

STATE OF MARYLAND



**MARYLAND HEALTH CARE COMMISSION**

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**BULLETIN 21-01**

**Changes to the Evaluation of Compliance With Performance Standards  
for Percutaneous Coronary Intervention (PCI) and Cardiac Surgery Programs  
for the Period Between January 2020 and December 2021**

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In March 2020, staff announced in a bulletin that specific standards for PCI and cardiac surgery programs would be waived during the state of emergency declared on March 5, 2020 by Maryland's Governor in response to the COVID-19 pandemic. In June 2021, the Governor announced the state of emergency would partially end effective July 1, 2021 and fully end on August 15, 2021. This Bulletin describes how the evaluation of compliance with specific standards will be handled for the period between January 2020 and December 2021, which includes the period when the state of emergency was in effect.

After reviewing the compliance with standards in 2020 through an analysis of hospital discharge data and the American College of Cardiology's National Cardiovascular Registry (ACC NCDR) CathPCI data, staff concluded that most hospitals were still able to meet the volume standards that the Maryland Health Care Commission (MHCC) waived during the state of emergency. We also determined that excluding only months when the state of emergency was in effect, as described in the March 2020 Bulletin, would create unusual performance measurement periods, which seem inconsistent with the broader goals of these standards. Therefore, we are revising the approach that will be taken to evaluating compliance for the period between January 2020 and December 2021. For Certificate of Ongoing Performance application reviews, a hospital's actual performance for the period between January 2020 and December 2021 will be included, with a note regarding the waiving of compliance with the applicable standard for the months of March through September.

The state of emergency may be over but new COVID-19 cases are substantial in most Maryland jurisdictions and total COVID-19 hospitalization are up more than 300 percent from the

June 2021 lows. If a hospital believes that it cannot meet certain standards for its cardiac surgery or PCI program due to the need to reduce elective surgeries and procedures in response to high COVID-19 admissions or for other reasons related to your COVID-19 response, please contact MHCC staff to discuss how to seek a waiver from specific standards.

### **Requirements for Cardiac Surgery Programs**

Because the state of emergency remained in effect for 18 months, much longer than staff anticipated, staff has slightly revised its approach to the calculation of cardiac surgery case volume for individual hospitals. For a program measuring case volume by calendar year, compliance with case volume standards will be waived for CY 2020 and CY 2021. For a program measuring case volume by fiscal years that begin in July and end in June, compliance will be waived for FY 2020 and FY 2021. Currently, staff plans to require compliance with case volume standard for CY 2022 and FY 2022. However, a hospital may ask for consideration of specific special circumstances tied to the pandemic as a reasonable justification for not meeting a standard, and staff will evaluate whether to grant an exception.

### **Changes to Requirements for PCI Programs**

MHCC staff's review of the ACC NCDR CathPCI data shows that only very rarely did a physician performing primary PCI at a hospital without cardiac surgery on-site perform an average of fewer than 50 cases annually between January 2019 and December 2020, as required in COMAR 10.24.17.07C(6)(a), (b), and (c). Rather than making an assumption about the number of PCI cases that would likely have been performed in each month during which a state of emergency remained in effect in Maryland, whether in effect for part or all of the month, MHCC staff will waive the standard for the period of January 2020 through December 2021. January 2022 will be the start of a new rolling 24-month period for evaluation of compliance with the standard for all physicians, unless a hospital requests and receives approval for an alternative approach. The same approach will be used with respect to the standards in COMAR 10.24.17.07D(7)(a), (b), and (c).

The calculation of compliance with the door-to-balloon time standard in COMAR 10.24.17.07D(4)(b) will be reported for the period January 2020 through December 2021, but compliance with the standard for that entire period will be waived because the state of emergency spanned 18 months in that period, and it will simplify the periods used for determining compliance to waive the standard for a full 24 continuous months. Alternatively, if a hospital requests and receives approval from Commission staff for a different time period to apply for the waiver of these standards, then a different time period will be used to calculate compliance with this standard.

### **Institutional Resources Standard for Primary PCI Programs**

As provided in COMAR 10.24.17.07D(4)(a), hospitals are required to track when primary PCI services are unavailable and patients are diverted from the hospital, transferred to another hospital, or receive suboptimal therapy because primary PCI was unavailable. Upon request of Commission staff, the hospital is required to provide documentation of these lapses. The Commission then considers the frequency of lapses and whether they could have been avoided in determining compliance with the requirement that primary PCI services be available 24 hours a day, seven days a week for all appropriate patients with acute myocardial infarction. As noted in

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the March 2020 Bulletin, Commission staff concluded that this standard allows for flexibility that accounts for the unique set of circumstances that some hospitals may have faced during the COVID-19 pandemic. It is not specifically waived.