PUBLIC COMMENT-2022-61 HS Statewide STEMI System

COMMENTOR AND ORGANIZATION	PUBLIC HEARING OR WRITTEN	RULE NUMBER	COMMENT	DHHS RESPONSE
Dr. Abed Asfour, MD, Corewell Health East and West	Public Hearing	General Comments regarding accreditation	I'm going to address a set of the rural hospitals in the State of Michigan, as well as I'm going to address, to some degree, but I will leave it to some of my colleagues, the open-heart surgery hospitals and the limitations and the advantages of looking into this rule in different prospect. Requiring accreditation may seem reasonable on paper, but it could be like chasing some (inaudible) in the rural hospitals. The costs, the complexities, the diversion of resources are very import-, very critical to these places.	The white paper *A Statewide System of Care For Time Sensitive Emergencies: The Integration of Stroke and STEMI Care into the Regional Trauma System*, and the admistative rules drafts were written by a group of stakeholders and professional subject matter experts including representatives from rural regions of the state. Systems of care take into consideration the geogrpahical differences and resource allocation across the state, and work to "incorporate a variety of disparate healtcare components into a formal structure that is established, supported and supervised within statutes, administrative rules and policy."Primary emergent treatment for an ST-Elevation Myocardial Infarction is to have a Percutaneous Coronary Intervention (PCI) in 120 minutes, failing that, IV therapeutics (clot buster) within 12 hours of after symptom onset (if appropriate). SCAI Expert Consensus Statement on PCI without On-Site Surgical Back-up reported a <0.1% rate of emergent bypass surgery post PCI. Open Heart Surgery as treatment for a STEMI is an important
Eric Jaklovac, Director of Heart and Vascular Services at Corewell Health and Beaumont University Hospita	Public Hearing	General Comments regarding accreditation	You know, we think that adding an additional accreditation to our cath labs and chest pain facilities, especially those that have these very robust programs and CV surgery and open-heart surgery back up, it seems a little redundant. You know, we have been working very hard to continue to improve our patient outcomes, with our quality, we continue to do so. And we don't necessarily think or see potentially the value of accreditation, on top of what we are already doing.	The Department has been charged with integration of the STEMI System of Care into the existing trauma system. Part of that charge is developing a process for designation of facilities. The stakeholders and professional subject matter experts that helped to draft these rules agreed that the process outlined in *A Statewide System of Care For Time Sensitive Emergencies: The Integration of Stroke and STEMI Care into the Regional Trauma System* including verfication of the level of care provided at each facility by written proof of certification or accreditation through a professional-nationally recognized organization would help to establish a minimum standard of care in the state. According to the American Heart Association System of Care for ST-Segment Elevation Myocardial Infarction: A Policy Statement from the AHA "STEMI referring hospitals and STEMI receiving centers have specific roles in a STEMI system of care, and each should be as prepared as possible to collaboratively perform evidence-based, lifesaving treatment." Accreditation is the process that identifies and establishes the roles and responsibilities. Thus ensuring that all partners, stakeholders and the public understand quickly what services each facility is capable of, limiting an important barrier to care delivery in a very time dependent emergency. STEMI SOC recommendations also state
		General Comments regarding accreditation	But there's also additional concerns we have when it comes to pay, when it comes to time, when it comes to resources to not only get accreditation, but to maintain that accreditation over the course of time. So, we've been all aware that there is a financial cost that would, we would incur choosing a third-party accreditation. But there's also the cost of who's going to continue to manage those data points that we need to, who's going to continue to keep things rolling if we're chucking everything, sending everything inappropriately and doing all that, as well as the time	In 2021 4.3% of Michigan residents were told by their doctor that they had a heart attack. Accreditation provides enhanced uniformity in care, opportunities to stregthen protocols, procedures, ensures patients are transferred to facilities that have the appropriate services and that data is collected to drive decision making, identify gaps and subsequent methods to address. STEMI Systems of Care have been in existence for years (Europe, Australia, US, India, Indodesia, Egypt, and others) as compelling evidence points to decrease in mortality when quality care is
Dr Samir Dabbous, MD, Interventional Cardiologist, Corewell Health East	Public Hearing	General Comments regarding accreditation	We really don't need another body that tells us exactly what we're supposed to do, whether how, whether we should be accredited or not because we have been doing this for quite a while. And instead of spending more money on accreditation and have FTEs to look at these metrics and report them to the ACC or whoever. I would rather make, focus more on staffing, patients that we're having major issues with right now, whether it is the nursing care or critical care area.	Accreditation is an objective evaluation process that can help organizations measure, assess and improve performance. White Paper: *A systematic approach to STEMI care ensures that STEMI patients are integrated into a system of regional healthcare providers who are well trained and have the resources to provide optimal care... It also ensures that all STEMI patients are part of a system of coordinated care based on standardized triage criteria and regional destination protocols.* R 330.205 Rule 5 A healthcare facility may participate in the system to the extent or level that it commits the resources necessary for the appropriate management of STEMI patients.
Colin McDonough, Michigan Government Relations Director for the American Heart Association	Public Hearing	R 330.201 (See DHHS response)	In R 330.201, the American Heart Association recommends updating the definitions of **"accreditation"** and "certification" and clarify and avoid confusion. For the definition of "disciplinary action", we suggest including EMS agencies as they may also fail to comply with the Code	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 330.203	For R 330.203, it is recommended that the definition of "PCI" align with the Michigan Department of Health and Human Services certificate of need review standards for cardiac catheterization services. Currently, the term does not include the inter-coronary administration of drugs, FFR, or IVUS where these are the only procedures performed.	The published definiiton was developed by the White Paper Expert Writing Group. Definitions must align and not contravene already adopted language. The definition of "PCI" was agreed upon by the stakeholders and professional subject matter experts from the administrative rules work group.
	Public Hearing	R 330.201	In R 330.201, the American Heart Association recommends updating the definitions of "accreditation" and **"certification"** and clarify and avoid confusion. For the definition of "disciplinary action", we suggest including EMS agencies as they may also fail to comply with the Code	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 330.201	In R 330.201, the American Heart Association recommends updating the definitions of "accreditation" and "certification" and clarify and avoid confusion. 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	The regional STEMI advisory council and the statewide STEMI care advisory subcommittee both pose ambiguity around their membership. For instance, is the American Heart Association considered a consumer under the regional STEMI advisory council? For both the council and subcommittee, we recommend a definition inclusive of expertise in this specific field, such as professional organization with expertise in STEMI 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(1)(p)	In section (1)(p), we suggest moving "education", "risk reduction", and "sub-acute". These seem to be beyond the scope of the administrative Code and capabilities of the Bureau	The definition of STEMI care was drafted by stake holders and professional subject matter experts to define the care that is provided by the facilities. These are programmatic standards that are used to measure the care provided by accredited and certified STEMI facilities.
		R 330.253(1)(t)	Additionally, the Association requests the removal of the word "comprehensive" in the definition of "statewide STEMI system of care".	The definition was agreed upon by the stakeholders and professional subject matter experts that drafted these administrative rules.
	Public Hearing	R 330.253(1)(m)	In totality, the American Heart Association believes STEMI should be replaced with "heart attack". The term STEMI is a medical term not often used and understood by the public.	The intention of the system is to address the time sensitive identification and treatment of ST Elevation Myocardial Infarction.There is an important distinction between the term heart attack and STEMI. A heart attack is a term that can be used to describe the outcome of a partially blocked coronary artery, an artery spasm, or a coronary artery tear. A STEMI is a specific kind of heart attack due to a complete blockage of a coronary atery that is treated in a specific, time sensitive manner. STEMI is a specific high-risk type of heart attack that requires prompt recognitiom amd emergent treatment.
	Public Hearing	General comment.	In that vein, we believe the definition of "STEMI referral facility" should include various other words like heart attack, chest pain center, and other relevant terms that hospitals may use to advertise themselves as providing STEMI or heart attack care.	The White Paper Expert Writing Group formalized the definitions. These were initially introduced in 2011 when the SOC discussion began. The definition was aggreed upon by the stakeholders and professional subject matter experts that helped to draft these rules.
	Public Hearing	R 330.254(1)(a)	R 330.204(1)(a) should remove the term "all-inclusive". In theory, all-inclusive indicates primary prevention through rehabilitation which may be beyond the scope and capabilities of the Bureau. Trauma regulations use all inclusive, but does this really include sub-acute and rehabilitation?	DHHS opposes this recommendation. Voluntary all-inclusive systems are the foundational model of the existing trauma system as well as the developing stroke system. 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)	The Association also believes (1)(e) should be modified because Michigan may have its own certification accreditation based on the definition of verification within the rules. Trauma regulations specifically reference the American College of Surgeons, and the American Heart Association strongly recommends adoption of the joint commission American Heart Association. At minimum, we suggest listing both the joint commission and the American College of Cardiology.	The language "nationally recognized professional certifying and accrediting organization" was aggreed upon by the stakeholders and professional subject matter experts that helped to draft this rule set. The group recognized that while the Trauma System has one accrediting organization, there are several organizations that certify and accredit for cardiac care. This language will allow for the department and the advisory body to review and update the list of apporved organizations though policy and procedure.
	Public Hearing	R 330.254(1)(f)	AHA believes the verbiage surrounding (1)(f) could lead to confusion and should be revisited.	The department designates STEMI refering hospitals and STEMI receiving facilities based on verification of The state has an established designation process for the Trauma System and intends to mirror this for the STEMI System.
	Public Hearing	General	Further, when developing a statewide STEMI data collection system, we believe MDHHS should follow the trauma regulations which read, quote: The Department shall do all of the following: a. Adopt the national trauma data standard elements in definitions as a minimum set of elements for data collection, with the addition of elements as recommended by the STAC, unquote.	As noted in the AHA paper cited above "Among the barriers remaining is establishing the ideal STEMI system of are are local and regional challenges, resource and financial issues and **no single US STEMI registry**." The White Paper recommendation is that *a statewide STEMI data registry will be established by the Department, including the establishment of a minimum data set, data dictionary, and the data upload and data verification process. The submission of data to the STEMI registry will be phased in in order to support the efficient and orderly establishment of designated STEMI facilities.*
		General	a. Adopt the national trauma data standard elements in definitions as a minimum set of elements for data collection, with the addition of elements as recommended by the STAC, unquote.	As noted in the AHA paper cited above "Among the barriers remaining is establishing the ideal STEMI system of are are local and regional challenges, resource and financial issues and **no single US STEMI registry**." The White Paper recommendation is that *a statewide STEMI data registry will be established by the Department, including the establishment of a minimum data set, data dictionary, and the data upload and data verification process. The submission of data to the STEMI registry will be phased in in order to support the efficient and orderly establishment of designated STEMI facilities.*
	Public Hearing	General	In these rules, the Association would like to see an exportation to get with the guidelines coronary artery disease.	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.
	Public Hearing	General	In disciplinary situations, the Department should include EMS, as well as the STEMI center or facility.	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 330.254(4)	Through the development of a statewide STEMI system of care listed in section (4), we suggest the addition of additional criteria that would incorporate national standards, like developing another registry and adopting national certification standards to make the program more efficient and cost-effective.	This is addressed in other sections of the rule set.
	Public Hearing	R 330.255	R 330.205 seems to conflict with the State's certificate of need for PCI. Can the State designate, verify, certify, or accredit STEMI receiving center Level 1 or 2 if the hospital hasn't met CON?	CON is not noted in the Rule document. The proposed rules do not supercede CON requirements and CON rules address this issue.
	Public Hearing	General	Additionally, we suggest removing CON to ensure it aligns with certification criteria. There are some CON requirements, including protocols, data collection and measures that may need to be addressed. CON for PCI without SOS requires accreditation for cardiovascular excellence, accreditation, or an equivalent body to perform an onsite review.	CON is not noted in the Rule document. The proposed rules do not supercede CON requirements and CON rules address this issue.
	Public Hearing	R 330.356	In R 330.206, the language should read "Level 1, TIG...TICHA comprehensive STEMI center or Level 2, TICHA primary heart attack center or ACC pain center" because it will align with stroke and trauma levels.	It is R 330.356. The definitions STEMI receiving center and STEMI referral described in the Rule language were drafted and outlined in the White Paper by the Expert Writing group and published on the SOC website, presented to the EMSCC, and reviewed by content experts at a statewide meeting in September 2022.
	Public Hearing	Unclear on which rule this is referencing?	In subsection (l), STEMI receiving centers will need to comply with CON regulations. Those are not mentioned here.	CON is not noted in the Rule document. The proposed rules do not supercede CON requirements and CON rules address this issue.
	Public Hearing	?	Section (b) should read "Level 3 TICHA acute heart attack ready center, or ACC non-PCI chest pain center" because it will align with the stroke and trauma levels.	The definitions STEMI receiving center and STEMI referral described in the Rule language were drafted and outlined in the White Paper by the Expert Writing group and published on the SOC website, presented to the EMSCC, and reviewed by content experts at a statewide meeting in September 2022
	Public Hearing		In section (8) we believe there is a mismatch between the rules in CON, which limits the number of facilities that can do PPCI STEMI receiving centers.	CON is not noted in the Rule document. The proposed rules do not supercede CON requirements and CON rules address this issue.
	Public Hearing		Additionally, the use of the word "level" should align with our Level 1, 2, and 3 in administrative language to demonstrate they exist.	The definitions STEMI receiving center and STEMI referral described in the Rule language were drafted and outlined in the White Paper by the Expert Writing group and published on the SOC website, presented to the EMSCC, and reviewed by content experts at a statewide meeting in September 2022
	Public Hearing	General comment	To effectively effectuate a STEMI system of care in Michigan, it is necessary to interface with Get with the Guidelines	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.
David Fuller, Corazon	Public Hearing	General comment regarding accreditation.	Currently, the proposed rule includes language that a provider would need to gain accreditation by a Department-approved, nationally recognized professional certifying and accreditation, accrediting organization. But it includes no information as to how such organizations are approved.	That process will be outlined in policy and as noted in the Rules 320.206 Rule 6 (4)(a)...as approved by the department with the advice of the STEMI advisory subcommittee pursuant to R 330.204(1)(1) and all the following[.]
	Public Hearing	General comment regarding accreditation.	The proposed rule then lists two organizations for this accreditation, yet amidst Corazon is a named provider despite our approved standing as an approved cardiovascular accrediting body by the Michigan Department of Health and Human Services, and our ability to meet or exceed the equivalent criteria maintained by the other named organizations. This omission is already created confusion among Corazon's Michigan accredited programs in terms of what the differences will be between the proposed STEMI accreditation and the current PCI accreditation requirements that already include the necessary quality and safety monitoring for the STEMI patient population.	DHHS has changed these rules to the following language: 206(4)(a) ...or a Corazon PCI/Catheterization program[.] and 206(4)(b) : or a Corazon chest pain center[.]
	Public Hearing	R 330.206(4)(a) and (b)	We request, request that paragraph (6)(4)(a) and (b) be amended to include Corazon PCI and chest pain center accreditation as recognized STEMI and receiving, and referral center accreditation because our experience and current accreditation process and requirements are already used by many Michigan hospitals.	DHHS has changed these rules to the following language: 206(4)(a) ...or a Corazon PCI/Catheterization program[.] and 206(4)(b) : or a Corazon chest pain center[.]
Dr. Abed Asfour, MD, Corewell Health East and West	Public Hearing	Response to previous testimony.	I don't think STEMI and stroke and trauma are the same when it comes to chest painers, because trauma, you can identify it; stroke, 90% or more, it's identified that it's a stroke. STEMI or chest pain for every, chest for every probably thousand chest painers, there less than one STEMI. So, if we're going to shift ambulances and move them away from local hospitals to just credential places, we are shifting the whole business.	Recognition of a STEMI begins with an EKG and symptom recognition. The EMS protocol Michigan Adult Cardiac Chest Pain/Acute Coronary Syndrome Step 2 states Obtain 12 lead as early as possible without delaying medication administration (MDHHS approval 6/3/2023). As noted, STEMI's are time sensitve emergencies similiar in some aspects to trauma and stroke requiring the right patient gets the right resource at the right time.
Alex Bou Chebl, MD, FSVIN Director, Harris Comprehensive Stroke Center Director, Division Vascular Neurology Chair, System Stroke Council Henry Ford Health	Written	General comment	Henry Ford Health also recommends a more consistent use of the terms "council", "committee", and "subcomittee" throughout the rules for uniformity and to remove any confusion.	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.	Numbering error. DHHS1 correct on final document.

