MDCH Recommendations for CON Standards Scheduled for 2011 Review

Open Heart Surgery (OHS) (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
Review current minimum requirements for initiation and maintenance of an open heart surgical program at 300 open heart surgical cases.	Yes.	The cardiac surgery volumes are declining across the state. The initiation and maintenance volumes should be reviewed to determine appropriateness on cost, quality and access, pending the CCSAC decision.
Consider modifications to Project Delivery Requirements.	Yes.	Review project delivery requirements for approved services that are enforceable and achieve major objectives of assuring affordable, quality open heart services without overwhelming providers.
Consider refinement to current utilization methodology.	Yes.	Review current methodology to assure it accurately reflects community need for open heart services. Update methodology, if continued, with revised weights according to current standards.

MDCH Staff Analysis of Open Heart Surgery (OHS) 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 OHS 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 five (5) organizations and is summarized as follows:

- 1. Georgia Fojtasek, Allegiance Health
 - Supports continued CON regulation.
 - Recommends review of the current minimum volume requirements for OHS.
 - In 2009 open heart volumes across the state, 17 of 33 (52%) adult programs fell below the current 300 minimum volume.
 - Advises as less invasive options continue to develop open heart volumes will only decrease and even more existing programs will struggle to meet minimum volumes.
- 2. Robert Meeker, Spectrum Health
 - Supports continued CON regulation.
 - Recommends no review of current OHS Standards as the number of open-heart procedures declined by 14% from 2005-2009 per the Michigan Annual Surveys of Hospitals.
- 3. Dennis McCafferty, Economic Alliance for Michigan
 - Supports continued CON regulation.
 - Supports the formation of an OHS SAC
 - Recommends review of the minimum annual volume requirements.
 - Recommends reviewing the standards to facilitate the consolidations and/or closure of OHS programs that consistently fail to meet the minimum annual volumes.
- 4. Sean Gehle, The Michigan Health Ministries of Ascension Health
 - Supports the continued CON regulation.
 - Recommends no review of current OHS Standards; specifically no formation of a SAC or workgroup at this time.
- 5. Jim Gilson, Beaumont Hospitals
 - Supports continued CON regulation.
 - Supports the current minimum procedure volume thresholds of 300.
 - Requests that "the Commission continue to pressure the Department to routinely and consistently enforce CON regulations, including volume requirements."

Summary of Covered Service

The Department did not receive any testimony against the de-regulation of Open Heart Surgery. Michigan is one of 27 states which regulate Open Heart Surgery within CON. In 2009, per the CON Annual Survey 12,674 patients underwent open heart surgery within one of the 34 approved facilities.

MDCH Staff Recommendations

- The Department recommends a three-month postponement of Commission action regarding a decision on a structured review of the Open Heart Surgery Standards. Currently a Cardiac Catheterization Standard Advisory Committee (CCSAC) has been seated and is currently deliberating issues that may have a concomitant effect on the Open Heart Surgery Standards.
- The Department proposes to revisit the Standards review question after the Commission and Department have had adequate opportunity to review the direction of the CCSAC.