**Draft Meeting Summary**
**Cardiac Surgery Advisory Committee Meeting**
**November 30, 2017**
**7:00 p.m. - 9:00 p.m.**
**MHCC, 4160 Patterson Avenue, Baltimore, MD 21215**

**Work Group Member Attendees:**

Jamie Brown, M.D. (Phone)
Blair Eig, M.D. (Phone)
Kristen Fletcher (Phone)
Josemartin Ilao
Paul Massimiano, M.D.
Rawn Salenger, M.D.
Stuart Seides, M.D.
Matthew Voss, M.D. (substitute)
John Wang, M.D.
Stafford Warren, M.D.
David Zimrin, M.D.

**Commission Staff Attendees:**

Eileen Fleck
Paul Parker
Ben Steffen
Suellen Wideman

Eileen Fleck welcomed members of the Cardiac Surgery Advisory Committee (CSAC) and all attendees introduced themselves. She commenced the meeting by providing a brief overview of the development of regulations for cardiac surgery and explained why MHCC staff proposes to make revisions. She stated that the regulations were first adopted in August of 2014 and revised in 2015.

**Revision of CON Policies and Standards for Cardiac Surgery**

She also explained that, in August 2016, the Health Services Review Commission formally (HSCRC) announced an official policy on market shifts of patient volume when a new hospital or clinical service is established. When a market shift is identified by the HSCRC, 50% of revenue is allotted to the new location for services, and 50% of revenue is retained by the former location for the same services. She explained that MHCC adopted the current standard for financial feasibility prior to knowing the policies that would be adopted by the HSCRC. MHCC staff is recommending revision of the financial feasibility standard so that the overall financial feasibility of the hospital will be assessed instead of only the financial feasibility of the proposed cardiac surgery program. MHCC staff wants feedback from CSAC members on this proposed change.

Stuart Seides, M.D. expressed concern about the proposed change. He noted that very few hospitals could accept receiving only 50% of the revenue otherwise due, and this approach would require ascertaining if a hospital could absorb the financial implications. He stated that this is a business decision by the hospital rather than a measure that should be governed by a regulatory policy.

Mr. Parker stated that the context of this standard is based on regulations that the Commission adopted years ago as a template for making Certificate of Need (CON) decisions. He

added that the template included broad criteria for assessing a program, one of which is determining the program's viability. He explained that in 2015, the HSCRC developed a market shift methodology for acknowledging that a market shift occurred when a new program or clinical service is introduced. He added that broad criteria for assessing the viability of a project were developed to assess the financial feasibility of the proposed program and the impact on the overall financial performance of the institution. He explained that it was based on these issues that MHCC staff is recommending a change in its policies that will specifically enable the Commission to consider the overall performance of an institution. Suellen Wideman clarified that this proposed change will make the financial feasibility standard consistent with the Commission's intent in 2014.

John Wang, M.D asked whether a cost neutral situation is permissible under the current financial feasibility standard or if a hospital has to be profitable. Mr. Parker responded that a hospital has to be profitable; breaking even is not acceptable. Dr. Seides asked about the duration of the 50% revenue split by HSCRC and expressed concern about whether adding a new service would be a good business decision. He added that eliminating all services and getting 50% for doing nothing potentially would be the best decision.

Mr. Parker explained that HSCRC's market shift model currently operates by identifying market shifts retrospectively for the occurrence of a shift. He added that the model assesses if there was a volume increase accompanied by a commensurate volume decline elsewhere, and the HSCRC policy for market shifts would apply only when there is evidence of a volume shift. Over time, market shares will stabilize. He stated that for some hospitals in the current review cycle, there is clearly the possibility of shifting volume from hospitals in the District of Columbia. If a Maryland hospital shifts volume from hospitals located outside the State, then the HSCRC's market shift policy would not apply, and the HSCRC would recognize a global budget adjustment for the full amount of new services. Dr. Wang asked how HSCRC staff will distinguish between growth within a particular program and volume shifts.

