TRANSCRIPT

2022-61 HS-STATEWIDE STEMI SYSTEM

August 22, 2023

1:00 p.m. – 4:00 p.m.

EILEEN WORDEN: Good afternoon. I am Eileen Worden, Section Manager of the. We're here this afternoon on the Statewide STEMI rules. I'd like to introduce my colleagues.

RAO: Good afternoon. I'm Mary Brennan, Regulatory Affairs Officer for the Department of Health, and Human Services. Emily?

EMILY BERQUIST: Emily Berquist, State Division Administrator, Systems of Care - Stroke and STEMI

AARON BROWN: Good afternoon, Aaron Brown, Systems of Care Coordinator.

KATELY SCHLABLE: Good afternoon. Katelyn Schlable, Department Manager, Systems of Care - Stroke and STEMI.

RAO: We are on the record today for MOAHR rule case number 2022-61 HS Statewide STEMI System. If you haven't signed in for this session, please do so before you leave today.

Some housekeeping matters: the restrooms are out the door, take a left, go down the ramp and make another quick left. If you would like to give testimony, please come up and speak at the podium. I will ask you to spell your name for purposes of the rule package. Your testimony will be recorded for purposes of a transcript. If you do not want to make a public comment, but just ask questions, you may do so, but the questions and answers will not become part of the record unless you want them to be.

For your convenience, I have placed two items on the board behind me. The first is the email box to send comments in the event of a 3:00 a.m. epiphany and you forgot to tell us. That is MDHHS-Adminrules-all one word- at michigan.gov. The second is the rule status website at the Administrative Rules Division LARA website: Https://ars.apps.lara.state.mi.us. Comments to the email box closes on Friday.

If there are no questions, let's begin. If anyone wishes to make a comment, please come forward.

DR. ABED ASFOUR: Good afternoon. My name is Dr. Abed Asfour. I am an interventionalist cardiologist for the last 21 years and, just to give you context of why I come here, I've been involved in STEMI programs for the last 21 years. I started two STEMI programs and one elective PCI without surgical backup. I take between five to ten days of calls for STEMI. This is

dear to me, and I work out of many, many hospitals. I am currently representing Corewell Health East and West and I appreciate the time of the committee and everybody here to address this. I'm going to address two sets of hospitals here: 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.

Corewell Health has rural hospitals in Big Rapids, Reed City, Ludington, Pennock, and a few other, and we have multiple open heart surgery hospitals between the west and the east of the State, and I feel like every one of them will be affected. I want to start with the rural hospital concept because these are safety net and, despite their size, these hospitals are the vital pillars of communities, and there will be, and they often stand as the initial refuge for the patients as they're first encounter. These, over time, have nurtured great relationships with the communities around them, and they service the patients 24/7. We are aware of what's the status of rural hospitals in America, in general. We are aware of their finances, we are aware of what's, what happens there. Adding more layers of demands and shifting resources in those hospitals to add more administrative rules and more compliance staff for those hospitals, and shifting it away from patient care, I think, is a major concern. Although the intention of this rule is amazing, and the centralization is something we all seek, but I feel sometimes that ideals and realities don't mean, necessarily, pleasantly.

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. These rural hospitals are like lifelines to the communities. Adding accreditation or not, patients will still come to the hospital, so, if they present with a STEMI, and I'm going to give you an example: I have patients, I'm going to use "John Smith" as a name, I had a patient who literally had symptoms while he was hiking close to Ludington. Had to be rushed there, had to be flown to a STEMI facility. He wouldn't care if it was accredited or not. He cares if there is a doctor who can take care of him there, if that hospital can provide, and if that hospital couldn't do it, they took him to the closest facility that could take care of it. So, adding more layers, I think, is going to be an issue. I see the investment in rural hospitals instead of investing in the actual accreditation, the hospital is improving the transport, from the rural hospitals to the actual facilities that can, to the receiving facilities, that should be taking care of the patients. And my concern when hospitals that have rural status and they're now out of the accreditation, we kind of lost them; they're nothing (inaudible) part of a system that should be integrating everybody that can support this system.

