Final Meeting Summary
Cardiac Services Advisory Committee (CSAC)
Wednesday, May 13, 2015
MHCC, 4160 Patterson Avenue, Baltimore, MD 21215

Work Group Member Attendees:
Jaime Brown, M.D. (by phone)
Nancy Bruce, R.N., M.B.A (by phone)
Blair Eig, M.D
Christopher Haas, D.O. (by phone)
Keith Horvath, M.D. (by phone)
Brett Kane (by phone- substitute for Jesus Cepero)
Paul Massimiano, M.D.
Mauro Moscucci, M.D
Lisa Myers, R.N., M.S.
Rawn Salenger, M.D. (substitute for James Gammie)
Juan Sanchez, M.D.
Sharon Sanders, R.N., M.B.A. (by phone)
Stuart Seides, M.D. (by phone)
Jerome Segal, M.D.
William Thomas, M.D.
Stafford Warren, M.D.
David Zimrin, M.D.

MHCC Staff Attendees:
Ben Steffen, Executive Director
Paul Parker, Director, Center for Health Care Facilities Planning & Development
Eileen Fleck, Chief, Acute Care Policy and Planning

Other Attendees:
Diane Alejo, Johns Hopkins Hospital
Jennifer Bobbitt, Washington Adventist
Amy Dukovcic, Washington Adventist Hosp.
Eddie Fonner
Maribeth Fonner
Marci Hunt, St. Agnes Hospital
Theressa Lee, MHCC
Kathy Ruben, MHCC
Karen Smith, AGS

Introduction

The meeting convened at approximately 6:40 pm. Ben Steffen thanked everyone for attending the meeting and then summarized the agenda and goals for the meeting. Mr. Steffen

noted that the order of agenda items changed slightly. A discussion of the treatment of Fellows at PCI programs at hospitals without cardiac surgery on-site was moved to the start of the agenda.

Mr. Steffen said that the majority of the meeting would focus on the informal public comments received on the draft amended COMAR 10.24.17 and reaching consensus on the ICD-9 codes to include in the definition of cardiac surgery. He also expressed appreciation for the CSAC members who participated in lengthy discussions about the cardiac surgery codes. Mr. Steffen noted that the ICD-9 codes are expected to be replaced by ICD-10 codes in approximately five months (October 1). Before turning the meeting over to Ms. Fleck, Mr. Steffen asked that everyone to introduce themselves.

Fellows at PCI Programs at Hospitals Without Cardiac Surgery On-Site

Ms. Fleck again noted the agenda change and suggested that it may be helpful to follow the discussion if people had a copy of the comments submitted to the MHCC and the draft amended COMAR 10.24.17. She began the discussion with an explanation of MHCC's concerns, noting that an external review is triggered for physicians who perform less than the minimum of 50 PCI procedures annually averaged over two years, and she thought Fellows might not obtain that volume of cases. Ms. Fleck asked whether fellows who fail to meet a minimum of 50 PCI cases should be subject to an external review of all cases. Ms. Fleck referred to page 41 on the track changes version of the draft Amendments to COMAR 10.24.17 and read the relevant text:

> *Each physician who performs primary PCI at a hospital without on-site cardiac surgery who does not perform a minimum of 50 PCI procedures annually averaged over a 24 month period, for reasons other than a leave of absence, will be subject to an external review of all cases in that 24-month period to evaluate the quality of care provided. The results of this evaluation shall be reported to MHCC. A hospital may be required to develop a plan of correction based on the results of the physician's evaluation.*

Ms. Fleck asked members of the CSAC how it should be handled when a Fellow fails to meet the required case volume. Mr. Steffen then asked about the approach that was taken under the C-PORT trial.

Ms. Fleck noted that most of the time, Fellows are at an institution where there is a cardiac surgery program, and a Fellow at a hospital with cardiac surgery that failed to meet a minimum volume standard would not be subject to an external review of all cases. However, there are Fellows as hospitals with only PCI programs. She asked whether the regulatory language triggered external review of a Fellow's PCI cases inappropriately.

