25 August 2023

Department of Health and Human Services - Public Health Administration

Administrative Rules for Statewide Stroke System Rule Set 2023-2 HS

To whom it may concern:

On August 22nd, 2023, the American Heart Association/American Stroke Association shared feedback during the hearing on Rule Set 2023-2 HS in Lansing, MI. As indicated in the testimony, these comments were to be a precursor to our formal, written testimony. Please see our recommended changes below.

The American Heart Association and American Stroke Association strongly believe any successful stroke systems of care program in Michigan should interface with Get with The Guidelines (GWTG)®-Stroke.

R 330.251

- 1(g): "Disciplinary action" should include EMS agencies. "'Disciplinary action' means an action taken by the department against a healthcare facility, EMS agency, or a regional stroke network for failure to comply with the code, rules, or protocols approved by the department.

R 330.253

- (1)(j): For the "Statewide stroke care advisory subcommittee," the Association believes a statement such as, "professional organization with expertise in stroke systems of care, such as the American Heart Association" would be appropriate. Additionally, there should be representation from Level 1- or Level 2-certified and Level 3- or Level 4-certified facilities. Finally, consideration should be given to a stroke nurse coordinator and a GWTG®-Stroke registrar.

R 330.254

- (1)(a): Should remove the phrase "all-inclusive." This could indicate primary prevention through rehabilitation, which would be beyond the scope and capabilities of the Bureau.
- (1)(e): The statement should be modified because Michigan may have its own certification/accreditation based on the definition of "verification" used previously in the rules.
- (1)(l): There is a typo. It should read "stroke" instead of "STEMI" and "stroke" instead of "stoke."
- (2): This section should also reference EMS agencies.
- (4): Should incorporate national standards, such as developing another registry and adopting national certification standards.

For any questions or follow-up, please contact:

Collin McDonough

Michigan Government Relations Director

American Heart Association

Collin.McDonough@heart.org

From: Ryan J. Reece, MD, FACEP
To: MDHHS-AdminRules
Subject: Administrative Rules Public Comment
Date: Friday, July 21, 2023 9:49:34 PM

Good Evening,

I'd like to submit written comments regarding the proposed administrative rules for the STEMI and Stroke systems of care.

I reviewed the draft language of both STEMI and Stroke systems of care. As previously discussed by the State; these systems closely mirror the trauma system. However, I'd like to see 'MCA Medical Director' language used in these rules. They use generic 'physician(s)' for committees that advise the State; they need specificity - vascular neurology for stroke system; interventional cards for STEMI system - MCA MD for both, etc.

As you know, EMS physicians have the experience and knowledge to support these systems of care uniquely from other types of physicians.

Therefore, I recommend using specific language in the administrative rules to include EMS physicians and Medical Control Authority Medical Directors. These such physicians will be necessary to oversee and advise the Department on the systems of care.

If you have any questions or would like to discuss this further, please let me know.

Best regards,

Ryan

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Society of NeuroInterventional Surgery
SNIS

July 24, 2023

Mary Brennan
Interim Director and Regulatory Affairs Officer; Bureau of Legal Affairs
Michigan Department of Health & Human Services

Eileen Worden
Systems of Care Manager; Bureau of EMS, Trauma & Preparedness
Michigan Department of Health & Human Services

Aaron Brown
Coordinator; Bureau of EMS, Trauma & Preparedness
Michigan Department of Health & Human Services

Emily Holstine-Baker
EMS Programs Manager; Bureau of EMS, Trauma & Preparedness
Michigan Department of Health & Human Services

RE: Support for amended rules to Michigan's Statewide Stroke System

On behalf of the Society of NeuroInterventional Surgery (SNIS), we want to thank you for your diligent work and collaborative efforts as well as allowing us to partner with you over the past two years in reviewing and proposing updates to Michigan's statewide EMS protocols, particularly those relating to triaging and transporting stroke patients. We appreciate being part of the process and sharing our perspective based on what we have encountered when treating patients suffering from critical cases of stroke such as those involving an emergent large vessel occlusion (ELVO).

In advance of the August 22nd public hearing on this matter, we are writing in strong support of the proposed amended rules to Michigan's Statewide Stroke System, particularly Rules 12-13 in relation to Destination Protocols (*R325.236*) and Stroke Patient Inter-Facility Transfer Protocols (*R325.237*) to ensure timely transport of critical stroke patients to the most optimal level of care. We believe these proposed amended rules will help prevent death and disability from serious strokes for men and women throughout the state. As you know, these updates also reflect those included in the latest version of the National Model EMS Clinical Guidelines released last year by the National Association of State EMS Officials (NASEMSO).