Ryan J. Reece, MD, EMT-P, FACEP Assistant Professor of Emergency Medicine Hurley Medical Center Division University of Michigan	Written	General comment	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.	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.
Frank Edward Ryan, JD, Senior Advisor, State Government Affairs-American College of Cardiology	Written	R 330.204; R 330.209	Accordingly, moving forward, we want to ensure that changes to the system do not produce duplication of tasks. For example, Rule 5 calls for implementation of an "all-inclusive STEMI system throughout this state that allows for the care of all STEMI patients in an integrated system of healthcare in the pre-hospital and healthcare facility environments by personnel that are well trained and equipped to care for STEMI patients." Allowing the use of an existing national data collection tool to be substituted for developing one de novo would prevent task duplication to the benefit of patients and practices. This also applies to Rule 9 (1) – which calls for a new, statewide registry. (See NCDR Natl CV Data Reg	Systems function to enhance efficiencies, coordinate and integrate to provide timely quality care. The Trauma System has a statewide patient registry. The STEMI system of care will integrate data collection in a statewide data collection tool.
Collin McDonough, Michiga Government Relations Director-American Heart Association.	Written	R 330.201	(1)(i): "Disciplinary action" should include EMS agencies. "'Disciplinary action' means an action taken by the department against a healthcare facility, EMS agency, or a regional STEMI 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 330.203(1)(a)	(1)(a): Align the definition of PCI with the definition from the CON Review Standards for Cardiac Catheterization Services: "'Percutaneous coronary intervention' (PCI) means a therapeutic cardiac catheterization procedure to resolve anatomic and/or physiologic problems in the coronary arteries of the heart. A PCI session may include several procedures including balloon angioplasty, atherectomy, laser, stent implantation and thrombectomy. The term does not include the intracoronary administration of drugs, FFR or IVUS where these are the only procedures performed." (Page 3).	The definition wasdrafted and agreed upon by the stakeholders and clinical subject matter experts that helped draft these rules. The definition was left broad to ackowledge the potential for changes in the standard of care based on updated evidenced based standards.
	Written	R 330.203(1)(k)	(1)(k): For the "Statewide STEMI care advisory subcommittee," the Association believes a statement such as, "professional organization with expertise in STEMI systems of care like the American Heart Association" would be appropriate.	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 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. 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 330.203(1)(m)	(1)(m): Remove the word "comprehensive" in the definition of "Statewide STEMI system of care."	The definition was agreed upon by the stakeholders and professional subject matter experts that drafted these administrative rules.
	Written	R 330.203(1)(p)	(1)(p): Remove the words "education, risk reduction, and subacute." These actions seem to be beyond the scope of the administrative code and capabilities of the Bureau.	The definition of STEMI care was drafted by stake holders and professional subject matter experts to define the care that is provided by the facilities. These are programmatic standards that are used to measure the care provided by accredited and certified STEMI facilities.
	Written	R 330.204(1)(e)	(1)(e): The Association would like to see inclusion of TJC-AHA and/or a nationally recognized certifying body, as deemed by the Department	The statement is develop and in-state process...based on a department approved nationally recognized professional certifying and accreditating orgnaization.
	Written	R 330.204(4)	(4): We recommend additional criteria that would incorporate national standards, such as developing another registry and adopting national certification standards.	This is addressed in other sections of the rule set.
	Written	R 330.205	This section would likely need to address protocols, data collection, and measures with CON requirements.	CON is not noted in the Rule document. The proposed rules do not supercede CON requirements and CON rules address this issue.
	Written	R 330.206(4)(a)	(4)(a): AHA would like to see designation of levels for the centers. This will allow for future development of the system of care—particularly for patients with STEMI that evolve to cardiac arrest and/or cardiogenic shock.	The STEMI Receiving Center and STEMI Refering Facility nomenclature defined in section R 330.206 were developed and agreed upon by the stakeholders and clinical subject matter experts that helped draft the rules. This recommendation was informed by the white paper *A Statewide System of Care For Time Sensitive Emergencies: The Integration of Stroke and STEMI Care into the Regional Trauma System* and the sentinal paper *Regional Systems of Care for Patients With ST-Elevation Myicardial Infarction: Being at the Right Place at the Right Time* written by Jacobs (2007).
	Written	R 330.206(4)(a)(i)	(4)(a)(i): STEMI receiving facilities will need to comply with CON regulations, which are not mentioned here.	CON is not noted in the Rule document. The proposed rules do not supercede CON requirements and CON rules address this issue.
	Written	R 330.206(4)(b)	(4)(b): The Association asks for the use of levels when referencing facilities. This will allow for future development of the system of care—particularly for patients with STEMI that evolve to cardiac arrest and/or cardiogenic shock.	A 2-Level STEMI system was distinctly expressed by content experts citing concerns for EMS being challenged to identify the needs of echmo/baloon pump patients in the field.
Dr. Natalie L. Biggio SVP, Patient Care Services Corewell Health South Joshua Kooistra Chief Medical Officer Corewell Health West	Written	General	Specifically, we find the following requirements and provisions burdensome: 1) requiring STEMI receiving AND referral centers to obtain certification or accreditation by nationally recognized professional organizations, 2) the language surrounding accreditation organizations, and 3) the overarching burden some of the requirements will place on some of our smaller/rural facilities.	Certification/Accreditation provides verification of resources needed to care for STEMI patients at that paricular level. The content experts that represent healthcare systems across the state crafted the recommendations and reviewed and supported the Administrative Rule language.
	Written	R 330.206(4)(b)	The process of obtaining and maintaining certification or accreditation from MDHHS-approved organizations adds a significant administrative burden to healthcare facilities, without evidence such accreditation would enhance the quality of care provided. The accreditation process often involves extensive documentation and site visits taking away valuable staff time and resources that could be better utilized delivering patient care and improving outcomes.	The Department has been charged with integration of the STEMI System of Care into the existing trauma system. Part of that charge is developing a process for designation of facilities. The stakeholders and professional subject matter experts that helped to draft these rules agreed that the process outlined in A Statewide System of Care For Time Sensitive Emergencies: The Integration of Stroke and STEMI Care into the Regional Trauma System including verfication of the level of care provided at each facility by written proof of certification or accreditation through a professional-nationally recognized organization would help to establish a minimum standard of care in the state. According to the American Heart Association System of Care for ST-Segment Elevation Myocardial Infarction: A Policy Statement from the AHA "STEMI referring hospitals and STEMI receiving centers have specific roles in a STEMI system of care, and each should be as prepared as possible to collaboratively perform evidence-based, lifesaving treatment." Accreditation is the process that identifies
	Written	General regarding accreditation	Requiring additional accreditation for cardiac catheterization (cath) labs and chest pain centers could be redundant and not necessarily indicative of improved patient outcomes.	Accreditation/certification standards for a STEMI Receiving Center are not confined to the cath lab only, but to ensure a full program of policies, procedures, data collection,education, performance improvement is in place to ensure quality care.
	Written	General regarding accreditation	An additional unanticipated outcome is the incorporation of STEMI treatment under the Chest Pain category within the framework of the accreditation process. This policy will redirect ambulance transfers away from facilities lacking accreditation, channeling them exclusively to accredited establishments. Consequently, this may induce a concentration of chest pain cases solely within accredited hospitals, potentially creating an advantage for one emergency department while placing undue strain on another and excluding a third.	Delays in treatment correspond to increases in mortality (a delay of 121-180 minutes corresponded to a mortality rate of 28% in a study published in JAMA in 2010 Aug 18; 304(7):763-71. Systems are designed to ensure the STEMI patient gets to the closest appropriate resource as soon as possible. Not knowing what the resources are (not certified or accredited) would have EMS providers bringing patients to facilities that may not have the necessary resources, requiring transfer, delaying care and increasing the risk of a poor outcome.
	Written	General regarding accreditation	Finally, requiring referral facilities to obtain accreditation is a costly proposal. We at Corewell Health have numerous rural facilities that are already sending STEMI and suspected STEMI patients to facilities that would or potentially qualify as receiving centers. Requiring a facility, especially rural facilities, to obtain accreditation may make this designation unobtainable.	Content experts included rural facilities, resource implications were discussed and the experts advised that the potential to improve care and outcomes and return Michiganders to a productive life were of signifficant benefit.
	Written	Accrediting Bodies Language - R 330.206 Rule 6(4)(a); R 330.206 Rule 6(4)(b).	Corewell Health appreciates the Bureau of Emergency Preparedness, EMS, and Systems of Care's efforts to offer broad language related to approved accrediting bodies. We also understand that no final decisions have been made related to the accrediting bodies. However, we believe that the Corazon accreditation should be recognized as a valid and valuable alternative, for facilities without on-site Open-Heart Surgery (OHS) services.	DHHS has changed these rules to the following language: 206(4)(a)'...or a Corazon PCI/Catheterization program[.] and 206(4)(b) : or a Corazon chest pain center[.]
	Written	Administrative Burden – R 330.201 – R 330.214	Requiring additional accreditation for cath labs and chest pain centers could be redundant and not necessarily indicative of improved patient outcomes. Facilities with mature on-site Open OHS services already possess a higher level of readiness to handle complex cases. OHS services ensure that emergency interventions can be carried out promptly. Therefore, it might be worth reconsidering the need for additional cath lab or chest pain center accreditation for such facilities, as the existing capabilities align with STEMI care goals.	The Department has been charged with integration of the STEMI System of Care into the existing trauma system. Part of that charge is developing a process for designation of facilities. The stakeholders and professional subject matter experts that helped to draft these rules agreed that the process outlined in A Statewide System of Care For Time Sensitive Emergencies: The Integration of Stroke and STEMI Care into the Regional Trauma System including verfication of the level of care provided at each facility by written proof of certification or accreditation through a professional-nationally recognized organization would help to establish a minimum standard of care in the state. The Department will be collaborating with the current accreditation processes for Cath Labs. SCAI Expert Consensus Statement on PCI without On-Site Surgical Back-up reported a <0.1% rate of emergent bypass surgery post PCI. Open Heart Surgery as treatment for a STEMI is an important option, not the primary method of treatment, surgically capable facilities are vital partners in the system.
Karen Hartman President & CEO Corazon, Inc. 5000 McKnight Road, Suite 300 Pittsburgh, PA David H. Fuller Executive Vice President, Accreditation Corazon, Inc. 5000 McKnight Road, Suite 300 Pittsburgh, PA 15237	Written	General regarding accreditation	Despite Corazon's standing as an approved cardiovascular accrediting body by MDHHS, Corazon was omitted from the proposed rule language. In fact, the rule language includes no information as to how the named organizations were approved by MDHHS to be included in the proposed rule or how other organizations may be approved in the future.	DHHS has changed these rules to the following language: 206(4)(a)'...or a Corazon PCI/Catheterization program[.] and 206(4)(b) : or a Corazon chest pain center[.]
	Written	General regarding accreditation	Two significant concerns related to pursuing new accreditations, particularly when related to a regulatory requirement, are the cost burden to the hospital and the timeliness of being able to achieve accreditation.	No response needed.
	Written	R 330.206	Based on the information presented, Corazon, and our clients, request that in R 330.206 Paragraphs 6(4)(a) and 6(4)(b) be amended as follows to include Corazon PCI and CPC accreditations as recognized STEMI receiving and referral center accreditations, respectively, to proactively meet the requirements of the proposed rule, avoid confusion, and avert additional spending that could otherwise be necessary.	DHHS has changed these rules to the following language: 206(4)(a)'...or a Corazon PCI/Catheterization program[.] and 206(4)(b) : or a Corazon chest pain center[.]
Henry Kim, MD, MPH, FACC System Chief of Cardiology Henry Ford Health Division Head, Cardiology Frank and Barbara Darrin Chair Edith and Benson Ford Heart and Vascular Institute Henry Ford Hospital	Written	R 330.206	Amend Rule 6. (4) (a) to add "Corazon Cath/PCI Program" as an additional qualifying certifying and accrediting organization for a STEMI receiving center.	DHHS has changed these rules to the following language: 206(4)(a)'...or a Corazon PCI/Catheterization program[.] and 206(4)(b) : or a Corazon chest pain center[.]
Ryan J. Reece, MD, FACEP Assistant Professor of Emergency Medicine Hurley Medical Center Division University of Michigan	Written	General comment	There should be rules outlining methods to optimize the 'Chain of Survival'. In the realm of 'time-sensitive emergencies', there's trauma, STEMI, stroke, and cardiac arrest. All of these conditions' outcomes are directly related to timeliness in recognition, response, treatment, transporting to the most appropriate facility, and system QI/QA activities. For me, it makes sense to write in language related to cardiac arrest care in the STEMI rules as these conditions are often related.	Cardiac arrest is certainly an important condition that should be managed timely. There are already many stakeholders in the state engaged in addressing cardiac arrest (saveMIheart) that are invested in providing education (bystander CPR, ALS, BLS), AED's, collecting data (CARES registry), implementing protocol and guideline driven care. There will be many opportunities for the STEMI system to intersect and collaborate with these groups invested in caring for those patients who have experienced cardiac arrest, particular those ROSC (return of spontaneous circulation) patients. Unfortunately, national data from the 2020 CARES report (https://mycares.net/sitepages/uploads/2021/2020_flipbook/index.html?page=32 states that 42.4% of patients with cardiac arrest are pronounced at the scene after resuscitative efforts were terminated and of those that did survive to be transported to a hospital the rate of survival to hospital discharge as 9.0%. The investment in STEMI care that manages risk factors, requires prompt treatment, care and follow-up demonstrates a commitment to limiting the number of Michigan residents who experience cardiac arrest and a poor outcome.
Alex Bou Chebl , MD, FSVIN Director, Harris Comprehensive Stroke Center Director, Division Vascular Neurology Chair, System Stroke Council Henry Ford Health	Written	General comment	Henry Ford Health also recommends a more consistent use of the terms "council", "committee", and "subcommittee",	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	R 330.204	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.	Numbering error. This will be corrected in the final rule set.