Nancy Bruce from Frederick Memorial Hospital (FMH) stated that they have Johns Hopkins Fellows training with their program and suggested that adding language to the regulations noting that the Fellow will be under the direct supervision of the Operator might address the issue.

Another CSAC member commented that if Fellows do not meet the 50 intervention volume requirement, then they will not graduate. Ms. Fleck asked for confirmation that the regulatory language is not a concern because a review would unlikely be triggered.

Ms. Bruce said that historically FMH has let the MHCC know that the Fellow operated only under the direct supervision of a primary operator. She also noted that the recent addition of Fellows at FMH may have triggered the discussion. Dr. David Zimrin noted that the Fellow would not be the primary operator.

Mr. Steffen explained that when the regulations were first developed, MHCC did not consider this issue. He noted that it appears that the regulations are inconsistent with standard practice. Therefore, the MHCC wanted to get feedback from the Committee. Ms. Fleck agreed with Mr. Steffen's comments.

Ms. Sharon Sanders from Carroll Hospital Center (CHC) discussed the role of Fellows at CHC. Dr. David Zimrin said there was a little confusion because there are no Fellows at CHC. He noted that each case is done by the operator, and Fellows cannot be the primary operator. Ms. Sanders agreed.

Dr. Mauro Moscucci said that Fellows would never do the procedures by themselves so the regulations should not apply to Fellows, only the operator. He also expressed concern about the cost of the external reviews. Ms. Bruce agreed that when Fellows are involved with a case, an interventional Cardiologist is always present. However, she stated that we need to answer the question about what is meant by direct supervision. She asked whether the attending physician is scrubbed-in and standing next to the Fellow or just present in the lab. She suggested that it would be helpful to hear from Hopkins and the University of Maryland on this issue. Dr. Zimrin replied that the attending physician is responsible for the procedure, but there is no definition of direct supervision. The extent of supervision depends on the skills of the Fellow. Dr. William Thomas noted that the Fellow will not be the physician of record. The attending is the one whose case will be reviewed externally. Fellows are reviewed internally.

Ms. Fleck said that since there seemed to be a consensus about this issue, she wanted to move on from this topic to discuss some of the comments that were received. She noted that the MHCC received several comments on the draft amendments to COMAR 10.24.17, and she wanted to review as many as possible. Mr. Steffen suggested Ms. Fleck provide an overview of the proposed changes.

Ms. Fleck said that MHCC staff focused primarily on adding external peer review requirements (Section .08), but also added a very brief section for internal review requirements (Section .09). In addition, MHCC staff updated some of the definitions and clarified some of the language regarding internal and external review.

Comments on Draft Amendments to COMAR 10.24.17

Peer Review Timing Requirements

Ms. Fleck reported that MedStar Health requested clarification on whether case reviews are required quarterly, semi-annually or annually for external and internal reviews. MHCC staff

changed the language regarding the frequency of external and internal review to order to allow for greater flexibility. Ms. Fleck explained that the intent was to allow hospitals to combine internal and external review, if they preferred that approach. For the internal review of individual physicians, Ms. Flecked noted that internal review would be sufficient and less costly. Ms. Fleck indicated that MHCC staff would review the language cited and consider changes to address the concerns raised by FMH and MedStar Health.

Quality Assurance Activities Report

MedStar Health also had questions about the requirement for filing a report on quality assurance activities included in .07C and .07D. MedStar Health wanted to know the specific information required and suggested that the information be included as part of an application for a Certificate of Ongoing Performance instead. Ms. Fleck commented that MHCC staff reconsidered the purpose of the annual report on quality assurance activities. MHCC staff proposed having an annual certification signed by the appropriate administrators affirming that the hospital complies with all of the quality assurance requirements, including for external and internal peer review. Ms. Fleck noted that MHCC staff also recommends specifying that detailed information be filed as part of a hospital's application for a Certificate of Ongoing Performance, such as the results of the external and internal peer review processes. Ms. Fleck asked if CSAC members agreed with those proposed changes. They did.