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Society of NeuroInterventional Surgery
SNIS

To ensure the best outcome for critical stroke patients, they should be triaged and transported to "Level 1" stroke centers as promptly as possible for the lifesaving care they need. More than two dozen other states – including our neighbor Ohio – have updated their protocols for triaging and transporting critical stroke patients.

As physicians who regularly treat stroke patients, we have witnessed the tragic outcomes when patients endure significant delays in appropriate level of care because of multiple transfers between facilities before ultimately reaching the one best-equipped to optimally care for them, including access to the state of the art techniques for rapid mechanical thrombectomy for an ELVO, but by then it is too late – too many brain cells have been lost because of the stroke. To provide patients with the best chance of surviving a critical stroke, we respectfully request your support for the proposed amended rules to update Michigan's Statewide Stroke System, particularly for triaging and transporting stroke patients.

Thank you for your consideration of this important matter, which we believe could save lives and prevent numerous disabilities in the future. We also appreciate the opportunity to have worked with you and other stakeholders on this important initiative to update our statewide EMS protocols throughout the past year.

Sincerely,

Neeraj Chaudhary, MD
University of Michigan Hospitals
Ann Arbor

Joseph Gemmete, MD
University of Michigan Hospitals
Ann Arbor

Aditya Pandey, MD
University of Michigan Hospitals
Ann Arbor

Zach Wilsek, MD
University of Michigan Hospitals
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Max Kole, MD
Henry Ford Hospital
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Horia Marin, MD
Henry Ford Hospital
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July 26, 2023

Mary Brennan
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Michigan Department of Health & Human Services

Eileen Worden
Systems of Care Manager; Bureau of EMS, Trauma & Preparedness
Michigan Department of Health & Human Services

Aaron Brown
Coordinator; Bureau of EMS, Trauma & Preparedness
Michigan Department of Health & Human Services

Emily Holstine-Baker
EMS Programs Manager; Bureau of EMS, Trauma & Preparedness
Michigan Department of Health & Human Services

RE: Support for amended rules to Michigan's Statewide Stroke System

Thank you for the hard work and effort you have dedicated to updating Michigan's EMS protocols. In advance of the public hearing, I am pleased to share my support for the proposed amended rules to Michigan's Statewide Stroke System, particularly Rules 12-13 in relation to Destination Protocols (*R325.236*) and Stroke Patient Inter-Facility Transfer Protocols (*R325.237*) to ensure timely transport of critical stroke patients.

For almost 20 years, I have provided emergency and non-emergency pre-hospital care to sick and injured patients in the community as a paramedic and firefighter. I also served as System Manager of the Oakland County Medical Control Authority (OCMCA) until the beginning of this year. In my capacity with the OCMCA, I helped lead the effort to review and update the county's EMS protocols for adult and pediatric medical emergencies, including stroke. Working with a variety of dedicated medical and health care professionals, we worked to ensure Oakland County's protocols aligned with the latest advancements in medicine and technology while improving timely access to care for the patients we served in the community.

I was proud to be part of the collaborative effort to improve OCMCA's protocols and I've been pleased to see the broader, national effort to update emergency triage and transport protocols, including for stroke. Last year, the National Association of State EMS Officials (NASEMSO) released the updated version of the National Model EMS Clinical Guidelines while states such as Ohio proactively updated their statewide EMS protocols.

Michigan is on the right track with the proposed amended rules to update the statewide stroke system. I encourage you to please support these amended rules, which I believe will help save lives. Thank you for your consideration.

Sincerely,

Geoff Lassers, AAS, Paramedic I/C
Lassers126@gmail.com
248-459-9052

HENRY FORD HEALTH

July 31, 2023

Ms. Mary Brennan
Interim Director and Regulatory Affairs Officer
Bureau of Legal Affairs

Ms. Eileen Worden
State Trauma Manager
Michigan Department of Health and Human Services

Re: Proposed Changes to the Statewide ST-Elevation Myocardial Infarction (STEMI) System (Rule Set 2022-61 HS)) and Statewide Stroke System (Rule Set 2023-2 HS))

Submitted via electronic mail to: *MDHHS-Adminrules@michigan.gov*

Dear Ms. Brennan and Ms. Worden:

On behalf of Henry Ford Health, I want to thank you for the opportunity to comment on the proposed changes for "Statewide ST-Elevation Myocardial Infarction (STEMI) System" (Rule Set 2022-61 HS) and "Statewide Stroke System" (Rule Set 2023-2 HS).

Henry Ford Health is a Michigan-based, not-for-profit corporation and one of the nation's largest integrated health care systems. Headquartered in Detroit, we have been committed to improving the health and wellbeing of the community for over 100 years. Henry Ford Health offers healthcare services across the continuum through a diverse network of facilities in Southeast Michigan (Metro Detroit) and South Central Michigan (Jackson). The system has over 33,000 employees and five acute care hospitals, including our flagship Henry Ford Hospital, a large academic safety net hospital located within the city of Detroit. The system also includes the Henry Ford Medical Group (HFMG), with 1,900 physicians and researchers in more than 40 specialties.