Ben Steffen asked Blair Eig, M.D. to comment on the experience of Holy Cross Hospital regarding market shifts. Dr. Eig stated that the market shift computation that the HSCRC is using, may not be effective because it does not recognize some significant market shifts. He added that HSCRC is already considering a hospital's overall global budget and overall viability, and HSCRC does not take into consideration the viability of an individual program. He added that hospitals are looking at the long-term outlook for services and not one or two year periods.

Paul Massimiano, M.D. commented that one reason for including the financial feasibility standard is to limit the proliferation of small programs that may not meet quality and safety requirements. He expressed concern that if the revised standard considers overall viability only, then the Commission will approve programs in any hospital that can demonstrate an overall viability even if a program will not be financially viable. Ms. Fleck stated that the HSCRC will provide MHCC staff with its opinion on a hospital's viability, and the volume standard is a check on the approval of new programs. Ms. Fleck asked if the volume standard is reasonable and would likely allow most programs to be viable. Dr. Massimiano noted that having a second check for a hospital considering a new program is valuable. Dr. Seides agreed with Dr. Massimiano and asked

if a program had ever been closed due to low volume. Mr. Steffen responded that no cardiac surgery program has been shut down. Mr. Steffen then proposed that the issue be set aside and discussed again another time. He noted that the current standard is unworkable. Josemartin Ilao agreed that the proliferation of small programs should be a concern. He asked whether there is any precedent in other specializations that could be used as a model. He also expressed concern that other hospital programs may be adversely affected as a result of a hospital adding cardiac surgery, given the policies of HSCRC. Mr. Steffen asked if the State Health Plan chapter for organ transplant services has a similar financial feasibility standard. He noted that staff is in the process of conducting CON reviews for proposed organ transplant programs. Ms. Fleck responded that the standard is different for organ transplant programs.

**Revision of Standards for Evaluation of Certificates of Ongoing Performance**

Ms. Fleck proposed discussing the all-cause 30-day risk adjusted mortality rates for PCI that are currently used as a performance metric for Certificates of Ongoing Performance. She explained that MHCC staff planned to have the American College of Cardiology (ACC) perform these calculations. However, because of the way the model is structured, the ACC can only compute national averages and individual hospital rates and not a valid statewide average. She further explained that staff would need to contract with someone to develop a new model, which would take a long time. One alternative that she proposed is replacement of the statewide average with the national average. She also proposed revising the performance standard to refer to use of either the national average or the statewide average. Ms. Fleck asked for feedback on these options.

Dr. Zimrin asked for clarification on the definition of elective PCI. Ms. Fleck explained that the PCI data is categorized based on a certain field in the ACC data. Mr. Parker also read the definition for elective PCI in MHCC's regulations. Dr. Seides commented that Dr. Zimrin's point, as he understands it, is that very little PCI is truly elective. Dr. Wang commented that there is more nuance than is captured by coding, and sometimes the clinical assessment of a physician does not align well with ACC guidelines for coding. He noted that the ACC uses the categories of STEMI and non-STEMI and generates reports on patient mortality for each category. Ms. Fleck noted that the ACC's mortality measures capture only in-hospital deaths, and the measure to be used by MHCC is different and requires using the Center for Disease Control's national death index data. Dr. Zimrin commented that the ACC does not require hospitals to collect data on 30-day outcomes, but it is an option, and he expects that it will later be incorporated into a new model and required.

Dr. Zimrin commented that the programs in the State are very variable in terms of the risk-level of patients. He noted that for the University of Maryland, mortality has been high in some reporting periods, and the reason was severely ill patients that are not accounted for in risk adjustment, specifically liver transplant patients. Their deaths were not related to PCI at all. He noted that the best way to improve mortality is not to take high risk patients. The University of Maryland mostly handles high risk patients, and it may not compare favorably to other hospitals or the statewide average. Dr. Zimrin proposed using process measures rather than mortality to evaluate each hospital's performance. Staff Warren, M.D. commented that most negative outcomes for PCI patients occur before discharge from a hospital. Dr. Wang agreed with Dr.