Combining Annual Internal Review of Physicians and Semi-Annual External Review

In written comments, Meritus asked for clarification on the opportunity to eliminate the annual internal peer review of individual PCI operators if external peer review is done in a certain way. Ms. Fleck confirmed that it is possible.

Quality Assurance Meeting Requirements

MedStar Health commented that the meeting requirements in the regulations are very detailed in terms of frequency and who must attend those staff meetings (.07C(4) and .07D(5)). MedStar Health noted that hospital requirements for quality assurance meetings are already thoroughly detailed by The Joint Commission and by hospital administrators. MedStar Health recommended that the standards be eliminated altogether. Ms. Fleck stated that while MHCC staff is open to suggestions for increasing the flexibility of the requirements, MHCC staff disagrees that the requirements should be eliminated altogether. Mr. Steffen added that the meeting requirements mirrored those of a clinical trial, and although you may not need the same level of quality review in standard medical care as in a clinical trial, MHCC should not abandon the standards altogether.

Dr. Thomas commented that cardiology is a heavily regulated area, noting that The Joint Commission can come in and review program records and processes anytime. Dr. Thomas added that he was concerned because clinical trials are very different, and it potentially confuses everyone by having several bodies dictating the meetings.

Dr. Warren agreed with Dr. Thomas's comments, and he added that we need to maintain the focus of internal review on difficult cases and cases where there is a difference of opinion. External review gives an independent look at the operators. He expressed concern that including

random cases for internal case review would detract from it. Dr. Jerome Segal agreed with Dr. Warren, and he added that there are already other committees such as the Executive Medical Committee looking at quality.

Dr. David Zimrin commented that they had been doing five percent of randomly selected cases for internal review plus the cases with complications. When regulations came out from the MHCC for ten percent of randomly selected cases plus complicated cases, Dr. Zimrin commented that valuable time was taken away from the review of other cases making the peer review meetings less effective as an education tool after MHCC adopted regulations requiring internal peer review for ten percent of randomly selected cases plus complicated cases. He stated that there is just not enough time to do ten percent plus the complicated cases.

Dr. Warren asked whether the frequency of case review meetings should be specified. Ms. Fleck noted that it is required either every month or every other month. Paul Parker read the requirements that Meritus commented on:

> *(a) The hospital shall develop a formal, regularly scheduled (meetings at least every other month) interventional case review that requires attendance by interventionalists and other physicians, nurses, and technicians who care for primary PCI patients.*
>
> *(b) The hospital shall create a multiple care area group (emergency department, coronary care unit, and cardiac catheterization laboratory) that includes, at a minimum, the physician and nursing leadership of each care area and meets monthly to review any and all issues related to the primary PCI system, identify problem areas, and develop solutions.*

Mr. Parker asked if there were objections to the meeting requirements that he just read. Dr. Warren commented that the requirements sound reasonable. Mr. Steffen asked if there was a representative from Meritus on the phone that wanted to comment.

Brett Kane stated that Meritus holds a meeting every other month that is an interdisciplinary meeting with ED, critical care, and cardiac catheterization lab staff present. The meeting includes case review, including ten percent of randomly selected cases. He added that Meritus had asked whether external review could replace the annual internal review of PCI operators.

Ms. Fleck replied that you can combine the two reviews and just do external review. She noted that Meritus also inquired whether the cases with complications or morbidity are considered on top of the ten percent of randomly selected cases. She said that cases that were selected for review due to morbidity, mortality, or for another reason should not be excluded from the random selection of cases. She noted that if a randomly case has already been reviewed, it does not need to be reviewed again or replaced with another case. Ms. Fleck commented that several CSAC members seem to have reservations about the value of reviewing a random ten percent sample of cases. Dr. Christopher Haas stated that he would opt for the internal review because it has a lot more value for learning. Ms. Fleck asked if anyone else

wanted to comment. Ms. Bruce commented that the regulations and terminology are confusing. Mr. Steffen responded that the MHCC will work on making the language clearer.

