Draft Meeting Summary
Cardiac Services Advisory Committee (CSAC)
Wednesday, March 4, 2015
MHCC, 4160 Patterson Avenue, Baltimore, MD 21215

Work Group Member Attendees:
Thomas Aversano, M.D. (by phone)
Jaime Brown, M.D. (by phone)
Nancy Bruce, R.N., M.B.A (by phone)
Jesus Cepero, Ph.D., R.N. (by phone)
John Conte, M.D. (by phone)
Blair Eig, M.D
Christopher Haas, D.O. (by phone)
Steven Hearn, M.D.
Keith Horvath (by phone)
Josemartin Ilao
Paul Massimiano, M.D.
Lisa Myers, R.N., M.S. (by phone)
Rawn Salenger, M.D. (substitute for Dr. Gammie)
Juan Sanchez, M.D.
Sharon Sanders, R.N., M.B.A.
Stuart Seides, M.D. (by phone)
Jerome Segal, M.D.
William Thomas, M.D.
Stafford Warren, M.D.

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

Other Attendees:
Julie Miller, M.D (guest speaker)
Stephen Plantholt, M.D (guest speaker)
Sara Captain
Amy Dukovcic, Washington Adventist Hosp.
Eddie Fonner, MCSQI
Terri Haber
Dawn Hamilton, St. Agnes Hospital
Yan Huang, Washington Adventist Hospital
Marci Hunt, St. Agnes Hospital
Theressa Lee, MHCC
Reba McVay, MedStar
Kathy Ruben, MHCC
Jill Swisher, St. Agnes Hospital

Introduction:

The meeting convened at approximately 6:45 pm. Ben Steffen, Executive Director of MHCC thanked everyone for attending the meeting and asked work group members to introduce themselves. Mr. Steffen then explained the goals for the meeting. These goals included

gathering additional input on the external review process for use in the development of regulations. Mr. Steffen then reviewed the agenda for the meeting. He noted that two guest speakers would describe different models for external peer review. Next, Ms. Fleck would lead a structured discussion based on ten questions pertaining to external review of PCI cases. The remainder of the meeting would cover topics related to MHCC's regulation of cardiac services, such as the review schedule for Certificates of Ongoing Performance.

Ms. Eileen Fleck noted that one of the three scheduled speakers, Dr. Mauro Moscucci, had to cancel his presentation. Ms. Fleck also noted that she sent a copy of the slides for Dr. Miller's presentation out to work group members by email, shortly before the meeting began.

Review of Meeting Summary

Ms. Fleck stated that there were a few proposed corrections from Lisa Myers for the November 5, 2014 meeting summary on page seven. Ms. Fleck asked if there were any other additions or corrections to the meeting summary. No other changes were noted. Ms. Fleck stated that she would send the revised meeting summary for everyone to review again. She then introduced the first guest speaker of the evening, Dr. Julie Miller.

Models for External Peer Review

Dr. Julie Miller thanked the Committee for the invitation to discuss external review of cardiac services on behalf of the Maryland Academic Consortium for Percutaneous Coronary Intervention Appropriateness and Quality (MACPAQ). MACPAQ formed over two years ago as a collaboration between the Divisions of Cardiology at the Johns Hopkins University and the University of Maryland to assure quality of PCI services. The purpose of MACPAQ is to perform ongoing, blinded, independent external peer review that focuses on both quality and appropriateness of services as well as procedural outcomes and the accuracy of reporting procedures. The method of the review is a physician-led, random review of 10% of cases. The goal is to provide objective feedback to hospitals and physicians. MACPAQ's primary review includes a three-fold review of "appropriateness" of PCI. Appropriateness is evaluated based on the ACC/AHA guidelines, standard clinical practice, and a review of the angiographic stenosis severity. MACPAQ also assesses procedure outcome and quality and the accuracy of reporting. MACPAQ has previously compared its results to an institution's NCDR report on appropriateness of PCI cases. MACPAQ also may evaluate if CABG was more appropriate than PCI and quantitatively evaluates lesions. MACPAQ also provides an option for selective extensive review, akin to internal review.

