

STATE OF MARYLAND



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BULLETIN 20-03

TO: Hospital CEOs
RE: Standards for Certificates of Ongoing Performance
DATE: March 31, 2020

Commission staff recognizes that public health and the health and safety of patients and staff at hospitals should be the first priority for hospitals during the state of emergency declared on March 5, 2020 by Maryland's Governor in response to the COVID-19 pandemic. As part of the public health response to the COVID-19 pandemic, hospitals have been directed to stop performing elective surgical procedures, and this may impact a hospital's ability to meet volume standards for cardiac surgery and a physician's ability to meet volume standards for percutaneous coronary intervention (PCI) procedures. The ability of hospitals to achieve the door-to-balloon time standards for primary PCI cases may be impacted by stretched resources in the emergency room, including the availability of staff and the need for extra precautions for infection control, such as wearing additional personal protection equipment or changes to disinfection practices for the cardiac catheterization laboratory. For this reason, the Maryland Health Care Commission will be waiving some of the standards for Certificates of Ongoing Performance for cardiac surgery and PCI services during the state of emergency, as described below. Cardiac surgery programs and PCI programs should still follow accepted standards of patient care and provide primary PCI services as soon as possible to appropriate patients.

Temporary Changes to Requirements for Cardiac Surgery Programs

The calculation of case volume with respect to the standards in COMAR 10.24.17.07B(6)(b) and (c) will exclude the months during which a state of emergency remains in effect in Maryland, beginning March 1, 2020, the first day of the month in which the state of emergency was declared and ending on the last day of the month during which the state of emergency ends. Alternatively, if a hospital requests and receives approval from Commission staff for an alternative time period to apply for the waiver of these standards, the alternative time period will be applied. In practice, this means that the volume of cases performed during the state

of emergency will be skipped over in calculations. For example, if a state of emergency remains in effect during March, April, and part of May, then the calculation of case volume for CY 2020 will include January, February, June, July, August, September, October, November, December, and the first three months of CY 2021.

Temporary Changes to Requirements for PCI Programs

The calculation of PCI case volume for physicians with respect to the standards in COMAR 10.24.17.07C(6)(a), (b), and (c) will be based on an assumption about the number of PCI cases that would likely have been performed in each month during which a state of emergency remains in effect in Maryland, whether in effect for part or all of the month. It will be assumed that the number of PCI cases performed in those months is equivalent to the average number of PCI cases performed per month in last rolling eight-quarter period for which the physician's volume was calculated, prior to March 2020. In most cases, the last rolling eight-quarter period for calculating PCI volume will be the rolling eight-quarters ending December 2019. Alternatively, if a hospital requests and receives approval from Commission staff for a different set of assumptions to be used, then a different set of assumptions may be used for calculating PCI case volume during the period that a state of emergency was in effect in Maryland. The same approach will be used with respect to the standards in COMAR 10.24.17.07D(7)(a), (b), and (c).

An example of this revised approach is the following. If a state of emergency remains in effect during March, April, and part of May, then the calculation of a physician's PCI case volume in the first two quarters of 2020 should assume that the physician's PCI volume for March, April, and May is the average number of PCI cases performed per month during the 24-month period beginning with January 2018 and ending in December 2019.

The calculation of compliance with the door-to-balloon time standard in COMAR 10.24.17.07D(4)(b) will exclude the months during which a state of emergency remains in effect in Maryland, beginning March 1, 2020, the first day of the month in which the state of emergency was declared and ending at the end of the month during which the state of emergency ends. 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. Although this standard will be waived for the period while the state of emergency is in effect in Maryland for the COVID-19 pandemic, hospitals should continue to track door-to-balloon times and strive to treat appropriate patients with primary PCI as quickly as possible.

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 the 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. Commission

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staff has concluded that this standard allows for flexibility that accounts for the unique set of circumstances that some hospitals may face during the COVID-19 pandemic.

If there are other standards for a Certificate of Ongoing Performance for cardiac surgery or PCI services that your hospital has concluded should also be temporarily modified, please alert Eileen Fleck or me and provide an explanation. Questions about this bulletin should be directed to Eileen Fleck at the Maryland Health Care Commission 410-764-3287 or eileen.fleck@maryland.gov.

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