Lifeline

2009 Michigan Outcomes Quality Report

Data compiled by
Lifeline Vascular Access

Lifeline Vascular Access Michigan

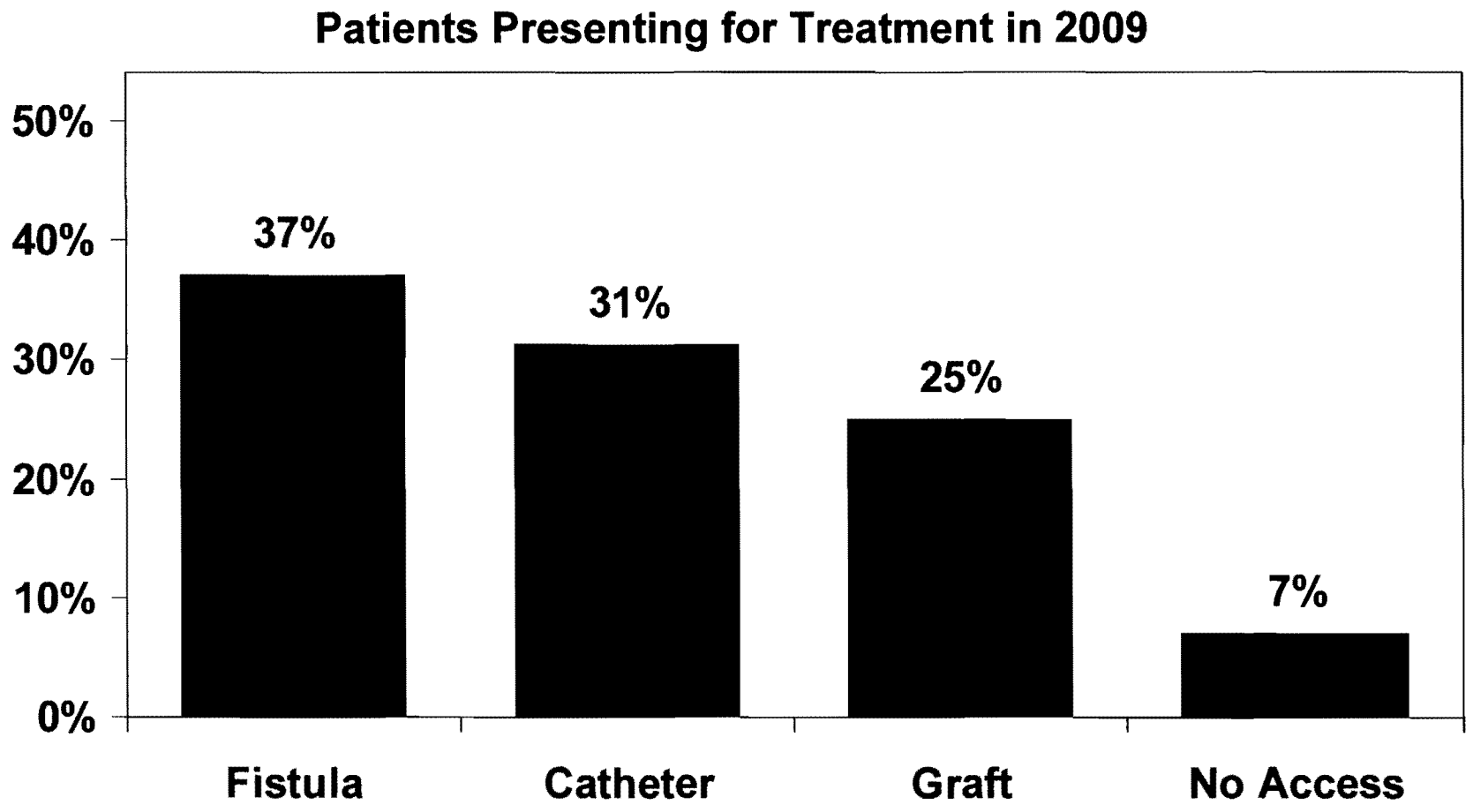
- 6 centers in the State
- 5 in Detroit; 1 in Ypsilanti
- 54 Physicians
- 7,533 patients treated in 2009
- All currently operate as a Physician Office Based Surgery Center
- All centers accredited by Joint Commission

Patient Demographics

Mean age of patients treated: 62 years

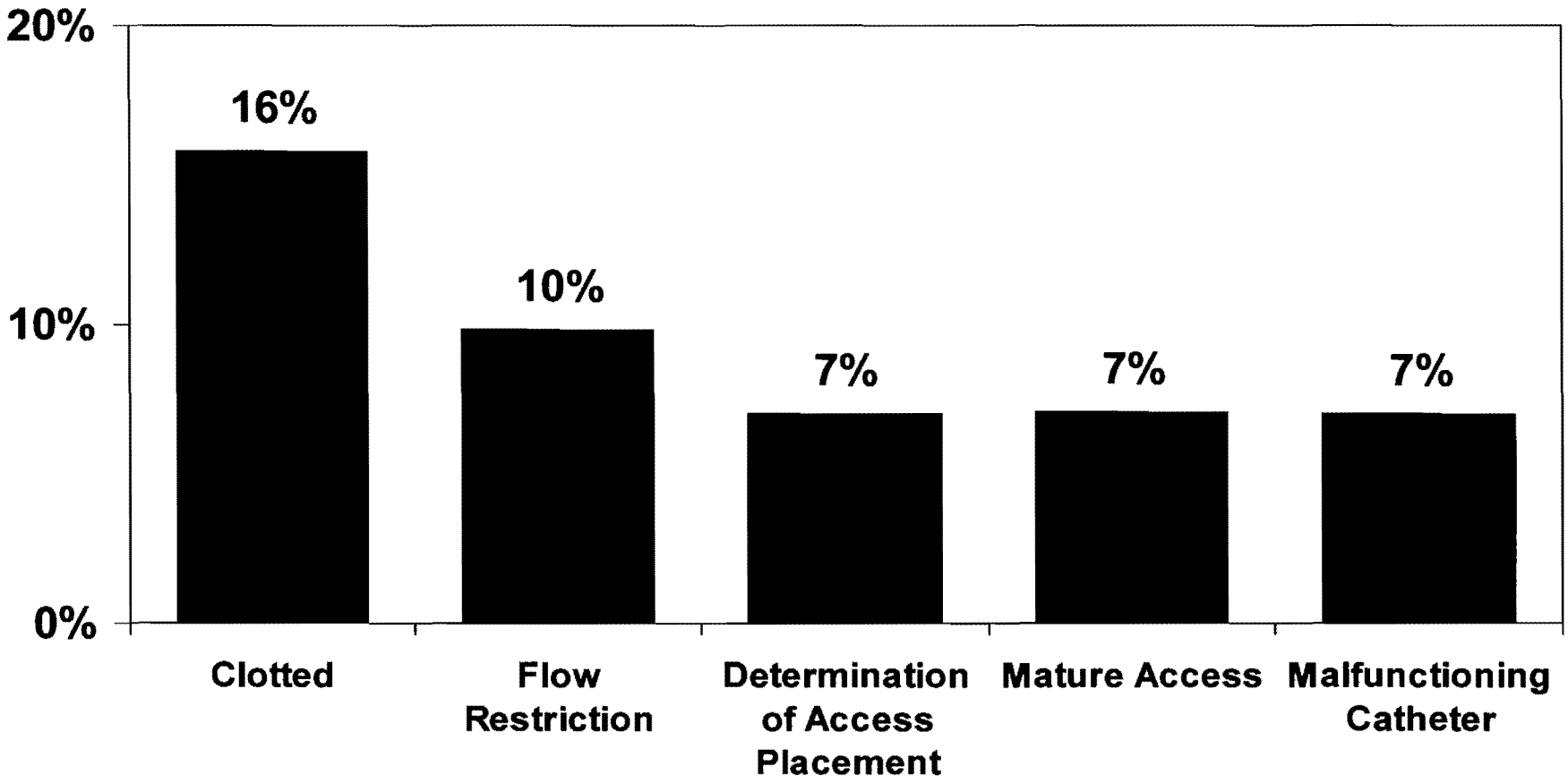
Gender mix:	52% male
	48% female
Racial distribution:	38% white
	57% black
	5% Hispanic
Diabetic patients:	59%

