DRAFT REGULATIONS FOR ASSURING THE QUALITY OF CARDIAC SURGERY AND PCI SERVICES

Senate Finance Committee Hearing

January 14, 2014

Key Terms

Cardiac Surgery means surgery on the heart or major blood vessels of the heart, including both open and closed heart surgery, identified by specified International Classification of Disease (ICD) procedure codes

Percutaneous Coronary Intervention (PCI) means a procedure whereby a catheter is inserted in a blood vessel and guided to the site of the narrowing of a coronary artery to relieve coronary narrowing, identified by specified ICD procedure codes

Primary or Emergency PCI is a PCI capable of relieving coronary vessel narrowing associated with ST Elevation Myocardial Infarction (STEMI) or, as defined by the Commission in Regulations, STEMI equivalent.

Elective PCI[1] (also known as "non-primary PCI") includes PCI provided to a patient who is not suffering from an acute coronary syndrome, but whose condition is appropriately treated with PCI based on regulations established by the Commission.

Clinical Advisory Group (CAG) means an expert panel used by MHCC in 2012-2013 to advise on standards for cardiac surgery and PCI

[1] This definition will be further revised based on recent comments.

Key Terms

Certificate of Conformance – Approval required from MHCC by a hospital to establish a new PCI program. Except under limited circumstances, this certification must initially be one to establish primary PCI services. Thus, only hospitals successful in providing primary PCI are eligible to receive a Certificate of Conformance to establish elective PCI services.

Certificate of Ongoing Performance – Periodic approval required from MHCC by a hospital to continue providing cardiac surgery or PCI services.

Focused Review means an investigation of limited scope that is undertaken directly by
Commission staff and or other persons, such as auditors with clinical expertise, to determine whether a cardiac surgery or PCI program is complying with the standards included in these regulations as well as with the expectation that a hospital shall provide high quality patient care and accurately report data collected for evaluating the quality of care provided.

Health Planning Regions (HPRs) – Eastern Region: Dorchester, Somerset, Wicomico, and Worcester Counties
Western Region: Allegany, Garrett, and Washington Counties.
Baltimore/Upper Shore: Anne Arundel, Baltimore, Caroline, Carroll, Cecil, Harford, Howard, Kent, Queen Anne's, and Talbot Counties, and Baltimore City.
Metropolitan Washington: Calvert, Charles, Frederick, Montgomery, Prince George's, and St. Mary's Counties, and the District of Columbia.

Legislative Background

- Research results showing that elective PCI services at hospitals without on-site cardiac surgery could be delivered safely and effectively prompted the Maryland legislature to pass a law directing the Commission to adopt new regulations for the oversight of PCI services at hospitals without on-site cardiac surgery.

- The law directs the Commission to establish a clinical advisory group (CAG) to advise the Commission on developing standards for cardiac surgery, emergency PCI services, and elective PCI services.

- The law also specifies that Certificate of Ongoing Performance review be established as the mechanism for an existing hospital providing specialized cardiovascular services to obtain approval for continuing these services and a Certificate of Conformance review be established as the mechanism for an acute general hospital to add emergency or elective PCI services without obtaining a certificate of need.

CAG's Scope of Work

- Identify key requirements for the establishment of cardiac surgery and/or PCI services, as well as an evaluation of the ongoing performance based on research and key guidelines.
- Determine which factors the Commission should use in considering the establishment of cardiac surgery and/or PCI services and ongoing review of existing programs.
- Determine points in the regulatory process where institutional accountability can inform the Commission in decision-making.
- Evaluate appropriate data sources to support program monitoring.
- Identify key considerations for accepting applications to create a cardiac surgery service, or initiate primary PCI or non-primary PCI services at a hospital without cardiac surgery on-site.
- Suggest appropriate duration for certificates.

