

Invasive Cardiac Services Advisory Committee (ICSAC)

October 21, 2015

3:00-5:00 p.m.

Minutes

Members Present:

Suzanne Cray, DPH, Chairperson

Clifford Berger, MD

Julie Bonenfant, RN

Daniel Fisher, MD

Jean-Pierre Geagea, MD

Alice Jacobs, MD

Aaron Kugelmass, MD

Anthony Marks, MD

Sharon-Lise Normand, PhD

Frederic Resnic, MD

Kenneth Rosenfield, MD

Members Absent:

Daniel Engelman, MD

Anuj Goel

Laura Mauri, MD

Sharon McKenna, RN

Karen Nelson

James Waters, MD

Department of Public Health (DPH) Staff Present:

Lauren Nelson, Director of the Office of Policy and Quality Improvement, Bureau of Health Care Safety and Quality

Rebecca Rodman, Office of General Counsel

1. ROUTINE ITEMS

Suzanne Cray, Chairperson, began the meeting at 3:15 p.m., when a quorum was in attendance. Ms. Cray, Director of the Office of Health Care Integration, introduced herself and Lauren Nelson, Director of Policy and Quality Improvement. Ms. Cray and Ms. Nelson represented Eric Sheehan, Interim Bureau Director of the Bureau of Health Care Safety and Quality. Mr. Sheehan had an unavoidable conflict and had to miss the meeting.

Ms. Cray thanked the members for attending the meeting. She explained that as regulation states, the ICSAC is responsible for advising the Department on issues related to invasive diagnostic and therapeutic cardiac services licensed by the Department.

Ms. Cray noted that the focus of the meeting was to discuss your feedback on the Department's regulation of cardiac services so that the Department can continue its review in line with the Governor's Executive Order 562.

Before discussing the regulation, Ms. Cray stated that the Department underwent a significant review of cardiac catheterization and did a presentation on the findings from this review at the Public Health Council meeting in May. This review demonstrated that the Department's regulations needed to be more comprehensively reviewed to identify areas in which updates needed to be made, especially to adjust to changes in medicine.

Dr. Marks asked what the difference is between regulation and circular letters. Ms. Nelson responded stating that circular letters may be impacted by change in regulation. If the regulation is changed, the circular letter may need to be updated. There was also discussion on the regulation process.

2. REGULATORY REVIEW

Ms. Cray transitioned to the next agenda item. She explained that Governor Baker signed Executive Order 562, which instructs all state agencies to do a comprehensive review of all of its state regulations to ensure that:

- There is a clearly identified need for each regulation;
- The costs of each regulation do not exceed the benefit;
- Each regulation does not exceed federal requirements or duplicate local requirements; and
- That less restrictive and intrusive alternatives have been considered and found less desirable than each regulation based on a sound evaluation.

Ms. Cray started the discussion by hearing any feedback on the provisions in these sections of the regulation. Instead of going section by section in the regulation, she proposed that the conversation focus on certain topics that are covered in the regulations.

The discussion began with feedback on "licensure." General feedback included:

- Dr. Resnic noted that removing the requirement for cardiac surgery to be on site for a hospital to be licensed to do PCI and other procedures may be problematic. It may be possible to create separate licensure categories:
 - A hospital with cardiac surgery;
 - A hospital that is qualified to do PCI but does not have cardiac surgery on site;
 - A hospital that is qualified to do only primary PCI; or
 - A hospital that can only do diagnostic catheterizations.
- Dr. Rosenfield stated that the regulation may be written in the positive or negative. We need provisions for hospitals with cardiac surgery and for those that are qualified without cardiac surgery.

- Dr. Resnic asked if the regulation needs to be updated based on the changes in the July 2014 circular letter pertaining to ACOs?
 - This would be under discussion based on other changes that may be adopted to the regulation.
- Dr. Kugelmass noted that when considering what to put in the regulations, we should think about if it will be burdensome in 10 years. Is it less burdensome to keep as is and do more circular letters?
- Dr. Rosenfield stated that we need to build a living, breathing document and build regulation around guidelines that are promoted by national standards.
- Many ICSAC members voiced support of developing guidelines that are based on national standards. If there are no guidelines, then that should be referenced. There was comment to note in the regulation that certain provisions will be “defined by circular letter or separate guidance.” Also suggestion to use “at minimum” when referring to compliance with national standards such as “minimum of compliance with the ACC/AHA standard.”
- There was also acknowledgment that there are areas where the national guidelines may conflict with regulation.
- Dr. Geagea suggested that the regulation could replicate the existing 130.920 to be a similar licensure process for PCI. Could add the standards discussed in the circular letter to this process.
- There was general consensus to create a licensure process for the community hospitals currently allowed to conduct PCI under existing special projects and waivers. There was also consensus to keep the current exclusions related to conducting procedures in place, perhaps in guidance.
- Dr. Fisher asked if licenses are just issued one-time or would the renewal process offer an opportunity to re-examine some issues? It was clarified that the license is reviewed during the hospital surveying process.
- Ms. Cray asked the members about how to address the hospitals engaged in the special project that want to perform non-emergency PCI.
- Dr. Jacobs advised for us to look at the NY process. Need to consider access and make a determination.
- There was general discussion about setting up a process to think about the patient experience and utilize the guidelines to set restrictions and protocols.
- There was discussion about how to set up in the regulations the ability for a hospital to perform non-emergency PCI after performing emergency PCI. There was support for specifying that process in the guidance and leaving the licensure category in the regulation. There was acknowledgment that having most of the guidance separate from the regulation may impact transparency. The guidance would need to be referred to in the regulation.
- Ms. Bonenfant stated that the ability to change a licensure status needs to be based on the principles of the guidelines and national standards.

Ms. Cray asked the members for their feedback on “volume minimums.” General feedback included:

- There was general consensus to keep volume minimums in the regulation. They should be based on national guidelines. There are national guidelines for PCI but not diagnostic catheterization. The national guidelines also reference geographic/access considerations.
- Dr. Resnic also stated that he was in favor of keeping board certifications noted on page 5 but could include exceptions for illness or other leaves.

Ms. Cray asked the members for their feedback on “quality measures.” General feedback included:

- Dr. Rosenfield stated that the regulations need to reference monitoring quality but the details should be in guidance. The monitoring should also include peer review.
- Dr. Resnic suggested that we should consider retaining 130 CMR 965 but need real enforcement and external review.

Ms. Cray asked the members for their feedback on “enforcement.” General feedback included:

- Dr. Marks stated that having a volume minimum doesn’t require the Department to enforce it. He would suggest that volume minimums be consistent with national standards.
- Dr. Resnic suggested that everything in the regulation and guidelines should be enforced. It may put the license at risk. The Department should consider developing a system of enforcement with different levels.

Ms. Cray offered her thanks on behalf of the Commissioner of DPH. She added that there will likely be another ICSAC meeting in 2016.

The meeting adjourned at 5:07 p.m.