

May 2, 2018

Mr. James Falahee, JD
CON Commission Chairperson
South Grand Building, 4th Floor
333 S. Grand Avenue
Lansing MI 48933

Dear Commissioner Falahee,

Henry Ford Health System (HFHS) would like to offer comments on Certificate of Need review standards for Cardiac Catheterization services, specifically for the newly added language for the replacement of a Cardiac Catheterization service to a new site simultaneously with an Open Heart service. While HFHS supports the overall intention of this language, we feel that the language in subsection (c) needs some revision.

Given planning areas are very large in these standards (up to 18 counties, spanning as much as 16,000 square miles), giving this level of flexibility to relocate a program to any part of the same planning area in subsection (d) may lead to unintended gaps or access issues in service within the planning area. HFHS requests the CON Commission consider adding a mileage parameter.

- Recommended language: The proposed new site is the same site where the existing OHS service is to be located and is within a 5-mile radius of the existing site for a metropolitan statistical area county or within a 10-mile radius for a rural or micropolitan statistical area county.

This revision will ensure a gap is not created in a region of the planning area and will also ensure access issues are not created due to the move of a program entirely out of the area currently being served.

Thank you for the opportunity to provide public comments.

Respectfully,

Barbara Bressack
Henry Ford Health System
Director, Planning & CON Strategy
One Ford Place, 4A
Detroit, MI 48202

From: Taglauer, Marty <Marty.Taglauer@scasurgery.com>
Sent: Wednesday, April 25, 2018 4:34 PM
To: MDHHS-ConWebTeam
Cc: Linscomb, Todd; Domann, Trey
Subject: MRI Public Hearing Comment 2-4-16 through 2-11-16

Good afternoon,

I am writing in support of allowing Permanent Pacemakers(PPM) and Internal Cardiac Defibrillators(ICD) to be implanted in an Ambulatory Surgery Center(ASC) in the state of Michigan.

CMS approved these devices to be implanted in the ASC space back in 2013 and many states such as Florida, Texas, and California have allowed these implants to be done outpatient for far many more years. In Texas these have been allowed by the state and reimbursed by commercial insurance for over 15 years. These procedures have very low risk of complications and patients have done very well in the ASC space. The majority of these procedures are done in the Hospital Out-Patient Department(HOPD) and are allowed to go home the same day as they would be in an ASC.

ASCs are set up much like a HOPD in that we have all the necessary emergency equipment needed to care for and stabilize a patient in the extremely rare occasion needed. ASCs also review every case to determine the appropriateness of admitting the patient into the ASC space and those patients who are not appropriate are then sent to a hospital for their implant.

Ambulatory Surgery Centers offer many advantages over traditional Hospitals in that we have lower infection rates, equal or lower complication rates, and better patient satisfaction scores.

Another ASC advantage is in our ability to offer these services in a lower cost of service setting saving hundreds of thousands, if not millions of dollars to PATIENTS and insurance companies.

ASC's are regulated entities that hold themselves to high standards of care provided to our patients.

I ask that you reconsider Michigan's position allowing these procedures to be done in the ASC space.

I am available to discuss this matter further, please feel free to reach out.

Thank you,

Marty

Marty Taglauer, RN
Surgical Care Affiliates
Manager, CV Clinical Ops Implementation
210-326-9322
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CST, based in Texas

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April 26, 2018

Certificate of Need Policy Section
Attention: CON Commissioners
South Grand Building, 5th Floor
333 S. Grand Avenue, P.O. Box 30195
Lansing, MI 48909

RE: Cardiac Catheterization and Open Heart Surgery Standards

Dear CON Commissioners:

At the March 27, 2018 CON Commission meeting the department recommended a language addition to both the Cardiac Catheterization (CC) and Open Heart Surgery (OHS) standards. Section 5 of the cardiac catheterization standard and Section 4 of the OHS standard states the requirements to replace an existing service. The language addresses the issue of a physical relocation of a hospital that currently has CC and OHS services.

A facility would need the above sections of each standard approved at the same time so both programs move when a hospital is relocated. This makes perfect sense. However, EAM is very concerned about the geographical provisions for replacing the standards proposed by the department. The key factor that pose possible threats to access of care to Michigan residents are:

- The proposed new site is within the same planning/service area of the site at which an existing OHS and CC program exists.