Dr. Ivan Hansen, Medical Director of Cardiac Catheterization Laboratory at William Beaumont University Hospital, Corewell East	Public Hearing	General Questions and Answers	And are there any concerns about using that distinction for STEMI specifically since STEMI care involves considerably different resources than some of those other systems of care?	The other thing that we are very clear about saying is we understand the geography is porous, and that patients flow is, can be conscribed by that piece of geography. However, we needed a structure so that the groups can sit in some sort of an arranged fashion. So, that's why we added the layers to the preparedness region. So, the systems discuss care in their geography with a loose affiliation understanding patients can ebb and flow. And they can also talk amongst each other, the eight regions can talk to each other. They have an organizational structure like that.
	Public Hearing	General Questions and Answers	How is the advisory committee chosen?	An application. There are some titles that we'd like to see represented on those advisory committees and, once there are submitted applications, we will look at them all we'll appoint them by then.
	Public Hearing	General Questions and Answers	What you're saying is that in terms of going forward should this pass, then they'll be an application process for an advisory committee.	That's correct.
	Public Hearing	General Questions and Answers	What is the estimated overall cost of this proposal should it be implemented overall.	The budget is $3 million.
	Public Hearing	General Questions and Answers	And the cost of each participating center or...?	We don't charge a fee. We don't charge anything, and our plan is in the RFP for the data, the IT project is that data entry would be free for them. It would allow them access to our system for no charge. No charge to them, it will cost us money, not them.
	Public Hearing	General Questions and Answers	The program will be funded by taxpayer dollars or grant?	General Fund
	Public Hearing	General Questions and Answers	In the white paper, there was some verbiage to the effect that its recommended that participating hospitals or centers be accredited by both joint commission/AHA and ACC, did I understand that correctly?	It's either/or. Or an equivalent. But we wrote that, we hope, to establish a baseline for standards because without them, we have anything (inaudible) in terms of what somebody would say, this is a STEMI facility. So that was the design is to create a nationally recognized standards set, however, any entity that can provide that, or an equivalent, or the advisory body tells us this is equivalent, that will be something we would accept.
	Public Hearing	General Questions and Answers	What about centers in my region of Southeast Michigan where we have multiple STEMI centers. How would this regulation impact us?	Not much, in terms of delivery, once the resources are categorized, the pre-hospital world understands who has what resources, that is, a provider in the field at the minute decision about whether or not they get an airway, whether or not the closest appropriate is , you know, and I know the resources are at this particular building. That is something that protocol and the pre-hospital provider will have that information, that very important information, to deliver those services. And that's the fundamental reason to do this. Categorizing resources so the pre-hospital provider and the sending facility understands where to go down the road next. That's often a problem. Who has got the cath lab that's 24/7 that doesn't have an interventionalist that I need to send them to, especially in the far-flung areas where they don't necessarily know? It's built on relationships, not exactly understanding resources. So, categorizing those really makes it much simpler to make those decisions. And if things didn't go well, why not? Let's have a conversation in a RPSRO environment where we can have a good "why didn't it work and what can we do better"?
	Public Hearing	General Questions and Answers	For well-established centers that have been providing STEMI care for a long time, that choose not to participate in accreditation bodies, if this proposal passes, what, would there be some type of punitive action against those centers or how would that affect them?	Well, if we don't understand your resources, if you haven't told us they've been categorized by any entity, then, then it's a challenge for us, right? We don't understand what area you deliver, I like, you could be the cath lab that is only has, doing diagnostics and would we want to stay there or stop there? Not necessarily ideal for the patient. So, so that is a consideration. We are also very clear this is voluntary and inclusive. Those systems are highly functioning 100% of the time when everybody participates. However, it is every facility's decision whether or not they choose to participate. We cannot designate you, which is only something a state can do, so not only are you accredited but are designated by the State of Michigan as a particular level of facility. We can't do that unless we've had some sort of process that verifies you do have the resources that you say you do. So, this is an effort to codify what we already know what the trauma surgeons are very confident about, that they have to deliver those services. The other thing we want to do is to talk about it from a system perspective. The EMS provider already knows that appropriately. Did they get to right place, do they have the right resources, was the care delivery the way you hoped it would be? If not, why not? Talk to your group, talk to your mentors, talk to your other buildings systems, how can we do this
Rosalie Tocco Bradley, Chief Clinical Officer, Trinity Health	Written	330.206(4)(a) and (b)	Unless the Department or the Bureau has found gaps in the standards Corazonhas proposed, we request the proposed rule language be amended as follows: Rule 6. (4) (a) A STEMI receiving center shall provide evidence of current certification or accreditation by a department-approved nationally recognized professional certifying and accrediting organization that the healthcare facility has the resources required to be certified as meeting all the criteria for a certified STEMI receiving center equivalent to a **Corazon Cath/PCI Program,** or a TJC-AHA comprehensive STEMI center or TJC-AHA primary heart attack center, or an ACC chest pain center with PCI, or subsequent equivalent certification or accreditation as approved by the department with the advice of the STEMI advisory subcommittee, pursuant to R 330.204(13)(), and all the following: Rule 6. (4) (b) A STEMI referral facility shall provide evidence of current certification or accreditation by a department-approved nationally recognized professional certifying and accrediting organization that the healthcare facility has the resources required to be certified as meeting all the criteria for a certified STEMI referral	DHHS has changed these rules to the following language: 206(4)(a) ...or a Corazon PCI/Catheterization program[.] and 206(4)(b) : or a Corazon chest pain center[.]
Michael Church, Corazon	Written	General	Email forwarded comments from Karen Hartman President & CEO Corazon, Inc. and David H. Fuller Executive Vice President, Accreditation Corazon, Inc.-See their comments above.	No comment needed
David Walker, Corewell	Written	General Comment	Email forwarded comments from Dr. Joshua Kooistra and Natalie Baggio, Corewell-See their responses above.	No comment needed

