



**MEMORANDUM**

**DATE:** April 14, 2023

**TO:** Commissioners

**FROM:** Wynee Hawk, Chief, Certificate of Need  
Caitlin Tepe, Assistant Attorney General

**RE:** Proposed Regulations: COMAR 10.24.01, *Procedural Regulations for Health Care Facilities and Services*

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**I. Background**

COMAR 10.24.01 are the procedural regulations governing the Maryland Health Care Commission's (MHCC or Commission) certificate of need (CON) program. The impetus for revising these regulations stems from the work of the MHCC CON Modernization Task Force convened in 2017-2018, Governor Hogan's 2015 Regulatory Reform Commission, and the significant changes in the MHCC's enabling statute since COMAR 10.24.01 was last modified in 2005.

In its [2018 Final Report](#) on Modernization of the Maryland CON Program, MHCC identified a number of recommendations for streamlining the CON review process and better aligning it with policy objectives. While many recommendations required statutory changes, some of those areas of modernization could be achieved through changes in COMAR 10.24.01. For example, changes in the proposed regulations that raise the threshold for qualifying as an interested party, added flexibility to the performance requirements, use a consent agenda to approve certain project changes, and limits to the completeness review process.

The [Governor's Regulatory Reform Commission](#) specifically called for the modernization of four health-planning chapters, including the CON procedural regulations. MHCC made significant changes to the Home Health Agency State Health Plan Chapter (COMAR 10.24.16) in 2016 and the Nursing Home State Health Plan Chapter (COMAR 10.24.20) in 2019. The legislature modified MHCC's oversight of Substance Abuse Disorder Intermediate Care Facility Services (ASAM 3.7) in 2019 by allowing established facilities to expand physical bed capacity without CON approval. Even more ambitious efforts by MHCC to fully remove SUD treatment facilities from CON oversight failed in the General Assembly

in 2018 in the face of staunch industry opposition. COMAR 10.24.01 is the last on the Reform Commission's list of MHCC regulations requiring modernization.

Lastly, MHCC's statutory authority over health facility planning and development has been modified several times since the last update of COMAR 10.24.01 in 2005. For example, the General Assembly:

- expanded MHCC's oversight of cardiac services in 2012;
- granted MHCC authority to approve the conversion of acute care hospitals to freestanding medical facilities without CON review in 2015;
- changed MHCC's oversight of ambulatory surgery, hospitals, and comprehensive care facilities in 2019, changes grounded in MHCC Report on CON Modernization recommendations; and
- made small changes to MHCC's statute affecting continuing care retirement communities in 2022.

Although COMAR 10.24.01 continues to be serviceable, it makes sense to align this regulation with other regulatory and statutory changes over the past decade.

## **II. Informal Comments**

Prior draft versions of the proposed regulations have been released for informal comment and feedback. MHCC published an initial draft of the proposed regulations on July 26, 2022 on its website and distributed a copy to stakeholders. The Commission received thirteen submissions. The Commission released another draft of the proposed regulations for a second round of informal review on January 26, 2023. On February 9, 2023, The Commission held an interactive webinar to present the proposed changes and engage with stakeholders. MHCC received 5 written submissions in the second round of informal comments.

## **III. Key Changes to the Regulations**

### **a. Streamlining CON Reviews**

One of the complaints routinely made regarding MHCC's CON program is the length of time for the Commission to make a decision on a CON application. Several revisions to the procedural regulations address this concern.

Before a CON application is formally docketed for review, MHCC staff review the application for completeness. Staff have historically engaged in several rounds of completeness questions with applicants to ensure that the application addresses all relevant standards and criteria. While MHCC's CON statute imposes deadlines for the Commission to decide on a CON application after it is docketed, the statute does not impose deadlines prior to



docketing. The completeness review can significantly delay the review of an application. The proposed regulations address this concern by imposing stricter limits on completeness reviews: while the proposed regulations extend the time for staff to complete an initial and more thorough review of an application, the regulations permit only one round of completeness questions, with a second round available only for good cause.

In addition, the proposed regulations limit who qualifies as an interested party in a CON review. Interested parties serve a valuable role and provide an important perspective in evaluating whether a CON application has met all required criteria. However, interested parties obtain significant rights in the review, such as the right to file an appeal of the Commission's decision, and their inclusion in a CON review can delay the review process and limit free economic competition. Under the current regulations, a person that is authorized to provide the same services as the applicant in the same or a contiguous planning region qualifies as an interested party without a showing of any potential negative impact. The proposed regulations, however, require a person to demonstrate that the quality of care of a health care facility the person operates would be materially affected or that the project would result in a substantial depletion of essential personnel or other resources to qualify as an interested party. Informal comments were mixed on this proposed change. Some commenters expressed that the definition was too narrow and left too much authority to a reviewer to determine whether a person qualifies as an interested party. Others urged the Commission to adopt more limiting language to further restrict who may qualify as an interested party. Staff believes that the proposed regulations strike the right balance.

