December 5, 2007

Sonia D. Chambers
West Virginia Health Care Authority
100 Dee Drive
Charleston, WV 25311

Dear Sonia:

Thank you for giving me the opportunity to comment on the Draft Cardiac Catheterization Standards. I have a number of personal, editorial comments concerning the provision of cardiac services in general and certain specific comments with regard to the proposed standards. Many of these observations come from looking back at my years at Thomas and looking forward to what it takes to care for cardiac patients.

**Diagnostic Standards:**

While the Authority has a responsibility to promulgate standards for the good of all West Virginians with regard to access, cost, and quality, many of the following comments pertain to Thomas and its relationship with other providers of cardiac cath services in the Kanawha Valley.

Since I'm not in your shoes, I can make this suggestion; if I were in your shoes I wouldn't approve any more new labs that can only perform diagnostic caths. From personal and professional experience patients resist being cathed at Thomas when they cannot be "fixed" at Thomas. In concert, physicians are

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reluctant to perform a diagnostic cath after they've informed the patient that if something is found that is treatable by therapeutic procedure the patient will have to be transferred to another facility with a sheath in their groin.

The approval of diagnostic only labs was probably appropriate ten years ago. Since then the technology of therapeutic catheterization and the training of interventional cardiology fellows has advanced to a point where this has now become the standard of care. Thomas has fourteen cardiologists on staff. Of those fourteen, eleven are interventional cardiologists and three are diagnostic cardiologists. Of those fourteen, eight have their primary practice at Thomas and six of the eight are interventional cardiologists able to perform diagnostic and therapeutic procedures, and two are diagnostic only. These eight cardiologists are some of the most recognized names in the Kanawha Valley, have performed thousands and thousands of diagnostic and therapeutic caths among them, but because of regulation cannot open a blockage diagnosed in the lab at Thomas. The patient must be transferred.

In addition to physician manpower, our cath lab team of radiologic technologists, R.N.s and hemodynamic monitor techs have performed in excess of 11,000 diagnostic and therapeutic procedures. And finally, we have the most recently installed, newest cath lab in the Kanawha Valley.

Our physicians can and do perform miraculous procedures in the cath lab on the vessels of the body. We have opened vessels in the arms, shoulders, and legs to restore circulation. We have opened renal arteries to restore kidney viability. We are able to open arterial venous grafts for dialysis patients. We can repair an abdominal aortic aneurysm with stenting where these patients previously were opened in surgery and spent months recovering. And shortly, we will be opening vessels in the brain. In short, we can and do successfully treat any and all vessels in the body except those of the heart.

We have the same physicians that perform these procedures at St. Francis and CAMC. We have the staff that has worked at St. Francis and CAMC. We have equipment that is the newest in the Kanawha Valley. We have a coronary intensive care unit and every other modality used to treat cardiac patients. We have patients admitted to Thomas on a daily basis who need this service. We have the ability but not the authority.

**Therapeutic Standards:**

The standard for emergency and elective PCI, to me, seems backwards. You have proposed to allow diagnostic labs that perform 300 caths a year for three years to perform emergency PCI if they can show a volume of 36 per year. What you are proposing is to allow access to PCI for cardiac emergencies and this is the right thing to do. It seems, however that you would or should have a lab

perform therapeutic procedures in a controlled, calmer setting than to allow "battlefield" cardiology to be practiced first. In a lab that has never performed an elective therapeutic procedure, it seems intuitively backward to allow treatment of emergency patients even if it does fall within the "golden hour".

I was able to pull Emergency Department visits by facility from the Authority's website. In 2006, the following facilities experienced tremendous volume:

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|---|---|
| St. Francis | 16131 |
| Teays Valley | 17768 |
| Thomas | 42547 |
| CAMC | 93968 – for 3 separate ER's |

Thomas Hospital has the single busiest Emergency Department of the six local departments listed. By proportion we receive an inordinate volume of cardiac emergencies. Because we have not had our catch lab open for three years and performed 300 diagnostic caths each of those three years we still cannot apply for emergency PCI and in some cases a transfer must be effectuated. From the draft standards:

> "Acute coronary intervention is now the treatment of choice with AMI and high risk acute coronary syndromes. Since this is the best treatment available, it is important to make it more available in community hospitals where most of the patients are currently presenting for treatment."