All the Henry Ford Health hospital locations have some level of certification by The Joint Commission to care for stroke patients and are equipped to care for heart attack patients. In 2021, Henry Ford Hospital earned recertification as a Comprehensive Stroke Center, which means that the hospital can provide the most advanced stroke care in the most expeditious manner possible. Staffed by a stroke interdisciplinary team and the Ford Acute Stroke Treatment (FAST) team, stroke suspected patients are rapidly evaluated in the Emergency Department and will receive a determination in minutes if they require medical, advanced surgical or catheter-based treatments. The flagship hospital is a Level 1 Trauma Center recognized for clinical excellence in cardiology and cardiovascular surgery, neurology and neurosurgery, orthopedics, sports medicine, multi-organ transplants, and cancer treatment.

Henry Ford Jackson Hospital also earned recertification by The Joint Commission as a Primary Stroke Center, demonstrating continuous compliance with performance standards and commitment to providing clinical programs across the continuum of care for stroke. Henry Ford Macomb Hospital and Henry Ford Wyandotte Hospital are also certified as Primary Stroke Centers. Henry Ford Health – Brownstone Emergency Department is certified as an Acute Stroke Ready Center and Henry Ford West Bloomfield is certified as a Thrombectomy-Capable Stroke Center.

Henry Ford Health strongly supports a Statewide System of Care for Stroke and STEMI patients. Getting patients with suspected stroke or STEMI symptoms to the right place in a time sensitive manner is the most

critical factor for improving survival and reducing risk of long-term disability. The proposed rules would build the infrastructure to implement this system of early intervention and lead to better outcomes to Michigan citizens who experience stroke or STEMI incidences. We do, however, want to highlight some minor concerns and areas of needed clarification to ensure that the system of care is implemented in the most efficient and effective way possible.

Reasonable Distance Definition

With regards to the stroke proposed rule, under R 330.261 – Destination Protocols, LARA proposes that stroke patients must be transported to the closest appropriate center as identified in regional and local Medical Control Authority (MCA) protocols. If the stroke receiving center is not within a *reasonable distance* from the incident scene, the patient must be transported to a level IV stroke center. Henry Ford Health requests clarification on the definition of "reasonable distance." We have concerns that the vagueness of this term could result in medical authorities choosing to go to a level I, II, or III center that are farther away as opposed to a level IV center, when treatment for patients who are candidates is time critical. Level IV centers are required by all certifying bodies to be equipped with 24/7 thrombolytic services and should not be routinely bypassed in lieu of a higher-level center unless the specific distance is clarified.

If the MCAs and stroke regions are to determine this definition when developing patient destination protocols, this should be a consideration when determining what works best for patients in their region based on the resources available to them and the geographical distribution of their stroke centers.

General Comments

Henry Ford Health also recommends a more consistent use of the terms "council", "committee", and "subcommittee" throughout the rules for uniformity and to remove any confusion.

In both rules, there does not appear to be a Rule 4. We request clarification whether this is due to a missing section or simply a numbering error.

In the stroke rule, under section R 330.254. Rule 5 (1)(l), the wording should be "establishment of the regional *stroke* system..." instead of the currently written "STEMI" system. This will remove confusion going forward.

Thank you again for the opportunity to comment on these proposed rules.

Sincerely,

Alex Bou Chebl, MD, FSVIN
Director, Harris Comprehensive Stroke Center
Director, Division Vascular Neurology
Chair, System Stroke Council
Henry Ford Health

Ascension

August 25, 2023

Ms. Mary Brennan
Interim Director and Regulatory Affairs Officer
Bureau of Legal Affairs

Ms. Eileen Worden
State Trauma Manager
Michigan Department of Health and Human Services

Submitted Electronically via: MDHHS-adminrules@michigan.gov

RE: Pending Administrative Rule: 2023-2 HS: Statewide Stroke System

Dear Ms. Brennan and Ms. Worden:

On behalf of Ascension Michigan please accept this as our response to the pending Administrative Rule: 2023-2 HS, Statewide Stroke System, as proposed by the Michigan Department of Health and Human Services.

Ascension Michigan operates 16 hospitals and employs more that 21,000 associates across the state of Michigan. As one of the leading non-profit and Catholic health systems in the country, Ascension is committed to delivering compassionate, personalized care to all, with special attention to persons living in poverty and those most vulnerable.

