

From: DoNotReply@michigan.gov
To: [MDCH-ConWebTeam](#)
Subject: July 17, 2013 Public Hearing Written Testimony (ContentID - 306550)
Date: Friday, July 19, 2013 11:45:32 AM

1. Name: Frank D. Sottile, MD
2. Organization: Crittenton Hospital Medical Center
3. Phone: 248-652-5985
4. Email: fsottile@crittenton.com
5. Standards: AA
6. Testimony: We applaud the work performed by the Open Heart Special Advisory Committee. Their comprehensive review of the current literature and their willingness to explore all positions was admirable. We appreciate the efforts they made to update the standards for the initiation and maintenance of cardiac surgery programs statewide. We agree that health resources are limited and it is appropriate that the health resources are limited and it is appropriate that the healthcare community be good stewards of these resources. We are especially supportive of the recommendation to insert robust quality standards into the evaluation of programs and the rejection of volume standards as a surrogate for quality metrics. With the well documented decrease in open heart procedures performed throughout the state (greater than 11,000 CABGs in 2001 to fewer than 6000 CABGs in 2011), continued adherence to volume criteria puts many OHS programs out of compliance with the current regulations and at risk for punitive action. We maintain that volume standards should never be a sole determinant of the maintenance of existing programs, but one piece of a broader analysis of the overall performance of the program. Open Heart Surgery programs have changed considerably since the advent of the original standards. Much work has been accomplished on the standardization of critical technical aspects of the procedure and precise quality metrics are available to determine adherence to key processes that determine patient outcomes. The focus of program maintenance standards should be heavily weighted on patient outcomes. The value of any program and the resource it consumes is directly related to its measurable quality and the outcomes of the patients they serve.
7. Testimony:
fpSpamBlock:

July 24, 2013

James B. Falahee, Jr., Chair
Certificate of Need Commission
C/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building, 201 Townsend Street
Lansing, Michigan 48913

Dear Mr. Falahee,

This is formal testimony by Spectrum Health about the proposed revisions to the CON Review Standards for Open-Heart Surgery, which were approved by the Commission for public comment at the June 13 meeting. Spectrum Health appreciates the opportunity to provide comment and supports the work of the CON Commission and the Open-Heart Surgery SAC in your efforts to develop good public policy in the CON regulation of cardiac surgery services.

The proposed revisions to the Standards include several improvements. Most noteworthy is the inclusion of quality standards as part of the Project Delivery Requirements. Based on a star-ranking system developed by the Society for Thoracic Surgery (STS), these proposed requirements represent a significant step toward including quality considerations, separate from volume, in the CON Standards.

An additional proposed change reduces the minimum annual volume per surgeon to 50 cases per year. This reflects the state of the art of thoracic surgery that suggests that performing non-cardiac chest surgery contributes to a surgeon's skills, in light of declining volumes of cardiac surgery.

A provision retained from the existing Standards is the requirement to project a minimum volume of 300 open-heart surgery cases in order to initiate a new open-heart surgery program. While the relationship between volume and quality has diminished, a minimum projected volume requirement is necessary to document need for a new open-heart service. It was generally agreed in the SAC that there is no need for additional open-heart surgery programs in Michigan. The threshold for a new program, therefore, should be sufficiently high to discourage the development of unnecessarily duplicative services. Spectrum Health supports retention of the existing requirement to project 300.

The revised Standards include a proposed reduction to the annual "maintenance" volume of any new open-heart surgery programs. Based on recommendations from MDCH, the maintenance requirement would decrease from 300 open-heart surgery cases per year to 150. Spectrum Health does not support this proposal.

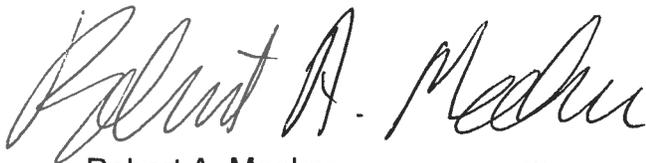
This change was neither debated nor recommended by the Open-Heart Surgery SAC. Furthermore, an annual requirement of 150 cases is not based on evidence. We urge the Commission to reconsider the annual maintenance volume contained in the Standards.

