UNIVERSITY OF MARYLAND
MEDICAL SYSTEM

250 W. Pratt Street
24th Floor
Baltimore, Maryland 21201-6829
www.umms.org

CORPORATE OFFICE

**VIA FAX (410 358-8811) and FIRST CLASS MAIL**

September 4, 2007

David A. Neumann, Ph.D.
Health Policy Analyst
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215

RE: COMAR 10.2.05 Research Waiver Applications: Atlantic C-Port Study of Non-primary PCI

Dear Doctor Neumann:

The University of Maryland Medical System offers the following comments regarding the draft regulations on non-primary PCI on behalf of three of its institutions: the University of Maryland Medical Center (UMMC), Baltimore Washington Medical Center (BWMC) and Shore Health System (SHS). First, we thank the Commission for this opportunity to comment and note that we are appreciative of the changes that resulted from the opportunity to submit comments in the informal comment phase. We would like to re-state several of our previous comments and add some further thoughts on the proposed draft regulations. Specifically:

1. 10.24.05.02 Purpose A

   Please clarify the term "one time process." If a qualified hospital applies for a waiver and is not approved, would it be able to re-apply under certain circumstances? Does "one time" mean that there will be only one time throughout the term of the study to apply for the waiver? What if a hospital loses its waiver – could another qualified hospital be permitted to apply? Will all six hospitals be awarded at the onset, or will some positions be held out for future participation by Western Maryland or the Eastern Shore which currently do not meet all of the initial waiver criteria. It seems important that Maryland's participation in the study begin as early as possible since timely patient accrual in the study is essential to its success. Clarity around these possible scenarios would be most helpful.

2. 10.24.05.05 Purpose C

   The proposed limit of six hospitals which will be approved for a waiver seems rather arbitrary. The overall study sets specific total patient enrollment targets; therefore, to

limit the study to six hospitals seems unnecessarily restrictive – especially if the hospital(s) currently participating in the PCI waiver are (1) successfully meeting the criteria and (2) providing quality outcomes, from a clinical outcomes perspective. To arbitrarily preclude such a hospital from participating seems unnecessarily limiting, especially since obtaining the overall, projected patient volume is so critical to this study. Furthermore, this six-hospital limit is further restricted by the provision for the encouragement of geographic representation in Western Maryland or the Eastern Shore as noted in 10.24.05.05 Waiver Application B. (2).

3. 5.10.24.05.04 Review of Application A(3)(a)

The purpose of the Atlantic C-Port Study of non-primary PCI is to study the safety and efficacy of non-primary PCI in hospitals without on-site cardiac surgery capabilities. That focus is clearly stated, yet it appears that these regulations dilute that focus by simultaneously trying to assure geographic access to the participants in this study. Aligning the non-primary study to include an assessment of geographic access could lead to a faulty design that is not likely to be beneficial to either assessment. We contend that geographic access to care should not be a factor in determining the appropriateness of an award of non-primary angioplasty to any hospital. We strongly encourage the Commission to focus on the primary outcome of the proposed study—safety and efficacy—and not cloud that with a desire for geographic diversification and access representation. Instead, we encourage the Commission to select hospital study participants based on a prior demonstration of solid outcomes in the C-Port I study and the ability to execute in the non-primary PCI trial for the stated purpose of determining the safety and efficacy of non-primary angioplasty in an environment without on-site cardiac surgery.

4. 10.24.05.04 Review of Application A.(3)(e)

The proposed regulations do not adequately address how a hospital's current performance under its primary PCI waiver is weighed against the four other factors that the Commission proposes to take into consideration for a non-primary angioplasty waiver (assuming for the minute that geographic access remains a factor). A hospital that has several years experience, has consistently supplied reliable research data, and is currently performing well under the PCI waiver criteria should be given greater consideration than hospitals without the benefit of this history and experience. A waiver ought to be granted to hospitals that are active participants in C-Port I with continued performance improvements, quality outcomes, and committed physicians, staff and administrators. These factors should be given greater consideration than the other identified factors related to geographic access or the ability to increase services to underserved populations.

5. 10.24.05.04 Review of Application (2)(c) and .06 Conditions for Maintaining a Waiver A.(4)

volume in both of these sections refers to primary PCI or non-primary PCI or a combination of both. The proposed regulations published on June 21st for informal comment appear to seek a combined number of primary and non-primary procedures for eligibility in the waiver. Yet, the draft regulations at hand do not. At a minimum, we believe that there should be a requisite combination of primary and non-primary PCI. In addition, there should be some requirement which prevents hospitals with a waiver for non-primary PCI from negatively affecting or limiting their capacity to provide 24-7 primary angioplasty.

6. Finally, we question whether the pre-application eligibility criteria can be satisfied by using pre-application volume statistics even if an applicant no longer has a current waiver. In other words, if a hospital previously had a waiver but does not have one as of this date, would the Commission consider the hospital's prior primary PCI volumes and outcomes if the hospital re-applies and is granted a waiver at a subsequent time.

Again, thank you for the opportunity comment on this important issue. We look forward to continuing the expansion of these much-needed cardiac services.

Sincerely,

Edmond F. Notebaert
President and CEO
University of Maryland Medical System