I can see, and we sat down as a team looking at it, what's the other side of the story, and we see what the importance of STEM (inaudible) care, we're all into STEM resicare. But it shouldn't be narrow vision to small accreditation bodies and restrict what's been already available, and our, I'm going to leave it to Eric to explore more about the open-heart surgery hospitals and other things, but we have matured this process; this has been going on, we have been taking

care of STEMI for the last 20 some years with high standards. We have clinical trials, both for urban areas, and we have clinical trials national and international, when it comes to rural facilities. And the standards of care is set and we continue to follow them. And we would never achieve perfection in medicine, but we always seek perfection.

I see that the resources and the energy should be directed in a different direction, but I appreciate your time and input on this, and also, we appreciate what the committee is doing and trying to achieve here. I think it's very novel, but we also appreciate that you're listening to us. Thank you.

RAO: Thank you. Next?

ERIC JAKOVAC: Thank you, Guys, for putting this on. My name is Eric Jakovac. I am the Director of Heart and Vascular Services at Corewell Health and Beaumont University Hospital, formerly Beaumont Health-Royal Oak, formerly William Beaumont Hospital. So, you know, I wanted to say thank you for taking the time allowing to have a public hearing to allow us to talk a little bit more about this and what we feel how this would impact kind of an administrative burden on our health system at our hospitals, specifically those hospitals that have very mature programs.

Corewell Health might be a new health organization but the hospitals in our system have been around for a very long time. Our Royal Oak campus, our Dearborn campus, our Troy campus, and our downtown Grand Rapids Butterworth campus have had a very robust, very mature CV surgery programs, as well as cardiovascular programs as well too, most of which are ranked within the State very highly and, most recently, our Royal Oak campus was ranked the top 25 in the nation with World News Report for Cardiovascular services.

So, I mention this for open heart surgery programs and our cardiac programs as you know, we do a lot; we have participated in many, many, many registries, and many pay-for-performance programs, including the MSTCVS for surgery and CDR Blue Cross & Blue Shield pay-for-performance programs and the BMC2PCI programs-some of which we do pay out of our pockets to participate in. We invest a lot of time in these, we spend a lot of time looking at our quality, looking at our metrics, looking at how we stack up against ourselves, how we stack up against our health system, how we stack up against our peers, regionally and nationally.

And we do believe that these registries that we do participate in really have set a really great quality standard and put ourselves up to a level that we are continuing to meet the metrics for STEMI, for cardiac care. You know, I could give many examples of things that we've done to improve what we look at toward balloon, reducing high contrast in cath labs, reducing radiation dosing, etc., but these are things that we look at and we know today that these are things we should be doing for our patients.

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. Not that standardizing care isn't a good thing, but I think the care is being standardized within our State right now with the different groups we participate in.

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 that it takes to do that. And we do think that some of that time and some of those resources does take away from the time and the care and the resources that we could be spending taking care of patients at the bedside or delivering care.

Our facilities with our open-heart surgery programs really possess a high level of readiness to handle complex cases. I know the facility I work at; we are a high… we take cases from all over internally within our system and externally without our system. We don't turn systems down, we take care of very complex, very ill patients. And I think a lot of that comes down to the collaboration that our CV surgeons have with our cardiologists, and visa versa. We do have a lot of, and this is across our entire system, a lot of collaboration. Structured collaboration within heart team meetings where we review high risk PCI cases versus open heart surgery, valve conferences where we look at, should we be doing transcutaneous valve replacements versus open and what's going to benefit the patient, and more informal, discussions where I know that in my cath lab I can call a CV surgeon and talk to them in the middle of a case or have them come into a lab to evaluate what's going on.

So, we do think we have this collaboration that is really able to continue to provide great care for our patients and it meets the standards of what we're doing for overall STEMI care in guiding our overall cardiology program.

So, we really think it would be worth reconsidering Corewell Health, as a whole, is asking that, you know, a reconsideration of this rule. We think it might add another layer of cost and complexity to continue doing what we're already doing within our health institution, and I imagine what other institutions are doing around our State as well too. And really in an era that we are trying to lower costs, deliver high quality care, become efficient, become streamline and really deliver care to the bedside, you know, we do think that this rule would add to our cost and complexity with our health system, Importantly, and I think ultimately, we do think that there would be a negative impact at the patient care bedside, and that, again, more time, more resource, and more money is being spent going after accreditation then what we could be delivering at, and investing at for our patients. I do appreciate your time and listening to us, and we do hope you hear us and consider our message. Thank you.