The citizens of the state are well-served by the existing open-heart surgery programs. Evidence was presented to the SAC that there are too many open-heart surgery programs currently operating in the state. Open-heart surgery volumes are declining, both nationally and in Michigan. According to the Michigan Annual Surveys of Hospitals, the number of open-heart procedures declined by 35% from 2000 – 2012. There are thirty-three (33) approved open-heart surgery programs in Michigan. Of them, twenty-three (23) (more than two-thirds) *do not meet* the current minimum standard of 300 cases per year. In fact, six of the existing programs fail to meet the proposed minimum volume of 150 cases per year. Additionally, since 1993, ten (10) new open-heart programs have been approved in Michigan, the most recent in 2006. In 2012, only two (2) of those new programs reached the annual requirement of 300 cases per year. The evident flaws in the previous open-heart surgery need methodology were corrected by the recommendations of an Open-Heart Surgery SAC in 2007, resulting in no additional CON approvals since then.

Assuming that the proposed revisions to the CON Standards for Open-Heart Surgery receive final approval this year, Spectrum Health strongly recommends that the next review of these standards be changed from 2014 to 2016, in order to provide the full three-year cycle to evaluate the effectiveness of the new Standards.

Spectrum Health appreciates the opportunity to present our views on these issues. We urge the Commission to consider retaining the existing annual maintenance volume of 300 open-heart surgery cases per year, before giving final approval to the revised CON Review Standards for Open-Heart Surgery at their meeting on September 17, 2013.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert A. Meeker". The signature is fluid and cursive, with the first name being the most prominent.

Robert A. Meeker
Strategic Program Manager

From: DoNotReply@michigan.gov
To: [MDCH-ConWebTeam](#)
Subject: July 17, 2013 Public Hearing Written Testimony (ContentID - 306550)
Date: Tuesday, July 23, 2013 2:56:07 PM

1. Name: Monica Harrison
2. Organization: Oakwood Healthcare
3. Phone: 313-586-5478
4. Email: monica.harrison@oakwood.org
5. Standards: AA
6. Testimony: Oakwood Healthcare appreciates the opportunity to provide testimony regarding the proposed open heart standards. Oakwood Healthcare System is comprised of four hospitals: Oakwood Annapolis Hospital, Oakwood Heritage Hospital, Oakwood Southshore Medical Center, and Oakwood Hospital and Medical Center. Oakwood Hospital and Medical Center has operated an open heart program for several years and performed 468 procedures in 2012.

We would like to commend the Standards Advisory Committee (SAC) for their excellent work and dedication to the revision of these standards. Dr. Sell did an outstanding job as chair of the committee.

Oakwood especially supports the inclusion of quality metrics into the CON standards. Specifically, the SAC recommended utilization of the Society of Thoracic Surgeons composite and star metrics for quality. It is expected that these quality metrics would be weighed heavily in evaluating program performance, with volume being only one of many considerations.

Again, thank you for the opportunity to provide comments regarding the proposed standards.

7. Testimony:
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From: DoNotReply@michigan.gov
To: [MDCH-ConWebTeam](#)
Subject: July 17, 2013 Public Hearing Written Testimony (ContentID - 306550)
Date: Wednesday, July 24, 2013 3:46:09 PM

1. Name: Sean Gehle
2. Organization: Ascension Health - Michigan
3. Phone: 517-482-1422
4. Email: sean.gehle@stjohn.org
5. Standards: AA
6. Testimony: Ascension Health - Michigan supports the modifications to the CON Open Heart standards as proposed and acted upon by the CON Commission at its last meeting. In particular Ascension Health - Michigan supports the inclusion of language in the project delivery requirements requiring applicants to participate in a data registry administered by the Department of Community Health as a means to measure quality and risk adjusted outcomes within Open Heart Surgery programs utilizing the STS Composite Star rating system and the corresponding actions required by programs who achieve sub par ratings within this rating system.

We appreciate the opportunity to provide these comments.

