LIFEBRIDGE
HEALTH

Sinai Hospital
Northwest Hospital
Levindale Hebrew Geriatric Center and Hospital
Courtland Gardens Nursing & Rehabilitation Center

Neil M. Meltzer
President and Chief Executive Officer

October 21, 2013

Ms. Eileen Fleck
Chief, Acute Care Policy & Planning
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Re: Draft for Informal Public Comment - State Health Plan for Facilities and Services: Specialized Cardiovascular Services, COMAR 10.24.17

Dear Ms. Fleck:

I am writing on behalf of LifeBridge Health, Inc., the parent of, among other entities, Sinai Hospital of Baltimore, Northwest Hospital Center and Levindale Hebrew Geriatric Center and Hospital. These comments are being submitted during the informal public comment period in response to the draft of the State Health Plan for Facilities and Services: Specialized Cardiovascular Services.

The draft regulations represent, in part, the work of the Clinical Advisory Group convened pursuant to the passage of legislation in 2012, now codified in Health-General §19-120.1, directing the Commission to develop a process and standards for providers to establish or continue to provide percutaneous coronary intervention (PCI) or cardiac surgery services.

LifeBridge commends the Commission for its extensive examination of the clinical, quality and regulatory oversight aspects of the new process. We observe that the Commission has stayed true to its stated goal to incorporate quality standards and performance measures into the State Health Plan for these services. This focus leads the State toward maintaining its system of high-value programs and ensures that Marylanders will continue to have access to specialized cardiovascular services in appropriate clinical settings.

One clear example of this appropriate focus is reflected in the requirement that an applicant for a primary PCI program must substantiate that a proposed program's population is receiving suboptimal therapy for STEMI. This type of requirement, reflected throughout the draft regulations, will ensure that programs truly meet a need before being approved. It provides protection against proliferation that could result in inefficient use of the scarce resources required to maintain a high quality system of cardiovascular services throughout the State.

On the other hand, the standard at Section .06B(3) seems to contradict this principle. By allowing an exception to waive volume requirements for addition of an elective PCI program to an existing primary PCI program solely based on permitting the PCI programs to achieve financial viability, the standard ignores the otherwise omnipresent quality-oriented standards that are the hallmark of the new regulatory oversight structure. We recommend, therefore, that this section be removed.

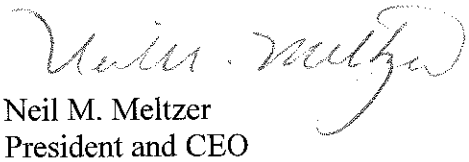
Opportunity to Cure / Plan of Correction. We strongly support the new authority of the MHCC to conduct peer and independent review, including focused review and, if necessary, to move toward closure. An essential step in this process is the requirement that programs be given an opportunity to address deficiencies prior to actual closure. This principle is reflected in the standard used throughout the document that the Commission "may" require an approved plan of correction for the program. We believe, however, that the intent of the provision in the legislation is much stronger than the draft's discretionary "may" language reflects.

We recommend revision of all instances where the language reads "may" with regard to submission of a plan of correction. It could read, for example, "The Commission shall allow the program to return to compliance through an acceptable plan of correction," or "The hospital is entitled to submit a plan of correction for approval by the Commission," as appropriate in the context of the section. The plan of correction concept is well established as a regulatory process, involving negotiations between an institution and agency until a plan is created that the agency can "approve," and thus the details of that process need not be delineated in the regulations. The "of right" status of a plan of correction must, however, be clarified in all applicable uses of the concept in the draft regulations.

In conclusion, it is clear to us that the Commission desires to ensure Marylanders access to the safest, most effective, highest quality cardiovascular services. In attempting to embrace new technologies and reflect changes in the health care system, the Commission evidences its commitment to ensuring this level of access, and we commend the Commission staff for seeking creative solutions to the problems posed by changes and improvements in medical care. We hope that as it continues to engage in the thoughtful, inclusive process at hand, it will exercise due diligence in achieving these goals by implementing the necessary steps as described above.

Thank you for the opportunity to comment.

Sincerely,



Neil M. Meltzer
President and CEO