Dr. Miller proceeded to describe the MACPAQ peer review system and provided a schematic to show the flow of the external peer review process. She presented an example of a case review to illustrate MACPAQ's review process.

MACPAQ receives an electronic copy of source clinical medical information from hospitals as well as a copy of the angiogram through image sharing at the coordinating center where it is blinded if it has not already been blinded. MACPAQ then distributes blinded data to physician review teams comprised of two physicians via a web-based link. The reviewers

evaluate the data and clinical records for appropriateness and quality. This is accomplished through a series of drop-down menus from which the reviewers select answers. Drop-down menus are used for consistency of nomenclature. Angiographic review of appropriateness is based on clinical judgment of the reviewers who select "A" Appropriate, "U" Uncertain, "I" Inappropriate, or "N/A" Not Applicable. Intervention Outcome selections include "successful", "partially successful" or "unsuccessful." Complications are also reviewed, but these are limited to those captured on the angiogram. If there is a disagreement among the two physicians, the information is sent to a third reviewer for evaluation. Finally, reviewers examine documentation to see if there is an agreement between the information in the reports and outcome assessment and what is documented in the chart. The MACPAQ coordinating center summarizes the review information and results in a report and returns the results to the hospital. The hospital receives an overall summary of the appropriateness rating. Operators are only identified by number in these reports.

Dr. Miller then answered questions about MACPAQ beginning with a question that had been posed by Ms. Fleck about the capability for expansion. Dr. Miller noted that MACPAQ has the structure to expand statewide and can accommodate different standards for evaluating cases. She commented that MACPAQ provides high value to the system at a low cost, and can help foster self-learning.

Mr. Steffen asked Dr. Miller to go back to her first schematic and review the blinding process. Mr. Steffen noted that since every record has unique hospital information and identifiers, it could be difficult to blind cases. He asked how MACPAQ can ensure that records are truly "blinded." Dr. Miller responded that it is fairly easy to remove patient identifiers from images working on an automated system. She added that removing identifiers from certain documents, such as medical records, can be more challenging, but information can be put in a generic format so that it will not be identifiable.

Mr. Steffen then asked Dr. Miller to describe MACPAQ's method of aggregating the two physician reviewers' reports. Dr. Miller described two different situations, the first being when the two reviewers agree and the second being a situation where the reviewers disagree. In the latter situation, a third reviewer is asked to review the information, and a consensus report is written which is reported back to the hospital.

Dr. Stafford Warren asked Dr. Miller to address the issue of cost of the external peer review. Dr. Miller replied that cost would depend on what has to be reviewed. She noted that MACPAQ has kept the cost down compared to the commercial cost, by conducting reviews within the current infrastructure. She estimated that the cost is at least 50 percent less than the commercial cost for a similar external review of PCI cases. She added that costs can also be kept down by making a review program of this type a maintenance of certification (MOC) activity rather than a reimbursed activity. MOC credit could be viewed by some participants as more valuable because those credits are often difficult to obtain.

Dr. William Thomas asked Dr. Miller about the volume of cases reviewed and the sustainability of the current infrastructure with an increased volume. Dr. Miller responded by noting that the current infrastructure can be used and has been used for a large volume of cases. From a research perspective, thousands of cases have been reviewed. In terms of the volume for

reviewers, it is a matter of training the reviewers. The volume of cases that MACPAC has handled for reviews of appropriateness of PCI is around 700 cases.