Dr. Warren said that he favors requiring monthly reviews instead of every other month, so the information is fresh. Dr. Zimrin noted that at St. Joseph's Hospital ten reviews within twelve months are required. Dr. Blair Eig said that at Holy Cross case review meetings are held on a monthly basis, but the volume is smaller than some of the other programs. He added that that everyone is already doing internal reviews, and the regulations can support the current practice. He also noted that Holy Cross combines internal case reviews and multiple care area meetings, but some flexibility should be allowed because some months it's very difficult to schedule a meeting.

Inconsistent Language in Section for Ongoing Performance

MedStar Health commented that the wording in Section .06A(5) is inconsistent with other sections describing the frequency of internal and external reviews. It suggested that the regulations be simplified to clarify the requirements. Ms. Fleck agreed that the language is inconsistent with other sections, and she proposed modifying the language to be consistent with other sections.

Ms. Fleck also noted that a primary PCI program that initially gets a Certificate of Conformance is expected to do an external review of five percent of cases, but once it obtains a Certificate of Ongoing Performance, such reviews are not required. Ms. Fleck noted that the decision not to require external review of primary PCI cases was based on feedback from the CSAC. However, MHCC staff received comments on the draft amended COMAR 10.24.17 suggesting that we should continue to review these cases. Ms. Fleck suggested that CSAC members review the comments from representatives from the Maryland Academic Consortium for Appropriateness and PCI Quality (MACPAQ). MACPAQ stated that in some cases cardiac surgery should be considered for STEMI patients. It was also noted that the guidelines for cases are continually changing and for consistency perhaps the cases should be reviewed. In written feedback, FMH also commented that it would be good to include STEMI cases, instead of excluding them from random external and internal review of cases.

Dr. Eig noted that there may be some confusion on whether external review is required for a hospital with only primary PCI. He noted that he neither favors nor opposes external review of primary PCI cases. However, he commented that it is important to be clear about the type of program subject to external review and how the cases are selected.

In response to the comments from Dr. Miller, a representative for MACPAQ, Dr. Warren noted that it was not a concern about STEMI cases that triggered the requirement for external review; it was a concern about elective cases. Dr. Warren stated that evaluating the appropriateness of STEMI cases would be low yield; almost all cases would be deemed appropriate. He added that the value of the external review process would be diluted by including STEMI.

Ms. Fleck asked about external review for new primary PCI programs. Dr. Warren did not think external review was necessary for new primary PCI programs either. Ms. Fleck asked others for feedback.

Dr. Thomas agreed with Dr. Warren. He reminded everyone to think about the original purpose of external review. The requirement for external review was not triggered because of inappropriate handling of STEMIs. He added that Commission may attach conditions to a CON, and those may be used to require external review of primary PCI cases.

Ms. Fleck said that it sounds like most people still favor not looking at primary PCI cases. She noted that Meritus had asked whether a hospital must review primary PCI cases, if an interventionalist only performed a few cases and all were primary PCI. Mr. Steffen asked Dr. Zimrin to comment on that particular scenario. Dr. Zimrin agreed that the scenario was a realistic possibility.

Dr. Moscucci commented that the cases should be reviewed by the multiple care area group. He suggested that MHCC should expand the subsection on quality to specifically state that some primary PCI cases should be reviewed.

Dr. Eig asked Ms. Fleck how many programs only perform primary PCI, and Ms. Fleck responded that there are three programs. Dr. Eig suggested that it may not make sense to have a lot of rules that apply to only three programs. He also mentioned that all cases at Holy Cross are reviewed.

