



MEMORANDUM

DATE: October 19, 2023

TO: Commissioners

FROM: Wynee Hawk, Director, Health Care Facilities Planning and Development
Caitlin Tepe, Assistant Attorney General

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

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.

The proposed final regulations help streamline the CON review process and better align it with policy objectives.

II. History of Comment Submissions and Review

The Commission published an initial draft of proposed amendments for informal comment on July 26, 2022, on its website and distributed to stakeholders. The Commission received thirteen sets of comments from stakeholders. The Commission released a second draft of the proposed regulations for another round of informal comment 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.

At the April 2023 Commission meeting, the Commission approved proposed regulations,¹ which were published in the Maryland Register on July 14, 2023, seeking formal comment.

¹ Staff's presentation and original cover memo are available as links to the April 2023 agenda appearing on the Commission website:

The Commission received comments from The University of Maryland Medical Systems, Baker Donelson, and Health Facilities Association of Maryland. Staff's analysis and recommendations in response to the comments are attached as Appendix 1. The full comments are attached as Exhibit 1.

III. Key Areas of Interest

a. Regulation of Non-CON Projects

Increasingly, the Commission has approved projects through other types of review permitted under statute that are not a full CON review process. This is particularly true given the trend of increasing health care facility consolidation, which involve transactions that generally do not require full 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 a more abbreviated, 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. MHCC has interpreted the regulations governing CON projects post-approval to apply to CON exemption projects, including performance requirements and post-approval project changes. The proposed regulations explicitly incorporate MHCC's longstanding interpretation and 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 stakeholders filed comments challenging the Commission's authority to monitor exemption projects after approval. However, the Commission has broad authority over the CON program 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."

https://mhcc.maryland.gov/mhcc/pages/home/meeting_schedule/documents/agenda/2023/MHCC_agd_20230420.pdf



Md. Code Ann., Health-Gen. §§ 19-120 & 19-103. Projects that may be approved by a CON exemption 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.

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.

b. 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.

IV. Staff Recommendation

Staff recommends minor, non-substantive changes to the proposed regulations, as indicated in the redlined version attached as Exhibit 2. In addition to the revisions noted in *Appendix I* in response to formal comments, Staff has made small additional corrections to the proposed regulations. Staff changed the word “meeting” to “hearing” in two places in Regulation .04 for consistency. Staff also added Regulation .02F to make explicit that a person shall request a determination of coverage in accordance with Regulation .14A if the person is unsure whether a project requires CON approval. This is language that appears in the current regulations and was inadvertently removed, although the proposed regulations outlined the process under Regulation .14A for requesting a determination.

Staff recommends the Commission adopt COMAR 10.24.01, *Procedural Regulations for Health Care Facilities and Services*, as final regulations.