7. Testimony:
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THE ECONOMIC ALLIANCE FOR MICHIGAN

The Statewide Business-Labor Coalition

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July 24, 2013

James Falahee, Chair
Certificate of Need Commission
C/O Michigan Department of Community Health
Certificate of Need Policy Section
Capital View Building, 201 Townsend Street
Lansing, Michigan 48913

Re: Public Comment on Proposed Open Heart Surgical Standards

Dear Mr. Falahee,

EAM had long held the position that, absent credible quality measures that were publicly available, the minimum annual volume of Open Heart Surgery (OHS) procedures performed by each OHS program would be the only valid determiner of the quality care being provided by an OHS program. In 2012, convincing arguments were advanced by the Michigan Society of Thoracic and Cardiovascular Surgeons (STS) Quality Collaborative that their publicly available quality measures should replace the minimum annual volumes as the determiner of quality of OHS programs in Michigan. In June 2013, the CON Commission adopted proposed new standards for OHS that would reduce the minimum annual maintenance volume from 300 to 150 and incorporate the Composite Score of the STS quality measures. The following is our member organizations response to these two changes.

Minimum Annual Maintenance Volume

Because changes in the CON standards are prospective, and the minimum annual maintenance volume in the OHS CON Standards was changed twice over the last 20 years, there are currently three different annual maintenance volume levels (zero, 200 and 300). The 33 Michigan OHS programs are subject to the annual minimum maintenance volume that was in effect when their OHS program's CON was approved.

The number of OHS procedures performed annually continues to decline, off by over 30% since year 2000. As a result, in 2012, 13 of the 33 OHS programs in Michigan were not meeting their CON's annual maintenance volume. This trend is expected to continue.

The 2012 OHS SAC's recommended that annual OHS volume is not an assurance of good quality. They also proposed including STS Quality Measures and Reporting requirements in the proposed new CON Standards for OHS. This change would only apply to current OHS programs if they have volunteered to adopt these new CON Standards.

As a result, the MDCH has been reluctant to take enforcement actions on OHS programs that may not be meeting the annual maintenance volume under their CON because they may still be performing more procedures than other OHS programs that have a CON with a lower annual minimum maintenance volume and their quality may be better than the higher volume OHS programs.

To help address these issues, MDCH has proposed lowering the annual minimum maintenance volume in these proposed new CON Standards from 300 to 150. Their goal is to have the current OHS programs that are not now meeting the annual minimum volume requirement of their OHS CON (which was 13 programs in 2012) to agree as part of a compliance action, to adopt the proposed new OHS Standards with the STS quality and reporting requirements. This would then allow the MDCH to take future compliance actions based upon the STS quality and reporting measurements.

Our concerns regarding this proposal to lower annual minimum maintenance volume to 150 are as follows:

- This will create a 4th OHS CON Standard annual maintenance volume (zero, 200, 300 and now 150). These new OHS Standards with the lower annual maintenance volumes would only apply to those OHS programs that have agreed to re-apply for their OHS CON as a result of a compliance action. While this may, over time, result in several of the lower volume OHS programs being subject to the new CON Standards with the STS Quality measure and reporting requirements, many of the other OHS programs will not. As a result, there will continue to be four levels of minimum annual volumes.
- We support maintaining the initiation volume of 300 as a determiner of community need for a new, OHS programs. Our concern is that this is open to criticism when the annual maintenance volume is one-half (150) of the projected volume to initiate a new program. Once someone projects a “community’s need” for 300 procedures to initiate a new program, they need only provide 150 procedures a year to avoid compliance actions. We believe that the initiation and annual maintenance volumes should be the more than just one-half of the volume to project the need for a new program.

Our recommendation is to reduce the annual maintenance volume to 200.

