

Title 64 Series 107

Department of Health and Human Resources

Bureau for Public Health

Designation of Comprehensive, Primary and Acute Stroke-Ready Hospitals.

Summary of Public Comments

COMMENTS AND RESPONSES

The descriptions of public comments below are a paraphrasing of the originally submitted comments. The full text of each public comment has been filed with the Secretary of State's Office.

Section 1 – General

Comment

1.5 Sunset Provision. 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.

Response

The Bureau is bound by the provisions of *W.Va. Code* §29A-3-19(a) which provides that “[a]ny new legislative rule [] shall include a sunset provision terminating the rule after five years” This same section authorizes the rule may be renewed for additional terms of five years or less by the Legislature pursuant to the rule-making procedures. If the Bureau would adopt the proposed recommendation the rule would be inconsistent with *W.Va. Code* §29A-3-19(a), therefore the Bureau declines to modify the rule as recommended.

Comment

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 rule 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.

Response

The proposed rule is intended to implement the provisions of *W.Va. Code* § 16-5B-18(a) which provides that a hospital [. . .] may apply to the Department of Health and Human Resources to be recognized and certified as a comprehensive stroke center, a primary stroke center or an acute stroke-ready hospital. Thus, designation as a comprehensive stroke center, a primary stroke center or an acute stroke-ready hospital is not required. To implement a system as proposed by the commenter would require legislative action.

Section 2 – Definitions

Comment

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.

Response

The proposed rules do not include any certifying bodies. Instead, the advisory committee will make recommendations to the Office of Emergency Medical Services annually as to which certifying bodies are acceptable for designation. (*See* § 3.7).

Comment

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.

Response

The authorizing statute, *W.Va. Code* §16-5B-18 provides that a hospital may apply to the Department to be recognized and certified as a comprehensive stroke center, a primary stroke center or an acute stroke-ready hospital. Until the new certification is approved, the Department will not consider including it to the designations prescribed by law.

Section 3 – State Stroke Advisory Committee**Comment**

3.1 Two tiered terms should suffice.

Response

The Department believes that given the size of the advisory committee and desire to include new and diverse ideas, the method of staggering terms contained in the proposed rules is appropriate.

Comment

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?

Response

The Department believes it is critical to gather relevant data related to the operation of stroke centers in the state. Currently, the OEMS is in the process of developing a process for the collection of relevant data. As indicated in subsection 18.1, 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.”

Section 9 – Request for Primary Stroke Center Designation**Comment**

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?

Response

The designation process requires administrative time and resources. The amount of the fee is intended to off-set the costs incurred by the Department to administer the designation process.

Sections 11 through 14 – Acute Stroke Ready Hospital (ASRH) Designation without National Certification.

Comment

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 through its own system must be removed. Only hospitals that meet national certifying bodies’ criteria and earn said national certification should be recognized with this level of stroke care.

Response

The Bureau has included a mechanism for small rural hospitals without the resources to achieve either a Primary Stroke Center (PSC) designation or Comprehensive Stroke Centers (CSC) designation, to become designated as an Acute Stroke–Ready Hospital (ASRH) without a national certification. Under the provisions of these rules, hospitals seeking an ASRH designation that do not have national certification must develop and utilize policies and procedures that are consistent with nationally recognized, evidence-based protocols for the provision of emergent stroke care. (*See* § 12.1). The criteria for ASRH designation of hospitals must meet current Joint Commission accreditation standards/guidelines. (*See* § 12.3). Consequently, while it is true that hospitals seeking ASRH designation will not need to seek and obtain the costlier national certification, they will be held to the same standards and guidelines required for certification.

Furthermore, the use of a mechanism for the designation of an ASRH without a national certification is not inconsistent with the provisions of the *W.Va. Code* § 16-5B-18(a) which provides that the “appropriate designation shall be granted by the Department of Health and Human Resources *based upon criteria recognized by the American Heart Association, the Joint Commission or other nationally recognized organization as set forth in legislative rules . . .*” (emphasis added). Thus, the authorizing statute does not require a hospital to be nationally certified, instead it requires only that the designation be based on criteria recognized by a nationally recognized accrediting body. The Bureau’s proposed rules provide that the criteria for a designation of an ASRH without a national certification must meet current Joint Commission accreditation standards/guidelines. Consequently, the Bureau will not modify the proposed rules as recommended.

Section 18 - Data collection and Submission

Comment

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?

Response

The Department believes it is critical to gather relevant data related to the operation of stroke centers in the state. Currently, the OEMS is in the process of developing a process for the collection of relevant data. As indicated in subsection 18.1 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.”

Miscellaneous

Comment

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.

Response

The Bureau agrees that the enabling statute mandates that the Secretary of the Department of Health and Human Resources propose rules for legislative approval include protocols for assessment, treatment and transport of stroke patients by licensed emergency medical service agencies. *W.Va. Code* 165B-18(d). The Bureau’s Office of Emergency Medical Services (OEMS) has implemented state-wide protocols and policies for the assessment, treatment, and transport of stroke patients by licensed emergency medical services agencies. These policies are published on the OEMS website and are available to state emergency medical service agencies and emergency medical service personnel. Because the protocols are subject to change as medical technology and best practices evolve, it would not be in the best interests of the public if these time sensitive protocols were codified in legislative rules. Currently, protocols developed by the OEMS’s Medical Director and reviewed by the Medical Policy and Care Committee.

Recognizing that the flexibility necessary in maintaining protocols, the Bureau included within the proposed rules section 21 (Protocols for Assessment, Treatment and Transport of Stroke Patients) that provides that 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. Consequently, the Bureau believes the inclusion of section 21 in these rule is consistent with the mandate contained in *W.Va. Code* § 16-5B-18, while also recognizing the need to quickly modify protocols when medically necessary.