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REGULATORY IMPACT STATEMENT and COST-BENEFIT ANALYSIS (RIS)

Agency Information:
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Rule Set Information:
ARD assigned rule set number:
2023-2 HS
Title of proposed rule set:
Statewide Stroke System

Comparison of Rule(s) to Federal/State/Association Standard

1. Compare the proposed rules to parallel federal rules or standards set by a state or national licensing agency or accreditation association, if any exist.

There are no parallel federal rules or standards. The rules parallel the evidenced based standards developed in collaboration with many state content experts and published in a White Paper titled A Statewide System of Care for Time Sensitive Emergencies, The Integration of Stroke and STEMI Care into the Regional Trauma System. The rules reflect national standards published by the American Heart Association, American Stroke Association, and the respective certifying and accrediting bodies.

A. Are these rules required by state law or federal mandate?

The rules are not required by federal law. Regarding state law, 2022 PA 166, http://www.legislature.mi.gov/documents/2021-2022/publicact/pdf/2022-PA-0166.pdf. provides the following information regarding the 2022-23 budget: Sec. 1186. (1) From the funds appropriated in part 1 for emergency medical services program, the department
shall allocate $3,000,000.00 for a statewide stroke and STEMI system of care for time-sensitive emergencies. This system must be integrated into the statewide trauma care system within the emergency medical services system and must include at least all of the following:
(a) The designation of facilities as stroke and STEMI facilities based on a verification that national certification or accreditation standards have been met.
(b) A requirement that a hospital is not required to be designated as providing certain levels of care for stroke or STEMI.
(c) The development and utilization of stroke and STEMI registries that utilize nationally recognized data platforms with confidentiality standards.

B. If these rules exceed a federal standard, please identify the federal standard or citation, describe why it is necessary that the proposed rules exceed the federal standard or law, and specify the costs and benefits arising out of the deviation.

The proposed rules do not exceed any federal standards.

2. Compare the proposed rules to standards in similarly situated states, based on geographic location, topography, natural resources, commonalities, or economic similarities.

As of 2018, 39 states have addressed one or more aspects of the prehospital or in hospital stroke care law. On average, states with at least one Stroke Systems of Care policy in effect demonstrated better performance or outcomes. While the research is less robust on the impact on STEMI systems of care, the principles are similar. These rules are similar to the rules of Minnesota, Illinois, and other states (such as Louisiana) that have adopted the standards set forth by the Joint Commission and other nationally recognized certifying and accrediting bodies for the verification of hospital resources to provide care to those experiencing symptoms of stroke and ST Elevation Myocardial Infarction (STEMI). This rule provides that every hospital may become a stroke or STEMI facility at the level appropriate to the local community and the resources of the hospital. The rules do not require that a hospital become a stroke/STEMI facility but do require that local medical control authorities promulgate protocols to ensure that patients experiencing a time sensitive emergency, such as a stroke or ST elevation myocardial infarction, are taken to an appropriate stroke/STEMI hospital whenever possible. The rules establish a regionalized, coordinated, and accountable stroke/STEMI system that makes the most efficient use of resources, establishes regional performance improvement plans to enhance patient care outcomes, develops population-based risk reduction, and supports data driven decision making.

A. If the rules exceed standards in those states, please explain why and specify the costs and benefits arising out of the deviation.

These rules do not exceed the standards in the states identified.

3. Identify any laws, rules, and other legal requirements that may duplicate, overlap, or conflict with the proposed rules.

These rules do not duplicate, overlap, or conflict with any existing rules, laws, or legal requirements.

A. Explain how the rules have been coordinated, to the extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter. This section should include a discussion of the efforts undertaken by the agency to avoid or minimize duplication.

This rule set was thoroughly reviewed by the Bureau, the Statewide Trauma Advisory Subcommittee, and the Emergency Medical Service Coordination Committee, and has been revised to reduce overlap with the existing "Emergency Medical Services – Life Support Agency & Medical Control" as well as "Trauma System" rules. Unnecessary duplicative language has been removed from these rules and every effort has been made to focus on operationalization through integration into the existing statewide trauma care system. The same process was applied to the drafting of the trauma administrative rules and their revision in 2017.

4. If MCL 24.232(8) applies and the proposed rules are more stringent than the applicable federally mandated standard, provide a statement of specific facts that establish the clear and convincing need to adopt the more stringent rules.

There are no federally mandated standards.