August 21, 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: Additional Comments on the Statewide ST-Elevation Myocardial Infarction (STEMI) System (Rule Set 2022-61 HS) Draft Rule

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

Dear Ms. Brennan and Ms. Worden:

On behalf of Henry Ford Health, I am pleased to submit comments in response to the Michigan Department of Health and Human Services' draft rule for a Statewide STEMI System (Rule Set 2022-61 HS). **These comments are *in addition* to Henry Ford Health's letter dated July 31, 2023**, which was submitted in response to MDHHS' draft rules for both the Statewide 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 healthcare 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, with 1,900 physicians and researchers in more than 40 specialties.

As one of the oldest and most experienced cardiovascular programs in the nation, experts at Henry Ford Health specialize in advanced treatments for heart and vascular disease. Our team delivers comprehensive cardiovascular disease care, which includes expert diagnosis, innovative treatments, a team-based approach, advanced technology, and life-saving treatment. We provide treatment for all types of heart conditions, including some of the most complex conditions such as arrhythmias, coronary artery disease, heart failure, and structural heart disease. Our internationally renowned team has saved thousands of lives with over 100 years of cardiovascular care, and is pioneering new treatments that are increasing the quality of life for heart patients.

Henry Ford Health strongly supports establishment of a statewide STEMI system of care to promote the health and wellbeing of our patients throughout the state. Patients with a life-threatening STEMI condition have better survival rates when there is early detection and transport to an appropriate

facility. We are already committed to providing excellent patient care for STEMI and suspected STEMI patients and support a statewide system that will provide greater certainty for our patients, providers, first responders, and communities.

Henry Ford Health has maintained accreditation for interventional cardiology services through Corazon, Inc. for several years. Corazon is a national organization that provides accreditation and other services for several specialties including heart and vascular care. The organization is recognized by MDHHS under the existing Certificate of Need Review Standards for Cardiac Catheterization Services. As part of this ongoing accreditation, Corazon evaluates our STEMI protocols and ability to manage these patients effectively. Furthermore, Corazon requires quarterly reporting of outcomes data to ensure ongoing improvement efforts related to key metrics, including timely treatment of STEMI patients and whether the patient presents to our organization or is a candidate for transfer. In our experience, Corazon operates a robust accreditation process that requires high standards of our cardiovascular program and involves regular interactions beyond a simple data submission.

In reviewing the draft rule language, accreditation by a "department-approved nationally recognized professional certifying and accrediting organization" is required for STEMI receiving centers and referral facilities. However, while Corazon has been approved by the State for cardiac catheterization services, Corazon is not included as a qualifying certifying and accrediting organization in the Statewide STEMI System draft rule. We understand that Corazon has submitted information to the State to attest to their status as an equivalent accreditation organization to those named in the draft rule language. To support our cardiology operations, ensure continuity of patient care, and avoid confusion among our community members, emergency medical services providers, and other stakeholders, we are asking MDHHS to include Corazon as a qualifying certifying and accrediting organization in the administrative rule.

Specifically, we request the language in the rule be amended as follows:

- Amend Rule 6. (4) (a) to add "Corazon Cath/PCI Program" as an additional qualifying certifying and accrediting organization for a STEMI receiving center.
- Amend Rule 6. (4) (b) to add "Corazon Chest Pain Center" as an additional qualifying certifying and accrediting organization for a STEMI referral facility.

We appreciate your consideration of these modifications and thank you again for the opportunity to comment on this draft rule.

Sincerely,

Henry E. Kim MD, MPH, FACC
System Chief of Cardiology
Henry Ford Health
Division Head, Cardiology
Frank and Barbara Darin Chair
Edith and Benson Ford Heart and Vascular Institute
Henry Ford Hospital

25 August 2023

Department of Health and Human Services

Public Health Administration

Administrative Rules for Statewide ST-Elevation Myocardial Infarction (STEMI) System Rule Set 2022-61 HS

To whom it may concern:

On August 22nd, 2023, the American Heart Association shared feedback during the hearing on Rule Set 2022-61 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 believes the term "STEMI" should be replaced with the term "Heart Attack." STEMI is a medical term not often used or understood by the public. This includes the definition of STEMI receiving and STEMI referral, which should use other terms that hospitals may utilize to advertise themselves as providing STEMI/heart attack care, such as heart attack and chest pain center.

The Association believes any successful platform will integrate with Get with The Guidelines (GWTG)®. This includes exportation for STEMI data collection to GWTG®-Coronary Artery Disease.