Mr. Josemartin Ilao asked Dr. Miller about the decision to maintain four categories of "appropriateness" for reviews by MACPAQ, noting that MHCC staff previously proposed a model with three categories. Dr. Miller responded that experienced interventionalists realized that there needed to be an expansion of appropriateness categories from three categories to four because not all cases fit into three categories. She noted that it is not possible to evaluate some cases with the ACC appropriate use criteria because not all clinical scenarios are addressed by the ACC guidelines. She highlighted the value of evaluating appropriateness in multiple ways, including standard clinical practice and the angiogram.

Dr. John Conte asked Dr. Miller how long she has been working at MACPAQ and how long it took to reach the level of sophistication present now. Dr. Miller responded that MACPAQ has been working on quality review for two to three years. Dr. Conte asked if there had been multiple discrete editions of MACPAQ or if it had continuously evolved. Dr. Miller estimated that 90% of the system has not changed since it was established. However, MACPAQ has evolved in how it obtains information and will continue to evolve as technology evolves.

Dr. Stuart Seides asked Dr. Miller if there is any mechanism in place for an appeals process, especially for cases that are judged to be "inappropriate" or "rarely appropriate." Dr. Miller replied that MACPAQ does envision an appeals process, and she agrees that it is essential. She added that some judgments may be based on the limited documentation available. Dr. Seides asked for confirmation that the results of reviews by MACPAQ are peer protected, and Dr. Miller confirmed that his understanding is correct. She also noted that names are not included on MACPAQ reports. She added that feedback is meant to be constructive.

Ms. Fleck asked if this issue has ever come up, even though her understanding is that the process is intended to be educational rather than punitive. She commented that hospitals would be likely to act if they find that a physician has a large number of "rarely appropriate" cases or physicians may feel that they are not fairly treated. Dr. Miller stated that the issue had never come up; a hospital or physician has not requested an appeals process.

Mr. Steffen asked Dr. Miller to go back to the sample summary sheet, and he asked members of the workgroup if they regarded it as useful. He also asked how hospitals look at the information and whether they are able to interpret it. Dr. Miller noted that the summary report goes to a hospital, but if the hospital wants additional information, a more extensive review can be done. A time frame is given to the hospitals for a certain percentage of cases to be sent for review. Dr. Miller commented that her understanding is that hospitals just look at patterns occurring over time and focus on outliers.

Dr. Christopher Haas asked about access to pre-procedural data (progress notes, results of stress test, etc.) when determining appropriateness and whether a reviewer just uses the cardiac catheterization report. Dr. Miller responded that the reviewer has access to other data, if it is sent by the hospital. If supporting documentation is not sent, the case may be categorized as

"uncertain." The core processing center for MACPAQ may also follow-up with a hospital to get information essential to evaluating a case.

Dr. Eig asked Dr. Miller if cases returned to hospitals that were labeled "inappropriate" resulted in some hospitals requesting the names of the doctors associated with those cases. Dr. Miller replied that no hospitals had made such a request. However, there have been requests for extensive reviews for an individual physician.

Ms. Nancy Bruce asked Dr. Miller whether it was possible for contracting hospitals to get a list of reviewers for MACPAQ and whether there is an opportunity for others to become reviewers. Dr. Miller responded that hospitals can get a list of reviewers for MACPAQ, and there is an opportunity to add physician reviewers from participating hospitals in MACPAQ.

Dr. Plantholt asked Dr. Miller if she could share which hospitals participate with MACPAQ. Dr. Miller replied that this was contractual information and could not be shared, but there were hospitals both in the system and out of the system that participate with MACPAQ.

Dr. Steve Hearn asked if MACPAQ supplies the hospital with information on how their numbers compare with national standards or benchmarks. Dr. Miller replied that most of the hospitals participate with the NCDR Data Registry, and it provides that kind of information on a large scale.

Mr. Steffen said that any additional questions for Dr. Miller can be directed to Ms. Fleck. The CSAC took a five minute break before the next speaker presented.