If a hospital relocates within the same city this is not an issue, but service areas include multiple counties with hospital systems having multiple facilities within a service area. This may lead to moving programs from areas where there is a need for access into communities where there is not. For example, a program may be eligible to move from Detroit to Oakland County (est. 30 miles), from Saginaw County to Iosco County (est. 80 miles), or from Kent County to Mason County (est. 96 miles).

The EAM urges the Commission to consider a tighter geographical area when allowing the CC/OHS standards to be replaced/relocated within a hospital system. This may prevent any future issues from occurring. Perhaps aligning the OHS and CC standards with the hospital bed standards would be a place to start.

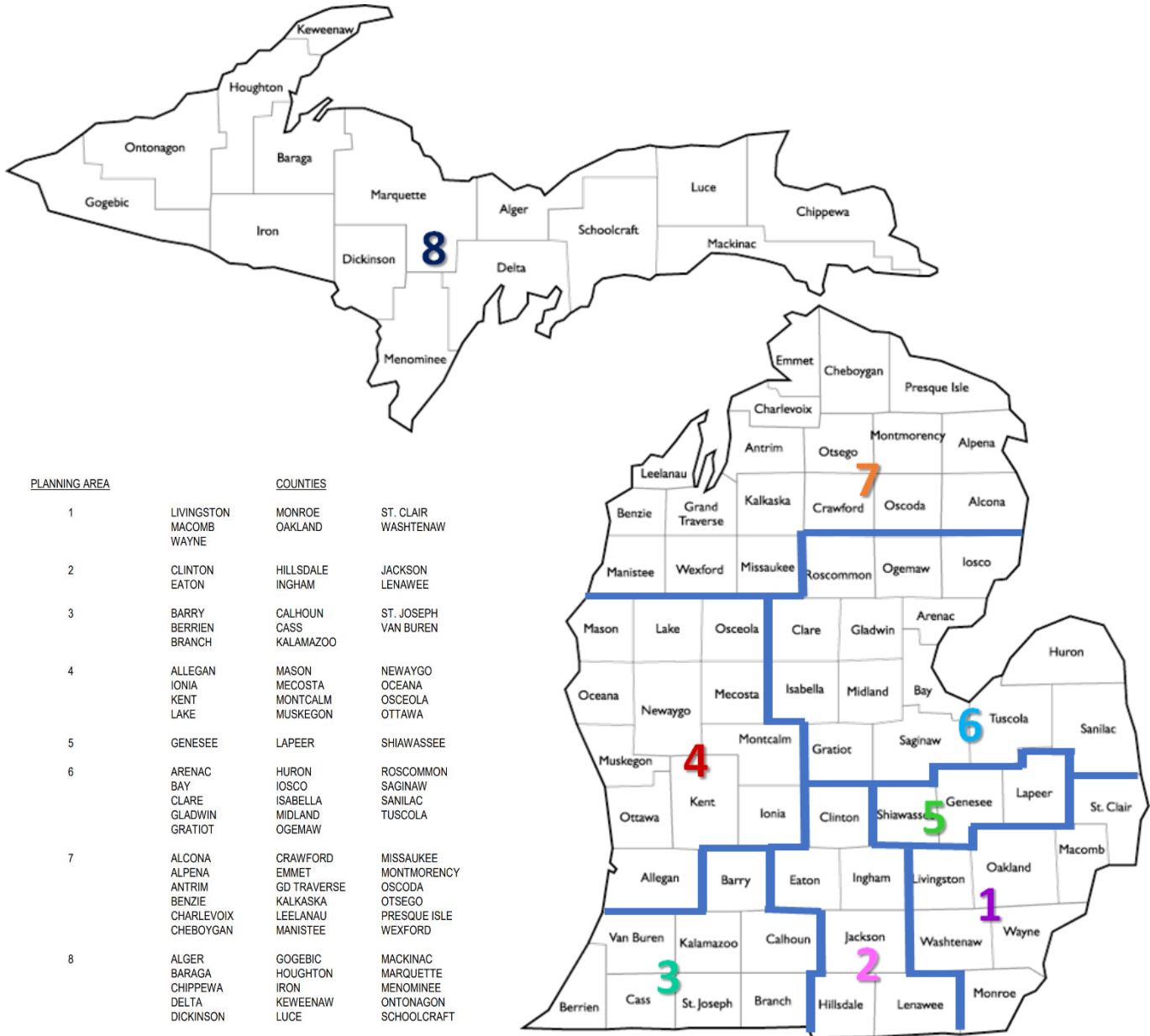
Sincerely,

Bret Jackson
President, EAM
bretjackson@eamonline.org

Enclosures/Attachments: Map of Open Heart Surgery & Cardiac Catheterization Planning/Service Areas