At Ascension Michigan, we have a state-wide network of stroke care. Our ERs, Primary Stroke Centers and Comprehensive Stroke Centers deliver advanced stroke care for even the most complex cases. This highly specialized stroke care helps support better outcomes at a time when you need it most. Our neurologists, neurosurgeons, neuroradiologists, neuro-intensivists, neurointerventional surgeons and rehabilitation specialists work together to deliver personalized, multi-specialty care at Ascension Michigan sites of care.

Neurologists at Ascension Michigan are dedicated to delivering advanced stroke care to those across the state. Through our telestroke program, neurologists provide virtual consultations as part of our network of stroke care. Using high-definition cameras, neurologists at multiple locations can work together to provide remote examinations, recommend diagnostic tests and

discuss treatment decisions with you and your care team. The benefits of participating in the Ascension Michigan Telestroke Program is the ability of hospitals to tap into the Ascension network of physician expertise which has proven to contribute to the overall achievement of excellent patient outcomes.

We appreciate the department's thorough review of the Statewide Stroke System and their commitment to ensuring the best outcomes possible for patients. We have the following comments to share for your consideration.

330.253 Rule 3 (g) consider defining the RSAC or the regional stroke advisory council, with less ambiguity –
Physician: Stroke Program Medical Director at Level 1 or 2 Stroke Center or Stroke or vascular neurologist or Critical care neurologist or Neuroendovascular surgeon
Nurse: Stroke Program Coordinator or Advance Practice Nurse with expertise in stroke

330.253 Rule 3 (j) consider defining the Statewide stroke care advisory committee to include the following subject matter experts:
Physician: Stroke Program Medical Director at Level 1 or 2 Stroke Center or Stroke or vascular neurologist or Critical care neurologist or Neuroendovascular surgeon
Nurse: Stroke Program Coordinator or Advance Practice Nurse with expertise in stroke

Ascension Michigan supports 330.261 Rule 12, Destination Protocols and 330.262 Rule 13, Stroke Patient Inter-Facility Transfer Protocols: Amend to ensure timely transport of critical stroke patients to the most optimal level of care.

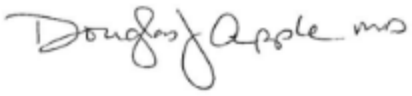
To ensure the best outcome for critical stroke patients, such as those involving an emergent large vessel occlusion (ELVO), ELVO patients should be triaged and transported to "Level 1" stroke centers as promptly as possible for the lifesaving care they need. We have witnessed the tragic outcomes when patients endure significant delays in appropriate level of care because of multiple transfers between facilities before ultimately reaching the one best-equipped to optimally care for them, including access to the state of the art techniques for rapid mechanical thrombectomy for an ELVO, but by then it is too late – too many brain cells have been lost because of the stroke. To provide patients with the best chance of surviving a critical stroke, we respectfully request your support for the proposed amended rules to update Michigan's Statewide Stroke System, particularly for triaging and transporting stroke patients.

We believe these proposed amended rules will help prevent death and disability from serious strokes for all Michiganders, while simultaneously working to improve the resource disparities in all of the regions throughout Michigan.

Thank you for your time and review of our comments. We look forward to our continued

collaboration and partnership. Should you have any further questions or concerns, please contact me at (586) 753-1120 or douglas.apple@ascension.org.

