

MDCH Recommendations for CON Standards Scheduled for 2011 Review

Cardiac Catheterization Services (Please refer to the attached MDCH staff analysis for additional details.)		
Should the covered service continue to be regulated?	Yes.	Continue regulation of this service as there is continued evidence that outcomes are positively impacted by volume and increase repetition.
Identified Issues	Recommended Review	Comments
Consider new percutaneous valve replacement procedures currently under FDA review.	Yes.	Consider appropriate requirements and limitations for proposed and existing hospitals approved to offer or currently offering therapeutic cardiac catheterization services.

MDCH Staff Analysis of the Cardiac Catheterization (CC) 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 CC 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 seven (7) days after the hearing. Testimony was received from three (3) organizations and is summarized as follows:

1. *Blue Cross Blue Shield of Michigan/ Blue Care Network*
 - Recommends that the CC standards be reviewed on a regular cycle as well as on an as needed basis; to keep the standards current and facilitate appropriate regulation of high cost and high tech medical services.
2. *Trinity Health*
 - Recommends and supports the need for continued regulation of Cardiac Catheterization Services.
3. *Economic Alliance for Michigan*
 - Provided comment and urges the Commission to consider the new valve replacement procedures utilizing catheters, rather than the current surgical process.

- Recommends evaluating the location of catheterization replacement valve procedures. Raises the question “Should these procedures only be done at high volume programs; high volume OHS or high volume therapeutic catheterization programs or both??”

Summary of Covered Service

The Department received no testimony for de-regulation of Cardiac Catheterization services. Michigan is one of 26 states that regulate Cardiac Catheterization services within CON. In 2009, per the CON Annual Survey 142,138 patients had a cardiac catheterization session, within one of the 191 approved lab facilities at the 64 hospitals offering this covered service.

Currently, the Commission voted and passed a motion at the January 28, 2010 meeting to seat a Standard Advisory Committee (SAC) based on the public comment and Commission discussion. The approved charge is as follows:

At a minimum, the Cardiac Catheterization Services SAC should consider reviewing and recommending any necessary changes to the Cardiac Catheterization Services Standards regarding the following:

1. Whether or not cardiac catheterization services should continue to be regulated. If regulation of this service should be maintained, make recommendations, if necessary, regarding any modifications to the requirements.
2. Determine if elective therapeutic cardiac catheterizations should be allowed at facilities that do not provide on-site open heart surgery services. If it is recommended that these services should be allowed, provide specific criteria for determining need for this service including patient safety and quality criteria.
3. Review and update, if necessary, the methodology for determining procedure equivalents. If needed, review existing methodologies for determining need.
4. Clarify what procedures shall count toward meeting volume requirements, including minimum volume requirements, specifically for diagnostic cardiac catheterization, therapeutic cardiac catheterization, and total laboratory volume requirements.
5. Review and update, if necessary, requirements to initiate primary PCI services for patients experiencing AMI.
6. Review existing criteria, volume requirements, and procedure equivalents to determine necessary modifications, if any, related to new cardiac catheterization technology, evolving medical techniques, e.g., percutaneous insertion of cardiac valves.

7. Consider separation of replace/upgrade requirements.

8. Consider any technical or other changes from the Department or SAC, e.g., updates or modifications consistent with other CON review standards and the Public Health Code.

MDCH Staff Recommendations

- **Although the CC SAC is currently underway, the Department will approach the CC SAC's leadership with an offer to work with the current SAC to review, consider, and implement, where applicable, some of the overarching principles of creating user-friendly format and language, simpler methodologies, streamlined equipment replacement requirements, and concise and value-added project delivery requirements. This is totally dependent on the CC SAC's schedule and attention to the charge they received from the CON Commission in June, 2010. The CC SAC has currently scheduled meetings monthly through May, 2011.**