Lastly, the Commission has informally maintained an inactive CON docket. Applicants have occasionally requested that the Commission stay review of their application while the applicant explores other options or negotiates with interested parties. In some cases, CON reviews have been put on hold for years. The proposed regulations permit an applicant or interested party to request a stay of a CON review for good cause for a period not exceeding six months.

#### **b. New Review Criteria**

In response to MHCC's first release for informal comment, the Office of the Attorney General's Health Education and Advocacy Unit (HEAU) proposed new CON review criteria to address health equity, character and competence, and compliance with applicable State and federal laws. Staff determined that a criterion requiring compliance with applicable State and federal laws was too broad and vague for meaningful review and may extend beyond the scope of the Commission's authority under Md. Code Ann., Health Gen. § 19-120. However, staff agrees with HEAU on the importance of focusing on health equity and assessing character and competence. The proposed regulations add review criteria requiring the Commission to consider how a proposed project will address health care disparities and to assess the applicant's character and competence. These changes align with the Commission's strong commitment to addressing disparities in health care access, quality, and outcomes in the State.



### c. Regulation of Non-CON Projects

Increasingly, the Commission has approved projects not through the full CON process, but through other types of review permitted under statute. This is particularly true given the increasing consolidation of health care facilities, which involve transactions that generally do not require CON review.

Under MHCC's statute, certain types of requests, including conversions of hospitals into freestanding medical facilities and consolidation of health care facilities, may be approved by the Commission through an exemption from CON review. The exemption review process still requires final approval by the Commission and review of the project's compliance with the State Health Plan, but it is intended to be an abbreviated, more flexible process than a full CON review. While current regulations provide guidance on conducting these reviews, they do not explicitly address how MHCC monitors exemption projects post-approval through implementation of the approved project. As a result, MHCC has interpreted regulations governing CON projects post-approval, including performance requirements and post-approval project changes, as applying to projects that have been approved through an exemption. The proposed regulations explicitly incorporate MHCC's longstanding application of its regulations. As with CONs, the proposed regulations require those who have received an exemption from CON review to develop a project implementation schedule, provide the Commission with progress reports, and make capital expenditure obligations by certain deadlines. In addition, the proposed regulations make explicitly clear that projects approved through an exemption can seek approval of certain project changes through a truncated project change request process, rather than having to seek a new exemption. Lastly, the proposed regulations explicitly permit the Commission to approve an exemption request with conditions, which provides the Commission with the flexibility to approve worthwhile projects that do not quite meet required standards.

Multiple commenters filed informal comments challenging the Commission's authority to monitor exemption projects after approval during implementation. However, the Commission has broad authority over the CON program and to "promote the development of a health regulatory system that provides financial and geographic access to quality health care services at a reasonable cost by" "enhancing the strengths of the current health care service delivery and regulatory system." Md. Code Ann., Health-Gen. §§ 19-120 & 19-103. Projects that may be approved through an exemption from CON are still significant health care projects that greatly impact access to and availability of health care services. There is a strong public interest in ensuring that these projects are properly implemented after they are approved.

The proposed regulations also add procedural regulations for reviewing certificate of conformance and certificate of ongoing performance applications. There is currently no defined procedure for conducting these reviews beyond standards established in the State Health Plan for cardiac surgery and percutaneous coronary intervention services. The proposed



regulations establish a clear process for conducting these reviews and ensure due process to applicants.

Lastly, to ensure prompt review of non-CON requests, the proposed regulations have incorporated strict deadlines for reviewing requests for exemption from CON review and requests for determinations of coverage. For most of these types of requests, if MHCC fails to act within prescribed deadlines, the project is deemed approved.

#### **d. Increased Flexibility Post-Approval**

Current regulations have strict deadlines for implementing approved projects which do not provide enough flexibility for the needs of projects of different scales and as a result, MHCC routinely receives extension requests. Instead of imposing strict deadlines, the proposed regulations require an applicant to propose in its application a reasonable schedule to implement the project.

The proposed regulations also allow the Commission to be more flexible with capital cost increases. Current regulations require a holder to obtain Commission approval if the capital costs for the project exceed the approved capital cost inflated by specific measures. Given the current market, MHCC has been receiving many project change requests related to increasing construction costs. The proposed regulations allow the Commission to develop guidance for calculating allowable inflation, which can be more flexible to the current market.

#### **e. Emergency CONs**

The current regulations governing the issuance of emergency CONs did not anticipate the COVID-19 crisis. The proposed regulations formalize some of the procedures established during the pandemic and increase flexibility in responding to future public health emergencies.

#### **f. Consent Agenda**

The proposed regulations enable the Commission to act on certain items through the use of a consent agenda. These items include:

- The adoption of final regulations that have been previously approved for release as proposed regulations if no written comments are received and no changes are made;
- Approval of project changes that do not include a change in the financing mechanism of a project;
- Confirmation of an emergency CON issued by the Executive Director; and
- Other items that the Commission votes to include on the consent docket.



The proposed regulations include a procedure for moving items from the consent agenda to the main agenda.

#### **IV. Staff Recommendation**

Staff recommends the Commission approve COMAR 10.24.01, *Procedural Regulations for Health Care Facilities and Services*, for formal publication as proposed regulations.