5. If MCL 24.232(9) applies and the proposed rules are more stringent than the applicable federal standard, provide either the Michigan statute that specifically authorizes the more stringent rules OR a statement of the specific facts that establish the clear and convincing need to adopt the more stringent rules.

There are no applicable federal standards.

Purpose and Objectives of the Rule(s)

6. Identify the behavior and frequency of behavior that the proposed rules are designed to alter.

In Michigan, age-adjusted mortality rates for stroke and STEMI remain well above the national average. Data from Michigan Vital Records show that age-adjusted mortality rates for stroke based on sex and race are increasing, especially among black residents. The same is true for STEMI. According to the 2022 AHA Statistical Update, the estimated direct medical cost of stroke is around $33.4 billion annually. When combined with other cardiovascular disease, including STEMI, the national average direct cost is over $220 billion. The overall goal of the rules for the statewide systems of care for stroke and STEMI is to increase awareness about early intervention and risk reduction, as well as to improve health outcomes for those who experience stroke or STEMI.

A. Estimate the change in the frequency of the targeted behavior expected from the proposed rules.

These rules are set forth to integrate and operationalize an inclusive, regionalized, coordinated, and accountable Stroke/STEMI system into the existing statewide trauma system that will include all agencies and hospitals with the capability to care for a person experiencing a time sensitive emergency such as a stroke or ST Elevation Myocardial Infarction.

B. Describe the difference between current behavior/practice and desired behavior/practice.

The overall goal of the statewide systems of care for stroke and STEMI is to increase awareness about early intervention and risk reduction, as well as to improve health outcomes for those who experience stroke or STEMI. These rules are designed to integrate into the existing trauma system administrative rules that create synergy and efficiencies in care for time dependent emergencies. The statewide stroke/STEMI system is responsible for initiatives ranging from risk reduction, stroke/STEMI response and transport, in-hospital stroke/STEMI care, and rehabilitation. The goal is to reduce incidence of stroke/STEMI, ensure that every person experiencing a time sensitive emergency such as stroke or ST elevation myocardial infarction is taken to the most appropriate level of hospital in the most timely manner possible, thus reducing multiple interfacility transports for a patient, long delays or long transport times that necessitate an ambulance be out of service for additional calls, that the Stroke/STEMI facility is verified as having the appropriate resources to provide the designated level of care, to improve stroke/STEMI care and system function through the analysis of data, and to support rehabilitation. The ultimate goal remains that the patient returns to their community, as closely as possible to their prior level of function and interaction with society.

C. What is the desired outcome?

As the system integrates with the existing Trauma System and matures, these rules will serve to reduce variation in Stroke/STEMI care quality across the state and within each System of Care region, capitalize on efficiencies, as well as limit redundancies by operationalizing a regionalized, coordinated, and accountable system of care for those that live in and visit Michigan.

7. Identify the harm resulting from the behavior that the proposed rules are designed to alter and the likelihood that the harm will occur in the absence of the rule.

The number of Michigan residents who die annually from cardiovascular disease and Stroke remains well above national trends. Without these rules, it is likely that the number and impacts of stroke/STEMI will continue to rise and the number of deaths and disabilities will increase, particularly in communities of color which are already hampered by diminished access to healthcare. The system would be siloed, redundancies continued, data collection inconsistent with limited or no sharing, and initiatives driven by anecdote. In the post pandemic environment, every effort must be implemented to make the best use of the existing resources. The rule organizes a system that provides a continuum of care for those that experience stroke/STEMI that enhances the opportunity for the best outcomes and the greatest chance of survival without disability. The lack of a rule would result in unorganized and ineffective stroke/STEMI care. These rules enhance the ability of the state to manage and coordinate development and integration of a system of care for stroke/STEMI through collaboration with regional and local healthcare systems and providers to standardize stroke/STEMI care that will integrate into the existing trauma system, thereby taking advantage of built relationships, regional organizations already functioning, and lessons learned from building the trauma system. The rule supports evidence-based and data-driven quality and performance improvement through accessing, planning, coordinating, and monitoring to ensure optimal care.

A. What is the rationale for changing the rules instead of leaving them as currently written?

This is a new rule set.

8. Describe how the proposed rules protect the health, safety, and welfare of Michigan citizens while promoting a regulatory environment in Michigan that is the least burdensome alternative for those required to comply.