Presentation by Dr. Steve Plantholt

Dr. Steve Plantholt is a clinical cardiologist and the chair of the quality assurance program for the Department of Medicine at St. Agnes Hospital. Dr. Plantholt began by describing the establishment of St. Agnes Hospital's quality assurance program for cardiac services. He noted that, initially, it included an evaluation of "door-to-needle time," when thrombolytics were given, and then evolved to focus on "door-to-balloon" (DTB) time. Dr. Plantholt noted that St. Agnes Hospital does approximately 1,400-1,500 diagnostic studies per year and 375-425 interventions per year. Their program had been limited to using in-house peer review for quality assurance, but the hospital saw a need for external peer review about two to three years ago and looked at several options. At that time they had a new chair, Dr. Rich Pomerantz, who contacted a former colleague, Dr. Fred Ling, at the University of Rochester Medical Center who agreed to review random cases. He noted that Dr. Pomerantz no longer performs PCI, and Dr. Ling does not know any of the interventionalists at St Agnes Hospital. He explained that there are four physicians who perform interventions at St. Agnes Hospital. Three interventionalists perform the vast majority of the procedures, and there is a fourth interventionalist who covers on the weekends, but he is a member of the staff at the University of Maryland Medical Center.

Starting about two to three years ago, St. Agnes started sending random cases from each of the interventionalists to Dr. Ling for an evaluation, using the ACC criteria, of the appropriateness of the cardiac catheterization and of the intervention. Dr. Ling determines

whether intervention was appropriate using various clinical criteria and objective measures such as stress imaging as well as criteria based on intravascular ultrasound (IVUS) imagingand fractional flow reserve (FFR) measurement. He noted that St. Agnes Hospital has since migrated to FFR for all prospective PCI patients because the Hospital regards it as the more appropriate standard of care.

Through December of 2014, St. Agnes Hospital reviewed 100% of its interventions. Beginning in January 2015 the reviews included 100% of STEMIs and about 10% to 20% of non-STEMI interventions based on time involved. Information is sent to Dr. Ling on a quarterly basis and the results are returned to the Quality Assurance Committee in Cardiology. It then goes to the Department of Medicine and then to the Medical Executive Committee, as well as the Board of Directors.

Dr. Plantholt concluded his presentation by noting that clinical practice at St. Agnes Hospital has been influenced by the results of its external peer review program including a shift from femoral access to greater use of the transradial approach. The change was made based on a concern about bleeding and the need for transfusions. St. Agnes has also modified the use of Heparin, an anticoagulant. The Hospital is currently looking at contrast agent-induced nephropathy, and in the future it may look at improving the incidence of strokes, but these complications occur in only a very small number of patients. Dr. Plantholt opened the floor for questions.

Dr. Warren asked about the blinding of cases. Dr. Plantholt explained that Dr. Ling does not know who the physicians are in the cases he reviews, but because their program is so small, the materials used in the review are not blinded.

Dr. Thomas asked how St. Agnes would handle external review if Dr. Ling were no longer available. Dr. Plantholt said that they would definitely look for an outside reviewer and consider utilizing their other contacts including those at Yale. One problem, however, would be the cost since Dr. Ling reviews cases at no cost to St. Agnes.

Dr. Eig commended St. Agnes Hospital for the significant process improvements they made based on the results of the external peer review. He wanted to know if Dr. Ling had provided feedback on how individual physicians could improve. Dr. Plantholt responded that such feedback had been received. He noted that for one cardiologist who had been using a larger, French-manufactured system, it was recommended that he use a smaller system, and he reduced his complications from bleeding.

Mr. Ilao asked Dr. Plantholt about the percentage of cases that are reviewed and how this would translate to reviews for all of Maryland because a very high percentage of cases historically have been reviewed by St. Agnes. Dr. Plantholt commented that only a small percentage of cases could be reviewed in the type of model proposed by the State rather than 100% of cases. He also noted that while all cases were reviewed prior to January 2015, fewer cases would be reviewed going forward.