Open Heart Surgery & Cardiac Catheterization Planning/Service Areas





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April 26, 2018

Mr. James Falahee, JD
Chairman
Certificate of Need Commission
Michigan Department of Health and Human Services
333 S. Grand Avenue
Lansing, Michigan 48933

Dear Chairman Falahee,

Thank you for this opportunity to provide comments on the proposed changes to the Certificate of Need Standards for Open Heart Surgery (OHS) and Cardiac Catheterization Services. Because these services and provisions are tied together, we will address both in these comments.

The Cardiac Catheterization Standards Advisory Committee (SAC) presented their recommendations to the Commission at the March 27th meeting. Sparrow strongly supports all of the recommendations from the SAC and believes these changes are in line with the goals of the Certificate of Need program and provide important updates based on changes in technology and practice.

However, despite concerns raised by several organizations as well as CON Commissioners, the Commission moved additional changes to the Cardiac Catheterization standards and Open Heart Surgery standards that were not recommended by the SAC and in fact were discussed and rejected almost unanimously with just one vote in favor. These revisions would add provisions for replacing both services to a new geographical location. We have two critical concerns with the language in its current form as follows:

- We believe the replacement zone proposed, health service area, is too large. Health Service Areas (HSAs) are multi-county areas of the State. Allowing a service to relocate anywhere within the same HSA could allow a program to move over a hundred miles in some HSAs. Replacement zones have always been intended to allow the movement of services while ensuring that they still provide those services to the same market. We do not believe the provision as proposed does this. We would instead recommend a 5 or 10 mile replacement zone, which would be in line with other CON standards. MRI, CT, and surgical services all have a 10 mile replacement zone, with the exception of an MRI host site which can only be replaced 5 miles.
- The provision included in the Cardiac Catheterization standards requires the program being relocated to be meeting minimum volumes in order to qualify. The Open Heart Surgery standards include a similar provision but an exception was added for a program that is being replaced as part of a replacement of an entire hospital. The CON Commission has been encouraging the Department to close down low-volume OHS

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programs for many, many, years. Not only are there concerns about utilizing resources of programs that just don't seem to be needed, but there have also been quality concerns when you spread an ever-decreasing number of OHS cases over an unnecessarily large number of OHS programs. Why would the Commission then allow a facility with a low-volume OHS program spend millions of dollars to replace it to a new site? You updated the Cardiac Cath standards 3 years ago to allow for elective PCI without on-site OHS with the promise that low-volume OHS programs would voluntarily close. That still has not happened. Volumes continue to decrease because of changes in patient care and safety, driving procedures to the catheterization lab rather than OHS. We simply no longer need 33 open heart surgery programs in this state. However, it is difficult for the Department to revoke CONs so arming them with more opportunities to encourage low-volume OHS programs to close voluntarily rather than removing those opportunities makes more sense. We would suggest that the minimum volume requirement be maintained in this provision across the board and remove the exception for OHS programs being replaced as part of a full hospital replacement.

Again, we very much appreciate the Department's desire to create consistency across CON standards and are supportive of the concept they have provided in their proposal, but believe the changes outlined above are critical to ensuring this change accomplishes the Department's goal without flying in the face of the goals of the CON program, to ensure access to high quality health care while making the most efficient use of limited healthcare dollars.

We appreciate your time in considering our concerns and suggestions and would be happy to discuss this further either at the next CON Commission meeting or prior directly. I can be reached at 517-253-6141

Respectfully,

A handwritten signature in black ink that reads "Maklena Hendershot".