This rule implements a comprehensive, all-inclusive, multi-disciplinary system of care for Stroke/STEMI intended to integrate into the existing Trauma System to provide for a seamless system of healthcare delivery in which all healthcare providers function in preplanned concert with each other. The System of Care for Stroke/STEMI is a partnership between public and private entities to address cardiovascular disease and stroke as a public health function with common interests and interdependent goals. These rules represent the minimum standards needed to implement, operationalize, and integrate the System of Care for Stroke/STEMI. Although the system is all-inclusive, allowing each hospital to determine the resources it wants to devote to stroke/STEMI care, participation is not mandatory. Those hospitals wishing to participate must only meet the minimum national standards required for verification and designation. Those hospitals that do not wish to participate are not addressed in these rules and have no participatory or reporting requirements. These hospitals may participate in the future should they decide to dedicate the resources required.

9. Describe any rules in the affected rule set that are obsolete or unnecessary and can be rescinded.

This is a new rule set.

Fiscal Impact on the Agency

Fiscal impact is an increase or decrease in expenditures from the current level of expenditures, i.e. hiring additional staff, higher contract costs, programming costs, changes in reimbursements rates, etc. over and above what is currently expended for that function. It does not include more intangible costs for benefits, such as opportunity costs, the value of time saved or lost, etc., unless those issues result in a measurable impact on expenditures.

10. Please provide the fiscal impact on the agency (an estimate of the cost of rule imposition or potential savings for the agency promulgating the rule).

The EMS and Systems of Care Division has been directed by the legislature to a build a system of care for stroke and STEMI and funds were appropriated to do that work. The funding reflects the work already done and ongoing to address a system of care for time dependent emergencies, the appropriation for the two cardiovascular emergencies (stroke and STEMI) will be operationalized and maintained for less than what is needed to build and maintain the trauma system. All three systems will integrate, use, and reuse similar processes, policies and procedures, capitalize on the existing regional structures, and history of performance improvement allowing for the new systems to be organized and operational in less time and in some cases share staffing resources.

11. Describe whether or not an agency appropriation has been made or a funding source provided for any expenditures associated with the proposed rules.

2022-23 Budget for DHHS, 2022 PA 166, http://www.legislature.mi.gov/documents/2021-2022/publicact/pdf/2022-PA-0166.pdf, Sec. 1186: (1) From the funds appropriated in part 1 for emergency medical services program, the department shall allocate $3,000,000 to establish a statewide stroke and STEMI system of care for time-sensitive emergencies. This system must be integrated into the statewide trauma care system within the emergency medical services system and must include at least all of the following:

(a)The designation of facilities as stroke and STEMI facilities based on verification that national certification or accreditation standards, as approved by the stroke advisory subcommittee and the STEMI advisory subcommittee as established under section 20901(1)(m) of the public health code, 1978 PA 368, MCL 333.20910 have been met.

(b)A requirement that a hospital is not required to be designated as providing certain levels of care for stroke and STEMI.

(c)The development and utilization of stroke and STEMI registries that utilize nationally recognized data platforms with confidentiality standards, as approved by the stroke advisory subcommittee and the STEMI advisory subcommittee, as established under section 20210(1)(m) of the public health code, 1978 PA 368, MCL 333.20910.

(2) for the purposes of this section, “STEMI” means ST-elevation myocardial infarction

Funding has been appropriated for FY 2023.

12. Describe how the proposed rules are necessary and suitable to accomplish their purpose, in relationship to the burden(s) the rules place on individuals. Burdens may include fiscal or administrative burdens, or duplicative acts.

The rules seek to accomplish their purpose through planning, coordination, cooperation, and improved performance of stroke/STEMI care providers. The rules provide the necessary framework for collaboration and partnership of public and private healthcare entities. They were modeled on the language used to effectively operationalize the trauma system and builds on those successes. Hospitals that choose to be state designated stroke/STEMI centers incur no additional fiscal or administrative burdens than are currently required by the nationally recognized certifying and accrediting bodies for stroke/STEMI verification requirements. The main administrative burden for hospitals will consist of the effort it takes to access and ensure that the facility has the resources required to deliver stroke/STEMI care at the level described, as well as expected quality improvement initiatives needed to improve care.

A. Despite the identified burden(s), identify how the requirements in the rules are still needed and reasonable compared to the burdens.