CAG's Recommendations Guided Draft Regulations

- The final report of the CAG was issued in June 2013.
- Staff used the recommendations of the CAG to draft regulations that were posted for public comment in September 2013.
- Staff revised the draft regulations further, based on the public comments received. The revised regulations were sent to the Senate Finance Committee and the House Health and Government Operations Committee in November 2013.

Regulatory Process will Implement Ongoing Oversight of Cardiac Services

- There should be a focus on monitoring programs through data collection that allows for longer than a two year interval between renewals of Certificates of Ongoing Performance.

- Focused reviews of programs should be conducted based on triggers, such as data reported to MHCC that raise concerns about the quality of patient care or accuracy of reporting.

- Review teams – external peer (PCI only) and focused review composed of clinical experts independent of programs under review.

Regulatory Process will Implement Ongoing Oversight (continued)

- Hospitals must participate in uniform data collection and reporting.
  - For cardiac surgery, the data registry of the Society of Thoracic Surgeons (STS) should be used.
  - For PCI programs, the data registry of the National Cardiovascular Data Registry of the American College of Cardiology should be used.
- Program closures are driven by volume or quality failures identified through focused reviews.
  - Programs have an opportunity to develop corrective action plans.
  - Hospitals required to voluntarily relinquish, if its corrective action plan fails.

Overview of Comments
Cardiac Surgery

- Effective Date
  - Two comments requested that MHCC clarify standards are prospective, and data collection will be required only going forward.
  - One comment proposed that the standards should apply to pending Certificate of Need (CON) reviews.

- Staff Response
  - Pending projects should not be subject to the new regulations.
  - MHCC has the authority to collect data on outcomes for cardiac surgery, prior to the implementation of new cardiac regulations.
  - All Maryland hospitals have already been participating in the data collection necessary to implement the draft regulations.

Overview of Comments
Cardiac Surgery

- Health Planning Regions (HPRs)
  - Several comments requested additional explanation of the proposed region or requested a change.
  - Proposed changes included adding a fifth HPR, maintaining the current regions, and assigning Frederick County to the Western region rather than the Metropolitan Washington region.

- Staff Response
  - New HPRs more closely reflect the actual utilization patterns by Maryland residents.
  - HPRs are primarily only relevant with regard to consideration of new programs. The service area of a hospital is used to evaluate the need for services and impact.

Overview of Comments
Cardiac Surgery

- Access
  - A few comments suggested that access to cardiac surgery should be discussed in greater depth in the regulations.
- Staff Response
  - Staff reviewed the utilization rates for cardiac surgery by age groups for Baltimore City and all counties in Maryland.
  - Historically, a drive-time standard of two hours has been used to evaluate access. Under this standard, it has previously been noted that virtually all Maryland residents have access to adult cardiac surgery services.

Overview of Comments
Cardiac Surgery

- Docketing Rules
  - Several comments expressed concern that an extended moratorium would result from the approval policies for a new program.

- Staff Response
  - Rather than stating the rate setting system must be adequately stable, Staff revised the language to state that a hospital needs to have a budget agreement with the Health Services Cost Review Commission, under the new payment model.
  - Staff also deleted the requirement that a full year of reporting on quality measures be available.

Overview of Comments
Cardiac Surgery

- Relocation of Programs
  - One comment stated that a discriminatory standard is being applied for cardiac surgery programs seeking to relocate.
  - Another comment suggested that the requirements may be redundant and unnecessary.

- Staff Response
  - The application of standards and criteria for the CON review process of cardiac surgery is similar to the current approach for other services subject to CON review.
  - Staff concluded that the requirements are necessary.

Overview of Comments
Cardiac Surgery

- Need Analysis
  - Several comments noted that a requirement to demonstrate a minimum of 250 cases by the end of the second year of operation was not consistent with the recommendation of the CAG.

- Staff Response
  - Staff changed the minimum requirement to 200 cases, to be consistent with the CAG's recommendation.

Overview of Comments
Cardiac Surgery

- Impact
  - One comment stated that the standard is too burdensome.
  - Other comments were critical of the idea that the impact on providers outside of Maryland would be considered.