Access Types

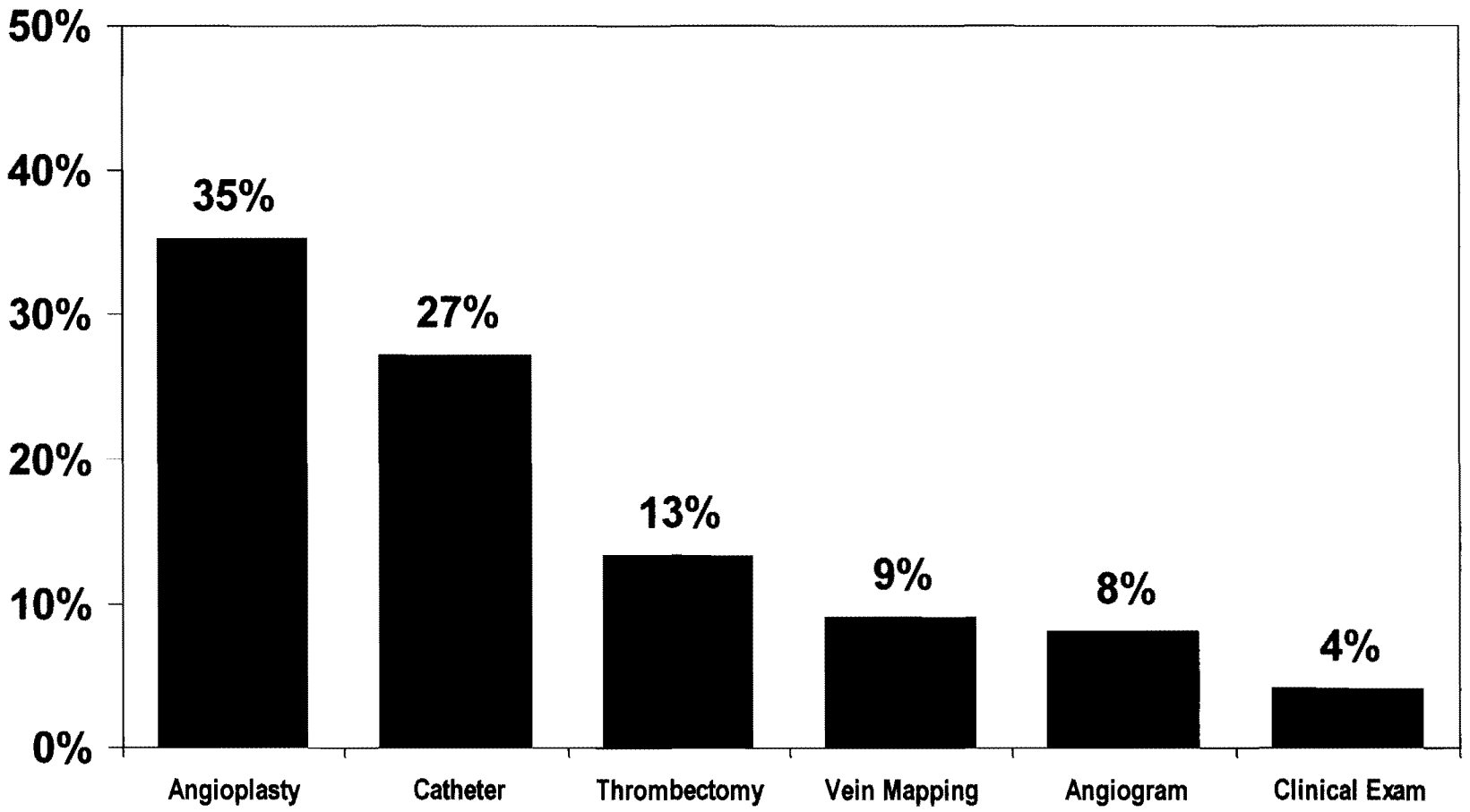


Top 5 Reasons

for Referral to the Access Centers

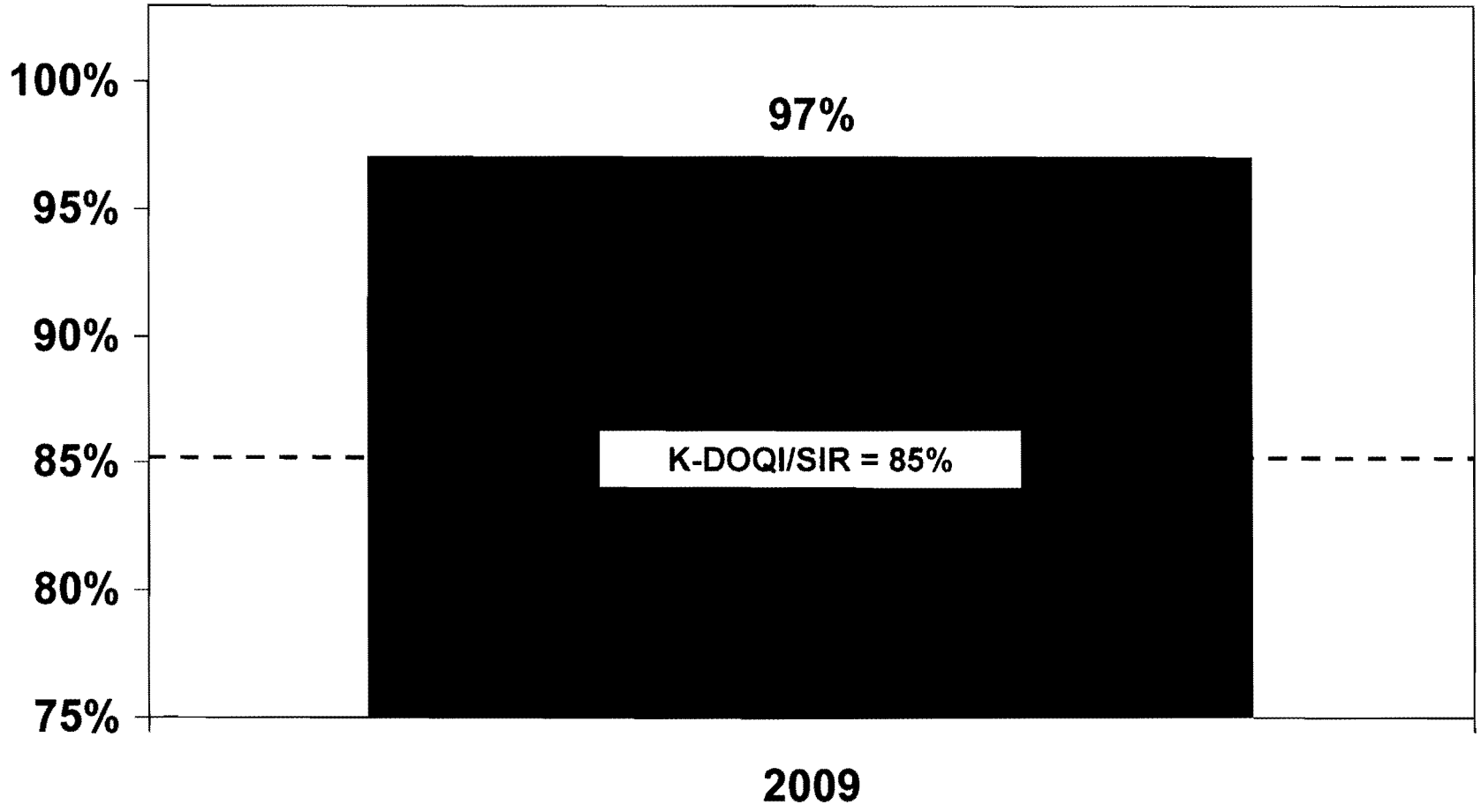


Most Common Procedures Performed

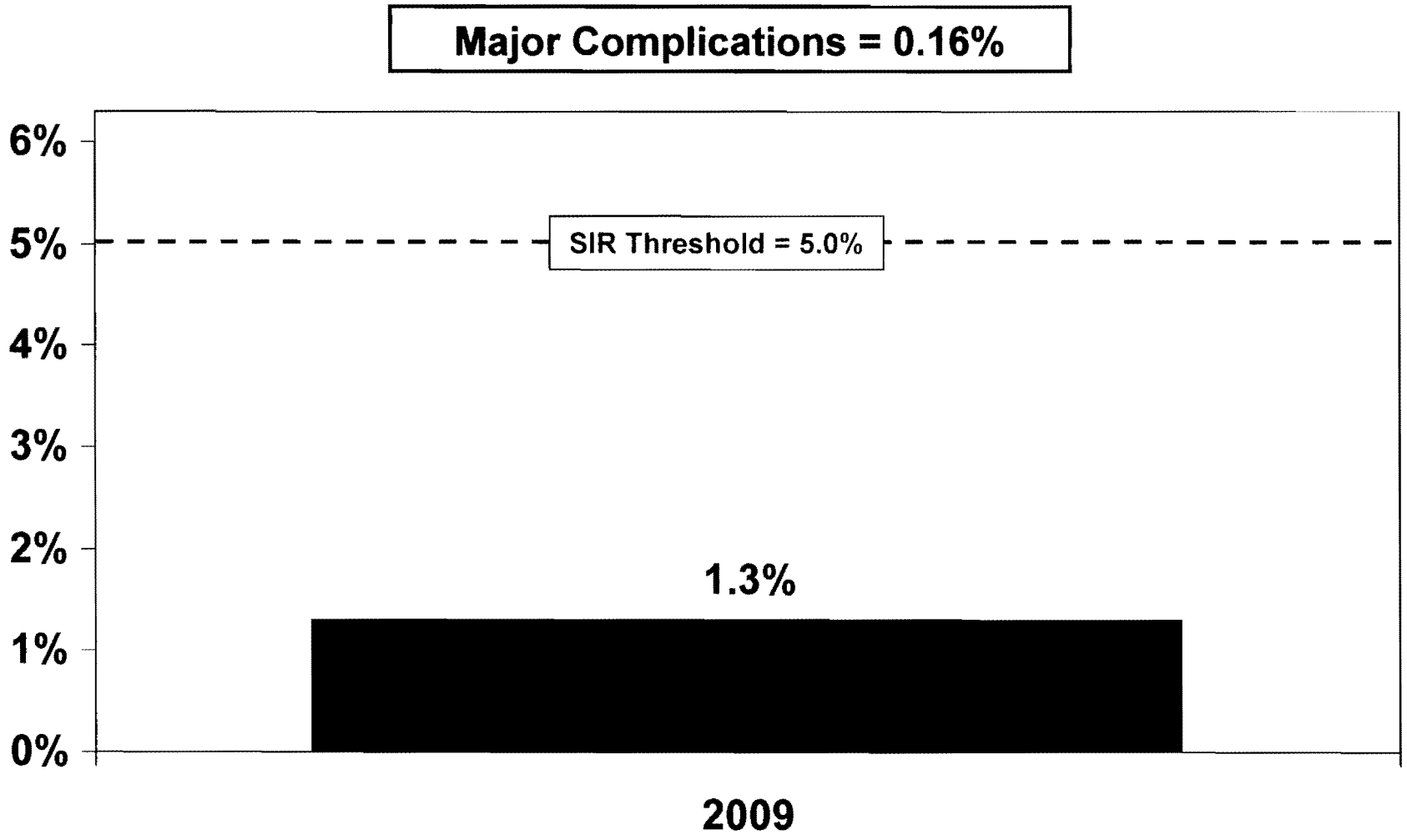


Success Rate is Excellent

Using SIR definition of success-resumption of normal dialysis for at least one session for declots and catheter placements, <30% residual stenosis on angioplasties. Graft declot success rate is 93%.

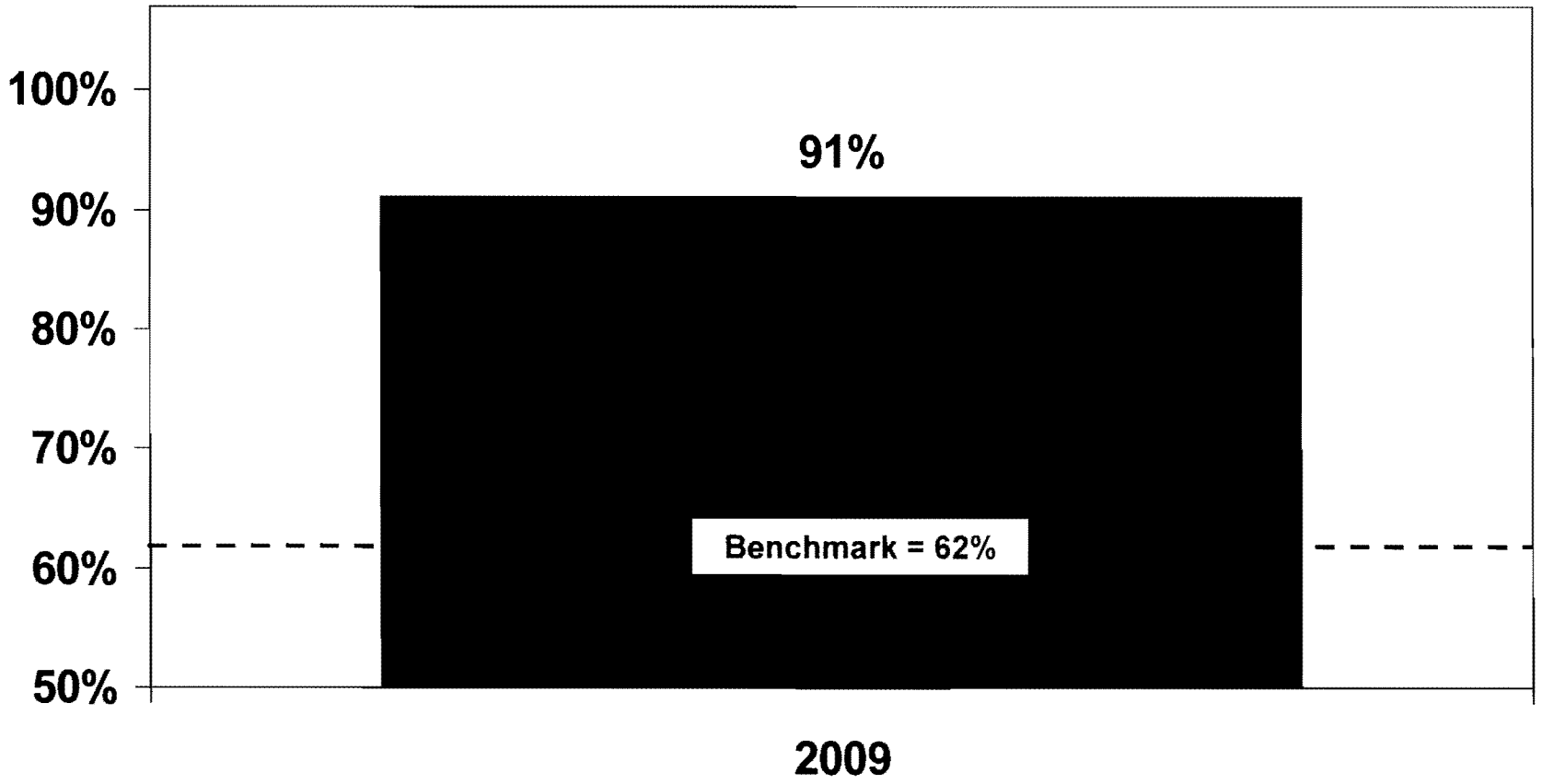


Complications are Low



Patient Satisfaction Survey Results

Overall Ratings of Very Good or Excellent

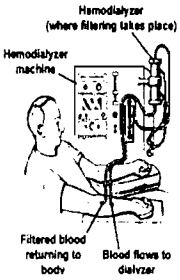


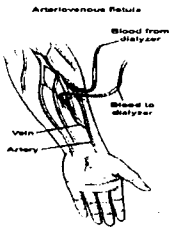
DETROIT 1 **Michigan Kidney Consultants, PC** 10861 Ten Mile Road Oak Park, MI 48237 **Jim Heffernan** **2/01** **1403**	1,282 pts/yr 9 MDs	248-541-7801	Public Testimony by: Joe Garcia of RMS Lifeline Fax: 248-541-7809
DETROIT 2 **East Side Vascular Access Center** St. John Prof. Bldg. Two 22201 Moross, Suite 155 Detroit, MI 48236 **Kim Pawlusiak** **5/02** **1404**	1,237 pts/yr 13 MDs	313-886-4832	Fax: 313-886-4940
DETROIT 3 **Nephrology Hypertension Clinic Access Center** 16507 Southfield Road Allen Park, MI 48101 **Wendy Larsen** **11/02** **1460**	1,522 pts/yr 8 MDs	313-389-0648	Fax: 313-389-3510
DETROIT 4 **Riverview Vascular Access Center** St. John Riverview Hospital Medical Center 7633 E. Jefferson Avenue, Suite 330 Detroit, MI 48214 **Kim Pawlusiak** **10/06** **1461**	585 pts/yr 8 MDS	313-823-5338	Fax: 313-823-5950
ROCHESTER HILLS **Michigan Kidney Consultants Access Center** 1886 West Auburn Road Suite 300 Rochester Hills, MI 48309 **Jim Heffernan** **7/06** **1431**	1,216 pts/yr 8 MDS	248-844-4835	Fax: 248-844-5672
YPSILANTI **Dialysis Access Center of Southeast Michigan** 2890 Washtenaw Avenue Ypsilanti, MI 48197 **Linda Kloss** **6/05** **1393**	1,691 pts/yr 8 MDS	734-528-9433	Fax: 734-528-9455

7,533 patient visits in 2009 in Michigan

Vascular Access – Frequently Asked Questions – 2010

- **What is Vascular Access for Dialysis?**
  - The "Lifeline" or connection point between body & machine
  - Requires on-going maintenance to minimize infections / hospitalizations
  - Three types of Access: 1) Fistulas, 2) Grafts, 3) Catheters
    - Fistulas are considered the "Gold Standard": Better blood flow, reduced infections, last longer, fewer missed treatments





- **What are Vascular Access Centers?**
  - Dedicated outpatient centers that focus on repair and maintenance of vascular access sites
  - ~199 Free Standing Vascular Access centers in US

- **What are the Advantages of Vascular Access Centers?**
  - More Effective: Patients receive continuity of care linked with their kidney care givers
  - More Efficient: Procedures can be performed in 2-4 hours vs. ½-2 days at hospital
  - Cost-Effective: Significantly lower cost than hospitals, especially if hospitalization is avoided
  - Specialized: VACs are specifically designed, equipped, supplied and staffed for vascular access repair and maintenance compared to other sites of service
  - Skilled and Relevant: Procedures performed by specially trained interventionalist
  - Higher Quality of Care: Superior clinical outcomes for procedures[1]
    - 98% procedure success rate which exceed the 85% K/DOQI target
    - 1.5% complications rate which is lower than the industry threshold of 5.0%
  - High Patient Satisfaction: Higher patient satisfaction than hospital setting[2]
    - 76% of patients state their vascular access center experience as better than their previous hospital experience (2008 survey)
    - 91% rate their VAC experience as very good or excellent
  - Support Fistula-First: Perform vessel mapping, fistula maturation studies and procedures in support of goal to increase prevalence of fistulas

[1] Lifeline Vascular Access clinical outcome results
[2] Lifeline Vascular Access 2009 patient satisfaction survey

- **What are the Aligned Goals between CMS and Vascular Access Centers?**
  - Patient access to high quality care
  - Lower cost of care
  - Increasing number of fistulas in ESRD population

- **What is "Fistula First"?**
  - A CMS breakthrough initiative with a goal maximize fistula construction & success rate to achieve 66% of prevalent patients, while reducing catheter use
  - CMS estimates that a 5 percent incremental improvement in fistulas yields **$230 million per year** in Medicare savings

- **How do Vascular Access Centers support CMS' Fistula First Initiative?**
  - Medical literature indicates that 20% to 50% of fistulas that are created never function or fail within a very short period and the need to salvage the early failure of fistulas has increased with Fistula First
  - Vascular Access Centers provide interventional care, fistulograms and angioplasties that are instrumental in the preservation of fistulas-in addition to the vessel mapping services they provide in assisting in the placement of fistulas
  - Vascular Access Centers record in improving outcomes and reducing costs places its providers in a strategic position to support ESRD Networks in achieving CMS goals of 66% AVF compliance for new hemodialysis patients
  - With the proliferation of Vascular Access Centers growing from 6 in 1998 to an estimated 199 in 2010, the prevalence of fistulas increased from 26% to 55.3%% during this period
  - Freestanding Vascular Access Centers are the key to continuing the growth of Arteriovenous (AV) Fistula Rates, which support CMS and ESRD networks Fistula First Initiative

- **How will Rate Reductions Impact Care?**
  - Continued cuts will lead to closure of vascular access centers and compromise quality of care to patients
  - Patient access to care will be negatively impacted
    - Patients will have to seek care at less convenient, more expensive locations
  - There will be an increased cost to tax-payers

1. Name: Amr Aref, M.D.
2. Organization: Radiation Oncology Specialists, P.C.
3. Phone: 586-868-9060
4. Email: Amr.Aref@stjohn.org
5. Standards: MRT
6. Testimony:

October 15, 2010

To Whom It May Concern:

On behalf of Radiation Oncology Specialists, P.C.; I would like to submit the following comments in regard to MRT CON requirements.

1.We agree that MRT should continue to be a CON covered service.

a). In the past few years there has been an increase in the number of MRT units as a result of initiation of new services or expansion of existing services. Few if any MRT units are operating now with maximum capacity. With changes in MichiganÆs economy, patient volumes have also declined.

b). Changes in technology also warrant review of the equivalent treatment visit (ETF) factor.

2. In view of the above noted remarks we support the formation of a SAC to revisit the MRT CON standards particularly in relation to initiation or expansion of MRT services.

Sincerely,

Amr Aref, M.D.
Chief of Radiation Oncology
St.John Hospital and Medical Center
VanElslander Cancer Center
Radiation Therapy

Paul Chuba, M.D., Ph.D.
Clinical Chief of Radiation Oncology
St.John Macomb Oakland Hospital
Webber Cancer Center

7. Attachment:

1. Name: Meg Tipton
2. Organization: Spectrum Health Hospitals
3. Phone: 616-391-2043
4. Email: meg.tipton@spectrum-health.org
5. Standards: PET
6. Testimony:

Content-Length: 34312

October 20, 2010

Edward B. Goldman, Chair
Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building, 201 Townsend Street
Lansing, MI 48913

Dear Commissioner Goldman,

This letter is written as formal testimony for the CON Review Standards for Positron Emission Tomography (PET) scanners. It is the position of Spectrum Health that the Positron Emission Tomography (PET) scanners standards should not be opened for review at this time. We believe that the CON Review Standards for Positron Emission Tomography (PET) scanners have served Michigan based hospitals and healthcare organizations very well. These standards have assured the availability of sufficient access to Positron Emission Tomography (PET) scanners to meet the needs of Michigan citizens, while enabling Michigan's health care organizations to provide quality care to their patients and therefore we do not suggest revisions or review of the current CON Review Standards for Positron Emission Tomography (PET) scanners.

Spectrum Health appreciates the opportunity to present our comment on the current CON Standards for Positron Emission Tomography (PET) scanners.

1. Name: Tina Weatherwax Grant
2. Organization: Trinity Health
3. Phone: 248-489-6765
4. Email: granttw@trinity-health.org
5. Standards: CC
6. Testimony:

Content-Length: 93936

TRINITY HEALTH
Novi, Michigan

27870 Cabot Drive
Novi, MI 48377-2920
ph 248.489.5004

34605 Twelve Mile Road
Farmington Hills, MI 48331-3221
ph 248.489.6000

www.trinity-health.org

October 20, 2010

Edward B. Goldman, J.D., Chairperson
Certificate of Need Commission
Michigan Department of Community Health
Lansing, MI 48913

Dear Chairman Goldman:

Trinity Health would like to thank the Certificate of Need Commission for the opportunity to comment on what, if any, changes need to be made to the Certificate of Need Standards. In consideration of the Cardiac Catheterization Services Standards scheduled for review in 2011, Trinity Health supports the ongoing efforts to seat a SAC to address the charge assigned by the Commission. Trinity Health is confident that this format will appropriately address the issues previously identified for review and/or change.

Trinity Health supports the need for continued regulation of Cardiac Catheterization Services.

Respectfully,

Garry C. Faja
President and CEO
Saint Joseph Mercy Health System
and
Regional Market Executive-East MI
Trinity Health

Roger W. Spoelman
President and CEO
Mercy Health Partners
and
Regional Market Executive-West MI
Trinity Health

Sponsored by Catholic Health Ministries

1. Name: Steven Szelag
2. Organization: University of Michigan Health System
3. Phone: 734-647-1163
4. Email: sszelag@umich.edu
5. Standards: HB
6. Testimony: Please see the attached file.

Content-Length: 22597

University of Michigan Health System
1500 East Medical Center Drive
Ann Arbor, MI 48109

Public Testimony
Certificate of Need (CoN) Review Standards for Hospital Beds
October 20, 2010

My name is Steven Szelag and I am a Strategic Planner at the University of Michigan Health System (UMHS). UMHS wishes to take this opportunity today to offer comments pertaining to the Certificate of Need (CoN) review standards for hospital beds.

UMHS strongly supports the overall regulations for the current hospital bed standards as they continue to function as a means of assuring appropriate and adequate access for the citizens of Michigan. More specifically, the high occupancy bed expansion provision enables providers to quantitatively demonstrate need and serves as a method for relieving physical capacity constraints within a hospital. The latest annual hospital survey conducted by the Michigan Department of Community Health indicates that recent applicants who have acquired incremental bed licenses under this provision continue to operate at an occupancy rate above the minimum threshold established by the CoN Commission. This metric and other metrics would suggest the hospital bed standards are functioning as intended. UMHS would recommend that these standards not be opened for review.

Thank you for according us the opportunity to make this statement today.

1. Name: Walter M. Sahijdak MD
2. Organization: Michigan Society of Therapeutic Radiologists and Oncologists
3. Phone: 734-712-3596
4. Email: sahijdak@trinity-health.org
5. Standards: MRT
6. Testimony:

Content-Length: 40078

Michigan Society of Therapeutic Radiologists and Oncologists
3031 West Grand Blvd., Suite 645
Detroit, Michigan 48202-5002

October 13, 2010

RE: Certificate of Need (CON) Review Standards for Megavoltage Radiation Therapy (MRT) Services/Units

Michigan Department of Community Health (MDCH)

Ladies and Gentlemen:

This comment is in reference to Certificate of Need Review Standards for Megavoltage Radiation Therapy (MRT) Services/Units.

The Michigan Society of Therapeutic Radiologists and Oncologists (MSTRO) is the state specialty society for radiation oncology whose members include over 75 practicing physicians in the state of Michigan.

MSTRO supports the continued regulation of Megavoltage Radiation Therapy (MRT) Services/Units and recommends the CON committee update the current review standards by appointing a Standard Advisory Committee (SAC).

Reasons for this recommendation are listed below:

1. The last MRT-SAC was held in 2005. Improvements in the technology to deliver radiation therapy have occurred since the last MRT-SAC that warrants an update of the current review standards including the equivalent treatment visit (ETV) factoring.
2. Changes in Michigan's demographics and population levels along with national changes in the standard of care practices for cancer patients have each decreased the number of patients receiving MRT. These factors need to be considered in determining MRT usage in Michigan to prevent over utilization.

Thank you for the opportunity to provide these comments and our recommendations. We are available for any questions or need for additional input.

Sincerely,

Walter M. Sahijdak MD

Walter Michael Sahijdak, MD
Chair/Past President,
Michigan Society of Therapeutic Radiologists and Oncologists

1. Name: Carlos Rodriguez, M.D.
2. Organization: Spectrum Health Hospitals
3. Phone: 616-391-8152
4. Email: carlos.rodriguez@spectrum-health.org
5. Standards: SS
6. Testimony:

Content-Length: 78996

October 14, 2010

Edward Goldman, 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. Goldman,

I am writing to request that the State of Michigan include provisions in the CON Surgical Services Review Standards for a full-time operating room dedicated to trauma care. I am aware that provisions once existed within the surgical standards to allow a licensed hospital to dedicate one (1) operating room to be used exclusively for the care of trauma patients. I would like to propose that language be reinstated into the surgical standards to once again allow a dedicated trauma operating room.

It is through my experience that I believe a dedicated trauma room would save significant time and provide better patient care at our very busy level I trauma center. Just last week a very badly injured patient was brought to our hospital and during the time it took to prepare a room, the patient continued to bleed. To that patient and to other trauma patients time equals blood loss and a higher mortality. In reality each second of bleeding is a second closer to death. The number and severity of trauma cases has continued to increase and with that so does the need for dedicated space. Each time that a trauma case arrives, we waste precious time in getting the next available room ready. During that time, the patient's condition may deteriorate while waiting. We would like to have a room ready and waiting for that critically injured patient. As a designated Level 1 Trauma Center it is our obligation to provide expedient medical care for all trauma patients that come through our doors. With that goal in mind, I propose the Standards for Surgical Services be modified to include a provision for a dedicated trauma operating room which could be excluded from the normal CON volume requirements.

On average there are over 1,200 trauma cases experienced at Spectrum Health Butterworth Hospital each year. This equates to an average of 3.5 trauma cases

each day which would easily justify the need for a dedicated trauma operating room. In closing, I would to thank the commission for the opportunity to present my recommendations for change to the current surgical standards.

Sincerely,

Carlos Rodriguez, MD, FACS
Interim Trauma Director
Medical Director of Perioperative Services
Assistant Professor of Surgery,
Michigan State University, College of Human Medicine

1. Name: Shyam Parekh
2. Organization: Spectrum Health
3. Phone: 616 391-1944
4. Email: shyam.parekh@spectrum-health.org
5. Standards: SS
6. Testimony: As Associate Medical Director of Anesthesiology for Spectrum Health Hospitals, I am writing to request that the State of Michigan include provisions in the CON Review Standards for Surgical Services for an operating room dedicated for research purposes. With the fast-paced changes in surgical techniques, more patients are being treated under research protocols, especially in large, busy referral centers. Procedures performed on patients under research protocols may require more time and specialized equipment than established procedures. In addition, experimental procedures can tie up operating rooms for extensive periods of time, as procedures done for research often are slower and require specialized room set up
Much of the surgical research that will be done in the future will be multidisciplinary in nature, often not supported by existing infrastructure. For instance, hybrid procedures which require involvement of both cardiologists and cardiac surgeons will allow us to study the feasibility of percutaneous aortic valve replacement. These sorts of procedures are unique in their requirement for an operating room with specialized imaging capabilities. In other words, the types of research which can be done are limited by the types of operating rooms which are created. In Massachusetts, one Harvard teaching hospital has created a room named "OR of the Future" specifically to study the effects of making specific changes to room design, equipment, and procedures on operating room workflow, efficiency and patient safety. Operating rooms dedicated to research encourage our best minds not only to study new procedures, but also to ask how we can make procedures more efficient, more cost eff
ective and safer.
If tertiary hospitals in Michigan were able to dedicate an operating room for research, more experimentation and innovation would be possible, without disrupting the precision and efficient operation of busy perioperative services. I am aware that CON Standards for other services have provisions for dedicated research purposes. I would like to see a similar provision added to the Surgical Standards.

7. Attachment:

1. Name: Robert Meeker
2. Organization: Spectrum Health
3. Phone: 616 391-2779
4. Email: robert.meeker@spectrum-health.org
5. Standards: OHS
6. Testimony: The CON Review Standards for Open-Heart Surgery are up for review in 2011. Spectrum Health believes that the current Standards are sufficient and do not need to be revised at this time. They have served well since they were reopened in 2007 and need no further revision.

There is no need for additional open-heart surgery programs in Michigan. The citizens of the state are well-served by the existing programs. In fact, there is evidence that there are too many open-heart surgery programs operating in the state now. 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 14% from 2005 û 2009. There are thirty-three (33) approved open-heart surgery programs in Michigan. Of them, eighteen (18) (more than half) do not meet the current minimum standard of 300 cases per year. Additionally, since 1993, eight (8) new open-heart programs have been approved in Michigan, most recently in 2006. According to the 2009 Annual Survey, none of those new programs reached the annual requirement of 300 cases per year. Research has repeatedly demonstrated the link between higher volume and better quality and outcomes for cardiac proced
ures.

For these reasons, Spectrum Health does not see the need for any revisions to the CON Review Standards for Open-Heart Surgery during this review cycle.

7. Attachment:

1. Name: Dennis McCafferty
2. Organization: The Economic Alliance for Michigan
3. Phone: 248 596 1006
4. Email: dennismccafferty@eamonline.org
5. Standards: SS
6. Testimony: If the formation of a SAC to review the Surgical Services standards is advocated by others and supported by the Department, we would support including changes that would improve proficiency, outcomes and cost-effectiveness, while addressing relevant access concerns.
The surgical standards already apply the same rules for both hospitals and physician owned free-standing surgical centers. We also support changes in the standards that would specify that surgical support staff of all free-standing surgical center be credentialed by appropriate national accreditation organizations.

7. Attachment:

1. Name: Dennis McCafferty
2. Organization: The Economic Alliance for Michigan
3. Phone: 248-596-1006
4. Email: dennismccafferty@eamonline.org
5. Standards: OHS
6. Testimony: Per hospital data reported to MDCH, Michigan OHS volume has dropped by 26% in nine years (15,811 in 2000 to 11,683 in 2009). The average number of cases per hospital has dropped even more (by 40%: 586 in 2000 to 354 in 2009) because the number of programs increased from 27 to 33). The decline in volume has impacted every region of the state and at nearly every program that was operational in 2000.
EAMÆs position is that there are already too many OHS programs in Michigan in terms of the negative impact on costs and quality. As the overall volumes for this service continue to decline, the minimum annual volumes at many programs has dropped below what would be required to maintain the highest skill level for surgeons and support staff. This puts patients at increased risk for adverse out-comes.
We would support the formation of an OHS SAC to review changes in the standards that would help facilitate the consolidations and/or closure of current OHS programs that consistently fail to meet the minimum annual volumes in the standards.

7. Attachment:

1. Name: Dennis McCafferty
2. Organization: The Economic Alliance for Michigan
3. Phone: 248 596 1006
4. Email: dennismccafferty@eamonline.org
5. Standards: MRT
6. Testimony: According to national news sources, various medical groups, and Federal agencies, patients around the country are being overexposed to radiation from diagnostic imaging and radiology treatment equipment. Some of the overexposure comes from defects in the machine or software; others are the result of operator errors. Sources cited in the articles believe these occurrences are avoidable. However, radiation technology is changing so quickly that it is outpacing staff training and the development of treatment protocols.

Citizens canÆt be sure if there is a problem in Michigan without careful investigation but it would seem unlikely that Michigan is not affected by these national trends. Many of these instances are not required to be reported to state or Federal authorities. Some instances have only become public when the patient or the family has taken legal action after becoming aware of their overexposure. Further, many of these legal cases result in a settlement agreement bound by confidentiality.

EAM supports the formation of a Workgroup to address strengthening the patient safety requirements related to MRT services. It should consider whether the standards for additional MRT units should be strengthened to better achieve greater proficiency, cost-effectiveness and appropriate access. The net gain for patient safety that would be provided by CON would be the ability to strengthen the requirements for the qualifications and proficiency of the health professionals that operate the MRT units, plan the treatment, interpret the results, etc. (Strengthening the reporting of adverse radiation events is now under consideration for inclusion in the radiation safety rules. That division has the better legal ability, and the staffing, to deal with adverse events and other machine issues.)

7. Attachment:

1. Name: Dennis McCafferty
2. Organization: The Economic Alliance for Michigan
3. Phone: 248-596-1006
4. Email:
5. Standards: HB
6. Testimony: Per MSU Geography Department research, almost 100% of Michigan citizens already reside within a 30-minute drive time of a hospital. That is the long-standing criterion of reasonable access to an inpatient hospital. But in fact, most Michigan residents are even closer than 30 minutes to a hospital and usually to multiple hospitals.

The total number of net excess beds among all 64 Michigan sub-areas, as of now is 5,266, (20% of the statewide hospital bed inventory of 26,305). Further, the statewide bed need of 21,039 was the result of the liberalization of the methodology in response to changes in medical practice. The methodology includes on average, an overall vacancy gap of about 20% to allow for variations in utilization during the week and over the course of the year. It was just a few years ago, prior to this liberalization we had a statewide need of about 17,000 beds. So statewide, Michigan has far more than enough hospital bed capacity.

Of course, the issue for patients and the health care system is the situation in each local area, not statewide. There are six hospital sub-areas the state for which there is a bed need, but those are all very minor amounts û 16 or fewer beds. (Five of those sub-areas are in sparsely settled areas on the southern edge of the state, or in northern Michigan or the UP.) Clearly that is not enough bed need in any sub-area of the state to justify another hospital.

It is notable that the two sub-areas with the greatest excess capacity are Oakland County (1,074 excess beds) and western Wayne County (644 excess beds).

A further indication of excess hospital capacity is that the overall statewide occupancy in 2009 was 57%. The number of total statewide patient days in 2009 was 5.4 million; the same as twelve years before in 1997 with only minor variation in the intervening years. The long-projected growth in need for more inpatient capacity û due to aging of the population and other factors û has not materialized. Reductions in average length of stay and shift to out-patient venues have offset the aging of the population and other factors. Clearly additional inpatient bed capacity is not needed. Nor is easier relocation of existing hospitals warranted: while central cities have excess capacity, so do suburban communities.

EAM would support the formation of a SAC to review the Hospital Bed Standards because of the far-reaching impact of the hospital standards on MichiganÆs healthcare system. Concerned groups should have the opportunity every three years to review their areas of concern with a SAC of hospital experts and representatives of the statutorily-defined interest groups: consumers, employers, insurance payers and providers.

It is time for the Commission to recognize the very high and widespread extent of hospital excess capacity indicated by the statistics that were summarized above. We recommend that the SAC should consider adding a provision in the standards that would limit hospitals who are replacing existing fully-depreciated and obsolete in-patient bed capacity. The number of replacement in-patient beds approved should not exceed actual average occupancy for that hospital for the prior two years, by more than 125%. This right-sizing of inpatient bed capacity would begin to adjust excess number of licensed capacity to actual average occupancy as hospitals are required to replace their out-dated and obsolete facilities.

7. Attachment:

1. Name: Jim Gilson
2. Organization: Beaumont Hospitals
3. Phone: 248.551.6405
4. Email: james.gilson@beaumonthospitals
6. Testimony:

Content-Length: 21968

Beaumont HOSPITALS

October 13, 2010

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 Certificate of Need Commission Members:

This letter is written as formal testimony about the C.O.N. Review Standards for Hospital Beds and Addendum for HIV Infected Individuals, Megavoltage Radiation Therapy (MRT) Services/Units, Open Heart Surgery Services, Positron Emission Tomography (PET) Scanner Services, and Surgical Services that are scheduled for review in 2011. Beaumont appreciates the opportunity to comment on these Standards.

Hospital Beds and Addendum for HIV Infected Individuals:
Beaumont supports the continued regulation of hospital beds. However, the comparative review criteria should be reviewed by the Commission because 53%-75% of the available points in a comparative review for hospital beds are determined by payor mix. In addition, the effect of the hospital tax more than compensates some hospitals for their higher Medicaid volumes. This does not reflect an appropriate balance of costs, quality and access, which are the goals of the C.O.N. program. These comparative review criteria should also be reviewed in light of health care reform and the resultant impact on costs, quality and access. Sources of payment or insurance should not be a C.O.N. factor.

Megavoltage Radiation Therapy (MRT) Services/Units:
Beaumont supports the continued regulation of MRT services, and recommends that the Commission review Section 4 and Section 12 relating to initiation of MRT Services: under the current standards, there is the potential for “double counting” of new cancer cases, which could result in overcapacity of MRT services.

Open Heart Surgery Services:
Beaumont supports the continued regulation of open heart services, and the 300 case minimum procedure volume thresholds. In addition, Beaumont requests that the Commission continue to pressure the Department to routinely and consistently enforce C.O.N regulations, including volume requirements.

Corporate Administration
3711 W. Thirteen Mile Rd.
Royal Oak, MI 48073-6769

Beaumont HOSPITALS

Positron Emission Tomography (PET) Scanner Services:
Beaumont supports the continued regulation of Positron Emission Tomography (PET) Scanner Services, and has the following three recommendations:

1.) There should be a review of the weights assigned to "bed positions" because the number and type of appropriate bed positions can be different depending on the manufacturer of the PET camera.
2.) For unanticipated downtime, CON regulations should provide for the temporary use of research PET, if available.
3.) Review of PET standards to consider the need to either make an exemption for the use of Positron Emission Mammography (PEM) or develop specific standards for the use of Positron Emission Mammography (PEM).
Medical literature and the experience at some academic medical center comprehensive breast programs in the US demonstrate a limited but very important clinical role for some women in making the best medical decision for their breast care. The lack of standards or exemption from PET CON standards confines the use of PEM to research protocols and denies comprehensive breast care programs in Michigan from offering women this important clinical tool. PEM has been shown to be of value for women who have a breast lesion thought to be benign. In these cases PEM is useful in determining if, and when, a biopsy is warranted. Also younger women with dense breasts who are at high risk of developing breast cancer can benefit from use of PEM when MRI is non-diagnostic or the women have a contraindication.

Surgical Services:
Beaumont supports the continued regulation of surgical services, but does not see the need for a comprehensive review of the standards at this time.

Thank you for the opportunity to provide comment on the C.O.N. Review Standards.

Sincerely,

Patrick O'Donovan
Vice President, Planning

Cc: L. Horvath

Corporate Administration
3711 W. Thirteen Mile Rd.
Royal Oak, MI 48073-6769

1. Name: Tina Weatherwax Grant
2. Organization: Trinity Health
3. Phone: 248-489-6765
4. Email: granttw@trinity-health.org
5. Standards: PET
6. Testimony:

Content-Length: 95018

TRINITY HEALTH
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October 20, 2010

Edward B. Goldman, J.D., Chairperson
Certificate of Need Commission
Michigan Department of Community Health
Lansing, MI 48913

Dear Chairman Goldman:

Trinity Health would like to thank the Certificate of Need Commission for the opportunity to comment on what, if any, changes need to be made to the Certificate of Need Standards. In consideration of the Positron Emission Tomography Scanner (PET) Standards scheduled for review in 2011, Trinity Health would like to request the Commission to direct the Department or a workgroup to propose language that establishes a formal definition of "radiation therapy patient visit."

Under Section 16 (c) of the PET Standards, radiation therapy patient visits contribute a substantial multiplier to the calculation of procedure equivalents. However, because the current standards do not include a definition of radiation therapy patient, there is opportunity for undercounting as well as overcounting in applying the standards to projects which propose expansion, replacement or initiation of a fixed PET from a mobile unit. Trinity Health believes lack of clarity creates the opportunity for an uneven application of the standards to PET-related projects and can be simply remedied through the addition of a definition for "radiation therapy patients."

Trinity Health supports the need for continued regulation of PET Scanner Services and encourages the Commission to address the need as stated above.

Respectfully,

Garry C. Faja
President and CEO
Saint Joseph Mercy Health System
and
Regional Market Executive-East MI
Trinity Health

Roger W. Spoelman
President and CEO
Mercy Health Partners
and
Regional Market Executive-West MI
Trinity Health

1. Name: Tina Weatherwax Grant
2. Organization: Trinity Health
3. Phone: 248-489-6765
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5. Standards: MRT
6. Testimony:

Content-Length: 94850

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October 20, 2010

Edward B. Goldman, J.D., Chairperson
Certificate of Need Commission
Michigan Department of Community Health
Lansing, MI 48913

Dear Chairman Goldman:

Trinity Health would like to thank the Certificate of Need Commission for the opportunity to comment on what, if any, changes need to be made to the Certificate of Need Standards. In consideration of the Megavoltage Radiation Therapy Standards scheduled for review in 2011, Trinity Health would like to request the Commission to consider establishing a workgroup to review, analyze and update the weights assigned to the Megavoltage Radiation Therapy Standards.

The current weights used to calculate equivalent treatment visits were established nearly 5 years ago and do not take into consideration recent changes in the technology, techniques and applications of radiation therapy. Because these weights are central to evaluating CON applications to initiate, expand, and replace/upgrade MRT scanners/services, Trinity Health supports the establishment of a workgroup to empirically update the weighting in alignment with current medical practices and technologies.

Trinity Health supports the need for continued regulation of MRT Services/Units and encourages the Commission to address the need as stated above.

Respectfully,

Garry C. Faja
President and CEO
Saint Joseph Mercy Health System
and
Regional Market Executive-East MI
Trinity Health

Roger W. Spoelman
President and CEO
Mercy Health Partners
and
Regional Market Executive-West MI
Trinity Health

1. Name: Tina Weatherwax Grant
2. Organization: Trinity Health
3. Phone: 248-489-6765
4. Email: granttw@trinity-health.org
5. Standards: HB
6. Testimony:

Content-Length: 96127

TRINITY HEALTH
Novi, Michigan

October 20, 2010

Edward B. Goldman, J.D., Chairperson
Certificate of Need Commission
Michigan Department of Community Health
Lansing, MI 48913

Dear Chairman Goldman:

Trinity Health would like to thank the Certificate of Need Commission for the opportunity to comment on what, if any, changes need to be made to the Certificate of Need Standards. In consideration of the Hospital Bed Standards scheduled for review in 2011, Trinity Health would like to request the Commission to consider opening the Hospital Beds Standards and establishing a workgroup to review and recommend proposed language that creates incentives to reduce the current oversupply of Hospital Beds.

Currently within the standards, there is no enforcement or action to be taken to move the state to a more appropriately-sized number of licensed beds. The Department's bed inventory indicates over 5,000 excess beds in the State. Trinity Health believes it is in the public and providers' best interest to have Certificate of Need policies that bring the total number of licensed beds into better alignment with patient need.

Trinity Health believes such a change would not negatively impact patient access or quality; excess beds are not critical to low occupancy hospitals' operations and do not provide any additional benefit to patients. Trinity Health is concerned, however, that excess beds do create the potential for unnecessary costs if hospitals are sizing renovation and replacement projects to maintain licensure of excess beds.

Trinity Health would support revising current Hospital Bed Standards language to include the release of some portion of excess beds when an applicant seeks CON review and approval of bed-related projects, such as renovations and replacements. Hospitals that might later experience high occupancy as a result of this bed de-licensing can remedy their situations by accessing the high occupancy provisions currently allowable under the Hospital Beds Standards.

Trinity Health supports the need for continued regulation of Hospital Beds and encourages the Commission to address the need as stated above.

Respectfully,

Garry C. Faja
President and CEO
Saint Joseph Mercy Health System
and
Regional Market Executive-East MI
Trinity Health

Roger W. Spoelman
President and CEO
Mercy Health Partners
and
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Michigan Ministry Organizations:

Battle Creek Health System
Denise Brooks-Williams
President and CEO

Chelsea Community Hospital
Kathleen Griffiths
President and CEO

Mercy Health Partners
Roger Spoelman
President and CEO

Mercy Hospital – Cadillac
John L. McLeod
President and CEO

Mercy Hospital - Grayling
Stephanie Riemer Matuzak
President and CEO

Saint Joseph Mercy Health System
Garry C. Faja
President and CEO

Saint Mary's Health Care
Philip H. McCorkle Jr.
President and CEO

St, Joseph Mercy Hospitals
Robert Casalou
President and CEO

St. Joseph Mercy Oakland
Jack Weiner
President and CEO

St. Joseph Mercy Port Huron
Peter Karadjoff
President and CEO

St. Mary Mercy Hospital
David Spivey
President and CEO

Trinity Senior Living Communities
Ken Robbins
Chief Executive Officer

Trinity Home Health Services
Grace McCauley
Chief Executive Officer

1. Name: Sean Gehle
2. Organization: The Michigan Health Ministries of Ascension Health
3. Phone: 517-482-1422
4. Email: sean.gehle@stjohn.org
5. Standards: SS
6. Testimony: Ascension Health û Michigan health systems support the continued regulation of Surgical Services. Given the prominence of these standards to the CON program we would recommend that a SAC or workgroup be formed to address any relevant issues.
7. Attachment:

1. Name: Sean Gehle
2. Organization: The Michigan Health Ministries of Ascension Health
3. Phone: 517-482-1422
4. Email: sean.gehle@stjohn.org
5. Standards: PET
6. Testimony: The Michigan Health Ministries of Ascension Health support the continued regulation of Positron Emission Tomography. We support the current standards as appropriate and do not recommend any changes to the existing standard nor do we recommend the formation of a workgroup or SAC at this time.

7. Attachment:

1. Name: Sean Gehle
2. Organization: The Michigan Health Ministries of Ascension Health
3. Phone: 517-482-1422
4. Email: sean.gehle@stjohn.org
5. Standards: OHS
6. Testimony:

Ascension Health û Michigan health systems support the continued regulation of Open Heart programs and do not recommend any changes to the standards at this time. More specifically, we would not recommend that a workgroup or SAC be formed at this time.

7. Attachment:

1. Name: Sean Gehle
2. Organization: The Michigan Health Ministries of Ascension Health
3. Phone: 517-482-1422
4. Email: sean.gehle@stjohn.org
5. Standards: MRT
6. Testimony: The Michigan Health Ministries of Ascension Health support the continued regulation of Megavoltage Radiation Therapy services and would specifically recommend that the language in the standards be modified to distinguish between replacement and upgrade. The MRT standards, unlike other CON standards, do not distinguish between replacement of equipment and upgrades to equipment. We believe that making this distinction in the standards is within the purview of the CON Commission, however could also be accomplished along with a review of the requirements for initiating a new MRT service through the formation of a Standard Advisory Committee.
7. Attachment:

1. Name: Sean Gehle
2. Organization: The Michigan Health Ministries of Ascension Health
3. Phone: 517-482-1422
4. Email: sean.gehle@stjohn.org
5. Standards: HB
6. Testimony: Ascension Health û Michigan supports the continued regulation of Hospital Beds and recommends that because of the prominence of these standards in the overall CON program that these standards be reviewed to evaluate them in the context of the overall CON programmatic goals of Cost, Quality and Access.
7. Attachment:

1. Name: Sean Gehle
2. Organization: The Michigan Health Ministries of Ascension Health
3. Phone: 517-482-1422
4. Email: sean.gehle@stjohn.org
6. Testimony:

Content-Length: 358966

THE MICHIGAN HEALTH MINISTRIES OF ASCENSION HEALTH

Advocacy Office:

328 West Ottawa Street
Lansing, MI 48933-1587

Phone: 517.482.1422
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Ascension Health – Michigan testimony on CON Standards eligible for Review in 2011

On behalf of the Michigan Health Ministries of Ascension Health (Borgess Health, Genesys Health System, St. John Providence Health System, St. Joseph Health System and St. Mary's of Michigan please accept our comments regarding the following CON Standards eligible for review by the CON Commission in 2011 (Hospital Beds and Addendum for HIV infected Individuals, Megavoltage Radiation Therapy Services/Units, Open Heart Surgery Services, Positron Emission Tomography Scanner Services, and Surgical Services).

Ascension Health – Michigan supports Michigan's Certificate of Need program and to the extent that an organization or interested party is interested in seeking modification to standards eligible to be reviewed in 2011, we encourage that this discussion occur in the context of the CON process. Please find our comments below relative to the following Standards eligible for review in 2011:

PET

The Michigan Health Ministries of Ascension Health support the continued regulation of Positron Emission Tomography. We support the current standards as appropriate and do not recommend any changes to the existing standard nor do we recommend the formation of a workgroup or SAC at this time.

MRT

The Michigan Health Ministries of Ascension Health support the continued regulation of Megavoltage Radiation Therapy services and would specifically recommend that the language in the standards be modified to distinguish between replacement and upgrade. The MRT standards, unlike other CON standards, do not distinguish between replacement of equipment and upgrades to equipment. We believe that making this distinction in the standards is within the purview of the CON Commission, however could also be accomplished along with a review of the requirements for initiating a new MRT service through the formation of a Standard Advisory Committee.

Surgical Services

Ascension Health – Michigan health systems support the continued regulation of Surgical Services. Given the prominence of these standards to the CON program we would recommend that a SAC or workgroup be formed to address any relevant issues.

Open Heart

Ascension Health – Michigan health systems support the continued regulation of Open Heart programs and do not recommend any changes to the standards at this time. More specifically, we would not recommend that a workgroup or SAC be formed at this time.

Hospital Beds

Ascension Health – Michigan supports the continued regulation of Hospital Beds and recommends that because of the prominence of these standards in the overall CON program that these standards be reviewed to evaluate them in the context of the overall CON programmatic goals of Cost, Quality and Access.

1. Name: Georgia Fojtasek, President and CEO
2. Organization: Allegiance Health
3. Phone: 517-788-4942
4. Email: georgia.fojtasek@allegiancehealth.org
5. Standards: OHS
6. Testimony:

Content-Length: 146025

Allegiance
HEALTH

October 20, 2010

Edward B. Goldman
Chair, Certificate of Need Commission
Michigan Department of Community Health
201 Townsend Street
Lansing, MI 48913

Dear Chairman Goldman,

I understand that the Certificate of Need Commission will be reviewing the work plan for 2011 in the coming months. In response the Notice of Public Hearing for October 13, 2010 on CON standards up for review in 2011, we would like to share our concerns with the current Certificate of Need Standards for Open Heart Surgery Services, and hope you will take them into consideration as you decide what action to take on these standards next year.

Allegiance Health received CON approval for our Open Heart Surgery service in September of 2006 and performed our first open heart surgery in February of 2008. Although our program is experiencing great success, we think it is important for the Commission to review the current minimum volume requirements for this service. We understand that the existing programs in the state fall into one of three different minimum volume requirements ranging from 0 to 300 per year. However, in looking at the 2009 open heart volumes across the state, 17 of 33 (52%) adult programs fell below the current 300 minimum volume. And of the 8 programs that are actually required to perform at least 300 open heart cases per year, only 1 actually met that volume (2 are new programs and not required to meet the volume yet, including ours).

I do not believe anyone would claim that 52% of our existing programs are of poor quality, but if we continue to define quality in the standards through a minimum volume requirement higher than what is being achieved by more than half of our programs, we are indirectly making that judgment. We, at Allegiance Health, believe that volume does not equal quality and believe that Michigan has some of the best cardiovascular programs in the country, despite declining volumes overall. Data from the Society of Thoracic Surgeon (STS) demonstrates this. A Composite Quality Rating for hospitals in Michigan's Adult Cardiac Surgery Programs, posted on the Michigan Society of Thoracic and Cardiovascular Surgeons Quality Collaborative (MSTCVSQC) website (http://www.mstcvs.org/qc/?q=node/14), shows Michigan programs are performing significantly higher than the national average. We have received the highest ranking (3 stars) for overall quality outcomes from the national STS.

As cardiac catheterization becomes more and more effective in treating cardiovascular conditions, fewer patients are requiring open heart surgery. This is fantastic for patient care and something that should be celebrated. It is important for the CON standards to recognize these changes in cardiovascular care and support them, not create a regulatory environment which incentivizes facilities to perform surgery rather than provide the less invasive options. We ask that the Commission seek alternative quality measures to replace minimum volume requirements in the CON

Standards for Open Heart Surgery Service. As less invasive options continue to develop open heart volumes will only continue to decrease and even more existing programs will struggle to meet minimum volumes. The time has come to make advancements in these standards to match the advancements in cardiovascular care. We look forward to the opportunity to work with the CON Commission on this issue in 2011.

Sincerely,

Georgia Fojtasek, CEO
Allegiance Health
Jackson, MI

1. Name: Dennis McCafferty
2. Organization: The Economic Alliance for Michigan
3. Phone: 248 596-1006
4. Email: dennismccafferty@eamonline.org
5. Standards: CC
6. Testimony: EAM supported the CommissionÆs authorization of a Cardiac Catheterization SAC at their June 2010 meeting. We look forward to this SAC being soon appointed and participating in this review process.
We urge the Commission to include in the charge to the Cardiac Cath SAC that it considers the new valve replacement procedures utilizing catheters, rather than the current surgical process. Given how new this catheterization replacement of a valve procedure is, should these procedures only be done at high volume programs; high volume OHS or high volume therapeutic cath programs or high volume for both?

7. Attachment:

1. Name: Barbara Winston Jackson
2. Organization: BCBSM/BCN
3. Phone: 248.448.2710
4. Email: bjackson3@bcbsm.com
6. Testimony: Testimony

Blue Cross Blue Shield of Michigan/Blue Care Network
MDCH Public Hearing
October 13, 2010

Thank you for the opportunity to provide testimony on behalf of Blue Cross Blue Shield of Michigan (BCBSM) and Blue Care Network (BCN). BCBSM and BCN continue to actively support the Certificate of Need (CON) program, designed to ensure the delivery of cost-effective, high quality health care to Michigan residents.

Due to our traditional posture supporting open and transparent discussion of key issues, BCBSM and BCN support the 2011 review of scheduled CON Review Standards which include:

- Cardiac Catheterization Services (set to be reviewed during 4th qtr 2010),
- Hospital Beds and Addendum for HIV infected individuals
- Megavoltage Radiations Services/Units
- Open Heart Surgery Services
- Positron Emission Tomography Scanner Services and Surgical Services

We feel that standards should be reviewed on a regular cycle as well as on an as needed basis. These review processes which include community input and expert consultation keep the standards current and facilitate the appropriate regulation of high cost high tech medical services.

BCBSM and BCN continue to actively support the CON program and the ongoing review of the CON Review standards in terms of cost, quality and/or access concerns. We applaud the CON Commission and MDCH staff as they continue to facilitate an objective review process, eliciting in-depth clinical expertise as well as input from consumers, purchasers, and payors. BCBSM/BCN will continue to be an open-minded, active participant in these endeavors. As always, BCBSM/BCN commends the CON Commissioners and MDCH staff for their diligent efforts in maintaining CON as a strong, vibrant program, to ensure the delivery of high quality, safe and effective health care to patients across the state.

Content-Length: 78356

Blue Cross
Blue Shield
Of Michigan

600 E. Lafayette Blvd.
Detroit, Michigan 48226-2998

Testimony
Blue Cross Blue Shield of Michigan/Blue Care Network
MDCH Public Hearing
October 13, 2010

Thank you for the opportunity to provide testimony on behalf of Blue Cross Blue Shield of Michigan (BCBSM) and Blue Care Network (BCN). BCBSM and BCN continue to actively support the Certificate of Need (CON) program, designed to ensure the delivery of cost-effective, high quality health care to Michigan residents.

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- Cardiac Catheterization Services (set to be reviewed during 4th qtr 2010),
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- Megavoltage Radiations Services/Units
- Open Heart Surgery Services
- Positron Emission Tomography Scanner Services and Surgical Services

We feel that standards should be reviewed on a regular cycle as well as on an as needed basis. These review processes which include community input and expert consultation keep the standards current and facilitate the appropriate regulation of high cost high tech medical services.

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1. Name: Meg Tipton
2. Organization: Spectrum Health Hospitals
3. Phone: 616-391-2043
4. Email: meg.tipton@spectrum-health.org
5. Standards: SS
6. Testimony:

Content-Length: 111191

October 14, 2010

Edward Goldman, 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. Goldman,

This letter is written to offer the comments of Spectrum Health on suggested changes to the CON Review Standards for Surgical Services. We believe that the CON Review Standards for Surgical Services have served Michigan based hospitals and healthcare organizations very well. These standards have assured the availability of sufficient surgical facilities to meet the needs of Michigan citizens, while enabling Michigan's health care organizations to provide quality surgical care to their patients. However, we would like to request considerations of additional provisions to allow dedicated trauma and research operating rooms exempted from CON volume requirements.

Spectrum Health proposes that the inventory of hospital operating rooms in a licensed hospital be changed to reflect the standards that were in effect in 1998 which included an allowance for the use of one (1) full-time operating room that could be used exclusively for the purpose of providing trauma care. This room would be ready at all times for a trauma surgery and could not be used for any other reason. In addition Spectrum Health is proposing that as part of the hospital operating room inventory, a licensed hospital may use one (1) operating room exclusively for the purpose of research. Included in this proposal should be the limitation for a licensed hospital to use no more than one (1) trauma care operating room and no more than one (1) research operating room for exclusion from the total inventory of operating rooms in a licensed hospital. Spectrum Health would like to suggest that the definition for "Trauma care" mean "surgical services provided to a trauma patient in a licensed hospital site that has been verified as meeting the standards of the American College of Surgeons for a Level I trauma center." Spectrum Health would also like to suggest that

"Research" mean "surgical services provided in a room under a research protocol approved by the applicant's IRB".

Spectrum Health has experienced an average of 1,275 trauma service admissions over the last three years, resulting in an average of 3.5 trauma patients per day. More specifically, we have averaged 140 patients per year or two patients per week, which require immediate surgery and have gone directly from the emergency room to the operating room upon arrival. Currently when a trauma patient arrives in the emergency room an operating room has to be identified, sometimes cleaned and prepped while assembling the appropriate physicians and staff to care for the patient. This process wastes precious time for the trauma patient when every second counts. With the allowance for a dedicated trauma operating room this time delay would be eliminated. A trauma room and dedicated staff could always be ready for the next trauma patient thus providing for the best care of that patient. In the most recent review of our level I trauma center, the ACS – COT (American College of Surgeons, Committee on Trauma) recommended that Spectrum Health take swift steps to identify and dedicate a full-time trauma room to better fulfill our requirements as a designated Trauma I medical center. In order to fulfill that recommendation Spectrum Health would like to see a provision in the standards that would allow for the use of one (1) operating room, from current inventory, dedicated to trauma.

Over the last five years Spectrum Health has experienced significant growth with the addition of the Meijer Heart Center, the Lemmen Holton Cancer Pavilion, the Helen DeVos Children's Hospital, currently near completion, and partnerships with the Michigan State University, College of Human Medicine in Grand Rapids, and the VanAndel Research Institute immediately adjacent to Butterworth Hospital. With these enhancements and the addition of major services such as Heart and Lung Transplant and Bone Marrow Transplant, it is natural to increase our research activities. Spectrum Health is enhancing its partnerships with the MSU Medical School and the VanAndel Institute, which will further the development of cutting edge research projects.

Spectrum Health appreciates the opportunity to present our recommendations for change to the current surgical standards and to suggest a potential remedy.