External Peer Review Comments

Ms. Fleck noted that Dr. Julie Miller and Dr. Jeff Brinker suggested removing the word "emergency" from page 55 of the draft amendments to COMAR 10.24.17. Ms. Fleck then read the relevant text:

> (a) *For PCI cases in which the patient received emergency PCI due to acute coronary syndrome, did the operator appropriately diagnose the patient as suffering from acute coronary syndrome?*

Ms. Fleck said that this was an oversight by the MHCC staff, and she agreed with removing the word "emergency." No one disagreed with the proposed change. She noted that it was also suggested that a second question be added regarding whether it is angiographically appropriate to perform the procedure. Ms. Fleck then read the relevant text:

> (b)*What is the estimated numerical percentage of stenosis, based on visual assessment of the patient's angiogram?*

Ms. Fleck asked for feedback on the proposed change. Dr Zimrin said that he had been part of the discussion that led to the formation of the above questions. He noted that adding to (b) was suggested because there are different levels of appropriateness such as angiographically or clinically appropriate as well as various guidelines. If it is uncertain, it is important to know if additional imaging was done. Ms. Fleck asked the Committee if they agreed with the addition to which members said yes.

FMH commented on another question that is shown below:

> *(f)Was PCI successful, partially successful, or unsuccessful?*

(i) A partially successful PCI procedure is defined as achievement of twenty percent to less than or equal to fifty percent residual stenosis and TIMI 3 flow;

(ii) An unsuccessful PCI procedure is defined as greater than twenty percent residual stenosis with a stent, or greater than fifty percent residual stenosis with plain balloon angioplasty or less than TIMI 2 flow.

FMH proposed the following changes:

A residual stenosis of < 50% with PTCA and normal TIMI 3 flow is successful; a residual stenosis of <30% for stent implant with TIMI 3 flow is successful. Unsuccessful for both involves residual stenosis of >50% or < TIMI 2 flow. Partially successful is achievement of TIMI 2 flow or PTCA residual stenosis that is an absolute reduction by 20% in the degree of stenosis with TIMI 3 flow or stent residual stenosis that in the 30-50% range with TIMI 3 flow.

Dr. Warren disagreed with using less than 30% to define success and advised no change. Ms. Fleck suggested that everyone read over the current language and also read the text for everyone. Dr. Warren commented that the existing text is simpler and clearer. Dr. Eig asked the cardiologists on the Committee if there is a standard. Dr. Moscucci said he would like to review the current standards. Ms. Fleck replied that it may be a good idea to review and handle feedback through email correspondence.

Qualifications of External Reviewer

Ms. Fleck stated that Dr. Miller and Dr. Brinker asked whether the case volume requirement of 750 cases for the external reviewer includes cases performed during a Fellowship. Ms. Fleck asked for additional feedback on the standard. Dr. Zimrin said that the point was not necessarily the number of cases, but if the cases done during Fellowship should count. Ms. Fleck asked for Dr. Zimrin's opinion on this issue to which he replied that since the requirement is to do 50 cases per year, if Fellowship cases count, it would take about 10 years to become an experienced operator. If Fellowship cases do not count, then it would take about 15 years to become an experienced operator. Dr. Zimrin felt there may be a shortage of experienced operators if the cases done during Fellowship do not count. Mr. Steffen said that would be taken under consideration.

Dr. Warren asked Dr. Zimrin how many cases Fellows typically complete during a Fellowship. Dr. Zimrin replied that Fellows need 250 cases to graduate.

Detail of Standards for External Reviewers

Ms. Fleck reported that MedStar Health commented that the regulations for external peer review are too detailed. However, MHCC staff concludes that the regulations need to be detailed in order to ensure a level playing field. She noted that there is not an accrediting organization that oversees external reviewers for PCI cases. She asked for additional feedback on the issue raised. Mr. Steffen commented that granting hospitals flexibility on their choice of an external reviewer makes having some standards necessary. Dr. Eig commented that the opportunity to

select an approved external reviewer as opposed to having a designated reviewer is a good option. Dr. Moscucci agreed with Dr. Eig.