RAO: Thank you. Next?

DR. SAMIR DABBOUS: Good afternoon, Everyone. My name is Samir Dabbous, interventional cardiologist at Corewell Health East, and I've been on staff almost 40 years right now. So, we run a very good interventional program at, what we call right now, Dearborn, and we work cohesively with the rest of the Corewell hospitals: Royal Oak, Trenton, and other hospitals that are in the Corewell Health East.

So, I can speak for what we're doing for quite a while right now. I'm the chair of the Quality Care Program for Cardiology at the Dearborn, and also chair the (inaudible) committee. We review, on a monthly basis, all the patients that come into the emergency room with a Kilo?, with a heart attack, with a STEMI, and, believe me when I say, we check and review every chart of every patient and look exactly at what time did the patient arrived to the ER, what time did the patient get the EKG, when was the cardiologist called; notified of the STEMI, and what time was it when the patient underwent cardio-angioplasty. And we also will take that information and relay it to the ER physician when the patient comes in with a kilo . And so, there's always that dialogue that goes on, on a day-to-day basis, and give that feedback to the ER doctor. And if there is any missing or delay in the care of the patient, we immediately take care of that, give the feedback to the physician, or the nurse, or whoever, whether it is positive or negative, and we make sure that we strive to get (inaudible) room time within 90 minutes in 100% of the time. And we make sure that everybody is taken care of promptly, immediately, and if there is any delay, we will address it almost within 24 hours.

So, what I want to say is that 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. Remember, we are just getting over a major health care scare, ok, because of the pandemic. We lost a lot of staffing, and now we are trying to, scrambling to get that staff back to normal. The last thing we want to do is spend more money on accreditation, or whatever we want to call it.

It's a great thing, it's a great effort. I applaud you for doing that but not to centers that have been doing this for, for decades. Thank you so much.

RAO: Thank you. Next?

COLIN MCDONOUGH: Good afternoon. Ms. Brennan, Ms. Worden, and the Michigan Department of Health and Human Services Bureau of Emergency Preparedness, EMS, and Systems of Care Section. My name is Colin McDonough and I am the Michigan Government Relations Director for the American Heart Association. Thank you for allowing me to speak today on the Statewide STEMI proposed rules.

The American Heart Association strongly supports efforts to enact a robust STEMI systems of care framework of care in Michigan that addresses both STEMI registries and facility designation. In this testimony I will be providing comments on behalf of the Association and will provide specific change recommendations through written testimony.

Getting the right patient to the right facility at the right time for appropriate care saves lives. The American Heart Association has identified the criteria for care…, for care facilities should meet to provide the most appropriate care possible for heart attack patients. States can use this criteria to officially recognize the medical centers for their levels of care and develop a system of care policy that ensures heart attack patients are transported to these facilities.

Systems of care must be based on the latest scientific guidelines, and an ideal system of care provides patients with seamless transitions for each stage of care to the next. There are gaps in each… gaps and needs at each stage of the care continuum, however, that could be addressed by more coordinated care. Research has shown that appropriate STEMI framework can lead to improved patient outcomes and is more cost-effective. We must ensure those experiencing STEMI receive the right treatment as quickly as possible. To discover and implement future improvements in systems of care for STEMI treatment, it is important for Michigan to set up a registry infrastructure and require participation by certified centers to track the response and outcome of each incident.

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. 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 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.

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. For example, is the Bureau going to improve sub-acute care like post discharge and rehabilitation? Additionally, the Association requests the removal of the word "comprehensive" in the definition of "statewide STEMI system of care".

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. 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.

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? 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.

AHA believes the verbiage surrounding (1)(f) could lead to confusion and should be revisited. 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.

The state work to develop a process of submitting data to the National Trauma Data Bank. In these rules, the Association would like to see an exportation to get with the guidelines coronary artery disease. In disciplinary situations, the Department should include EMS, as well as the STEMI center or facility.

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. 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? 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. Is the Bureau considered an equivalent body?

