Interim Report – Open Heart Surgery Standard Advisory Committee

Current status of the SAC is summarized with comments organized according to individual charges. We have just completed our third meeting, and the progress made so far has been facilitated by the formation of two subcommittees. One subcommittee has focused on Charge 2, and the other Charge 4.

Charge 1. Review and update, if necessary, the initiation and maintenance volume requirements given that OHS volumes are declining.

Currently, there are three separate volume requirements for OHS programs in the state ranging from 0 – 300 cases per year, depending upon the time at which the CON was granted for each program. The fact that OHS volumes have been steadily declining since 2000 has caused several programs to fall short of their required annual case requirement. In a presentation by the Economic Alliance of Michigan, declining OHS volumes were equated with decreasing need for OHS programs and prompted their proposal that up to ten lower volume hospitals should likely be closed. In addition, they felt that OHS program initiation volume requirements should be kept high in order to block the opening of new, unneeded OHS sites. They presented data suggesting that lower volume hospitals had significantly worse outcomes clinically; however, their numbers were found to be inaccurate due to their extrapolations. In addition, their conclusions were not supported by multiple scientific articles within the CV surgery specialty that show minimal correlation with OHS volume for an institution and clinical outcomes for CABG.

The discussion is ongoing, but hinges primarily on the questions:
a.) If institutional OHS numbers do not correlate with quality, do they need to be as high as they are for the maintenance of a program?
b.) How do you justify keeping a high initiation number if the maintenance number is not as important as once thought?

Charge 2. Review project delivery requirements to assure quality, measurability, and affordability for both the provider and consumer.

We formed a subcommittee headed by Dr. Gaetano Paone to help address this issue, and our ongoing discussions are showing that Charges 1 and 2 are really quite closely linked. A presentation by the Open Heart Coalition helped to frame the issue of how to measure and report quality in an ongoing manner. Despite the fact that the clinical indicators they selected were accepted as important, the benchmarks they suggested were felt by many on the committee to be unrealistic. This prompted a discussion of the work of the Michigan Society of Thoracic and Cardiovascular Surgeons (MSTCVS) that emphasized the complexity of measuring the quality of an OHS program. Consequently, the MSTCVS is in the process of deciding if it, as an organization, can suggest modifications to the Coalition proposal, or present a methodology that they consider to be superior. We hope to have a presentation from the MSTCVS within the next two SAC meetings.

Affordability was discussed at length, but actual cost data are not readily available. It was felt that the cost to the insurers/payers/purchasers was similar from program to program based on the similarity of Medicare payments throughout the state and the fact that commercial insurers typically follow suit with Medicare. Similarly, it was felt that direct costs to patients would be similar from hospital to hospital. This would leave the individual hospital profit margin as the primary variable in the equation. So, in essence, what we are concluding so far is that each hospital would look the same or very similar from a cost standpoint to a patient and to the payer, but hospitals may have variable profitability. In reality, the overall picture likely is not this simple, so a couple of the payers on the SAC are continuing to look into this matter.

Charge 3. Review and update, if necessary, the methodologies to assure they accurately reflect community need for OHS services.

We have had minimal discussion of this topic so far. On the surface, the calculations to project actual volume of a new program seem too complex for a SAC to revise in the limited time and with the limited resources available. We did review a 2010 population map of the state compared to a diagram showing locations of current OHS programs surrounded by calculated 30 and 60 – minute driving radiuses. This

showed no higher population center outside of the 60 – minute drive to an OHS site and is another potential indicator that there is unlikely to be current unmet need for OHS services in the state.

Charge 4. Propose standards for percutaneous insertion of heart valves.

This charge was examined by a subcommittee chaired by Dr. Al Delucia. This committee was able to reach a consensus and made the recommendation to the SAC that no CON level standards be developed for Transcatheter Aortic Valve Replacement (TAVR). A motion was made and passed to this effect at our May meeting. The recommendation was based largely on the 2012 multispecialty consensus document on TAVR published in the Annals of Thoracic Surgery (Ann Thorac Surg 2012;93:1340-1395) and the May 1, 2012 Decision Memo by the Centers for Medicare and Medicaid Services (CMS) regarding TAVR.

The opinion of the SAC was that the CMS TAVR Decision Memo constituted very strict guidelines by which OHS programs employing TAVR procedures would be reimbursed for services, and that, given the expense of the procedure, essentially no OHS program would elect to utilize this technology without reimbursement. The SAC believes that all other payers will also adopt the CMS standards regarding reimbursement. In addition, it was felt that the qualifications required of OHS programs to perform TAVR would limit the adoption of this technology to larger centers with greater aortic valve surgery experience. Further, the opinion of the SAC was that an attempt to duplicate the CMS TAVR requirements in a CON regulation would be unnecessarily complicated and may be too slow in keeping pace with potential changes in the technology and any modifications to the CMS reimbursement decision.

Charge 5. Consider any necessary technical or other changes, e.g., updates or modifications consistent with other CON review standards and the Public Health Code.

The concept of retroactive vs. prospective regulations required a lengthy discussion before members of the SAC were comfortable with their understanding. Once that point was reached, a fairly uniform

message came from the SAC members. Assuming that this SAC develops specific quality metrics, the members felt that all programs should be measured in the same way, and all should have the same reporting requirements. They felt that it made little sense to measure quality only on programs that are new, newly acquired, or low on numbers. The SAC has not moved this issue to the level of asking the CON Commission to effect this change for all programs, but it seems likely that it will make that recommendation before the SAC work is concluded. The technical change, then, would be to identify a way to allow the quality measures requirement to apply to all programs.

Respectfully submitted,

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6/13/12