Documentation of Data Sources

Ms. Fleck said that there were a few comments from Dr. Zimrin, Dr. Miller, and Dr. Brinker suggesting minor changes to the data sources for external review. For example, they noted that some patients may not have a discharge summary if they were not admitted to the hospital and only under observation. MHCC staff agrees with making the proposed changes, no one expressed dissent.

Exemptions from External Review

Ms Fleck also noted that Dr. Steven Hearn commented that there should be an exemption for hospitals under a Corporate Integrity Agreement. Ms. Fleck stated that MHCC staff is not opposed to adding wording changes to the regulations and asked whether others agreed. No one disagreed with the proposed change.

Number of External Reviewers

Ms. Fleck explained that Dr. Miller recommended that there should be two external reviewers instead of one for all cases reviewed. In contrast, FMH commented that a second reviewer should not be required for any cases reviewed. As described in Section .08C(2), MHCC staff currently proposes that only one reviewer is required unless a case is deemed rarely appropriate or inappropriate. Ms. Fleck asked for feedback from others on the issue.

Ms. Bruce said that requiring a second reviewer is overreaching and expensive. Especially since the Commission has other data for evaluating the quality of programs. Ms. Fleck noted that the external reviewer has better information for evaluating the appropriateness of PCI procedures, specifically the angiogram. Mr. Steffen said that MHCC wants to avoid overreaching. Ms. Bruce asked if a second reviewer could be an optional requirement. Dr. Moscucci agreed that an optional requirement may be a good idea.

Dr. Thomas explained that the way it works with external peer review protects the hospital. If you have one negative review a physician is likely to be defensive. With two negative reviews, it's more difficult to discount the negative reviews. However, he stated that doing two reviews for all cases is costly and inefficient. It is easier to go back to a physician when you have two reviewers both with bad reviews. Dr. Warren agreed with Dr. Thomas's comments.

Dr. Warren asked about the process for discordant reviews with two reviewers which can be more difficult. Mr. Parker read the draft amendment for discordant reviews. It states that a third reviewer is required if the first two reviewers disagree. Dr. Thomas said that he has seen external reviews conducted in many ways. Sometimes the two reviewers who disagree with talk to each other to try and work out their differences. Ms. Bruce said that she would still prefer that the use of a second or third reviewer be optional.

Selection of Cases for Review

FMH commented that the required process for random selection of cases for reviews is unnecessarily restrictive. Ms. Bruce said that she assumes the reviewer will randomly select cases, and that if the organization is approved by the Commission, then the process does not need to be specified. Ms. Fleck noted that all review organizations are expected to use the same process, and she thought the CSAC previously discussed the importance of a standard process for random selection of cases. Dr. Warren agreed with Ms. Fleck. Ms. Fleck said that MHCC staff would review the language again.

Definitions and Other Concerns

MedStar Health commented the codes included in the definition of PCI have to be updated. Ms. Fleck agreed and asked for volunteers, but no one volunteered.

MedStar Health also expressed concern about distinguishing emergency PCI from primary PCI. Ms. Fleck commented that MHCC staff reviewed these definitions, and they seem consistent with historical usage and language in statute. Ms. Fleck suggested that CSAC members contact MHCC staff with specific proposed changes, if they believe the definitions need to be updated.

MedStar Health also expressed concerns with the definitions "primary PCI operator" and "target volume." However, MHCC staff concluded that the definitions are fine without change. Ms. Fleck asked if anyone disagreed, and no one commented. MedStar Health also recommended deleting the word plain from the term "plain balloon angioplasty." MHCC staff agreed to make this suggested change.

Meritus suggested that the regulations specify the amount of time given to a hospital to prepare for a focused review. Ms. Fleck commented that it would be challenging to include an appropriate timeframe because it would depend on the trigger for the focused review. Ms. Fleck asked others for feedback, but no one commented. Ms. Fleck stated that she interpreted the silence to mean that spelling out a timeframe in regulations is not necessary.

FMH reported that they would have difficulty calculating the performance outcome measure related to 30 day mortality. Ms. Fleck commented that she was not expecting hospitals to perform those calculations. MHCC staff is planning to have a contractor perform those calculations.

