



Ms. Eileen Fleck
Chief of Specialized Services
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

May 8, 2015

Dear Ms. Fleck,

Thank you for the opportunity to publicly comment on the proposed draft amendments to COMAR 10.24.17 which specifically address the topics of external peer review, internal review of interventional cardiologists and conduct of annual/semi-annual/quarterly performance reviews. Overall, Frederick Memorial Hospital (FMH) appreciates the Commissions' efforts to ensure rigor and standardization surrounding the peer review process, however finds that some of the draft changes are either confusing, over-reaching or conflict with one another. After a thorough review of the proposed changes we have the following questions, suggestions and comments.

We advocate for a more clearly understood requirement surrounding the percentage and/or number of PCI cases to be reviewed both internally and externally. First and foremost we strongly recommend inclusion of both pPCI and npPCI in the total number of external cases reviewed and that the number of cases be 10% calculated semiannually. For an institution such as FMH, this would be approximately 35 cases annually, a reasonable number that reflects what we've historically sent out for external review as well as a volume that is not onerous to prepare and send to a review organization. The per operator external review volume should be 10% also with the minimum set at all cases if fewer than 10 cases are performed at an institution. An annual internal review of approximately 10 cases per operator is also sufficient. The "quarterly or other review period" is unnecessary and confusing. If an institution or operator is deemed to be below the Commission's standard, the MHCC has the authority to require a focused review.

While the Patient Outcome Measures are not in the draft section of the proposed amendments, please note that the metric "30 day all-cause mortality" for elective or primary PCI cases is not obtainable unless the MHCC has a method to do so. In addition the 95% confidence interval is also not known. The metric that is easily available is the in-house risk adjusted mortality for either pPCI or npPCI. We would look forward to an example of how the 30 day all-cause mortality would be applied to Maryland hospitals.

Under the External Peer Review section, Method for Selecting Cases to be Reviewed is unnecessarily restrictive. If an external peer review organization is approved by the MHCC, a hospital should be able to assume that random selection of cases (both pPCI and npPCI) is done appropriately. As FMH has done with all of its external reviews, we have given the organization a list of all PCI and the organization then randomly selects cases. The methodology described is beyond the authority of a hospital to ensure compliance.

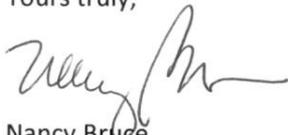
For the Requirements for External Peer Review Required Questions, specifically section 08.C.f for a successful procedure, we disagree with the standards for partially successful and unsuccessful. A residual stenosis of <50% with PTCA and normal TIMI3 flow is successful; a residual stenosis of <30% for stent implant with TIMI3 flow is successful. Unsuccessful for both involves residual stenosis of >50% or <TIMI 2 flow. Partially successful is achievement of TIMI 2 flow or PTCA residual stenosis that is an absolute reduction by 20% in the degree of stenosis with TIMI 3 flow or stent residual stenosis that in the 30-50% range with TIMI 3 flow.

Under the Additional Review proposed requirements, the second and third reviewer should be an option of the facility, not a requirement. While inappropriate procedures are rare, they do (and will) occur and should not in and of themselves trigger a second (or third) review. Trends of inappropriate procedures are a much better indicator of quality than individual cases. Monitoring of appropriateness is done very well on an aggregate basis via the Cath/PCI registry metrics which the Commission receives on a quarterly basis.

Regarding the Requirements for External Peer Review Organizations, the blinding process is challenging and at times nearly impossible. To rid an entire record of hospital identifiers and/or physician identification is very difficult. Records are embedded with identifying information. Abstraction and preparation of medical records to send for external review takes a significant amount of manpower, the additional burden of de-identification and blinding would mean that each page of the medical record would need to be printed, reviewed, and "blacked" out whenever a patient name/or operator/or other facility identifier is mentioned. The records would then need to either be scanned and sent electronically or printed out on paper and sent.

Again, on behalf of FMH and our Interventional Cardiology Program, I would like to thank the Commission for the opportunity to comment on these draft regulations. Please let me know if you have any questions or further comments,

Yours truly,



Nancy Bruce
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