Categorizing resources ensures that prehospital providers, the community, and stakeholders are knowledgeable about the level of care available and will inform decision making to ensure the correct patient gets to the right resource at the right time. Organizing the system allows for all the participating entities to engage in informed discussions in the appropriate setting so that when issues arise those gaps can be addressed.

Following national certifying, accreditation standards smooth out variations in care and can lead to stronger performance outcomes. Active engagement in performance improvement and data driven change can be used to address all aspects of healthcare delivery. Healthcare professionals can lead the way by sharing best practices, thereby enhancing the healthcare delivery system in Michigan.

Impact on Other State or Local Governmental Units

13. Estimate any increase or decrease in revenues to other state or local governmental units (i.e. cities, counties, school districts) as a result of the rule. Estimate the cost increases or reductions for other state or local governmental units (i.e. cities, counties, school districts) as a result of the rule. Include the cost of equipment, supplies, labor, and increased administrative costs in both the initial imposition of the rule and any ongoing monitoring.

There are no anticipated increases or decreases in revenue for state or local government, nor are there any anticipated cost increases or reductions for other state or local governmental units as a result of the rule.

14. Discuss any program, service, duty, or responsibility imposed upon any city, county, town, village, or school district by the rules.

There are no programs, duties, or responsibilities imposed on any city, county, town, village, or school district resulting from these rules.

A. Describe any actions that governmental units must take to be in compliance with the rules. This section should include items such as record keeping and reporting requirements or changing operational practices.

The are no actions that governmental units will be required to take to be in compliance with these rules.

15. Describe whether or not an appropriation to state or local governmental units has been made or a funding source provided for any additional expenditures associated with the proposed rules.

The appropriation has been made from the General Fund to the Bureau in Emergency Preparedness, EMS, and Systems of Care, EMS and Systems of Care Division as noted in section 10. There are no additional expenditures that will require an appropriation.

Rural Impact

16. In general, what impact will the rules have on rural areas?

Public and private healthcare providers in rural areas will be provided the opportunity to fully participate in the system regionally, as well as in educational opportunities provided by the department. Also, the formal Regional Professional Standards Review Committee provides a confidential forum to discuss patient care, follow up, and mentoring.

A. Describe the types of public or private interests in rural areas that will be affected by the rules.

Rural residents will experience improved outcomes from standardization of stroke/STEMI care, quality improvements, and cooperative relationships among providers.

Environmental Impact

17. Do the proposed rules have any impact on the environment? If yes, please explain.

These rules do not impact the environment.

Small Business Impact Statement

18. Describe whether and how the agency considered exempting small businesses from the proposed rules.

Small businesses (small hospitals) are not required to participate in the stroke/STEMI system; those not participating as stroke/STEMI care facilities are exempted from the rules. As with the operationalization of the trauma system the agency has supported system development including resourcing a data collection system, education, and training.

19. If small businesses are not exempt, describe (a) the manner in which the agency reduced the economic impact of the proposed rules on small businesses, including a detailed recitation of the efforts of the agency to comply with the mandate to reduce the disproportionate impact of the rules upon small businesses as described below (in accordance with MCL 24.240(1)(a-d)), or (b) the reasons such a reduction was not lawful or feasible.

The department has given small hospitals the ability to opt out of the reporting. For those small business that choose to participate, the appropriations provided to DHHS should reduce any disproportionate impact to small businesses by placing the cost burden on the department.

A. Identify and estimate the number of small businesses affected by the proposed rules and the probable effect on small businesses.

An estimated 70-90 small hospitals may be affected by the proposed rule. Some of these facilities are (either fully or partially) affiliated with larger hospital systems, the level of support they receive as a member of a system may be variable. The most probable effect for those hospitals that choose to participate is an improvement in the quality of stroke/ STEMI care they deliver within their communities.

B. Describe how the agency established differing compliance or reporting requirements or timetables for small businesses under the rules after projecting the required reporting, record-keeping, and other administrative costs.

The rule language, including compliance reporting requirements and timetables, were written in collaboration with partners and stakeholders using the trauma system experience which included the smaller facilities. Their voice informed the decision making and resulting language. The charge was to integrate into the existing trauma system, reduce redundancy, and streamline efficiencies.

C. Describe how the agency consolidated or simplified the compliance and reporting requirements for small businesses and identify the skills necessary to comply with the reporting requirements.

The consensus form stakeholders and meeting documents reflects the plan (yet to be formalized contractually with a vendor) is to provide a software platform that collects the minimum data set needed to manage and monitor the system maintained by the state that will allow for system performance improvement, research, and reporting.