Sincerely,



Douglas J. Apple, MD, MS, FHM
Chief Clinical Officer, Ascension Michigan

PUBLIC COMMENT: 2023-02 HS Statewide Stroke System

NAME/ORGANIZATION OF COMMENTOR	COMMENT MADE (PUBLIC OR WRITTEN)	RULE NUMBER	COMMENT	DHHS RESPONSE
Dr. Alex Chebl-Director of the Harris Complex Stroke at Henry Ford Health, and the Director of the Stroke and Vascular Neurology Division at Henry Ford Hospital, and member of the American Heart Association and American Stroke Association.	Public Hearing	R 330.251(n)	MDHHS to ensure data can be exported to the state database and allow exportation of state data to get with the guideline stroke.	The details related to data exchange will be developed in depth in policy after the administrative rules are adopted. The trauma system has policy and process in place. This will inform the development of data use agreements, and import/export processes for the Michigan Stroke Registry. The department intends to provide a direct entry model at no cost to hospital partners.
	Public Hearing	R 330.251	The Associations recommend changes to the definitions of **accreditation** and certification as the designation is used for the powers and duties of the Department. The language for accreditation and certification and verification could cause confusion.	DHHS opposes this recommendation. It appears that the commentor may have inadvertently used a previous draft of the rule set. There is no definition of accreditation. The definition of accreditation was removed because it is not used in the body of the document. Stroke programs receive certification from national professional review organizations.
	Public Hearing	R 330.251(c)	The Associations recommend changes to the definitions of accreditation and **certification** as the designation is used for the powers and duties of the Department. The language for accreditation and certification and verification could cause confusion.	DHHS opposes this recommendation.The department is charged with integration of the Stroke System of Care into the existing Trauma System. The definition of certification was agreed upon by the administrative rules work group made up of stakeholders and professional subject matter experts across the state of Michigan. Integration requires consistency across the service lines. Certification provides verification of resources that the departments uses to designate facilities based upon the level that the hospital is certified as.
	Public Hearing	R 330.251(g)	For the definition of disciplinary action, we suggest including EMS agencies, as they may also fail to comply with the Code.	DHHS opposes this suggestion. EMS regulations are addressed in the EMS rule set. Disciplinary action for EMS agencies is fully described in Mich Admin Code R 325.22126.
	Public Hearing	R 330.253(g)	The **regional stroke advisory council** and the statewide stroke care advisory subcommittee both pose ambiguity around their membership. For instance, is the American Heart Association considered a consumer under the regional stroke advisory council? For both the council and the subcommittee we recommend the definition include, inclusive of expertise in the specific field such as professional organization, with expertise in stroke systems of care.	The Regional Advisory Council membership is modeled on Mich Admin Code R 325.127. Rule 3(h) which supports the intended system integration by including broad stakeholder titles: MCA personnel, emergency medical services (EMS) personnel, life support agency representatives, health care facility representatives, physician, nurses and consumers to avoid being over prescriptive and inadvertently exclusive of an important partner/stakeholder. Policy will further refine roles with stakeholder input as described in *A Statewide System of Care for Time Sensitive Emergencies: The Integration of Stroke and STEMI Care into the Regional Trauma System* . A Consumer will be a Michigan resident who has experience with the system who can provide perspective and input on system impacts and how to improve. A national organization would not be considered a consumer. It is expected that the content experts on the advisory council and committee are members of and/or participate with national organizations and can reflect the current position of these bodies as it relates to the state.
	Public Hearing	R 330.253(j)	The regional stroke advisory council and the **statewide stroke care advisory subcommittee** both pose ambiguity around their membership. For instance, is the American Heart Association considered a consumer under the regional stroke advisory council? For both the council and the subcommittee we recommend the definition include, inclusive of expertise in the specific field such as professional organization, with expertise in stroke systems of care.	The Regional Advisory Council membership is modeled on Mich Admin Code R 325.127. Rule 3(h) which supports the intended system integration by including broad stakeholder titles: MCA personnel, emergency medical services (EMS) personnel, life support agency representatives, health care facility representatives, physician, nurses and consumers to avoid being over prescriptive and inadvertently exclusive of an important partner/stakeholder. Policy will further refine roles with stakeholder input as described in *A Statewide System of Care for Time Sensitive Emergencies: The Integraration of Stroke and STEMI Care into the Regional Trauma System* . A Consumer will be a Michigan resident who has experience with the system who can provide perspective and input on system impacts and how to improve. A national organization would not be considered a consumer. It is expected that the content experts on the advisory council and committee are members of and/or participate with national organizations and can reflect the current position of these bodies as it relates to the state.
	Public Hearing	R 330.253(q)	The State trauma committee has representation from Level 1 and 2 trauma hospitals certified by the American College of Surgery. At a minimum, we suggest a Level 1 CSC, or Level 2 TSC certified, and Level 3 PSC or Level 4 ASR. CSC IS comprehensive stroke center, TSC is thrombectomy stroke center, PSC is primary stroke center, and ASR is acute stroke ready. And, let's see, Level 4, administrative representation should be allowable.	This is correct and a similar model will be followed for the Stroke advisory committee, with an application process (link) and considerations for representation from urban, rural, regional geography and capability. All of which will be outlined in policy which allows for a slight amount of flexibility to ensure the system is represented accurately and effectively and which allows for some latitude for clinicians who may not be able make a commitment to serve, for effective group dynamics, preserving institutional memory and to effect system building. Titles that are too descriptive/prescriptive limit the pool of candidates, positions go unfilled and the important advising function of the committee is compromised.