In R 330.206, the language should read “Level 1, TG…TJCHA comprehensive STEMI center or Level 2, TJCHA primary heart attack center or ACC pain center” because it will align with stroke and trauma levels. This will allow for future development of the system of care, especially for patients STEMI that involved cardiac arrest and/or cardiogenic shock. In subsection (i), STEMI receiving centers will need to comply with CON regulations. Those are not mentioned here. Section (b) should read “Level 3 TJCHA acute heart attack ready center, or ACC non-PCI chest pain center” because it will align with the stroke and trauma levels. This will allow for future

developments in the system of care, especially for patients with STEMI that involved cardiac arrest and/or cardiogenic shock. 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. Additionally, the use of the word "level" should align with our Level 1, 2, and 3 in administrative language to demonstrate they exist.

To effectively effectuate a STEMI system of care in Michigan, it is necessary to interface with Get with the Guidelines. We strongly support the changes mentioned to ensure we can better serve Michigan STEMI patients and serve lives, save lives. Thank you for your time today and I will provide contact information for any questions you might have.

RAO: Thank you. Next?

DAVID FULLER: Hi, Everyone. My name is David Fuller, and I'm from Corazon, I'm joined by a couple of my colleagues here today. Thank you for letting us present our, our opinions on this important matter. So, Corazon has long been an expert in the field of cardiovascular program development and management, and its in its 10th year as an accrediting body for interventional cardiology services, as well as other cardiovascular programing including chest pain centers. Our accreditation services are endorsed by the Society for Coronary and Angiography Interventions, which is the leading nonprofit medical society for invasive and interventional cardiology. Furthermore, Corazon has been recognized by the Department of Health and Human Services as an accrediting body under the existing CON review standards for cardiac catheterizations services since 2015, demonstrating an ongoing commitment to the health and safety of patients in community, communities across the State.

Corazon supports the goal of standardizing STEMI care across the State of Michigan to improve cardiovascular patient outcomes. In fact, Corazon has long recognized the importance of standardizing STEMI care by incorporating STEMI procedures and protocols into our current PCI and chest pain center 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 of protocols, Corazon's PCI and chest pain accreditations require quarterly submissions of key clinical outcomes data, including indices related to the timely treatment or transfer of STEMI patients.

Corazon STEMI requirements are based on the same clinical guidelines and best practices as the other accrediting organizations that are named in the proposed rule. This includes the same requirements related to program readiness, 24 hours a day, seven days a week, access to emergency services, and the ability 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 on site, validation of quality infrastructure, and a quarterly review of program outcomes. However, it is important to note that Corazon's accreditation does not require a specific registry to participate. Therefore, not only is Corazon accreditation poised to better comply with the proposed rule, as a registry aspect has not yet been defined, but it also prevents additional cost burdens for program, programs that may not otherwise need to participate in additional registries. For example, some providers may manage chest pain outcomes through an internal dashboard, particularly for a STEMI referral center, while others may already have the required information available through the Michigan BMC 2 Registry. From our understanding, the BMC 2 Registry is not currently recognized by the other named accrediting bodies, but it would be recognized by Corazon.

Corazon currently accredits 23 hospitals in Michigan for PCI or chest pain services. 10 of these hospitals have PCI programs that are required to achieve and maintain accreditation by the State of Michigan's CON review standards. Corazon already maintains a national accreditation data-, client-base, and has the capacity to accredit the Michigan providers affected by the proposed rule. Historically, Corazon's wait time for an onsite survey averages just two to four weeks.

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. However, 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.

There are also concerns related to the confusion this may cause within the community served by our clients with EMS providers in the State, and possibly even within the Department, as to the good standing of these programs. In speaking with our clients, we want to be sure that there will be no additional financial or procedural burden placed on them by requiring an additional accreditation.

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.

We look forward to continuing to work with the Department and the State of Michigan to ensure Michigan patients receive the best care in the country. Thank you for your consideration in this matter.

RAO: Thank you. Next?

DR. ABED ASFOUR: Ah, yes, Abed Asfour. I just want to follow up on the previous comment that was made regarding the, 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. We are dooming some hospitals for failure; financially, and we're congesting hospitals that deliver STEMI programs, we're bottlenecking them drastically. So, I really don't think they're all in the same category, although, I agree with you on every point where we want to improve the care for patients, but it falls into a different umbrella of conditions. And I really would want it consider, you to consider this point because it will be very, in fact, unintended consequences at this point could be drastic to the livelihood to a lot of hospitals in the areas. Between rural or even urban areas, because you're, we are going to be, if, if any hospital loses accreditation for it, they, for any reason, they'll lose massive business that could doom them to failure. So, I want to just, consider this point, and thank you for very much for allowing me to (unintelligible).