R. 330.201

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

R 330.203

- (1)(a): Align the definition of PCI with the definition from the CON Review Standards for Cardiac Catheterization Services: "'Percutaneous coronary intervention' (PCI) means a therapeutic cardiac catheterization procedure to resolve anatomic and/or physiologic problems in the coronary arteries of the heart. A PCI session may include several procedures including balloon angioplasty, atherectomy, laser, stent implantation and thrombectomy. The term does not include the intracoronary administration of drugs, FFR or IVUS where these are the only procedures performed." (Page 3).
- (1)(k): For the "Statewide STEMI care advisory subcommittee," the Association believes a statement such as, "professional organization with expertise in STEMI systems of care like the American Heart Association" would be appropriate.
- (1)(m): Remove the word "comprehensive" in the definition of "Statewide STEMI system of care."
- (1)(p): Remove the words "education, risk reduction, and subacute." These actions seem to be beyond the scope of the administrative code and capabilities of the Bureau.

R 330.204

- (1)(e): The Association would like to see inclusion of TJC-AHA and/or a nationally recognized certifying body, as deemed by the Department.
- (4): We recommend additional criteria that would incorporate national standards, such as developing another registry and adopting national certification standards.

R 330.205

- This section would likely need to address protocols, data collection, and measures with CON requirements.

R 330.206

- (4)(a): AHA would like to see designation of Levels for the centers. This will allow for future development of the system of care—particularly for patients with STEMI that evolve to cardiac arrest and/or cardiogenic shock.
- (4)(a)(i): STEMI receiving facilities will need to comply with CON regulations, which are not mentioned here.
- (4)(b): The Association asks for the use of Levels when referencing facilities. This will allow for future development of the system of care—particularly for patients with STEMI that evolve to cardiac arrest and/or cardiogenic shock.

For any questions or follow-up, please contact:

Collin McDonough

Michigan Government Relations Director

American Heart Association

Collin.McDonough@heart.org

(231)675-4326

From: Ryan J. Reece, MD, FACEP
To: MDHHS-AdminRules
Subject: Comment on STEMI Admin Rules; Incorporating Cardiac Arrest Language
Date: Wednesday, July 26, 2023 11:15:08 AM

Greetings,

The STEMI system of care should incorporate best practices regarding cardiac arrest care. There should be rules outlining methods to optimize the 'Chain of Survival'. In the realm of 'time-sensitive emergencies', there's trauma, STEMI, stroke, and cardiac arrest. All of these conditions' outcomes are directly related to timeliness in recognition, response, treatment, transporting to the most appropriate facility, and system QI/QA activities. For me, it makes sense to write in language related to cardiac arrest care in the STEMI rules as these conditions are often related.

Here's a link to resources from the Resuscitation Academy (https://www.resuscitationacademy.org/); an organization whose mission is to improve cardiac arrest care.

https://drive.google.com/drive/folders/1L5S1Pdkh_CQm5vQLxCE4hCfbIy3cW5HV?usp=sharing

I'd be happy to talk more about these suggestions if that would be helpful. I, unfortunately, will be out of town on the day of the open meeting.

Best regards,

Ryan

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Ryan J. Reece, MD, FACEP
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University of Michigan
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August 25, 2023

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

Ms. Eileen Worden
State Trauma Manager
Bureau of Emergency Preparedness, EMS, and Systems of Care

Michigan Department of Health and Human Services
333 S. Grand Avenue
P.O. Box 30195
Lansing, MI 48909

Subject: Statewide STEMI System R 330.201 – R 330.230 ***(Pending Rule Set 2022-61 HS)***

Department Representatives,

Corazon is writing in support of our clients who are Michigan hospitals maintaining active cardiovascular accreditations with Corazon and to request minor changes to the pending administrative rule set 2022-61 HS regarding establishing a statewide STEMI system of care. Corazon supports the need for a statewide STEMI system of care to support the health and wellbeing of Michiganders by enhancing standardization and providing greater certainty for first responders and communities related to the care provided at hospitals across the state.

Corazon has long been an expert in the field of cardiovascular program development and management and is in its 10th year as an accrediting body for cardiovascular programs across the country. Corazon provides accreditation for interventional cardiology (PCI), Chest Pain Center (CPC), electrophysiology (EP), peripheral vascular intervention (PVI), open heart surgery (OHS), transcatheter aortic valve replacement (TAVR), and heart failure (HF) programs. Corazon accreditation services are endorsed by the Society for Coronary Angiography and Interventions (or SCAI), the leading non-profit medical society for invasive and interventional cardiology, founded in 1978. Additionally, **Corazon has been recognized by the Michigan Department of Health and Human Services (MDHHS) as an accrediting body under the existing CON Review Standards for Cardiac Catheterization Services since 2015**, demonstrating an ongoing commitment to the health and safety of patients and communities across this state. As an approved accrediting body, MDHHS has recognized Corazon's ability to comply with state requirements to monitor cardiovascular program quality.

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In addition to Michigan, Corazon has been recognized by other states that require ongoing oversight for various cardiovascular programs, including, but not limited to:

- Florida Agency for Health Care Administration: Since 2009, Corazon has supported hospitals pursuing Level I or Level II Licensure for Adult Cardiovascular Services through an attestation process.
- Georgia Department of Community Health: Since 2005, Corazon has been recognized as a third-party verification entity to confirm programs seeking to offer PCI services have met the requirements outlined in the applicable regulations.
- Pennsylvania Department of Health: Since 2013, Corazon has been recognized as a named accrediting body for PCI programs with offsite OHS backup, as required in the established PCI exception procedure language.
- New Jersey Department of Health: Since 2019, Corazon has been an approved third party to assist providers in developing performance improvement plans to maintain PCI services and comply with the state's defined quality requirements.
- Nationally, Corazon supports hospitals of all sizes in pursuing service expansion with an emphasis on ensuring program quality and compliance with all applicable regulatory requirements. For providers that elect to forego program accreditation, Corazon conducts assessments prior to program expansions to ensure readiness of the staff, adequacy of resources, and dedication to quality and patient safety.

Corazon has long recognized the importance of standardizing STEMI care by incorporating STEMI procedures and protocols into its current PCI and CPC accreditation standards. This includes the ability of hospitals to appropriately manage STEMI and suspected STEMI patients with an emphasis on timely identification, treatment, and evidence-based medical decisions. In addition to reviewing providers' standards and protocols, Corazon's PCI and CPC accreditations require quarterly submission of key clinical outcomes data, including indices related to the timely treatment or transfer of STEMI patients. As you are likely aware, "time is muscle" when it comes to treating STEMI patients, and the importance of these critical timeframes to achieve optimal outcomes has always been present in Corazon's accreditation standards.

Corazon's STEMI requirements are based on the same clinical guidelines and best practices as the other accrediting organizations that are named in the proposed rule, as well as Corazon's experience working with more than 750 hospitals across the country. In addition to Corazon's work as an accrediting body for the last 10 years, the firm has provided consultative services to support cardiovascular program development for more than 20 years. In its history, Corazon has supported more than 85 providers in the development of new PCI and STEMI programming.

The STEMI standards included in Corazon accreditation include requirements related to program readiness 24 hours per day, 7 days per week; access to emergency services; and the availability of cardiology expertise, as appropriate to the designated level of care. As part of its accreditation process, Corazon ensures medical providers maintain good standing and experience in line with current practice recommendations from medical societies. Corazon actively participates in ongoing quality improvement efforts, including

participation in quality meetings while onsite, validation of quality infrastructure, and ongoing quarterly review of program outcomes.

These requirements match or exceed what is included within the published standards of the two organizations named in the proposed rule as “department-approved nationally recognized professional certifying and accrediting organizations.” Despite this, and despite Corazon’s standing as an approved cardiovascular accrediting body by MDHHS, Corazon was omitted from the proposed rule language. In fact, the rule language includes no information as to how the named organizations were approved by MDHHS to be included in the proposed rule or how other organizations may be approved in the future.

This omission has already created confusion among Corazon’s Michigan accredited programs in terms of what the differences will be between the proposed STEMI accreditation and their current PCI accreditation which already includes the necessary quality and safety monitoring required for STEMI patients. There are also concerns related to confusion this may cause within the communities served by these providers, with EMS providers in the state, and possibly even within MDHHS as to the good standing of these programs if Corazon accreditation is not proactively recognized. In speaking with our Michigan-based accreditation clients, we collectively want to be assured there will be no additional financial or procedural burden placed on them by requiring an additional accreditation beyond what they already maintain.

Similarly, it is important to note that Corazon accreditation does not require participation in a specific registry, but can use internal data points or available information from any registry a hospital participates in. This approach better positions Corazon accreditation to comply with the proposed rule, as the registry and data collection requirements have not yet been defined. Additionally, this allows Michigan providers to avoid additional cost burdens for programs that may not otherwise need to participate in additional registries. For example, providers may manage CPC outcomes through an internal dashboard, particularly for a STEMI referral center, while others may already have the required information available through the Michigan BMC2 registry. From our understanding, the Michigan BMC2 registry is not currently recognized by the other named accrediting bodies but would be recognized by Corazon.

Two significant concerns related to pursuing new accreditations, particularly when related to a regulatory requirement, are the cost burden to the hospital and the timeliness of being able to achieve accreditation. Corazon has a history of working with providers to ensure cost effective accreditation services are available based on the size and scope of the program under review, while also highlighting cost savings opportunities for hospitals that can be realized with improved efficiencies through the accreditation process. Historically, Corazon’s wait time to schedule an onsite survey averages just 2 to 4 weeks, compared to other organizations which may have survey backlogs of 6 months or longer. Corazon also works with providers to achieve accreditation readiness in the shortest feasible timeframe, while ensuring quality of care and the ability to demonstrate compliance with all accreditation standards.