- **This avoids adding a fourth tier of annual minimum maintenance volume requirements.**
- **Based upon the 2012 reported volumes, eleven of OHS programs could be willing to adopt the new OHS Standards with the STS Quality measures and reporting requirements as the result of compliance actions.**
- **Reducing the annual maintenance volume to 150, 13 OHS programs (just 2 more) could be willing to adopt the new OHS Standards with the STS Quality measures and reporting requirements as the result of compliance actions.**

STS Quality and Reporting Requirements

While EAM supports the development of valid, publicly available health care quality measures, we do have some concerns regarding how the proposed STS quality data will be used:

1. The STS Composite Score is made up of four scores; two outcome measurements, (risk adjusted absence of Mortality and risk adjusted absence of Morbidity) and two process compliance scores, (Use of Mammary Artery and Receipt of Required Medications). Our review of the STS composite scores for the two most recent 12-month periods available shows the following:
 - OHS programs that improved their Composite Score did so by improving their process compliance scores without making improvements in their outcome measures of absence of mortality and absence of morbidity.
 - Other OHS programs improved their Composite Score with improvements in their process compliance scores while their risk adjusted absence of morbidity score decreased.

We would recommend that the CON Standards also use the scores for the absence of mortality and the absence of morbidity in addition to the composite score as the basis for taking compliance action.

2. The proposed one-star score indicates that an OHS program is in the lowest 16% of all OHS programs in the U.S. that are participating in the STS quality collaborative. Is this setting the bar too low?
 - The STS Quality ratings also show the actual numerical score for the Composite and each of the four quality rating measurements. **We would propose that the actual score is a much better measure of quality than using the star rating.** (See attached tables of STS Quality Ratings)
 - For the Composite Score, 96.8% was the average for the 31 Michigan OHS programs that made their results public for the most recent, July 2011 to June 2012 reporting period. Only (3) program reported a Composite Score of less than 96%. **We would recommend that the MDCH use the Composite Score of 96% or below as an indicator of the need for a compliance review.**
 - For the risk adjusted Absence of Mortality rating, 97.9% was the average for both years for the 31 Michigan OHS programs that made their results public. Only one OHS program reported a score below 97% during the two years of reported scores. **We would recommend that the MDCH use the risk adjusted Absence of Mortality score of below 97% as an indicator of the need for a compliance review.**
 - For the risk adjusted Absence of Morbidity rating. The average decreased from 85.9% in the first annual report to 84.9% in the second annual report for the 31 OHS programs in Michigan that made their data publicly available. Of the OHS programs publicly reporting Absence of Morbidity scores, (4) of Michigan's OHS programs had scores of less than 81% in the first year and (7) had scores of less than 81% in the second year. **We would recommend that the MDCH use the risk adjusted Absence of Morbidity scores of less than 81% as an indicator of the need for compliance review.**

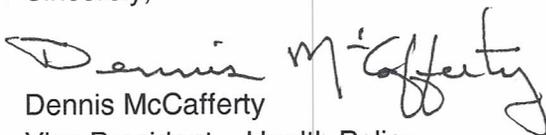
Over time, as the STS Quality measures improve and the quality of care being provided by Michigan's OHS programs improve, the CON Commission may want to adjust the above recommended levels.

3. While all 33 of Michigan's OHS programs participate in the STS quality collaborative, only 2 have chosen to not make their STS scores public. **We would recommend that once these new standards are in force, that the Department, when deciding on which OHS programs should be selected for compliance review, they should first look at those OHS program with annual volumes below their CON maintenance minimums that have chosen to not make their STS scores public.**

The Economic Alliance for Michigan is one of the few organizations representing purchaser and consumer of health care services in Michigan that actively participates in the CON process. Our member employers and unions strongly support adding to the CON Standards for OHS programs in Michigan, meaningful quality measurement information that is publicly reported. We believe that the proposed changes in the CON Standards for OHS programs are a step in the right direction. Our recommendations and comments are intended to make these proposed changes even more meaningful to the consumers and purchasers we represent.

We hope that the CON Commissioners find these suggestions helpful. We also hope that once the new OHS Standards are approved and in effect, the MDCH would be able to resume its efforts of verifying if the existing OHS programs are in compliance with their version of the OHS Standards and if not, to take appropriate compliance action.

