**Invasive Cardiac Services Advisory Committee (ICSAC)**
**Percutaneous Coronary Intervention (PCI) Oversight Subgroup Meeting**
**February 6, 2014**
**3-5 p.m.**
**Minutes**

**Attendance**

**Subgroup Members:**
Cliff Berger, MD
Madeleine Biondolillo, MD
Aaron Kugelmass, MD
Anthony Marks, MD
Laura Mauri, MD
Frederic Resnic, MD
Kenneth Rosenfield, MD

**Department of Public Health (DPH) Staff:**
Nancy Murphy
Alexandra Rubin (for presentation on Conflict of Interest only)
Darrell Villaruz

**ICSAC Members:**
Anuj Goel
James Waters, MD

Madeleine Biondolillo began the meeting at 3:05 p.m. by welcoming everyone. After introductions, Dr. Biondolillo announced they would re-order the agenda and Alexandra Rubin, DPH Deputy General Counsel, presented the group with information about the state Conflict of Interest Law (MGL Chapter 268A). Attorney Rubin distributed two handouts:

1) A summary of the Conflict of Interest Law, including an acknowledgement of receipt, which each member of the subgroup and Dr. Waters, but not including Dr. Biondolillo, signed and returned to Nancy Murphy; and

2) Instructions regarding the Conflict of Interest Law Online Training Program, which each member of the group must complete.

Attorney Rubin also provided the members with her contact information as well as the contact information for the Attorney of the Day at the State Ethics Commission (617.371.9500) for questions about individual determinations of conflicts. She noted that there are penalties for violations of the law.

Attorney Rubin stated that because the members were appointed because of a specified affiliation they are subject to exceptions and may participate in general discussion of

policy. If, however, there is discussion of a particular matter regarding a member's hospital, the member must recuse him/herself. Recusal means no participation (no discussion, advice or questions) and the individual must leave the room. She continued that there is a form for "Disclosure of Appearance of Conflict of Interest" that may be filed with Dr. Biondolillo.

There were general comments of concern regarding the fact that these discussions and resulting recommendations could impact all of the members. Another concern is that each of the members not only represents a hospital or hospitals but also any affiliated hospitals. Dr. Biondolillo responded that it is the goal of this group to develop general principles.

There was some confusion about the prohibition of outside employment. Attorney Rubin commented that these are the broad guidelines and reminded the members that they are subject to the exception. Dr. Mauri asked what the exceptions are. Attorney Rubin suggested that the members generate questions for a group submission to the Ethics Commission. Members may forward these questions to Nancy Murphy.

The group then returned to the first agenda item: Approval of the December 10, 2013 Meeting Minutes. The Minutes were unanimously approved.

Dr. Biondolillo then presented the third item on the agenda, an Update on Mass-DAC 30-day PCI outcome reporting. She noted that the discussion at the Mass-DAC Hospital Outlier Committee in January had helped the Department revisit the 30-day reporting instructions that had been sent to hospitals in October. In summary, Mass-DAC will conduct analysis of 30-day patient status through linkages with other databases for the FY13 and FY14 PCI patients. Hospitals should continue to establish systems to collect the 30-day outcomes and will now submit the data beginning with FY15 patient data. This postpones the hospital 30-day data submission for one year.

Dr. Rosenfield noted that his hospital has been tracking patients and this is a huge task. He asked that it be clarified that beginning with 10/1/14 PCI patients, Mass-DAC will perform linkages for in-state patients. Hospitals will be required to track outcomes for only out-of-state PCI patients.

Dr. Resnic asked why not have Mass-DAC avail itself of the Center for Disease Control and Prevention's National Death Index which costs approximately $8,000 rather than have each hospital, which may be using that same system, request and pay for it? He noted that the issue has been raised that the data are not available in a timely manner, adding that 2012 data will be available in March 2014.

Anuj Goel noted that he is looking at the issue and the additional cost.

Dr. Mauri added that even in her work with clinical trials they still don't get the data.

Dr. Biondolillo then turned the discussion to agenda item 4, Guidelines for Non-Emergency Angioplasty ("Post MASS COMM"). She noted that Dr. Marks has drafted a framework that the group will build upon to form guidance for the ICSAC. Based on the guidance, the ICSAC will make a recommendation to DPH Commissioner Bartlett about what makes sense in terms of policy for non-emergency angioplasty going forward. Commissioner Bartlett will present this information to John Polanowicz, the Secretary of the Executive Office of Health and Human Services. She added that the main consideration on which a recommendation will be based is what the right thing is for patients. She then turned to Dr. Marks to walk the group through the draft document.

Dr. Marks brought printed copies of the May 2008 DPH Circular Letter DHCQ 08-05-486 regarding implementation of the statewide STEMI point-of-entry criteria, the cardiac catheterization services section of the DPH hospital licensure regulations, the Primary Angioplasty Special Project Guidelines (note: these copies do not include the *revised* section VII of the protocol), and excerpts from the MASS COMM Trial Protocol for the group.

