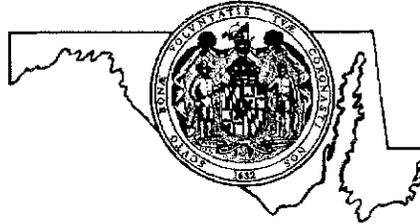


Craig P. Tanio, M.D.
CHAIR



Ben Steffen
EXECUTIVE DIRECTOR

MARYLAND HEALTH CARE COMMISSION

4160 PATTERSON AVENUE – BALTIMORE, MARYLAND 21215
TELEPHONE: 410-764-3460 FAX: 410-358-1236

MEMORANDUM

TO: Commissioners

FROM: Eileen Fleck *E.F.*
Chief, Acute Care Policy and Planning

DATE: October 15, 2015

RE: Staff Recommendation for Final Permanent Regulations: State Health Plan for Cardiac Surgery and Percutaneous Coronary Intervention Services (COMAR 10.24.17); Analysis of Comments Received

Maryland Health Care Commission (MHCC) staff is requesting that the Commission adopt as final permanent regulations a replacement COMAR 10.24.17: State Health Plan Chapter for Cardiac Surgery and Percutaneous Coronary Intervention Services (“Chapter”). Initial draft amendments to the Chapter were posted for informal public comment on April 17, 2015 with comments accepted through May 8, 2015. Seven individuals or organizations commented on this early draft. A copy of these informal comments is available on the MHCC web site.¹

Commission staff discussed the comments received with members of the Commission’s Cardiac Services Advisory Committee (CSAC) at a meeting held on May 13, 2015. Staff then revised the draft Chapter based on the informal comments, discussion by the CSAC, and additional internal staff review. As a result of changes to the definition of cardiac surgery, specifically the list of ICD-9 codes included, and the replacement of many references to cardiac surgery with open heart surgery, Staff decided to again post draft amendments to the Chapter for informal public comment on June 18, 2015 with comments accepted through July 6, 2015. Staff received comments from six individuals or organizations during this comment period. A copy of these comments is available on the MHCC website.²

¹http://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_shp/hcfs_shp.aspx

²http://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_shp/hcfs_shp.aspx

Following the posting of draft amendments to the Chapter, the Division of State Documents informed Commission staff that due to the number of changes (many of which involved minor formatting and word changes), amendments should be processed as repealing and replacing the Chapter. At the Commission meeting held in July 2015, Staff presented a summary of the informal comments received and Staff's response to these comments.

During the formal comment period for the proposed permanent regulation (August 21-September 21), Staff received no written comments. However, some of the cardiac surgeons from the CSAC raised concerns about the categorization of certain ICD-9 codes in the definitions of "open heart surgery" and "cardiac surgery," before and after the official public comment period. Staff and members of the CSAC exchanged email messages and two meetings were held. All of the cardiac surgeons were invited to the second meeting, but only some surgeons were able to attend. All CSAC members who attended this meeting (Jaime Brown, M.D., John Conte, M.D., Keith Horvath, M.D. Juan Sanchez, M.D, Rawn Salenger, M.D., and Stafford Warren, M.D.) agreed that MHCC staff should continue with its plan to request adoption of final permanent regulations, but commit to working with members of the CSAC to re-evaluate how the scope of cardiac surgery is defined in COMAR 10.24.17. MHCC staff agreed with this proposed approach.

In addition to the concerns raised about the categorization of certain ICD-9 codes, Dr. Warren raised five minor concerns on October 7, 2015. Staff proposes four minor non-substantive changes in response to these concerns, as described below. Attached is a copy of the Chapter that Staff recommends the Commission adopt as final permanent regulations (Appendix 1).

Proposed Additional Non-Substantive Changes

Dr. Warren expressed concern that physicians who recently completed a fellowship in interventional cardiology and normally become board certified one or two years later would lose their skills if unable to perform PCI immediately following a fellowship. Commission staff agrees that the language on page 44 of the proposed permanent regulation in .07C(6)(e) should be amended. The proposed amended language is underlined, as shown below. Staff notes that the text in .07C(6)(f) was intended to convey the same meaning, and the additional text provides greater clarity.

(e) Each physician shall be board certified in interventional cardiology with an exception for those who performed interventional procedures before 1998 or who completed training before 1998 and did not seek board certification before 2003 or physicians who completed a fellowship in interventional cardiology less than three years ago.

(f) Each physician shall obtain board certification in interventional cardiology within three years of completion of a fellowship in interventional cardiology.

Dr. Warren also suggested that on page 50 of the proposed regulation in .07D(5)(ii), it is unclear if the 10% of cases reviewed for evaluation of an individual interventionalist may overlap with the 5% required for external review. Staff agrees that overlap of the two

reviews is acceptable. However, we recommend addressing the need for additional clarity through additional correspondence with hospitals rather than changing the regulations.

Dr. Warren also suggested that a patient's name should be added to the description of information that must be blinded in .08D(1)(i) on page 59 of the proposed regulation. In addition, Staff determined that clarifying language should be added regarding the location of the physician identifying information that should be blinded. The proposed amended language is underlined, as shown below.

(i) A plan that describes an appropriate blinding process that the organization will use to assure that an external reviewer does not know the patient name or identity of any physician included in the patient's medical records or the hospital that is undergoing the external review;

Dr. Warren also suggested that the reference to laboratory studies on page 61 of the proposed regulation should specifically mention stress test results if stress testing was performed. Staff agrees that this proposed change is minor and adds clarity. The proposed amended language in .08G is underlined, as shown below.

(3) Laboratory studies, including stress test results if performed;

Dr. Warren also suggested that on page 62 of the proposed regulation the description of information that should be blinded should also include certain patient information. Staff agrees that amending .08H will add clarity. In addition, for consistency and clarity Staff proposes the language pertaining to blinding the identity of a physician be amended. The proposed amended language is shown below, with strikethroughs for deletions and additions underlined.

(2) The identity of physicians included in the patient's medical records ~~the physician who performed the PCI procedure under review;~~ or

(3) The patient's name.