

December 13, 2007

Ms. Sonia Chambers  
West Virginia Health Care Authority  
Certificate of Need  
100 Dee Drive  
Suite 201  
Charleston, WV 25311

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2007 DEC 14 PM 1:08  
WV HEALTH CARE  
AUTHORITY

Dear Sonia:

On behalf of Saint Francis Hospital, the Thomas Health System and its Board of Trustees, we wish to thank the Authority for the opportunity to comment on the proposed Cardiac Catheterization Certificate of Need Standards issued by the Authority on November 14, 2007. We also wish to extend to the Authority our sincere gratitude for being chosen as a Demonstration Pilot Project site for therapeutic cardiac catheterization. We believe over the past four years that our volumes and outcomes have contributed to the improved health of cardiac patients in our community.

We wish the Authority to consider the following comments and/or changes to the Cardiac Catheterization Standards issued November 14, 2007:

➤ **The therapeutic Cardiac Catheterization Services Need Methodology needs clarification in regard to Demonstration Pilot Project providers applying for CON;**

It is unclear in the standards as written, whether the volumes and experience of the demonstration site projects will be taken into consideration in demonstrating need. Based on our reading of the standards, it would appear that the Authority has concluded that improvements in accessibility to therapeutic cardiac catheterization services would best serve the needs of West Virginia residents. However, the three Demonstration Project providers would all be required to address a population based need methodology. Although the results of this need methodology are inconclusive at this time, it is possible that one or more of the programs would not be able to demonstrate need for continuation of the program. Therefore, we recommend that the Authority insert additional language in the standards that definitively states that existing Demonstration Project providers have sufficiently demonstrated need if volumes for the preceding 12 months exceed 200 procedures. If desired, the Authority should also consider language that ties the continuation of the Demonstration Pilot Project providers to their ability to deliver quality care by comparing outcomes to industry norms.

It is also unclear, from our reading of the standards, whether existing Demonstration Pilot Project Providers must address any standard regarding the Primary PCI project. That is, does an existing Demonstration Pilot Project provider have to first apply for Primary PCI approval? Although we do not believe this was the intent of the standards, it is not definitively stated in the standards. We envision others to challenge our permanent CON request on this issue should the standards not be clarified in this respect. We recommend that the Authority revise Section XI of the standards as follows:

“Hospitals currently approved to participate in the Demonstration Pilot Project must apply for a Certificate of Need to provide elective Therapeutic Cardiac Catheterization services within six months of the effective date of these Standards.” Those facilities that are existing participants in the Demonstration Pilot Project are not required to address any standard related to the provision of Primary PCI. Therefore, Section IV. C.1. of the standards is not applicable to existing Demonstration Pilot Project participants.

- **On Page 10, item 6a, it is not clear what is meant by “involvement in credentialing criteria and recommendations for physicians approved to perform Primary PCI.” by the Cardiac Surgery Facility in the required agreement.**

The identified concern is the violation of State Code-30-3C-1. This would require opening the credentialing process of the physicians to an independent external entity, voiding peer review protection for the process and on any subsequent or latent liability exposure. Under the statute, only the specific physician or facility may waive protection, but it would not be the interest of either party to do so. This process as described in the current proposal would negate the Medical Staff and Governing Body’s legal authority to credential, privilege and monitor providers within their specific facilities. This would also circumvent the JCAHO standards, specifically (MS Chapter) MS1.20, MS 2.2, MS4.10, MS 4.20 and possibly CMS conditions of participation.

- **On Page 11, Item f, the word “tested” should be removed from the sentence “The protocols shall be reviewed/tested on a quarterly basis.”**

Protocols should be reviewed on a quarterly basis but it seems unclear as to what is meant by tested or by what method of testing should be used to meet this requirement.

- **Number 7 page 13 the sentence Primary PCI volume shall be documented that the applicant transferred enough ST segment elevation AMI cases during the most recent 12 month period preceding the date the application was filed to maintain Primary PCI cases annually. This requirement is in direct conflict with the Authority’s statement on page 9 that acute coronary intervention is now the treatment of choice with AMI and high risk acute coronary syndromes.**

Therefore, the Authority needs to include in the projection other such cardiac emergencies other than just documented STEMI’s that require emergent PCI for a hospital to maintain emergent PCI services. To transfer an emergent patient with a non STEMI, doesn’t make sense from a patient care prospective.

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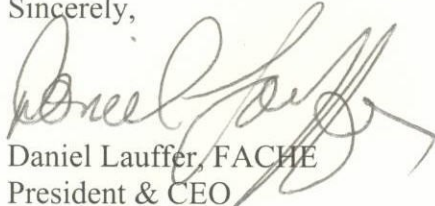
**Hospital "Systems" that have performed the procedures within the system and share the same cath lab staff and trained interventional cardiologists should be able to offer emergent PCI if they have a cath lab available on site.**

The Thomas Health System was created in January of 2007. The system of Saint Francis Hospital and Thomas Memorial Hospital are cooperating and creating excellence through the sharing of both management and clinical practices. This extends to cardiac care of the patient. We have merged cath lab teams and have interventional cardiologists that are credentialed at both facilities. Saint Francis Hospital has proven that PCI done both electively and emergently have greatly benefited the patients of the Kanawha Valley. Extending that expertise and knowledge to Thomas Memorial Hospital can only benefit a patient by performing emergent PCI on site at Thomas Memorial Hospital rather than subject the patient to a transfer to either Saint Francis Hospital or CAMC. It is clearly in the best interest of the patient to have a life saving procedure as quickly as possible.

We strongly urge the Health Care Authority to consider the changes we have suggested. Saint Francis Hospital, the Thomas Health System and its Board of Trustees appreciates the Authority's duty to strike a balance among the many objectives of cost, quality, accessibility, and the standards of care in writing such standards. It is certainly in all of our interests to improve the patient care delivery system to all West Virginians.

If you should have any questions or would like further comment on the above changes, please do not hesitate to call me. Your comments and questions are always welcomed.

Sincerely,



Daniel Lauffer, FACHE  
President & CEO  
Saint Francis Hospital