby PREMIS data would be merged with Get With The Guidelines (GWTG) data to create a system that captured both the prehospital and in-hospital care of stroke patients. I note that sections 12 3.2, 12.3.9, 13.4.6 requires hospitals seeking acute stroke ready hospital designation to participate in a data collection system. Ideally, it would be desirable if the same system could be used by all hospitals. I know that the AHA had created a pricing tier for smaller hospitals to make participation in GWTG more feasible. Is there any discussion of requiring one system or a standard set of data elements? This would be ideal, and if the group is still interested in pursuing such an endeavor, then perhaps section 64–107–18 could eventually be revised to reflect such a plan. I realize we may not be able to mandate the use of only one system despite the fact that it would be most desirable in the interest of standardization. Just some initial thoughts.

I believe that this is an amazing start, and remain honored to be able to serve on this important council. If you have any additional questions, please kindly contact me at your convenience.

Best,

Steve Davis
Interim Vice-Chair for Research and Scholarship
Director, Clinical Research
Adjunct Professor
Department of Emergency Medicine
WVU School of Medicine

Adjunct Associate Professor
Health Policy, Management, and Leadership
WVU School of Public Health