



Maryland Health Care Commission

COMAR 10.24.01 FINAL REGULATIONS PRESENTATION

OCTOBER 19, 2023



Agenda

- Background
- Timeline for Promulgating Regulations
- Formal Comments and Proposed Amendments



Background



History of CON Modernization

- Governor Hogan's Regulatory Reform Commission called for modernization of the CON procedural regulations
- MHCC CON Modernization Task Force convened in 2017- 2018
- Multiple recommendations requiring regulatory changes, statutory changes and recommendations for further studies
- Some recommendations can be achieved through changes in COMAR 10.24.01
 - Raise the threshold for qualifying as an interested party
 - Add flexibility to the performance requirements
 - Use a consent agenda to approve certain project changes
 - Limit the completeness review process

[Full report: con modernization workgroup final report 20181221.pdf \(maryland.gov\)](#)



Changes in statute since 2005

- 2012: Expanded MHCC's oversight of cardiac services
- 2015: Granted MHCC authority to approve the conversion of acute care hospitals to freestanding medical facilities without CON review
- 2019: Changed MHCC's oversight of ambulatory surgery, hospitals, and comprehensive care facilities changes grounded in MHCC Report on CON Modernization recommendations
- 2022: Small changes to MHCC's statute affecting continuing care retirement communities



Timeline



Timeline for Draft Regulations

- 2021-2023: Staff drafts regulations
- July 2022: Published for informal comment, round #1
- September 2022: Received 13 submissions, round #1
- January 2023: Revised draft and re-published for informal comments, round #2
- February 2023: Held Webinar
- February 2023: Received 5 submissions, round # 2
- April 2023: Commission approves proposed regulations
- July 26, 2023: Published for formal comments
- August 2023: Received 3 submission
- October 2023: Return to Commission for adoption as final regulations



Review of Formal Comments and Proposed Amendments

Formal Comments



- Received three submissions:
 - (1) University of Maryland Medical Systems
 - (2) Health Facilities Association of Maryland
 - (3) Baker Donelson

- Staff's analysis and recommendations in Appendix 1

- Formal comments attached as Exhibit 1



Non- substantive changes

- Staff made non- substantive changes since the Commission approved the proposed regulations
- Merged asset system definition 10.24.01.01B(44):
 - Merged asset system means an organization entity compromise of one or more regulated health care facilities under common ownership or control



Streamlining CON reviews

- Stricter limits on completeness reviews:
 - Limited to ONE request for additional information + ONE additional request for good cause shown
 - Staff must complete the completeness review within 15- 20 business days (depending on project)
 - Extended time for applicant responses to requests for additional information from 10 calendar days to 15 business days

Streamlining CON Reviews



- Limit who qualifies as an interested party
 - New definition: 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.
- 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.
- Staff believes that this definition in the Draft Regulations strikes the right balance.

New Review Criteria



- Health Equity
 - The Commission shall consider how a proposed project will address health care disparities in availability, accessibility, and quality of care among different populations within the service area. The Commission shall consider how social determinants within the service area of the proposed project create disparities in the delivery of health care.
- Character and Competence
 - The Commission shall assess the character and competence of an applicant based upon experience and past performance, including any records of violation in operating a health care service or facility.



Regulation of Non- CON projects

- ▶ Increasingly, the Commission is approving projects outside the full CON process (exemptions).
- ▶ Regulations explicitly address how MHCC monitors exemption projects post-approval through implementation in the following ways:
 - ▶ Project implementation schedule, make capital expenditures by certain deadlines
 - ▶ Post- approval project changes
 - ▶ Require progress reports
 - ▶ Approve with conditions (worthwhile projects that do not quite meet the standards)



Regulation of Non- CON projects

- 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.



Increased Flexibility Post Approval

- Current regulations have strict deadlines for implementing approved projects who does not provide flexibility for the needs and different scales of projects. As a result, applicants routinely ask for extensions.
- The Draft Regulations allows applicants more flexibility and certainty by allowing the applicant to propose their own schedule for implementation of their project. (See COMAR 10.24.01.12A).



Emergency CONs: COMAR 10.24.01.20

- Current regulations did not anticipate the COVID- 19 crisis.
- (1) An emergency CON shall be extended automatically during any period in which the applicant has properly sought a CON to retain the capacity or project approved on an emergency basis.
 - This change recognizes the potential disruption in services without the automatic extension.
- (2) Permits an emergency CON applicant to seek reconsideration by the Commission if the Executive Director denies an emergency CON.
 - To preserve procedural rights



Questions?

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