Warren. Dr. Zimrin commented that mortality is low for PCI and using mortality as a metric for quality is not optimal. Jamie Brown, M.D. agreed. He added that some patients are not appropriately risk-adjusted. Dr. Wang responded that there are ways to handle a lack of appropriate risk adjustment.

Ms. Fleck commented that if a hospital's risk-adjusted mortality rate is high, it will trigger further investigation, rather than an automatic punitive action by the Commission. Dr. Voss commented that process measures should be used, as proposed by Dr. Zimrin. He mentioned door-to-balloon time, participation in the ACC registry, and other examples. Dr. Seides responded that patients are not killed by PCI, unless the operator is incompetent; patients die from underlying disease. He added that measuring what is measureable is not what is important. Everyone likes mortality because it is easy to understand, but it does not appropriately inform about the quality of PCI services provided. Dr. Seides agreed that process measures are more informative. Mr. Ilao commented that any hindrance to process of perfecting procedures would be a mistake. Rawn Salenger, M.D. agreed with Mr. Ilao.

Dr. Salenger stated that quality as a science is not well developed, but process measures alone are insufficient. He acknowledged that everyone is uncomfortable because of a physician's lack of control over some outcomes, but he still recommended that outcome measures be included for performance measurement. Dr. Wang agreed with Dr. Salenger. Dr. Wang explained that if only processes are considered, then a program may never improve and still avoid any penalty. He commented that there is no perfect outcome measure, but the first one considered should be PCI mortality. He added that the biggest offender for STEMI mortality is performing PCI on patients who are too far gone, and in-hospital mortality will capture most of those patients.

Ms. Fleck noted that she understands the concern about how information may be interpreted, but the mortality indices are reported with confidence intervals and not as single values. Dr. Wang stated that as long as hospitals have the opportunity to explain mortality cases, it should be fine. All hospitals have patients whose death was unrelated to the quality of care provided. Dr. Zimrin again indicated that he disagreed with using outcome measures, and Ms. Fleck asked what would be a better way to measure outcomes to assess quality. Dr. Zimrin proposed success rates for PCI, and Dr. Voss proposed bleeding and door-to- balloon time. Another member commented that those measures may be useful for STEMI patients, but those measures do not work well for other patients. Dr. Wang also commented that it is unrealistic to expect that CSAC members will find an outcome measure that the ACC has not yet developed. Mr. Steffen commented that outcome measures are needed; relying on process measures only would be unacceptable. Dr. Warren agreed with Mr. Steffen.

Ms. Fleck described a few different options for revising the 30-day risk-adjusted mortality standard for PCI services. She proposed that a poll with different options may be useful for gaining additional feedback from all 24 PCI programs in Maryland. She added that MHCC staff wants to reach closure on the issue within the next few months. Dr. Wang commented that comparing like groups of hospitals should address concerns about comparing academic and community hospitals. Ms. Fleck responded by noting that the comparison would be to the statewide average for all Maryland hospitals. Dr. Voss commented that the categories used by the ACC for comparing

program are a national average and "like" programs, which is determined based on the number of cases performed in the CathPCI data registry.

Ms. Fleck again explained that the results on outcome performance measures will be used as a trigger for further investigation. She stated that the information will be in public reports, but it will not be on MHCC's web site labeled as public reporting, and the plan is to work with hospitals on the presentation of the data. Mr. Ilao asked that someone explain the argument against using the in-hospital mortality rate for PCI. Dr. Wang commented that he favors using the in-hospital mortality rate because getting the 30-day mortality rate would be too much work for an imperfect outcome measure.

Dr. Salenger suggested that the period of time used to evaluate mortality for cardiac surgery patients could be reduced, for example, from 30 to 21 days. Mr. Steffen responded that a former advisory group, the Clinical Advisory Group (CAG), discussed the optimal number of days to measure mortality, and the CAG agreed that a 30-day mortality measure was best for evaluating some process measures. However, he also commented that using in-hospital mortality would be acceptable. Dr. Warren added that MHCC should avoid taking any actions that would discourage hospitals from taking high-risk cases. Another work group member responded that risk adjustment is used, so there should not be much concern about taking high-risk patients. Ms. Fleck wrapped up the issue by saying that she would encourage people who did not attend the meeting to offer their opinions.