Cardiac Surgery Codes

Mr. Steffen reported that updating the cardiac surgery codes was a more complex process than originally anticipated. Before discussing coding changes, the Committee took a five minute recess.

Ms. Fleck reconvened the meeting and began by asking if there were any cardiac surgeons on the phone. Both Dr. Jamie Brown and Dr. Keith Horvath were on the phone, and the cardiac surgeons present in the room identified themselves (Dr. Massimiano, Dr. Salenger, and Dr. Sanchez).

Ms. Fleck stated that it is important to preserve the quality of cardiac surgery programs, and based on that goal, MHCC staff determined that the focus should be on open heart surgery cases when counting volume at programs. She noted that research suggests programs with less than 100 cases often have poorer outcomes than larger volume programs.

Ms. Fleck reviewed the email message sent to CSAC members that described proposed changes to the list of ICD-9 codes included in the definition of cardiac surgery and that flagged specific codes for discussion by the CSAC. She also noted that MedStar Health recommended that TAVR cases should be excluded.

Mr. Steffen explained that a broad list of codes for cardiac surgery that also is used to count case volume is problematic. Therefore, MHCC staff proposes a narrower range of codes be used to count case volume, and a broader set of codes be used to define procedures that are only appropriately provided at hospitals with cardiac surgery programs. MHCC Staff thinks the proposed approach is a good compromise. Mr. Steffen asked for feedback on the proposed approach, but then decided to first recognize the CSAC members who worked on coding issues: Dr. John Conte, Dr. Juan Sanchez, Dr. Stuart Seides, Dr. Rawn Salenger, and Dr. Stafford Warren.

Dr. Warren acknowledged that it would be simpler to have this approach. However, he asked for clarification on when a review would be triggered based on volume. Ms. Fleck responded that 100 is the critical number, and it would not be worth reviewing a program if the volume falls slightly below 200 cases. Mr. Steffen confirmed that the performance standard for volume would be based on open heart procedures.

Dr. Salenger noted that cardiac surgery can be described very broadly ranging open heart to trans-catheter procedures, and very different skill sets are involved with each. With regard to the volume-quality relationship, he noted that it has not been well defined for trans-catheter procedures, and while it exists for open heart procedures, it is not perfect. Therefore, he suggested that MHCC should be careful in its evaluation of low-volume programs and evaluate quality separately. However, he agreed that the proposed approach to definitions is appropriate.

Dr. Sanchez agreed with Dr. Salenger. He also commented that his understanding is that the approach is consistent with how MHCC has counted volume at cardiac surgery programs and not much was changing. Mr. Steffen confirmed that his understanding is correct.

Dr. Horvath said he was concerned if not much would be changing because the previous list of codes was very limited. They did not include procedures such as aneurysms or removal of tumors. He suggested that any case requiring bypass should be counted as open heart surgery. Ms. Fleck and physicians who had volunteered to review the codes closely responded that codes were being added. Dr. Massimiano noted that the approach is right.

Dr. Horvath asked why two different lists of cardiac surgery codes are need if the primary concern is volume. Ms. Fleck replied that the two lists would clarify when a hospital requires a CON for cardiac surgery, even though she thinks that is unlikely someone would perform cardiac surgery procedures at a hospital without a cardiac surgery program.

Codes Removed from Volume Count

Ms. Fleck discussed the cardiac codes proposed for removal, meaning they would not count for the volume standards. She stated that 35.00 through 35.04 are proposed for removal, and those codes refer to closed heart valvotomy procedures. She also noted that 35.55, repair of ventricular septal defect with prosthesis (closed technique) is proposed for removal. Ms. Fleck noted that there was consensus among the volunteers to remove these codes, but asked if anyone disagreed. No one disagreed.