Sincerely,



Dennis McCafferty
Vice President – Health Policy
The Economic Alliance for Michigan

Attachments:

STS Tables with actual scores for both July 2010 to June 2011 and July 2011 to June 2012

STS Quality Rating

OHS Hospitals	City	Cardio Artrial Bypass Graff (CABG) 7/11-6/12					Perioperative medications
		Composite score	Absence of Mortality	Absence of Major Morbidity	Use of Mammary Artery		
Allegiance	Jackson	96.8	97.8	85.1	99.2	93.3	
Beaumont	Royal Oak	96.4	97.7	80.4	98.9	98.8	
Beaumont	Troy	97.3	97.9	85.0	99.4	99.0	
Borgess	Kalamazoo	96.9	98.0	88.0	99.3	85.3	
Bronson	Kalamazoo	97.2	98.0	89.2	98.0	94.4	
Covenant	Saginaw	97.0	98.1	88.2	98.6	89.6	
Crittenton	Rochester	97.5	98.2	87.7	99.0	95.4	
Harper University	Detroit	95.2	97.5	74.6	99.2	93.3	
Genesys	Grand Blanc	96.4	97.6	85.6	99.4	83.9	
Henry Ford	Detroit	98.0	98.0	91.7	98.9	98.1	
Henry Ford-Macomb	Clinton Twp	97.4	98.3	87.4	99.4	93.7	
Lakeland	St Joseph	96.6	98.2	83.4	98.3	93.6	
Marquette	Marquette	96.6	97.7	83.2	99.3	93.3	
McLaren	Bay City	97.4	98.2	88.7	98.5	95.7	
McLaren	Flint	NR	NR	NR	NR	NR	
McLaren	Lansing	95.6	98.3	77.5	98.8	84.0	
McLaren Northern	Petoskey	97.4	97.9	86.8	98.9	98.0	
McLaren	Mt. Clemens	NR	NR	NR	NR	NR	
Mercy General	Muskegon	96.2	98.1	76.4	99.3	96.7	
Mid Michigan	Midland	96.7	97.7	87.4	98.3	90.4	
Munson	Traverse City	96.7	98.5	80.8	98.9	98.8	
Oakwood	Dearborn	96.6	97.7	86.5	98.8	88.4	
Port Huron	Port Huron	96.6	97.8	87.3	99.1	84.2	
St. Joseph Mercy	Pontiac	96.2	97.8	82.1	98.9	91.5	
St. Joseph Mercy	Ann Arbor	97.7	98.3	88.0	99.1	97.9	
St. Mary's	Saginaw	94.8	96.7	76.1	99.0	91.4	
Sinai-Grace	Detroit	96.4	97.7	82.5	99.1	93.2	
Sparrow	Lansing	97.1	98.0	87.9	98.4	93.4	
Spectrum	Grand Rapids	96.2	98.2	79.7	98.9	92.5	
St. John Providence	Southfield	97.6	98.1	87.9	98.9	98.6	
St. John Providence	Detroit	98.3	98.3	92.5	99.4	97.5	
St. John Providence	Warren	98.0	98.2	89.5	99.3	98.6	
University of Michigan	Ann Arbor	96.4	97.7	86.0	98.7	86.5	
		3001.2	3036.2	2633.1	3067.2	2889	
Average of those reporting		96.8	97.9	84.9	98.9	93.2	

STS Quality Rating

Star Rating

Of the 423 Cardiac Surgical programs in the U.S.A. that participated in the 7/11-6/12 STS Qualitive Initiative and publicly reported results:

One Star *	Only 23 reported received this lowest rating of one star for their Composite Score (5.4%)
Two Stars **	311 reported received this middle rating of two stars for their Composite Score (73.5%)
Three Stars ***	89 reported received this highest rating of three stars for their Composite Score (21%)
NR	Not Reported - Declined to make their quality scores publicly available

