

MARYLAND REGISTER

Proposed Action on Regulations

Transmittal Sheet PROPOSED OR REPROPOSED Actions on Regulations	Date Filed with AELR Committee	TO BE COMPLETED BY DSD
	04/18/2014	Date Filed with Division of State Documents
		Document Number
		Date of Publication in MD Register

1. Desired date of publication in Maryland Register: 5/30/2014

2. COMAR Codification

Title Subtitle Chapter Regulation

10 24 17 01

3. Name of Promulgating Authority

Maryland Health Care Commission

4. Name of Regulations Coordinator

Amelia T Rutledge

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(410) 764-3322

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4160 Patterson Avenue

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Baltimore MD 21215

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5. Name of Person to Call About this Document

Suellen Wideman

Telephone No.

(410)764-3326

Email Address

suellen.wideman@maryland.gov

6. Check applicable items:

X- New Regulations

Amendments to Existing Regulations
Date when existing text was downloaded from COMAR online: .
 Repeal of Existing Regulations
 Recodification
 Incorporation by Reference of Documents Requiring DSD Approval
 Reproposal of Substantively Different Text:
: Md. R
(vol.) (issue) (page nos) (date)
Under Maryland Register docket no.: --P.

7. Is there emergency text which is identical to this proposal:

Yes No

8. Incorporation by Reference

Check if applicable: Incorporation by Reference (IBR) approval form(s) attached and 18 copies of documents proposed for incorporation submitted to DSD. (Submit 18 paper copies of IBR document to DSD and one copy to AELR.)

9. Public Body - Open Meeting

OPTIONAL - If promulgating authority is a public body, check to include a sentence in the Notice of Proposed Action that proposed action was considered at an open meeting held pursuant to State Government Article, §10-506(c), Annotated Code of Maryland.

OPTIONAL - If promulgating authority is a public body, check to include a paragraph that final action will be considered at an open meeting.

10. Children's Environmental Health and Protection

Check if the system should send a copy of the proposal to the Children's Environmental Health and Protection Advisory Council.

11. Certificate of Authorized Officer

I certify that the attached document is in compliance with the Administrative Procedure Act. I also certify that the attached text has been approved for legality by Suellen Wideman, Assistant Attorney General, (telephone #(410) 764-3326) on April 17, 2014. A written copy of the approval is on file at this agency.

Name of Authorized Officer

Craig P. Tanio, M.D.

Title

Chairman

Telephone No.

(410) 764-3460

Date

April 17, 2014

Title 10

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 24 MARYLAND HEALTH CARE COMMISSION

10.24.17 State Health Plan for Facilities and Services: Specialized Health Care Services — Cardiac Surgery and Percutaneous Coronary Intervention Services

Authority: Health-General Article, §§19-109(a)(1) and 19-118, Annotated Code of Maryland

Notice of Proposed Action

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The Maryland Health Care Commission proposes to repeal and replace Regulation .01 under COMAR 10.24.17 State Health Plan for Facilities and Services: Specialized Health Care Services – Cardiac Surgery and Percutaneous Coronary Intervention Services.

This action was considered by the Commission at an open meeting on April 17, 2014, notice of which was given through publication in the Maryland Register, pursuant to State Government Article, §10-506, Annotated Code of Maryland.

Statement of Purpose

The purpose of this action is to implement Health General Article §19-120.1, which directed the MHCC to update the chapter of the State Health Plan for Facilities and Services that addresses quality, access, and cost for cardiac surgery and emergency and elective percutaneous coronary intervention (PCI) services. The regulations establish a process and set minimum standards and requirements that a hospital must satisfy in order for the MHCC to award a certificate of conformance authorizing a hospital to provide emergency PCI services or to provide elective PCI services. The regulations also establish a process and set minimum standards and requirements that a hospital must satisfy in order for the MHCC to award a certificate of ongoing performance authorizing a hospital to continue to provide cardiac surgery services, to continue to provide emergency PCI services, or to continue to provide elective PCI services. In addition, the regulations establish standards the Commission to award a certificate of need to establish or relocate cardiac surgery services.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

I. Summary of Economic Impact.

MHCC and the 23 general acute care hospitals providing emergency PCI services, emergency and elective PCI services, or cardiac surgery and emergency and elective PCI services will have higher expenditures as a result of the proposed regulations. Hospital expenditures are expected to be higher due to the requirement for external peer review of at least five percent of PCI cases on, at minimum, a semi-annual basis and the potential

expense associated with participation in a focused review triggered by concerns about the quality of services provided by the hospital. Ten of the 23 hospitals (those that provide both cardiac surgery and PCI) will incur the expenses associated with on-going performance review of these services. For the remaining 13 non-cardiac surgery hospitals that provide only emergency PCI services or emergency and elective PCI services, ongoing performance review will replace the Commission’s established “waiver renewal” review process in which these hospitals participate. Consequently, the expenses incurred by these hospitals related to routine compliance (i.e., not including peer review) with standards for PCI programs will likely not change from those that arise from current regulatory oversight.