Dr. Sanchez commented that he thought Code 35.06 (transapical replacement of aortic valve) was discussed by the volunteers as one to include as an open heart procedure. Dr. Salenger added that he thought 35.08 should also be included as an open heart procedure. Dr. Warren mentioned another procedure should be counted too. Ms. Fleck agreed that 36.06 and 35.08 had been discussed for inclusion by the volunteers. She suggested that describing what to count could facilitate the transition to ICD 10 codes without revisiting the regulations. However, Dr. Sanchez stated that the codes should be examined again. Dr. Salenger suggested any approach other than transfemoral should be counted, and Dr. Warren agreed. Dr. Eig suggested that listing specific codes may be problematic. However, Ms. Fleck explained the advantages of including specific codes; everyone understands what to count for the volume standards and for the utilization projection.

Ms. Fleck next reviewed several specific codes, requesting feedback on how to handle them. She first asked about 37.25 (biopsy of the heart) and 37.36 (excision, destruction, or exclusion of left atrial appendage). Dr. Warren commented that anytime 37.25 is open, he would expect that it is done in conjunction with another cardiac procedure, so it should be on the list for cardiac surgery, but not open heart surgery. Ms. Fleck next asked for feedback on 37.36 (excision, destruction, or exclusion of left atrial appendage). Dr. Warren commented that categorizing the code is tricky because it could be open or closed. Dr. Salenger noted that not many are performed as a standalone procedure. He suggested counting it when a cardiac surgeon performs the procedure and not counting it when an interventionalist performs the procedure. Ms. Fleck noted that MHCC would need a list of the cardiac surgeons' identification numbers. Dr. Salenger mentioned that there is another procedure that may be performed by both cardiac surgeons and interventionalists.

Ms. Fleck next asked for feedback on 37.37, but then determined that she understood how to handle the code. Dr. Salenger commented that some codes in the range 38.XX should be counted as open heart surgery. He noted that the abdominal procedures should be excluded, but the aortic procedures included. Specific codes mentioned for inclusion were 38.05, 38.14, and 39.23. It was also noted that codes 39.30, 39.31, and 39.32 should be left out because they might occur at hospitals without cardiac surgery that are treating patients with injuries. CSAC members were unsure if 39.23 might be performed at hospitals without a cardiac surgery program. Dr. Massimiano suggested that those cases could be examined more closely. Dr. Brown asked about cardiac stripping. Dr. Sanchez noted that it should not occur at hospitals without cardiac surgery and had been discussed with the other volunteers. Ms. Fleck added that it was suggested that when it showed up at hospitals without cardiac surgery, it could be upcoding and not a reflection of the actual procedure performed.

Ms. Fleck next asked about 39.65, which refers to extracorporeal membrane oxygenation (ECMO). Ms. Fleck noted that ECMO could also be performed for respiratory distress, organ transplant patients, or for cardiac conditions. Ms. Fleck asked if it should be left off the list for open heart surgery or if additional information should be used to determine which specific cases should be counted. Dr. Brown commented that it should definitely count as cardiac surgery and maybe it should not count when it is used only to support a patient's lungs. Dr. Salenger agreed. Dr. Sanchez commented that the same competence is required. Dr. Massimiano commented that it would probably be unusual to be on cardiac ECMO and not have other cardiac procedures. He agreed that cardiac ECMO should be counted, but not ECMO only for respiratory support. For code 39.66, Dr. Sanchez asked if it would be counted as cardiac surgery. Dr. Salenger commented that it should count for cardiac surgery, but not open heart surgery. Ms. Fleck asked Dr. Salenger to send an updated list following the meeting.

Next Steps

Ms. Fleck said that she would welcome additional feedback by email on the cardiac surgery codes or other issues. She also thanked everyone for their participation in the meeting. Ms. Fleck commented that although she had hoped to bring a proposed regulation to the June Commissioners meeting, it may be the July meeting. Mr. Steffen said that the next step would be to broadly distribute a revised document. He also stated that updating the regulations is a top priority that will be done as soon as possible. Ms. Fleck said that the next meeting would likely be sometime in the fall. The meeting adjourned at approximately 8:55 p.m.