Dr. Marks began by stating that the draft is a working document. It provides for consideration:

- the history of cardiac catheterization service regulation in Massachusetts;
- a description of the institutional and operator volume requirements in national guidelines and the DPH regulations; and
- information regarding the decrease in the volume of PCI procedures nationally as well as in Massachusetts.

Dr. Marks provided the many factors that should be considered in the development of policy regarding PCI. These include, but are not limited to:

- geography
- patient access to care
- systems of care
- volume criteria, including consideration of the implications for existing institutions of expanding the number of services providing PCI
- support for primary angioplasty programs
- ongoing monitoring of performance, case selection and outcomes to ensure safety and quality

The draft outlines an eleven point proposal for development.

Dr. Kugelmass brought up the issue of establishing regulations and enforcing them, stating that existing volume criteria are not enforced, e.g., for low volume diagnostic laboratories. He noted that there are huge fixed costs for a cardiac catheterization service. There was a brief discussion of low volume labs, with Dr. Biondolillo noting that there is no appetite for eliminating services now, but the Department is looking for the group's guidance on what represents good patient care.

Dr. Rosenfield noted that volume is a factor, but not the only factor. Oversight is important. Dr. Biondolillo added that 'cross-fertilization' of institutions is also critical.

Dr. Marks commented that there is what the regulations say and what hospitals actually do. With that in mind, he added that you can put specific requirements in place, but if the Department is not enforcing them, what do you tell additional hospitals that want to perform PCIs. There was a brief discussion of how easy it is to 'spin' numbers to project volume that would meet a minimum of 200 PCIs. Dr. Rosenfield noted that the Department does not want to encourage unnecessary procedures. Dr. Resnic added that the assumption is that DPH will enforce whatever regulations are recommended.

Dr. Biondolillo added that when the Department writes a regulation it also has the opportunity to create a waiver provision. Dr. Resnic responded that the proposal should include ways of advising waivers. Dr. Biondolillo stated that the Department may wish to raise the bar but not drive good providers out.

Dr. Mauri supported comments on the need for evenhandedness with respect to those providing the procedure and those seeking to add it.

Regarding the regulations, Dr.Biondolillo added that DPH would like to broaden them and use guidance to fill them out. The Department will pay attention to the new ACC Guidelines, but needs a consensus from the subgroup to bring to the ICSAC, which could include that the regulations need updating and these principles should apply. Dr. Marks added that it is important to remember that MASS COMM was highly regulated.

The group then reviewed the elements of the draft proposal.

#1: regarding former MASS COMM non-surgery-on-site (non-SOS) hospitals - is already done.
#2: regarding primary angioplasty - no specific comment.
#3: regarding elective PCI procedures – Dr. Berger asked where the 600 catheterization procedures came from. There was a discussion of the current regulations and the volume numbers being out of date. The group asked for:

- the median volume of former MASS COMM non-SOS hospitals; and
- de-identified hospital diagnostic and PCI volume.

Dr. Biondolillo commented that Commissioner Bartlett feels the regulations need to be updated. Dr. Rosenfield commented that 75 PCI volume minimum in the American College of Cardiology Guidelines has now been reduced to 50 (averaged over two years) because most operators were not meeting the 75. He commented that in California the average volume is 30 PCIs per operator. How will Massachusetts prevent opening the floodgates?

#4: regarding collaboration agreement with tertiary facility – no specific comment.

#5: regarding Joint QA conferences at least every six months – it was recommended that this item be amended to require regular participation in the peer review and oversight process.

#6: regarding credentialing of Interventional Cardiologists at a SOS hospital. There was a discussion of what this requirement was trying to address. There was agreement that the physicians should be equally qualified and that the operators at a non-SOS site need to be linked to the SOS site, but that that did not necessarily mean having privileges. This item was tabled for further consideration.

#7: regarding Board Certification in Interventional Cardiology – Dr. Resnic commented that this requirement is not enforced.

#8: regarding PCI minimum operator volume – Dr. Marks commented that experienced operators should get some kind of volume credit for scrubbing in. What that credit should be is to be determined.

#9: regarding PCI program participation in the Mass-DAC adjudication process - the group agreed that the principle is correct. Each hospital must send a representative.

#10: regarding peer review process – to be discussed at next meeting.

#11: regarding the inclusion/exclusion criteria for non-emergency PCI at the non-SOS hospitals – it was noted that there has been discussion about whether the criteria were too liberal, e.g., allowing patients with renal failure and procedures on lesions located in vein grafts. It was agreed that the group should consider the coming Guidelines, but be mindful of the concern about specificity in regulations.

Dr. Biondolillo thanked Dr. Marks for drafting the document. There will be another subcommittee meeting in March and a full ICSAC meeting in April.

The meeting adjourned at 5:02 p.m.