MHCC will have higher expenditures due to the requirements of routine auditing of hospitals with both cardiac surgery and PCI services. In addition, there will likely be a cost to obtain certain data analyses from the Society of Thoracic Surgeons or from vendors. Additionally, MHCC will incur expenses necessary to conduct independent focused reviews triggered by non-compliance issues related to specific standards in the regulations. The expenditures by MHCC and hospitals for external review will mean additional revenue for providers of external review services.

Additional data collection requirements will likely be minimal and primarily related to a focused review or renewal of a Certificate of Ongoing Performance. Hospitals previously operating under waivers to provide emergency or emergency and elective PCI services will not likely have to spend any additional time under this replacement oversight. All hospitals currently participate in the data collection required for PCI services, and all hospitals also have a history of participating in the data collection required for cardiac surgery services. The same data will be submitted to Commission staff so that hospitals will not face duplicate data collection.

No impact on other State agencies is expected to result from these regulations. Other agencies involved in regulating hospitals generally or the emergency services that they provide, such as the Office of Health Care Quality of the Department of Health and Mental Hygiene and the Maryland Institute for Emergency Medical Services Systems, are not expected to take on additional responsibilities or workload as a result of the proposed regulations. No impact is expected for local governments. Local governments are not involved in the direct regulation of cardiac surgery services or PCI services. Small businesses will not be directly impacted by the regulation. Potentially, if some of the providers of external case review services are small businesses that are hired by hospitals, there could be a benefit. However, hospitals have several options for external review of cases.

II. Types of Economic Impact.	Revenue (R+/R-)	
	Expenditure (E+/E-)	Magnitude
A. On issuing agency:	(E+)	Within Budget
B. On other State agencies:	NONE	
C. On local governments:	NONE	

	Benefit (+) Cost (-)	Magnitude
D. On regulated industries or trade groups:		
(1) Hospitals with Cardiac Surgery	(-)	Minimal
(2) Hospitals with PCI Services Only	(-)	Minimal
E. On other industries or trade groups:		
Providers of external case review services	(+)	Minimal
F. Direct and indirect effects on public:	NONE	

III. Assumptions. (Identified by Impact Letter and Number from Section II.)

A. A. The Commission expects to audit data annually for two to three hospitals that provide cardiac surgery services, equivalent to approximately ten percent of the statewide cardiac surgery case volume. The Society for Thoracic Surgeons, which established the database that will be used by Maryland hospitals for reporting patient information and evaluating quality, reported that auditing of a hospital's STS data, on average, charges \$3,000 for a review of 20 cases and many, but not all, data elements are audited. However, Staff anticipates that the audits it requests will be of greater depth and will likely be more expensive, approximately \$300 per case, for a total cost of \$120,000 to audit 400 cases.

The Commission currently expects to audit data annually for approximately five percent of the case volume reported to the ACC-NCDR registry, a total of 400 cases. Staff estimates that the cost of auditing these cases and providing some additional data analyses will be approximately \$120,000.

For the focused reviews, based on the experience of New York, Maryland could expect two focused reviews of cardiac surgery programs each year in the first three years, and one review or fewer per year in future years. New York is able to rely on volunteers for its focused reviews and covers only travel costs, which may be approximately \$4,000 total for four people (cardiac surgeon, cardiac nurse, interventional cardiologist, and cardiac catheterization nurse/administrator). It may be possible to offer an additional stipend to volunteers, such as \$1,500 for physicians and \$500 for nurses, which would result in cost of \$8,000 per focused review. However, if a professional organization is hired, the cost would likely be around \$30,000-\$40,000. Staff believes the estimated financial impact should be based on the conservative assumption that, at least initially, a professional organization will be used rather than volunteers. Based on the assumption that there will be two focused reviews of cardiac surgery programs and two focused reviews of PCI programs per year, Staff estimates a cost of \$120,000- \$160,000 for MHCC. With regard to the cost for hospitals that are subject to a focused review, information provided based on the experience of New York suggests a cost of \$4,000 for each site or \$16,000 total if four focused reviews are conducted at Maryland hospitals. Potentially, the cost could be absorbed by a redistribution of responsibilities among staff, even on just a temporary basis. However, Staff has included this expense in the

total estimated costs for hospitals.

With regard to the additional staff hours required, it is estimated that an additional 600-700 hours of staff time will be required, at a cost of approximately \$35,000- \$40,000. This estimate is based on an assumption that an additional 30-35 hours annually of staff time will be required for each program not previously subject to ongoing review, such as the existing ten cardiac surgery programs and the ten emergency and elective PCI programs at hospitals with cardiac surgery. The additional cost estimate also accounts for longer average periodic review schedules for ongoing performance than have been used in waiver renewals. Compared to the standard two-year cycle that has been used in waiver authorizations, there may be as many as five years between reviews. It is likely that this additional expense will not be met through hiring more full-time equivalent employees, but rather through delaying work according to priority level.

In terms of analyzing the data provided by cardiac surgery hospitals and calculating the statewide risk-adjusted mortality rate that will be used as a benchmark, Staff may need to rely on STS to provide the calculation. The cost of this service is estimated to be approximately \$2,400 on an annual basis.