Ms. Fleck next raised the issue of the addition of performance metrics for cardiac surgery. She noted that MHCC staff wants to start a conversation on this issue, but there is not a need to adopt more measures now. She specifically asked if other types of cases, besides coronary artery bypass surgery (CABG) should be considered. Dr. Massimiano stated that CABG was selected because it is the most common cardiac surgery procedure, and for small programs, it will be hard to compare across many other indices for other types of surgeries. He proposed considering various metrics for CABG, and he suggested that rolling two or three year periods be avoided because the longer time frame will not let MHCC staff identify problems in real time. Dr. Brown agreed.

**Revision of Standards for Evaluation of Certificates of Ongoing Performance**

MHCC staff recommended revising the regulations to provide that when PCI services are unexpectedly unavailable, a hospital should be required to notify MHCC within two business days of the unexpected downtime. Hospitals are already required to have PCI services available 24 hours per day and seven days a week, and MHCC staff seeks only to clarify the notification requirements. Dr. Seides recommended that the standard be written in a way that is not excessively punitive because temporary interruptions of services commonly occur. Dr. Zimrin agreed. Dr. Seides suggested that a lack of PCI services be defined as the need to reroute emergency patients or by a timeframe. Dr. Voss mentioned that a hospital may have multiple cases at the same time, and Ms. Fleck clarified that the Commission wants to know when there are no PCI services available. She added that she will follow up with the Maryland Institute for Emergency Medical Services and Systems on its policies pertaining to unavailable cardiac catheterization laboratories.

**ICD-10 Cardiac Surgery Codes**

MHCC staff are trying to conclude a discussion of the cardiac codes within the next couple of months. Ms. Fleck reminded members of the written request for feedback on which ICD-10 cardiac codes to count for volume, and she suggested that members include an explanation with their recommendations. She suggested that members decide which procedures should count for volume based on the use of the codes in MHCC's regulations. For example, the utilization projections for cardiac surgery that are used for CON reviews are developed based on procedures that are defined as cardiac surgery. In addition, the evaluation of the impact of a proposed program on the volume of existing programs will be affected by which procedures are counted for volume and compliance with minimum volume standards for Certificates of Ongoing Performance. She noted that heart transplant procedures are regulated separately, and from MHCC staff's perspective, should not be counted for volume when evaluating proposed and existing CON programs.

Dr. Warren asked whether 200 cases is the right number of cardiac surgery cases for evaluating volume. Another work group member responded that the issue has been talked about extensively already and further discussion is not warranted. Ms. Fleck agreed, and Dr. Seides defended the current standard. Dr. Seides explained that procedures that count for volume should be those that will be meaningful surrogates for the surgeons' operative skills and post-operative care for patients. Dr. Salenger agreed with Dr. Seides. He reminded members that the definition of cardiac surgery previously agreed upon included: incision in the chest wall, operation on the heart or great vessels, and cardiopulmonary bypass. A procedure with at least two of the three criteria would generally be considered cardiac surgery. Dr. Salenger commented that it is reasonable to exclude heart transplants because they are regulated separately. In addition, he concluded that excluding transfemoral ECMO cases and transfemoral percutaneous structural cases is reasonable. Dr. Massimiano agreed with Dr. Salenger. It was also noted that volume below 100 cardiac surgery cases, not 200 cases, is the trigger for review of a cardiac surgery program, based on volume.

**Next Steps**

MHCC staff plans to convene another meeting in January and announced that a poll would be sent out with dates. At the January meeting, MHCC staff wants to wrap up a few key issues, such as revisions to the financial feasibility standard and the PCI mortality standard, as well as categorization of the ICD-10 cardiac codes. Staff will develop draft regulations, and there will be an opportunity to submit informal comments, before Staff asks the Commission to consider draft regulations for adoption as proposed regulations. Ms. Fleck closed the meeting at 9:00 p.m.