Maklena Hendershot
Director of Strategic Planning
Sparrow Health System

Mr. James Falahee, Chairperson
Certificate of Need Commission
c/o Michigan Department of Health and Human Services
Certificate of Need Policy Section
South Grand Building, 5th Floor
333 S. Grand Ave
Lansing, Michigan 48933

Dear Chairperson Falahee,

Thank you for this opportunity to provide public comment regarding the proposed changes to the CON Review Standards for Cardiac Catheterization Services and Open Heart Surgery (OHS) Services.

Spectrum Health fully supports the recommendations of the recent Cardiac Catheterization Standards Advisory Committee, which are included in the current draft standards.

Spectrum Health also appreciates the Department's efforts to add language that would bring consistency between the Cardiac Catheterization and OHS standards and other standards. Spectrum Health is a strong supporter of clarity and consistency between standards. However, we have concerns with two of the provisions included in the Department's recommendations.

The Department's recommendations for both the Cardiac Catheterization and OHS standards include a provision that would allow for the replacement of a facility's Cardiac Catheterization and OHS services to a new site anywhere in the same planning area, which in this instance is the Health Service Area - large multi-county areas. For instance, Spectrum Health belongs to Health Service Area 4, which includes 12 counties. Spectrum Health is concerned with the geographic size of the planning area replacement zone. Theoretically, this would allow a facility to move its services to an entirely new market, which could negatively impact patient care. Some patients may not be able to travel the distance to the new facility, which could increase the risk of mortality. Additionally, should a service move into an area where an existing service is already located, without the requirement to project need in that area, it may dilute the cases in the area, reducing volumes, which in turn could negatively affect patient care.

Spectrum Health believes a five (5) mile replacement zone in a metropolitan county and a ten (10) mile replacement zone in a micropolitan or rural county is more appropriate for patient care and consistent with other CON standards.

The Department's recommendations for the OHS standards, also includes a provision that would exempt programs from having to meet the minimum volume requirements in order to qualify for replacement if it is part of a full hospital replacement. This has the potential to allow low volume programs to be replaced at the highest cost, which is not in the best interest of the residents of the state and contrary to the whole purpose of the Certificate of Need program. This provision should be removed from the Department's recommendations and all programs should be required to be meeting minimum volume requirements in order to qualify for replacement to a new site, which is completely consistent with all other similar provisions in the rest of the standards.

Again, thank you for the opportunity to provide feedback on the CON Review Standards for Cardiac Catheterization Services and Open Heart Surgery Services. Spectrum Health appreciates the Commission's consideration of our comments.

Sincerely,



Tracey Burke, MBA, MSA, RVT, RDMS
Vice President, Cardiovascular Health

May 2, 2018

Mr. James Falahee, JD
CON Commission Chairperson
South Grand Building, 4th Floor
333 S. Grand Avenue
Lansing MI 48933

Dear Commissioner Falahee,

Henry Ford Health System (HFHS) would like to offer comments on Certificate of Need review standards for Open Heart Surgery services, specifically for the newly added language for the replacement of an OHS service to a new site. While HFHS supports the overall intention of this language, we feel that the language in subsection (d) and (e) needs some revision.

Given planning areas are very large in these standards (up to 18 counties, spanning as much as 16,000 square miles) giving this level of flexibility to relocate a program to any part of the same planning area in subsection (d) may lead to unintended gaps or access issues in service within the planning area. HFHS requests the CON Commission consider adding a mileage parameter.

- Recommended language: The proposed new site is within the same planning area and within a 5-mile radius of the existing site for a metropolitan statistical area county or within a 10-mile radius for a rural or micropolitan statistical area county.

This revision will ensure a gap is not created in a region of the planning area and will also ensure access issues are not created due to the move of a program entirely out of the area currently being served.

Additionally, subsection (e) allows an OHS service that is being replaced as part of the replacement of an entire hospital to a new geographic site to not meet minimum volume requirements. This type of volume exception does not exist in other similar standards and we would not recommend including it here. To ensure the service continues to offer high quality service, we are recommending that this type of relocation be required to meet minimum volume requirements for OHS.

- Recommended Language Change: HFHS recommends removing the language “unless the OHS service being replaced is part of the replacement of an entire hospital to a new geographic site” from the subsection.

Thank you for the opportunity to provide public comments.

Respectfully,

Barbara Bressack
Henry Ford Health System
Director, Planning & CON Strategy
One Ford Place, 4A
Detroit, MI 48202