D(1). Hospitals with cardiac surgery will be faced with new requirements for both cardiac and PCI services. Staff estimates that a minimum additional two or three hours a week may be required for the staff of a hospital's cardiac or PCI program to handle these new requirements. Staff estimates the cost for a PCI or cardiac surgery program would be \$5,000- \$7,500 per year. Each hospital with a cardiac surgery program also has emergency and elective PCI services, so the per hospital cost is \$10,000 -\$15,000 per year. Assuming there continue to be 10 hospitals with cardiac surgery programs, the total cost is estimated to be \$100,000 to \$150,000.

Hospitals with only emergency PCI services or with emergency and elective PCI services will be required to perform, at minimum, a semi-annual review of at least five percent of PCI cases performed within the preceding six months. Statewide, the volume of PCI services was approximately 9,000 cases in 2012; five percent would be 450 cases. Based on an assumed cost per case of \$150 to \$300, the total cost for all hospitals would be \$67,500 to \$135,000. The total cost for hospitals with only emergency PCI services or with emergency and elective PCI is estimated to be only 30 percent of the total for all hospitals because 70 percent of PCI cases are performed in hospitals with both cardiac surgery and PCI services. The cost per case is based on costs estimates obtained from one Maryland hospital, the Accreditation Agency for Cardiovascular Excellence (ACE), and the Maryland Academic Consortium for Percutaneous Coronary Intervention Appropriateness and Quality (MACPAQ). To some extent the cost of reviews will depend on the depth of the review and amount of material collected; this point was emphasized by both ACE and MACPAQ. There also could be opportunities to lower the cost through all hospitals in the State using the same external reviewer for all cases

D(2). Hospitals without cardiac surgery services that provide both elective and primary PCI services (a total of 13 hospitals) will have some reduction in staff hours, due to

eliminating the requirements of the C-PORT E study which are being maintained until new regulations are implemented. Staff obtained an estimate from one hospital that suggests about \$5,000 could be saved each month by the hospital, through eliminating the extra time required for patient consent, data collection, and reporting on adverse events. The additional number of hours per month is 102.5 and the assumed cost for staff time is \$40 per hour and an additional twenty percent for benefits. Assuming that the other 12 sites have a similar case volume and staff costs, potentially \$65,000 would be saved each month. However, Staff believes that only accounting for these potential cost savings is not appropriate because it would be based on assumptions about delayed effective regulations. It could also be viewed as costs that have already been incurred that could have been avoided if new regulations had been adopted already.

E. The money spent by hospitals on the external review of PCI cases will be a benefit for providers of external review services. This amount could range from \$67,500 to \$135,000 dollars. Staff expects that some hospitals will participate in MACPAQ in order to meet the external case review requirement. MACPAQ is an organization that already provides external peer review for two academic hospitals in Maryland. It appears that this option would likely be less expensive for a hospital as compared with contracting with another organization that provides external peer review services, based on information provided by one hospital that obtained two cost estimates, one of which was from MACPAQ, and information provided by MACPAQ directly. The money spent by the Commission hiring auditors for focused review would also be a benefit for providers of external review services; this amount was estimated to be \$120,000 to \$160,000 annually.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Paul Parker, Director, Center for Health Care Facilities Planning & Development, Maryland Health Care Commission, 4160 Patterson Avenue, Baltimore, Maryland 21215, or call (410) 764-3261, or email to , or fax to (410) 358-1236. Comments will be accepted through 4:40 P.M. on June 30, 2014. A public hearing has not been scheduled.

Open Meeting

Final action on the proposal will be considered by the Commission during a public meeting to be held on July 17, 2014 at 1:00 P.M., at 4160 Patterson Ave, Conference Room 100, Baltimore, Maryland 21215.

Economic Impact Statement Part C

A. Fiscal Year in which regulations will become effective: FY 2015

B. Does the budget for the fiscal year in which regulations become effective contain funds to implement the regulations?

Yes

C. If 'yes', state whether general, special (exact name), or federal funds will be used:

Maryland Health Care Commission
Special Funds

D. If 'no', identify the source(s) of funds necessary for implementation of these regulations:

E. If these regulations have no economic impact under Part A, indicate reason briefly:

F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason and attach small business worksheet.

G. Small Business Worksheet:

Attached Document:

Incorporation by Reference
APPROVAL FORM

Date: April 3, 2014
COMAR: 10.24.17.01

Amelia T. Rutledge
Administrator
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215-2299

Dear Amelia:

The document entitled "State Health Plan for Facilities and Services: Specialized Health Care Services — Cardiac Surgery and Percutaneous Coronary Intervention Services " is approved for incorporation by reference.

Please note the following special instructions: None

Attach a copy of this approval form when submitting an emergency or proposed regulation to the AELR Committee and when submitting a proposed

regulation to DSD for publication in the Maryland Register. If submitting through ELF, include as part of the attachment.

Any future changes to the incorporated documents do not automatically become part of the regulation. If there are subsequent changes to the incorporated documents, and the agency wishes those changes to become a part of its regulations, the agency must amend the regulation incorporating the documents.

Please call us if you have any questions.

Sincerely,
Gail S. Klakring
Senior Editor