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October 21, 2013

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

Re: Comments on the Draft State Health Plan for Facilities and Services:  
Specialized Cardiovascular Services. COMAR 10.24.17

To Ms. Fleck and the Commission Staff:

The Draft Regulations for the State Health Plan for Facilities and Services: Specialized Cardiovascular Services [COMAR 10.24.17] (Draft SHP) was released for informal comment with public comments due prior to 5:00pm on October 21, 2013. Doctors Hospital, Inc. is submitting these comments with respect to the Draft SHP.

At the outset, it is worth noting that the Draft SHP is being released as directed by the 2012 legislation that, among other things, directed the MHCC to adopt new regulations for the oversight of Cardiac Surgery and Percutaneous Coronary Intervention (PCI) services in the state, now codified at Health-General Article, § 19-120.1 et seq. The MHCC was directed to establish a process for an initial approval (the Certificate of Conformance, § 19-120.1) and renewal (the Certificate of Ongoing Performance) of PCI programs, including PCI programs at hospitals with on-site cardiac surgery programs.

Doctors Hospital participated in the C-PORT study for more than three years but voluntarily relinquished its program because it could not gain sufficient volumes of emergency cases due to the frequent diversion of emergency patients to hospitals with on-site cardiac surgery. Doctors Hospital is not located in a rural office and is not a sole community provider, so under the Draft SHP it would not be in a preferred position, but its experienced cardiologists wish to provide enhanced cardiology services to their patients in the area. This is particularly important in that Doctors Hospital is significantly less costly than the open heart hospital in Prince George's County. The Draft SHP would essentially prevent any hospital similar to Doctors from providing PCI services in the future. We urge the Commission to reflect the results of the studies –most notably the C-PORT E Study – that found that high volume (both in the case of the institution and the interventionalist) programs were safe and provided high quality. Doctors Hospital believes that some avenue should be open to hospitals that demonstrate the ability to meet all of the quality and cost standards to receive permission to offer PCI services.

## 10.24.17.03 –ISSUES AND POLICIES

Doctors Hospital firmly supports the Policies enumerated in this chapter of the Draft SHP. Consideration of the cost effectiveness of an applicant as compared to existing providers should be an important factor, and performance measures to evaluate programs are an important factor in ensuring that only programs that consistently offer high quality programs continue to provide this service. The Policies, taken together, promote the availability, quality and cost effectiveness of this service.

### *Cost of Care and the New Waiver*

While Doctors Hospital appreciates the challenges posed by the transition to a waiver that is measured by the cost/beneficiary for all hospital services, compared to the old system that only looked to the increase in the cost/inpatient admission, we believe that an open ended moratorium to be ended only when “more certainty is assured concerning how hospitals will be reimbursed for services” provides insufficient clarity to this important issue. Perhaps some time limit could be provided in this section.

### *Quality of Care*

Although reference is made to quite dated studies (between 1995 and 2003) on the relationship between volumes and quality for PCI programs, the CAG considered more recent data and the ACCF/AHA/SCAI 2013 Update to recommend a target volume of 200 PCI cases. Doctors believes this standard should apply to all hospitals providing PCI, with preference given to applicants that can demonstrate the likelihood of quickly achieving and continuing to meet and exceed the volume standard.

### *Access to Care*

We appreciate the benefit of emergency PCI services for appropriate patients, and the fact that access may at one time have been a bigger issue in the more rural areas of the State. However, access does not end with that issue. Patients who need elective PCI will generally be referred by their own physicians in a non-emergency situation, and physician and patient choice should not be ignored in the consideration of elective PCI. Moreover, the discussion in the Policies largely ignores the important issue of cost-effective care, which may be present (as in Doctors case) even in areas that are not rural and which may have adequate access to emergency PCI care.

## 10.24.17.04–COMMISSION PROGRAM POLICIES

### A. Consideration of New Programs

#### (2) Elective PCI

Section (b) of this Policy requires a hospital seeking a Certificate of Conformance to have provided emergency PCI for at least two years before applying for permission to provide elective PCI “unless the hospital is located in a part of Maryland that does not have sufficient access to emergency PCI services,” which is to be shown by a demonstration of “suboptimal therapy for STEMI. Doctors Hospital believes this to be misguided policy, which basically assumes that the only reason to permit elective PCI is to assist hospitals with the cost of providing emergency PCI service. As noted earlier, this ignores the importance of considering cost effectiveness of an additional service, even at a hospital that is located in an area with access to emergency services. Doctors Hospital believes that the issue of ensuring high quality, reasonable cost cardiac services to the State’s residents does not begin and end with emergency care, and linking the two will effectively preclude many hospitals from offering high quality low cost cardiac services to their patients. The reports on which the Commission is relying focus on quality and the relationship of high quality to sufficient volumes by both the institution and the physician. There are many hospitals that have the high quality medical staffs capable of providing PCI that will be effectively precluded from offering the services simply because they are not rural or are located in an urban area that has existing providers.

Doctors Hospital agrees with the requirement to offer both emergency and elective PCI services, but believes quite frankly that the difficulty lies in providing emergency services, not elective services, so that an applicant should be permitted to present its case that it is fully capable to meeting the quality, volume and cost requirements in the Draft SHP without offering 2 full years of emergency services only.

#### COMAR 10.24.17.06. Certificate of Conformance Criteria

##### B. Elective PCI Services

It is the Hospital understands that the primary reason for the long delay to permit the Commission to evaluate the results of the C-PORT E study was to determine whether a properly structured elective PCI program that maintained sufficient volume both with respect to the Hospital and the physician and treated appropriate patients presented any risk to patients. The Study and others like it demonstrate clearly that the answer is that they do not, and an important treatment for some forms of cardiac disease can therefore be provided in frequently lower cost community hospitals. The quality standards in the Draft Plan are supposed to ensure that hospitals providing this service continue to earn the right to do so, and to expand availability to this now quite basic service.

However, the Draft Plan appears to be focused almost entirely on the expansion of emergency PCI services, to the extent that permission to perform elective PCI is dependent on an applicant’s need for financial support. The “Need” section states that an applying hospital (having been required to provide emergency PCI services alone for two years) “must demonstrate that its proposed elective PCI program is needed to preserve timely access to emergency PCI services for the population to be served.” COMAR 10.24.17.06.B(1).

Moreover, the quality standard from the C-PORT E study and the ACCF/AHA/SCAI 2013 Update – the core of the need to ensure that volumes are sufficient to support high quality, can be waived if an applicant demonstrates a need for the financial support of the elective program.

Doctors Hospital does not object to making exceptions for presumably smaller hospitals that might have difficulty affording the high cost of an emergency only program that requires 24/7 staffing to treat as little as 36 cases annually. However, it objects to the Draft SHP being drafted entirely around the emergency PCI issue and ignoring the Policies that were identified to drive this Chapter. Any hospital that can demonstrate that it can provide high quality, high volume PCI services (both emergency and elective) and meet all of the other quality standards in the Draft SHP should have at least the opportunity to apply, even in areas that may not have inadequate access to emergency PCI services. Doctors Hospital respectfully requests that the Chapter be modestly revised to reflect that PCI is more than an emergency service, as important as that emergency service is, and that the requirement is to provide both with reasonable volumes and at a high quality.

Thank you for considering these comments.

Respectfully yours,

A handwritten signature in blue ink that reads "Philip B. Down". The signature is written in a cursive, flowing style.

Philip B. Down, President  
Doctors Hospital, Inc.