- Staff Response
  - Staff eliminated the language cited as particularly burdensome and added language to promote greater consideration of impact on high quality programs.
  - Staff concluded that it is necessary and appropriate to consider the impact on providers outside of Maryland where Maryland residents receive services.

Overview of Comments
Cardiac Surgery

- Quality Measures
  - Several comments were received objecting to the specific internal and external peer review requirements. It was noted that the CAG did not endorse these requirement for cardiac surgery services.

- Staff Response
  - Staff deleted the specific requirements related to internal and external peer review and included general language regarding reporting on quality assurance activities.

Overview of Comments
Cardiac Surgery

- Program Closure
  - One comment expressed concern about allowing a program with a one-star rating to continue for two years before instituting a formal review process.
  - Some comments questioned the authority of the Commission to require a program to voluntarily relinquish its program.

- Staff Response
  - Staff added language to state that a program with two consecutive one star ratings will be subject to a focused review.
  - Staff concluded that it is necessary and fair to require a cardiac surgery program to voluntarily relinquish its program when it fails to meet performance standards. The two cardiac surgery programs that were recently established must meet certain conditions or voluntarily relinquish their programs.

Overview of Comments
PCI Services

- Commission Program Policies
  - One comment disagreed with the emphasis on looking at whether primary PCI services are needed, in deciding whether the addition of elective PCI services should be allowed.

- Staff Response
  - Staff did not make changes in response to this comment because Staff concluded that the need for emergency PCI services must be a primary consideration.

Overview of Comments
PCI Services

- Financial Viability
  - Some comments objected to the language that allows the Commission to waive the volume requirement in .06B(2), if the applicant demonstrates that adding an elective PCI program will permit the hospital's overall PCI services to achieve financial viability.

- Staff Response
  - Staff did not make changes in response to this comment because other language included in the draft regulations assures that only a hospital that provides needed access to emergency PCI services can add elective PCI services without meeting volume criteria.

Overview of Comments
PCI Services

- Preference for Existing Primary PCI Programs
  - One comment stated that favorable consideration had not been given to existing programs with emergency (primary) PCI services.

- Staff Response
  - Staff added language stating that a hospital with an existing primary PCI program that proposes to add elective PCI services will be given preference over another hospital without PCI services, when the two hospitals have an overlapping service area.

Overview of Comments
PCI Services

- PCI Program Closure
  - Comments requested clarification on how enforcement of standards would be handled.
  - One comment requested that the right to appeal should be the same for CON and new PCI programs.

- Staff Response
  - Staff clarified how the enforcement of standards will be handled.
  - The statue requires that a hospital that fails to meet standards for a Certificate of Conformance or a Certificate of Ongoing Performance agree to voluntarily relinquish its authority to provide PCI services.

Next Steps

- Staff will continue to revise the draft regulations based on feedback from the Senate Finance Committee and House Health and Government Operations Committee.

- Staff will recommend that the Commission adopt proposed regulations for cardiac surgery and PCI services at the first available opportunity, following completion of revisions.

- Once proposed regulations are published in the *Maryland Register,* there will be a formal 30 day period for public comments. Staff will review these comments and present a response to these comments at a monthly Commission meeting, along with a request to adopt final regulations, if no major changes are needed.

Timeline Following the Effective Date of Final Regulations

- A review schedule for new cardiac surgery programs will be published for health planning regions where at least one hospital without cardiac surgery services has a budget agreement with HSCRC under the new payment model.
- A review schedule for Certificates of Conformance will be published for existing primary PCI programs seeking to add elective PCI services.
- A review schedule for Certificates of Conformance to establish new PCI programs may be established after existing primary PCI programs have had an opportunity for review of the proposed addition of elective PCI services or such reviews may be unscheduled.
- Certificates of Ongoing Performance for existing cardiac surgery and PCI programs will be scheduled when such programs are beyond initial development or relocation stages, sufficient performance information is available for consideration, and as current PCI waivers expire.