Corazon maintains a national accreditation client base and has the capacity to accredit any and all of the Michigan providers affected by the proposed rule. Corazon currently accredits 23 hospitals in Michigan for PCI or CPC services, representing 23 facilities who would not have to seek an additional accreditation if Corazon is proactively recognized under the proposed rule. While Corazon's complete client list is not available publicly, many programs accredited by Corazon, within Michigan and across the country, are part of major health systems. A sample of the health systems utilizing Corazon accreditation includes the following organizations::

Michigan:

- Ascension
- Corewell Health
- Henry Ford Health System
- McLaren Health Care Corporation
- Michigan Medicine
- MyMichigan Health
- Prime Healthcare
- Trinity Health
- Independent Hospitals

Nationwide:

- AdventHealth
- Adventist Health
- Allegheny Health Network
- Atrium Health
- Community Health Systems
- HCA Healthcare
- LifePoint Health
- Main Line Health
- Penn Highlands Healthcare
- Prime Healthcare
- Trinity Health
- UNC Health Care
- UPMC
- WellSpan Health
- WVU Medicine
- Independent Hospitals

Corazon monitors critical quality metrics for all accredited programs. Corazon evaluated key performance metrics (e.g., major adverse events, percent of patients receiving PCI within 90 mins, etc.) among its Michigan PCI accreditation clients from 2015 to 2022. This review demonstrated improvement by **all Corazon accreditation clients** in at least one key metric since achieving its accreditation through Corazon. Additionally, 91% report performance in the 90th percentile nationally for **multiple key metrics**. Finally, 84% of **all**

individual metrics tracked across all Corazon-accredited PCI programs in Michigan have improved **since initiating accreditation with Corazon**. Similar improvements have been realized by Corazon's clients outside of Michigan as well. These outcomes demonstrate the positive impact Corazon accreditation has on the delivery of patient care.

Some of Corazon's Michigan accreditation clients have submitted comments as well supporting the assertion that Corazon be recognized in the proposed rule. Those that have been shared with Corazon are attached to this document.

Through preliminary discussions with representatives from the Bureau of Emergency Preparedness, EMS, and Systems of Care within MDHHS, Corazon shared its current standards for PCI and CPC accreditation, summaries of which are attached hereto. Corazon received positive feedback that these would meet or exceed the goals of the proposed rule.

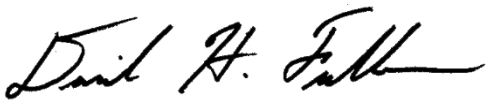
Based on the information presented, Corazon, and our clients, request that in R 330.206 Paragraphs 6(4)(a) and 6(4)(b) be amended as follows to include Corazon PCI and CPC accreditations as recognized STEMI receiving and referral center accreditations, respectively, to proactively meet the requirements of the proposed rule, avoid confusion, and avert additional spending that could otherwise be necessary:

> Rule 6. (4) (a) A STEMI receiving center shall provide evidence of current certification or accreditation by a department-approved nationally recognized professional certifying and accrediting organization that the healthcare facility has the resources required to be certified as meeting all the criteria for a certified STEMI receiving center equivalent to a Corazon Cath/PCI Program, or a TJC-AHA comprehensive STEMI center or TJC-AHA primary heart attack center, or an ACC chest pain center with PCI, or subsequent equivalent certification or accreditation as approved by the department with the advice of the STEMI advisory subcommittee, pursuant to R 330.204(1)(l), and all the following:
>
> Rule 6. (4) (b) A STEMI referral facility shall provide evidence of current certification or accreditation by a department-approved nationally recognized professional certifying and accrediting organization that the healthcare facility has the resources required to be certified as meeting all the criteria for a certified STEMI referral facility equivalent to a Corazon Chest Pain Center, or a TJC-AHA acute heart attack ready center or ACC non-PCI chest pain center or subsequent equivalent certification or accreditation as approved by the department with the advice of the STEMI advisory subcommittee, pursuant to R 330.204(1)(l), and all the following:

If needed, Corazon would be happy to provide additional information to MDHHS to verify the standards included in PCI and CPC accreditation related to STEMI patient care.

We appreciate your attention to this matter and look forward to the positive impact this system of care can have on patients across the state.

Sincerely,



Karen Hartman
President & CEO
Corazon, Inc.
5000 McKnight Road, Suite 300
Pittsburgh, PA 15237

David H. Fuller
Executive Vice President, Accreditation
Corazon, Inc.
5000 McKnight Road, Suite 300
Pittsburgh, PA 15237

CC: Elizabeth Hertel, Department of Health and Human Services Director
Sarah Lyon-Callo, Senior Deputy Director of Public Health Administration
Jay Fiedler, State Bureau Administrator
David Knezek, Chief Deputy Director of Administration

CORAZON PCI ACCREDITATION STANDARDS SUMMARY

Corazon interventional cardiology (PCI) Accreditation validates a hospital's compliance with the most recent and relevant national society guidelines for the provision of interventional cardiology services. Corazon Accreditation includes an onsite survey to observe and measure program operations as well as routine data review to ensure quality metrics are maintained.

Corazon standards are based on both societal guidelines and Corazon's experience with a multitude of programs across the country. The following list is a summary of Corazon PCI Accreditation standards to be evaluated for each program:

- Pre-hospital care evaluation (in the field evaluation of chest pain/STEMI population, review of formal agreements with pre-hospital providers, pre-hospital metric evaluation, etc.).
- Governance and leadership of the PCI program, including, but not limited to, the medical director of the PCI program, multi-disciplinary team (which may include ED physicians and nursing personnel), pre-hospital providers, Cath Lab Manager/Director, STEMI Coordinator, Data Abstractor, and other key personnel.
- Formal Heart Team approach for all patients in need of a coronary intervention.
- Demonstrated quality infrastructure, including a formal continuous quality improvement (CQI) initiative and policies to track and monitor program and patient outcomes, including a formal door-to-balloon (D2B) or STEMI committee for real-time feedback for that patient population.
- All policies, procedures, protocols, order sets, and patient algorithms associated with the provision of PCI services.
- Appropriateness of equipment and supplies and the ability to appropriately manage patients for the timely completion of any additional testing for clinical decision making.
- Randomly identified PCI patient charts, including elective, urgent, and emergent (STEMI) patients presenting in the ED or in-house or transferred from a non-primary PCI center.
- Comprehensive education plan for clinical nursing departments and non-clinical staff.
- All community outreach efforts (education forums, pre-hospital collaboration, etc.).
- Availability of non-invasive testing, the process for scheduling, and hours of availability.

- Critical timing metrics specific to the STEMI and nSTEMI patient populations (e.g. critical lab tests, door to ECG, D2B, door to door transfer, door to fibrolytic therapy, etc.).
- Way finding specific to the cardiac, PCI, and STEMI patient populations across the facility.
- Formal patient follow up processes for patients treated at the PCI center.

CORAZON CHEST PAIN CENTER ACCREDITATION STANDARDS SUMMARY

Corazon Chest Pain Center (CPC) Accreditation validates a hospital's compliance with the most recent and relevant national society guidelines for the management of low, moderate, and acute chest pain patients. Corazon Accreditation includes an onsite survey to observe and measure program operations as well as routine data review to ensure quality metrics are maintained.

Corazon standards are based on both societal guidelines and Corazon's experience with a multitude of programs across the country. The following list is a summary of Corazon CPC Accreditation standards to be evaluated for each program:

- Pre-hospital care evaluation (in the field evaluation of chest pain population, review of formal agreements with pre-hospital providers, pre-hospital metric evaluation, etc.).
- Governance and leadership of the CPC, including, but not limited to, the medical director of the CPC, Chest Pain or STEMI Coordinator, Data Abstractor, and other key personnel.
- Demonstrated quality infrastructure, including a formal continuous quality improvement (CQI) initiative and policies to track and monitor program and patient outcomes.
- All policies, procedures, protocols, order sets, and patient algorithms associated with the CPC.
- Appropriateness of equipment and supplies and the ability to appropriately manage patients for the timely completion of any additional testing for clinical decision making.
- Randomly identified chest pain patient charts.
- Comprehensive education plan for clinical nursing departments and non-clinical staff.
- All community outreach efforts (education forums, pre-hospital collaboration, etc.).
- Availability of non-invasive testing, the process for scheduling, and hours of availability.
- Critical timing metrics specific to the chest pain patient (e.g. critical lab tests, door to ECG, door to balloon, door to transfer, door to fibrolytic therapy, etc.).
- Way finding specific to the chest pain patient population across the facility.
- Formal patient follow up processes for patients treated at or transferred from the CPC.

Corazon Cardiovascular Accreditation Services

Description	Chest Pain Center (CPC) Accreditation	Interventional Cardiology (Cath/PCI) Accreditation	Open Heart Surgery (OHS) Accreditation	Cardiovascular Service Line of Excellence (CV SLoE) Accreditation

Accreditation Overview	CPC Accreditation focuses on pre-hospital care and response, triage, diagnosis, patient navigation, and coordination of resources. Hospitals qualify for this accreditation by providing care for patients presenting with the following:
	• Acute Coronary Syndrome (ACS)
	• ST Elevation Myocardial Infarction (STEMI) (formal STEMI transfer protocols are required if PCI not offered)
	• nSTEMI patients with care pathways for non-invasive strategies
	• STEMI with lytic therapy (if/when indicated)
	• Low risk chest pain
	• Transfer protocols to a higher level of care if needed
	
	Cardiac Intervention is not required to achieve Corazon CPC accreditation.
		Cath/PCI Accreditation evaluates the care provided to interventional cardiology patients, including emergent, urgent, and elective procedures. Hospitals qualify for this accreditation by providing the following:
		• Diagnostic Cardiac Catheterization
		• Elective and Primary (emergent) Cardiac Intervention
		• Management of Cardiogenic Shock Patients (may include transfer to a tertiary provider)
		• Management of patients requiring hemodynamic stabilization (insertion of IMPELLA or IABP)
		• Cardiac Rehabilitation Services (onsite or through a partner entity)
			OHS Accreditation evaluates the care provided to cardiac surgery patients, including emergent, urgent, and elective procedures. Hospitals qualify for this accreditation by providing the following:
			• Cardiac Surgery Procedures
			  ○ CABG,
			  ○ Surgical Valve Repair/ Replacement
			• Perfusion Services
			• Full Respiratory Services
			• Full Laboratory Services
			• Blood Bank (onsite)
			• Onsite Cardiac Rehabilitation Services
				Cardiovascular Service Line of Excellence Accreditation is awarded to any program achieving three (3) or more accreditations through Corazon. It attests to the quality of care being provided across that hospital's cardiovascular services. Three of the following must be accredited:
				• Open Heart Surgery
				• Cath/PCI
				• Chest Pain Center
				• Peripheral Vascular Intervention (PVI)
				• Electrophysiology
				• Transcatheter Aortic Valve Replacement (TAVR)