	Public Hearing		Consideration should be given about a stroke nurse coordinator and get with the guidelines registrar, similar to the trauma committee.	DHHS agrees with this comment and this will be addressed in policy.
	Public Hearing	R 330.254(1)(a)	Under R 330.254(1)(a), the American Heart Association recommends the removal of the phrase “all-inclusive”.	DHHS opposes this recommendation. Voluntary all-inclusive systems are the foundational model of the existing trauma system as well as the developing stroke system. The sentinel paper regarding stroke systems of care, Schwam et al (2005) explain," A stroke system should coordinate and promote patient access to the full range of activities and services associated with stroke prevention, treatment, and rehabilitation...). Systems function best if all components participate to the best of their available resources. The system is inclusive and voluntary.
	Public Hearing	R 330.254(1)(e)	In Section 1(e), AHA recommends the statement be modified because Michigan may have its own certification accredited or /accreditation based on the definition of verification used previously.	DHHS opposes this recommendation. Stroke center certification provides verification that the hospital has the resources to provide stroke care at that level.
	Public Hearing	R 330.254(1)(i) (See DH	Section 1(i) states “to develop a statewide process for a statewide stroke center.” This is similar to trauma but could create an issue(s).	DHHS does not belief this will create an issue(s). This is displayed as Mich Admin Code R 330.254(1)(f) in the current rules. The verification process reflects application submission after certification of level of care by a nationally recognized professional stroke center certification organization, review, and development of Michigan specific criteria around data submission, risk reduction activities and regional performance improvement work.
	Public Hearing	R 330.254(1)(n) (See DHHS response)	In Section (1)(n), there is a typo. It should likely read “the establishment of the regional stroke system does limit , does not limit the transfer or transport stroke patients between in regions of the State.	This is actually displayed as Mich Admin Code R 330.254(1)(l) This will be corrected in the final rules.
	Public Hearing	R 330.254(2)	In Section 2, we recommend including the inclusion of EMS.	DHHS opposes this recommendation. Within the Bureau of Emergency Preparedness, EMS and Systems of Care Section, the EMS Section has the statutory responsibility for EMS compliance.
	Public Hearing	R 330.254(4)	For Section 4, AHA believe some of the activities suggested are not an efficient, cost-effective, and do not incorporate national standards like developing another registry and not adopting national certification standards. The state is already funded through Coverdell (Grant). And we believe this is a duplication of efforts.	DHHS disagrees with this statement. Section 4 states….. the department shall consider all the following factors: (a) Efficient implementation and operation (b) decrease in morbidity and mortality (c) cost effective implementation (d) incorporation of national standards (c) availability of money for implementation. Many states in the US implemented Systems because they are designed to make the best use of available resources and get the right patient to the right resource at the right time. Trauma has demonstrated that efficient systems decrease deaths. Data collection is an essential component of system evaluation, monitoring quality of care and drives change. Coverdell is a CDC supported competitive grant awarded to a small number of states, funding is not guaranteed from grant cycle to grant cycle and the work required is determined by the funder. The department does recognize existing national stroke center certification such as TJC, ACHC and DNV. Hospital have the option to continue to participate in GWTG or Coverdell.
	Public Hearing	No specific rule.	To effectively effectuate a stroke system of care program in Michigan, it is necessary to interface with Get with the Guidelines-Stroke.	A common set of data elements and corresponding data dictionary that interfaces with all three systems and EMS patient care records and allows for file transfer to other databases is outlined in *A Statewide System of Care for Time Sensitive Emergencies The Integration of Stroke and STEMI Care into the Regional Trauma System* (pg16) and included in the current Request for Proposal for a contract with a company who can provide this.
Colin McDonough, Michigan Government Relations Director American Heart Association	Written	R 330.251(g)	1(g): “Disciplinary action” should include EMS agencies. “’Disciplinary action’ means an action taken by the department against a healthcare facility, EMS agency, or a regional stroke network for failure to comply with the code, rules, or protocols approved by the department.	DHHS opposes this suggestion. EMS regulations are addressed in the EMS rule set. Disciplinary action for EMS agencies is fully described in Mich Admin Code R 325.22126.
	Written	R 330.253(1)(j)	(1)(j): For the “Statewide stroke care advisory subcommittee,” the Association believes a statement such as, “professional organization with expertise in stroke systems of care, such as the American Heart Association” would be appropriate. Additionally, there should be representation from Level 1- or Level 2-certified and Level 3- or Level 4-certified facilities. Finally, consideration should be given to a stroke nurse coordinator and a GWTG®-Stroke registrar.	DHHS opposes part of this comment. The Regional Advisory Council membership is modeled on Mich Admin Code R 325.127. Rule 3(h) which supports the intended system integration by including broad stakeholder titles: MCA personnel, emergency medical services (EMS) personnel, life support agency representatives, health care facility representatives, physician, nurses and consumers to avoid being over prescriptive and inadvertently exclusive of an important partner/stakeholder. Policy will further refine roles with stakeholder input as described in *A Statewide System of Care for Time Sensitive Emergencies: The Integraration of Stroke and STEMI Care into the Regional Trauma System* . It is expected that the content experts on the advisory council and committee are members of and/or participate with national organizations and can reflect the current position of these bodies as it relates to the state. DHHS agrees with the comment regarding the stroke nurse and Get with the Guidelines comment. The stroke nurse will be addressed in policy and the GWTG issue will be addressed in the contract specifications.