D. Describe how the agency established performance standards to replace design or operation standards required by the proposed rules.

The department reviewed the data available within the required reports to establish performance improvement standards in the rules. Performance standards that were measurable within the reporting requirements were eliminated. All of the performance and operation standards in the rule were reviewed, revised, and approved by the Stroke and STEMI stakeholder work groups and the Emergency Medical Services Coordination Committee.

20. Identify any disproportionate impact the proposed rules may have on small businesses because of their size or geographic location.

Hospitals are not required to become stroke/STEMI facilities; those that choose not to participate will not routinely receive stroke/STEMI patients, which may be perceived as potential loss of revenue. Small hospitals that choose to participate may incur some additional expense in obtaining, maintaining, and verifying the resources required to treat stroke/STEMI patients.

21. Identify the nature of any report and the estimated cost of its preparation by small businesses required to comply with the proposed rules.

All stroke/STEMI facilities, large and small, are required to prepare documents that attest to the status of their stroke/STEMI resources prior to verification review every two years. The cost of preparing the attestation documents is individual to each hospital and depends on the gap between their perceived resources and the actual stroke/STEMI resources they possess. The greatest cost for document preparation will be associated with the initial verification period; re-verification in the subsequent two years will consist of updating the initial documents. Any small hospital that chooses to participate in the stroke/STEMI system will incur some cost for data collection. This cost is incremental and depends on the number of patients the hospital treats.

22. Analyze the costs of compliance for all small businesses affected by the proposed rules, including costs of equipment, supplies, labor, and increased administrative costs.

This cost will be individual to each hospital and will reflect its current readiness status to care for stoke/STEMI patients and is also dependent upon the number of stroke/STEMI patients the hospital treats.

23. Identify the nature and estimated cost of any legal, consulting, or accounting services that small businesses would incur in complying with the proposed rules.

Small hospitals need not incur any costs for legal, consultative, or accounting services resulting from these rules.

24. Estimate the ability of small businesses to absorb the costs without suffering economic harm and without adversely affecting competition in the marketplace.

There is potential for economic harm to a small hospital that chooses not to participate in the Stroke/STEMI system. Patients experiencing a time sensitive emergency such as stroke or ST elevation myocardial infarction who are transported by ambulance will be delivered to a designated stroke/STEMI facility. Small hospitals that choose to participate in the stroke/STEMI system will incur some extra costs for compliance that are potentially offset by reimbursements for stroke/STEMI services. Conversely, caring for a stroke/STEMI patient who requires resources beyond the facility's ability to provide can be economically harmful, especially if the outcome is unfavorable.

25. Estimate the cost, if any, to the agency of administering or enforcing a rule that exempts or sets lesser standards for compliance by small businesses.

These rules do not contain exemptions or lesser standards for small hospitals. The hospital makes a self-determination of the level of resources it is able to provide and is designated at the appropriate level when those resources are independently verified.

26. Identify the impact on the public interest of exempting or setting lesser standards of compliance for small businesses.

The purpose of the rule is to establish a standard for the required resources at each level of stroke/STEMI designation. Setting a lesser standard or exemption for small hospitals would negate the reliability of the resource standards and would jeopardize public safety and public health.

27. Describe whether and how the agency has involved small businesses in the development of the proposed rules.

The stakeholder work groups were assembled from the Stroke/STEMI service lines. Efforts were made to ensure that representation included rural regions of the state, as well as a majority of health systems where possible. All requests to participate were honored. Once the development process was in place and draft work was available, advisory bodies to the Bureau, the Emergency Medical Services Coordination Committee and the Statewide Trauma Advisory Subcommittee were involved in the discussion and asked to provide input and subsequently their recommendation/support of the rules.

A. If small businesses were involved in the development of the rules, please identify the business(es).

The advisory bodies mentioned are established in the Public Health Care, including their representative memberships. The members include the Michigan Hospital Association, Michigan College of Emergency Physicians, Michigan Association of Ambulance Services, the Michigan Fire Chief's Association, the Society of Michigan Emergency Medical Services Instructor-Coordinators, the Michigan Association of Emergency Medical Technicians, the Michigan Association of Air Medical Services, the Michigan Association of Emergency Medical Services Systems, and labor organizations; each of these organizations has one representative from a county with a population less that 100,000 in order to include rural populations. These rural areas are the most likely to have a small hospital affected by this rule. In addition, the committee has a consumer and a municipal representative from a government in a county with a population less than 100,000. The representation of the Statewide Trauma Advisory Subcommittee consists of trauma surgeons that are currently trauma center directors; a trauma nurse coordinator; a trauma registrar; an emergency physician; a hospital administrator from a Level I or Level II trauma center and a hospital administrator from a non-Level I or non-Level II trauma center; a life support agency manager; a medical control authority from a rural county and medical control authority from a non-rural county. The two broad-based groups representing rural and non-rural businesses were involved in the development of these rules.

Cost-Benefit Analysis of Rules (independent of statutory impact)

28. Estimate the actual statewide compliance costs of the rule amendments on businesses or groups.

There are no actual statewide compliance costs to those small hospitals that choose not to participate with the reporting. With the $3 million appropriated to DHHS, any actual compliance costs to businesses or groups would be negligible.

A. Identify the businesses or groups who will be directly affected by, bear the cost of, or directly benefit from the proposed rules.

Providing care for a Michigan resident who has a stroke, or a STEMI, is standard operating procedure. Hospitals that volunteer to participate in the system will be affected by the rules. Conversely, they stand to directly benefit as the rules will assist in smoothing out the standardization of care, provide a category of easily recognized resources, contribute data to assist regional monitoring of the system, identify gaps, and address initiatives to manage them.

B. What additional costs will be imposed on businesses and other groups as a result of these proposed rules (i.e. new equipment, supplies, labor, accounting, or recordkeeping)? Please identify the types and number of businesses and groups. Be sure to quantify how each entity will be affected.

For participants, additional costs for Stroke/STEMI patient data entry may be incurred. Hospitals volunteering to be designated as a Stroke/STEMI facility will incur other equipment and staffing costs based upon gaps between existing resources and resources required for Stroke/STEMI center verification. These potential costs will also depend upon the chosen level of Stroke/STEMI center designation pursued.

29. Estimate the actual statewide compliance costs of the proposed rules on individuals (regulated individuals or the public). Include the costs of education, training, application fees, examination fees, license fees, new equipment, supplies, labor, accounting, or recordkeeping.

There are no compliance costs for individuals in these rules.

A. How many and what category of individuals will be affected by the rules?

There are no individuals, only entities, regulated by the rules.

B. What qualitative and quantitative impact do the proposed changes in rules have on these individuals?

The public, as represented by Stroke/STEMI patients, will qualitatively and quantitatively benefit from being transported by ambulance to the closest, most appropriate stroke/STEMI facility based on standardized physiological and anatomical assessment of severity, as well as standardized transport protocols.

30. Quantify any cost reductions to businesses, individuals, groups of individuals, or governmental units as a result of the proposed rules.

Although costs may not be reduced by the rule, compliance with the state Stroke/STEMI designation criteria, improved adherence to care standards, protocols, and guidelines will improve patient care, including time to treatment that will potentially lead to lower patient costs, lower inpatient mortality, and better outcomes.

31. Estimate the primary and direct benefits and any secondary or indirect benefits of the proposed rules. Please provide both quantitative and qualitative information, as well as your assumptions.

Stroke/Cardiovascular disease has consistently ranked among the top five causes of death in the state. The American Heart Association reported in the 2022 Heart Disease and Stroke Statistical Update that between 2015 and 2018 cardiovascular disease direct costs were $226.2 billion and $151.8 billion was lost in productivity/mortality. Early work published by Lancet suggested that the 12-month risk of incidental cardiovascular diseases is substantially higher in COVID-19 survivors than non-COVID-19 controls. The intended benefit of the rule is to decrease mortality and morbidity related to stroke/STEMI by establishing and maintaining a system of care for time sensitive emergencies in Michigan that is dynamic, that evolves in response to lessons learned, and that changes with the shifts on population and demographics, as well as the issues and sequela that result from the support recovery from the pandemic.

32. Explain how the proposed rules will impact business growth and job creation (or elimination) in Michigan.

Michigan residents, employers, and visitors to the state expect to receive the kind of care that a regionalized, coordinated, and accountable stroke/STEMI system of care can provide. While the rule is not anticipated to affect business growth or job creation, regulated care for stroke/STEMI is an expectation of public service. The intent is to utilize existing resources in a more effective and efficient system of care for time sensitive emergencies with decreased redundancy.

33. Identify any individuals or businesses who will be disproportionately affected by the rules as a result of their industrial sector, segment of the public, business size, or geographic location.

Theoretically, very small hospitals in rural areas may have more challenges assembling the required resources for stroke/STEMI facility verification than larger urban hospitals. However, mergers and acquisitions have the potential to allow these facilities access to greater resources.

34. Identify the sources the agency relied upon in compiling the regulatory impact statement, including the methodology utilized in determining the existence and extent of the impact of the proposed rules and a cost-benefit analysis of the proposed rules.

2020 Geocoded Michigan Death Certificate Registry. Division for Vital Records & Health Statistics, Michigan Department of Health & Human Services; Population Estimate (latest update 7/2020), National Center for Health Statistics, U.S. Census Populations With Bridged Race Categories .

A Statewide System of Care For Time Sensitive Emergencies: The Integration of Stroke and STEMI Care into the Regional Trauma System, A White Paper. (2020). Bureau of EMS, Trauma, and Preparedness

Adeoye, O., et al. (2019). Recommendations for the Establishment of Stroke Systems of Care: A 2019 Update. Stroke. Retrieved from https://doi.org/10.1161/STR.0000000000000173

Bailey, M., & Omeaku, N. (2022). Stroke Systems of Care (SSOC) Policy Projects Update. Centers for Disease Control and Prevention. Retrieved from Stroke Systems of Care (SSOC) Policy Projects Update (cdc.gov)

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Gilchrist, S., Sloan, A. A., Bhuiya, A. R., Taylor, L. N., Shantharam, S. S., Barbero, C., & Fulmer, E. B. (2020). Establishing a Baseline: Evidence-Supported State Laws to Advance Stroke Care. Journal of public health management and practice: JPHMP, 26 Suppl 2, Advancing Legal Epidemiology, S19–S28. https://doi.org/10.1097/PHH.0000000000001126

Jacobs, A. et al. (2021). Systems of Care for ST-Elevation Myocardial Infarction: A Policy Statement from The American Heart Association. Circulation. Retrieved from https://doi.org/10.1161/CIR.0000000000001025

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Wang. W., Wang, C., Wang, S., & Wei, J.C. (2022). Long-term cardiovascular outcomes in COVId-19 survivors among non-vaccinated population: A retrospective cohort from the TriNEtx US collaborative networks. The Lancet. Retrieved from https://doi.org/10.1016/j.eclinm.2022.101619

Ward, B., Patrick, C., Dickson, R., Crocker, K., Gleisberg, G. (2016). Improving Systems of Caare in Time-sensitive Emergencies. JEMS.

A. How were estimates made, and what were your assumptions? Include internal and external sources, published reports, information provided by associations or organizations, etc., that demonstrate a need for the proposed rules.

Estimates were made based on data and information from collective experience of implementation of the Trauma System, the Michigan Vital Records & Health Statistics, and the sources identified in question 34.

Alternative to Regulation

35. Identify any reasonable alternatives to the proposed rules that would achieve the same or similar goals.

There are no perceived reasonable alternatives to the proposed rules.

A. Please include any statutory amendments that may be necessary to achieve such alternatives.

There are no necessary statutory amendments.

36. Discuss the feasibility of establishing a regulatory program similar to that proposed in the rules that would operate through private market-based mechanisms. Please include a discussion of private market-based systems utilized by other states.

Private market-based systems are not utilized by states to implement a coordinated state-wide system of care for stroke/STEMI. The American Heart Association, the American Stroke Association, the National Highway Traffic Safety Association, and the United Stated Department of Health and Human Services in the case of trauma systems recommend focused efforts by states to coordinate stroke/STEMI systems.

37. Discuss all significant alternatives the agency considered during rule development and why they were not incorporated into the rules. This section should include ideas considered both during internal discussions and discussions with stakeholders, affected parties, or advisory groups.

The appropriation boilerplate directed MDHHS to establish a statewide stroke and STEMI system of care for time sensitive emergencies. The MDHHS has the authority to conduct rulemaking, these will codify the appropriation language to ensure uniform system development.

Additional Information

38. As required by MCL 24.245b(1)(c), please describe any instructions regarding the method of complying with the rules, if applicable.

The White Paper previously cited in this document is foundational to describing how the rules will be implemented, and implementation will be driven by experience and lessons learned when operationalizing the trauma system. Policies and guidance documents will be created to compliment the rule language and to ensure compliance with the rules.