Corazon Cardiovascular Accreditation Services

Program Requirements	CPC Accreditation requires: • Patient selection criteria and risk stratification consistent with current standards • Collaborative agreement with a nearby OHS program (if not also providing OHS onsite) • Standards and documentation of training and competency of all key clinical staff • Hospital requirements for credentialing of participating physicians • Availability of the service 24/7/365 • Emergency care protocols to ensure rapid treatment • Availability of MI Registry reports or equivalent data on a quarterly basis • Outcomes which meet or exceed the 50th percentile for key metrics • Continuous quality improvement initiative, including key outcomes • Adequate policies, procedures, and documentation • Appropriateness of available equipment and supplies • Ability to successfully manage dry-run test patient scenarios	Cath/PCI Accreditation requires: • Patient selection criteria and risk stratification consistent with current standards • Collaborative agreement with an OHS program within 60 minutes (if not providing OHS onsite) • Vascular surgery back up (either onsite or protocols for immediate transfer, if indicated) • Standards and documentation of training and competency of all key clinical staff • Hospital requirements for credentialing of participating physicians • Availability of the service 24/7/365 • Emergency care protocols to ensure rapid treatment • Collaborative structure evidenced by a Heart Care Team approach • Availability of Cath/PCI Registry reports or equivalent data on a quarterly basis • Outcomes which meet or exceed the 50th percentile for key metrics • Continuous quality improvement initiative, including key outcomes	OHS Accreditation requires: • Patient selection criteria and risk stratification consistent with current standards • Standards and documentation of training and competency of all key clinical staff • Hospital requirements for credentialing of participating physicians • Availability of the service 24/7/365 • Emergency care protocols to ensure rapid treatment • Collaborative structure evidenced by a Heart Care Team approach • Availability of STS Registry reports or equivalent data on a quarterly basis • Outcomes which meet or exceed the 50th percentile for key metrics • Continuous quality improvement initiative, including key outcomes • Adequate policies, procedures, and documentation • Appropriateness of available equipment and supplies	CV SLoE Accreditation requires: • Accreditation of the most complex cardiovascular service offered (i.e. OHS or Cath/PCI) • Accreditation of a total of three (3) cardiovascular services • Maintain “good standing” in all accreditations

		• Adequate policies, procedures, and documentation • Appropriateness of available equipment and supplies • Ability to successfully manage dry-run test patient scenarios	• Ability to successfully manage dry-run test patient scenarios	
Case Review Requirements	• Review of 6 random charts during the onsite survey to represent various chest pain patient types	• Review of 10 random charts and direct case observation (if feasible) during the onsite survey • Review of 20 cases by a physician reviewer for appropriateness and documentation	• Review of 10 random charts and direct case observation during the onsite survey • Review of 20 cases (CABG and/or valve) by a physician reviewer for appropriateness and documentation	• Completed through individual accreditations as applicable
Accreditation Touchpoints	• Initial planning call to schedule survey • Onsite survey and exit presentation (including outcome of survey) • Participation in quality forum meeting during onsite survey • Quarterly calls to review outcomes data • Quarterly Accreditation Client Forum call participation (optional) • Re-accreditation survey every two (2) years	• Initial planning call to schedule survey • Onsite survey and exit presentation (including outcome of survey) • Participation in quality forum meeting during onsite survey • Feedback following physician case review • Quarterly calls to review outcomes data • Quarterly Accreditation Client Forum call participation (optional) • Re-accreditation survey every two (2) years	• Initial planning call to schedule survey • Onsite survey and exit presentation (including outcome of survey) • Participation in quality forum meeting during onsite survey • Feedback following physician case review • Quarterly calls to review outcomes data • Quarterly Accreditation Client Forum call participation (optional) • Re-accreditation survey every two (2) years	• All scheduled touchpoints through each individual accreditation • Up to eight (8) hours per year of consultative support (participation in meetings, data analysis, or other program needs)

Corazon Cardiovascular Accreditation Services

Heart Attack Systems of Care Equivalency	Corazon CPC Accreditation is typically consistent with a Level III heart attack/STEMI referring hospital as described in the Systems of Care for ST-Segment-Elevation Myocardial Infarction: A Policy Statement from the American Heart Association which focuses on timely reperfusion therapies for STEMI, NSTEMI, and other life-threatening, time-sensitive cardiac emergencies.	Corazon Cath/PCI Accreditation is typically consistent with a Level II heart attack/STEMI receiving hospital as described in the Systems of Care for ST-Segment-Elevation Myocardial Infarction: A Policy Statement from the American Heart Association which focuses on timely reperfusion therapies for STEMI, NSTEMI, and other life-threatening, time-sensitive cardiac emergencies. Corazon does not require minimum volumes for accreditation, unless required for compliance with state regulations.	OHS Accreditation is typically consistent with a Level I heart attack/STEMI receiving hospital as described in the Systems of Care for ST-Segment-Elevation Myocardial Infarction: A Policy Statement from the American Heart Association which focuses on timely reperfusion therapies for STEMI, NSTEMI, and other life-threatening, time-sensitive cardiac emergencies. Corazon does not require minimum volumes for accreditation, unless required for compliance with state regulations. Corazon does not require ECMO or LVAD, however they will be evaluated if offered by the facility.	CV SLoE Accreditation can apply to a variety of heart attack center descriptions depending on the services accredited within that facility.

August 22, 2023

Elizabeth Hertel, Director
Department of Health and Human Services

Sarah Lyon-Callo, Senior Deputy Director
Public Health Administration

Jay Fiedler, State Bureau Administrator
Eileen Worden, Systems of Care Manager
Bureau of Emergency Preparedness, EMS, and Systems of Care

333 S. Grand Avenue
P.O. Box 30195
Lansing, MI 48909

Subject: Statewide STEMI System R 330.201 – R 330.230 ***(Pending Rule Set 2022-61 HS)***

Department Representatives,

I am writing on behalf of Trinity Health Michigan regarding the pending administrative rule set 2022-61 HS regarding establishing a statewide STEMI system of care. Our organization strongly supports the need for this type of system of care for the health and wellbeing of Michiganders across our state. We are already committed to providing excellent patient care for STEMI and suspected STEMI patients and support a system which will provide greater certainty for our first responders and communities related to the care they receive.

In fact, it is our existing commitment to STEMI and other cardiovascular care that is the reason for this letter. Trinity Health Michigan has maintained accreditation for interventional cardiology services through Corazon, Inc. for several years. Corazon is recognized by the Michigan Department of Health and Human Services under the existing CON Review Standards for Cardiac Catheterization Services. As part of this ongoing accreditation, Corazon evaluates our STEMI protocols and ability to manage these patients effectively. Furthermore, Corazon requires quarterly reporting of outcomes data to ensure ongoing improvement efforts related to key metrics, including timely treatment of STEMI patients, whether the patient presents to our organization or is a candidate for transfer.

In reviewing the proposed rule language, accreditation by a “department-approved nationally recognized professional certifying and accrediting organization” is required. While Corazon has been approved by the Department previously for Cardiac Catheterization Services, Corazon is not named in the proposed statewide STEMI system

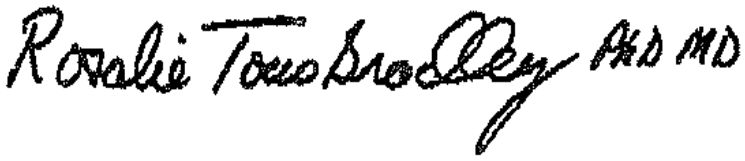
rule. To avoid confusion, and based on our organization's experience with Corazon and the standards they require of our current cardiovascular program, Corazon should be named under the proposed administrative rule. Otherwise, this could cause confusion within our community, with the Emergency Medical Services providers in our region, and even with the Department as to the good standing of our program.

In further discussion with Corazon, we understand they have submitted information to the Bureau of Emergency Preparedness, EMS, and Systems of Care to attest to their status as an equivalent accreditation organization to those named in the proposed rule language. Unless the Department or the Bureau has found gaps in the standards Corazon has proposed, we request the proposed rule language be amended as follows:

> Rule 6. (4) (a) A STEMI receiving center shall provide evidence of current certification or accreditation by a department-approved nationally recognized professional certifying and accrediting organization that the healthcare facility has the resources required to be certified as meeting all the criteria for a certified STEMI receiving center equivalent to a Corazon Cath/PCI Program, or a TJC-AHA comprehensive STEMI center or TJC-AHA primary heart attack center, or an ACC chest pain center with PCI, or subsequent equivalent certification or accreditation as approved by the department with the advice of the STEMI advisory subcommittee, pursuant to R 330.204(1)(l), and all the following:
>
> Rule 6. (4) (b) A STEMI referral facility shall provide evidence of current certification or accreditation by a department-approved nationally recognized professional certifying and accrediting organization that the healthcare facility has the resources required to be certified as meeting all the criteria for a certified STEMI referral facility equivalent to a Corazon Chest Pain Center, or a TJC-AHA acute heart attack ready center or ACC non-PCI chest pain center or subsequent equivalent certification or accreditation as approved by the department with the advice of the STEMI advisory subcommittee, pursuant to R 330.204(1)(l), and all the following:

We appreciate your attention to this matter and look forward to the positive impact this system of care can have on patients across the state.

Sincerely,



Rosalie Tocco Bradley, PhD, MD, MHSA
Chief Clinical Officer, Trinity Health Michigan

August 25, 2023

Mary Brennan
Eileen Worden
Michigan Department of Health & Human Services
Bureau of Emergency Preparedness, EMS, & Systems of Care
1001 Terminal Road
Lansing, Michigan 48906

Submitted Electronically

Re: Administrative Rules for Statewide ST-Elevation Myocardial Infarction (STEMI) System R 330.201 – R 330.230 [Rule Set 2022-61 HS]

Dear Ms. Brennan and Ms. Worden,

Corewell Health appreciates the opportunity to provide comments on the pending Administrative Rules for Statewide ST-Elevation Myocardial Infarction (STEMI) System rule set (2022-61). Corewell Health is a Michigan-based not-for-profit integrated health system with a team of 60,000+ dedicated people including more than 11,500 physicians and advanced practice providers and more than 15,000 nurses providing care and services in 22 hospitals, 300+ outpatient locations and several post-acute facilities. In addition, as an integrated health system, Corewell Health includes Priority Health, a health plan that insures more than 1.2 million lives. Corewell Health is not only Michigan's largest health system but also Michigan's largest private employer. Through experience and collaboration, we are reimagining a better, more equitable model of health and wellness.

Corewell Health appreciates and thanks the Michigan Department of Health and Human Services (MDHHS) for putting these proposed rules forward. We recognize the significant amount of work and collaboration required to draft proposed rules and particularly appreciate the thoughtful effort to build off of existing structures to accomplish the intent of the STEMI rules.

Corewell Health has been and remains committed to providing exceptional patient care for STEMI and suspected STEMI patients and are concerned that the accreditation requirements included in the rule set may have some potential unintended consequences. Specifically, we find the following requirements and provisions burdensome: 1) requiring STEMI receiving **AND** referral centers to obtain certification or accreditation by nationally recognized professional organizations, 2) the language surrounding accreditation organizations, and 3) the overarching burden some of the requirements will place on some of our smaller/rural facilities.

Receiving and Referral Facilities - R 330.206 Rule 6(4)(b)

The process of obtaining and maintaining certification or accreditation from MDHHS-approved organizations adds a significant administrative burden to healthcare facilities, without evidence such accreditation would enhance the quality of care provided. The accreditation process often involves extensive documentation and site visits taking away valuable staff time and resources that could be better utilized delivering patient care and improving outcomes.

In the current state, significant time and resources are already invested in setting up and running these programs. Corewell Health participates in quality outcome registries such as BMC2 and the National Cardiovascular Data Registry (NCDR), which demonstrates our commitment to

maintaining high standards of care. Adding another layer of accreditation further diverts resources away from patient care and potentially hinders innovation and improvement efforts. Further, these registries already support many STEMI quality metrics, and it is difficult to imagine why a duplicative registry would be necessary.

Additionally, healthcare facilities already have comprehensive cardiovascular surgery programs with stringent requirements. These requirements ensure the necessary resources and expertise are in place to handle complex cases, including cardiac surgeries. **Requiring additional accreditation for cardiac catheterization (cath) labs and chest pain centers could be redundant and not necessarily indicative of improved patient outcomes.**

Furthermore, an additional unanticipated outcome is the incorporation of STEMI treatment under the Chest Pain category within the framework of the accreditation process. This policy will redirect ambulance transfers away from facilities lacking accreditation, channeling them exclusively to accredited establishments. Consequently, this may induce a concentration of chest pain cases solely within accredited hospitals, potentially creating an advantage for one emergency department while placing undue strain on another and excluding a third. **While this tactic may be effective for handling trauma and stroke cases, it neglects to recognize that not all occurrences of chest pain inherently indicate a STEMI event.**

Finally, requiring **referral** facilities to obtain accreditation is a costly proposal. We at Corewell Health have numerous rural facilities that are already sending STEMI and suspected STEMI patients to facilities that would or potentially qualify as receiving centers. Requiring a facility, especially rural facilities, to obtain accreditation may make this designation unobtainable. **Ultimately, if rural facilities are unable to obtain accreditation, they will continue to send STEMI and STEMI-suspected patients to STEMI receiving centers without participating in the system this rule set proposes.**

Accrediting Bodies Language - R 330.206 Rule 6(4)(a); R 330.206 Rule 6(4)(b); R 330.206 Rule 6(5); R 330.206 Rule 6(6)

Corewell Health appreciates the Bureau of Emergency Preparedness, EMS, and Systems of Care's efforts to offer broad language related to approved accrediting bodies. We also understand that no final decisions have been made related to the accrediting bodies. **However, we believe that the Corazon accreditation should be recognized as a valid and valuable alternative, for facilities without on-site Open-Heart Surgery (OHS) services.** This accreditation might be more appropriate for certain facilities to acknowledge their unique strengths and areas of expertise. Recognizing a broader range of accreditations, for facilities without on-site OHS services, may also encourage diversity in quality improvement and patient care approaches.

Additionally, the MDHHS Certificate of Need, Evaluation Section has approved Corazon previously for Cardiac Catheterization Services so it should be listed for consistency. Otherwise, this could cause confusion within our community and with the Emergency Medical Services (EMS) providers in our region.

Corewell Health welcomes and appreciates the Bureau of Emergency Preparedness, EMS, and Systems of Care including the ACC as an approved accrediting body. We strongly support this requirement being finalized in addition to adding Corazon for facilities without on-site OHS services.

Administrative Burden – R 330.201 – R 330.214

Finally, many health care facilities already have mature, comprehensive cardiovascular surgery programs with stringent requirements. These requirements ensure the necessary resources and expertise are in place to handle complex cases, including cardiac surgeries. Requiring additional accreditation for cath labs and chest pain centers could be redundant and not necessarily indicative of improved patient outcomes. Facilities with mature on-site Open OHS services already possess a higher level of readiness to handle complex cases. OHS services ensure that emergency interventions can be carried out promptly. **Therefore, it might be worth reconsidering the need for additional cath lab or chest pain center accreditation for such facilities, as the existing capabilities align with STEMI care goals.**

While the intent of the rule is to ensure high standards of care for STEMI patients, it is crucial to recognize the potential drawbacks and unintended consequences of implementing such a requirement. The healthcare landscape is diverse, and a one-size-fits-all approach to accreditation may not be the most effective way to achieve better patient outcomes. Instead, a more flexible and inclusive process, considering established programs, specialized accreditations, and on-site OHS services, could better serve the interests of both healthcare providers and patients. In short, these rules add another layer of cost and complexity to continue doing what we are already doing, in mature programs. These rules only add cost and complexity in an industry faced with financial challenges and rising costs. Importantly, this ultimately negatively impacts the patient as we will be forced to divert limited resources (time/money/labor) to comply with the proposed rules.

Sincerely,

Dr. Joshua Kooistra
Chief Medical Officer
Corewell Health West

Natalie L. Baggio
SVP, Patient Care Services
Corewell Health South

Brennan, Mary (DHHS)

From: Michael Church <mchurch@corazoninc.com>
Sent: Friday, August 25, 2023 12:38 PM
To: MDHHS-AdminRules
Cc: Karen Hartman; David Fuller; Amy Newell
Subject: Corazon Comments on Statewide STEMI System R330.201-R330.230
Attachments: Corazon Written Comments - MDHHS STEMI.pdf

Department Representatives,

Please find attached Corazon's comments regarding the proposed rule set R330.201-R330.230 regarding the establishment of a statewide STEMI system of care, as well as supporting documentation related to our requested revisions. Please let us know when this is received and if there are any questions or if any additional information is needed. We look forward to the next steps in this approval process.

Warm regards,

Mike

Michael Church
Director
Corazon, Inc.
Named 'A Best Place to Work' in Healthcare

5000 McKnight Road, Suite 300
Pittsburgh, PA 15237
T: (412) 364-8200 x153 F: (412) 364-8201

Corazon is proud to officially announce our partnership with the Society for Cardiovascular Angiography and Interventions. SCAI's endorsement of Corazon Accreditation serves as a seal of approval to our long-standing best practices. Check out the press release here and contact us today to learn more!

From:	Walker, Dave A.
To:	MDHHS-AdminRules
Subject:	Comment Letter on Rule Set 2022-61 HS - Administrative Rules for Statewide ST-Elevation Myocardial Infarction (STEMI) System
Date:	Friday, August 25, 2023 4:51:16 PM
Attachments:	image001.png FINAL Corewell Health STEMI Comment Letter.pdf

Good afternoon,

Please find attached a comment letter on Rule Set 2022-61 HS - Administrative Rules for Statewide ST-Elevation Myocardial Infarction (STEMI) System. Should you have any questions or need anything else, please do not hesitate to contact me. Please confirm receipt of this email. Have a great weekend!
Best,
Dave

David A. Walker, MPA
(He/him/his)
Government Affairs Advisor

616.391.2043 Direct
202.821.8217 Cell (preferred)
corewellhealth.org

Corewell Health™

100 Michigan Street NE | MC065
Grand Rapids, MI 49503

From: Frank Ryan
To: MDHHS-AdminRules
Subject: STEMI Systems of care comments
Date: Friday, August 25, 2023 4:59:15 PM

Dear Ms. Brennan and Ms. Worden/Michigan Department of Health & Human Services:
Below please find comments from the Michigan Chapter of the American College of Cardiology on STEMI Systems of Care.
Sincerely,
Frank Ryan

AMERICAN COLLEGE of CARDIOLOGY
Frank Edward Ryan, JD
Senior Advisor, State Government Affairs
American College of Cardiology
240-620-9352 fryan@*ACC*.org www.*ACC*.org

The American College of Cardiology (ACC) and the Michigan Chapter of the American College of Cardiology (MI-ACC) appreciate the opportunity to comment on the Department of Health & Human Services proposed rule for establishing a STEMI systems of care framework that includes facilities designation.
MI-ACC has a proud history of working with Michigan policymakers, stakeholders, and patient advocacy groups, such as the American Heart Association, to increase access to timely, quality, emergency care for heart attack patients.
The proposed rule reflects best practices for patient safety and quality care delivery and will go a long way to improve outcomes for cardiovascular patients and we look forward to working with MI-HHS and stakeholders to implement them.
Accordingly, moving forward, we want to ensure that changes to the system do not produce duplication of tasks. For example, Rule 5 calls for *implementation of an "all-inclusive STEMI system throughout this state that allows for the care of all STEMI patients in an integrated system of healthcare in the pre-hospital and healthcare facility environments by personnel that are well trained and equipped to care for STEMI patients."* Allowing the use of an existing national data collection tool to be substituted for developing one de novo would prevent task duplication to the benefit of patients and practices. This also applies to Rule 9 (1) – which calls for a new, statewide registry. (See NCDR Natl CV Data Reg)
We are available to answer questions and provide additional information. Thank you for your commitment to improving cardiovascular health for all Michiganders.

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
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Director, Division Vascular Neurology
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