STS Quality Rating

STS Quality Rating

		Cardio Artrial Bypass Graff (CABG) 7/10-6/11				
OHS Hospitals	City	Composite score	Absence of Mortality	Absence of Major Morbidity	Use of Mammary Artery	Perioperative medications
Allegiance	Jackson	96.7	98.1	88.1	96.3	96.2
Beaumont	Royal Oak	96.7	98.1	87.0	97.7	96.4
Beaumont	Troy	97.0	98.0	88.0	98.1	97.5
Borgess	Kalamazoo	95.9	97.6	88.0	95.2	91.2
Bronson	Kalamazoo	96.8	97.9	88.0	97.8	95.8
Covenant	Saginaw	96.2	98.5	88.4	95.8	83.8
Crittenton	Rochester	95.8	98.0	84.5	96.3	91.0
Harper University	Detroit	91.5	96.0	71.7	94.2	91.6
Genesys	Grand Blanc	96.8	98.1	90.7	96.9	87.6
Henry Ford	Detroit	96.2	97.5	89.1	96.9	88.2
Henry Ford-Macomb	Clinton Twp	95.6	97.7	85.1	96.9	88.2
Lakeland	St Joseph	95.3	98.1	84.4	95.7	85.7
Marquette	Marquette	95.8	98.2	83.0	97.3	92.1
McLaren	Bay City	96.1	97.4	86.6	97.1	94.9
McLaren	Flint	NR	NR	NR	NR	NR
McLaren	Lansing	94.8	97.9	86.6	93.8	77.1
McLaren Northern	Petoskey	94.9	98.0	82.7	96.3	81.0
McLaren	Mt. Clemens	NR	NR	NR	NR	NR
Mercy General	Muskegon	95.3	98.2	79.5	97.6	91.3
Mid Michigan	Midland	96.4	98.6	89.5	92.7	92.5
Munson	Traverse City	97.2	98.8	87.2	98.2	94.2
Oakwood	Dearborn	94.2	97.8	80.5	93.2	85.9
Port Huron	Port Huron	94.4	96.4	86.2	96.4	79.0
St. Joseph Mercy	Pontiac	94.2	97.4	76.7	98.1	89.3
St. Joseph Mercy	Ann Arbor	96.9	98.0	89.8	97.3	94.2
St. Mary's	Saginaw	95.1	97.8	82.6	96.6	87.5
Sinai-Grace	Detroit	95.9	98.4	84.7	95.3	91.0
Sparrow	Lansing	96.1	98.1	83.5	97.7	93.9
Spectrum	Grand Rapids	96.2	98.7	85.8	97.9	81.9
St. John Providence	Southfield	96.9	98.3	87.1	97.6	95.8
St. John Providence	Detroit	96.4	97.0	87.4	98.5	98.0
St. John Providence	Warren	96.9	98.1	87.0	98.1	96.3
University of Michigan	Ann Arbor	95.6	98.1	89.1	92.3	84.3
		2969.8	3034.8	2648.5	2989.8	2793.4
Average of those reporting		95.8	97.9	85.4	96.4	90.1

STS Quality Rating

Star Rating	Of the 413 Cardiac Surgical programs in the U.S.A. that participated in the 7/10-6/11 STS Qualitive Initiative and publicly reported results:
One Star *	Only 23 reported received this lowest rating of one star for their Composite Score (5.6%)
Two Stars **	301 received this middle rating of two stars for their Composite Score (71.1%)
Three Stars ***	89 received this highest rating of three stars for their Composite Score (21.5%)
NR	Not Reported - Declined to make their quality scores publicly available

STS Quality Rating

From: DoNotReply@michigan.gov
To: [MDCH-ConWebTeam](#)
Subject: July 17, 2013 Public Hearing Written Testimony (ContentID - 306550)
Date: Monday, July 22, 2013 2:31:39 PM

1. Name: Michael Bekheet
2. Organization: Henry Ford Health System
3. Phone: 313-874-4951
4. Email: mbekhee1@hfhs.org
5. Standards: AA
6. Testimony: Henry Ford Health System supports the proposed volume changes to the open heart surgery (OHS) standards with regard to lowering the attending surgeon annual volume requirement to 50 adult OHS cases and reducing the annual maintenance volume requirement to 150 adult OHS cases. In addition, Henry Ford supports the use of the STS Composite Star Rating System as a means to measure OHS quality and risk-adjusted outcomes, as well as serve as an additional method for assuring compliance with the OHS standards.
7. Testimony:
fpSpamBlock: