

MDCH Recommendations for CON Standards Scheduled for 2011 Review

Surgical Services (Please refer to the attached MDCH staff analysis for additional details.)		
Should the covered service continue to be regulated?	Yes	Surgical services located within a hospital or freestanding facility requires large initial capital investment as well as long term operating costs. Once licensed as a hospital or freestanding surgery center, providers are allowed to include a facility fee when billing for all surgical procedures performed within these sites.
Identified Issues	Recommended Review	Comments
Consider exception for dedicated trauma operating room without volume requirement.	No	Current Standards already provide exception for trauma services at licensed hospitals.
Consider exception for dedicated research operating room without volume requirement.	No	No clear evidence to suggest immediate need for new exception for research operating room.
Consider exception for existing non-licensed vascular centers to initiate surgical services as a federally certified ASC site.	No	Current volume requirements to initiate new FSOF or ASC sites with a single operating room does not present a major barrier to existing vascular centers. The barrier to initiation is not the volume requirement set forth within the standard but specifically that these vascular surgical procedures have not been historically performed in licensed operating rooms.
Consider refinement to current volume requirements for operating rooms.	Yes	Round volume requirements to whole numbers for replacement, expansion and maintenance of operating rooms.
Consider new requirements for procedure rooms on a sterile/restricted corridor in a hospital or freestanding surgery center.	Yes	Procedure rooms on a sterile/restricted corridor can be used and billed as if an operating room. Current standards are vague on prohibiting procedure rooms on sterile/restricted corridors.

Consider new requirements for operating rooms that are equipped with cardiac catheterization equipment.	Yes	With FDA consideration of percutaneous valve replacement/repair, more hospitals are installing cardiac catheterization equipment in operating rooms. These dual purpose rooms may require reduced volume requirements as procedures performed in these rooms will be limited.
Consider modifications to Project Delivery Requirements.	Yes	Reduce number of project delivery requirements for approved services that are enforceable and achieve major objectives of assuring affordable, quality surgical services without overwhelming providers.

MDCH Staff Analysis of the Surgical Services Standards

Statutory Assignment

Pursuant to MCL 333.22215 (1)(m), the Certificate of Need (CON) Commission is to "...review, and if necessary, revise each set of CON standards at least every 3 years." In accordance with the established review schedule on the Commission Work Plan, the Surgical Services Standards are scheduled for review in calendar year 2011.

Public Hearing Testimony

The Department held a Public Hearing to receive testimony regarding the Standards on October 13, 2010, with written testimony being received for an additional 7 days after the hearing. Testimony was received from three organizations and is summarized as follows:

1. Joe Garcia, RMS Lifeline

- Gave a brief overview of Lifeline Vascular Access in Michigan.
- Requests to change the Certificate of Need Standard so that six clinics that perform procedures to install and maintain catheters and fistulas for kidney dialysis patients are reclassified as ambulatory surgical centers. Maintains this request is because clinics are currently under economic distress because of reductions in physician payments, and that's the only payment which sustains the clinics currently.

2. Meg Tipton, Spectrum Health Hospitals

- Supports continued regulation of surgical services with the following recommendations:
- Proposes the inventory of hospital operating rooms in a licensed hospital be changed to reflect an allowance for the use of one (1) full-time operating room that could be used exclusively for the purpose of providing trauma care.
- Suggests 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."

- Suggests “Research” mean “surgical services provided in a room under research protocol approved by the applicant’s IRB.”

3. *Carlos Rodriguez, MD, Spectrum Health Hospitals*

- Supports continued regulation of surgical services with the following recommendation:
- Proposes the Surgical Services Standards be modified to include a provision for a dedicated trauma operating room which could be excluded from the normal CON volume requirements.

4. *Shayam Parekh, Spectrum Health Hospitals*

- Supports continued regulation of surgical services with the following recommendations:
- Proposes a provision be added to the Surgical Services Standards dedicating an operating room for research.
- Contends that with the added provision; more experimentation and innovation would be possible without disrupting the precision and efficient operation of busy perioperative services.
- Further contends the types of research which can be done are limited by the types of operating rooms which are created.

5. *Dennis McCafferty, Economic Alliance for Michigan (EAM)*

- Supports continued regulation of surgical services and the formation of a SAC workgroup.
- Supports changes that would improve proficiency, outcomes, and cost-effectiveness, while addressing relevant access concerns.
- Also supports changes in the standards that would specify surgical support staff of all free-standing surgical centers be credentialed by appropriate national accreditation organizations.

6. *Sean Gehle, The Michigan Health Ministries of Ascension Health*

- Supports continued regulation of surgical services and the formation of a SAC workgroup to address any relevant issues.

Summary of Covered Service

The Department did not receive any testimony against de-regulation of Surgical Services. Michigan is one of 27 states which regulate surgical services within CON. In accordance with 2009 CON Annual Survey, there were 1,286,779 surgical procedures performed within one of the 1,343 approved operating rooms at the 246 hospitals that offer this covered service.

MDCH Staff Recommendations:

- **Conduct departmental review of standards with an emphasis to assure uniformity among the various standards, where applicable, and create a user-friendly format.**
- **Conduct departmental review of project delivery requirements. Project delivery requirements are those requirements that a recipient of an approved CON must comply with throughout the life of the services, or unless modified by a subsequent CON approval. Review is to assure that each requirement is measurable, comports with today's standard of care, does not duplicate other regulatory requirements already established, and have cost-effective value in achieving the goals and objectives of the program to assure affordable, quality health care services for both the consumer and provider.**
- **Conduct departmental review to simplify projection and utilization methodologies, where possible, in a manner that is comparable to existing thresholds but reduces the labor-intensive collection process for the provider and potential applicants using readily available data.**
- **Conduct departmental review to simplify replacement requirements for existing providers where the site of the surgical service will not change, only the location of the operating room within the existing site changes.**
- **Present proposed draft standards to Commission at the September 22, 2011 meeting.**