	Written	R 330.254(1)(a)	(1)(a): Should remove the phrase “all-inclusive.” This could indicate primary prevention through rehabilitation, which would be beyond the scope and capabilities of the Bureau.	DHHS opposes this recommendation. Voluntary all-inclusive systems are the foundational model of the existing trauma system as well as the developing stroke system. The sentinel paper regarding stroke systems of care, Schwam *et al.* (2005) explain," A stroke system should coordinate and promote patient access to the full range of activities and services associated with stroke prevention, treatment, and rehabilitation...). Systems function best if all components participate to the best of their available resources. The system is inclusive and voluntary.
	Written	R 330.254(1)(e)	(1)(e): The statement should be modified because Michigan may have its own certification/accreditation based on the definition of “verification” used previously in the rules.	DHHS opposes this recommendation. Stroke center certification provides verification that the hospital has the resources to provide stroke care at that level.
	Written	R 330.254(1)(l)	(1)(l): There is a typo. It should read “stroke” instead of “STEMI” and “stroke” instead of “stoke.”	This will be corrected in the final rules.
	Written	R 330.254(2)	(2): This section should also reference EMS agencies.	DHHS opposes this suggestion. EMS regulations are addressed in the EMS rule set. Disciplinary action for EMS agencies is fully described in Mich Admin Code R 325.22126.
	Written	R 330.254(4)	(4): Should incorporate national standards, such as developing another registry and adopting national certification standards.	This is addressed in other sections of the rule set. (d) Incorporation of national standards.
Douglas J. Apple, MD, MS, FHM-Chief Clinical Officer, Ascension, Michigan	Written	R 330.253(g)	330.253 Rule 3 (g) consider defining the RSAC or the regional stroke advisory council, with less ambiguity- Physician: Stroke Program Medical Director at Level 1 or 2 Stroke Center or Stroke or vascular neurologist or Critical care neurologist or Neuroendovascular surgeon Nurse: Stroke Program Coordinator or Advance Practice Nurse with expertise in stroke -	DHHS opposes this comment. The Regional Advisory Council membership is modeled on Mich Admin Code R 325.127. Rule 3(h) which supports the intended system integration by including broad stakeholder titles: MCA personnel, emergency medical services (EMS) personnel, life support agency representatives, health care facility representatives, physician, nurses and consumers to avoid being over prescriptive and inadvertently exclusive of an important partner/stakeholder. Policy will further refine roles with stakeholder input as described in *A Statewide System of Care for Time Sensitive Emergencies: The Integration of Stroke and STEMI Care into the Regional Trauma System* . A national organization would not be considered a consumer. It is expected that the content experts on the advisory council and committee are members of and/or participate with national organizations and can reflect the current position of these bodies as it relates to the state.
	Written	R 330.253(j)	330.253 Rule 3 (j) consider defining the Statewide stroke care advisory committee to include the following subject matter experts: Physician: Stroke Program Medical Director at Level 1 or 2 Stroke Center or Stroke or vascular neurologist or Critical care neurologist or Neuroendovascular surgeon Nurse: Stroke Program Coordinator or Advance Practice Nurse with expertise in stroke	DHHS opposes this comment. The Regional Advisory Council membership is modeled on Mich Admin Code R 325.127. Rule 3(h) which supports the intended system integration by including broad stakeholder titles: MCA personnel, emergency medical services (EMS) personnel, life support agency representatives, health care facility representatives, physician, nurses and consumers to avoid being over prescriptive and inadvertently exclusive of an important partner/stakeholder. Policy will further refine roles with stakeholder input as described in *A Statewide System of Care for Time Sensitive Emergencies: The Integration of Stroke and STEMI Care into the Regional Trauma System.* It is expected that the content experts on the advisory council and committee are members of and/or participate with national organizations and can reflect the current position of these bodies as it relates to the state.
	Written	R 330.261	Ascension Michigan supports 330.261 Rule 12, Destination Protocols and	No comment needed.
	Written	R 330.262	330.262 Rule 13, Stroke Patient Inter-Facility Transfer Protocols: Amend to ensure timely transport of critical stroke patients to the most optimal level of care.	DHHS opposes this comment. Interfacility transfers are protocol driven, systems enhance effective transfers by categorizing resources, publishing transfer guidelines, organizing opportunities to review and effect change for transfer challenges, building organizational support.

Alex Bou Chebl, MD, FSVIN Director, Harris Comprehensive Stroke Center Director, Division Vascular Neurology Chair, System Stroke Council Henry Ford Health Diane Valade, Henry Ford Health, Health Policy	Written	R 330.261	Under R 330.261- Destination Protocols, LARA proposes that stroke patients must be transported to the closest appropriate center as identified in regional and local Medical Control Authority (MCA) protocols. If the stroke receiving center is not within a reasonable distance from the incident scene, the patient must be transported to a level IV stroke center. Henry Ford Health requests clarification on the definition of "reasonable distance." We have concerns that the vagueness of this term could result in medical authorities choosing to go to a level I, II, or Ill center that are farther away as opposed to a level IV center, when treatment for patients who are candidates is time critical. Level IV	DHHS opposes this comment. EMS providers are charged with determining (based on protocol, judgement and if needed guidance from the MCA) the closest appropriate facility. In each Regional Professional Standards Review Organization MCA staff, regional stroke content experts, ED physicians, will consider as part of system review, cases where closest appropriate may not have been the facility chosen and if there were other options not chosen and why. The EMSCC Quality Assurance Task Force oversees all EMS protocol changes and adoption.
	Written	General comment	Henry Ford Health also recommends a more consistent use of the terms "council", "committee", and subcommittee throughout.	DHHS opposes this recommendation. Integration requires consistent use of terms and definitions. The terms and their use were taken directly from the established Trauma System rules, and were agreed upon by the stakeholders and professional subject matter experts that drafted this rule set.
	Written	General comment	In both rules, there does not appear to be a Rule 4. We request clarification whether this is due to a missing section or simply a numbering error.	This will be corrected in the final rules.
	Written	R 330.254	In the stroke rule, under section R 330.254. Rule 5 (1)(1), the wording should be "establishment of the regional stroke system ... " instead of the currently written "STEMI" system. This will remove confusion going forward.	This will be corrected in the final rules.
Geoff Lassers, AAS, Paramedic I/C	Written	General comment	Thank you for the hard work and effort you have dedicated to updating Michigan's EMS protocols. In advance of the public hearing, I am pleased to share my support for the proposed amended rules to Michigan's Statewide Stroke System, particularly Rules 12-13 in relation to Destination Protocols (R325.236) and Stroke Patient Inter-Facility Transfer Protocols (R325.237) to ensure timely transport of critical stroke patients.	No comment needed.
Neeraj Chaudhary, MD University of Michigan Hospitals Ann Arbor Aditya Pandey, MD University of Michigan Hospitals Ann Arbor Max Kole, MD Henry Ford Hospital Detroit Justin Singer, MD Corewell Health Butterworth Hospital Grand Rapids Julius Griauzde, MD Ascension Providence Novi Joseph Gemmete, MD University of Michigan Hospitals Ann Arbor Zach Wilsek, MD University of Michigan Hospitals Ann Arbor Horia Marin, MD Henry Ford Hospital Detroit Paul Mazaris, MD Corewell Health Butterworth Hospital Grand Rapids Chris Kazmierczak, MD Corewell Health East	Written	General comment	As physicians who regularly treat stroke patients, we have witnessed the tragic outcomes when patients endure significant delays in appropriate level of care because of multiple transfers between facilities before ultimately reaching the one best-equipped to optimally care for them, including access to the state of the art techniques for rapid mechanical thrombectomy for an ELVO, but by then it is too late – too many brain cells have been lost because of the stroke. To provide patients with the best chance of surviving a critical stroke, we respectfully request your support for the proposed amended rules to update Michigan's Statewide Stroke System, particularly for triaging and transporting	No comment needed.

Ryan J Reece, MD, FACEP	Written	General comment	I reviewed the draft language of both STEMI and Stroke systems of care. As previously discussed by the State; these systems closely mirror the trauma system. However, I'd like to see 'MCA Medical Director' language used in these rules. They use generic 'physician(s)' for committees that advise the State; they need specificity - vascular neurology for stroke system; interventional cards for STEMI system - MCA MD for both, etc. As you know, EMS physicians have the experience and knowledge to support these systems of care uniquely from other types of physicians. Therefore, I recommend using specific language in the administrative rules to include EMS physicians and Medical Control Authority	DHHS opposes this comment.The Regional Advisory Council membership is modeled on Mich Admin Code R 325.127. Rule 3(h) which supports the intended system integration by including broad stakeholder titles: MCA personnel, emergency medical services (EMS) personnel, life support agency representatives, health care facility representatives, physician, nurses and consumers to avoid being over prescriptive and inadvertently exclusive of an important partner/stakeholder. Policy will further refine roles with stakeholder input as described in *A Statewide System of Care for Time Sensitive Emergencies: The Integration of Stroke and STEMI Care into the Regional Trauma System* . It is expected that the content experts on the advisory council and committee are members of and/or participate with national organizations and can reflect the current position of these bodies as it relates to the state.