Mr. Steffen raised the issue of what constitutes an independent review. He asked how an independent review could be assured in the situation described by Dr. Plantholt. Dr. Plantholt responded that it was as close to an independent review as they could achieve since Dr. Ling did not know any of the interventionalists performing PCI. Although he knows Dr. Pomerantz, there is no relationship or even acquaintance between the reviewer and those being reviewed.

Mr. Steffen asked if there were any other questions for Dr. Plantholt. Hearing none, he noted that these presentations show the range of programs that have been developed for external review and present a framework of elements that need to be considered in developing regulations for assuring competent external peer review programs.

Discussion Guide Questions

Ms. Fleck next led a discussion of external peer review. Ms. Fleck noted that the last CSAC meeting did not produce a clear consensus on the requirement for blinding cases for external review. She noted that members seemed to agree that blinding may be ideal and also agreed on the information that needs to be removed from a case in order to blind it, but members also expressed concerns about the cost of blinding cases. Mr. Steffen suggested that defining what blinding means would be helpful in terms of developing regulations.

Dr. Segal commented that identifiers of operators and institutions would have to be removed. Dr. Seides commented that because Maryland is a small state some people may be able to recognize the origin of a case even without that information. He noted that even though blinding is challenging, it may be the only reasonable way to move forward. He then asked if the State is going to indemnify the reviewers and the review organizations. Mr. Steffen responded that the State would not indemnify reviewers or review organizations. He suggested that Suellen Wideman of h the Attorney General's office comment further on the issue. She explained that MHCC has medical review status on documents, and hospitals have their own medical review committees. She noted that an external reviewer can be a medical review committee for a hospital under certain statutes, if the hospital takes the appropriate actions. She added that unless a physician who loses his or her privileges sues a hospital, the external review records are confidential and cannot be used for civil litigation.

Dr. Thomas reminded the CSAC that the peer review process being discussed is a scan of approximately10% of cases without the names of operators identified. These are not focused reviews. No one can come back to the reviewer because the review is blinded. External review of randomly selected cases is not the same thing as a hospital peer review committee. He also commented that he believes blinding cases is necessary.

Dr. Eig agreed and stated that a hospital may then choose to do an extended review of a certain practitioner based on the random review. He commented that a hospital may have already looked at some of the cases internally, and external review is a good way to look at the overall performance of your program. Another member, Dr. Segal, also agreed with Dr. Eig and added that it could be used to detect problems with the internal peer review process.

Ms. Fleck noted that there appeared to be consensus that blinding is essential and then moved on to the second discussion question regarding the questions to be answered by an external reviewer. Ms. Fleck stated that MACPAQ was used partially as a model in developing the questions for an external reviewer. Ms. Fleck asked members for feedback on the list of questions proposed.

Dr. Warren commented that perhaps the last two bullet points were overlapping and keeping only the second to last question should be sufficient. Dr. Eig commented that some of the information referenced, such as "alternative therapies," should be included as part of the process of getting informed consent. Another member, Dr. Segal, commented that two of the questions address quality and not appropriateness. Ms. Fleck responded that the proposed questions were not intended to reflect an expectation that a reviewer delve into the details of a case, but if there was an obvious deficiency apparent in the documentation, then a reviewer would have an opportunity to comment on it. Dr. Segal asked whether MACPAQ evaluates quality in its reviews and commented that much more data needs to be collected in order to comment on quality in addition to appropriateness.

Dr. Miller responded that information is collected about the success of a PCI procedure. However, MACPAQ doesn't provide all of the details that may be in an extended review. Dr. Warren commented that he thinks it is appropriate to include some basic metric of quality because it is an opportunity for learning. Dr. Miller agreed with Dr. Warren that both appropriateness and some basic measures of quality should be considered because of the learning that can be accomplished by external review. She added that certain information is collected by MACPAQ more for documentation confirmation rather than for quality.