RAO: Thank you. Next?

RAO: Off the record.

DR. IVAN HANSEN: Thank you. And thank you to the panel for allowing me to comment today. I just had a, my name is Ivan Hansen, the Medical Director of Cardiac Catheterization Laboratory at William Beaumont University Hospital, Corewell East, that's a mouthful, formerly Beaumont Royal Oak, and I just had a few questions, actually, about the proposal.

The way I understand it is that there are eight STEMI systems that are being proposed, and it seems that they parallel the accredited chest pain centers, is that correct? In terms of the chest pain centers that are accredited and the zones in Michigan…

EMILY BERQUEST: Oh, regions. Yes, there are eight regions.

EILEEN WORDEN: They mirror the emergency preparedness regions and the trauma regions, and then we use that same piece of geography because that is already organized to add those other two service centers for Stroke and STEMI, so they'll be integrated into that existing organizational structure.

DR. HANSEN: Ok, thank you. 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?

EILEEN WORDEN: 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.

DR. HANSEN: Ok, understood. Thank you. And another question I had was how are the, how is the advisory committee chosen?

EILEEN WORDEN: 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. Are you asking about the regional advisory committees or the state advisory committee?

DR. HANSEN: Sorry, maybe the choice of wording was poor. The advisory committee on the creation of this proposal, because it was an advisory committee names listed in the back of the…

EILEEN WORDEN: Oh, so that evolved from the conversations started in '06, then we invited a group of panel of (inaudible) of (inaudible) groups. They met for two years on, Aaron chaired those workgroups, representing all of the health care systems and the content expertise they're in, and they advised the Department. And that was the result of that paper we had printed, the white paper.

DR. HANSEN: Ok, right. And so, 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.

EILEEN WORDEN: That's correct.

DR. HANSEN: Ok.

EILEEN WORDEN: There'll be an advisory committee to advise the system as a whole. There is also each region, each piece of geography that I already described, will have its organizational board, a regional network council, and we're using the terms (inaudible) and integrational works the same. A regional professional standards review organization which already exists, and they are responsible for the care and delivery for stroke and STEMI In that piece of geography, so that's their work.

DR. HANSEN: Ok, thank you. And what is the estimated overall cost of this proposal should it be implemented overall.

EILEEN WORDEN: The budget is $3 million.

DR. HANSEN: Ok. And the cost of each participating center or…

EILEEN WORDEN: That I can't speak to.

EMILY BERQUIST: We don't charge a fee.

EILEEN WORDEN: We don't, we don't charge anything, and we are hoping to, our plan is in the RFP for the data, the IT project is that data entry would be free for them.

EMILY BERQUIST: It would allow them access to our system for no charge. No charge to them, it will cost us money, not them.

EILEEN WORDEN: The analysis is that everything else we can feed reports back to them, we can do inventories, we can do (inaudible), that they will get back from us.

DR. HANSEN: Ok. So, the program will be funded by taxpayer dollars, grant…

EILEEN WORDEN: General fund.

DR. HANSEN: Ok. 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?

EILEEN WORDEN: No, it's either/or.

DR. HANSEN: Either/or, ok.

EILEEN WORDEN: 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.

DR. HANSEN: Ok. My last question is, my overall sense from this effort is that, if the goal is to improve access to STEMI care for people who live in Michigan, a lot of effort is being directed toward geographical areas where there would be no, there would be no access to PCI within 90 minutes of their presentation and even access to fibrinolytic therapy, maybe, not ideal. So that certainly of, you know, of an area of concern. Now what about centers in my region of Southeast Michigan where we have multiple STEMI centers. How would this regulation impact us?

EILEEN WORDEN: 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"?

DR. HANSEN: Thank you. And, I lied, I had one more question. Piggybacking off…

EILEEN WORDEN: We have until 4.

DR. HANSEN: So, 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?

EILEEN WORDEN: 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, 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 building surgeons, how can we do this better? And I say this with such passion because I know Trauma did it extraordinarily well and continues to do it well. And we would really like to move out that same process to other service lines.

DR. HANSEN: Thank you. I have no further questions. Thank you.

RAO: Any other comments? Off the record.

RAO: Back on the record. It is now 4:00 p.m. The public hearing has ended.