Again, we can document that physicians practicing at Thomas have done greater than 300 caths (in fact greater than 300 interventions). Staff that has performed greater than 300 caths (interventions), equipment capable of treating emergency PCIs, and the highest volume Emergency Department around. And only because of the age of the lab we are unable to apply for emergency PCI. Again, we have ER patients and patients admitted to Thomas on a daily basis who need this service. We have the ability but not the authority.

Under the draft therapeutic standards a facility must be open and perform 300 diagnostic caths per year for three years before they can apply for emergency PCI. Once this approval is granted the provider must perform at least 36 primary PCIs a year for three years and 300 diagnostic caths before being allowed to apply for elective therapeutic cases. Thomas Hospital's diagnostic cath lab opened in 2006. Assuming everything lined up perfectly it would be 2009 before we could apply for primary PCI and 2012 before we could apply for therapeutic capability. In the three years since opening the diagnostic lab we'll have 130,000 patients go through our emergency room without access for primary PCI. If we had no emergency patients or modest volume this may seem reasonable. But to deny immediate access to a lab that has every piece in place to perform primary and elective therapeutic cases seems unreasonable, unsafe, and limiting.

While your responsibility is to balance access, cost, and quality of service to all of West Virginia it has to be difficult to address and satisfy the needs of every county and every provider.

As you are aware, Thomas experienced great difficulty in obtaining approval for diagnostic cath service because we operated “in the shadow” of CAMC and St. Francis. Once we opened we experienced some push-back from patients and practicing cardiologists to perform diagnostic caths in a facility were the patient could not be “treated”. With facilities close to Thomas that provide these same services it would appear reasonable to a logical health planner that Thomas did not need to be providing intensive cardiac services. The reality is Thomas has a huge patient base, a huge ER volume, a medical staff of 303 physicians, a huge number of outpatient visits, a huge number of surgeries, etc, etc, etc. We have the responsibility and the ability to provide these services but not the authority.

**Specific Suggestions for Primary PCI and Therapeutic Caths:**

IV.B.1: “The applicant’s adult diagnostic cardiac catheterization service, both physicians, collectively, and staff, collectively, in any approved diagnostic or therapeutic lab have performed an average of 300 diagnostic procedures annually during the most recent three-year period…”. An exception applies to a Hospital System that blends the physician and clinical staff between facilities. As

a system the capability exists to perform cardiac catheterization at two or more sites as long as all other criteria are met.

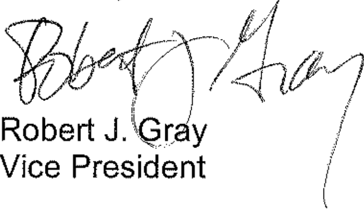
The age of the lab should not be the trigger for an applicant to apply for therapeutic capability. The quality, ability, and experience of those who actually perform the procedures is by far a stronger indicator of quality care than is the age of the lab.

IV.B.7: An applicant for PCI with an annual emergency room volume in excess of 40,000 visits, a functioning cath lab, and a medical staff that can document the completion of 300 therapeutic procedures per annum over the previous three years in any therapeutic lab shall be exempt from projecting a minimum of 36 Primary PCI procedures by the third 12 months of operation. "An applicant shall project a minimum of 36 Primary PCI..."

IV.C.2.d: If the applicant is licensed for 175 or more acute care beds and provides a full array of secondary level acute care services, a medical staff of at least two interventional cardiologists that can document at least 300 therapeutic caths performed each year over the previous three years, and a diagnostic catheterization lab, it is not required to subtract the number of catheterization procedures performed by existing providers located in the study area.

Thank you for giving me the opportunity to comment on the Draft Cardiac Catheterization Standards. These standards are vitally important to West Virginians.

Sincerely,



Robert J. Gray
Vice President

RJG/dka