Mr. Steffen suggested moving on to the third discussion question. Ms. Fleck noted that it was closely tied to the second discussion question. Ms. Fleck further explained that the idea is to give a reviewer a way to address quality in a limited way, without expecting the reviewer to answer dozens of questions. Ms. Saunders asked whether the information collected would be for the State or for the hospital. Ms. Fleck responded that it would be for the hospital's benefit because she thinks the State's role is to make sure that hospitals respond appropriately to information obtained from the external review.

Mr. Steffen moved to the next question, whether primary PCI cases, other than STEMI cases should be externally reviewed. Ms. Fleck commented that at the last CSAC meeting it was suggested that STEMI cases do not need to be reviewed because MIEMMS already reviews some of those cases, and a very high percentage of those cases are appropriate. Ms. Myers corrected Ms. Fleck, noting that MIEMSS does not evaluate the appropriateness of STEMI cases in the systematic or standardized way under discussion.. MIEMSS validates that documentation is present. It is not external peer review. Ms. Fleck commented that she understood.

Dr. Thomas Aversano commented that his understanding is that 98% of acute coronary syndrome cases are appropriate, based on his recollection of an article published in the *Journal of the American Medical Association*. He was skeptical of the benefit of having external review of STEMI cases. Dr. Warren commented that the trigger for having external review was a

problem with elective PCI cases. He suggested that all non-STEMI PCI cases be reviewed. Dr. Aversano commented that the same argument for not externally reviewing STEMI cases holds for other acute coronary syndrome cases; the issue is only whether cases were appropriately categorized. Dr. Seides commented that it is necessary to evaluate the non-STEMI PCI cases. Dr. Aversano commented that the list of questions for the external reviewer needs to include whether a patient was appropriately categorized as having acute coronary syndrome rather than stable angina. Ms. Fleck commented that there seemed to be consensus on the issue and moved to the next question regarding the data sources to be used for external review.

Ms. Fleck asked for feedback on the appropriateness of the list of proposed data sources. No one objected to the proposed list. Dr. Aversano suggested asking the guest speakers, Dr. Miller and Dr. Plantholt, about the data sources that they use. Dr. Miller responded that most of the data sources are used, but MACPAQ does not always get all of the laboratory studies, the cardiac catheterization laboratory log sheets, or the discharge summary sheet. The angiogram, cardiac catheterization lab report, and the pre-procedure history and exam are essential. Dr. Eig asked whether it was fairly easy to get most of this information. Dr. Miller confirmed that getting the information was not a problem. Ms. Fleck noted that Dr. Plantholt was no longer present at the meeting and moved on to the next question.

Ms. Fleck asked about the need for a deadline to complete external reviews and whether everyone should be on the same schedule or, as an alternative, one of two schedules. She added that it seemed reasonable to require that reviews be completed within some window of time and before the next review. Dr. Hearn stated that three months was reasonable, as well as having two schedules. Dr. Eig asked how often records are currently sent for review. Dr. Miller responded that records are submitted quarterly or sometimes every six months. She suggested that three months may be ambitious for the review of cases covering six months. Ms. Myers asked what list of cases would be used for random selection. She noted that the NCDR data registry information is not always entered in a timely manner. Ms. Fleck commented that information should come from a hospital's own records. Ms. Bruce commented that she had been through the external review process and recommended an annual process, but she was not sure what the regulations stated. Ms. Fleck noted that external review is required twice a year, for the prior six-month period. Ms. Bruce agreed that using a hospital's list of cases is best.

Mr. Steffen asked about the turnaround time required for case reviews. Ms. Bruce noted that it may take four to six weeks for staff to gather the appropriate information for submission of 10% of cases. Dr. Miller commented that three months is reasonable if hospitals submit data quarterly.

Dr. Thomas commented that he believed it would be ideal for a hospital's internal review system to have a chance to operate before the external review is completed. However, he commented that he is not certain about the timing of the internal review process for most hospitals. Ms. Fleck commented that the regulations indicate that peer review should be occurring, at a minimum, every other month. She added that external review should complement the hospital's internal review. Another member commented that he did not see an issue with delays because information should be captured quickly apart from the NCDR data registry. Dr.

