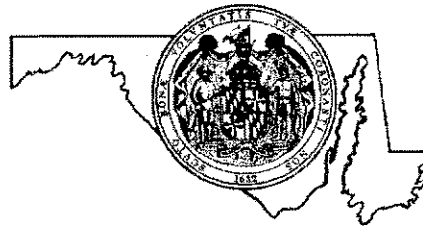


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BULLETIN 15-01

TO: Hospital CEOs and Cardiac Catheterization Directors

RE: External Review of PCI Cases

DATE: October 20, 2015

On October 15, 2015, the Maryland Health Care Commission (MHCC) approved as final permanent regulations COMAR 10.24.17, the State Health Plan chapter for cardiac surgery and percutaneous coronary intervention (PCI) services. The effective date of these regulations will be ten days after publication in the *Maryland Register*. At the earliest, Commission staff expects the notice will be published on October 30, 2015, and then the final effective date would be November 9, 2015. Commission staff will provide notice directly to you once the effective date is established.

In previous correspondence, Commission staff advised that all hospitals with PCI programs should be conducting at least a semiannual external review of their PCI programs consistent with the effective date for the requirement, August 18, 2014. However, MHCC staff will accept as sufficient, a semiannual external review of randomly selected PCI cases that begins with cases performed in January 2015. Hospitals that have not completed one or more of the required semiannual external reviews are advised to catch up by randomly selecting the appropriate number of PCI cases, at least five percent, for any review period missed and completing the review as soon as possible.

For at least the first semiannual review cycle, beginning with cases performed in January 2015 or earlier, hospitals should select cases for external review based on the regulations with an effective date of August 2014. However, hospitals may rely on the final regulations adopted by the Commission on October 15, 2015 for guidance on the content to be covered in the first cycle for external review of cases. Subsequent reviews may be based on the regulations in effect on the end date for the review cycle. For example, if the end date for the review cycle is October 31, 2015 or earlier, then cases should be selected based on the regulations effective August 2014. Please note the following key differences in the case selection process for COMAR 10.24.17 with an effective date of August 2014 and the final replacement regulations approved by MHCC on October 15, 2015 (effective date not yet known).

- The replacement regulations approved by the Commission on October 15, 2015 exclude STEMI PCI cases from the required semiannual external review of five percent of PCI cases; however, these cases are not excluded under the regulations with the effective date of August 2014.
- The replacement regulations approved by the Commission on October 15, 2015 include a requirement for the semiannual external review of five percent of PCI cases (excluding STEMI cases) to include a minimum of three cases per interventionalist or all cases if fewer than three cases were performed. The regulations with an effective date of August 2014 did not include a minimum number of cases per interventionalist for the external review. Cases shall be randomly selected from a single list.
- Once the final replacement regulations are effective (anticipate effective date is November 9, 2015), a hospital with only a primary PCI program is not required to perform an external review of five percent of randomly selected PCI cases.
- Once the final replacement regulations are effective, the cases of an interventionalist who performs only primary PCI (for STEMI cases) at a hospital with both a primary and elective PCI program do not have to be included among the list of cases randomly selected for external review.

Commission staff expects to send additional supplemental information summarizing the requirements for Certificates of Ongoing Performance. However, the following is a brief overview of the expectations for external and internal review of PCI cases based on the regulations approved by the Commission on October 15, 2015. As provided in COMAR 10.24.17.07C(4)(c), a hospital with both a primary and elective PCI program shall conduct an external review of at least five percent of randomly selected PCI cases at least semiannually that includes at least three cases per interventionalist or, if the interventionalist has performed fewer than three cases, then all cases. In addition, as provided in COMAR 10.24.17.07C(4)(d)(ii), the previously mentioned external review may be used to meet the requirement for a hospital to evaluate the performance of individual interventionalists through random selection of three cases or 10% of cases, whichever is greater. Alternatively, a hospital may meet the requirement for an evaluation of an individual interventionalist through an annual external or internal review of the higher of 10 cases or 10% of randomly selected PCI cases or all cases if less than 10 cases were performed. A hospital may also conduct reviews quarterly or use another review period, as long as the annual requirement is still met. COMAR 10.24.17D(5)(c)(ii) and (iii) establish the same requirements for the evaluation of individual interventionalists at hospitals with both primary and elective PCI programs, as described above. For a hospital with only a primary PCI program, the hospital must evaluate the performance of each interventionalist through an internal or external review of 10 cases or 10 percent of randomly selected primary PCI cases, or all cases if the interventionalist performed fewer than 10 cases as provided in COMAR 10.24.17D(5)(c)(i).

Additional details regarding the specific requirements for external peer review, external peer review organizations, qualifications of external reviewers, the review schedule, data sources, and the blinding of cases are included in COMAR 10.24.17.08. Please review the

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provisions in this regulation to assure that your hospital complies with the requirements for external peer review. There are two external peer review organizations that have been approved by the Commission; one of these has been approved conditionally. However, as stated in COMAR 10.24.17.08D(3) a hospital may choose to use an external peer review organization that has not been approved by the Commission “provided that the hospital certify and, if requested by Commission staff, demonstrate as part of its application of a Certificate of Ongoing Performance that the external review organization conducted its review consistent with Commission standards for external reviews.”

Questions about this bulletin should be directed to Eileen Fleck at the Maryland Health Care Commission 410-764-3287.

A handwritten signature in black ink, appearing to read "Eileen Fleck", written in a cursive style.

Eileen Fleck
Chief of Acute Care Policy and Planning.