Segal commented that external review for his hospital occurs on a quarterly basis. Ms. Fleck asked if anyone else wanted to comment on the necessity of having one or two schedules. Mr. Steffen agreed that it is necessary to have one or two schedules. Ms. Fleck moved on to the next question regarding the submission by hospitals of a report on their quality assurance activities, including internal and external peer review of cases.

Ms. Fleck explained that she felt it was important to cover the issue now as regulations are being developed. She suggested that one option would for MHCC to ask generally about the findings from the external review and what actions the hospital is taking in response to the external review, if any. She proposed that MHCC would not initially obtain a copy of the results of external review, and MHCC would only potentially seek out the results, if there appeared to be a concern that was not being addressed because it persisted over time. She noted that she felt that approach would strike the right balance between getting useful information from the external review without being overly intrusive. Ms. Fleck added that she hoped the information provided by Ms. Wideman provided assurance to hospitals about the confidentiality of information collected through the external review process.

Dr. Warren suggested that it would be useful to find out from the hospitals what they do with their internal review process and have a subgroup of the CSAC look at the information before setting down requirements.

Dr. Eig commented that he assumed that as part of the process of evaluating whether to issue a hospital a Certificate of Ongoing Performance, MHCC will request information about quality assurance activities. He added that he was not sure how frequently Certificates of Ongoing Performance would be issued or renewed. Ms. Fleck commented that the time period for renewals could change over time from one or two years to several years. He noted that the hospital's internal review process is for the benefit of hospitals and if the hospital is not improving, then MHCC should get involved. Ms. Fleck commented that she agreed with that approach. Mr. Steffen asked for other comments on the issue.

Dr. Hearn suggested perhaps submitting minutes from quality assurance meetings with redaction of information that could compromise patient privacy. He suggested that might be an easy way to do it. Dr. Thomas proposed that it would be better to have clinicians overseeing hospitals rather than the government and having the government getting involved in the oversight of cardiac catheterization labs could generate a lot of concern. Ms. Fleck commented that she understood his concern and believed that MHCC staff would need to consult with clinicians if there were concerns. She noted that she is assuming that MHCC staff can make a judgment about whether there is a concern and the hospital should be taking some action. Mr. Steffen commented that MHCC cannot abdicate its authority to a clinical body.

Ms. Fleck skipped over the eighth question on the discussion guide and moved on to the ninth question regarding whether documentation demonstrating that cases were randomly selected be required. A member asked Dr. Miller about random selection of cases by MACPAQ. She responded that from a list of cases, there is a random selection of cases. Mr. Steffen

commented that there should be some provision in the State Health Plan for assuring an adequate random selection process is developed for selection of cases.

Ms. Fleck moved on to the last discussion question regarding the review schedules for Certificates of Ongoing Performance for PCI services and cardiac surgery services. She explained that the proposed schedule was based on Staff's desire to have an audit of the STS data completed and regulations for external review of PCI cases in place first. She also noted that hospitals were grouped according to health planning regions, with consideration given to dividing the workload for MHCC staff. Ms. Fleck suggested members review the Proposed Schedule for Reviews of Certificates of Ongoing Performance that was developed and email her with any additional suggestions or concerns about the proposed schedule. She hopes to formulate draft regulations for informal feedback by the next meeting.

Dr. Eig asked about the implementation of external review and the timing required based on plans for reviews of Certificates of Ongoing Performance. Mr. Steffen responded that reviews should be undertaken as soon as possible. Ms. Fleck commented that having the first external reviews before developing regulations may be helpful in figuring out what needs to be addressed in regulations. Ms. Fleck thanked the members for their participation, and the meeting was adjourned at approximately 8:45 p.m.